નામ:_____

સરનામુ:_____

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મો નં:_____

તા.:_____

પ્રતિ,

માનનીય મુખ્યમંત્રીશ્રી,

ગુજરાત રાજ્ય ટાસ્ક ફોર્સ (કોવીડ-૧૯)

૩-જો માળ, સ્વર્ણિમ સંકુલ-૧, નવા સચિવાલય, ગાંધીનગર.

અગ્ર મુખ્ય સચિવશ્રી,

આરોગ્ય અને પરિવાર કલ્યાણ વિભાગ, ગુજરાત રાજ્ય,

૭-મો માળ, બ્લોક-૭, નવા સચિવાલય, ગાંધીનગર.

પોલીસ મહાનિર્દેશક અને મુખ્ય પોલીસ અધિકારીશ્રી,

પહેલો માળ, પોલીસ ભવન, સેક્ટર-૧૮, ગાંધીનગર, ગુજરાત.

અગ્ર મુખ્ય સચિવશ્રી,

ગુજરાત રાજ્ય ડીઝાસ્ટર મેનેજમેન્ટ ઓથોરીટી ,

૫-મો માળ, બ્લોક-૧૧, ઉદ્યોગ ભવન, ગાંધીનગર.

અગ્ર મુખ્ય સચિવશ્રી,

શિક્ષણ વિભાગ, ગુજરાત સરકાર,

૮-મો માળ, બ્લોક-૫, ઉદ્યોગ ભવન, ગાંધીનગર.

વિષય :- ગુજરાત સરકાર દ્વારા જાહેર કરવામાં આવેલ નિયમો કે કોઈપણ સરકારી કે પ્રાઈવેટ જગ્યાએ પ્રવેશ મેળવવા માટે તેમજ સુવિધા મેળવવા માટે ફરજીયાત બંને વેક્સિનના ડોઝ અને સ્વસ્થ હોવા છતાં માસ્ક હંમેશા ફરજીયાત પહેરવું એ સંપૂર્ણ ગેર-કાયદેસર, ગેર-બંધારણીય તેમજ ભારત સરકારના આરોગ્ય અને પરિવાર કલ્યાણ મંત્રાલય, WHO અને રાષ્ટ્રીય આરોગ્ય મિશન, ICMR દ્વારા બહાર પાડવામાં આવેલ Covid-19 ગાઈડલાઈનની વિરુધ્ધ હોવાથી મને અને મારા પરિવારને આ બાબતોથી સ્વતંત્ર કરવા નિવેદન.

સાદર પ્રણામ,

જય ભારત સાથે જણાવવાનું કે અમે ભારતનાં જાગૃત અને નિષ્ઠાવાન નાગરિક તરીકે આપ સાહેબશ્રીને સવિનય સાથે જણાવવાનું કે આપશ્રી આમારી સેવા અને મદદ માટે તથા અમારા સંરક્ષણ માટે નિયુક્ત થયેલ છે. જે અમારા માટે આવકાર દાયક છે. તેમજ આપ આગળ પણ સદૈવ અમારી મદદ માટે તત્પર રહેશો. એવી અમારી અપેક્ષાઓ છે.

સમગ્ર ભારત દેશમાં " Apedemic Disasters Managment ACT-2005 તથા ગુજરાતમાં "ગુજરાત રાજ્ય આપતકાલીન આપત્તિ વ્યવસ્થાપક એક્ટ" દ્વારા તા.૨૬-૩-૨૦૨૦ ના રોજ લાગુ પાડેલ છે. જેમાંના કેટલાક નિયમો વિશે મને અને મારા પરિવાર તરફથી કેટલીક રજૂઆત છે, જે ભારતના બંધારણ, WHO, ICMR, MoHFW અને સુપ્રીમ કોર્ટના અનુસાર રજૂઆત કરવી અને માંગ કરવીએ વ્યાજબી અને યોગ્ય છે. જેની વિગતો નીચે મુજબ છે.

❖ **<u>રજૂઆતો</u>** :-

➢ **<u>વેક્સિન અંગેની રજુઆતો :-</u>**

૦૧. આપને જાણવાનું કે હું અને મારો પરિવાર સનાતન હિંદુ ધર્મને પાળતો આવે છે અને પાળે છે. તેમજ અમે શુધ્ધ શાકાહારી છીએ. અમે માંસાહાર જેવી વસ્તુને સ્પર્શ કે ભોજન કરતા નથી. તેની સખ્ત મનાઈ છે. આથી આપને જણાવવા માંગું છું કે કોવીડ-૧૯ વેક્સિનના ઉત્પાદનમાં (Fetal Bovine Serum) નો ઉપયોગ થઈ છે. (નવજાત કે જન્મેલા ગાયના વાછરડાના ભ્રુણના લોહી, તેમજ અન્ય ભૂંડના ભ્રુણ, વાંદરાની કીડની સેલ, માનવ ભ્રુણ જેવા પદાર્થોનો ઉપયોગ કરેલ છે)

- એથી ભારતીય બંધારણીય Article 21 (Right to Religious Beliefs)ના પ્રમાણે અમે કોવીડ-૧૯ વેક્સિન લેવાના નિયમનથી સ્વતંત્ર છીએ.
- તેમજ અમેરિકામાં પણ વેક્સિન કોર્ટ Religious and Philosophical Exemption Act – 1986 મુજબ ધર્મના આધારે રસીકરણમાંથી મુક્તિની જોગવાઈ કરેલ છે.
- આને લાગતી અમે ભારત સરકાર અને RTI માં પૂછવામાં આવેલ છે કે શું વેક્સિન બનાવવામાં FBS નો ઉપયોગ થાય છે. એમને જવાબમાં હા પાડેલ છે. **(જોડાણ-૧)**

૦૨. સૌથી મહત્વની વાત છે વેક્સિન બનાવનાર કંપનીએ તેની ફેક્ટ શીટમાં કીધું છે કે વેક્સિન લેવી ફરજીયાત નથી સ્વૈચ્છિક છે. તેમજ ખાસ કીધું છે કે આ કેટેગરીના લોકોએ વેક્સિન બિલકુલ ના લેવી જોઈએ. નહિતર આડઅસર કે મૃત્યુ થઈ શકે છે. જે ભારત સરકારની ICMR ની વેબસાઈટ પર ઉપલબ્ધ છે **(જોડાણ-૨ A)**

- જેમ કે (કોઈ અલર્જી, હૃદયના દર્દી, કોઈ અંત ગંભીર રોગ, તાવ, ગર્ભવતી સ્ત્રીઓ, રક્તસ્ત્રાવ, સ્તનપાન, પાતળું લોહી કે જેને પોતાની રોગપ્રતિકારક શક્તિ હોય વગેરે અને એમ કીધું છે કે જો વેક્સિન લીધા બાદ મૃત્યુ થાય તો અમારી કોઈ જવાબદારી રહેશે નહી અને વળતર pan મળશે નહી. **(જોડાણ-૨ B)**

૦૩. ત્યારબાદ ગુજરાત આરોગ્ય અને પરિવાર કલ્યાણ વિભાગમાં RTI કરેલ છે કે શું સરકારી કે ખાનગી જગ્યાએ પ્રવેશ કે સુવિધાઓ મેળવવા માટે ફરજીયાત કોવીડ-૧૯ વેક્સિન બંને ડોઝ લેવા ફરજીયાત છે. તો તેમને કીધું કે સ્વૈચ્છિક છે, ફરજીયાત એવો કોઈ પરિપત્ર નથી. **(જોડાણ-૩)**

- **ministry of health and family welfare of India દ્વારા covid -19 વેક્સિન ની ગાઈડલાઈન બહાર પાડેલ છે જેમાં ચોખ્ખું કીધું છે કે covid-19 વેક્સિન લેવી સ્વૈચ્છિક છે. (જોડાણ ૩)**

૦૪. ત્યારબાદ આજ RTI સામાન્ય વહીવટ વિભાગ ગુજરાત માં કરવામાં આવી. જેમાં પણ કીધું કોઈ ફોર્સ કે ફરજીયાત ના કરી શકે. **(જોડાણ-૪)**

૦૫. ભારત સરકારને RTI કરેલ છે જેમાં કીધું છે કે વેક્સિન લેવી સ્વૈચ્છિક છે, ફરજીયાત નથી. **(જોડાણ-૫)**

૦૬. સુપ્રીમ કોર્ટે તા.૧૩-૦૧-૨૦૨૨ ના રોજ Writ Petition (civil) No.580 of 2021) શપથપત્ર આપેલ છે કે વેક્સિન માટે ફોર્સ કે ફરજીયાત ના કરી શકાય અને ભેદભાવ પણ ન કરી શકાય. **(જોડાણ-૬)**

૦૭. મેઘાલય હાઈકોર્ટમાં તા.૨૩-૦૬-૨૦૨૧ ના રોજ PIL No.6/2021 કરવામાં આવી હતી. જેમાં કીધું છે કે કોવીડ-૧૯ વેક્સિન ફરજીયાત કરી શકાય નહી અને ભેદભાવ પણ ન કરી શકાય. **(જોડાણ-૭)**

૦૮. ગોહાટી હાઈકોર્ટમાં તા.૦૨-૦૮-૨૦૨૧ ના રોજ Case No.WP(C)/37/2020 કરવામાં આવી હતી. જેમાં ચુકાદામાં કીધું છે કે વેક્સિન લીધા બાદ પણ કોરોના થઈ શકે છે અને વેક્સિન લીધેલ અને ના લીધેલ વ્યક્તિઓમાં વેક્સિન લીધેલ વ્યક્તિ વધારે કોરોના ફેલાવી શકે છે. તો તેના સ્ટેટ્સના આધારે ભેદભાવ ના કરી શકાય. **(જોડાણ-૮)**

૦૯. તા.૨૨-૦૨-૨૦૨૨ ના રોજ બોમ્બે હાઈકોર્ટ માં PIL No.84 of 2021 કરવામાં આવી હતી. જેમાં પણ કીધું છે કે વેક્સિન લેવા માટે કોઈ ફરજીયાત ના કરી શકે. **(જોડાણ-૯)**

➢ **<u>માસ્ક અંગેની રજુઆતો :-</u>**

૦૧. તા.૨૭-૦૫-૨૦૨૧ ના રોજ કરેલ RTI (FILE NO.Z.28016/133/2021-DM (CELL) માં પૂછવામાં આવ્યું હતું કે શું વ્યક્તિએ માસ્ક પહેરવું ફરજીયાત છે, ત્યારે જવાબમાં કીધું છે કે ફરજીયાત નથી). **(જોડાણ-૧)**

૦૨ . **વૈજ્ઞાનિક રીતે જોઈએ તો માસ્ક ના છિદ્રો નું કદ એ વાયરસ ના કદ કરતા ત્રણ ગણું મોટું છે તો માસ્ક વાયરસ ને રોકવા માટે કારગર સાબિત જ નથી થતું. (જોડાણ ૨)**

૦૩. સુપ્રીમકોર્ટ દ્વારા તા:- 14.03.2020 ના રોજ બહાર પાડવામાં આવેલ જાહેરનામા (F.NO.212/MISC/PF/2020/SCA(G) મુજબ (પેજ નં.10 પર) જણાવેલ છે, સ્વસ્થ વ્યક્તિએ માસ્ક ના જ પહેરેવું જોઈએ. **(જોડાણ-૩)**

૦૪. તેમજ બોમ્બ હાઈકોર્ટમાં તા: 19/1/2022 ના રોજ નાખેલ (CRIMINAL WRIT PETITION NO.1546 OF 2020) રતફખાન પર પોલીસ કમસિારીએ ગેરકાનુની રીતે માસ્ક ન પહરેતા દંડ અને સજા કરતા, કોર્ટે આર્દેશ કરતા જણાયું કે તમે જે 188 કલમ લગાવીને માસ્ક પર દંડિત કરો છો. એ તમારી પાસે કોઈ પાવર નથી અને કોઈ કરી પણ ન શકે. કારણકે આ આપાતકાલીન DMA ACT-2005 લાગ પાડલે છે. **(જોડાણ-૪)**

૦૫. MOHFW (Ministry of health and family welfare) દ્વાર 12/03/2020 ના રોજ પાડલે પરરપત્ર (ક્રમાંક નં.: NHMHP-IDSP/1/2020-IDSP-SECTION-NATIONAL HEALTH MISSION-HP 2470)માં પેજ નં. 4 પર માસ્ક ની ગાઈડલાઈન મુજબ સ્વસ્થ વ્યક્તિએ માસ્ક બિલકુલ ના જ પહેરેવું જોઈએ.**(જોડાણ-૫)**

૦૬. ત્યારબાદ NHM(NATIONAL HEALTH MISSION) દ્વાર બહાર પાડલે GUIDLINE મુજબ (પેજ નં. 6) માત્ર હેલ્થ કેર અને બીમાર વ્યક્તિઓ માટે જ માસ્ક પહેરવું તેવું કીધું છે. નહિતર માસ્ક અને ભારતની સંપતિનો દુરઉપયોગ છે.**(જોડાણ-૬)**

૦૭. WHO ની GUIDLINE મુજબ જ્યારે કોઈ ફિઝીકલી એક્ટીવીટી કરતા હોય કે તમે સ્વસ્થ વ્યક્તિ હોય તો માસ્ક બિલકુલ ના પહેરેવું જોઈએ. નહિતર એ તમારા સ્વાસ્થ્ય માટે હાનીકારક બની શકે છે. જીવન જોખમાઈ શકે છે.**(જોડાણ-૭)**

- Ministry of Helth and family welfare ની માસ્ક માટે ગાઈડલાઈન છે જેના અનુસાર 5 થી 11 વર્ષના બાળકોને બિલકુલ માસ્ક ના જ પહેરવું જોઈએ ઉલટું કીધું તેમને માસ્ક પહેરવાથી સ્વાસ્થ્ય બગડી સકે છે અને તેની જરૂરિયાત પણ નથી. **(જોડાણ-૭)**

૦૮. તેમજ ખાસ મહત્વની વાત એ પણ છે કે માસ્ક ના ઉપયોગ FDA (FOOD AND DRUGS ADMINISTRATION) દ્વારા કોરોના વાયરસ ને રોકવા માટે મેડીકલ ટ્રીટમેન્ટ ફોર પબ્લિકની પરવાનગી આપેલ નથી. તેને લાઈસન્સ ફક્ત EUA ઈમરજન્સી યુઝ ઓથોરાઈઝ માટે આપેલ છે. તો કોઈ વ્યક્તિ કે સરકાર આના માટે ફરજીયાત કે જબરજસ્તી કઈ રીતે કરી શકે? **(જોડાણ-૮)**

૦૯. તેમજ આપને ખાસ જાણવાનું કે માસ્ક પહેરવાથી શું શું સ્વાસ્થય ને નુકશાન થાય છે તે "who" જણાવેલ છે , જેમાં (શ્વાસ લેવામાં તકલીફ, હૃદય ની ગતિ વધવી, શુસ્તી, ચકર આવવા, માથામાં દુખાવા, બેભાન થઈ જવું , મંદ દ્રષ્ટિ, બહેરાશપણું,હાયપરકેપીનીયા, રક્તવાહિનીઓ અને મસ્તક વાહિનીઓ ને સંબધિત સમસ્યા, શ્વસન ક્રિયા ને હાની,પાચનક્રિયા સંબધિત સમસ્યાઓ, ન્યુરોસાયકિયાટ્રિક માં અવ્યવસ્થા ઊભી થવી, ગર્ભિત મહિલાને લાગતી સમસ્યાઓ, અસ્થમા, ફેફસાં ના કેન્સર , ન્યુમોનિયા, ત્વચા માં જ્વલન થવી, એલર્જી , હૃદયના દર્દી ને હૃદય ફેલ થવું, સ્ટોર્ક(આઘાત લાગવો), વગેરે જેવી ગંભીર સમસ્યાઓ માસ્ક પહેરવાથી થાય છે.**(જોડાણ ૯)**

૧૦. તેમજ સૌથી મહત્વની બાબતએ છે કે ભારત ના બંધારણની જોગવાઈ ATRICLE 19 FUNDAMENTAL RIGHTS અને ARTICLE 21A RIGHT TO LIFE AND PERSONAL LIBERTY ના અનુસાર ભારતના દરેક વ્યકિતને RIGHT TO TERMINATE આપેલ છે. જેથી દરેક વ્યકિત સ્વતંત્ર રીતે કોઈપણ (આયુર્વેદિક, હોમિયોપેથીક, નેચરોપેથી કે એલોપેથી) સારવાર લઈ શકે છે.

- **માત્ર અલોપેથીની જ ટ્રીટમેન્ટ કે ગાઈડલાઈને જ પાલન કરવી એવો કોઈ કાયદો નથી. એથી આ ફરજીયાત વેક્સિન અને માસ્ક પહરેવું એ નિયમ ગેર-બંધારણીય અને WHO, ICMR, MOHFW, NHM, NATINAL HUMAN RIGHTS COMMISSION અને ભારત સરકારની વિરુધ્ધ છે.**

- **આથી સાહબેશ્રીને વિનંતી છે કે આ બંને બાબતોને ખુબ જ ગંભીરતાથી લઈ અમને આ બાબતોના પ્રતિબંધોથી સ્વતંત્ર કરવા. તેમજ બને તેટલી વહેલી તકે આ અઠવાડિયાના અંત સુધીમાં જવાબ આપશો. એવું અમારું આપને નિવેદન છે.**

- **જો અમારી આ વાતને ગંભીરતાથી નહિ લેવામાં આવે તો અમે ન્યાય હેતુથી કાનૂની કાર્યવાહી કરવા માટે મજબુર થઈશું. જેની ખાસ નોંધ લેવી. જેની હું આપને નોટીસ પણ આપું છું.**

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

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Online RTI Status Form

Note:Fields marked with * are Mandatory.

Enter Registration Number	CDSCO/R/T/21/00016
Name	Dipak Jatapara
Date of filing	07/01/2021
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Status	REQUEST DISPOSED OF
Date of action	12/03/2021
Reply :- As per the information received from the concerned division, the reply is as under: As per New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act,1940 and in light of urgent need due to COVID pandemic situation in the country, this office has granted permission to manufacture two COVID-19 vaccines as under: 1. M/s Serum Institute of India Pvt., Ltd., Pune for manufacture of the COVID-19 Vaccine [COVISHIELD] for restricted use in emergency situation with various conditions/restrictions. 2. M/s Bharat Biotech International Limited, Hyderabad for manufacture of the COVID-19 Vaccine [COVAXIN] for restricted use in emergency situation in public interest with various conditions/restrictions. Further, as per information provided by firm, new born calf serum is used in revival process of Vero Cells which is used for the production of Corona Virus during the manufacturing of COVAXIN bulk vaccine of M/s Bharat Biotech. However, the finished formulation of COVISHIELD and COVAXIN does not contain non-vegetarian ingredient as per the records on the composition of these vaccines provided by the manufacturers.	
CPIO Details :-	Sushanta Sarkar Phone: 011-23216367 rti.cell@cdsco.nic.in
First Appellate Authority Details :-	A. K. Pradhan Phone: 011-23216367 rti.cell@cdsco.nic.in
Nodal Officer Details :-	
Telephone Number	011-23236973
Email Id	jayantwz[at]gmail[dot]com

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Version 2.0
An Initiative of Department of Personnel & Training, Government of India

Final Status of CDSCO/R/T/21/00110

Applicant Name	Vikas Patni
Date of receipt	15/04/2021
Request Filed With	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Text of Application	Provide me full info reagring vaccine, vaccination on rsepective 12 points below- 1 what are the contents of vaccines and how is it made ? 2 How much is the expiry date of corona vaccine from the date of manufacturing which is best for possible results ? 3 Is taking corona vaccine is mandatory ? 4 Under which rule or law any person without vaccination getting restiriction from goverments and companies for traveling, movement, services or compulsory for jobs, workers and service ? 5 Does vaccines gives gurranty that one should not have corona after taking two doses? 6 Is vaccine provides lifetime protection from corona after taking two doses or it have any time limit? 7 Does corona vaccine should be taken every year if corona continues ? 8 Does vaccines procedures used FBS in making of corona vaccines in any form, composition or ingredient made by Bharat Biotech, serum insitute and approved by indian Government or deparments ? 9 Is taking Vaccine have any adverse side effects or it is completely safe ? 10 How many peoples died by taking corona vaccine ? 11 What compensation will somebody be given if he or she have adverse reaction, disablity or death by vaccination? 12 Is indian government, health Department or vaccination manufacturer took responsibility of any deaths or adverse side effects of peoples who are taking vaccines ?
Request document *(if any)*	document not provided
Status	**REQUEST DISPOSED OF** as on 08/06/2021
Date of Action	08/06/2021
Remarks	**Reply** :- Point wise reply is as under: Point No. 1 & 2: All the ingredients, shelf life of approved COVID-19 vaccines are available in Summary of Product Characteristics (SmPC), package insert and factsheet and the same information is publicly available on CDSCO website i.e. www.cdsco.gov.in. Point No. 3 & 4, 9,10: CDSCO has no information in this regard. Point No. 5 to 7: Brief of clinical trial results/information containing safety, immunogenicity and efficacy results of approved COVID-19 vaccines of M/s Serum, M/s Bharat biotech and Dr. Reddys Laboratories are available in Summary of Product Characteristics (SmPC)/Package Insert/factsheet which are publically available on CDSCO website i.e. www.cdsco.gov.in. Point No. 8: As per information provided by firm, new born calf serum is used in revival process of Vero Cells which is used for the production of Corona Virus during the manufacturing of COVAXIN bulk vaccine of M/s Bharat Biotech. Point No. 11 & 12: There is no provision under Drugs and Cosmetics Act and Rules, there under for providing compensation due to side effects, disability and deaths after approval of Vaccines.
	Print

FACT SHEET FOR VACCINE RECIPIENTS & CAREGIVERS

RESTRICTED USE OF COVAXIN™ UNDER CLINICAL TRIAL MODE

THE BHARAT BIOTECH COVID-19 VACCINE

COVAXIN™

TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

PRIORITIZED GROUPS OF INDIVIDUALS WHO HAVE BEEN INFORMED BY THE MINISTRY OF HEALTH & FAMILY WELFARE TO ATTEND A BOOTH SPECIFIED FOR COVAXIN™ BASED VACCINATION

You are being offered the Bharat Biotech COVID-19 Vaccine **(COVAXIN™)** to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Bharat Biotech COVID-19 Vaccine **(COVAXIN™)**

REPORTING OF SIDE EFFECTS

As with any new medicine, this vaccine will be closely monitored to allow quick identification of any new safety information. You can help by reporting any side effects you may get after vaccination to Bharat Biotech who is the manufacturer of **COVAXIN™** vaccine on 24x7 Toll-Free Number: 18001022245 or at **email pvg@bharatbiotech.**com. For more information, please read this Information Sheet carefully.

Please read this Fact Sheet for information about the Bharat Biotech COVID-19 Vaccine (COVAXIN™). Talk to Vaccinator/ Officer supervising your vaccination if you have any questions. It is your choice to receive the Bharat Biotech COVID-19 Vaccine (COVAXIN™). The Bharat Biotech COVID-19 Vaccine (COVAXIN™) is administered as a 2-dose series, 4 weeks apart, into the deltoid muscle of the upper arm.

WHAT IS COVID-19?

COVID-19 disease is caused by a Coronavirus called SARS-CoV-2. This type of Coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 may experience wide range of symptoms of mild to severe category. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; loss of taste or smell of recent onset; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

The Bharat Biotech COVID-19 Vaccine (COVAXIN™) is a vaccine with approval for restricted use in emergency situation that may prevent COVID-19. The Central Licensing Authority has granted permission for the sale or distribution of COVAXIN™ for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode.

In phase 1 and phase 2 clinical trials, COVAXIN™ has demonstrated the ability to produce antibodies against COVID-19. However, the clinical efficacy of COVAXIN™ is yet to be established and it is still being studied in phase 3 clinical trial. Hence, it is important to appreciate that receiving the vaccine does not mean that other precautions related to Covid-19 need not be followed.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The Vaccinator/ Officer supervising your vaccination may include your vaccination information in your state/National Immunization Information System or another designated system. This will ensure that you receive the same vaccine when you return for the second dose. Please also note that privacy and confidentiality pertaining to any information provided by you and archived in the National Immunization Information System will be maintained.

WHAT IS RESTRICTED USE IN EMERGENCY SITUATION?

COVAXIN™ is permitted for restricted use in emergency situation under Clinical Trial Mode. This means that the vaccine offered under this plan will be offered to the restricted prioritized groups only. As you fell under this category, you have been invited to this booth for administration of COVAXIN™. This administration will take place under clinical trial mode, which is different from clinical trial as effect of COVAXIN™ will not be examined against any other intervention through this effort. You will be monitored for any adverse event under this clinical trial mode and supported for medical care under the existing public health program.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE COVAXIN™ COVID-19 VACCINE?

Tell the Vaccinator/ Officer supervising your vaccination about all of your medical conditions, including if you:

- Are you on regular medication for any illness? If yes, for how long and for which condition?It is advisable not to take the vaccine in any of these conditions
- Have any allergies
- Have fever
- Have a bleeding disorder or are on a blood thinner
- Are immunocompromised or are you on a medicine that affects your immune system
- Are pregnant
- Are breastfeeding
- Have received another COVID-19 vaccine

} It is advisable not to take the vaccine in any of these conditions

WHO IS ELIGIBLE TO GET THE BHARAT BIOTECH COVID-19 VACCINE?

CDSCO has authorized the Restricted Use of COVAXIN™ under Clinical Trial Mode. Individuals who are prioritized under the public health program of the Ministry of Health & Family Welfare, Government of India will be covered under this endeavor. Informing the individuals about the offer for vaccination with COVAXIN™ will rest with the respective Government Program Officials. Those offered COVAXIN™ at pre-specified booths will have the options to receive or reject administration of the vaccine.

WHO SHOULD NOT GET BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

You should not get the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) if you:

- Have any history of allergies.
- Have fever.
- Have a bleeding disorder or are on a blood thinner.
- Are immune-compromised or are on a medicine that affects your immune system
- Are pregnant.
- Are breastfeeding.
- Have received another COVID-19 vaccine.
- Any other serious health related issues, as determined by the Vaccinator/Officer supervising vaccination.

WHAT ARE THE INGREDIENTS IN THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

The BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) includes the following ingredients: COVAXIN™ contains 6μg of whole-virion inactivated SARS-CoV-2 antigen (Strain: NIV-2020-770), and the other inactive ingredients such as aluminum hydroxide gel (250 μg), TLR 7/8 agonist (imidazoquinolinone) 15 μg, 2-phenoxyethanol 2.5 mg, and phosphate buffer saline up to 0.5 ml. The vaccine (COVAXIN™) thus has been developed by using inactivated/killed virus along with the aforementioned chemicals.

HOW IS THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) GIVEN?

The BHARAT BIOTECH COVID-19 VACCINE will be given to you as an injection into the deltoid muscle of the upper arm. The BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) vaccination series is 2 doses given 4 weeks apart.

HAS BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) BEEN USED BEFORE?

The Central Licensing Authority has granted permission for the sale or distribution of COVAXIN™ for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode. In phase 1 and Phase 2 clinical trials, about 680 (300 in Phase 1, and 380 in Phase 2) were administered with 2-doses of COVAXIN™. Phase 3 clinical trial is ongoing in 25,800 participants, and all the participants have received the first dose, as on 06th Jan 2021.

WHAT ARE THE BENEFITS OF BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

In an ongoing clinical trial, the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) has been shown to generate immunity following 2 doses given 4 weeks apart.

However, the clinical efficacy of COVAXIN™ is yet to be established and it is still being studied in phase 3 clinical trial. Hence, it is important to appreciate that receiving the vaccine does not mean that other precautions related to Covid-19 need not be followed.

WHAT ARE THE RISKS OF BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

Side effects that have been reported with the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) include:

- Injection site pain
- Injection site swelling
- Injection site redness
- Injection site itching
- Stiffness in the upper arm
- Weakness in injection arm
- Body ache
- Headache
- Fever
- Malaise
- Weakness
- Rashes
- Nausea
- Vomiting

There is a remote chance that the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) could cause a severe allergic reaction. A severe allergic reaction may very rarely occur after getting a dose of the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™). For this reason, your vaccination provider will ask you to stay for 30 minutes after each dose of vaccination at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty in breathing
- Swelling of your face and throat
- A fast heart beat
- Rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™). Serious and unexpected side effects may occur. BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience any side effect(s), please contact/visit your health provider/Vaccinator/ Officer supervising your vaccination or immediately go to the nearest hospital.

WHAT IF I DECIDE NOT TO GET THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

It is your choice to receive or not to receive the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™).

CAN I RECEIVE THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) WITH OTHER VACCINES?

There is no scientific information yet available on the appropriateness of use of the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) along with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, you should not get the vaccine as the effect of the vaccine has not been studied in pregnant women and nursing mothers.

WILL THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) GIVE ME COVID-19?

No. BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) is an inactivated (killed) vaccine, and hence, there is no chance of getting COVID-19 because of COVAXIN™ vaccination.

HOW LONG WILL I HAVE TO PARTICPATE IN THIS PROGRAM?

All the Vaccine recipients will be followed-up for a period of 3 months after the 2nd dose of vaccination.

In case of any serious adverse events, Vaccine recipients will be provided medically recognized standard of care in the government designated and authorized centers/hospitals. The compensation for serious adverse event will be paid by sponsor (BBIL) if the SAE is proven to be causally related to the vaccine. The compensation will be determined by the ICMR Central Ethics Committee, as appropriate.

All the recipients need to report to the health care provider/site/sponsor, if they are having signs and symptoms of COVID-19 or diagnosed with COVID-19. If any Vaccine recipient develops symptoms of COVID-19, Vaccine recipient will be provided medically recognized standard of care in the government designated and authorized centers/hospitals. COVID-19 Positive outcomes must be documented in Adverse Event Form. Proof of positive RT-PCR (tests conducted under the existing government program and from approved laboratories) should be provided to establish the diagnosis of COVID-19. Vaccine recipient's verbal recall will not confirm the diagnosis.

BHARAT BIOTECH

Manufactured and Marketed by:
Bharat Biotech International Limited Genome Valley Turkapally, Shamirpet Hyderabad, Telangana 500 078

प्राप्तिकर्ताओं और देखरेख प्रदाता फैक्ट शीट

चिकित्सकीय परीक्षण मोड में COVAXIN™ का प्रतिबंधित उपयोग

कोरोनावाइरस रोग 2019 (COVID-19) टालने के लिए भारत बायोटेक COVID-19 टीका

COVAXIN™

ऐसे व्यक्तियों के प्राधान्यताप्राप्त समूह, जिन्हें COVAXIN™ आधारित टीकाकरण के लिए विहित बूथ में उपस्थित रहने के लिए स्वास्थ्य और परिवार कल्याण मंत्रालय द्वारा सूचित किया गया है

SARS-CoV-2 के कारण होनेवाले कोरोनावाइरस रोग 2019 (COVID-19) को रोकने के लिए आपको भारत बायोटेक COVID-19 वैक्सीन (COVAXIN™) की पेशकश की जा रही है।इस फैक्ट शीट में भारत बायोटेक COVID-19 वैक्सीन (COVAXIN™) के जोखिमों और लाभों को समझने में आपकी मदद करने के लिए जानकारी शामिल रहेगी।

दुष्प्रभावों की रिपोर्टिंग

जैसा किसी भी नई दवा के मामले में होता है, किसी भी नई सुरक्षा जानकारी की त्वरित पहचान की अनुमति देने के लिए इस टीके पर कड़ी निगरानी रखी जाएगी। के टीकाकरण के बाद आपको होने वाले किसी भी दुष्प्रभाव की 24x7 टोल-फ्री नंबर: 18001022245 या pvg@bharatbiotech.com. पर ईमेल करके रिपोर्ट करके आप भारत बायोटेक को, जो COVAXIN™ टीका के निर्माता है। अधिक जानकारी के लिए, कृपया इस सूचना पत्र को ध्यान से देखें।

भारत बायोटेक COVID-19 टीका (COVAXIN™) के बारे में जानकारी के लिए कृपया इस फैक्ट शीट को पढ़ें। यदि आपके कोई प्रश्न हैं, तो अपने टीकाकरण की देखरेख करने वाले टीकाकर्ता / अधिकारी से बात करें। भारत बायोटेक से COVID-19 वैक्सीन (COVAXIN™) से प्राप्त करना आपकी पसंद है। भारत बायोटेक COVID-19 वैक्सीन (COVAXIN™) को 2-खुराक की श्रृंखला के रूप में ऊपरी बांह की डेल्टॉयड मांसपेशी में 4 सप्ताह के अंतर से प्रदान किया जाता है।

COVID-19 क्या है?

COVID-19 रोग SARS-CoV-2 नामक कोरोनावाइरस के कारण होता है। इस प्रकार के कोरोनावाइरस पहले नहीं देखे गए हैं। आप COVID -19 को किसी अन्य व्यक्ति के संपर्क से प्राप्त सकते हैं, जिसे उस विषाणु का संक्रमण हो। यह मुख्य रूप से एक श्वसनतंत्रसंबंधी बीमारी है, जो अन्य अंगों को प्रभावित कर सकती है। COVID-19 वाले लोग हल्के से गंभीर श्रेणी के अनेकों प्रकार के लक्षणों का अनुभव कर सकते हैं। विषाणु के संपर्क में आने के 2 से 14 दिन बाद लक्षण दिखाई दे सकते हैं। इसके लक्षणों में बुखार या ठंड लगना; खांसी; सांस लेने में तकलीफ़; थकान; मांसपेशियों या शरीर में दर्द; सरदर्द; हाल की शुरुआत के स्वाद या गंध की हानि; गले में खराश; नाक में जमाव या बहती नाक; उलटी अथवा मितली; दस्त शामिल हो सकते हैं।

भारत बायोटेक COVID-19 टीका (COVAXIN™) क्या है?

भारत बायोटेक COVID-19 टीका (COVAXIN™) COVID-19 को प्रतिबंधित कर सकने वाला टीका है, जिसे आपातकालीन परिस्थिति में प्रतिबंधित उपयोग के लिए अनुमोदन दिया जा चुका है। केंद्रीय अनुज्ञप्ति प्राधिकरण ने सार्वजनिक रूप से नैदानिक परीक्षण मोड में सहायक सावधानी के रूप में जनहित में और आपातकालीन परिस्थिति में प्रतिबंधित उपयोग के लिए COVAXIN™ की बिक्री या वितरण की अनुमति दी है।

चरण 1 और चरण 2 नैदानिक परीक्षणों में, COVAXIN™ ने COVID -19 के विरुद्ध प्रतिजैविकों का उत्पादन करने की क्षमता दर्शाई है। हालाँकि, COVAXIN™ की नैदानिक प्रभावकारिता अभी स्थापित नहीं की गई है और इसका चरण 3 नैदानिक परीक्षण में अभी भी अध्ययन किया जा रहा है। इसलिए, यह जानना महत्वपूर्ण होगा कि टीका प्राप्त करने का मतलब यह नहीं कि COVID -19 से संबंधित अन्य सावधानियों का पालन नहीं किया जाना चाहिए।

मेरी टीकाकरण जानकारी को कहां दर्ज किया जाएगा?

आपके टीकाकरण का पर्यवेक्षण करने वाले टीकाकर्ता / अधिकारी आपके टीकाकरण की जानकारी को आपके राज्य / राष्ट्रीय टीकाकरण सूचना प्रणाली या अन्य निर्दिष्ट प्रणाली में शामिल कर सकते हैं। यह सुनिश्चित करेगा कि दूसरी खुराक के लिए लौटने पर आपको वही टीका मिले। कृपया ध्यान दें कि आपके द्वारा प्रदान की गई और राष्ट्रीय प्रतिरक्षण सूचना प्रणाली में संग्रहीत किसी भी जानकारी से संबंधित निजता और गोपनीयता की संभाल की जाएगी।

आपातकालीन परिस्थिति में प्रतिबंधित उपयोग क्या होता है ?

नैदानिक परीक्षण मोड के तहत आपातकालीन परिस्थिति में प्रतिबंधित उपयोग के लिए COVAXIN™ की अनुमति है। इसका मतलब यह है कि इस योजना के तहत दी जाने वाला टीके की पेशकश केवल चुनिंदा प्राथमिकता वाले समूहों को की जाएगी। चूंकि आप इस श्रेणी में आते हैं, आपको COVAXIN™ लगाने के लिए इस बूथ पर आमंत्रित किया गया है। यह प्रशासन नैदानिक परीक्षण मोड के तहत होगा, जो नैदानिक परीक्षण से अलग है क्योंकि इस प्रयास के माध्यम से किसी अन्य हस्तक्षेप के खिलाफ COVAXIN™ के प्रभाव की जांच नहीं की जाएगी। इस नैदानिक परीक्षण मोड के तहत किसी भी प्रतिकूल घटना न हो, इस उद्देश्य से आपकी निगरानी की जाएगी और मौजूदा सार्वजनिक स्वास्थ्य कार्यक्रम के तहत चिकित्सा देखभाल के लिए समर्थन किया जाएगा।

COVID-19 वैक्सीन प्राप्त करने से पहले आपको अपने टीका प्रधान करता को क्या जानकारी देना चाहिए ?

अपने टीकाकरण की निगरानी करने वाले टीकाकर्ता / अधिकारी को अपनी सभी वैद्यकीय परिस्थितियों के बारे में बताएं, यदि आप

- क्या आप किसी बीमारी के लिए नियमित दवा पर हैं? यदि हाँ, तो कब तक और किस परिस्थिति के लिए?
- कोई भी एलर्जी हो
- बुखार होना
- रक्तस्राव विकार हो या ब्लड थिनर का उपयोग कर रहे हों
- इम्युनोकॉप्रोमाइज्ड हों या आप ऐसी दवा ले रहे हैं,जो आपकी प्रतिरक्षा प्रणाली को प्रभावित करता है
- क्या आप गर्भवती हैं
- क्या आप स्तनपान करा रहे हैं
- कोई और COVID-19 टीका आपको लगाया गया है

} इनमें से किसी परिस्थिति में आपको टीका न लगाना ही हितकर है

कौन भारत बायोटेक COVID-19 टीका प्राप्त होने के लिए पात्र है?

CDSCO ने नैदानिक परीक्षण मोड के अंतर्गत COVAXIN™ के प्रतिबंधित उपयोग को अधिकृत किया है। स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार के सार्वजनिक स्वास्थ्य कार्यक्रम के अंतर्गत प्राथमिकता प्राप्त व्यक्तियों को इस प्रयास के तहत आच्छादित किया जाएगा। COVAXIN™ के साथ टीकाकरण के प्रस्ताव के बारे में व्यक्तियों को सूचित करना संबंधित सरकारी कार्यक्रम अधिकारियों की जिम्मेदारी होगी। पूर्व-निर्दिष्ट बूथों पर COVAXIN™ की पेशकश करने वालों के पास टीका प्राप्त करने या अस्वीकार करने के विकल्प होंगे।

भारत बायोटेक COVID-19 टीका (COVAXIN™) किसे नहीं मिलना चाहिए?

आपको भारत बायोटेक COVID-19 टीका (COVAXIN™) नहीं मिलना चाहिए, यदि आप?

- को एलर्जी का कोई इतिहास हो
- बुखार होना
- रक्तस्राव विकार हो या ब्लड थिनर का उपयोग कर रहे हों
- इम्युनोकॉप्रोमाइज्ड हों या आप ऐसी दवा ले रहे हैं,जो आपकी प्रतिरक्षा प्रणाली को
- प्रभावित करता है
- क्या आप गर्भवती हैं.
- क्या आप स्तनपान करा रहे हैं.
- कोई और COVID-19 टीका आपको लगाया गया है

टीकाकरण की देखरेख करने वाले टीकाकर्ता / अधिकारी द्वारा निर्धारित किसी अन्य गंभीर स्वास्थ्य संबंधी समस्या।

भारत बायोटेक COVID-19 VACCINE (COVAXIN™) में कौन से घटक समाविष्ट हैं?

भारत बायोटेक COVID-19 VACCINE (COVAXIN™) में निम्नलिखित सामग्रियां शामिल हैं: COVAXIN™ में 6µg ऑल-विरिऑन निष्क्रिय SARS-CoV-2 एंटीजन (तनाव, NIV-2020-770), और अन्य निष्क्रिय तत्व जैसे एल्यूमीनियम हाइड्रोक्साइड जेल (250 माइक्रोग्राम), टीएलआर 7/8 एगोनिस्ट (इमिडाजोक्विनोलिनोन) 15 माइक्रोग्राम, 2-फिनोक्सीथेनॉल 2.5 मिलीग्राम और फॉस्फेट बफर खारा 0.5 मिली तक। वैक्सीन (COVAXIN™) इस प्रकार उपरोक्त रसायनों के साथ निष्क्रिय / मृत विषाणु का उपयोग करके विकसित किया गया है।

भारत बायोटेक COVID-19 VACCINE (COVAXIN™) कैसे दी जाती है?

भारत बायोटेक COVID-19 टीका आपको ऊपरी बांह की डेल्टोइड मांसपेशी में एक इंजेक्शन के रूप में दिया जाएगा। भारत बायोटेक COVID-19 टीका (COVAXIN™) टीकाकरण श्रृंखला 2 खुराक है, जो 4 सप्ताह के अंतराल से दी गई है।

क्या भारत बायोटेक कोविड-19 टीका (COVAXIN™) पहले उपयोग में लाया गया है?

केंद्रीय लाइसेंसिंग प्राधिकरण ने नैदानिक परीक्षण मोड में, सार्वजनिक हित में आपातकालीन स्थिति में प्रचुर खुराक में एहतियात के रूप में प्रतिबंधित उपयोग के लिए COVAXIN™ की बिक्री या वितरण की अनुमति दी है। चरण 1 और चरण 2 नैदानिक परीक्षणों में, लगभग 680 (चरण 1 में 300, और चरण 2 में 380) को COVAXIN™ की 2-खुराक के साथ प्रशासित किया गया था। चरण 3 नैदानिक परीक्षण 25,800 प्रतिभागियों में चल रहा है, और सभी प्रतिभागियों को 06 जनवरी 2021 को पहली खुराक मिली है।

भारत बायोटेक COVID-19 टीका (COVAXIN™) के क्या लाभ हैं?

चल रहे नैदानिक परीक्षण में, भारत बायोटेक COVID-19 टीके (COVAXIN™) को 4 सप्ताह दिए गए 2 खुराक के बाद प्रतिरक्षा उत्पन्न करने के लिए दिखाया गया है।

हालाँकि, COVAXIN™ की चिकित्सकीय प्रभावकारिता अभी स्थापित नहीं की गई है और अभी भी 3 नैदानिक परीक्षण अंतर्गत चरण का अध्ययन किया जा रहा है। इसीलिए, यह जानना महत्वपूर्ण होगा कि टीका प्राप्त करने का मतलब यह नहीं है कि Covid -19 से संबंधित अन्य सावधानियों का पालन नहीं किया जाए।

भारत बायोटेक COVID-19 टीके (COVAXIN™) के क्या जोखिम हैं?

कौन-से दुष्प्रभावों की रिपोर्टिंग भारत बायोटेक COVID-19 टीके (COVAXIN™) में की गई है:

- इंजेक्शन स्थल में दर्द
- इंजेक्शन स्थल में सूजन
- इंजेक्शन स्थल में लाली
- इंजेक्शन स्थल में खुजली
- ऊपरी बांह में अकड़न
- इंजेक्शन बांह में कमजोरी
- शरीर में दर्द
- सरदर्द
- बुखार
- अस्वस्थता
- कमजोरी
- चकत्ते
- जी मिचलाना
- उल्टी

अत्यंत कम संभावना है कि भारत बायोटेक COVID-19 टीके (COVAXIN™) किसी गंभीर एलर्जी प्रतिक्रिया का कारण बन सकता है। भारत बायोटेक COVID-19 टीके (COVAXIN™)की एक खुराक प्राप्त करने के बाद एक गंभीर एलर्जी की प्रतिक्रिया बहुत कम हो सकती है

भारत बायोटेक COVID-19 टीका (COVAXIN™)। इस कारण से, आपका टीकाकरण प्रदाता आपको टीकाकरण की प्रत्येक खुराक के बाद 30 मिनट के लिए उस स्थान पर रहने के लिए कहेगा, जहाँ आपने टीकाकरण के बाद निगरानी के लिए अपना टीका प्राप्त किया था। एक गंभीर एलर्जी प्रतिक्रिया के लक्षण शामिल हो सकते हैं:

- सांस लेने में दिक्कत
- आपके चेहरे और गले की सूजन
- तेज़ दिल की धड़कन
- पूरे शरीर पर चकत्ते
- चक्कर आना और कमजोरी

ये सभी भारत बायोटेक COVID-19 टीके(COVAXIN™) के सभी संभावित दुष्प्रभाव नहीं हो सकते हैं है। गंभीर और अप्रत्याशित दुष्प्रभाव हो सकते हैं। BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) का अभी भी नैदानिक परीक्षणों में अध्ययन किया जा रहा है।

मुझे दुष्प्रभावों के बारे में क्या करना चाहिए?

यदि आपको किसी दुष्प्रभाव का अनुभव होता है, तो कृपया अपने स्वास्थ्य प्रदाता / टीकाकर्ता / अधिकारी से संपर्क करें या अपने टीकाकरण का निरीक्षण करें या तुरंत नजदीकी अस्पताल में जाएं।

क्या होगा यदि मैं भारत बायोटेक कोविड-19 टीका(COVAXIN™) प्राप्त न करूं?

भारत बायोटेक COVID-19 टीका (COVAXIN™) प्राप्त करना या न करना आपकी पसंद है।

क्या मैं अन्य टीकों के साथ भारत बायोटेक -19 टीका (COVAXIN™) प्राप्त कर सकता हूं?

अन्य किसी टीके के साथ भारत बायोटेक -19 टीका (COVAXIN™) की उपयुक्तता पर अभी तक कोई वैज्ञानिक जानकारी उपलब्ध नहीं है।

क्या होगा, यदि गर्भवती होऊं या स्तनपान करवा रही होऊं?

यदि आप गर्भवती हैं या स्तनपान करवा रही हैं, तो आपको टीका नहीं लगवाना चाहिए क्योंकि टीके के प्रभाव का गर्भवती महिलाओं और नर्सिंग माताओं में अध्ययन नहीं किया गया है।

क्या भारत बायोटेक -19 टीका (COVAXIN™) से मुझे COVID-19 हो सकता है?

भारत बायोटेक -19 टीका (COVAXIN™) एक निष्क्रिय किया गया (मृत) टीका है, और इसलिए, COVAXIN™ टीकाकरण से मुझे COVID -19 प्राप्त होने की कोई संभावना नहीं है।

इस कार्यक्रम में भाग लेने के लिए मुझे कितना समय लगेगा?

टीकाकरण की दूसरी खुराक के बाद 3 महीने बाद तक सभी टीका प्राप्तकर्ताओं का फॉलो-अप किया जाएगा।

किसी भी गंभीर प्रतिकूल घटनाओं के मामले में, टीका प्राप्तकर्ताओं को सरकार द्वारा निर्दिष्ट और अधिकृत केंद्रों / अस्पतालों में चिकित्सकीय रूप से मान्यता प्राप्त मानक प्रदान किया जाएगा। गंभीर प्रतिकूल घटना के लिए मुआवजे का भुगतान प्रायोजक (बीबीआईएल) द्वारा किया जाएगा यदि एसएई वैक्सीन से संबंधित कार्य सिद्ध होता है। मुआवजे का निर्धारण ICMR सेंट्रल एथिक्स कमेटी द्वारा किया जाएगा।

सभी प्राप्तिकर्ता को स्वास्थ्य देखभाल प्रदाता / साइट / प्रायोजक को रिपोर्ट करने की आवश्यकता होती है, यदि वे COVID-19 के संकेत और लक्षण हैं या COVID-19 के साथ का निदान करते हैं। यदि कोई टीका प्राप्तिकर्ता में COVID-19 के लक्षण विकसित होते हैं, तो टीका प्राप्तिकर्ता को सरकार द्वारा नामित और अधिकृत केंद्रों / अस्पतालों में चिकित्सकीय रूप से मान्यता प्राप्त मानक प्रदान किया जाएगा। COVID-19 सकारात्मक परिणामों को प्रतिकूल घटना प्रारूप में प्रलेखित किया जाना चाहिए। सकारात्मक RT-PCR (मौजूदा सरकारी कार्यक्रम के अंतर्गत और अनुमोदित प्रयोगशालाओं से परीक्षण) का प्रमाण COVID -19 के निदान को स्थापित करने के लिए प्रदान किया जाना चाहिए। टीका प्राप्तकर्ता की मौखिक रिकॉल निदान की पुष्टि नहीं करेगी।

BHARAT BIOTECH

Manufactured and Marketed by:
Bharat Biotech International Limited Genome Valley Turkapally, Shamirpet Hyderabad, Telangana 500 078

FACT SHEET FOR VACCINE RECIPIENT
APPROVED FOR RESTRICTED USE IN EMERGENCY SITUATION OF
ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant)
COVISHIELD™
IN PREVENTION OF (COVID-19) DISEASE IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

This vaccine has been given restricted use license for emergency situation. It does not have a marketing authorization, however, this approval for the restricted use in emergency situation grants permission for the vaccine to be used for active immunization of individuals aged 18 years and older for the prevention of coronavirus disease 2019 (COVID-19).

Reporting of side effects

As with any new medicine, this vaccine will be closely monitored to allow quick identification of new safety information. You can help by reporting any side effects you may get after vaccination to the Serum Institute of India Pvt Ltd who is the manufacturer of COVISHIELD™ vaccine on 24 x 7 Toll-Free Number: +91-1800 1200124 or at pharmacovigilance@seruminstitute.com.
For more information read this fact sheet carefully.

You are being offered the Serum Institute of India Pvt. Ltd. (SIIPL) **COVISHIELD™** Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the **COVISHIELD™** Vaccine, which you may receive because there is currently a pandemic of COVID-19 disease.

The **COVISHIELD™** is a vaccine and may prevent you from getting COVID-19 disease.

Read this Fact Sheet for information about the **COVISHIELD™** Vaccine. Talk to the healthcare provider if you have questions. It is your choice to receive the **COVISHIELD™** Vaccine.

The **COVISHIELD™** vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.

For intramuscular (IM) injection only.

The **COVISHIELD™** may not protect everyone.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE SIIPL COVISHIELD™ VACCINE?

The **COVISHIELD™** is approved for restricted use in emergency situation vaccine that may prevent COVID-19 disease in individuals 18 years of age and older.

WHAT SHOULD YOU MENTION TO YOUR HEALTHCARE PROVIDER BEFORE YOU GET COVISHIELD™ VACCINE?

Tell the healthcare provider about all of your medical conditions, including:

- If you have ever had a severe allergic reaction (anaphylaxis) after any drug, food, any vaccine or any ingredients of COVISHIELD™ vaccine
- If you have fever
- If you have a bleeding disorder or are on a blood thinner
- If you are immunocompromised or are on a medicine that affects your immune system
- If you are pregnant or plan to become pregnant
- If you are breastfeeding
- If you have received another COVID-19 vaccine

You should consult your healthcare provider before deciding to take the vaccine.

WHO SHOULD GET THE COVISHIELD™ VACCINE?

COVISHIELD™ Vaccine has been approved for restricted use in emergency situation in individuals 18 years of age and older.

WHO SHOULD NOT GET THE COVISHIELD™ VACCINE?

You should not get the **COVISHIELD™** Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE COVISHIELD™ VACCINE?

The **COVISHIELD™** Vaccine includes the following ingredients:
L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate (EDTA), Water for injection.

HOW IS THE COVISHIELD™ GIVEN?

The **COVISHIELD™** Vaccine will be given to you as an intramuscular (IM) injection only, preferably in the deltoid muscle.

The **COVISHIELD™** vaccination course consists of two separate doses of 0.5 ml each.

If you receive one dose of the **COVISHIELD™** vaccine, then the second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.

If you miss your second dose

If you forget to go back at the scheduled time, ask your healthcare provider for advice. It is important that you return for your second dose of **COVISHIELD™** vaccine.

HAS THE COVISHIELD™ VACCINE BEEN USED BEFORE?

The **COVISHIELD™** is used in clinical trials, a number of participants received one or two doses in overseas and Indian trials.

WHAT ARE THE BENEFITS OF THE COVISHIELD™ VACCINE?

In ongoing clinical trials, the **COVISHIELD™** Vaccine has been shown to prevent COVID-19 disease following 2 doses given between 4 and 12 weeks apart. The duration of protection against COVID-19 disease is currently unknown.
You may get protective immune response 4 weeks after the second dose of **COVISHIELD™** vaccine.

WHAT ARE THE RISKS OF THE COVISHIELD™ VACCINE?

Side effects that have been reported with the COVISHIELD™ Vaccine include:

Very Common (may affect more than 1 in 10 people)

- tenderness, pain, warmth, redness, itching, swelling or bruising where the injection is given
- generally feeling unwell
- feeling tired (fatigue)
- chills or feeling feverish
- headache
- feeling sick (nausea)
- joint pain or muscle ache

Common (may affect up to 1 in 10 people)

- a lump at the injection site
- fever
- being sick (vomiting)
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

Uncommon (may affect up to 1 in 100 people)

- feeling dizzy
- decreased appetite
- abdominal pain
- enlarged lymph nodes
- excessive sweating, itchy skin or rash

These may not be all the possible side effects of the **COVISHIELD™** Vaccine. Serious and unexpected side effects may occur. **COVISHIELD™ Vaccine is still being studied in clinical trials.**

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call or go to the nearest hospital.
Call the healthcare provider if you have any side effects that bother you or do not go away.
In addition, you can report side effects after vaccination to Serum Institute of India Pvt Ltd who is the manufacturer of **COVISHIELD™** vaccine as below.

- 24 x 7 Call Center Toll-Free Number (For Medical and Adverse Event Related Queries Only): +91-1800 1200124
- **pharmacovigilance@seruminstitute.com**

WHAT IF I DECIDE NOT TO GET THE COVISHIELD™ VACCINE?

It is your choice to receive or not receive the **COVISHIELD™** Vaccine. You may prefer to consult your healthcare provider.

CAN I RECEIVE THE COVISHIELD™ VACCINE WITH OTHER VACCINES?

There is no information on the use of the **COVISHIELD™** Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

You may discuss your options with the healthcare provider.

WILL THE COVISHIELD™ VACCINE GIVE ME COVID-19 INFECTION?

No. The **COVISHIELD™** COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19 infection.

KEEP YOUR VACCINATION CARD

When you get your dose, please discuss with your healthcare provider regarding the option of your vaccination record on digital platform, if available.

HOW CAN I LEARN MORE?

- Ask the healthcare provider.
- Contact your local or state public health department.

Revised: 01 January 2021

Manufactured by:
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411 028, INDIA

Marketed by:
SERUM INSTITUTE LIFE SCIENCES PVT. LTD.
401, Sarosh Bhavan, 16-B/1, Dr. Ambedkar Road, Pune - 411 001, INDIA

20017291/0

टीका प्राप्त करने वाले व्यक्ति के लिए तथ्य पत्र (फैक्ट शीट)
18 वर्ष या उससे अधिक की उम्र वाले लोगों के लिए रोग (कोविड-19) की रोकथाम के लिए आपातस्थिति में सीमित प्रयोग के लिए अनुमोदित
ChAdOx1 nCoV-19 कोरोना वायरस टीका (पुनःसंयोजक)
कोविशील्ड™

यह टीका केवल आपात स्थिति में सीमित उपयोग के लिए है। इस टीके का विपणन करने की अनुमति नहीं है, लेकिन आपातस्थिति में सीमित प्रयोग के लिए अनुमोदित यह टीका 18 वर्ष और उससे अधिक उम्र के लोगों में कोरोना वायरस रोग 2019 (कोविड-19) की रोकथाम हेतु सक्रिय टीकाकरण करने के लिए इस्तेमाल किया जा सकता है।

प्रतिकूल प्रभावों की रिपोर्टिंग

जैसा कि हर नई दवा के साथ होता है, टीके की बारीकी से निगरानी की जाएगी जिससे इस टीके के संबंध में सुरक्षा संबंधी नयी जानकारी त्वरित रूप से पता की जा सके। टीकाकरण के बाद किसी भी प्रतिकूल प्रभाव की सूचना कोविशील्ड के निर्माता, सीरम इंस्टिट्यूट ऑफ इंडिया प्राइवेट लिमिटेड को 24 x 7 टोल-फ्री हेल्प लाइन: +91-1800 1200124 या pharmacovigilance@seruminstitute.com पर देकर आप मदद कर सकते हैं।
और जानकारी के लिए इस तथ्य पत्र को ध्यान से पढ़ें।

आपको सीरम इंस्टिट्यूट ऑफ इंडिया प्राइवेट लिमिटेड **कोविशील्ड™** (एस आई आई पी एल) द्वारा सार्स कोव-2 के कारण होने वाले कोरोनावायरस रोग 2019 (कोविड-19) की रोकथाम के लिए **कोविशील्ड™** टीके की पेशकश की जा रही है। इस तथ्य पत्र में **कोविशील्ड™** टीके के जोखिमों और लाभों को समझने में मदद करने के लिए जानकारी दी गई है। कोविड-19 महामारी के कारण आपको यह टीका दिया जा सकता है।

कोविशील्ड™ एक टीका है जिससे आप कोविड-19 रोग से पीड़ित होने से बच सकते हैं।

कोविशील्ड™ टीके के बारे में जानकारी प्राप्त करने के लिए इस तथ्य पत्र को पढ़ें। अगर आपको कुछ पूछना है तो स्वास्थ्य सेवा प्रदाता से बात करें। यह आपकी इच्छा पर निर्भर करता है कि आप **कोविशील्ड™** टीका लेंगे या नहीं।

कोविशील्ड™ टीके के कोर्स में 0.5 ml की दो अलग अलग खुराके हैं। प्रथम खुराक प्राप्त करने के 4 से 6 सप्ताह के बीच दूसरी खुराक दी जानी चाहिए। लेकिन विदेश में हुए अध्ययनों से उपलब्ध आकड़े और जानकारी दर्शाते है कि प्रथम खुराक प्राप्त करने के 12 सप्ताह तक दूसरी खुराक दी जा सकती है।

यह केवल मांसपेशीय इंजेक्शन(आई.एम.) के रूप में ही दिया जाना चाहिए।

हो सकता है कि **कोविशील्ड™** सबको सुरक्षा न प्रदान करें।

इस टीके को प्राप्त करने से पहले वह बातें जिनकी आपको जानकारी होनी आवश्यक है

कोविड-19 क्या है?

कोविड-19 एक रोग है जो सार्स-कोव-२ नामक कोरोना वायरस से होता है। इस प्रकार का कोरोना वायरस पहले कभी नहीं देखा गया था। आपको किसी कोविड-19 से पीड़ित व्यक्ति के संपर्क में आने से यह रोग हो सकता है। मुख्य रूप से यह श्वसन तंत्र का रोग है जो अन्य अंगों को प्रभावित कर सकता है। कोविड-19 से पीडित लोगों द्वारा विभिन्न प्रकार के लक्षणों जैसे कि मामूली लक्षणों से लेकर गंभीर लक्षणों तक के बारे में सूचना दी गई है, वायरस के संपर्क में आने के 2 से 14 दिनों के भीतर यह लक्षण नज़र आ सकते हैं। वह लक्षण जो दिख सकते हैं: बुखार या कंपकंपी; खाँसी; साँस फूलना; थकान; मांसपेशियों या शरीर में दर्द; सरदर्द; हाल ही में स्वाद या गंध न महसूस होना; गले में खराश; बंद नाक या बहती नाक; उलटी अथवा मतली; दस्त।

एस आई आई पी एल कोविशील्ड™ टीका क्या है?

कोविशील्ड™ टीका 18 वर्ष और उससे अधिक उम्र के लोगों में कोविड-19 रोग की रोकथाम के लिए आपात स्थितियों में सीमित उपयोग के लिए अनुमोदित किया गया है।

कोविशील्ड™ टीका लेने से पहले आपको अपने स्वास्थ्य प्रदाता को क्या बताना चाहिए?

स्वास्थ्य प्रदाता को अपनी स्वास्थ्य संबंधी **परिस्थितियों** के बारे में सब कुछ बताएं, जिसमें निम्नलिखित बातें शामिल होनी चाहिए:

- अगर आपको किसी दवा, खाद्य पदार्थ, किसी टीके या **कोविशील्ड™** टीके के किसी भी सामग्री के कारण गंभीर
- अलर्जी (तीव्रग्राहिता) हुई है
- अगर आपको बुखार है
- अगर आपको रक्त बहने संबंधी विकार है या आप रक्त पतला करने की कोई दवा ले रहे हैं
- अगर आपकी प्रतिरक्षा क्षमता कम है या आप ऐसी दवाएं लेते हैं जो आपके प्रतिरक्षा तंत्र को प्रभावित करती हैं
- अगर आप गर्भवती हैं या गर्भ धारण करने के बारे में सोच रही हैं
- अगर आप स्तनपान कराती हैं
- अगर आपको कोविड-19 के खिलाफ कोई अन्य टीका दिया जा चुका है

इस टीके को लेने से पहले आप अपने स्वास्थ्य प्रदाता से इसके बारे में परामर्श करें।

किन लोगों को कोविशील्ड™ टीका लेना चाहिए?

कोविशील्ड™ टीका 18 वर्ष और उससे अधिक उम्र के लोगों के लिए आपात स्थितियों में सीमित उपयोग के लिए अनुमोदित किया गया है।

किन लोगों को कोविशील्ड™ टीका नहीं लेना चाहिए?

आपको **कोविशील्ड™** टीका नहीं लेना चाहिए अगर आपको :

- इस टीके की पिछली खुराक के बाद गंभीर रूप से अलर्जी हुई थी।
- इस टीके में शामिल किसी भी सामग्री से आपको गंभीर रूप से अलर्जी हुई थी।

कोविशील्ड™ टीके में क्या सामग्री शामिल हैं?

कोविशील्ड™ टीके में निम्नलिखित सामग्री है:

एल-हिस्टिडीन, एल-हिस्टिडीन हाइड्रोक्लोराइड मोनोहाइड्रेट, मेग्नीशियम क्लोराइड हेक्साहाइड्रेट, पॉलिसोर्बेट 80, इथेनॉल, सुकरोज़, सोडियम क्लोराइड, डायसोडियम इडेटेट डायहाइड्रेट (ईडीटीए), इंजेक्शन के लिए पानी

कोविशील्ड™ टीका कैसे दिया जाता है?

कोविशील्ड™ टीका केवल मांसपेशीय इंजेक्शन(आईएम) के रूप में ही **आपको दिया जाएगा**, आदर्श रूप से डेल्टॉइड मांसपेशी में।

कोविशील्ड™ टीके के कोर्स में 0.5 ml की दो अलग अलग खुराके हैं।

अगर आपको **कोविशील्ड™** की पहली खुराक दी जा चुकी है, तो प्रथम खुराक प्राप्त करने के 4 से 6 सप्ताह की बीच दूसरी खुराक दी जानी चाहिए। लेकिन विदेश में हुए अध्ययनों से उपलब्ध आकड़े और जानकारी दर्शाते है कि प्रथम खुराक प्राप्त करने के 12 सप्ताह तक दूसरी खुराक दी जा सकती है।

अगर आप दूसरी खुराक लेना भूल जाते हैं

अगर आप नियत समय पर दूसरी खुराक लेना भूल जाते हैं, तो अपने स्वास्थ्य प्रदाता से सलाह लें। जरूरी है कि आप **कोविशील्ड™** टीके की दूसरी खुराक लेने वापस आएं।

क्या कोविशील्ड™ टीके का पहले इस्तेमाल हुआ है?

कोविशील्ड™ का प्रयोग नैदानिक परीक्षणों में किया गया है, विदेश और भारत में हुए परीक्षणों में कई सहभागियों को **कोविशील्ड™** की एक या दोनो खुराकें दी गई थीं।

कोविशील्ड™ टीके के क्या लाभ हैं?

जारी नैदानिक परीक्षणों में देखा गया है कि **कोविशील्ड™** टीके से कोविड-19 रोग की रोकथाम होती है जब 4 से 12 सप्ताह के अंतराल पर 2 खुराके दी जाती हैं। कोविड-19 से सुरक्षा की अवधि के बारे में फिलहाल कोई जानकारी नहीं है। **कोविशील्ड™** टीके की दूसरी खुराक प्राप्त करने के 4 सप्ताह बाद आप में सुरक्षात्मक प्रतिरक्षा क्षमता उत्पन्न हो सकती है।

कोविशील्ड™ टीके से संबंधित क्या जोखिम हैं?

कोविशील्ड™ टीके से जुड़े प्रतिकूल प्रभाव जो रिपोर्ट किए गए हैं, उनमें शामिल हैं:

बहुत आम है (जो 10 में से 1 से अधिक व्यक्ति को प्रभावित करते हैं)

- इंजेक्शन लगाए जाने के स्थान पर दबाने से दर्द, दर्द, गर्माहट, लालिमा, खुजली, सूजन या घाव
- सामान्य तौर पर तबियत ठीक नहीं लगना
- थकान महसूस होना (कमज़ोरी)
- कंपकंपी या बुखार सा महसूस होना
- सरदर्द
- तबियत खराब लगना (मतली)
- जोड़ों में दर्द या मांसपेशियों में दर्द

आम है (जो 10 में से 1 व्यक्ति तक को प्रभावित करते हैं)

- इंजेक्शन लगने के स्थान पर गाठ बनना
- बुखार
- तबियत खराब लगना (उलटी करना)
- फ्लू जैसे लक्षण, जैसे कि तेज बुखार, गले में खराश, बहती नाक, खाँसी और
- कंपकंपी

आम नहीं है (जो 100 में से 1 व्यक्ति तक को प्रभावित करते हैं)

- चक्कर आना
- भूख में कमी
- पेट में दर्द
- फूले हुए लिम्फ नोड्स (लसीका पर्व)
- अत्यधिक पसीना आना, त्वचा में खुजली या चकते

उपरोक्त दुष्प्रभाव **कोविशील्ड™** से संबंधित संभव दुष्प्रभावों की पूर्ण सूची शायद नहीं है।

गंभीर और अप्रत्याशित दुष्प्रभाव हो सकते हैं। **कोविशील्ड™** टीके के नैदानिक परीक्षणों में अध्ययन अभी भी जारी है।

प्रतिकूल प्रभावों के बारे में मुझे क्या करना चाहिए?

अगर आपको गंभीर अलर्जी होती है, तो नज़दीकी अस्पताल को कॉल करें या वहाँ जाएं।

स्वास्थ्य प्रदाता से बात करें अगर कोई भी दुष्प्रभाव आपको परेशान करता है या उसकी तीव्रता कम नहीं हो रही है।

इसके अतिरिक्त आप टीके के बाद होने वाले प्रतिकूल प्रभावों की जानकारी सीरम इंस्टिट्यूट ऑफ इंडिया प्राइवेट लिमिटेड को निम्नलिखित तरीके से दे सकते हैं। सीरम इंस्टिट्यूट ऑफ इंडिया प्राइवेट लिमिटेड **कोविशील्ड™** टीके का निर्माता है।

- 24 x 7 कॉल सेंटर का टोल फ्री नम्बर (केवल चिकित्सीय और प्रतिकूल प्रभावों से संबंधित प्रश्न पूछने के लिए): +91-1800 1200124
- **pharmacovigilance@seruminstitute.com**

क्या होगा अगर मैं कोविशील्ड™ टीका नहीं लेता?

यह आपकी इच्छा पर निर्भर करता है कि आप **कोविशील्ड™** टीका लेंगे या नहीं। आप अपने स्वास्थ्य प्रदाता से इसके बारे में परामर्श ले सकते हैं।

क्या मैं अन्य टीकों के साथ कोविशील्ड™ टीका ले सकता हूँ?

कोविशील्ड™ टीके का अन्य टीकों के साथ लिए जाने के बारे में अभी तक कोई जानकारी मौजूद नहीं है।

अगर मैं गर्भवती हूँ या स्तनपान कराती हूँ तो क्या?

आपके सामने मौजूद विकल्पों के बारे में अपने स्वास्थ्य प्रदाता से चर्चा करें।

क्या कोविशील्ड™ टीके से मुझे कोविड-१९ संक्रमण हो सकता है?

नहीं। **कोविशील्ड™** कोविड-१९ टीके में सार्स-कोव-2 मौजूद नहीं है और इससे कोविड-१९ संक्रमण नहीं हो सकता।

अपना टीकाकरण कार्ड अपने पास रखें

अगर डिजिटल प्लैटफॉर्म पर टीकाकरण रिकॉर्ड का विकल्प उपलब्ध हो तो जब आपको खुराक दे दी जाए, तो अपने स्वास्थ्य प्रदाता से इसके बारे में चर्चा करें।

मुझे इसके बारे में और जानकारी कहाँ से मिल सकती है?

- अपने स्वास्थ्य प्रदाता से पूछें।
- अपने स्थानीय या राज्य के जन स्वास्थ्य विभाग से संपर्क करें।

संशोधित: 01 जनवरी 2021

निर्माता
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411 028, INDIA

विपणन:
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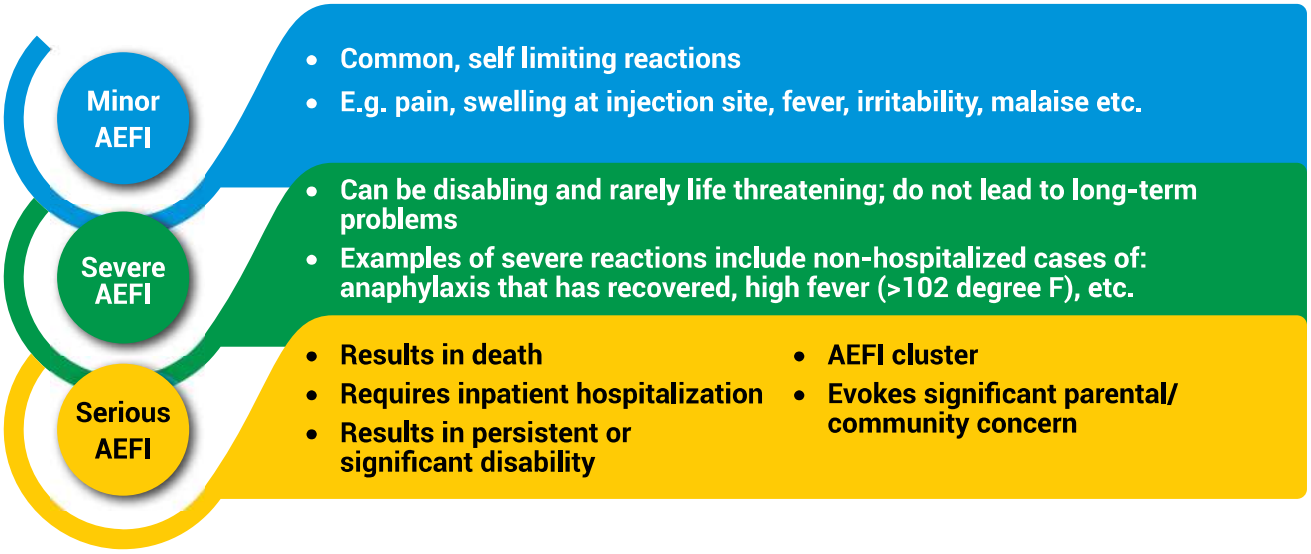
401, Sarosh Bhavan, 16-B/1, Dr. Ambedkar Road, Pune - 411 001, INDIA

10.3 ADVERSE EVENTS FOLLOWING IMMUNIZATION

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended disease, symptom, sign or abnormal laboratory finding. Reported adverse events can either be true adverse events, i.e. really a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization.

For purposes of reporting, AEFIs can be classified as minor, severe and serious



10.3.1 PREVENTION OF AEFIs

Injectable COVID-19 vaccines are expected to be given in a campaign mode and these vaccines may have different modalities of administration. Appropriate measures need to be taken to avoid possibilities of anxiety reactions in individuals and clusters. Programme managers and implementers must plan to prevent and minimize chances of occurrence of preventable AEFIs. Beneficiaries should be observed at the session site for at least 30 minutes post-vaccination to detect, manage and treat immediate adverse reactions.

10.3.2 PREVENTING ANXIETY REACTIONS

Session sites should be planned in such a way that there is a separate area for those waiting for vaccination, site of actual vaccination and post-vaccination observation area.

- Ensure vaccinations occur in comfortable, well-ventilated and airy settings. Beneficiaries who seem anxious or nervous should be identified and made to calm down or their attention diverted from the process and the pain. After vaccination, they should be asked to remain seated for some time and observed. If they feel light-headed or giddy, they should be asked to lie down for some time.

10.3.3 PREVENTING PROGRAMME ERRORS

Ensure guidelines for safe injection practises are followed at the session site. Special attention should be on the following:

- Ensure nothing other than vaccines / diluents are stored in ILRs;
- If reconstitution is required, separate reconstitution syringes should be used for each vial and diluent;

(જુઓ નિયમ ૪(૧))

અરજદારને માહિતી આપવા બાબત.

નં.પ.ક./૨૦૨૧-૨૨/ઇમ્યું./આર.ટી.આઇ/દિપકભાઈ જતાપરા/ગાંધીનગર/માહિતી/૮૦૪૭૬૧/૬૬૪/૨૦૨૧
જાહેર માહિતી અધિકારી અને નાયબ નિયામકશ્રી(MCH) કમિશ્નરશ્રી,આરોગ્ય ત.સેવાઓ અને ત.શિક્ષણ (આ.વિ.), પરિવાર કલ્યાણ શાખા, બ્લોક નં.૫/૨, ડો.જીવરાજ મહેતા ભવન,ગાંધીનગર, તા. ૧૦/૧૨/૨૦૨૧

પ્રતિ,
દિપકભાઈ જતાપરા

વિષયઃ માહિતી મેળવવાના અધિકાર અધિનિયમ-૨૦૦૫ હેઠળ માહિતી પુરી પાડવા બાબત
સંદર્ભઃ માહિતી અધિનિયમ અન્વયે આપશ્રીની તા.૦૯/૧૨/૨૦૨૧ની અરજી

શ્રીમાન,

આપના ધ્વારા તારીખઃ ૦૯/૧૨/૨૦૨૧ની અરજી અત્રેની કચેરીને તા.૧૦/૧૨/૨૦૨૧ના રોજ મળેલ છે. આપના દ્વારા નીચે મુજબ માહિતી માંગવામાં આવેલ છે.

<u>ક્રમ</u>	<u>પ્રશ્ન</u>	<u>જવાબ</u>
૧	કોવીશિલ્ડ તથા કોવેક્સીનની ફેક્ટ શીટમાં દર્શાવેલ મુજબ કોઈ પણ પ્રકારની એલર્જી, કોઈ પણ બીમારી માટે નિયમિત દવા લેનાર, રક્ત વિકાર અથવા રક્ત સંબંધી કોઈ દવા લેનાર, ઈમ્યોનોકોપ્રોમાઈઝડ અથવા કોઈ એસી દવા લેતા હોય જેનાથી પ્રતિરક્ષા પ્રણાલી પ્રભાવિત થતી હોય, ગર્ભવતી અથવા ગર્ભ ધારણ માટે વિચારનાર મહિલા, સ્તનપાન કરાવનાર વગેરે વ્યક્તિને વેક્સીન લેવાની મનાઈ કરવામાં આવેલ છે તો આવા વ્યક્તિને આપના તરફથી વેક્સીન લેવામાંથી મુક્તિ આપવામાં આવેલ છે તે જણાવવા વિનંતી.	આપશ્રીની રજુઆત અનુસંધાને જણાવવાનું કે આપના નિવાસસ્થાનની નજીકના સરકારી દવાખાનામાં ફિઝીશીયનની સલાહ સુચનો અનુસાર કોરોનાની રસી લઈ શકો છો.
૨	ભારત સરકાર હેલ્થ વિભાગ દ્વારા વેક્સીન ફરજીયાત કરેલ નથી તથા કોઈપણ પ્રકારની સવલત નોકરી, વેપાર ધંધા સાથે સંકળાયેલ ફેક્ટરી કામકાજ, બસ ટ્રાવેલિંગ કોઈ સાર્વજનિક સ્થળ પ્રવેશ કરવા કે કોઈપણ પ્રકારની સેવા માટે વેક્સીન લેવી ફરજીયાત કરવામાં આવેલ નથી, પરંતુ અમુક નગરપાલીકા, મહાનગરપાલિકા, અધિકારીઓ કોઈપણ પ્રકારની સવલત નોકરી, વેપાર ધંધા સાથે સંકળાયેલ ફેક્ટરી કામકાજ, બસ ટ્રાવેલિંગ, કોઈ સાર્વજનિક સ્થળ પ્રવેશ કરવા કે કોઈપણ પ્રકારની સેવા માટે વેક્સીન ફરજીયાત લેવા	આ પ્રકારનો કોઈ પરિપત્ર કે સુચના આપવામાં આવેલ નથી.

	માટે દબાણ તથા પરિપત્ર બહાર પાડી રહ્યા છે, તો આ બાબતે આપના હેલ્થ વિભાગ તરફથી કોઈ વેક્સીન ફરજીયાત માટે આવા પ્રકારનો કોઈ પરિપત્ર કે સુચના આપવામાં આવેલ છે કે નહી તે જણાવવા વિનંતી.	

ઉક્ત પ્રત્યુત્તરથી નારાજ હોય તો આપ અધિક નિયામકશ્રી(પ.ક.), ગાંધીનગરને સમયમર્યાદામાં અપીલ કરી શકો છો.

આપનો વિશ્વાસું

(ડો. આર.આર. વૈદ્ય)
જાહેર માહિતી અધિકારી અને
નાયબ નિયામક (એમ.સી.એચ)
આરોગ્ય ત. સે. અને ત.શિ.(આ.વિ.) ગાંધીનગર
E-mail IDdydir.health.mch@gmail.com

- નકલ રવાના:-

જાહેર માહિતી અધિકારી અને સેક્શન અધિકારી (બ-૧), ગાંધીનગરના પત્રકમાંક આરટીઆઈ/૧૦૨૦૨૧/૪૨/બ-૧, તા.૦૯/૧૨/૨૦૨૧.

❖ **THE MINSTRY OF HELTH AND FAIMLY WELFARE GUIDELINES SAID THAT COVID -19 VACCINATION IS VOLUNTARY.**

➢ https://www.mohfw.gov.in/covid_vaccination/vaccination/index.html

scheduled anytime soon for me?

Is it mandatory to take the vaccine? −

Vaccination for COVID-19 is voluntary. However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers.

Will the vaccine be safe as it +

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Q&A
IS IT MANDATORY FOR ALL TO TAKE THE VACCINE?
NO, GETTING VACCINATED IS VOLUNTARY. HOWEVER, IT IS ADVISABLE TO COMPLETE THE SCHEDULE OF VACCINE TO LIMIT THE SPREAD OF THE VIRUS

Ministry of Health & Family Welfare
Government of India

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Q&A

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Azadi Ka Amrit Mahotsav

By Regd. Post (A.D.)
Reply under RTI Act, 2005

નમૂનો 'ગ'

(ગુજરાત માહિતીના અધિકાર બાબતના નિયમો, ૨૦૧૦ના નિયમ ૪(૧))

ક્રમાંક:આરટીઆઈ-૧૦૨૦૨૨-૦૨-૮
જાહેર માહિતી અધિકારી અને સેકશન અધિકારી(૮)
સામાન્ય વહીવટ વિભાગ,
બ્લોક નં.૭/૧, સરદાર ભવન,
સચિવાલય, ગાંધીનગર.
તારીખ:૨૪/૦૧/૨૦૨૨

પ્રતિ,
શ્રી દિપકભાઇ

શ્રીમાન,

માહિતીનો અધિકાર અધિનિયમ-2005 હેઠળની આપની તા.૧૭.૦૧.૨૦૨૨ની અરજી આ જાહેર સત્તામંડળને તા.૨૧.૦૧.૨૦૨૨ના રોજ મળેલ છે. આપે આપની સદર અરજીથી માંગેલ માહિતીમાં તે માહિતી અધિકાર અધિનિયમ, ૨૦૦૫, કલમ-૫ની પેટા કલમ (૨)ના પરંતુક અથવા કલમ-૬ ની પેટા કલમ (૩)ના પરંતુકને આધીન માંગવામાં આવેલ માહિતી, કોઇ વ્યકિતની જિંદગી અથવા સ્વતંત્રતા સાથે સંબંધિત હોય ત્યારે વિનંતી મળ્યાના અડતાલિસ કલાકની અંદર તે માહિતી ચુકી પાડવી જોઇશે તેમ જણાવી માહિતી ફરજીયાત વેકસિન સંબંધી હોઇ તે જિંદગી અને સ્વતંત્રતા સાથે સંબંધિત હોઇ ૪૮ કલાકમાં આપવા વિનંતી કરેલ છે.

(૨) આ બાબતે જણાવવાનું કે, માહિતી અધિકાર અધિનિયમ ૨૦૦૫ની કલમ-૭(૧)ના પરંતુકની જોગવાઇ અનુસાર માંગેલ માહિતી પૈકી કોઇ માહિતી અરૂજકર્તાની જિંદગી અને સ્વતંત્રતા સાથે સંકળાયેલ હોય તો તે ૪૮ કલાકમાં પૂરી પાડવાની જોગવાઇ છે. પ્રથમ દર્શને આપે માંગેલ માહિતી જોતા તે જિંદગી અને સ્વતંત્રતા સાથે સંકળાયેલ હોય તેમ જણાયેલ ન હોઇ માહિતી અધિકાર અધિનિયમ, ૨૦૦૫ની કલમ ૭(૧)ની જોગવાઇ અનુસાર મહત્તમ દિન-૩૦ની નિયત થયેલ મર્યાદામાં માહિતી/પ્રત્યુત્તર પાઠવવાનો રહે છે.

(૩) આથી, આપની અરજીના સંબંધમાં જણાવવાનું કે, આપે માંગેલ માહિતી મુદાવાર નીચે મુજબ છે.

ક્રમ	માંગેલ માહિતીનો મુદ્દો	જાહેર માહિતી અધિકારીનો પ્રતિભાવ
૧	નેશનલ ઓથોરિટી ભારત સરકાર તથા હેલ્થ મિનિસ્ટ્રી ભારત સરકાર દ્વારા વેક્સિન લેવી સ્વૈચ્છિક છે. ડિજાસ્ટર મેનેજમેન્ટ એકટ-૨૦૦૫ મુજબ નેશનલ ઓથોરિટી વિરુધ્ધ કોઇપણ ગાઇડ લાઇન બહાર પાડી ન શકે, તો આપે ક્યા રૂલ્સ અને કાનૂન મુજબ પરિપત્ર ક્રમાંક-પરચ-૧૦૨૦૨૦૫૦૧૮ તા.૩૧-૧૨-૨૦૨૧ બહાર પાડેલ છે (કોઇપણ ઓફિસ પ્રવેશ પુર્વે વેક્સિન લગાવેલ ફરજિયાત કરેલ છે) તેની માહિતી આપવા વિનંતી.	અત્રે જણાવવાનું કે, સદર પરિપત્રની કોઇ બાબત કોઇપણ નાગરિકને કોવિડ-૧૯ની વેક્સિન ફરજિયાત લેવાની ફરજ પાડતી નથી. પરંતુ તે જાહેરહિતમાં તા.૦૧.૦૧.૨૦૨૨થી તેમાં ઉલ્લેખિત કચેરીઓમાં માત્ર મુલાકાતીઓના પ્રવેશના હેતુસર કોરોનાની રસીના બન્ને ડોઝ લીધેલ હોવાની જરૂરીયાત દર્શાવે છે. સદર પરિપત્રમાં ઉલ્લેખિત કચેરીઓમાં ફરજ બજાવતા કર્મચારીઓ તથા પોત પોતાના કામકાજ અર્થે આવી કચેરીઓમાં આવેલ મુલાકાતી અરજદાર/નાગરિકોના આરોગ્ય હિતમાં કોવિડ-૧૯ સંક્રમણના પ્રસારને અટકાવવાના જાહેરહિતના વિશાળ હેતુસર સરકારશ્રીએ આ નિયંત્રણ લાગુ કરેલ છે.
૨	પરિપત્ર ક્રમાંક-પરચ-૧૦૨૦૨૦૫૦૧૮ તા.૩૧-૧૨-૨૦૨૧ કોઇપણ ઓફિસ પ્રવેશ પુર્વે વેક્સિન લગાવેલ ફરજિયાત કરેલ છે તે હેલ્થ વિભાગના ક્યા સૂચન અથવા પરિપત્રના આધારે કરેલ છે તેની નકલ આપવા વિનંતિ.	ઉપર (૧) મુજબ.

3	પરિપત્ર ક્રમાંક-પરચ-૧૦૨૦૨૦૫૦૧૮ તા.૩૧-૧૨-૨૦૨૧ (કોઇપણ ઓફિસ પ્રવેશ પુર્વે વેક્સિન લગાવેલ ફરજિયાત કરેલ છે) તો આપે વેક્સિન ન લગાવેલ વ્યક્તિને ઓફિસમાં પ્રવેશ થી વંચિત કયા આધારે ભેદભાવ કરેલ છે તેની માહિતી આપવા વિનંતી.	સદર નિયંત્રણથી કોઇ જ ભેદભાવ થતો નથી. વધુમાં ઉપર (૧) મુજબ.

ઉપરના નિર્ણયથી આપ નારાજ થયેલ હોય તો નિર્ણય મળ્યાની તારીખથી ૩૦ દિવસની અંદર આપશ્રી એ.એસ.ગામીત, અપીલ અધિકારી અને ઉપસચિવશ્રી (સંકલન), સામાન્ય વહીવટ વિભાગ, બ્લોક નં. ૧/૪ મો માળ, સચિવાલય, ગાંધીનગર. ૩૮૨૦૧૦ ને અપીલ કરી શકશો.

આપનો વિશ્વાસુ

(અશ્વિન જાટીયા)

જાહેર માહિતી અધિકારી અને સેકશન અધિકારી,

સામાન્ય વહીવટ વિભાગ,

ગુજરાત સરકાર

ટે.નં.૨૩૨૫૪૬૩૧(૦)

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

Final Status of MOHFW/R/E/22/00152

Applicant Name	Dipak Jatapara
Date of receipt	10/01/2022
Request Filed With	Department of Health & Family Welfare
Text of Application	KYA BHARAT SARKAR KE SWATHYA VIBHAG DWARA VACCINE LENA ANIVARYA HAI EK VYAKTI JISE VACCINE NAHI LAGVAYA HAI RAJYA KE ADHIKARI YA VIBHAG SARKARI YA KOI SARVAJANIK STHAN, BUS, GARDEN PRAVESH KARNE SE ROK SHAKTE HAI KYA YADI RAJYA KA KOI ADHIKARI YA VIBHAG BHARAT SARKAR KE SWATHYA VIBHAG KA AADESH KA PALAN NAHI KARTA HAI TO HAME KYA KARNA CHAHIYE Please provide information within 48 hours to be related to life and freedom subsection 2 of section 5 or Sub section 3 of section 6 of the Right to Information Act 2005
Request document *(if any)*	
Status	REQUEST DISPOSED OF as on 11/01/2022
Date of Action	11/01/2022
Remarks	Reply :- आपका आरटीआई आवेदन अधोहस्ताक्षरी को आरटीआई सेल, MoHFW/अन्य CPIO से प्राप्त हुआ है। जहां तक इस कार्यालय/सीपीआईओ यानी कोविड-19 वैक्सीन एडमिनिस्ट्रेशन सेल (सीवीएसी)/अंडरहस्ताक्षरित सीपीआईओ का संबंध है, यह सूचित किया जाता है कि COVID-19 के लिए टीकाकरण स्वैच्छिक है। हालांकि, इस बीमारी से खुद को बचाने के लिए COVID-19 वैक्सीन का पूरा शेड्यूल प्राप्त करना उचित है और इस बीमारी के प्रसार को परिवार के सदस्यों, दोस्तों, रिश्तेदारों और सहकर्मियों सहित करीबी संपर्कों तक पहुँचने से रोकना है। यह ध्यान दिया जा सकता है कि स्पष्टीकरण और प्रश्नात्मक/काल्पनिक प्रश्नों का उत्तर प्रदान करना आरटीआई अधिनियम के अंतर्गत नहीं आता है। COVID-19 के लिए टीकाकरण स्वैच्छिक है, हालाँकि, राज्य सरकार या जिला प्रशासन या किसी कार्यालय (कार्यालयों) आदि द्वारा या राज्य सरकार के सक्षम प्राधिकारी के आदेश के तहत या आपदा प्रबंधन के तहत जारी कोई भी आदेश / निर्देश आदि या निजी क्षेत्र, निजी कंपनियों, कार्यालयों आदि द्वारा कोविड-19 के लिए अनिवार्य टीकाकरण के संबंध में अधिनियम या कोई अन्य प्रावधान/विनियम/नियम आदि आरटीआई अधिनियम के अनुसार केंद्रीय लोक सूचना अधिकारी (सीपीआईओ) के अधिकार क्षेत्र में नहीं आता है। सूचना/स्पष्टीकरण संबंधित राज्यों/कार्यालयों/संगठन से प्राप्त करें। यदि आप प्रदान की गई जानकारी के संबंध में अपील के लिए जाना चाहते हैं, तो आप श्री सचिन कुमार, उप सचिव और प्रथम अपीलीय प्राधिकरण, स्वास्थ्य और परिवार कल्याण मंत्रालय, निर्माण भवन, नई दिल्ली से इस उत्तर की प्राप्ति की तिथि से 30 दिनों के भीतर अपील कर सकते हैं।

Print

Final Status of MOHFW/R/E/22/00486

Applicant Name	Dipak Jatapara
Date of receipt	27/01/2022
Request Filed With	Department of Health & Family Welfare
Text of Application	1 Does a school college or vaccine provider have to get a consent form from parents before giving corona vaccine to 15-18 year old children 3 Does the vaccinator or medical officer have to take a consent form before giving corona vaccine to 15 to 18 year old children 4 What medical considerations should the vaccinator or medical officer take care of before giving corona vaccine to 15-18 year old children 5 How can children who need to be vaccinated know that I am eligible for it 6 What should be done if any child gets injured or side effects after vaccination? And who is responsible for taking care of those things 7 Is it mandatory for children to get vaccinated If so please send those documents 8 If a child has side effects or injuries who is to pay for it And who to report to Please provide information within 48 hours to be related to life and freedom subsection 2 of section 5 or Sub section 3 of section 6 of the Right to Information Act 2005
Request document *(if any)*	document not provided
Status	REQUEST DISPOSED OF as on 31/01/2022
Date of Action	31/01/2022
Remarks	Reply :- Your RTI application has been received from RTI Cell, MoHFW/other CPIO. As far as this Office/CPIO i.e. COVID-19 Vaccine Administration Cell (CVAC)/Undersigned CPIO is concerned, the information/reply is as under: 1&3. As per the existing guidelines, there is no provisions for forcing any citizen/person to book appointment for Covid Vaccination on COWIN or visit Covid Vaccination Center for vaccination. if an eligible person visits a Covid Vaccination Centre by his/her choice for vaccination, it implies that she/he is voluntarily coming to the center to get the benefit of Covid Vaccination. Hence, no separate written consent should be required from the person who has voluntarily come to the Covid Vaccination Center, to get the Vaccination. 2. Applicant has missed to type Sl. No.2.

4. You may refer COVID-19 vaccine operational guidelines (28.12.2020) https://www.mohfw.gov.in/covid_vaccination/vaccination /dist/images/documents/COVID19VaccineOG111Chapter16.pdf

5. Please see MoHFWs website refer link
https://www.mohfw.gov.in
/pdf/GuidelinesforCOVID19VaccinationofChildrenbetween15to18yearsandPrecautionDosetoHCWsFLWs&60populationwithcomorbidities.pdf for Guidelines for COVID-19 vaccination of children between
15-18 years and precaution dose to HCWs, FLWs & 60 plus
population with comorbidities (27.12.2021)

6&8. COVID Vaccines like other drugs are licensed after due deliberations and consideration of safety data by Drug Controller General of India (DCGI). If anyone is concerned for any specific health reason before COVID Vaccination, please consult a doctor/Health Care Provider. Vaccination for COVID-19 is voluntary. There is no provision of financial assistance/compensation for adverse event following COVID-19 Vaccine, if any. However, severe and serious Adverse Events Following Immunization (AEFI) cases may be reported to and treated at Government Hospital/facilities. You may refer COVID-19 vaccine operational guidelines (28.12.2020) https://www.mohfw.gov.in /covid_vaccination/vaccination/dist/images/documents/COVID19VaccineOG111Chapter16.pdf (Page no. 105 specifically for Adverse Events Following Immunization).

7. Vaccination for COVID-19 is voluntary. However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers.

As far as COVID-19 Vaccine Administration is concerned, it is kind to inform that since the crux of the information/guidelines/Standard Operating Procedure (SoP) etc has being communicated to the States/UTs and citizens through MoHFW/Press Information Bureau s website and also explained by the experts on various media forums (both print and electronic), therefore, the issue of imminent impact on life and liberty of Indian citizen does not arise. However, information is being provided as above.

In case, you want to go for an appeal in connection with the information provided, you may appeal to the Shri Sachin Kumar, Deputy Secretary & First Appellate Authority, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi within 30 days from the date of receipt of this reply.

Print

F. No. Z.28016/133/2021-DM Cell
Government of India
Ministry of Health & Family Welfare
(DM Cell)

Nirman Bhavan, New Delhi.
Dated the 27th May 2021.

To

Sourav Bysack
Saradapally Mathurdingi, Mrigalal,
Tantipara Haspu, Dankuni, Pin:712311
bysack.sourav@gmail.com

Subject: Request for information under RTI Act 2005.

With reference to your online RTI application bearing registration no. MOHFW/R/E/21/01528dated 15/04/2021 for providing information on the above-mentioned subject. The point wise reply is as under:-

S No.	Question	Answer
1.	Is face Masks are mandatory for everyone.	Use of mask/face cover has been advised to all in various SOPs/Guidelines issued by MoHFW. However as per these guidelines/SOPs its use has not been explicitly made mandatory.
2.	what are the side effects of face mask.	No such information is available in records of DM Cell, MoHFW
3.	how long use of face mask is safe.	Mask has to be worn for a maximum of 8 hours of use or earlier if it becomes wet or visibly soiled.
4.	if a person feel very uncomfortable while using face mask then what he/she should do.	No such information is available in records of DM Cell, MoHFW.
5.	Is face masks lower the oxygen saturation level in blood.	As per MoHFW's Guidelines on Preventive Measures to Contain Spread of COVID-19 in Yoga Institutes & Gymnasiums issued on 1st March 2021 (available at: https://www.mohfw.gov.in/pdf/GuidelinesonPreventiveMeasurestoContainSpreadofCOVID19inYogaInstitutes&Gymnasiums.pdf), use of mask (in particular N-95 masks) during exercise may cause difficulty in breathing. No further information is available in records of DM Cell, MoHFW.
6.	Is government of India conducted any trial/study on using face mask and face mask side effects .	No such information is available in records of DM Cell, MoHFW.
7.	what type of mask is	No such information is available in records of DM Cell, MoHFW.

	effective and why with scientific evidence	

If you are not satisfied with the above reply, you can prefer an appeal to Appellate Authority i.e. Shri. Govind Jaiswal, Director PH, Ministry of Health & Family Welfare, Room No. 205 "D", Nirman Bhavan, New Delhi, as per the provision of RTI Act, 2005.

Yours sincerely

(Dr.Yogesh)
CPIO&CMO (EMR)
Tel. No. 011- 23060777

Online RTI Request Form Details

RTI Request Details :-

RTI Request Registration number	NIOVP/R/E/21/00012
Public Authority	ICMR-National Institute of Virology (NIV), Pune

Personal Details of RTI Applicant:-

Name	[redacted]
Gender	[redacted]
Address	[redacted]
Pincode	[redacted]
Country	India
State	
Status	Details not provided
Educational Status	Details not provided
Phone Number	Details not provided
Mobile Number	[redacted]
Email-ID	[redacted]

Request Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No

(Description of Information sought (upto 500 characters)

Description of Information Sought
1. Is it mandatory for a citizen of India to wear face mask, use hand sanitizers and follow social distancing in a public area? 2. Please give copy of research material that proves effectiveness or ineffectiveness of masks during a pandemic. 3. Please give copy of research material that proves effectiveness or ineffectiveness of hand sanitizers during a pandemic. 4. Please give copy of research material that proves effectiveness or ineffectiveness of social distancing during a pandemic. 5. What is the size of the Covid-19 virus i.e. the length of the virus end to end? 6. What is the pore size of the standard as well as surgical masks? 7. Which is the department and the personnel incharge for designing policies for preventive measures for Covid-19? 8. Which is the department and the personnel incharge for execution of the above Covid-19 preventive policies?

Concerned CPIO	Nodal Officer
Supporting document ***(only pdf upto 1 MB)***	Supporting document not provided

Print Close

Online RTI Status Form

Note:Fields marked with * are Mandatory.

Details not providedDetails not provided

Enter Registration Number	NIOVP/R/E/21/00012
Name	[redacted]
Date of filing	26/04/2021
Public Authority	ICMR-National Institute of Virology (NIV), Pune
Status	RTI REQUEST APPLICATION RETURNED TO APPLICANT
Date of action	11/05/2021
Reply / Remarks :-1-4)This information is not part of our records. For more information you may visit the Ministry of Health and Family Welfare, ICMR websites on www.mohfw.gov.in or www.icmr.gov.in 5)SARS-CoV-2 virus is round shaped virus with an average size of 70-80 nm. 6)Pore size of standard surgical mask and N95 mask is 0.3 – 10 µm & 0.1 – 0.3 µm respectively. 7-8)This information is not part of our records. For more information you may visit the Ministry of Health and Family Welfare ICMR websites.	
Nodal Officer Details :-	
Telephone Number	02026006201
Email Id	priya[dot]abraham[at]icmr[dot]gov[dot]in

Print RTI Application Print Status Go Back

- **SUPREAM COURT CIRCULER ON MASK**

F.NO.212/MISC/PF/2020/SCA(G)

DATE: 14.03.2020

- https://main.sci.gov.in/pdf/cir/covid19_14032020.pdf

- **BOMBAY HIGH COURT JUDGMENT ON MASK**

- **CRIMINAL WRITE PETITION NO.1546 OF 2020**
- **PETITIONER : Rafat khan**

SUPREME COURT OF INDIA

(Admn. General Branch)

F. No. 212/MISC/PF/2020/SCA(G)

Date: 14.03.2020

CIRCULAR

In view of the advisory issued by the Government of India cautioning against mass gathering(s), to avoid the spread of Novel Coronavirus (COVID-19) infection and to avoid gathering which are considered unsafe, following precautionary measures are being put in place:

1) Non-essential visits to the Supreme Court premises are discouraged and accordingly the entry of casual visitors shall remain restricted until further orders;
2) All cafeterias, including the Departmental Canteen, are being advised to remain closed until further orders;
3) The Guided Tour of the Supreme Court shall remain suspended & Supreme Court Museum shall remain closed to visitors, both until further orders;
4) All licensed vendors are being asked to compulsorily stock alcohol-based sanitizer(s) with dispenser(s), for use by customers as and when required;
5) All common areas including restrooms, corridors, staircases, etc. shall be sanitized after 6.00 p.m. and hence stakeholders are requested to vacate their respective offices/establishments and exit the premises preferably by 5.30 pm ;
6) All stakeholders who may have a travel history to the affected areas/countries, as may be notified from time to time by the Government(s), or who may have symptoms of fever, sore throat, cough, runny nose or breathing difficulty, are advised to self-restrain themselves from presently visiting the Supreme Court premises;

P.T.O...

7) All entrants to the Supreme Court premises may be required to subject themselves to thermal-screening and persons detected with high body temperature would be denied entry and further, may be subject to the SOP prescribed by the Government of India, Ministry of Health from time to time; in this regard, all concerned may note that the Government of NCT of Delhi has already invoked the relevant provisions of the Epidemic Diseases Act, 1897 and notified **The Delhi Epidemic Diseases, COVID-19 Regulations, 2020** thereunder vide No. F. 51/DGHS/PH-IV/COVID-019/202-215 dated 12.03.2020; **(copy enclosed)**

8) Lawyers and litigants from across the country who would presently like to avoid travel or a visit to the Supreme Court of India, may write to the Registry by email to **office.regj1@sci.nic.in**, apprising such fact and details of their case(s) with request that their matter(s) may not be listed until the aforesaid restrictions remain in force;

9) All entrants, including lawyers/litigants/clerks entering Courts, would be advised not to crowd at any spot and to exit the premises as soon as their official business has ended, thereby helping themselves and others remain safe;

10) All concerned may refer to the aforesaid Regulations, more particularly on **'screening'** and **'dealing with suspect and symptomatic cases'**, and also refer to **Guidelines for 'Home Quarantine', Guidelines for 'Use of masks by public'** and the **'Do's and Don'ts'** issued by the Ministry of Health and Family Welfare, Govt. of India, and co-operate in ensuring compliance thereof. **(Copies enclosed)**

This issues with the approval of the Competent Authority.

Sd/-
(Dr. Sushil Kr. Sharma)
Assistant Registrar (AG)

Encl. As above

(TO BE PUBLISHED IN PART-IV OF DELHI GAZETTE EXTRA ORDINARY)
GOVERNMENT OF NATIONAL CAPITAL TERRITORY OF DELHI
HEALTH & FAMILY WELFARE DEPARTMENT
9TH LEVEL, A-WING, DELHI SECRETARIAT, IP ESTATE, NEW DELHI - 110 002

No. F. 51/DGHS/PH-IV/COVID-19/ 202-215 Date: 12/3/2020
(CD-000597848)

NOTIFICATION

In exercise of the powers conferred under Section 2, 3 & 4 of The Epidemic Diseases Act, 1897, The Lt. Governor of Delhi is pleased to issue following regulations COVID-19 (Corona Virus Disease - 2019).

1. These regulations may be called The Delhi Epidemic Diseases, COVID-19 Regulations, 2020.
2. "Epidemic Disease" in these regulations means COVID-19 (Corona Virus Disease 2019)
3. Authorized Persons under this act are Secretary (Health & FW), Director General Health Services (DGHS), at State Level and District Magistate, Chief District Medical Officer (CDMO), Sub Divisional Magistrate (SDM) and District Surveillance Officer (DSO) in the districts and officers as authorized by Department of Health & Family Welfare Department, Govt. of NCT of Delhi.
4. All Hospitals (Government & Private) should have Flu corners for screening of suspected cases COVID-19 (Corona Virus Disease 2019).
5. All Hospitals (Government & Private) during screening of such cases shall record to ascertain history of travel of the person if he/she has travelled to any country or area where COVID-19 has been reported. In addition the history of coming in contact with a suspected or confirmed case of COVID-19 shall be recorded.

    i) In case the person has any such history in last 14 days and the person is asymptomatic then the person must be kept in home quarantine for 14 days from the day of exposure
    ii) In case the person has any such history in last 14days and the person is symptomatic as per case definition of COVID-19, person must be isolated in a hospital and will be tested for COVID-19 as per protocol.
    iii) Information of all such cases should be given to office of CDMO of the respective District immediately.

6. No person/institution/organization will use any print or electronic media for information regarding COVID-19 without prior permission of the Department of Health & Family Welfare, Govt. of NCT of Delhi. This is to avoid spread of any rumour or unauthenticated information regarding COVID-19. In case any person/ institution /organization is found indulging in such activity, it will be treated as a punishable offence under these regulations.

7. No Private Laboratory has been authorized to take or test samples for COVID-19 in the NCT of Delhi. All such samples will be collected as per guidelines of Government of India and these will be sent to designated laboratory by the Nodal Officer by the designated hospitals of the Department of Health & Family Welfare Department, Govt. of NCT of Delhi of the concerned District under intimation to District Surveillance Officer (DSO) of concerned District.

8. If any person with a history of travel in last 14days to a country or area from where COVID-19 has been reported, develop symptoms, he must contact the State/District control rooms (as per Annexure-I) so that necessary measures if required may be initiated by the Department of Health & Family Welfare, Govt. of NCT of Delhi.

9. All persons with a history of travel to a country or area from where COVID-19 has been reported in last 14days, but who do not have any symptoms of cough, fever, difficulty in breathing, should isolate themselves at home. Such persons must take precautions to avoid contact with any person including family members for 14 days from the date of arrival from such area.

10. Authorized persons as per section 3 of these regulations are authorized under this act to admit a person and isolate the person if required in case he/she has a history of visit to an area where COVID-19 is endemic and the concerned person is symptomatic.

11. If there are sufficient reasons, cause or information to suspect or believe that any persons could be infected with COVID-19 and his continued presence in a premises is hazardous to the public safety, it shall be lawful for a Surveillance Personnel to enter any such premises, after giving reasonable opportunity to the owner/occupier, for the purpose of surveillance of instances of fever or cough or respiratory difficulty, enquire into or undertake physical examination, as he/she thinks fit, and such person(s) shall be bound to cooperate and render all possible assistance to facilitate such surveillance, inspection, enquiry and examination.

12. If consequent upon such inquiry, inspection, examination or otherwise, Surveillance Personnel has reason to believe or suspect that such a person could be infected with COVID-19, the Surveillance Personnel may direct/arrange to put that person(s) in home quarantine or direct/escort that persons(s) to an 'Institutional Quarantine Facility' or an 'Isolation Facility'.

13. It shall be mandatory for Medical Officers in Government Health Institutions and registered Private Medical Practitioners, including AYUSH practitioners, to notify such person(s) to the concerned District Surveillance Unit, along with duly filled up self declaration forms, who, within their knowledge, are having travel history to COVID-19 affected countries as per the extant guidelines and are having complaints of fever or cough or respiratory difficulty or even without any signs and symptoms of the Epidemic disease.

14. If the owner or occupier(s) of any premises or any individual suspected/confirmed with COVID-19, refuses to take measures for prevention or treatment i.e., Home quarantine/Institutional Quarantine/Isolation or any such person refuses to co-operate with, render assistance to or comply with the directions of the Surveillance Personnel, the concerned District Magistrate having jurisdiction and specifically authorized by the District Magistrate in this regard, may pass an appropriate order and may proceed with proceedings under Section 133 of the Code of Criminal Procedure, 1973 (2 of 1974) or take any other coercive action as deemed necessary and expedient for enforcing such cooperation and assistance. In case of a minor, such Order shall be directed to the guardian or any other adult member of the family of the minor.

15. All advisories issued/to be issued by the Government of India on COVID-19 will ipso-facto be treated as directions under this Act in NCT of Delhi.

16. If cases of COVID-19 are reported from a defined geographic area, the Authorized Person(s) with the approval of State Task Force constituted for containment of COVID-19 shall have the right to implement following containment measures, but not limited to these, in order to prevent spread of the disease

    i) Sealing of the geographical area,
    ii) Banning entry and exit of population from the containment area.
    iii) Closure of schools, offices and banning public gatherings.
    iv) Banning vehicular movement in the area.
    v) Initiating active and passive surveillance of COVID-19 cases.
    vi) Hospital isolation of all suspected cases.
    vii) Designating any Government building as containment unit for isolation of the cases.
    viii) Staff of all Government departments will be at disposal of District administration of the concerned area for discharging the duty of containment measures.
    ix) Any other measure as directed by Department of Health & Family Welfare, Govt. of NCT of Delhi.

17. With the concurrence of Health & Family Welfare Department of Govt of NCT of Delhi, District Disaster Management Committee headed by District Magistrate is authorized for planning strategy regarding containment measures for COVID-19 in their respective districts. The District Magistrate may co opt more officers from different departments for District Disaster Management Committee for this activity under these regulations.

18. **Penalty:** Any person /institution/organization found violating any provision of these regulations shall be deemed to have committed an offence punishable under section 188 of Indian Penal Code (45 of 1860). Principal

Secretary/Secretary, Health & Family Welfare or District Magistrate of a District may penalize any person/institution/organization if found violating provisions of these regulations or any further orders issued by Government under these regulations.

19. **Protection to person acting under ACT**: No suit or legal proceeding shall lie against any person for anything done or intended to be done in good faith under this act unless proved otherwise.

20. These regulations shall come into force immediately and shall remain valid for a period of one year from the date of publication of this notification.

By order and in the name of
Lt. Governor of National Capital Territory of Delhi

(Ajay Bisht)
Deputy Secretary (Health & FW)

No. F. 51/DGHS/PH-IV/COVID-19/202-215 Date: **12-03-2020**

Copy to:

1. Addl. Chief Secretary (Transport), Govt. of Delhi
2. Addl. Chief Secretary (Home), Govt. of Delhi
3. Commissioner of Police
4. Chairman, NDMC
5. Pr. Secretary to Hon'ble LG, Raj Niwas, Delhi
6. Additional Secretary to Hon'ble CM, Govt of Delhi
7. OSD to Hon'ble Minister of Health
8. OSD to Chief Secretary, Govt. of Delhi
9. All Pr. Secretaries/Secretaries//HODs/Heads of all Autonomous Bodies/Institutions/Colleges under Govt. of NCT of Delhi
10. Secretary (GAD), Govt. of NCT of Delhi
11. Director General Health Services, Govt. of NCT of Delhi, Delhi - 32
12. All the District Magistrates, Govt. of NCT of Delhi
13. Director, Directorate of Family Welfare, GNCT of Delhi, New Delhi
14. All MSs/Directors of all Hospitals under Govt. of NCT of Delhi.
15. All Chief District Medical Officers, Govt. of NCT of Delhi

(Ajay Bisht)
Deputy Secretary (Health & FW)

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
(EMR Division)

Guidelines for home quarantine

Scope

Detection of a travel related/unrelated suspect case of novel Coronavirus Disease (COVID-19) will be followed by rapid isolation of such cases in designated health facilities and line listing of all contacts of such cases.Home quarantine is applicable to all such contacts of a suspect or confirmed case of COVID-19.

This intervention will be limited to the initial phase of India reporting only (i) travel related cases and (ii) focal clusters arising from a travel related/unrelated case where cluster containment strategy is adopted (iii) Persons coming from COVID-19 affected areas where local and community transmission is evident.

Definition of contact

A contact is defined as ahealthyperson that has been in such association with aninfected person or a contaminated environment as to have exposed and is therefore at a higher risk of developing disease.

A contact in the context of COVID-19 is:

- A person living in the same household as a COVID-19 case;
- A person having had direct physical contact with a COVID-19 case or his/her infectious secretions without recommended personal protective equipment (PPE) or with a possible breach of PPE
- A person who was in a closed environment or had face to face contact with a COVID-19 case at a distance of within1metre including air travel;

The epidemiological link may have occurred within a 14-day period before the onset of illness in the case under consideration.

Instructions for contacts being home quarantined

The home quarantined person should:

Stay in a well-ventilated single-room preferably with an attached/separate toilet. If another family member needs to stay in the same room, it’s advisable to maintain a distance of at least 1 meter between the two.

- Needs to stay away from elderly people, pregnant women, children and persons with co-morbidities within the household.

- Restrict his/her movement within the house.
- Under no circumstances attend any social/religious gathering e.g. wedding, condolences, etc.

He should also follow the under mentioned public health measures at all times:

- Wash hand as often thoroughly with soap and water or with alcohol-based hand sanitizer
- Avoid sharing household items e.g. dishes, drinking glasses, cups, eating utensils, towels, bedding, or other items with other people at home.
- Wear a surgical mask at all the time. The mask should be changed every 6-8 hours and disposedoff.Disposable masks are never to be reused.
- Masks used by patients / care givers/ close contacts during home care should be disinfected using ordinary bleach solution (5%) or sodium hypochlorite solution (1%) and then disposed of either by burning or deep burial.
- Used mask should be considered as potentially infected.
- If symptoms appear (cough/fever/difficulty in breathing), he/she should immediately inform the nearest health centre or call 011-23978046.

Instructions for the family members of persons being home quarantined

- Only an assigned family member should be tasked with taking care of the such person
- Avoid shaking the soiled linen or direct contact with skin
- Use disposable gloves when cleaning the surfaces or handling soiled linen
- Wash hands after removing gloves
- Visitors should not be allowed
- In case the person being quarantined becomes symptomatic, all his close contacts will be home quarantined (for 14 days) and followed up for an additional 14days or till the report of such case turns out negative on lab testing

Environmental sanitation

a) Clean and disinfect frequently touched surfaces in the quarantined person's room (e.g. bed frames, tables etc.) daily with 1%Sodium Hypochlorite Solution.
b) Clean and disinfect toilet surfaces daily with regular household bleach solution/phenolic disinfectants
c) Clean the clothes and other linen used by the person separately using common household detergent and dry.

Duration of home quarantine

a) The home quarantine period is for 14 days from contact with a confirmed case or earlier if a suspect case (of whom the index person is a contact) turns out negative on laboratory testing

Ministry of Health and Family Welfare
Directorate General of Health Services
[Emergency Medical Relief]

Novel Corornavirus Disease (COVID-19)

Guidelines on use of masks by public

1. Introduction

A new disease named novel coronavirus (COVID-19) emerged in early December 2019 in China and has now spread to over 90 countries. As on 9th March 2020, India has reported 42 cases mostly among those who had travelled from affected countries. It causes a minor illness in majority of patients with symptoms of fever and or cough. A small proportion of such persons may progress to severe disease with difficulty in breathing.

It is spread by an infected person with COVID coughing and the droplets from his cough infecting others in close vicinity (less than 1 metre).

Any such new disease invariably related to cough leads to suggestions from various quarters, especially in social media, to use mask by general public to prevent the disease.

2. Purpose of this document

The purpose of this document is to give correct evidence based information to general public on use of mask.

3. Medical masks

Medical masks of different size and shapes are available in the market. The common ones are flat pleated masks of woven fabric which covers the nose and mouth and affixed behind the head with straps/ elastic fasteners. There are also conical or duck bill shaped masks with valves (or without valves) that fit in the contour of face over the nose and mouth, but are costlier.

4. Use of masks by general public

4.1. Persons having no symptoms are not to use mask

Medical masks should not be used by healthy persons who are not having any symptoms because it create a false sense of security that can lead to neglecting other essential measures such as washing of hands.

Further, there is no scientific evidence to show health benefit of using masks for non-sick persons in the community. In fact erroneous use of masks or continuous use of a disposable mask for longer than 6 hours or repeated use of same mask may actually increase risk of getting an infection. It also incurs unnecessary cost.

In such situation, more effective steps are:

i. Wash hands frequently with soap and water for 40 seconds. An alcohol based hand sanitizer with 70% alcohol must be used for 20 seconds. If hands are dirty or soiled, do not use alcohol based hand sanitizer, but wash hands preferably with soap and water.

ii. While coughing or sneezing cover nose and mouth with handkerchief, paper tissue. If handkerchief or tissue paper is not available cough into the flexed elbow. Dispose of tissue immediately after use and wash hands.

iii. Refrain from touching **face, mouth, nose and eyes.**

iv. Stay at least a metre away from those coughing or sneezing.

v. Monitor your body temperature.

4.2. When and who should use medical masks (apart from health care worker).

4.2.1. When a person develops cough or fever.

Use of medical three layer masks when ill, will prevent your infection from spreading to others. However you also need to wash your hands frequently to avoid spreading infection to others.

4.2.2. While visiting a healthcare facility.

4.2.3. When you are caring for an ill person.

4.2.4. Close family contacts of such suspect/confirmed cases undergoing home care should also use Triple layer medical mask.

4.3. Duration for which a medical mask will remain effective

A medical mask, if properly worn, will be effective for 8 hours. If it gets wet in between, it needs to be changed immediately.

4.4. Correct procedure of wearing triple layer mask

While wearing a medical mask, the steps given below needs to be followed. If you do not follow them, you may get infected from the mask itself. These steps are:

- Unfold the pleats; make sure that they are facing down.
- Place over nose, mouth and chin.
- Fit flexible nose piece (a metallic strip that can easily be located) over nose-bridge.

- Secure with tie strings (upper string to be tied on top of head above the ears – lower string at the back of the neck.)
- Ensure there are no gaps on either side of the mask, adjust to fit.
- While in use, avoid touching the mask.
- Do not let the mask hanging from the neck.
- Change the mask after six hours or as soon as they become wet.
- Disposable masks are never to be reused and should be disposed off.
- While removing the mask great care must be taken not to touch the potentially contaminated outer surface of the mask
- To remove mask first untie the string below and then the string above and handle the mask using the upper strings.

4.5. Disposal of used masks

Used mask should be considered as potentially infected. Masks used by patients / care givers/ close contacts during home care should be disinfected using ordinary bleach solution (5%) or sodium hypochlorite solution (1%) and then disposed of either by burning or deep burial.

Ministry of Health & Family Welfare
Government of India

Help us to help you

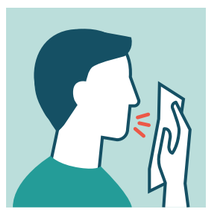
NOVEL CORONAVIRUS (COVID-19)

Protect yourself and others!

Follow these Do's and Don'ts

Do's

Practice frequent hand washing. Wash hands with soap and water or use alcohol based hand rub. Wash hands even if they are visibly clean



Cover your nose and mouth with handkerchief/tissue while sneezing and coughing

Throw used tissues into closed bins immediately after use

See a doctor if you feel unwell (fever, difficult breathing and cough). While visiting doctor wear a mask/cloth to cover your mouth and nose

If you have these signs/symptoms please call State helpline number or Ministry of Health & Family Welfare's 24X7 helpline at 011-23978046

Avoid participating in large gatherings

Don'ts

Have a close contact with anyone, if you're experiencing cough and fever

Touch your eyes, nose and mouth

Spit in public

Together we can fight Coronavirus

For further information :

Call at Ministry of Health, Govt. of India's 24X7 control room number

+91-11-2397 8046

Email at ncov2019@gmail.com

mohfw.gov.in @MoHFWIndia @MoHFW_INDIA mohfwindia

IN THE HIGH COURT OF JUDICATURE OF BOMBAY
BENCH AT AURANGABAD

CRIMINAL WRIT PETITION NO.1546 OF 2020

Rafat Khan s/o Samad Yar Khan
Age : 39 years, occ : business
R/o Mill Corner, Aurangabad. Petitioner

Versus

1. The State of Maharashtra

2. Atmaram Tukaram Gawli
Age : 46 years, occ : service
R/o Nandanwan Colony,
Aurangabad. Respondents

...

Mrs. Rashmi S. Kulkarni, Advocate for the petitioner.
Mr. S.S. Dande, A.P.P. for respondent No. 1 – State.
Respondent No. 2 served.

...

CORAM : **V.K. JADHAV AND**
SANDIPKUMAR C. MORE, JJ.

DATE : 19-01-2022.

Judgment (Per Sandipkumar C. More) :

1. Rule. Rule made returnable forthwith. By consent of the parties, heard finally at the stage of admission.

2. The present petitioner, by invoking writ jurisdiction under Article 226 of the Constitution of India, has preferred this petition for quashing the F.I.R. in Crime No.0196 of 2020 for the offences punishable under Sections

186 and 188 of the Indian Penal Code (for short "I.P.C.") dated 17.04.2020 registered with City Chowk Police Station, Aurangabad and the criminal proceedings arising out of the same bearing S.C.C. No. 7144/2020, pending on the file of the learned Judicial Magistrate, First Class, Aurangabad.

3. According to the present respondent No.2, who is the informant in this case, he was the member of squad of Zone-1 under the leadership of one Daulat Mhaske. The said squad was formed under the Divisional Head Mr. Pramod Jadhav, who was asked by the Municipal Commissioner, Aurangabad to do certain acts for prohibition of spread of Covid-19 under letter bearing No. जा.क्र.मनपा/घ.क.व्य/२०२०/१४१, dated 11.03.2020. Zone-1 squad of which the present respondent No. 2 was the Member, was supposed to act for doing certain prohibitory things in respect of spreading of Covid-19 in the areas of Mill Corner, Padegaon, Bhavsingpura, Budhilen, Aref Colony, etc. On 17.04.2020 respondent No.2 alongwith the members of aforesaid squad was taking round in the aforesaid Zone-1 and at about 4.10 p.m. they found 4 to 5 persons sitting in Relax Medical Shop at Mill Corner without wearing masks. Respondent No. 2 and his associates made them aware about the order of Commissioner of

Municipal Corporation, Aurangabad dated 09.04.2020 and asked them as to why they did not wear the masks and for taking action about the same. Accordingly they asked one person who was without mask about his name. The said person told his name as Anis Ali. Therefore, as per rule respondent No. 2 and his associates prepared fine receipt and asked him to pay the same. However, one another person sitting in the said shop told Anis Ali for not to pay the fine amount as he had called the present petitioner, who is the husband of the then Corporator of Mill Corner Ward. Within short period the petitioner alongwith 2 to 3 persons came there in the said shop and threatened respondent No. 2 and his associates as to why they were taking action in his ward. The petitioner at the relevant time also told them that they had no right to take such action. As such, respondent No.2 lodged the aforesaid F.I.R. against the petitioner as he obstructed them while discharging their duties.

4. Learned Counsel for the petitioner submits that respondent No. 2 was not at all a public servant, therefore, no question arises of lodging F.I.R. under Sections 186 and 188 of I.P.C. by him. She further pointed out that in view of Section 195 (1) of the Code of Criminal Procedure (for short

"Cr.P.C.") no Court can take cognizance of such F.I.R. and the crime registered on the basis of it. She further submits that filing of charge-sheet under the said crime is itself an abuse of process of law, and therefore, even if the allegations in the F.I.R. are taken as proved, then also no offence under aforesaid sections is made out.

5. Despite service of notice to respondent No.2, he remained absent.

6. Learned A.P.P. for respondent No.1 – State strongly opposed the submissions made by learned Counsel for the petitioner and on the basis of investigation papers supported the action taken against the petitioner. According to the learned A.P.P., the concerned Investigating Officer rightly arrived at a conclusion that the petitioner committed offences under Sections 186 and 188 of the I.P.C., and therefore, the Investigating Officer after due investigation filed charge-sheet against the petitioner in the Court of the learned Judicial Magistrate, First Class (3rd Court), Aurangabad.

7. It is significant to note that the prosecution has claimed that the petitioner has committed offences under

Sections 186 and 188 of the I.P.C., and therefore, for quick reference, we would like to reproduce those sections hereunder :

> "*186. Obstructing public servant in discharge of public functions.—Whoever voluntarily obstructs any public servant in the discharge of his public functions, shall be punished with imprisonment of either description for a term which may extend to three months, or with fine which may extend to five hundred rupees, or with both.*
>
> *188. Disobedience to order duly promulgated by public servant.—Whoever, knowing that, by an order promulgated by a public servant lawfully empowered to promulgate such order, he is directed to abstain from a certain act, or to take certain order with certain property in his possession or under his management, disobeys such direction, shall, if such disobedience causes or tends to cause obstruction, annoyance or injury, or risk of obstruction, annoyance or injury, to any person lawfully employed, be punished with simple imprisonment for a term which may extend to one month or with fine which may extend to two hundred rupees, or with both; and if such disobedience causes or trends to cause danger to human life, health or safety, or causes or tends to cause a riot or affray, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both*".

8. On perusal of the aforesaid sections, it appears that Section 186 of I.P.C. has provided punishment to a person who voluntarily obstructs any public servant in discharge is his public functions. Further Section 188 of

I.P.C. also provides punishment for any person for dis-obedience of any order promulgated by a public servant lawfully empowered to promulgate such order.

9. Learned Counsel for the petitioner has relied upon the following two judgments :

(i) Judgment dated 21.09.2020 passed by this Court (Coram : V.M. Deshpande and Amit B. Borkar, JJ.) at Nagpur Bench, in Criminal Application (APL) No. 453 of 2020

(ii) Judgment dated 06.10.2021 passed by this Court (Coram : V.K. Jadhav and Shrikant D. Kulkarni, JJ.) in Criminal Writ Petition No. 853 of 2020)

According to learned Counsel for the petitioner, filing of charge-sheet in the present crime is itself barred under Section 195 (1) of Cr.P.C. Further, the respondent No.2 who is the informant in the present case, cannot be a public servant at all.

10. We have carefully gone through Section 195 (1) of Cr.P.C., which we would like to reproduce below :

"195- (1) No Court shall take cognizance-

(a) (i) of any offence punishable under sections 172 to 188 (both inclusive) of the Indian Penal Code or

(ii) of any abetment of, or attempt to commit, such offence, or

(iii) of any criminal conspiracy to commit such offence, except on the complaint in writing of the public servant concerned

or of some other public servant to whom he is administratively subordinate".

11. On going through the aforesaid section, it is clearly evident that there is clear-cut bar for taking cognizance of the offence punishable under Sections 172 to 188 (both inclusive) except on the complaint in writing of the public servant concerned or of some other public servant to whom he is administratively subordinate. Further, in the first case relied on by the learned Counsel for the petitioner, there is reference of the observation of Hon'ble Supreme Court in the case of **M.S. Ahlawat vs. State of Haryana [2000 (1) SCC 278]**, wherein it is held in para 5 as below :

> *"5. ..... Provisions of section 195 CrPC are mandatory and no Court has jurisdiction to take cognizance of any of the offences mentioned therein unless there is a complaint in writing as required under that section".*

12. Further, a reference of another case before the Supreme Court i.e. Daulat Ram vs. State of Punjab (AIR 1962 SC 1206) has given, wherein the Hon'ble Supreme Court has held that the prosecution under Section 182 of the I.P.C. must be on a complaint in writing by the Tahsildar (public servant). In view of absolute bar against the Courts for taking cognizance of the offence punishable under Section 182 of the I.P.C., except in the manner provided by Section 195 of

Cr.P.C., the said judgment equally applies to the offence under Section 188 also.

13. This Court, in the second judgment relied on by the learned Counsel for the petitioner, has also taken similar view for quashing the F.I.R. under Section 188 of I.P.C.

14. In the present case, the informant i.e. respondent No.2 is not a public servant as contemplated in Section 186 of I.P.C. He was merely a Member of squad which was formed to take prohibitory measures in spreading of Covid-19 at the relevant time. Further, from the F.I.R. itself it appears that he was merely working in Corporation, Aurangabad in the Solid Waste Department. Further, at the time of the alleged incident he was not discharging any duty of public servant, but was merely appointed for taking precautionary measures during the spread of Covid-19. He was not even an administrative subordinate of the Commissioner of Municipal Corporation, Aurangabad, who had promulgated order under subject. Therefore, the bar under Section 195 (1) of Cr.P.C. clearly applies in the instant matter, and thus , the learned Judicial Magistrate, First Class, Aurangabad in whose Court S.C.C. No. 7144 of 2020 is pending in respect of the aforesaid crime, is not at all empowered to take cognizance of the same.

15. Therefore, having regard to the aforesaid facts and discussion, we are of the opinion that the criminal prosecution launched against the present petitioner under Sections 186 and 188 of the I.P.C. is liable to be quashed in view of the specific bar under Section 195 (1) of Cr.P.C. Accordingly, we pass the following order.

ORDER

(i) Criminal Writ Petition is hereby allowed in terms of prayer clause [A].

(ii) Rule is made absolute in above terms.

(iii) Criminal Writ Petition is accordingly disposed of.

(SANDIPKUMAR C. MORE, J.) **(V.K. JADHAV, J.)**

VD_Dhirde

❖ MASK GUIDLINE ACCORDING NHM(NATIONAL HELTH MISSION) OF INDIA

- http://nrhmhp.gov.in/sites/default/files/files/Dissemination%20of%20mask.pdf

File No.NHMHP-IDSP/1/2020-IDSP-Section-NATIONAL HEALTH MISSION-HP 2470

National Health Mission
SDA Complex, Kasumpti, Shimla-9
Himachal Pradesh
Dated: Shimla-171009, the 12th March 2020

MISSION DIRECTOR (NHM)
12 MAR 2020
New Shimla-9 (H.P.)

To

All the Chief Medical Officers,
Himachal Pradesh

All the Principals,
Government Medical Colleges,
Himachal Pradesh

All the Medical Superintendents,
Himachal Pradesh

Dated Shimla-9 the

Subject: **Guidelines regarding COVID-19**

Sir/Madam,

Please find enclosed the following guidelines as received from Ministry of Health and Family Welfare, Government of India for dissemination and further necessary action please:

1. Guidelines on the use of mask by General Public.
2. Guidelines for Home quarantine.
3. Guidelines for containment plan.

You are requested to take further necessary action for the control of the disease.

Yours sincerely,

12/3/20

Special Secretary (Health) cum
Mission Director, NHM
Himachal Pradesh, Shimla – 9

MISSION DIRECTOR (NHM)
12 MAR 2020
New Shimla-9 (H.P.)

Endst. No. As above. **Dated Shimla-9 the**

Copy to:

1. The Additional Chief Secretary (Health) to the Govt. of Himachal for information please.
2. All Deputy Commissioners, Himachal Pradesh for information and necessary action please.
3. The Director Health Services, H.P. for information.

4. The Director Medical Education, H.P for information.

1/3/20.

Special Secretary (Health) cum
Mission Director, NHM
Himachal Pradesh, Shimla – 9

Ministry of Health and Family Welfare
Directorate General of Health Services
[Emergency Medical Relief]

Novel CorornavirusDisease (COVID-19)

Guidelines on use of masksby public

1. Introduction

A new disease named novel coronavirus (COVID-19) emerged in early December 2019 in China and has now spread to over 90 countries. As on 9thMarch 2020,India has reported 42cases mostly among those who had travelled from affected countries. It causes a minor illness in majority of patients with symptoms of fever and or cough.A small proportion of such persons may progress to severe disease with difficulty in breathing.

It is spread by an infected person with COVID coughing and the droplets from his cough infecting others in close vicinity (less than 1 metre).

Any such new disease invariably related to cough leads to suggestions from various quarters, especially in social media, to use mask by general public to prevent the disease.

2. Purpose of this document

The purpose of this document is to give correct evidence based information to general public on use of mask.

3. Medical masks

Medical masks of different size and shapes are available in the market. The common ones are flat pleated masks of woven fabric which covers the nose and mouth and affixed behind the head with straps/ elastic fasteners. There are also conical or duck bill shaped masks with valves (or without valves) that fit in the contour of face over the nose and mouth, but are costlier.

4. Use of masks by general public

4.1. Persons having no symptoms are not to use mask

Medical masks should not be used by healthy persons who are not having any symptoms because itcreate a false sense of security that can lead to neglecting other essential measures such as washing of hands.

Further, there is no scientific evidence to show health benefit of using masks for non-sick persons in the community. In fact erroneous use of masks or continuous use of a disposable mask for longer than 6 hours or repeated use of same mask may actually increase risk of getting an infection. It also incurs unnecessary cost.

In such situation, more effective steps are:

i. Wash hands frequently with soap and water for 40 seconds. An alcohol based hand sanitizer with 70% alcohol must be used for 20 seconds. If hands are dirty or soiled, do not use alcohol based hand sanitizer, but wash hands preferably with soap and water.

ii. While coughing or sneezing cover nose and mouth with handkerchief, paper tissue. If handkerchief or tissue paper is not availablecough into the flexed elbow. Dispose of tissue immediately after use and wash hands.

iii. Refrain from touching **face, mouth, nose and eyes.** iv. Stay at least a metre away from those coughing or sneezing.

v. Monitor your body temperature.

4.2. When and who should use medical masks (apart from health care worker).

4.2.1. When a person develops cough or fever.

Use of medical three layer masks when ill,will prevent your infection from spreading to others. However you alsoneed to wash your hands frequently to avoid spreading infection to others.

4.2.2. Whilevisiting a healthcare facility.

4.2.3. When you are caring for an ill person.

4.2.4. Close family contacts of such suspect/confirmed cases undergoing home care should also use Triple layer medical mask.

4.3. Duration for which a medical mask will remain effective

A medical mask, if properly worn, will be effective for 8 hours. If it gets wet in between, it needs to be changed immediately.

4.4. Correct procedure of wearing triple layer mask

While wearing a medical mask, thesteps given below needs to be followed. If you do not follow them, you may get infected from the mask itself. These steps are:

- Unfold the pleats; make sure that they are facingdown.
- Place over nose, mouth andchin.
- Fit flexible nose piece (a metallic strip that can easily be located) over nosebridge.
- Secure with tie strings (upper string to be tied on top of head above the ears – lower string at the back of theneck.)
- Ensure there are no gaps on either side of the mask, adjust tofit.

- While in use, avoid touching the mask.
- Do not let the mask hanging from theneck.
- Change the mask after six hours or as soon as they becomewet.
- Disposable masks are never to be reused and should be disposedoff.
- While removing the mask great care must be taken not to touchthe potentially contaminated outer surface of themask
- To remove mask first untie the string below and then the string above and handle the mask using the upperstrings.

4.5. Disposal of usedmasks

Used mask should be considered as potentially infected. Masks used by patients / care givers/ close contacts during home care should be disinfected using ordinary bleach solution (5%) or sodium hypochlorite solution (1%)and then disposed of either by burning or deepburial.

DRAFT

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
(EMR Division)

Guidelines for home quarantine

Scope

Detection of a travel related/unrelated suspect case of novel Coronavirus Disease (COVID-19) will be followed by rapid isolation of such cases in designated health facilities and line listing of all contacts of such cases.Home quarantine is applicable to all such contacts of a suspect or confirmed case of COVID-19.

This intervention will be limited to the initial phase of India reporting only (i) travel related cases and (ii) focal clusters arising from a travel related/unrelated case where cluster containment strategy is adopted (iii) Persons coming from COVID-19 affected areas where local and community transmission is evident.

Definition of contact

A contact is defined as ahealthyperson that has been in such association with aninfected person or a contaminated environment as to have exposed and is therefore at a higher risk of developing disease.

A contact in the context of COVID-19 is:

- A person living in the same household as a COVID-19 case;
- A person having had direct physical contact with a COVID-19 case or his/her infectious secretions without recommended personal protective equipment (PPE) or with a possible breach of PPE
- A person who was in a closed environment or had face to face contact with a COVID-19 case at a distance of within1metre including air travel;

The epidemiological link may have occurred within a 14-day period before the onset of illness in the case under consideration.

Instructions for contacts being home quarantined

The home quarantined person should:

Stay in a well-ventilated single-room preferably with an attached/separate toilet. If another family member needs to stay in the same room, it's advisable to maintain a distance of at least 1 meter between the two.

- Needs to stay away from elderly people, pregnant women, children and persons with comorbidities within the household.
- Restrict his/her movement within the house.
- Under no circumstances attend any social/religious gathering e.g. wedding, condolences, etc.

He should also follow the under mentioned public health measures at all times:

- Wash hand as often thoroughly with soap and water or with alcohol-based hand sanitizer
- Avoid sharing household items e.g. dishes, drinking glasses, cups, eating utensils, towels, bedding, or other items with other people at home.
- Wear a surgical mask at all the time. The mask should be changed every 6-8 hours and disposedoff.Disposable masks are never to be reused.

- Masks used by patients / care givers/ close contacts during home care should be disinfected using ordinary bleach solution (5%) or sodium hypochlorite solution (1%) and then disposed of either by burning or deep burial.
- Used mask should be considered as potentially infected.
- If symptoms appear (cough/fever/difficulty in breathing), he/she should immediately inform the nearest health centre or call 011-23978046.

Instructions for the family members of persons being home quarantined

- Only an assigned family member should be tasked with taking care of the such person
- Avoid shaking the soiled linen or direct contact with skin
- Use disposable gloves when cleaning the surfaces or handling soiled linen
- Wash hands after removing gloves
- Visitors should not be allowed
- In case the person being quarantined becomes symptomatic, all his close contacts will be home quarantined (for 14 days) and followed up for an additional 14days or till the report of such case turns out negative on lab testing

Environmental sanitation

a) Clean and disinfect frequently touched surfaces in the quarantined person's room (e.g. bed frames, tables etc.) daily with 1%Sodium Hypochlorite Solution.
b) Clean and disinfect toilet surfaces daily with regular household bleach solution/phenolic disinfectants
c) Clean the clothes and other linen used by the person separately using common household detergent and dry. **Duration of home quarantine**

a) The home quarantine period is for 14 days from contact with a confirmed case or earlier if a suspect case (of whom the index person is a contact) turns out negative on laboratory testing

ontainment Plan

Novel Coronavirus Disease 2019

(COVID 19)

Ministry of Health & Family Welfare
Government of India

1. INTRODUCTION

1.1 Background

On 31st December 2019, the World Health Organization (WHO) China Country Office was informed of cases of pneumonia of unknown etiology (unknown cause) detected in Wuhan City, Hubei Province of China. On 7th January 2020, Chinese authorities identified a new strain of Coronavirus as the causative agent for the disease. The virus has been renamed by WHO as SARS-CoV-2 and the disease caused by it as COVID-19. The disease since its first detection has affected all the provinces of China and 40 other countries (including Hong Kong, Macau and Taiwan). As per WHO (as of 26th February, 2020), there has been a total of 81109 confirmed cases of COVID-19 worldwide including 78191 confirmed cases and 2718 deaths reported from China. Besides China, 2918 confirmed cases and 44 deaths have been reported from 37 countries.

In India, as on 26th February, 2020, three travel related cases (from Hubei province, China), were reported (all from Kerala). All these cases were clinically stable during the period of hospitalization and discharged as per the discharge policy.

1.2. Risk Assessment

The risk for spread has been assessed by World Health Organization and currently (as on 26th February, 2020) it is very high for China and high at regional and global levels. WHO on 30th January, 2020 declared the current novel coronavirus outbreak as a Public Health Emergency of International Concern (PHEIC). According to WHO, "all countries should be prepared for containment, including active surveillance, early detection, isolation and case management, contact tracing and prevention of onward spread of SARS-CoV-2 infection.

Clusters have appeared in many countries including USA, France, Germany and local transmission in Hong Kong, Singapore, Republic of Korea, Iran and Italy.

1.3. Epidemiology

Coronaviruses belong to a large family of viruses, some causing illness in people and others that circulate among animals, including camels, cats, bats etc. Rarely, animal corona viruses may evolve and infect people and then spread between people as witnessed during the outbreak of Severe Acute Respiratory Syndrome (SARS, 2003) and Middle East Respiratory Syndrome (MERS, 2014). The etiologic agent responsible for current outbreak of SARS-CoV-2 is a novel coronavirus is closely related to SARS-Coronavirus.

In humans, the transmission of SARS-CoV-2 can occur via respiratory secretions (directly through droplets from coughing or sneezing, or indirectly through contaminated objects or surfaces as well as close contacts). Nosocomial transmission has been described as an important driver in the epidemiology of SARS and MERS and has also documented in COVID-19.

Current estimates of the incubation period of COVID range from 2-14 days, and these estimates will be refined as more data become available. Most common symptoms include fever, fatigue, dry cough and breathing difficulty. Upper respiratory tract symptoms like sore throat, rhinorrhoea, and gastrointestinal symptoms like diarrhoea and nausea/ vomiting are seen in about 20% of cases.

Due to paucity of scientific literature based on community based studies, the available data on host factors is skewed towards cases requiring hospitalization. As per analysis of the biggest cohort reported by Chinese CDC, about 81% of the cases are mild, 14% require hospitalization and 5% require ventilator and critical care management. The deaths reported are mainly among elderly population particularly those with co-morbidities.

At the time of writing this document, many of the crucial epidemiological information particularly source of infection, mode of transmission, period of infectivity, etc. are still under investigation.

2. STRATEGIC APPROACH

India would be following a scenario based approach for the following possible scenarios:

i. Travel related case reported in India
ii. Local transmission of COVID-19
iii. Community Transmission of COVID-19 disease
iv. India becomes endemic for COVID-19

2.1. Strategic Approach for Current Scenario: "only travel related cases reported from India"

(i) Inter-ministerial coordination (Group of Ministers, Committee of Secretaries) and Centre-State Co-ordination been established.
(ii) Early Detection through Points of Entry (PoE) screening of passengers coming from China, Honk Kong, Indonesia, Japan, Malaysia, Republic of Korea, Singapore, Thailand and Vietnam through 21 designated airports, 12 major ports, 65 minor ports and 8 land crossings.
(iii)) Surveillance and contact tracing through Integrated Disease Surveillance Programme (IDSP) for tracking travellers in the community who have travelled from affected countries and to detect clustering, if any, of acute respiratory illness.
(iv) Early diagnosis through a network of 15 laboratories of ICMR which are testing samples of suspect cases.
(v) Buffer stock of personal protective equipment maintained.
(vi) Risk communication for creating awareness among public to follow preventive public health measures.

2. 2. Local transmission of COVID-2019 disease

The strategy will remain the same as explained in para 2.1 as above. In addition cluster containment strategy will be initiated with:

- Active surveillance in containment zone with contact tracing within and outside the containment zone.
- Expanding laboratory capacity for testing all suspect samples and
- Establishing surge capacities for isolating all suspect / confirmed cases for medical care.
- Implementing social distancing measures.
- Intensive risk communication.

3. SCOPE OF THIS DOCUMENT

In alignment with strategic approach, this document provides action that needs to be taken for containing a cluster. The actions for control of large outbreaks will be dealt separately under a mitigation plan.

4. OBJECTIVES

The objective of cluster containment is to stop transmission, morbidity and mortality due to COVID-19.

5. CLUSTER CONTAINMENT

5.1. Definition of Cluster

A cluster is defined as 'an unusual aggregation of health events that are grouped together in time and space and that are reported to a health agency' (Source CDC). Clusters of human cases are formed when there is local transmission. The local transmission is defined as a laboratory confirmed case of COVID-19:

(i) Who has not travelled from an area reporting confirmed cases of COVID-19 or

(ii) Who had no exposure to a person travelling from COVID-19 affected area or other known exposure to an infected person

There could be single or multiple foci of local transmission. There may or may not be an epidemiological link to a travel related case.

5.2. Cluster Containment Strategy

The cluster containment strategy would be to contain the disease with in a defined geographic area by early detection, breaking the chain of transmission and thus preventing its spread to new areas. This would include geographic quarantine, social distancing measures, enhanced active surveillance, testing all suspected cases, isolation of cases, home quarantine of contacts, social mobilization to follow preventive public health measures.

5.3. Evidence base for cluster containment

Large scale measures to contain COVID-19 have been tried in China and Republic of Korea and also in countries that reported small clusters such as Germany, France, Singapore and Italy. Since COVID-19 is an airborne infection and there is efficient human to human transmission, success of containment operations cannot be guaranteed. Interventions to limit morbidity, mortality and social disruption associated with SARS in 2003 demonstrated that it was possible then to mobilize complex public health operation to contain SARS outbreak. Mathematical modeling studies suggest containment might be possible.

5.4. Factors affecting cluster containment

A number of variables determine the success of the containment operations. These are:

(i) Size of the cluster.
(ii) How efficiently the virus is transmitting in Indian population.
(iii) Time since first case/ cluster of cases originated. Detection, laboratory confirmation and reporting of first few cases must happen quickly.
(iv) Active case finding and laboratory diagnosis.
(v) Isolation of cases and quarantine of contacts.
(vi) Geographical characteristics of the area (e.g. accessibility, natural boundaries)
(vii) Population density and their movement (including migrant population).
(viii) Resources that can be mobilized swiftly by the State Government/ Central Government.
(ix) Ability to ensure basic infrastructure and essential services.

5.5. Assumptions

(i) The virus is not circulating in Indian Population.
(ii) Even if there is a global pandemic, there is large part of the country which remains unaffected and large population which remains susceptible.

6. ACTION PLAN FOR CLUSTER CONTAINMENT

6.1. Institutional mechanisms and Inter-Sectoral Co-ordination

At the National Level, the National Crisis Management Committee (NCMC) will be activated. The co-ordination with health and non-health sectors will be managed by NCMC, on issues, flagged by Ministry of Health. Ministry of Health and Family Welfare will activate its Crisis Management Plan.

The Concerned State will activate State Crisis Management Committee or the State Disaster Management Authority, as the case may be to manage the clusters of COVID-19.

There will be daily co-ordination meetings between the centre and the concerned State through video conference.

The State should review the existing legal instruments to implement the containment plan. Some of the Acts/ Rules for consideration could be (i) Disaster Management Act (2005) (ii) Epidemic Act (1897) (iii) Cr.PC and (iv) State Specific Public Health Acts.

6.2. Trigger for Action

The trigger could be the IDSP identifying a cluster of Influenza like Illness (ILI) or Severe Acute Respiratory syndrome (SARI), which may or may not have epidemiological linkage to a travel related case. It could also be through other informal reporting mechanisms (Media/ civil society/ hospitals (government / private sector) etc. The State will ensure early diagnosis through the ICMR/VRDL (Virus Research and Diagnostic Laboratory) Network. A positive case will trigger a series of actions for containment of the cluster.

6.3. Deployment of Rapid Response Teams (RRT)

Emergency Medical Relief (EMR) division, Ministry of Health and Family Welfare will deploy the Central Rapid Response Team (RRT) to support and advice the State. The State will deploy its State RRT and District RRT.

6.4. Identify geographically-defined Containment zone and Buffer zone

6.4.1. Containment zone

The containment zone will be defined based on:

(i) The index case / cluster, which will be the designated epicenter
(ii) The listing and mapping of contacts.
(iii) Geographical distribution of cases and contacts around the epicenter.
(iv) Administrative boundaries within urban cities /town/ rural area.

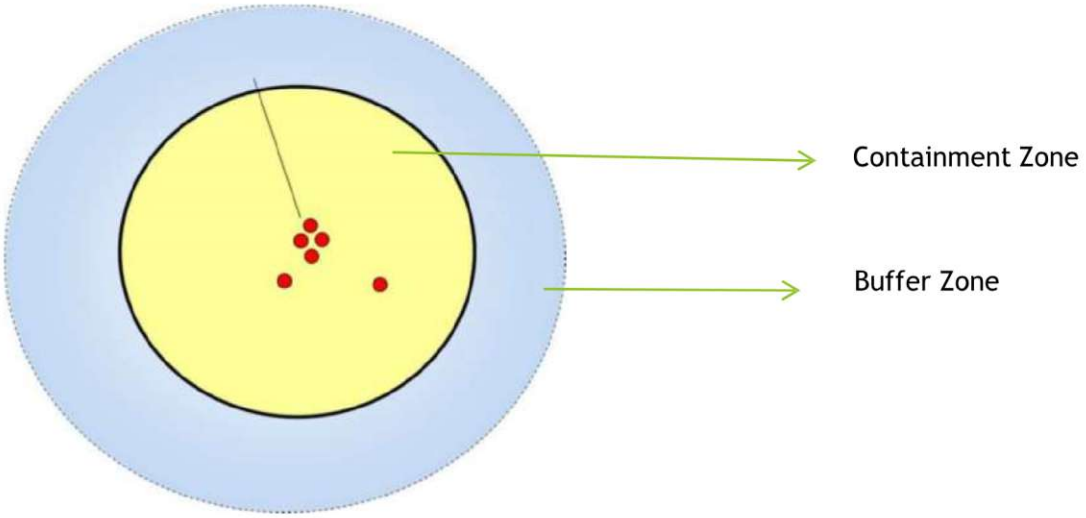
The RRT will do listing of cases, contacts and their mapping. This will help in deciding the perimeter for action. The decision of the geographic limit and extent of perimeter control will be that of the State Government. However, likely scenarios and possible characteristics of the containment and buffer zone are given in Table-1.

Table 1: Scenarios for determining containment and buffer zones

S. No.	Scenario	Containment zone characteristics
1	A small cluster in closed environment such as residential schools, military barracks, hostels or a hospital.	Containment zone will be determined by the mapping of the persons in such institution including cases and contacts. A buffer zone of additional 5 Km radius*will be identified.
2	Single cluster in a residential colony	Administrative boundary of the residential colony and a buffer zone of additional 5 Km radius.*
3	Multiple clusters in communities (residential colony, schools, offices, hospitals etc.) with in an administrative jurisdiction	Administrative boundary of the urban district and a buffer zone of neighboring urban districts.
4	Multiple clusters spatially separated in different parts administrative districts of a city	Administrative boundary of city/ town and congruent population in the peri-urban areas as the buffer zone.**
5	Cluster in a rural setting	3 Km radius of containment zone and additional 7 Kms radius of buffer zone.

* The perimeter of the containment zone will be determined by the continuous real time risk assessment.

** The decision to follow a containment protocol will be based on the risk assessment and feasibility of perimeter control.



The Central RRT will help the State/ District administration in mapping the Containment Zone.

If the epidemiological assessment process is to take time (>12-24 hrs), then a containment zone of 3 Kms and a buffer zone of 7 Kms will be decided which may be subsequently revised, if required, based on epidemiologic investigation. Except for rural settings.

6.4.2. Buffer zone

Buffer zone is an area around the containment zone, where new cases are most likely to appear. There will not be any perimeter control for the buffer zone. The activities of buffer zone are listed under paragraph 7.2.

6.4.3. Perimeter

Perimeter of the containment zone will be decided by the District administration based on criteria defined in Para 6.4.1. Clear entry and exit points will be established. The perimeter controls that need to be applied is in para 7.3.

7. SURVEILLANCE

7.1. Surveillance in containment zone

7.1.1. Contact listing

The RRTs will list the contacts of the suspect / laboratory confirmed case of COVID-19. The District Surveillance Officer (in whose jurisdiction, the laboratory confirmed case/ suspect case falls) along with the RRT will map the contacts to determine the potential spread of the disease. If the residential address of the contact is beyond that district, the district IDSP will inform the concerned District IDSP/State IDSP.

7.1.2. Mapping of the containment and buffer zones

The containment and buffer zones will be mapped to identify the health facilities (both government and private) and health workforce available (primary healthcare workers, Anganwadi workers and doctors in PHCs/CHCs/District hospitals).

7.1.3. Active Surveillance

The residential areas will be divided into sectors for the ASHAs/Anganwadi workers/ANMs each covering 50 households (30 households in difficult areas). Additional workforce would be mobilized from neighboring districts (except buffer zone) to cover all the households in the containment zone. This workforce will have supervisory officers (PHC/CHC doctors) in the ratio of 1:4.

The field workers will be performing active house to house surveillance daily in the containment zone from 8:00 AM to 2:00 PM. They will line list the family members and those having symptoms. The field worker will provide a mask to the suspect case and to the care giver identified by the family. The patient will be isolated at home till such time he/she is examined by the supervisory officer. They will also follow up contacts identified by the RRTs within the sector allocated to them.

All ILI/SARI cases reported in the last 14 days by the IDSP in the containment zone will be tracked and reviewed to identify any missed case of COVID-19 in the community.

Any case falling within the case definition will be conveyed to the supervisory officer who in turn will visit the house of the concerned, confirm that diagnosis as per case definition and will make arrangements to shift the suspect case to the designated treatment facility. The supervisory officer will collect data from the health workers under him/ her, collate and provide the daily and cumulative data to the control room by 4.00 P.M. daily.

7.1.4 Passive Surveillance

All health facilities in the containment zone will be listed as a part of mapping exercise. All such facilities both in Government and private sector (including clinics) shall report clinically suspect cases of COVID-19 on real time basis (including 'Nil' reports) to the control room at the district level.

7.1.5. Contact Tracing

The contacts of the laboratory confirmed case/ suspect case of COVID-19 will be line-listed and tracked and kept under surveillance at home for 28 days (by the designated field worker). The Supervisory officer in whose jurisdiction, the laboratory confirmed case/ suspect case falls shall inform the Control Room about all the contacts and their residential addresses. The control room will in turn inform the supervisory officers of concerned sectors for surveillance of the contacts. If the residential address of the contact is beyond the allotted sector, the district IDSP will inform the concerned Supervisory officer/concerned District IDSP/State IDSP.

7.2. Surveillance in Buffer zone

The surveillance activities to be followed in the buffer zone are as follows:

i. Review of ILI/SARI cases reported in the last 14 days by the District Health Officials to identify any missed case of COVID-19 in the community.

ii. Enhanced passive surveillance for ILI and SARI cases in the buffer zone through the existing Integrated Disease Surveillance Programme.

iii. In case of any identified case of ILI/SARI, sample should be collected and sent to the designated laboratories for testing COVID-19.

All health facilities in the buffer zone will be listed as a part of mapping exercise. All such facilities both in Government and private sector (including clinics) shall report clinically suspect cases of COVID-19 on real time basis (including 'Nil' reports) to the control room at the district level. Measures such as personal hygiene, hand hygiene, social distancing to be enhanced through enhanced IEC activities in the buffer zone.

7.3. Perimeter Control

The perimeter control will ensure that there is no unchecked outward movement of population from the containment zone except for maintaining essential services (including medical emergencies) and government business continuity. It will also limit unchecked influx of population into the containment zone. The authorities at these entry points will be required to inform the incoming travelers about precautions to be taken and will also provide such travelers with an information pamphlet and mask.

All vehicular movement, movement of public transport and personnel movement will be restricted. All roads including rural roads connecting the containment zone will be guarded by police.

The District administration will post signs and create awareness informing public about the perimeter control. Health workers posted at the exit point will perform screening (e.g. interview travelers, measure temperature, record the place and duration of intended visit and keep complete record of intended place of stay).

Details of all persons moving out of perimeter zone for essential/ emergency services will be recorded and they will be followed up through IDSP. All vehicles moving out of the perimeter control will be decontaminated with sodium hypochlorite (1%) solution.

8. LABORATORY SUPPORT

8.1 Designated laboratories

The identified VRDL network laboratory, nearest to the affected area, will be further strengthened to test samples. The other available govt. laboratories and private laboratories (BSL 2 following BSL 3 precautions) if required, shall also be engaged to test samples, after ensuring quality assurance by ICMR/VRDL network. If the number of samples exceeds its surge capacity, samples will be shipped to other nearby laboratories or to NCDC, Delhi or NIV, Pune or to other ICMR lab networks depending upon geographic proximity.

All test results should be available within 12 hours of sampling. ICMR along with the State Government will ensure that there are designated agencies for sample transportation to identified laboratories. The contact number of such courier agencies shall be a part of the micro-plan.

The designated laboratory will provide daily update (daily and cumulative) to District, State and Central Control Rooms on:

i. No. of samples received
ii.
iii.

No. of samples tested
No. of samples under testing

iv. No. of positive samples

8.2 Testing criteria

All suspect cases conforming to the case definition will be tested. The testing of suspect cases in the containment and buffer zones will continue till 14 days from the date, the last confirmed case is declared negative by laboratory test.

9. HO PIT L C RE S A A

All suspect cases detected in the containment/buffer zones (till a diagnosis is made), will be hospitalized and kept in isolation in a designated facility till such time they are tested negative. Persons testing positive for COVID-19 will remain to be hospitalized till such time 2 of their samples are tested negative as per discharge policy. About 15% of the patients are likely to develop pneumonia, 5 % of whom requires ventilator management. Hence dedicated Intensive care beds need to be identified earmarked. Some among them may progress to multi organ failure and hence critical care facility/ dialysis facility/ and Salvage therapy [Extra Corporeal Membrane Oxygenator (ECMO)] facility for managing the respiratory/renal complications/ multi-organ failure shall be required. If such facilities are not available in the containment zone, nearest tertiary care facility in Government / private sector needs to be identified, that becomes a part of the micro-plan.

9.1 Surge capacity

Based on the risk assessment, if the situation so warrants (data suggested an exponential rise in the number of cases), the surge capacity of the identified hospitals will be enhanced, logistic requirements shall be worked out.

9.2 Pre-hospital care (ambulance facility)

Ambulances need to be in place for transportation of suspect/confirmed cases. Such ambulances shall be manned by personnel adequately trained in infection prevention control, use of PPE and protocol that needs to be followed for disinfection of ambulances (by 1% sodium hypochlorite solution using knapsack sprayers).

9.3 Infection Prevention Control Practices

Nosocomial infection in fellow patients and attending healthcare personnel are well documented in the current COVID-19 outbreak as well. There shall be strict adherence to Infection prevention control practices in all health facilities. IPC committees would be formed (if not already in place) with the mandate to ensure that all healthcare personnel are well aware of IPC practices and suitable arrangements for requisite PPE and other logistic (hand sanitizer, soap, water etc.) are in place. The designated hospitals will ensure that all healthcare staff is

trained in washing of hands, respiratory etiquettes, donning/doffing & proper disposal of PPEs and bio-medical waste management.

At all times doctors, nurses and para-medics working in the clinical areas will wear three layered surgical mask and gloves. The medical personnel working in isolation and critical care facilities will wear full complement of PPE (including N95 masks).

The support staff engaged in cleaning and disinfection will also wear full complement of PPE. Environmental cleaning should be done twice daily and consist of damp dusting and floor mopping with Lysol or other phenolic disinfectants and cleaning of surfaces with sodium hypochlorite solution. Detailed guidelines available on MoHFW's website may be followed.

10. CLINICAL MANAGEMENT

10.1. Clinical Management

The hospitalized cases may require symptomatic treatment for fever. Paracetamol is the drug of choice. Suspect cases with co-morbid conditions, if any, will require appropriate management of co-morbid conditions.

For patients with severe acute respiratory illness (SARI), having respiratory distress may require, pulse oxymetry, oxygen therapy, non-invasive and invasive ventilator therapy. Detailed guidelines available on MoHFW's website and updated from time to time, may be followed.

10.2. Discharge Policy

Discharge policy for suspected cases of COVID-19 tested negative will be based on the clinical assessment of the treating physician. For those tested positive for COVID-19, their discharge from hospital will be governed by consecutive two samples tested negative and the patient is free from symptoms.

11. PHARMACEUTICAL INTERVENTIONS

As of now there is no approved drug or vaccine for treatment of COVID-19.

12. NON-PHARMACEUTICAL INTERVENTIONS

In the absence of proven drug or vaccine, non-pharmaceutical interventions will be the main stay for containment of COVID-19 cluster.

12.1. Preventive public health measures

There will be social mobilization among the population in containment and buffer zone for adoption of community-wide practice of frequent washing of hands and respiratory etiquettes in schools, colleges, work places and homes. The community will also be encouraged to self-

monitor their health and report to the visiting ASHA/Anganwadi worker or to nearest health facility.

12.2. Quarantine and isolation

Quarantine and Isolation are important mainstay of cluster containment. These measures help by breaking the chain of transmission in the community.

12.2.1. Quarantine

Quarantine refers to separation of individuals who are not yet ill but have been exposed to COVID-19 and therefore have a potential to become ill. There will be voluntary home quarantine of contacts of suspect /confirmed cases. The guideline on home quarantine available on the website of the Ministry provides detail guidance on home quarantine.

12.2.2. Isolation

Isolation refers to separation of individuals who are ill and suspected or confirmed of COVID-19. There are various modalities of isolating a patient. Ideally, patients can be isolated in individual isolation rooms or negative pressure rooms with 12 or more air-changes per hour.

In resource constrained settings, all positive COVID-19 cases can be cohorted in a ward with good ventilation. Similarly, all suspect cases should also be cohorted in a separate ward. However under no circumstances these cases should be mixed up. A minimum distance of 1 meter needs to be maintained between adjacent beds. All such patients need to wear a triple layer surgical mask at all times.

12.3 Social distancing measures

For the cluster containment, social distancing measures are key interventions to rapidly curtail the community transmission of COVID-19 by limiting interaction between infected persons and susceptible hosts. The following measures would be taken:

12.3.1 Closure of schools, colleges and work places

Administrative orders will be issued to close schools, colleges and work places in containment and buffer zones. Intensive risk communication campaign will be followed to encourage all persons to stay indoors for an initial period of 28 days, to be extended based on the risk assessment. Based on the risk assessment and indication of successful containment operations, an approach of staggered work and market hours may be put into practice.

12.3.2 Cancellation of mass gatherings

All mass gathering events and meetings in public or private places, in the containment and buffer zones shall be cancelled / banned till such time, the area is declared to be free of COVID-19 or the outbreak has increased to such scales to warrant mitigation measures instead of containment.

12.3.3. Advisory to avoid public places

The public in the containment and buffer zones will be advised to avoid public places and only if necessary for attending to essential services. The administration will ensure supply of enough triple layer masks to the households in the containment and buffer zones.

12.3.4. Cancellation of public transport (bus/rail)

There will be prohibition for persons entering the containment zone and on persons exiting the containment zone. To facilitate this, if there are major bus transit hubs or railway stations in the containment zone, the same would be made dysfunctional temporarily. Additionally, irrespective of fact that there is a rail/road transit hub, the perimeter control will take care of prohibiting people exiting the containment zone including those using private vehicles and taxies.

As a significant inconvenience is caused to the public by adopting these measures in the containment zone, State government would proactively engage the community and work with them to make them understand the benefits of such measures.

13. MATERIAL LOGISTICS

13.1. Personal Protective Equipment

The type of personal protective equipment for different categories of:

S. No.	Name of the item	Category of personnel
1	PPE Kit, N 95, Mask, Gloves, Goggles, cap and shoe cover)	□ Doctors and nurses attending to patients in isolation, ICU/ critical care facilities of hospitals in the containment zone. □ Para-medical staff in the back cabin of ambulance. □ Auxillary/ support staff involved in disinfection vehicles/ ambulances and surface cleaning of hospital floors and other surfaces
2	N-95 Mask and gloves	□ Supervisory doctors verifying a suspect case □ Persons collecting samples. □ Doctors/nurses attending patients in primary health care facilities
3	Triple Layer Surgical mask	□ To be used by Field workers doing surveillance work □ Staff providing essential services. □ Suspect cases and care giver / by stander of the suspect case □ Security staff. □ Ambulance drivers □ Residents permitted to go out for essential services .

The State Government has to ensure adequate stock of personal protective equipment. The quantity required for a containment operation will depend upon the size & extent of the cluster and the time required containing it. A containment of a cluster, lasting a month or two

in a population of 100,000 may require 20,00,000 triple layer masks; 2,00,000 gloves; 100,000 N-95 masks and about 50,000 PPE Kits. The foregoing number is to illustrate that State need to have a rate contract and assured supply for these items.

13.2. Transportation

A large number of vehicles will be required for mobilizing the surveillance and supervisory teams. The vehicles will be pooled from Government departments. The shortfall, if any, will be met by hiring of vehicles.

13.3. Stay arrangements for the field staff

The field staff brought in for the surveillance activities and that for providing perimeter control need to be accommodated with in the containment zone. Facilities such as schools, community buildings etc. will be identified for sheltering. Catering arrangement will need to be made at these locations.

13.4 Bio-medical waste management

A large quantity of bio-medical waste is expected to be generated from containment zone. Arrangement would also be required for such bio-medical waste (discarded PPEs etc.), preferably by utilizing the bio-medical waste management services at the designated hospital.

14. RISK COMMUNICATION

14.1 Risk communication material

Risk communication materials [comprising of (i) posters and pamphlets; (ii) audio only material; (iii) AV films] prepared by PIB/MoHFW will be prepared and kept ready for targeted roll out in the containment and buffer zones.

14.2 Communication channels

14.2.1 Interpersonal communication

During house to house surveillance, ASHAs/ other community health workers will interact with the community (i) for reporting symptomatic cases (ii) contact tracing (iii) information on preventive public health measures.

14.2.2 Mass communication

Awareness will be created among the community through miking, distribution of pamphlets, mass SMS and social media. Also use of radio and television (using local channels) will ensure penetration of health messages in the target community.

14.2.3 Dedicated helpline

A dedicated helpline number will be provided at the Control room (district headquarter) and its number will be widely circulated for providing general population with information on risks of COVID-19 transmission, the preventive measures required and the need for prompt reporting to health facilities, availability of essential services and administrative orders on perimeter control.

14.2.4 Media Management

At the Central level, only Secretary (H) or representative nominated by her shall address the media. There will be regular press briefings/ press releases to keep media updated on the developments and avoid stigmatization of affected communities. Every effort shall be made to address and dispel any misinformation circulating in media incl. social media.

At the State level, only Principal Secretary (H), his/her nominee will speak to the media.

15. INFORMATION MANAGEMENT

15.1 Control room at State & District Headquarters

A control room (if not already in place) shall be set up at State and District headquarters. This shall be manned by State and District Surveillance Officer (respectively) under which data managers (deployed from IDSP/ NHM) responsible for collecting, collating and analyzing data from field and health facilities. Daily situation reports will be put up.

The state will provide aggregate data on daily basis on the following (for the day and cumulative):

i. Total number of suspect cases
ii. Total number of confirmed cases
iii. Total number of critical cases on ventilator
iv. Total number of deaths
v. Total number of contacts under surveillance

15.2 Control room in the containment zone

A control room shall be set up inside the containment zone to facilitate collection, collation and dissemination of data from various field units to District and State control rooms. This shall be manned by an epidemiologist under which data managers (deployed from IDSP/ NHM) will be responsible for collecting, collating and analyzing data from field and health facilities.

This control room will provide daily input to the District control room for preparation of daily situation report.

15.3 Alerting the neighboring districts/States

The control room at State Government will alert all neighboring districts. There shall be enhanced surveillance in all such districts for detection of clustering of symptomatic illness. Awareness will be created in the community for them to report symptomatic cases/contacts.

Also suitable provisions shall be created for enhancing horizontal communication between adjacent districts, especially for contact tracing exercise and follow up of persons exiting the containment zone.

16. CAPACITY BUILDING

16.1 Training content

Trainings will be designed to suit requirement of each and every section of healthcare worker involved in the containment operations. These trainings for different target groups shall cover:

1. Field surveillance, contact tracing, data management and reporting
2. Surveillance at designated exit points from the containment zone
3. Sampling, packaging and shipment of specimen
4. Hospital infection prevention and control including use of appropriate PPEs and bio-medical waste management
5. Clinical care of suspect and confirmed cases including ventilator management, critical care management
6. Risk communication to general community

16.2 Target trainee population

Various sections of healthcare workforce (including specialist doctors, medical officers, nurses, ANMs, Block Extension Educators, MHWs, ASHAs) and workforce from non-health sector (security personnel, Anganwadi Workers, support staff etc.). Trainings will be tailored to requirements of each of these sections.

The training will be conducted by the RRT a day prior to containment operations are initiated.

16.3 Replication of training in other districts

The State Govt. will ensure that unaffected districts are also trained along the same lines so as to strengthen the core capacities of their RRTs, doctors, nurses, support staff and non-health field formations. These trainings should be accompanied with functional training exercises like mock-drills.

17. FINANCING OF CONTAINMENT OPERATIONS

The fund requirement would be estimated taking into account the inputs in the micro-plan and funds will be made available to the district collector from NHM flexi-fund.

17.1 Scaling down of operations

The operations will be scaled down if no secondary laboratory confirmed COVID-19 case is reported from the containment and buffer zones for at-least 4 weeks after the last confirmed test has been isolated and all his contacts have been followed up for 28 days. The containment operation shall be deemed to be over 28 days from the discharge of last confirmed case (following negative tests as per discharge policy) from the designated health facility i.e. when the follow up of hospital contacts will be complete.

The closing of the surveillance for the clusters could be independent of one another provided there is no geographic continuity between clusters. However the surveillance will continue for ILI/SARI.

However, if the containment plan is not able to contain the outbreak and large numbers of cases start appearing, then a decision will need to be taken by State administration to abandon the containment plan and start on mitigation activities.

18. IMPLEMENTATION OF THE MICRO-PLAN

Based on the above activities, the State/ District will prepare an event specific micro-plan and implement the containment operations.

Guidelines on Clinical management of severe acute respiratory illness (SARI) in suspect/confirmed novel coronavirus (nCoV) cases

Coronaviruses are respiratory viruses and broadly distributed in humans and other mammals. Some causing illness in people and others that circulate among animals, including camels, cats and bats. Rarely, animal corona viruses can evolve and infect people and then spread between people such as has been seen with MERS and SARS. Although most human coronavirus infections are mild, the epidemics of the severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV), have caused more than 10000 cumulative cases in the past two decades, with mortality rates of 10% for SARS-CoV and 37% for MERS-CoV. The current outbreak was initially noticed in a seafood market in Wuhan city in Hubei Province of China on 12th December, 2019 and has spread across China and many countries.

Purpose and scope of document

This document is intended for clinicians taking care of hospitalised adult and paediatric patients with severe acute respiratory infection (SARI) when an nCoV infection is suspected. It is not meant to replace clinical judgment or specialist consultation but rather to strengthen clinical management of these patients and provide to up-to-date guidance. Best practices for SARI including IPC and optimized supportive care for severely ill patients are essential.

This document aims to provide clinicians with updated interim guidance on timely, effective, and safe supportive management of patients with nCoV and SARI, particularly those with critical illness. The recommendations in this document are derived from WHO publications.

A. Triage: Early recognition of patients with SARI associated with nCoV infection.

The purpose of triage is to recognize and sort all patients with SARI at first point of contact with health care system (such as the emergency department). Consider nCOV as a possible etiology of SARI under certain conditions (see Table 1). Triage patients and start emergency treatments based based on disease severity.

Table 1: Definitions of patients with SARI, suspected of nCoV*

SARI	An ARI with history of fever or measured temperature ≥38 C° and cough; onset within the last ~10 days; and requiring hospitalization. However, the absence of fever does NOT exclude viral infection.

Surveillance case definitions for nCoV*	**1.** Severe acute respiratory infection (SARI) in a person, with history of fever and cough requiring admission to hospital, with no other etiology that fully explains the clinical presentation[1] (clinicians should also be alert to the possibility of atypical presentations in patients who are immunocompromised); AND any of the following: a) A history of travel to Wuhan, Hubei Province China in the 14 days prior to symptom onset; or **b) the disease occurs in a health care worker who has been working in an environment where patients with severe acute respiratory infections are being cared for, without regard to place of residence or history of travel; or** c) the person develops an unusual or unexpected clinical course, especially sudden deterioration despite appropriate treatment, without regard to place of residence or history of travel, even if another etiology has been identified that fully explains the clinical presentation **2.** A person with acute respiratory illness of any degree of severity who,
	within 14 days before onset of illness, had any of the following exposures: close physical contact[2] with a confirmed case of nCoV a) infection, while that patient was symptomatic; or a healthcare facility in a country where hospital-associated b) nCoV infections have been reported;

*** see https://mohfw.gov.in/media/disease-alerts for latest case definition**

1- Testing should be according to local guidance for management of community-acquired pneumonia. Examples of other etiologies include Streptococcus pneumoniae, Haemophilus influenza type B, Legionella pneumophila, other recognized primary bacterial pneumonias, influenza viruses, and respiratory syncytial virus.

2- **Close contact is defined as:**

- Health care associated exposure, including providing direct care for nCoV patients, working with health care workers infected with nCoV, visiting patients or staying in the same close environment of a nCoV patient
- Working together in close proximity or sharing the same classroom environment with a with nCoV patient
- Traveling together with nCoV patient in any kind of conveyance
- Living in the same household as a nCoV patient

The epidemiological link may have occurred within a 14-day period before or after the onset of illness in the case under consideration

Novel Coronavirus may present with mild, moderate, or severe illness; the latter includes severe pneumonia, ARDS, sepsis and septic shock. Early recognition of suspected patients allows for timely initiation of IPC (see Table 2). Early identification of those with severe manifestations (see Table 2) allows for immediate optimized supportive care treatments and safe, rapid admission (or referral) to intensive care unit according to institutional or national protocols. For those with mild illness, hospitalization may not be required unless there is concern for rapid deterioration. All patients discharged home should be instructed to return to hospital if they develop any worsening of illness.

Table 2: Clinical syndromes associated with nCoV infection

Uncomplicated illness	Patients with uncomplicated upper respiratory tract viral infection, may have non-specific symptoms such as fever, cough, sore throat, nasal congestion, malaise, headache, muscle pain or malaise. The elderly and immunosuppressed may present with atypical symptoms. These patients do not have any signs of dehydration, sepsis or shortness of breath
Mild pneumonia	Patient with pneumonia and no signs of severe pneumonia. Child with non-severe pneumonia has cough or difficulty breathing + fast breathing: fast breathing (in breaths/min): <2 months, ≥60; 2–11 months, ≥50; 1–5 years, >40 and no signs of severe pneumonia
Severe pneumonia	Adolescent or adult: fever or suspected respiratory infection, plus one of respiratory rate >30 breaths/min, severe respiratory distress, or SpO2 <90% on room air Child with cough or difficulty in breathing, plus at least one of the following: central cyanosis or SpO2 <90%; severe respiratory distress (e.g. grunting, very severe chest indrawing); signs of pneumonia with a general danger sign: inability to breastfeed or drink, lethargy or unconsciousness, or convulsions. Other signs of pneumonia may be present: chest indrawing, fast breathing (in breaths/min): <2 months, ≥60; 2 11 months, ≥50; 1 5 years, ≥40. The diagnosis is clinical; chest imaging can exclude complications.
Acute Respiratory Distress Syndrome	**Onset**: new or worsening respiratory symptoms within one week of known clinical insult. **Chest imaging (radiograph, CT scan, or lung ultrasound)**: bilateral opacities, not fully explained by effusions, lobar or lung collapse, or nodules.
	Origin of oedema: respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic cause of oedema if no risk factor present. **Oxygenation** • Mild ARDS: 2( )0 mmHg < PaO2/Fi(O2 ≤ 300 mmHg (with PEEP or CPAP ≥5 **(adults)** cm H_2O, or non-ventilated) • Moderate ARDS: 100 mmHg < PaO 2/FiO2 ≤200 mmHg with PEEP ≥5 cm H_2O, or non-ventilated) • Severe ARDS: PaO2/FiO2 ≤ 100 mm Hg with PEEP ≥5 cmH2O, or non-ventilated) When PaO_2 is not available, SpO_2/FiO $_2$ ≤315 suggests ARDS (including in non-ventilated patients) Index using Oxygenation (children; SpO_2) note OI = Oxygenation Index and OSI = Oxygenation • Bilevel NIV 26 CPAP ≥5 cmH2O via a full face mask: PaO_2/FiO_2 ≤ 300 mmHg or SpO_2/FiO_2 ≤ 264 • Mild ARDS (invasively ventilated): 4 ≤ OI < 8 or 5 ≤ OSI < 7.5 • Moderate ARDS (invasively ventilated): 8 ≤ OI < 16 or 7.5 ≤ OSI < 12.3 • Severe ARDS: OI > 16 or OSI > 12.3

Sepsis	**Adults**: life-threatening organ dysfunction caused by a dysregulated host response to suspected or proven infection, with organ dysfunction. Signs of organ dysfunction include: altered mental status, difficult or fast breathing, low oxygen saturation, reduced urine output, fast heart rate, weak pulse, cold extremities or low blood pressure, skin mottling, or laboratory evidence of coagulopathy, thrombocytopenia, acidosis, high lactate or hyperbilirubinemia. **Children**: suspected or proven infection and ≥2 SIRS criteria, of which one must be abnormal temperature or white blood cell count
Septic shock	**Adults**: persisting hypotension despite volume resuscitation, requiring vasopressors to maintain MAP ≥65 mmHg and serum lactate level >2 mmol/L **Children**: any hypotension (SBP <5th centile or >2 SD below normal for age) or 2-3 of the following: altered mental state; tachycardia or bradycardia (HR <90 bpm or >160 bpm in infants and HR <70 bpm or >150 bpm in children); prolonged capillary refill (>2 sec) or warm vasodilation with bounding pulses; tachypnea; mottled skin or petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia

B. Immediate implementation of appropriate IPC measures

IPC is a critical and integral part of clinical management of patients and should be initiated at the point of entry of the patient to hospital (typically the Emergency Department). Standard precautions should always be routinely applied in all areas of health care facilities. Standard precautions include

hand hygiene; use of PPE to avoid direct contact with patients' blood, body fluids, secretions (including respiratory secretions) and non-intact skin. Standard precautions also include prevention of needle-stick or sharps injury; safe waste management; cleaning and disinfection of equipment; and cleaning of the environment.

Table 3: How to implement infection prevention and control measures for patients with suspected or confirmed nCoV infection

At triage	• Give suspect patient a medical mask and direct patient to separate area, an isolation room if available. Keep at least 1meter distance between suspected patients and other patients. Instruct all patients to cover nose and mouth during coughing or sneezing with tissue or flexed elbow for others. Perform
	hand hygiene after contact with respiratory secretions
Apply droplet precautions	• Droplet precautions prevent large droplet transmission of respiratory viruses. Use a medical mask if working within 1-2 metres of the patient. Place patients in single rooms, or group together those with the same etiological diagnosis. If an etiological diagnosis is not possible, group patients with similar clinical diagnosis and based on epidemiological risk factors, with a spatial separation. When providing care in close contact with a patient with respiratory symptoms (e.g. coughing or sneezing), use eye protection (face-mask or goggles), because sprays of secretions may occur. Limit patient movement within the institution and ensure that patients wear medical masks when outside their rooms

Apply contact precautions	• Droplet and contact precautions prevent direct or indirect transmission from contact with contaminated surfaces or equipment (i.e. contact with contaminated oxygen tubing/interfaces). Use PPE (medical mask, eye protection, gloves and gown) when entering room and remove PPE when leaving. If possible, use either disposable or dedicated equipment (e.g. stethoscopes, blood pressure cuffs and thermometers). If equipment needs to be shared among patients, clean and disinfect between each patient use. Ensure that health care workers refrain from touching their eyes, nose, and mouth with potentially contaminated gloved or ungloved hands. Avoid contaminating environmental surfaces that are not directly related to patient care (e.g. door handles and light switches). Ensure adequate room ventilation. Avoid movement of patients or transport. Perform hand hygiene
Apply airborne precautions when performing an aerosol generating procedure	• Ensure that healthcare workers performing aerosol-generating procedures (i.e. open suctioning of respiratory tract, intubation, bronchoscopy, cardiopulmonary resuscitation) use PPE, including gloves, long-sleeved gowns, eye protection, and fit-tested particulate respirators (N95 or equivalent, or higher level of protection). (The scheduled fit test should not be confused with user seal check before each use.) Whenever possible, use adequately ventilated single rooms when performing aerosol-generating procedures, meaning negative pressure rooms with minimum of 12 air changes per hour or at least 160 litres/second/patient in facilities with natural ventilation. Avoid the presence of unnecessary individuals in the room. Care for the patient in the same type of room after mechanical ventilation commences

Abbreviations: ARI, acute respiratory infection; PPE, personal protective equipment

C. Early supportive therapy and monitoring

a.

Give supplemental oxygen therapy immediately to patients with SARI and respiratory distress, hypoxaemia, or shock: Initiate oxygen therapy at 5 L/min and titrate flow rates to reach target SpO_2 $\geq$90% in non-pregnant adults and SpO_2 $\geq$92-95 % in pregnant patients. Children with emergency signs (obstructed or absent breathing, severe respiratory distress, central cyanosis, shock, coma or convulsions) should receive oxygen therapy during resuscitation to target SpO_2 $\geq$94%; otherwise, the target SpO_2 is $\geq$90%. All areas where patients with SARI are cared for should be equipped with pulse oximeters, functioning oxygen systems and disposable, single-use, oxygen-delivering interfaces (nasal cannula, simple face mask, and mask with reservoir bag). Use contact precautions when handling contaminated oxygen interfaces of patients with nCoV infection

b. Use conservative fluid management in patients with SARI when there is no evidence of shock: Patients with SARI should be treated cautiously with intravenous fluids, because aggressive fluid resuscitation may worsen oxygenation, especially in settings where there is limited availability of mechanical ventilation

c. Give empiric antimicrobials to treat all likely pathogens causing SARI. Give antimicrobials within one hour of initial patient assessment for patients with sepsis: Although the patient may be suspected to have nCoV, administer appropriate empiric antimicrobials within ONE hour of identification of sepsis. Empiric antibiotic treatment should be based on the clinical diagnosis (community-acquired pneumonia, health care-associated pneumonia [if infection was acquired in healthcare setting], or sepsis), local epidemiology and susceptibility data, and treatment guidelines. Empiric therapy includes a neuraminidase inhibitor for treatment of influenza when there is local

circulation or other risk factors, including travel history or exposure to animal influenza viruses.18 Empiric therapy should be de-escalated on the basis of microbiology results and clinical judgment

d. Do not routinely give systemic corticosteroids for treatment of viral pneumonia or ARDS outside of clinical trials unless they are indicated for another reason: A systematic review of observational studies of corticosteroids administered to patients with SARS reported no survival benefit and possible harms (avascular necrosis, psychosis, diabetes, and delayed viral clearance). A systematic review of observational studies in influenza found a higher risk of mortality and secondary infections with corticosteroids; the evidence was judged as very low to low quality due to confounding by indication. A subsequent study that addressed this limitation by adjusting for time-varying confounders found no effect on mortality. Finally, a recent study of patients receiving corticosteroids for MERS used a similar statistical approach and found no effect of corticosteroids on mortality but delayed lower respiratory tract (LRT) clearance of MERS-CoV. Given lack of effectiveness and possible harm, routine corticosteroids should be avoided unless they are indicated for another reason. See section F for the use of corticosteroids in sepsis. e. Closely monitor patients with SARI for signs of clinical deterioration, such as rapidly progressive respiratory failure and sepsis, and apply supportive care interventions immediately: Application of timely, effective, and safe supportive therapies is the cornerstone of therapy for patients that develop severe manifestations of nCoV

f. Understand the patient's co-morbid condition(s) to tailor the management of critical illness and appreciate the prognosis: During intensive care management of SARI, determine which chronic therapies should be continued and which therapies should be stopped temporarily

g. Communicate early with patient and family: Communicate proactively with patients and families and provide support and prognostic information. Understand the patient's values and preferences regarding life-sustaining interventions

D. Collection of specimens for laboratory diagnosis

Guidance on specimen collection, processing, transportation, including related biosafety procedures, is available on **https://mohfw.gov.in/media/disease-alerts**

Points to remember

- Collect blood cultures for bacteria that cause pneumonia and sepsis, ideally before antimicrobial therapy. DO NOT delay antimicrobial therapy to collect blood cultures
- Collect specimens from BOTH the upper respiratory tract (URT; nasopharyngeal and oropharyngeal) AND lower respiratory tract (LRT; expectorated sputum, endotracheal aspirate, or bronchoalveolar lavage) for nCoV testing by RT-PCR. Clinicians may elect to collect only LRT samples when these are readily available (for example, in mechanically ventilated patients)
- Use appropriate PPE for specimen collection (droplet and contact precautions for URT specimens; airborne precautions for LRT specimens). When collecting URT samples, use viral swabs (sterile Dacron or rayon, not cotton) and viral transport media. Do not sample the nostrils or tonsils. In a patient with suspected novel coronavirus, especially with pneumonia or severe illness, a single URT sample does not exclude the diagnosis, and additional URT and LRT samples are recommended. LRT (vs. URT) samples are more likely to be positive and for a longer period. Clinicians may elect to collect only LRT samples when these are readily available (for example, in mechanically ventilated patients). Sputum induction should be avoided due to increased risk of increasing aerosol transmission.

Dual infections with other respiratory viral infections have been found in SARS and MERS cases. At this stage we need detailed microbiologic studies in all suspected cases. Both URT and LRT specimens can tested for other respiratory viruses, such as influenza A and B (including zoonotic influenza A), respiratory syncytial virus, parainfluenza viruses, rhinoviruses, adenoviruses, enteroviruses (e.g. EVD68), human metapneumovirus, and endemic human coronaviruses (i.e. HKU1, OC43, NL63, and 229E). LRT specimens can also be tested for bacterial pathogens, including Legionella pneumophila

In hospitalized patients with confirmed nCoV infection, repeat URT and LRT samples should be collected to demonstrate viral clearance. The frequency of specimen collection will depend on local circumstances but should be at least every 2 to 4 days until there are two consecutive negative results (both URT and LRT samples if both are collected) in a clinically recovered patient at least 24 hours apart. If local infection control practice requires two negative results before removal of droplet precautions, specimens may be collected as often as daily

E. Management of hypoxemic respiratory failure and ARDS

Recognize severe hypoxemic respiratory failure when a patient with respiratory distress is failing standard oxygen therapy. Patients may continue to have increased work of breathing or hypoxemia even when oxygen is delivered via a face mask with reservoir bag (flow rates of 10-15 L/min, which is typically the minimum flow required to maintain bag inflation; FiO_2 0.60-0.95). Hypoxemic respiratory failure in ARDS commonly results from intrapulmonary ventilation-perfusion mismatch or shunt and usually requires mechanical ventilation

High-flow nasal oxygen (HFNO) or non-invasive ventilation (NIV) should only be used in selected patients with hypoxemic respiratory failure. The risk of treatment failure is high in patients with MERS treated with NIV, and patients treated with either HFNO or NIV should be closely monitored for clinical deterioration. HFNO systems can deliver 60 L/min of gas flow and FiO_2 up to 1.0; paediatric circuits generally only handle up to 15 L/min, and many children will require an adult circuit to deliver adequate flow. Compared to standard oxygen therapy, HFNO reduces the need for intubation. Patients with hypercapnia (exacerbation of obstructive lung disease, cardiogenic pulmonary oedema), hemodynamic instability, multi-organ failure, or abnormal mental status should generally not receive HFNO, although emerging data suggest that HFNO may be safe in patients with mild-moderate and non-worsening hypercapnia.25 Patients receiving HFNO should be in a monitored setting and cared for by experienced personnel capable of endotracheal intubation in case the patient acutely deteriorates or does not improve after a short trial (about 1 hr). Evidence-based guidelines on HFNO do not exist, and reports on HFNO in MERS patients are limited.

NIV guidelines make no recommendation on use in hypoxemic respiratory failure (apart from cardiogenic pulmonary oedema and post-operative respiratory failure) or pandemic viral illness (referring to studies of SARS and pandemic influenza). Risks include delayed intubation, large tidal volumes, and injurious transpulmonary pressures. Limited data suggest a high failure rate when MERS patients receive NIV. Patients receiving a trial of NIV should be in a monitored setting and cared for by experienced personnel capable of endotracheal intubation in case the patient acutely deteriorates or does not improve after a short trial (about 1 hr). Patients with hemodynamic instability, multiorgan failure, or abnormal mental status should not receive NIV.

Recent publications suggest that newer HFNO and NIV systems with good interface fitting do not create widespread dispersion of exhaled air and therefore should be associated with low risk of airborne transmission.

Endotracheal intubation should be performed by a trained and experienced provider using airborne precautions. Patients with ARDS, especially young children or those who are obese or pregnant, may desaturate quickly during intubation. Pre-oxygenate with 100% FiO_2 for 5 minutes, via a face mask with reservoir bag, bag-valve mask, HFNO, or NIV. Rapid sequence intubation is appropriate after an airway assessment that identifies no signs of difficult intubation.

Implement mechanical ventilation using lower tidal volumes (4 8 ml/kg predicted body weight, PBW) and lower inspiratory pressures (plateau pressure <30 cmH_2O). This is a strong recommendation from a clinical guideline for patients with ARDS, and is suggested for patients with sepsis-induced respiratory failure who do not meet ARDS criteria. The initial tidal volume is 6 ml/kg PBW; tidal volume up to 8 ml/kg PBW is allowed if undesirable side effects occur (e.g. dyssynchrony, pH <7.15). Hypercapnia is permitted if meeting the pH goal of 7.30-7.45. Ventilator protocols are available. The use of deep sedation may be required to control respiratory drive and

achieve tidal volume targets. Although high driving pressure (plateau pressure−PEEP) may more accurately predict increased mortality in ARDS compared to high tidal volume or plateau pressure, RCTs of ventilation strategies that target driving pressure are not currently available.

In patients with severe ARDS, prone ventilation for >12 hours per day is recommended. Application of prone ventilation is strongly recommended for adult and paediatric patients with severe ARDS but requires sufficient human resources and expertise to be performed safely.

Use a conservative fluid management strategy for ARDS patients without tissue hypoperfusion.

In patients with moderate or severe ARDS, higher PEEP instead of lower PEEP is suggested. PEEP titration requires consideration of benefits (reducing atelectrauma and improving alveolar recruitment) vs. risks (end-inspiratory overdistension leading to lung injury and higher pulmonary vascular resistance). Tables are available to guide PEEP titration based on the FiO_2 required to maintain SpO_2. A related intervention of recruitment manoeuvres (RMs) is delivered as episodic periods of high continuous positive airway pressure [30 40 cm H_2O], progressive incremental increases in PEEP with constant driving pressure, or high driving pressure; considerations of benefits vs. risks are similar. Higher PEEP and RMs were both conditionally recommended in a clinical practice guideline. For PEEP, the guideline considered an individual patient data meta-analysis of 3 RCTs. However, a subsequent RCT of high PEEP and prolonged high-pressure RMs showed harm, suggesting that the protocol in this RCT should be avoided. Monitoring of patients to identify those who respond to the initial application of higher PEEP or a different RM protocol, and stopping these interventions in non-responders, is suggested.

In patients with moderate-severe ARDS (PaO_2/FiO_2 <150), neuromuscular blockade by continuous infusion should not be routinely used. One trial found that this strategy improved survival in patients with severe ARDS (PaO2/FiO2 <150) without causing significant weakness, but results of a recent larger trial found that use of neuromuscular blockage with high PEEP strategy was not associated with

survival when compared to a light sedation strategy without neuromuscular blockade. Continuous neuromuscular blockade may still be considered in patients with ARDS in certain situations: ventilator dyssnchony despite sedation, such that tidal volume limitation cannot be reliably achieved; or refractory hypoxemia or hypercapnia.

In settings with access to expertise in extracorporeal life support (ECLS), consider referral of patients with refractory hypoxemia despite lung protective ventilation. A recent guideline made no recommendation about ECLS in patients with ARDS. Since then, an RCT of ECLS for patients with ARDS was stopped early and found no statistically significant difference in the primary outcome of 60-day mortality between ECLS and standard medical management (including prone positioning and neuromuscular blockade). However, ECLS was associated with a reduced risk of the composite outcome of mortality and crossover to ECLS, and a post hoc Bayesian analysis of this RCT showed that ECLS is very likely to reduce mortality across a range of prior assumptions. In patients with MERS-CoV infection, ECLS vs. conventional treatment was associated with reduced mortality in a cohort study. ECLS should only be offered in expert centres with a sufficient case volume to maintain expertise and that can apply the IPC measures required for nCoV patients

Avoid disconnecting the patient from the ventilator, which results in loss of PEEP and atelectasis. Use in-line catheters for airway suctioning and clamp endotracheal tube when disconnection is required (for example, transfer to a transport ventilator)

F. Management of septic shock

Recognize septic shock in adults when infection is suspected or confirmed AND vasopressors are needed to maintain mean arterial pressure (MAP) $\geq$65 mmHg AND lactate is $\geq$2 mmol/L, in absence of hypovolemia. Recognize septic shock in children with any hypotension (systolic blood pressure [SBP] <5th centile or >2 SD below normal for age) or 2-3 of the following: altered mental state; tachycardia or bradycardia (HR <90 bpm or >160 bpm in infants and HR <70 bpm or >150 bpm in children); prolonged capillary refill (>2 sec) or warm vasodilation with bounding pulses; tachypnea; mottled skin or petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia.

In the absence of a lactate measurement, use MAP and clinical signs of perfusion to define shock. Standard care includes early recognition and the following treatments within 1 hour of recognition: antimicrobial therapy and fluid loading and vasopressors for hypotension. The use of central venous and arterial catheters should be based on resource availability and individual patient needs. Detailed guidelines are available for the management of septic shock in adults and children.

In resuscitation from septic shock in adults, give at least 30 ml/kg of isotonic crystalloid in adults in the first 3 hours. In resuscitation from septic shock in children in well-resourced settings, give 20 ml/kg as a rapid bolus and up to 40-60 ml/kg in the first 1 hr.
Do not use hypotonic crystalloids, starches, or gelatins for resuscitation.

Fluid resuscitation may lead to volume overload, including respiratory failure. If there is no response to fluid loading and signs of volume overload appear (for example, jugular venous distension, crackles on lung auscultation, pulmonary oedema on imaging, or hepatomegaly in children), then reduce or

discontinue fluid administration. This step is particularly important where mechanical ventilation is not available. Alternate fluid regimens are suggested when caring for children in resource-limited settings.

Crystalloids include normal saline and Ringer's lactate. Determine need for additional fluid boluses (250-1000 ml in adults or 10-20 ml/kg in children) based on clinical response and improvement of perfusion targets. Perfusion targets include MAP (>65 mmHg or age-appropriate targets in children), urine output (>0.5 ml/kg/hr in adults, 1 ml/kg/hr in children), and improvement of skin mottling, capillary refill, level of consciousness, and lactate. Consider dynamic indices of volume responsiveness to guide volume administration beyond initial resuscitation based on local resources and experience. These indices include passive leg raises, fluid challenges with serial stroke volume measurements, or variations in systolic pressure, pulse pressure, inferior vena cava size, or stroke volume in response to changes in intrathoracic pressure during mechanical ventilation.

Starches are associated with an increased risk of death and acute kidney injury vs. crystalloids. The effects of gelatins are less clear, but they are more expensive than cyrstalloids. Hypotonic (vs. isotonic) solutions are less effective at increasing intravascular volume. Surviving Sepsis also suggests albumin for resuscitation when patients require substantial amounts of crystalloids, but this conditional recommendation is based on low-quality evidence.

Administer vasopressors when shock persists during or after fluid resuscitation. The initial blood pressure target is MAP ≥65 mmHg in adults and age-appropriate targets in children.

If central venous catheters are not available, vasopressors can be given through a peripheral IV, but use a large vein and closely monitor for signs of extravasation and local tissue necrosis. If extravasation occurs, stop infusion. Vasopressors can also be administered through intraosseous needles.

If signs of poor perfusion and cardiac dysfunction persist despite achieving MAP target with fluids and vasopressors, consider an inotrope such as dobutamine

Vasopressors (i.e. norepinephrine, epinephrine, vasopressin, and dopamine) are most safely given through a central venous catheter at a strictly controlled rate, but it is also possible to safely administer them via peripheral vein and intraosseous needle. Monitor blood pressure frequently and titrate the vasopressor to the minimum dose necessary to maintain perfusion and prevent side effects. Norepinephrine is considered first-line in adult patients; epinephrine or vasopressin can be added to achieve the MAP target. Because of the risk of tachyarrhythmia, reserve dopamine for selected patients with low risk of tachyarrhythmia or those with bradycardia. In children with cold shock (more common), epinephrine is considered first-line, while norepinephrine is used in patients with warm shock (less common).

G. Prevention of complications

Implement the following interventions (Table 4) to prevent complications associated with critical illness. These interventions are based on Surviving Sepsis or other guidelines, and are generally limited to feasible recommendations based on high quality evidence.

Table 4: Prevention of complications

Anticipated Outcome	Interventions
Reduce days of invasive mechanical ventilation	• Use weaning protocols that include daily assessment for readiness to breathe spontaneously • Minimize continuous or intermittent sedation, targeting specific titration endpoints (light sedation unless contraindicated) or with daily interruption of continuous sedative infusions
Reduce incidence of ventilator associated pneumonia	• Oral intubation is preferable to nasal intubation in adolescents and adults • Keep patient in semi-recumbent position (head of bed elevation 30-45º) Use • a closed suctioning system; periodically drain and discard condensate in tubing • Use a new ventilator circuit for each patient; once patient is ventilated, change circuit if it is soiled or damaged but not routinely • Change heat moisture exchanger when it malfunctions, when soiled, or every 5 7 days
Reduce incidence of venous thromboembolism	• Use pharmacological prophylaxis (low molecular-weight heparin [preferred if available] or heparin 5000 units subcutaneously twice daily) in adolescents and adults without contraindications. For those with contraindications, use mechanical prophylaxis (intermittent pneumatic compression devices).
Reduce incidence of catheter related bloodstream infection	• Use a checklist with completion verified by a real-time observer as reminder of each step needed for sterile insertion and as a daily reminder to remove catheter if no longer needed
Reduce incidence of pressure ulcers	• Turn patient every two hours
Reduce incidence of stress ulcers and gastrointestinal bleeding	• Give early enteral nutrition (within 24 48 hours of admission) • Administer histamine-2 receptor blockers or proton-pump inhibitors in patients with risk factors for GI bleeding. Risk factors for gastrointestinal bleeding include mechanical ventilation for ≥48 hours, coagulopathy, renal replacement • therapy, liver disease, multiple comorbidities, and higher organ failure score
Reduce incidence of ICU-related weakness	• Actively mobilize the patient early in the course of illness when safe to do so

H. Specific anti-Novel-CoV treatments and clinical research

There is no current evidence from RCTs to recommend any specific anti-nCoV treatment for patients with suspected or confirmed nCoV. Unlicensed treatments should be administered only in the context of ethically-approved clinical trials or the Monitored Emergency Use of Unregistered Interventions Framework (MEURI), with strict monitoring.

Clinical characterization protocols are available, including the SPRINT-SARI https://isaric.tghn.org/sprint-sari/ and WHOISARIC forms available at https://isaric.tghn.org/protocols/severe-acute-respiratory-infection-data-tools/.

I. Special considerations for pregnant patients

Pregnant women with suspected or confirmed nCoV should be treated with supportive therapies as described above, taking into account the physiologic adaptations of pregnancy.

The use of investigational therapeutic agents outside of a research study should be guided by individual risk-benefit analysis based on potential benefit for mother and safety to fetus, with consultation from an obstetric specialist and ethics committee.

Emergency delivery and pregnancy termination decisions are challenging and based on many factors: gestational age, maternal condition, and fetal stability. Consultations with obstetric, neonatal, and intensive care specialists (depending on the condition of the mother) are essential.

Note: These guidelines are preliminary in nature and will be updated as soon as more information on clinical profile and treatment are available.

MINISTRY OF HEALTH AND FAMILY WELFARE

Detailed Guidelines for Infection Prevention Control for suspected cases of 2019nCoV Acute Respiratory Disease

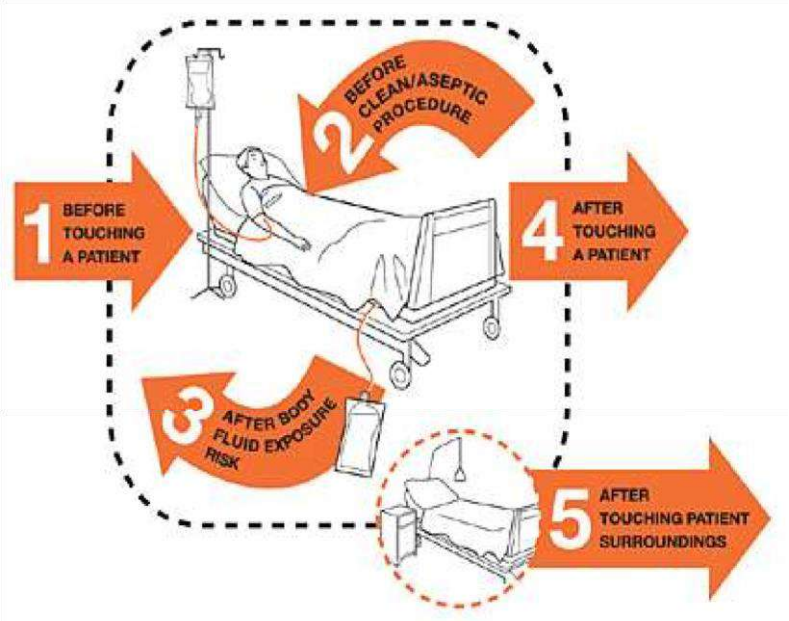
Clinical triage includes early recognition and immediate placement of patients in separate area from other patients (source control). Triaging Station-Offer mask, follow hand hygiene and respiratory etiquettes. Minimize the waiting time at triage station. A self-declaration form should be filled up for all suspected cases reporting to the hospital. All individuals, including family members, visitors and HCWs should apply standard, contact and droplet precautions. Place patients in adequately ventilated single rooms. When single rooms are not available, cohort patients suspected of 2019-nCoV acute respiratory disease together with minimum distance between two patients to be 1 meter.

IPC strategies to prevent or limit infection transmission in health-care settings include the following:

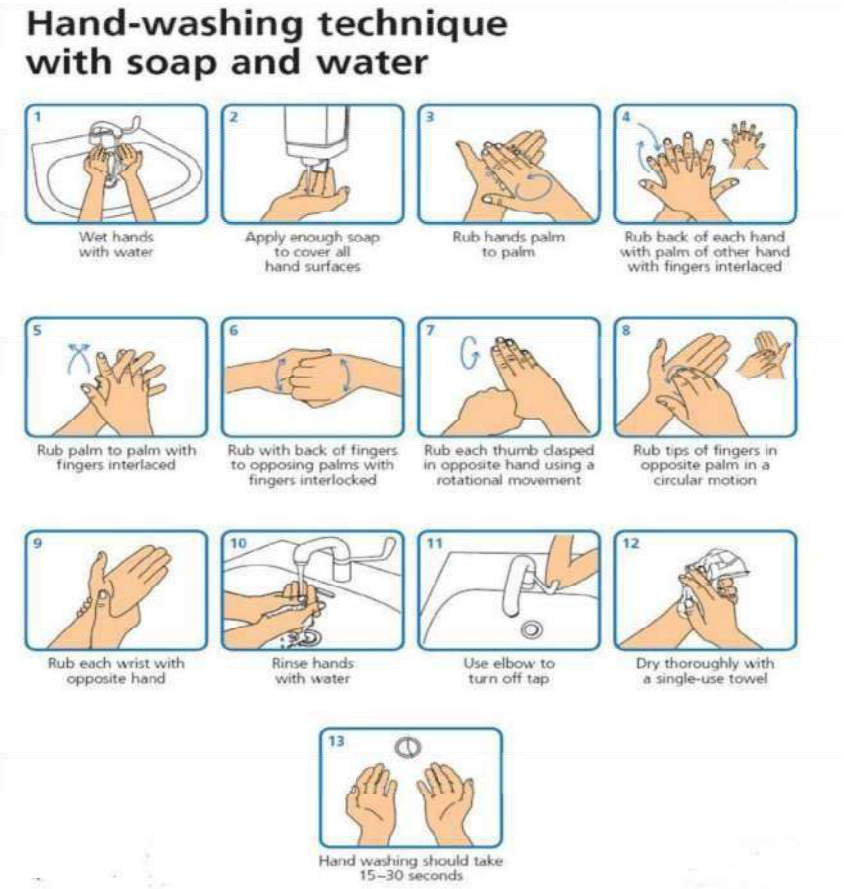
1. **Standard Precautions**
   - 1.1 Hand hygiene
   - 1.2 Respiratory hygiene
   - 1.3 Personal protective equipment (PPE)
2. **Additional Precautions**
3. **Bio Medical waste management**
4. **Laundry management**
5. **Sample collection, storage and transportation**
6. **Monitor health of HCWs providing care to cases of 2019-nCoV Acute Respiratory Disease**
7. **Hospital Disinfection (Environmental)**

1.1 Hand Hygiene

- **Moments of Hand Hygiene**



- **Steps of Hand Hygiene**



1.2 Respiratory Hygiene

- Offer a medical/surgical mask for suspected 2019-nCoV acute respiratory disease case for those who can tolerate it.
- Cover nose and mouth during coughing or sneezing with tissue or flexed elbow for others.
- Perform hand hygiene after contact with respiratory secretions.

1.3 Personal Protective Equipment (PPE)

- PPE includes shoe cover, gown, mask, eye protection & gloves.
- Shoe cover should always be worn before entering the patient care area (Isolation ward etc.).
- If gowns are not fluid resistant, use a waterproof apron for procedures with expected high fluid volumes that might penetrate the gown.

Donning & Doffing procedures should be diligently & carefully followed as given below.

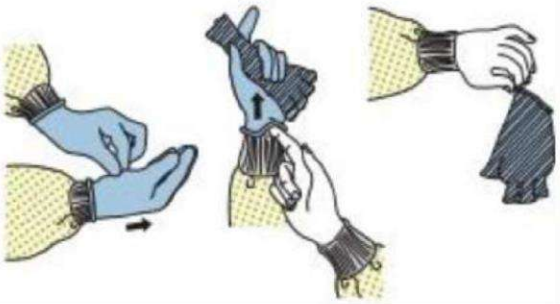
- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform Hand Hygiene

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container



2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

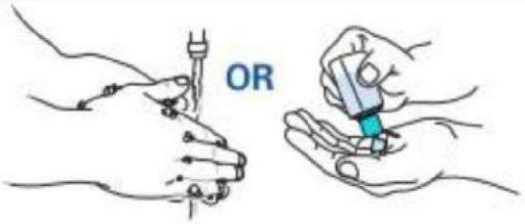
3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in a waste container

4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container

5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

2. Additional precautions

- Cohort HCWs to exclusively care for cases to reduce the risk of spreading transmission.
- Place patient beds at least 1m apart;
- Perform procedures in an adequately ventilated room; i.e. at least natural ventilation with at least 160 l/s/patient air flow or negative pressure rooms with at least 12 air changes per hour (ACH) and controlled direction of air flow when using mechanical ventilation
- Limit the number of persons present in the room to the absolute minimum required for the patient's care and support.
- Use either single use disposable equipment or dedicated equipment (e.g. stethoscopes, blood pressure cuffs and thermometers). If equipment needs to be shared among patients, clean and disinfect between each patient use (e.g. ethyl alcohol 70%);
- Refrain from touching eyes, nose or mouth with potentially contaminated hands;
- Some **aerosol generating procedures** have been associated with increased risk of transmission of coronaviruses such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation and bronchoscopy. Ensure that HCWs performing aerosolgenerating procedures use PPE with particulate respirator at least as protective as a NIOSH-certified N95, EU FFP2 or equivalent. When putting on a disposable particulate respirator, always perform the seal-check. Note that if the wearer has facial hear (beard) this can prevent a proper respirator fit.
- Avoid the movement and transport of patients out of the room or area unless medically necessary.
- Use designated portable X-ray equipment and/or other important diagnostic equipment.
- If transport is required, use pre-determined transport routes to minimize exposures to staff, other patients and visitors and apply medical mask to patient;

- Ensure that HCWs who are transporting patients wear appropriate PPE as described in this section and perform hand hygiene;
- Notify the receiving area of necessary precautions as soon as possible before the patient's arrival;

- Routinely clean and disinfect patient-contact surfaces;
- Limit the number of HCWs, family members and visitors in contact with a patient with suspected 2019 nCoV- Acute Respiratory Disease;
- Maintain a record of all persons entering the patient's room including all staff and visitors.
- Duration of contact and droplet precautions for 2019 nCoV- Acute Respiratory Disease Standard precautions should always be applied at all times. Additional contact and droplet precautions should continue until the patient is asymptomatic.

3. Bio Medical Waste Management from suspected case of nCoV

- All articles like swab, syringes, IV set, PPE etc are to be discarded in yellow bag.
- All sharps like needle etc are to be collected in puncture proof container which should be discarded in yellow bag.

4. Laundry

- All soiled clothing bedding and linen should be gathered without creating much motion / fluffing.
- Do not shake sheets when removing them from the bed.
- Always perform hand hygiene after handling soiled laundry items.
- Laundry should be disinfected in freshly prepared 1% bleach and then transported to laundry in tightly sealed and labeled plastic bag.

5. Sample collection, storage and transportation

- Collection and handling of laboratory specimens from patients with suspected 2019 nCoV- Acute Respiratory Disease. All specimens collected for laboratory investigations should be regarded as potentially infectious, and HCWs who collect,

or transport clinical specimens should adhere rigorously to Standard Precautions to minimize the possibility of exposure to pathogens.

- Ensure that HCWs who collect specimens use appropriate PPE (eye protection, medical mask, long-sleeved gown, gloves).

- If the specimen is collected under aerosol generating procedure, personnel should wear a particulate respirator at least as protective as a NIOSH-certified N95, EU FFP2 or equivalent
- Ensure that all personnel who transport specimens are trained in safe handling practices and spill decontamination procedures (As per Hospital Policy).

Samples to be collected:

- Nasopharyngeal swab / Nasal Swabs 2
- Throat Swab
- Before collecting the samples, it requires to be ensured that neck is in extended position. Nasopharyngeal swab will be collected with the per nasal swab provided in the kit, after taking out the swab it is passed along the floor of nasal cavity and left there for about five second and transferred into VTM and transported to the designated lab at 4 degree Celsius as soon as possible (same day).
- For collection of samples from throat area the other sterilized swab is swabbed over the tonsillar area and posterior pharyngeal wall and finally transferred into VTM and stored and transported to the designated lab at 4 degree Celsius as soon as possible (same day).
- Other respiratory material like endotracheal aspirated / broncheo-alveolar lavage in patients with more severe respiratory disease can also be collected and transported in the same way.
- Place specimens for transport in leak-proof specimen bags /Zip lock pouch (secondary container) with the patient's label on the specimen container (primary container), and a clearly written laboratory request form.

- Ensure that health-care facility laboratories adhere to appropriate biosafety practices and transport requirements according to the type of organism being handled.
- Deliver all specimens by hand whenever possible.
- Document patients full name, age / date of birth of suspected 2019-nCoV case of potential concern clearly on the accompanying laboratory request form.
- Notify the laboratory as soon as possible that the specimen is being transported.

6. Monitor health of HCWs providing care to cases of 2019-nCoV Acute Respiratory Disease

HCWs and housekeeping staff providing care to cases of 2019-nCoV acute respiratory diseases cases shall be monitored daily for development of any symptoms as per the suspect case definition including charting of their temperature twice daily for 14 days after last exposure. If they develop any symptoms then standard protocol laid down for management of suspect case of 2019-nCoV acute respiratory disease shall be followed.

7. Hospital Disinfection (Environmental)

- Environmental surfaces or objects contaminated with blood, other body fluids, secretions or excretions should be cleaned and disinfected using standard hospital detergents/disinfectants e.g. freshly prepared 1%Sodium Hypochlorite or5% Lysol. Spray the surface with 0.5% to 1% solution of Sodium Hypochlorite.
- The contact period of the chemical with the surface should be min. of 30 Minutes.
- Disinfect all external surfaces of specimen containers thoroughly (using an effective disinfectant) prior to transport. E.g. Sodium hypochlorite at 1%, 500 ppm available chlorine (i.e. 1:100 dilution of household bleach at initial concentration of 5%) or5%Lys
- Environmental surfaces or objects contaminated with blood, other body fluids, secretions or excretions should be cleaned and disinfected using standard hospital detergents/disinfectants e.g. freshly prepared 1%Sodium Hypochlorite or5% Lysol

- Do not spray (i.e. fog) occupied or unoccupied clinical areas with disinfectant. This is a potentially dangerous practice that has no proven disease control benefit.
- Wear gloves, gown, mask and closed shoes (e.g. boots) when cleaning the environment and handling infectious waste. Cleaning heavily soiled surfaces (e.g. soiled with vomit or blood) increases the risk of splashes. On these occasions, facial protection should be worn in addition to gloves, gown and closed, resistant shoes. Wear gloves, gown, closed shoes and goggles/facial protection, when handling liquid infectious waste (e.g. any secretion or excretion

with visible blood even if it originated from a normally sterile body cavity). Avoid splashing when disposing of liquid infectious waste.

- Clean and disinfect mattress impermeable covers.
- Non-critical instruments /equipment (that are those in contact with intact skin and no contact with mucous membrane) require only intermediate or low level disinfection before and after use.

Intermediate Level disinfectant: Alcohols, chlorine compounds, hydrogen Peroxide, chlorhexidine,
Low level disinfectants: Benzalkonium chloride, some soaps

LIQUID SPILL MANAGEMENT:

- Promptly clean and decontaminate spills of blood and other potentially infectious materials.
- Wear protective gloves.
- Using a pair of forceps and gloves, carefully retrieve broken glass and sharps if any, and use a large amount of folded absorbent paper to collect small glass splinters. Place the broken items into the puncture proof sharps container.
- Cover spills of infected or potentially infected material on the floor with paper towel/ blotting paper/newspaper. Pour 0.5%freshly prepared sodium hypochlorite.

Leave for 30 minutes for contact

Place all soiled absorbent material and contaminated swabs into a designated waste container.

Then clean the area with gauze or mop with water and detergent with gloved hands

References

- Infection Prevention Control Guidelines for suspected cases of Novel Coronavirus (nCoV) Atal Bihari Vajpayee Institute of Medical Sciences & Dr Ram Manohar Lohia Hospital, New Delhi-110001
- Infection prevention and control during health care when novel coronavirus (2019-nCoV) infection is suspected Interim guidance January 2020 WHO/2019-nCoV/IPC/v2020.1
- CDC guidelines on PPE https://www.cdc.gov/HAI/pdfs/ppe/PPEslides6-29-04.pdf

Specimen Collection, Packaging and Transport Guidelines for 2019 novel Coronavirus (2019-nCoV)

Title: Specimen Collection, Packaging and Transport Guidelines for 2019 Novel Coronavirus (2019-nCoV)	SOP number: ICMR-NIV/2019-nCoV/Specimens_01 Prepared by: Dr. Y.K. Gurav Date: 19/01/2020 Reviewed by: Dr. V. Potdar Date: 20/01/2020 Approved by: Dr. P. Abraham Date: 20/01/2020

Scope:

To be used by the Government health authorities/ hospitals/ clinicians/ laboratories planning to collect appropriate clinical samples as indicated for diagnosis of 2019-nCoV.

Purpose:

This document describes the information for collection, packaging and transport of clinical specimens to Influenza group at ICMR-National Institute of Virology (NIV), Pune, Maharashtra for diagnosis of 2019 Novel Coronavirus (2019-nCoV)

Responsibilities:

- The clinician should decide necessity for collection of clinical specimens for laboratory testing of 2019-nCoV only after following the case definition as given by the health authorities, Government of India.
- Appropriate clinical sample need to be collected by laboratory personnel/ health care worker trained in specimen collection in presence of a clinician.
- By following all biosafety precautions and using personal protective equipment (PPEs), clinical samples need to be sent to the designated laboratory (ICMR-NIV, Pune) by following standard triple packaging.

Selection of patient:

Any person who presents with Severe Acute Respiratory Illness (SARI) AND any one of the following i.e. a history of travel from Wuhan, China in 14 days prior to symptoms onset; disease in healthcare worker working in an environment of SARI patients; unusual or unexpected clinical course, especially sudden deterioration despite appropriate treatment; should be urgently investigated. Updated case definition need to be followed as per MOHFW, Govt of India which is available on the website www.mohfw.gov.in

Specimen collection details:

(Adapted from the WHO guidelines on 2019-nCoV):

Specimen type	Collection materials	Transport to laboratory	Storage till testing	Comment
Nasopharyngeal and oropharyngeal swab	Dacron or polyester flocked swabs*	4 °C	≤5 days: 4 °C >5 days: -70 °C	The nasopharyngeal and oropharyngeal swabs should be placed in the same tube to increase the viral load.
Bronchoalveolar lavage	sterile container*	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	There may be some dilution of pathogen, but still a worthwhile specimen
Tracheal aspirate, nasopharyngeal aspirate or nasal wash	sterile container*	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	Not applicable
Sputum	sterile container	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	Ensure the material is from the lower respiratory tract
Tissue from biopsy or autopsy including from lung	sterile container with saline	4 °C	≤24 hours: 4 °C >24 hours: –70 °C	Autopsy sample collection preferably to be avoided
Serum (2 samples – acute and convalescent)	Serum separator tubes (adults: collect 3-5 ml whole blood)	4 °C	≤5 days: 4 °C >5 days: –70 °C	Collect paired samples: • acute – first week of illness • convalescent – 2 to 3 weeks later

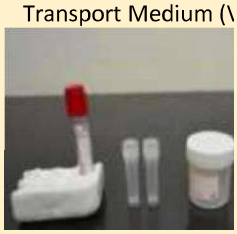
**For transport of samples for viral detection, use VTM (viral transport medium) containing antifungal and antibiotic supplements. Avoid repeated freezing and thawing of specimens.*

Specimen labelling and processing:

- Personal protective equipment (apron, hand gloves, face shield, N95 Masks etc.) need to be used and all biosafety precautions should be followed so as to protect individuals and the environment.
- Proper labelling (name/age/gender/specimen ID) need to be done on specimen container and other details of sender (name/address/phone number) on the outer container by mentioning "To be tested for 2019-nCoV"
- For any queries, the nodal officer from ICMR-NIV Pune (Dr Yogesh K. Gurav, Scientist E) may be contacted (Phone 020-26006290/ 26006390; Email: gurav.yk@gmail.com/gurav.yk@gov.in) and need to be informed in advance before sending specimens to ICMR-NIV, Pune.

Requirements for Clinical Samples Collection, Packaging and Transport

1. Sample vials and Vir
Transport Medium (\



2. Adsorbent material
(cotton, tissue paper
paraffin, seizer, cello t

ape

3. A leak-proof secondary container e.g.,

ziplock pouch, cryobox, 50 mL centrifuge tube, plastic container

4. Hard-frozen Gel Pack

5. A suitable outer container (e.g., thermo
(minimum dimensions: 10 x 10 x 10 cm

ocol box, ice-box, hard-boa

Procedure for Specimen Packaging and Transport

1. Use PPE while handling specimen

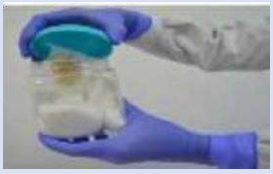
2. Seal the neck of the sample vials using parafilm

3. Cover the sample vials using absorbent material

4. Arrange primary container (vial) in secondary container

5. Placing the centrifuge tub inside a zip-lock pouch

6. Placing the zip-lock pouch inside a sturdy plastic container and seal the neck of the container



Note: *Sample vials can also be placed inside a zip-lock pouch, covered in absorbent material and secured by heat-sealing or rubber bands. Then, the zip-lock pouch should be placed inside another plastic pouch and secured*

7. Using a thermocol bo
an outer container ar
placing the secondary
container within it,
surrounded by hard-
frozen gel packs

7. Using a hard card-board bo
as an outer container and
placing the secondary
container and the gel packs

8. Placing the completed Specimen Referral Form (available on www.niv.co.in) and request letter inside a leak-proof, zip-lock pouch

9. Securing the zip-lock pouch with the Specimen Referral Form on the outer container

10. Attaching the lab
- Senders' address, co
number; Consig
address /contactnum
- Biological substa
Category B;
- 'UN 3373'; Orienta
label, Handle with ca

Documents to accompany:

1) Packaging list/proforma Invoice 2) Air way bill (for air transport) (to be prepared by sender or shipper) 3) Value equivalence document (for road/rail/sea transport) [Note: 1. A vaccine-carrier/ice-box can also be used as an outer container 2. The minimum dimensions of the outer container should be 10 x 10 x 10 cm (length x width x height)]

Routing of samples:

- Clinical specimens, official documents and Specimen request forms for testing of 2019-nCoV need to be sent to the ICMR-NIV address (The Director, ICMR-National Institute of Virology, 20-A, Dr Ambedkar Road, Pune, Maharashtra, Pin: 4110001 .
- For shipment-related queries information, kindly contact Dr Sumit Bharadwaj Scientist B, Influenza Group on email: sumitduttbhardwaj@gmail.com, phone 020-26006290 [redacted]26006390

Specimen Collection, Packaging and Transport Guid .lines for 2019 novel Coronavirus (2019-nCoV)

Specimen Collection, Packaging and Transport Guidelines for 2019 nCoV - Acute Respiratory Disease

Title: Specimen Collection, Packaging and Transport Guidelines for 2019 nCoV - Acute Respiratory Disease

Scope: To be used by the treating physicians, public health experts and laboratory personnel from Government health authorities/ hospitals/ planning to collect appropriate clinical samples as indicated for diagnosis of 2019 nCoV - Acute Respiratory Disease.

Purpose: Specimen collection, packaging and transport of clinical specimens to Influenza Lab in Division of Microbiology at National Centre for Disease control for diagnosis of 2019 nCoV - Acute Respiratory Disease.

Roles and Responsibilities:

• The clinicians with updated interim guidance on timely, effective, and safe supportive management of patients with 2019 nCoV - Acute Respiratory Disease should be well versed with suspected case definition from MOHFW https://mohfw.gov.in/sites/default/files/Guidelines%20on%20Clinical%20management%20of%20severe%20acute%20respiratory%20illness.pdf

• The suspected case definition as given by the health authorities, Government of India must be followed.

• The appropriate clinical sample needs to be collected by health care worker trained in specimen collection in presence of a clinician.

• Samples should be collected with all biosafety precautions and should be accompanied with detailed history of patient on the proforma which can be obtained from the testing laboratory in standard triple packaging.

• Personal protective equipment (apron, hand gloves, face shield, N95 Masks etc.) need to be used and all biosafety precautions should be followed while carrying out sample collection and packaging.

Specimen collection, storage and transport details:

(Adapted from WHO guidelines 2019 nCoV - Acute Respiratory Disease)

Specimen type	Collection materials	Transport to laboratory (48 -72 hrs)	Storage till testing
Nasopharyngeal and oropharyngeal swab (Both swabs should be placed in the same tube to increase the viral load)	Dacron or polyester flocked swabs*	4 °C	≤72 hrs: 4 °C >72 hrs: -70 °C
Bronchoalveolar lavage	Sterile container*	4 °C	≤48 hours: 4 °C >48 hours: –70 °C
Tracheal aspirate, nasopharyngeal aspirate or nasal wash	Sterile container*	4 °C	≤48 hours: 4 °C >48 hours: –70 °C
Sputum (Ensure the material is from the lower respiratory tract)	Sterile container	4 °C	≤48 hours: 4 °C >48 hours: –70 °C

For transport of samples for viral detection, use VTM (viral transport medium). Avoid repeated freezing and thawing of specimens.

Specimen packaging and transport:

Sample should be safely packed in Triple container packing and should be transported under cold chain to the reference laboratory with prior intimation. The packaging consists of three layers as follows.

1. Primary receptacle: A labelled primary watertight, leak-proof receptacle containing the specimen. The receptacle is wrapped in enough absorbent material to absorb all fluid in case of breakage.
2. Secondary receptacle: A second durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in one secondary receptacle. Sufficient additional absorbent material must be used to cushion multiple primary receptacles.
3. Outer shipping package. The secondary receptacle is placed in an outer shipping package which protects it and its contents from outside influences such as physical damage and water while in transit.

Specimen data forms, letters and other types of information that identify or describe the specimen for "testing of 2019 nCoV - Acute Respiratory Disease " and also identify the shipper and receiver should be taped to the outside of the secondary receptacle.

- NATIONAL HELTH MISSION SAID THAT DON'T WAST MASK AND USE ONLY FOR HELTH WORKER AND SICK PERSONS

  - Detail Question and Answers on COVID-19 for Public - MoHFW

  - https://www.mohfw.gov.in/pdf/FAQ.pdf

Detail Question and Answers on COVID-19 for Public

What is corona virus

Corona viruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes coronavirus disease COVID-19.

What is COVID-19

COVID-19 is the infectious disease caused by the most recently discovered corona virus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

What are the symptoms of COVID-19

The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. People with fever, cough and difficulty breathing should seek medical attention.

How does COVID-19 spread

People can catch COVID-19 from others who have the virus. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. These droplets land on objects and surfaces around the person. Other people then catch COVID-19 by touching these objects or surfaces, then touching their eyes, nose or mouth. People can also catch COVID-19 if they breathe in droplets from a person with COVID-19 who coughs out or exhales droplets. This is why it is important to stay more than 1 meter (3 feet) away from a

person who is sick. **Can the virus that causes COVID-19 be transmitted through the air?**

Studies to date suggest that the virus that causes COVID-19 is mainly transmitted through contact with respiratory droplets rather than through the air. See previous answer on "How does COVID-19 spread?" **Can CoVID-19 be caught from a person who has no symptoms?**

The main way the disease spreads is through respiratory droplets expelled by someone who is coughing. The risk of catching COVID-19 from someone with no symptoms at all is very low. However, many people with COVID-19 experience only mild symptoms. This is particularly true at the early stages of the disease. It is therefore possible to catch COVID-19 from someone who has, for example, just a mild cough and does not feel ill. **Can I catch COVID-19 from the feces of someone with the disease?**

The risk of catching COVID-19 from the feces of an infected person appears to be low. While initial investigations suggest the virus may be present in feces in some cases, spread through this route is not a main feature of the outbreak. The ongoing research on the ways COVID-19 is spread and will continue to share new findings. Because this is a risk, however, it is another reason to clean hands regularly, after using the bathroom and before eating.

What can I do to protect myself and prevent the spread of disease

Protection measures for everyone

Stay aware of the latest information on the COVID-19 outbreak, available on the national,state and local public health authority. Many countries around the world have seen cases of COVID-19 and several have seen outbreaks. Authorities in China and some other countries have succeeded in slowing or stopping their outbreaks. However, the situation is unpredictable so check regularly for the latest news.

You can reduce your chances of being infected or spreading COVID- 19 by taking some simple precautions:

- Regularly and thoroughly clean your hands with an alcohol- based hand rub or wash them with soap and water. Why? Washing your hands with soap and water or using alcohol-based hand rub kills viruses that may be on your hands.
- Maintain at least 1 metre (3 feet) distance between yourself and anyone who is coughing or sneezing. Why?
  When someone coughs or sneezes they spray small liquid droplets from their nose or mouth which may contain virus. If you are too close, you can breathe in the droplets, including the COVID-19 virus if the person coughing has the disease.
- Avoid touching eyes, nose and mouth. Why? Hands touch many surfaces and can pick up viruses. Once contaminated, hands can transfer the virus to your eyes, nose or mouth. From there, the virus can enter your body and can make you sick.
- Make sure you, and the people around you, follow good respiratory hygiene. This means covering your mouth and nose with your bent elbow or tissue when you

cough or sneeze. Then dispose of the used tissue immediately. Why? Droplets spread virus. By following good respiratory hygiene you protect the people around you from viruses such as cold, flu and COVID-19.

- Stay home if you feel unwell. If you have a fever, cough and difficulty breathing, seek medical attention and call in advance. Follow the directions of your local health authority. Why? National and local authorities will have the most up to date information on the situation in your area. Calling in advance will allow your health care provider to quickly direct you to the right health facility. This will also protect you and help prevent spread of viruses and other infections.
- Keep up to date on the latest COVID-19 hotspots (cities or local areas where COVID-19 is spreading widely). If possible, avoid traveling to places – especially if you are an older person or have diabetes, heart or lung disease. Why? You have a higher chance of catching COVID-19 in one of these areas.

Protection measures for persons who are in or have recently visited (past 14 days) areas where COVID-19 is spreading

- Follow the guidance outlined above (Protection measures for everyone)
- Self-isolate by staying at home if you begin to feel unwell, even with mild symptoms such as headache, low grade fever (37.3 C or above) and slight runny nose, until you recover. If it is essential for you to have someone bring you supplies or to go out, e.g. to buy food, then wear a mask to avoid infecting other people. Why? Avoiding contact with others and visits to medical facilities will allow these facilities to operate more effectively and help protect you and others from possible COVID-19 and other viruses.
- If you develop fever, cough and difficulty breathing, seek medical advice promptly as this may be due to a respiratory infection or other serious condition. Call in advance and tell your provider of any recent travel or contact with travelers. Why? Calling in advance will allow your health care provider to quickly direct you to the right health facility. This will also help to prevent possible spread of COVID-19 and other viruses.

How likely am I to catch COVID-19?

The risk depends on where you are - and more specifically, whether there is a COVID-19 outbreak unfolding there.

For most people in most locations the risk of catching COVID-19 is still low. However, there are now places around the world (cities or areas) where the disease is spreading. For people living in, or visiting, these areas the risk of catching COVID-19 is higher. Governments and health authorities are taking vigorous action every time a new case of COVID-19 is identified. Be sure to comply with any local restrictions on travel, movement or large gatherings. Cooperating with disease control efforts will reduce your risk of catching or spreading COVID-19.

COVID-19 outbreaks can be contained and transmission stopped, as has been shown in China and some other countries. Unfortunately, new outbreaks can emerge rapidly. It's important to be aware of the situation where you are or intend to go.

Should I worry about COVID-19?

Illness due to COVID-19 infection is generally mild, especially for children and young adults. However, it can cause serious illness: about 1 in every 5 people who catch it need hospital care. It is therefore quite normal for people to worry about how the COVID-19 outbreak will affect them and their loved ones.

We can channel our concerns into actions to protect ourselves, our loved ones and our communities. First and foremost among these actions is regular and thorough hand-washing and good respiratory hygiene. Secondly, keep informed and follow the advice of the local health authorities including any restrictions put in place on travel, movement and gatherings.

Who is at risk of developing severe illness

While we are still learning about how COVID-2019 affects people, older persons and persons with pre-existing medical conditions (such as high blood pressure, heart disease, lung disease, cancer or diabetes) appear to develop serious illness more often than others.

Are antibiotics effective in preventing or treating the COVID-19?

No. Antibiotics do not work against viruses, they only work on bacterial infections. COVID-19 is caused by a virus, so antibiotics do not work. Antibiotics should not be used as a means of prevention or treatment of COVID-19. They should only be used as directed by a physician to treat a bacterial infection.

Are there any medicines or therapies that can prevent or cure COVID-19

While some western, traditional or home remedies may provide comfort and alleviate symptoms of COVID-19, there is no evidence that current medicine can prevent or cure the disease. We does not recommend self-medication with any medicines, including antibiotics, as a prevention or cure for COVID-19. However, there are several ongoing clinical trials that include both western and traditional medicines. We will continue to provide updated information as soon as clinical findings are available.

Is COVID-19 the same as SARS?

No. The virus that causes COVID-19 and the one that caused the outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003 are related to each other genetically, but the diseases they cause are quite different.

SARS was more deadly but much less infectious than COVID-19. There have been no outbreaks of SARS anywhere in the world since 2003.

Should I wear mask to protect myself

Only wear a mask if you are ill with COVID-19 symptoms (especially coughing) or looking after someone who may have COVID-19. Disposable face mask can only be used once. If you are not ill or looking after someone who is ill then you are wasting a mask. There is a world-wide shortage of masks, so We urge people to use masks wisely.

We advises rational use of medical masks to avoid unnecessary wastage of precious resources and mis-use of masks The most effective ways to protect yourself and others against COVID-19 are to frequently clean your hands, cover your cough with the bend of elbow or tissue and maintain a distance of at least 1 meter (3 feet) from people who are coughing or sneezing.

- **How to put on use take off and dispose of a mask?**

1. Remember, a mask should only be used by health workers, care takers, and individuals with respiratory symptoms, such as fever and cough.
2. Before touching the mask, clean hands with an alcohol-based hand rub or soap and water
3. Take the mask and inspect it for tears or holes.
4. Orient which side is the top side (where the metal strip is).
5. Ensure the proper side of the mask faces outwards (the coloured side).
6. Place the mask to your face. Pinch the metal strip or stiff edge of the mask so it moulds to the shape of your nose.
7. Pull down the mask's bottom so it covers your mouth and your chin.
8. After use, take off the mask; remove the elastic loops from behind the ears while keeping the mask away from your face and clothes, to avoid touching potentially contaminated surfaces of the mask.
9. Discard the mask in a closed bin immediately after use.
10. Perform hand hygiene after touching or discarding the mask – Use alcohol-based hand rub or, if visibly soiled, wash your hands with soap and water.

How long is the incubation period for COVID-19?

The "incubation period" means the time between catching the virus and beginning to have symptoms of the disease. Most estimates of the incubation period for COVID-19 range from 1-14 days, most commonly around five days. These estimates will be updated as more data become available.

Can humans become infected with the COVID-19 from an animal source?

Coronaviruses are a large family of viruses that are common in animals. Occasionally, people get infected with these viruses which may then spread to other people. For example, SARS-CoV was

associated with civet cats and MERS-CoV is transmitted by dromedary camels. Possible animal sources of COVID-19 have not yet been confirmed.

To protect yourself, such as when visiting live animal markets, avoid direct contact with animals and surfaces in contact with animals. Ensure good food safety practices at all times. Handle raw meat, milk or animal organs with care to avoid contamination of uncooked foods and avoid consuming raw or undercooked animal products.

Can I catch COVID-19 from my pet?

While there has been one instance of a dog being infected in Hong Kong, to date, there is no evidence that a dog, cat or any pet can transmit COVID-19. COVID-19 is mainly spread through droplets produced when an infected person coughs, sneezes, or speaks. To protect yourself, clean your hands frequently and thoroughly.

We continues to monitor the latest research on this and other COVID- 19 topics and will update as new findings are available.

How long does the virus survive on surfaces?

It is not certain how long the virus that causes COVID-19 survives on surfaces, but it seems to behave like other corona viruses. Studies suggest that corona viruses (including preliminary information on the COVID-19 virus) may persist on surfaces for a few hours or up to several days. This may vary under different conditions (e.g. type of surface, temperature or humidity of the environment).

If you think a surface may be infected, clean it with simple disinfectant to kill the virus and protect yourself and others. Clean your hands with an alcohol-based hand rub or wash them with soap and water. Avoid touching your eyes, mouth, or nose.

Is it safe to receive a package from any area where COVID-19 has been reported?

Yes. The likelihood of an infected person contaminating commercial goods is low and the risk of catching the virus that causes COVID-19 from a package that has been moved, travelled, and exposed to different conditions and temperature is also low.

Is there anything I should not do?

The following measures **ARE NOT** effective against COVID-2019 and can be harmful:

- Smoking
- Wearing multiple masks
- Taking antibiotics (See question 10 "*Are there any medicines of therapies that can prevent or cure COVID-19?*")

In any case, if you have fever, cough and difficulty breathing seek medical care early to reduce the risk of developing a more severe infection and be sure to share your recent travel history with your health care provider.

❖ **MINISTRY OF HELTH AND FAIMLY WELFARE GUIDLINE FOR CHILDREN'S SAID THAT DON'T WEAR MASK**

➢ https://www.mohfw.gov.in/pdf/RevisedComprehensiveGuidelinesforManagementofCOVID19inChildrenandAdolescentsbelow18years.pdf

Dated 20th January 2022

Government of India
Ministry of Health and Family Welfare

Revised Comprehensive Guidelines for Management of COVID-19 in Children and Adolescents (below 18 years)

The Comprehensive Guidelines for Management of COVID-19 in CHILDREN and ADOLESCENTS (below 18 years) were reviewed by the group of experts in view of the current surge mainly attributed to the Omicron variant of concern. The available data from other countries suggests that disease caused by the Omicron variant is less severe; however, there is need for a careful watch, as the current wave evolves. These guidelines are dynamic, and will be reviewed and updated, on availability of new evidence.

The experts have assessed the available evidence and overall, the management remains unchanged, barring a few changes outlined below.

1. Title of the document has been changed from Comprehensive Guidelines for Management of COVID-19 in CHILDREN (below 18 years) to Comprehensive Guidelines for Management of COVID-19 in CHILDREN and ADOLESCENTS (below 18 years).

2. Use of antivirals or monoclonal antibodies is not recommended for children less than 18 years of age, irrespective of the severity of infection.

3. For diagnosing MIS-C, caution should be exercised while interpreting an isolated increase in COVID antibodies.

4. The CRP level for diagnosis of MIS-C has been revised as >5mg/dL.

5. If steroids are used, they should be tapered over 10-14 days, subject to clinical improvement.

6. Use of anticoagulants has been revised.

7. New section on post-COVID care has been added.

Attention is drawn to the following MoHFW guidelines:

- FAQs on SARS-CoV-2 Variant-Omicron, available at https://www.mohfw.gov.in/pdf/FAQsonOmicron.pdf
- Revised guidelines for Home Isolation of mild /asymptomatic COVID-19 cases, available at https://www.mohfw.gov.in/pdf/RevisedHomeIsolationGuidelines05012022.pdf
- Guidelines for COVID-19 vaccination of children between 15-18 years, available at

https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19VaccinationofChildrenbetween15to18yearsandPreca utionDosetoHCWsFLWs&60populationwithcomorbidities.pdf

COVID Appropriate Behavior is recommended to prevent SARS-CoV-2 infections:

3Ws:

○ Watch your distance (more than 2 meters) ○ Wash your hands ○ Wear a mask

2Vs: ○ Ventilation – open spaces are less risky than closed or poorly ventilated areas ○ Vaccination – for 15-18 years age group

Asymptomatic

- Positive without symptoms

Home isolation (tele consultation SOS)

Mainstay of Treatment

- Infants and younger children to stay under immediate care of parents/guardians
- No specific medication required for COVID-19 infection
- Continue medications for other conditions, if any
- Promote COVID appropriate behaviour (mask, strict hand hygiene, physical distancing; please see **guide for using mask** (refer page 9)
- Fluids and feeds: ensure oral fluids to maintain hydration and give a nutritious diet
- Advise older children and family to stay connected and engage in positive talks through phone, video-calls, etc.
- Parent/caregivers to contact the doctor in case of appearance of symptoms

Investigations

- No investigations needed

Mild

- Sore throat, rhinorrhoea
- Cough without breathing difficulty
- SpO_2 ≥94% on room air
- For other symptoms, see **COVID-19 symptoms – at a glance**

Home isolation* (tele consultation SOS) or COVID Care Centre

Mainstay of Treatment

- For fever, give paracetamol 10-15mg/kg/dose; may repeat every 4-6 hours
- For cough, give throat soothing agents and warm saline gargles in older children and adolescents
- Fluids and feeds: ensure oral fluids to maintain hydration and give a nutritious diet
- No other COVID-19 specific medication needed
- Antimicrobials are not indicated
- Maintain monitoring chart including counting of respiratory rate 2-3 times a day, look for chest indrawing, cold extremities, urine output, oxygen saturation, fluid intake, activity level, especially for young children
- Promote COVID appropriate behaviour (mask, strict hand hygiene, physical distancing); please see **guide for using mask** (refer page 9)
- Advise older children and family to stay connected and engage in positive talks through phone, video-calls, etc.
- Parent/caregivers to contact the doctor in case of deterioration of symptoms

Investigations

- No investigations needed

Moderate

- In addition to symptoms in mild cases, check for pneumonia which may not be apparent
- Rapid respiration (age-based): **<2 months** RR ≥60/min; **2-12 months**, RR ≥50/min; **1-5 years**, RR ≥40/min; **>5 years**, RR ≥30/min; **AND/OR** SpO_2 90–93% on room air
- For other symptoms, see **COVID-19 symptoms – at a glance**

Admit in DCHC or COVID-19 Hospital

Mainstay of Treatment

- Initiate oxygen if SpO_2 is <94% and maintain between 94–96%
- Maintain fluid and electrolyte balance
  - Encourage oral fluids (breast feeds in infants)
  - Initiate intravenous fluid therapy if oral intake is poor
- Corticosteroids are not required in all children with moderate illness; they may be administered in rapidly progressive disease
- Fever with temperature >38°C (or 100.4°F): Paracetamol 10-15mg/kg/dose; may repeat every 4-6 hours
- Anti-microbials to be administered if there is evidence/strong suspicion of superadded bacterial infection; please see **antimicrobial use guide**
- Supportive care for comorbid conditions, if any

Investigations

- Baseline: CBC including ESR, blood glucose
- Chest X-Ray

Severe

- SpO_2 <90% on room air
- Any of the following – signs of severe pneumonia, acute respiratory distress syndrome, septic shock, multi-organ dysfunction syndrome, or pneumonia with cyanosis, grunting, severe retraction of chest, lethargy, somnolence, seizure
- For other symptoms, see COVID-19 symptoms – at a glance

Admit in HDU/ICU of COVID-19 Hospital

Mainstay of Treatment

- Initiate immediate oxygen therapy and maintain target SpO_2 94–96%
- Maintain fluid and electrolyte balance
- Corticosteroids therapy to be initiated
- Anticoagulants may also be indicated; see anticoagulants guide
- Exercise caution- see use of corticosteroids and anticoagulants guide (refer page 6)
- In case Acute Respiratory Distress Syndrome (ARDS) or shock develops, initiate necessary management; see ARDS and Shock guide
- Antimicrobials to be administered if there is evidence/strong suspicion of superadded bacterial infection; see antimicrobial use guide
- May need organ support in case of organ dysfunction e.g. renal replacement therapy

Investigations

- Baseline: CBC including ESR, blood glucose, CRP, LFT, KFT, serum ferritin, D-Dimer
- Chest X-Ray

CT chest is not indicated in diagnosis or management of COVID-19 infection in children
Consider CT chest only if no improvement in respiratory status

As of now, in absence of safety and efficacy data, the use of antivirals such as Remdesivir, Favipiravir, Molnupiravir, Fluvoxamine, and monoclonal antibodies such as Sotrovimab, Casirivimab+Imdevimab, are NOT recommended for children less than 18 years of age irrespective of severity of illness

Children with comorbidities should continue to receive appropriate management for their underlying disease

COVID-19 symptoms in children – at a glance

Common symptoms

Fever	Sore throat/throat irritation	Diarrhoea
Cough	Body ache/headache	Anorexia/nausea/vomiting
Rhinorrhoea	Malaise/weakness	Loss of sense of smell and/or taste

Differentiating symptoms/signs	Asymptomatic	Mild	Moderate	Severe
Respiratory rate/min	**Normal** with age dependent variation	**Normal** with age dependent variation	**Rapid respiration** (age based) <2 months ≥60/min 2-12 months ≥50/min 1-5 years ≥40/min >5 years ≥30/min	**Rapid respiration** (age based) <2 months ≥60/min 2-12 months ≥50/min 1-5 years ≥40/min >5 years ≥30/min
SpO_2 on room air	≥94%	≥94%	90–93%	<90%
Grunting, severe retraction of chest	×	×	×	+/-
Lethargy, somnolence	×	×	×	+/-
Seizure	×	×	×	+/-

* Decision for home isolation for children with immunocompromised state or chronic illness should be taken after proper assessment and discussion with family

Management of Acute Respiratory Distress Syndrome (ARDS) and Shock Guide:

ARDS may be classified based on Pediatric Acute Lung Injury Consensus Conference (PALICC) definition into mild, moderate and severe

i) Mild ARDS

- High flow nasal oxygen (start with 0.5 L/kg/min to begin with and increase to 2 L/kg/min with monitoring) or non-invasive ventilation (BiPAP or CPAP) may be given

ii) Moderate-Severe ARDS

- Lung protective mechanical ventilation may be initiated, low tidal volume (4-8 ml/kg); plateau pressure <28-30 cmH_2O, MAP <18-20 cmH_2O; driving pressure <15 cmH_20; PEEP 6-10 cm H_20 (or higher if severe ARDS), FiO_2, <60% sedoanalgesia ± neuromuscular blockers; cuffed ETT, inline suction, heat and moisture exchange filters (HMEF)
- Avoid frequent disconnection of ventilator circuit, nebulization or metered dose inhaler ○ Restrict fluids; calculate fluid overload percentage, keeping it <10% ○ Prone position may be considered in hypoxemic children if they are able to tolerate it ○ Daily assessment for weaning and early extubation; enteral nutrition within 24 hours, achieve full feeds by 48 hours ○ Transfusion trigger Hb <7g/dL if stable oxygenation and hemodynamics and <10 g/dL if refractory hypoxemia or shock

Management of shock:

- Consider crystalloid fluid bolus 10-20 ml/kg cautiously over 30-60 minutes with early vasoactive support (epinephrine)
- Start antimicrobials within the first hour, after taking blood cultures, according to hospital antibiogram or treatment guidelines
- Consider inotropes (milrinone or dobutamine) if poor perfusion and myocardial dysfunction persists despite fluid boluses, vasoactive drugs and achievement of target mean arterial pressure
- Hydrocortisone may be added if there is fluid refractory catecholamine resistant shock (avoid if already on dexamethasone or methylprednisolone)
- Once stabilized, restrict IV fluids to avoid fluid overload
- Initiate enteral nutrition-sooner the better
- Transfusion trigger Hb <7g/dL if stable oxygenation and hemodynamics, and <10 g/dL if refractory hypoxemia or shock

Management of Multisystem Inflammatory Syndrome (MIS-C) in children and adolescents temporally related to

COVID-19

Multi System Inflammatory Syndrome in Children (MIS-C) is a new syndrome in children characterized by unremitting fever >38°C and epidemiological linkage with SARS-CoV-2

Diagnostic criteria (WHO)

- Children and adolescents 0-18 years of age with fever ≥3 days
- **And <u>any two</u>** of the following: ○ Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet)

  ○ Hypotension or shock ○ Features of myocardial dysfunction, pericarditis, valvulitis, or coronary abnormalities (including ECHO findings or elevated Troponin/NT-proBNP)

  ○ Evidence of coagulopathy (PT, PTT, elevated D-Dimers)

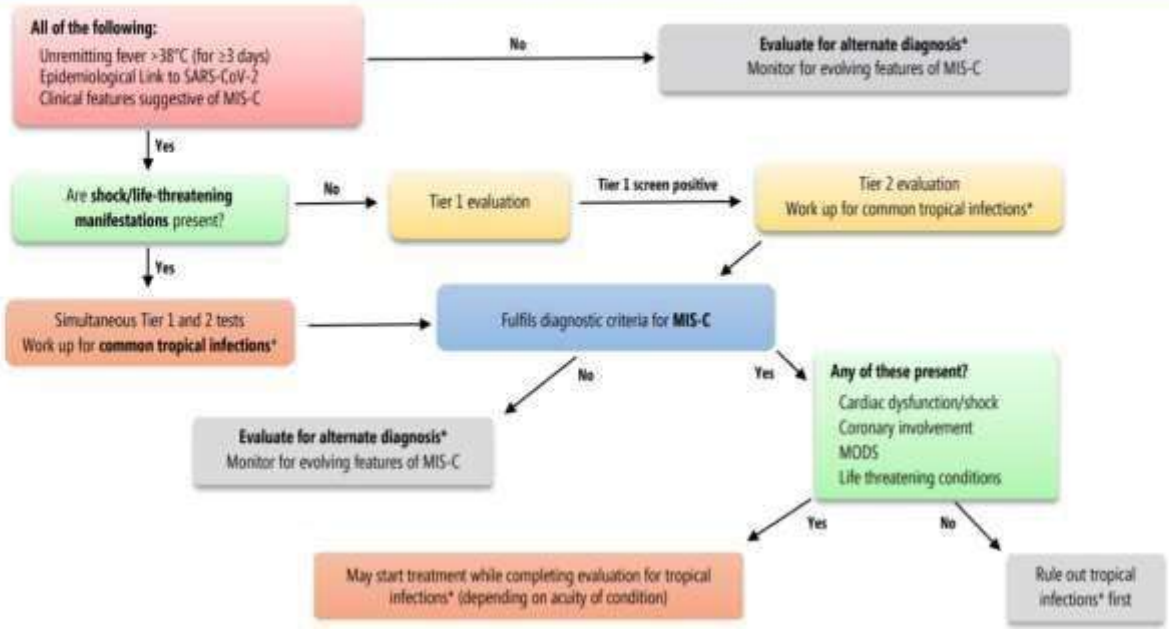
  ○ Acute gastrointestinal problems (diarrhea, vomiting, or abdominal pain
- **And** elevated markers of inflammation such as ESR (>40 mm), C-Reactive Protein (>5 mg/dL), or procalcitonin
- **And** no other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syndromes
- **And** evidence of recent COVID-19 infection (RT-PCR antigen test or serology positive), or likely contact with patients with COVID-19

Alternative diagnoses that must be excluded before making a diagnosis of MIS-C

- Tropical fevers (malaria, dengue, scrub typhus, enteric fever)
- Toxic shock syndrome (staphylococcal or streptococcal)
- Bacterial sepsis

MIS-C with Kawasaki Disease (KD) phenotype is characterized by fever, conjunctival redness, oropharyngeal findings (red and/or cracked lips, strawberry tongue), rash, swollen and/or erythematous hands and feet and cervical lymphadenopathy

Stepwise investigations in a patient with MIS-C



Tier 1 tests (may be done at Covid Care Centre, Dedicated Covid Health Centre): CBC, complete metabolic profile (LFT/KFT/blood gas/glucose), CRP and/or ESR, SARS-CoV-2 serology and/or RT-PCR, blood culture

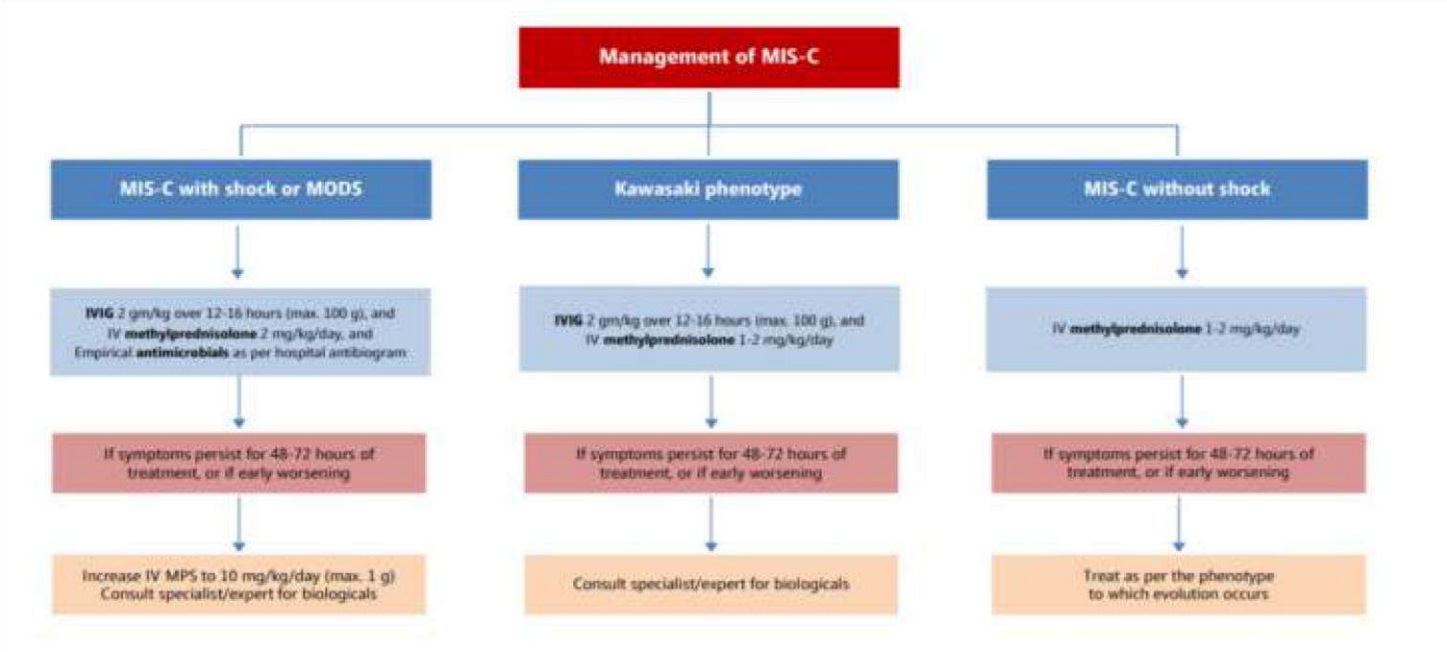
Positive Tier 1 screen (***both*** of these should be present):

1. CRP >5 mg/dL ***and/or*** ESR >40 mm/hour
2. At least ***one*** of these: ALC <1000/µL, platelet count <150,000/µL, Na <135 mEq/L, neutrophilia, hypoalbuminemia

Tier 2 tests (may be done at Dedicated Covid Hospital): Cardiac (ECG, echocardiogram, BNP, troponin T); inflammatory markers (procalcitonin, ferritin, PT, PTT, D-Dimer, fibrinogen, LDH, triglyceride, cytokine panel); blood smear; SARS-CoV-2 serology

Isolated increased COVID-19 antibodies are NOT SYNONYMOUS with MIS-C

* For diagnosis of MIS-C, it is mandatory to rule out common tropical infections including malaria, dengue, enteric fever, rickettsia illness (scrub typhus), etc.



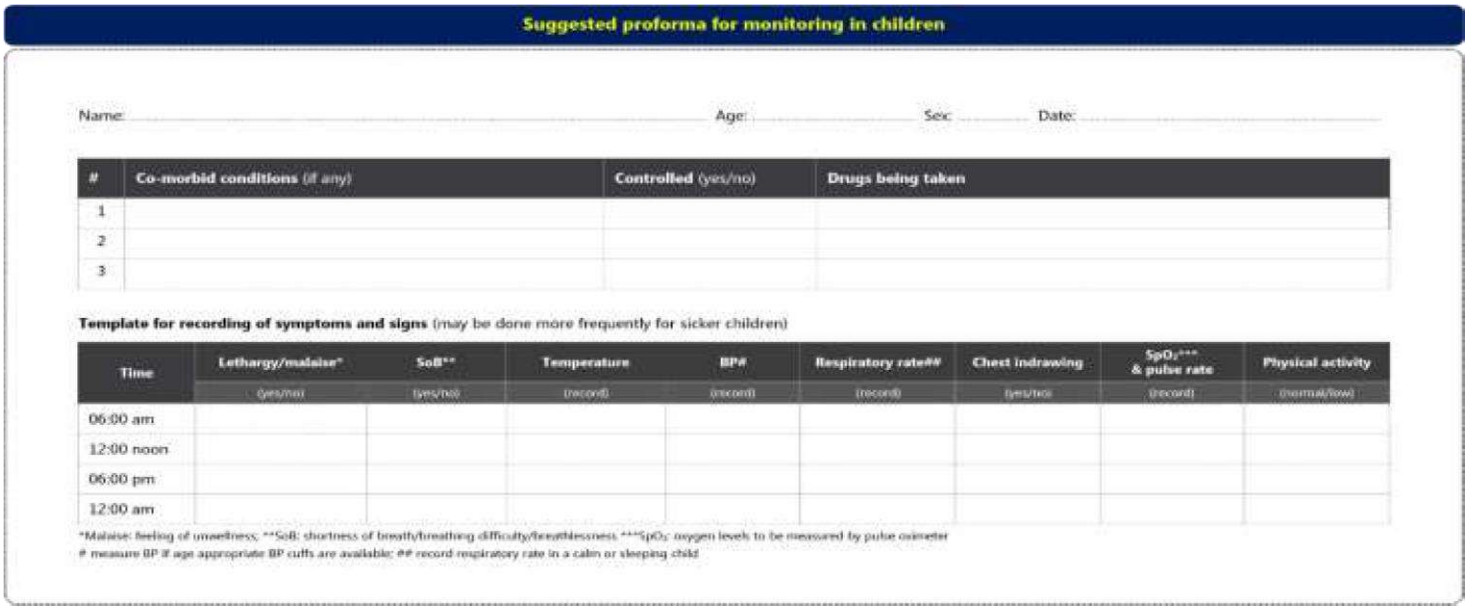
- Appropriate supportive care is needed preferably in ICU for treatment of cardiac dysfunction, coronary involvement, shock or multi-organ dysfunction syndrome (MODS)
- IVIG to be given slower (over up to 48 hours) in children

  with cardiac failure/ fluid overload

gicals only after expert
rtiary care only

- Taper steroids over 2-3 weeks with clinical and CRP monitoring
- Aspirin 3-5 mg/kg/day, maximum 75 mg/day in all children for 4-6 weeks (with platelet count >80,000/µL) for at least 4-6 weeks or longer for those with coronary aneurysms
- Low molecular weight heparin (Enoxaparin) 1 mg/kg/dose twice daily s/c in >2 months (0.75mg/kg/dose in <2 months) if patient has thrombosis or giant aneurysm with absolute coronary diameter ≥8 mm or Z score ≥10 or LVEF <30%

- For children with cardiac involvement, repeat ECG 48 hourly & repeat ECHO at 7–14 days and



Suggested proforma for monitoring in children

Name: ..... Age: ..... Sex: ..... Date: .....

#	Co-morbid conditions (if any)	Controlled (yes/no)	Drugs being taken
1			
2			
3			

Template for recording of symptoms and signs (may be done more frequently for sicker children)

Time	Lethargy/malaise* (yes/no)	SoB** (yes/no)	Temperature (record)	BP# (record)	Respiratory rate## (record)	Chest indrawing (yes/no)	SpO_2*** & pulse rate (record)	Physical activity (normal/low)
06:00 am								
12:00 noon								
06:00 pm								
12:00 am								

*Malaise: feeling of unwellness; **SoB: shortness of breath/breathing difficulty/breathlessness ***SpO_2: oxygen levels to be measured by pulse oximeter
measure BP if age appropriate BP cuffs are available; ## record respiratory rate in a calm or sleeping child

between 4 to

6 weeks, and after 1 year if initial ECHO was abnormal

Infection Prevention and Control (IPC)

Every COVID care facility should have a multidisciplinary hospital infection control committee; key components of infection control strategy are:

- Standard precautions
- Droplet precautions
- Airborne precautions
- Contact precautions and hand hygiene
- Physical Distancing
- Cough etiquette/respiratory hygiene
- Well ventilated rooms
- Monitor healthcare associated infections
- Train all health care workers to develop IPC skills
- Environment cleaning, disinfection, and sanitation
- Cleaning/disinfection of frequently touched surfaces/equipment
- Cleaning and disinfection of linen
- Safe management of bio-medical waste
- Triple layer mask to be worn by patient as per guidance below
- Masks for care givers (home/hospital)

Guide for using mask

- Masks are not recommended for children aged 5 years and under
- Children aged 6-11 years may wear a mask depending on the ability of child to use a mask safely and appropriately under direct supervision of parents/guardians
- Children aged 12 years and over should wear a mask under the same conditions as adults
- Ensure hands are kept clean with soap and water, or an alcohol-based hand rub, while handling masks

Antimicrobial use guide

COVID-19 is a viral infection and antimicrobials have no role in the management of uncomplicated COVID-19 infection

- **Asymptomatic and mild cases**: antimicrobials are not recommended for therapy or prophylaxis
- **Moderate and severe cases:** antimicrobials should not be prescribed unless there is clinical suspicion of a superadded infection
- **Septic shock:** empirical antimicrobials (according to body weight) are frequently added to cover all likely pathogens based on clinical judgement, patient host factors, local epidemiology and antimicrobial policy of the hospital

Use of steroids and anticoagulants; Post COVID care

Steroids:

- **Steroids are not indicated and are harmful in asymptomatic and mild cases of COVID-19**
- Indicated only in hospitalized severe and critically ill COVID-19 cases
- Steroids should be used at the **right time**, in **right dose** and **duration**

edication of steroids
st be avoided for the **right**

- Indications and recommended dose of corticosteroids-may be used in rapidly progressive moderate and all severe cases ○ Dexamethasone 0.15 mg/kg, maximum dose 6 mg once a day **OR** ○ Methylprednisolone 0.75 mg/kg, maximum dose 30 mg once a day
- Continue for 5-7 days and taper up to 10-14 days, depending on clinical assessment on daily basis
- Avoid steroids in first 3-5 days since onset of symptoms as it prolongs viral shedding

Anticoagulants:

- Not indicated routinely
- All hospitalized children should be evaluated for risk of developing thrombosis and monitored for development of thrombosis
- **Prophylactic anticoagulant** is indicated in following circumstances (the decision to administer prophylactic anticoagulation must be balanced with the child's bleeding risk):

  a) strong personal or family history of VTE, or

  b) an indwelling central venous line and two or more additional risk factors*, or c) four or more risk factors*

  (*Predisposing risk factors for development of thrombosis – personal history of venous thrombotic events (VTE), family history of first-degree relative with VTE, presence of central venous line, decreased mobility from baseline, burns, active malignancy, estrogen therapy, flare of inflammatory disease, morbid obesity, severe dehydration, recent surgery or trauma)

- Prophylactic dose of low molecular weight heparin (Enoxaparin): 0.5 mg/kg twice daily, till child is discharged from hospital
- On suspicion of thrombosis, confirm by appropriate investigations and start on low molecular weight heparin in therapeutic doses for period of 12 weeks with monitoring
- Children already on anticoagulation therapy may continue same unless they develop active bleeding
- Therapeutic dose of low molecular weight heparin (Enoxaparin): 1 mg/kg twice daily.

Post COVID Care:

- Children with asymptomatic infection or mild disease should receive routine childcare, appropriate vaccination (if eligible), nutrition counselling, and psychological support on follow up
- In addition to above, for children with moderate to severe COVID, at discharge from hospital, parents/caregivers should be counselled regarding monitoring for persistence/worsening respiratory difficulty and explained the indications for bringing the child back to facility
- Children who develop any organ specific dysfunction during hospital stay or subsequently should receive appropriate care

❖ **WHO advises that people should not wear masks during vigorous intensity physical activity (143) because masks may reduce the ability to breathe comfortably :**

➢ **WHO-2019-nCov-IPC_Masks-2020.5-eng.pdf**

❖ **What is meaning of physical activities according to "WHO" ?**

➢ **https://www.who.int/newsroom/factsheets/detail/physical-activityWhat**

❖ **Whata are the Types of Physical Activities ?**

➢ **ANSWER:** (non color) https://www.researchgate.net/profile/Chathuranga-Ranasinghe/publication/347179596_World_Health_Organization_2020_guidelines_on_physical_activity_and_sedentary_behaviour/links/5fe0cc38a6fdccdcb8ef5635/World-HealthOrganization-2020-guidelines-on-physical-activity-and-sedentary-behaviour.pdf

➢ https://www.who.int/publications/i/item/9789240015128(clr)

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WHO GUIDELINES ON PHYSICAL ACTIVITY AND SEDENTARY BEHAVIOUR

World Health Organization

WHO GUIDELINES ON

PHYSICAL ACTIVITY AND SEDENTARY BEHAVIOUR

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WHO guidelines on physical activity and sedentary behaviour

ISBN 978-92-4-001512-8 (electronic version) ISBN 978-92-4-001513-5 (print edition)

Suggested citation. WHO guidelines on physical activity and sedentary behaviour. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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Design: Eddy Hill Design

Printed in Switzerland

CONTENTS

Web Annex: Evidence profiles
https://apps.who.int/iris/bitstream/handle/10665/336657/9789240015111-eng.pdf

ACKNOWLEDGEMENTS

The World Health Organization (WHO) gratefully acknowledges the contribution to and support of the following individuals and organizations in the development of these guidelines:

Fiona Bull and Juana Willumsen led the process of developing these guidelines. Valentina Baltag, Maurice Bucagu, Alex Butchart, Neerja Chowdhary, Regina Guthold, Riitta-Maija Hämäläinen, Andre Ilbawi, Wasiq Khan, Lindsay Lee, Alana Officer, Leanne Riley and Gojka Roglic were members of the WHO Steering Group that managed the guideline development process.

The members of the Guideline Development Group (GDG) included Salih Saad Al-Ansari, Stuart Biddle, Katja Borodulin, Matthew Buman, Greet Cardon (co-chair), Catherine Carty, Jean-Philippe Chaput, Sebastien Chastin, Paddy Dempsey, Loretta DiPietro, Ulf Ekelund, Joseph Firth, Christine Friedenreich, Leandro Garcia, Muthoni Gichu, Russ Jago, Peter Katzmarzyk, Estelle V. Lambert, Michael Leitzmann, Karen Milton, Francisco B. Ortega, Chathuranga Ranasinghe, Emmanuel Stamatakis (co-chair), Anne Tiedemann, Richard Troiano, Hidde van der Ploeg, Vicky Wari. Roger Chou served as GRADE methodologist. The external review group included Kingsley Akinroye, Huda Alsiyabi, Alberto Flórez-Pregonero, Shigeru Inoue, Agus Mahendra, Deborah Salvo and Jasper Schipperijn.

Systematic reviews of evidence prepared for *2018 US Physical Activity Guidelines Advisory Committee Scientific Report to the Secretary of Health and Human Services* were updated thanks to additional literature searches conducted by Kyle Sprow (National Cancer Institutes, National Institutes of Health, Maryland, USA). Additional support to review papers identified was provided by Elif Eroglu (University of Sydney), Andrea Hillreiner (University of Regensburg), Bo-Huei Huang (University of Sydney), Carmen Jochem (University of Regensburg), Jairo H. Migueles (University of Granada), Chelsea Stone (University of Calgary) and Léonie Uijtdewilligen (Amsterdam UMC).

Summaries of evidence and GRADE tables were prepared by Carrie Patnode and Michelle Henninger (The Kaiser Foundation Hospitals, Center for Health Research, Portland, Oregon, USA).

Additional reviews of evidence were conducted by N Fairhall, J Oliveira, M Pinheiro, and C Sherrington (Institute for Musculoskeletal Health, School of Public Health, The University of Sydney, Sydney, Australia) and A Bauman (Prevention Research Collaboration, School of Public Health, The University of Sydney, Sydney, Australia; and WHO Collaborating Centre for Physical Activity, Nutrition and Obesity); S Mabweazara, M-J Laguette, K Larmuth, F Odunitan-Wayas (Research Centre for Health through Physical Activity, Lifestyle and Sports Medicine, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa), L Leach, S Onagbiye (Department of Sport, Recreation and Exercise Science, Faculty of Health Sciences, University of the Western Cape, Cape Town, South Africa), M Mthethwa (Chronic Disease Initiative for Africa, University of Cape Town, Cape Town, South Africa), P Smith (The Desmond Tutu HIV Centre, Institute for Infectious Disease and Molecular Medicine, Faculty of Health Sciences, University of Cape Town,

Cape Town, South Africa) and F Mashili (Department of Physiology, Muhimbili University of Allied Sciences, Dar Es Salaam, United Republic of Tanzania); B Cillekens, M Lang, W van Mechelen, E Verhagen, M Huysmans, A van der Beek, P Coenen (Department of Public and Occupational Health at Amsterdam University Medical Centre, Amsterdam, Netherlands).

The Public Health Agency of Canada and the Government of Norway provided financial support, without which this work could not have been completed.

ABBREVIATIONS AND ACRONYMS

ADHD attention deficit hyperactive disorder	
AOR	adjusted odds ratio
BMI	body mass index
CI	confidence interval
CVD	cardiovascular disease
DBP	diastolic blood pressure
EtD	Evidence to Decisions
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HR	hazards ratio
MET	Metabolic Equivalent of Task
MD	mean difference
MICT	moderate intensity continuous training
NCD	noncommunicable disease
OR	odds ratio
PA	physical activity
PAGAC	United States Physical Activity Guidelines Advisory Committee
PI/ECO	Population, Intervention/Exposure, Comparison, Outcome
RaR	Relative attributable risk
RCT	randomized control trial

RR	relative risk
SBP	systolic blood pressure
SMD	standardized mean difference
SPPB	short physical performance battery
TV	television
WHA	World Health Assembly
WHO	World Health Organization

GLOSSARY OF TERMS

Term	Definition
Aerobic physical activity	Activity in which the body's large muscles move in a rhythmic manner for a sustained period of time. Aerobic activity – also called endurance activity – improves cardiorespiratory fitness. Examples include walking, running, swimming, and bicycling.
Anaerobic physical activity	Anaerobic physical activity consists of brief intense bursts of exercise, such as weightlifting and sprints, where oxygen demand surpasses oxygen supply.
Balance training	Static and dynamic exercises that are designed to improve an individual's ability to withstand challenges from postural sway or destabilizing stimuli caused by selfmotion, the environment, or other objects.
Body mass index (BMI)	Weight (kg) / height $(m)^2$
BMI-forage or BMI z-score	BMI adjusted for age, standardized for children. BMI standard deviation scores are measures of relative weight adjusted for child age and sex. Given a child's age, sex, BMI, and an appropriate reference standard, a BMI z-score (or its equivalent BMIfor-age percentile) can be determined.
Bonestrengthening activity	Physical activity primarily designed to increase the strength of specific sites in bones that make up the skeletal system. Bone-strengthening activities produce an impact or tension force on the bones that promotes bone growth and strength. Running, jumping rope, and lifting weights are examples of bone-strengthening activities.
Cardiometabolic health	The interplay of blood pressure, blood lipids, blood glucose and insulin on health.
Cardiorespiratory fitness (endurance)	A health-related component of physical fitness. The ability of the circulatory and respiratory systems to supply oxygen during sustained physical activity. Usually expressed as measured or estimated maximal oxygen uptake (VO_2 max).
Cognitive function	Cerebral activities, i.e. reasoning, memory, attention, and language that lead to the attainment of information and knowledge. This can also include learning.
Disability	From the International Classification of Functioning, Disability and Health, an umbrella term for impairments, activity limitations, and participation restrictions, denoting the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors).

Domains of physical activity	Physical activity levels can be assessed in various domains, including one of more of the following: leisure-time, occupation, education, household and/or transportation.
Exercise	A subcategory of physical activity that is planned, structured, repetitive, and purposeful in the sense that the improvement or maintenance of one or more components of physical fitness is the objective. “Exercise” and “exercise training” frequently are used interchangeably and generally refer to physical activity performed during leisure time with the primary purpose of improving or maintaining physical fitness, physical performance, or health.
Executive function	Includes constructs such as: working memory, cognitive flexibility (also called flexible thinking) and inhibitory control (which includes self-control).
Fitness	A measure of the body's ability to function efficiently and effectively in work and leisure activities, and includes, for example, physical fitness and cardiorespiratory fitness.
Flexibility	A health- and performance-related component of physical fitness that is the range of motion possible at a joint. Flexibility is specific to each joint and depends on a number of specific variables including, but not limited to, the tightness of specific ligaments and tendons. Flexibility exercises enhance the ability of a joint to move through its full range of motion.
Functional exercises	Exercises that can be embedded into everyday tasks to improve lower-body strength, balance, and motor performance. Examples include tandem and one-leg stands, squatting, chair stands, toe raises, and stepping over obstacles.
Household domain physical activity	Physical activity undertaken in the home for domestic duties (such as cleaning, caring for children, gardening etc.).
Leisure-domain physical activity	Physical activity performed by an individual that is not required as an essential activity of daily living and is performed at the discretion of the individual. Such activities include sports participation, exercise conditioning or training, and recreational activities such as going for a walk, dancing, and gardening.

Term Definition

Light-intensity physical activity	Light-intensity physical activity is between 1.5 and 3 METs, i.e. activities with energy cost less than 3 times the energy expenditure at rest for that person. This can include slow walking, bathing, or other incidental activities that do not result in a substantial increase in heart rate or breathing rate.
Major muscle groups	Major muscle groups include the legs, back, abdomen, chest, shoulders and arms.
Metabolic equivalent of task (MET)	The metabolic equivalent of task, or simply metabolic equivalent, is a physiological measure expressing the intensity of physical activities. One MET is the energy equivalent expended by an individual while seated at rest.

Moderate-intensity physical activity	On an absolute scale, moderate-intensity refers to the physical activity that is performed between 3 and less than 6 times the intensity of rest. On a scale relative to an individual's personal capacity, moderate-intensity physical activity is usually a 5 or 6 on a scale of 0–10.
Musclestrengthening activity	Physical activity and exercise that increase skeletal muscle strength, power, endurance, and mass (e.g. strength training, resistance training, or muscular strength and endurance exercises).
Multicomponent physical activity	For older adults, multicomponent physical activity is important to improve physical function and decrease the risk of falls or injury from a fall. These activities can be done at home or in a structured group setting. Many studied interventions combine all types of exercise (aerobic, muscle strengthening, and balance training) into a session, and this has been shown to be effective. An example of a multicomponent physical activity programme could include walking (aerobic activity), lifting weights
	(muscle strengthening), and incorporates balance training. Examples of balance training can include walking backwards or sideways or standing on one foot while doing an upper body muscle-strengthening activity, such as bicep curls. Dancing also combines aerobic and balance components.
Occupation domain physical activity	See work domain physical activity.
Physical activity	Any bodily movement produced by skeletal muscles that requires energy expenditure.
Physical inactivity	An insufficient physical activity level to meet present physical activity recommendations.
Psychosocial health	Include mental, emotional and social dimensions of health.
Recreational screen	Time spent watching screens (television (TV), computer, mobile devices) for **time** purposes other than those related to education/study or work.
Sedentary screen time	Time spent watching screen-based entertainment (TV, computer, mobile devices). Does not include active screen-based games where physical activity or movement is required.
Sedentary behaviour	Any waking behaviour characterized by an energy expenditure of 1.5 METS or lower while sitting, reclining, or lying. Most desk-based office work, driving a car, and watching television are examples of sedentary behaviours; these can also apply to those unable to stand, such as wheelchair users. The guidelines operationalize the definition of sedentary behaviour to include selfreported low movement sitting (leisure time, occupational, and total), television (TV viewing or screen time, and low levels of movement measured by devices that assess movement or posture).

Sport	Sport covers a range of activities performed within a set of rules and undertaken as part of leisure or competition. Sporting activities involve physical activity carried out by teams or individuals and may be supported by an institutional framework, such as a sporting agency.
Transport domain physical activity	Physical activity performed for the purpose of getting to and from places, and refers to walking, cycling and wheeling (the use of non-motorized means of locomotion with wheels, such as scooters, rollerblades, manual wheelchair etc.).
Vigorous-intensity physical activity	On an absolute scale, vigorous-intensity refers to physical activity that is performed at 6.0 or more METS. On a scale relative to an individual's personal capacity, vigorous-intensity physical activity is usually a 7 or 8 on a scale of 0–10.
Work domain physical activity	Physical activity undertaken during paid or voluntary work.

Glossary of terms

The *WHO Guidelines on physical activity and sedentary behaviour* provide evidence-based public health recommendations for children, adolescents, adults and older adults on the amount of physical activity (frequency, intensity and duration) required to offer significant health benefits and mitigate health risks. For the first time, recommendations are provided on the associations between sedentary behaviour and health outcomes, as well as for subpopulations, such as pregnant and postpartum women, and people living with chronic conditions or disability.

The guidelines are intended for policy-makers in high-, middle-, and low-income countries in ministries of health, education, youth, sport and/or social or family welfare; government officials responsible for developing national, sub regional or municipal plans to increase physical activity and reduce sedentary behaviour in population groups through guidance documents; people working in nongovernmental organizations, the education sector, private sector, research; and healthcare providers.

The guidelines were prepared in accordance with the *WHO handbook for guideline development.* Systematic reviews of evidence were conducted for the critical and important outcomes, and recommendations were developed after consideration of the benefits and harms, values, preferences, feasibility and acceptability, and the implications for equity and resources.

The final public health recommendations presented are for all populations and age groups ranging from 5 years to 65 years and older, irrespective of gender, cultural background or socioeconomic status, and are relevant for people of all abilities. Those with chronic medical conditions and/or disability and pregnant and postpartum women should try to meet the recommendations where possible and as able. The development of these guidelines provide a set of evidence-based recommendations that governments can adopt as part of their national policy frameworks to support comprehensive approaches to increasing population levels of physical activity. Within the adoption process, consideration should be given to the need to contextualize the guidelines. Practical tools to support adoption, dissemination, communication campaigns and implementation of the guidelines will support governments and stakeholders work together to increase physical activity and reduce sedentary behaviours across the life course. These supporting resources will be available through the WHO website following publication of the guidelines

Despite the large quantity of supporting data relating physical activity and, increasingly, sedentary behaviours to health outcomes across the life-span, important evidence gaps remain. In particular, there is less evidence from low- and middle-income countries and economically disadvantaged or underserved communities, and a

dearth of evidence from subpopulations including people living with disabilities. Investment in more research is needed to build evidence particularly in these areas. In addition, the changes introduced to these recommendations will have some implications for surveillance systems and assessment instruments currently used to monitor national levels of physical activity. Existing global and national instruments should be reviewed, and reporting protocols updated, to inform future reporting against the new guidelines.

The *Global action plan on physical activity 2018–2030* set a target to reduce physical inactivity by 15% by 2030, and outlined 20 recommended policy actions and interventions. These guidelines support all countries to implement the GAPPA recommendations and "ACTIVE", the technical package of toolkits that provides guidance on how to promote physical activity across the life course and through multiple settings.

CHILDREN AND ADOLESCENTS
(aged 5–17 years)

GOOD PRACTICE STATEMENTS

In children and adolescents, physical activity confers benefits for the following health outcomes: improved physical fitness (cardiorespiratory and muscular fitness), cardiometabolic health (blood pressure, dyslipidaemia, glucose, and insulin resistance), bone health, cognitive outcomes (academic performance, executive function), mental health (reduced symptoms of depression); and reduced adiposity.

It is recommended that:

› **Children and adolescents should do at least an average of 60 minutes per day of moderate- to vigorous-intensity, mostly aerobic, physical activity, across the week.**

Strong recommendation, moderate certainty evidence

› **Vigorous-intensity aerobic activities, as well as those that strengthen muscle and bone, should be incorporated at least 3 days a week.**

Strong recommendation, moderate certainty evidence

- Doing some physical activity is better than doing none.
- If children and adolescents are not meeting the recommendations, doing some physical activity will benefit their health.
- Children and adolescents should start by doing small amounts of physical activity, and gradually increase the frequency, intensity and duration over time.
- It is important to provide all children and adolescents with safe and equitable opportunities, and encouragement, to participate in physical activities that are enjoyable, offer variety, and are appropriate for their age and ability.

In children and adolescents, higher amounts of sedentary behaviour are associated with the following poor health outcomes: increased adiposity; poorer cardiometabolic health, fitness, behavioural conduct/pro-social behaviour; and reduced sleep duration.

LIMIT

the amount of time spent being sedentary , particularly recreational screen time.

It is recommended that:

› **Children and adolescents should limit the amount of time spent being sedentary, particularly the amount of recreational screen time.**

Strong recommendation, low certainty evidence

ADULTS
(aged 18–64 years)

In adults, physical activity confers benefits for the following health outcomes: improved all-cause mortality, cardiovascular disease mortality, incident hypertension, incident site-specific cancers,[21] incident type-2 diabetes, mental health (reduced symptoms of anxiety and depression); cognitive health, and sleep; measures of adiposity may also improve.

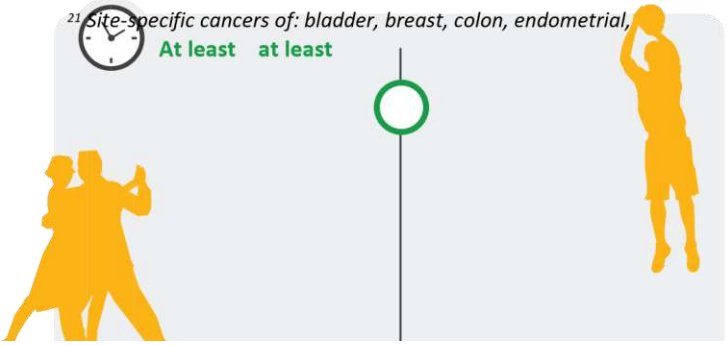
It is recommended that:

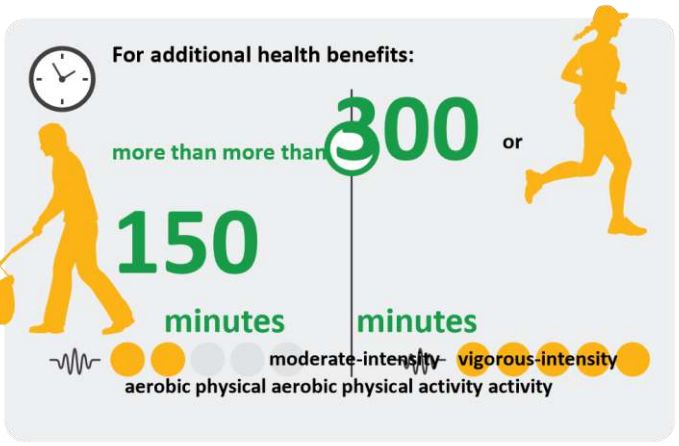
› All adults should undertake regular physical activity.
Strong recommendation, moderate certainty evidence

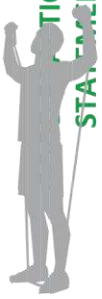
› Adults should do at least 150– 300 minutes of moderate-intensity aerobic physical activity; or at least 75–150 minutes of vigorousintensity aerobic physical activity; or an equivalent combination of moderate- and vigorous-intensity activity throughout the week, for substantial health benefits.

Strong recommendation, moderate certainty evidence

[21] *Site-specific cancers of: bladder, breast, colon, endometrial,*







- Doing some physical activity is better than doing none.

Adults may increase moderate-intensity aerobic physical activity to more than 300 minutes; or do more than 150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous-intensity activity throughout the week for additional health benefits.

150 minutes moderate-intensity aerobic physical activity **or 75** minutes vigorous-intensity aerobic physical activity activity **to 300 to 150**

or an equivalent combination throughout the week

Adults should also do musclestrengthening activities at moderate or greater intensity that involve all major muscle groups on 2 or more days a week, as these provide additional health benefits.

Strong recommendation, moderate certainty evidence

Conditional recommendation, moderate certainty evidence

oesophageal adenocarcinoma, gastric, and renal. 42

- If adults are not meeting these recommendations, doing some physical activity will benefit their health.
- Adults should start by doing small amounts of physical activity, and gradually increase the frequency, intensity and duration over time.

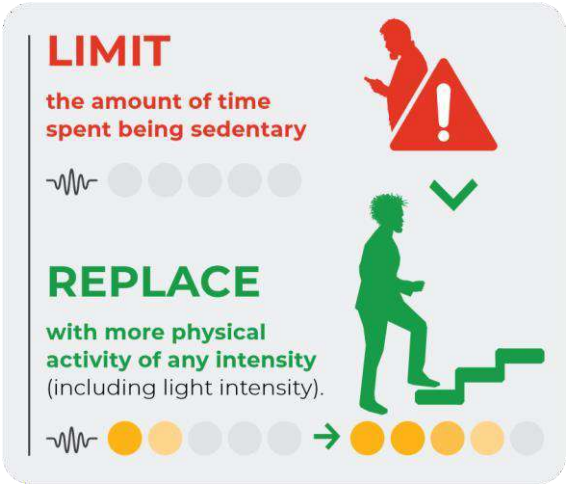
In adults, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality, cardiovascular disease mortality and cancer mortality and incidence of cardiovascular disease, cancer and type-2 diabetes.

It is recommended that:

› Adults should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.

Strong recommendation, moderate certainty evidence

› To help reduce the detrimental effects of high levels of sedentary behaviour on health, adults



should aim to do more than the recommended levels of moderate- to vigorous-intensity

physical activity.

Strong recommendation, moderate certainty evidence

In older adults, physical activity confers benefits for the following health outcomes: improved all-cause mortality, cardiovascular disease mortality, incident hypertension, incident site-specific cancers, incident type-2 diabetes, mental health (reduced symptoms of anxiety and depression), cognitive health, and sleep; measures of adiposity may also improve. In older adults, physical activity helps prevent falls and falls-related injuries and declines in bone health and functional ability.

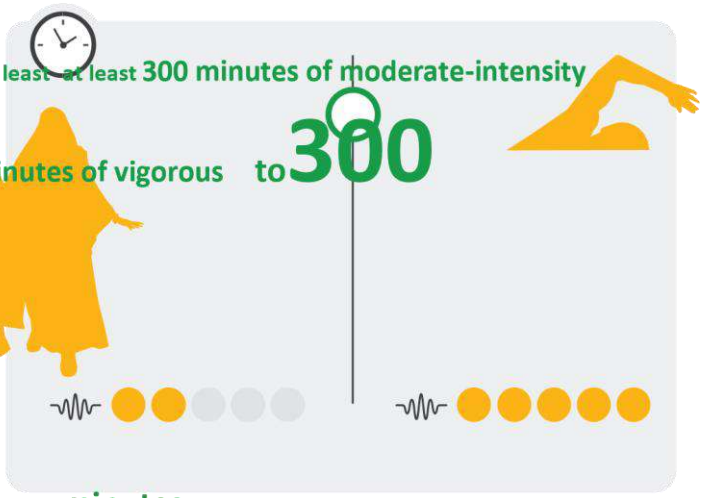
It is recommended that:

› All older adults should undertake regular physical activity.

Strong recommendation, moderate certainty evidence

› Older adults should do at least 150–300 minutes of moderate-intensity aerobic physical activity; or at least 75–150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous-intensity activity throughout the week, for substantial health benefits.

Strong recommendation, moderate certainty evidence



For additional health benefits: Older adults should also do muscle-strengthening activities at moderate or greater intensity that involve all major muscle groups on 2 or more days a week, as these provide additional health benefits.

Strong recommendation, moderate certainty evidence

On at least 2 days a week, muscle-strengthening activities at moderate or greater intensity that involve all major muscle groups.

On at least 3 days a week, varied multicomponent physical activity that emphasizes functional balance and strength training at moderate or greater intensity.

› As part of their weekly physical activity, older adults should do varied multicomponent physical activity that emphasizes functional balance and strength training at moderate or greater intensity, on 3 or more days a week, to enhance functional capacity and to prevent falls.

Strong recommendation, moderate certainty evidence

For additional health benefits:

more than 300 minutes of moderate-intensity aerobic physical activity; or more than 150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination throughout the week

150

minutes **minutes**

moderate-intensity vigorous-intensity aerobic physical aerobic physical activity activity

or an equivalent combination throughout the week

moderate- and

- Doing some physical activity is better than doing none.

Older adults may increase moderateintensity aerobic physical activity to more than 300 minutes; or do more than 150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of

vigorousintensity activity throughout the week, for additional health benefits.

Conditional recommendation, moderate certainty evidence

- If older adults are not meeting the recommendations, doing some physical activity will bring benefits to health.
- Older adults should start by doing small amounts of physical activity, and gradually increase the frequency, intensity and duration over time.
- Older adults should be as physically active as their functional ability allows, and adjust their level of effort for physical activity relative to their level of fitness.

In older adults, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality, cardiovascular disease mortality and cancer mortality, and incidence of cardiovascular disease, cancer and incidence of type-2 diabetes.

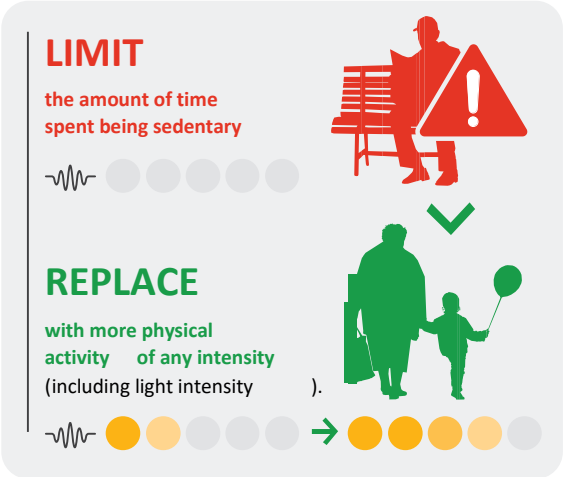
It is recommended that:

› Older adults should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.

Strong recommendation, moderate certainty evidence

› To help reduce the detrimental effects of high levels of sedentary behaviour on health, older adults should aim to do more than the recommended levels of moderate- to vigorousintensity physical activity.

Strong recommendation, moderate certainty evidence

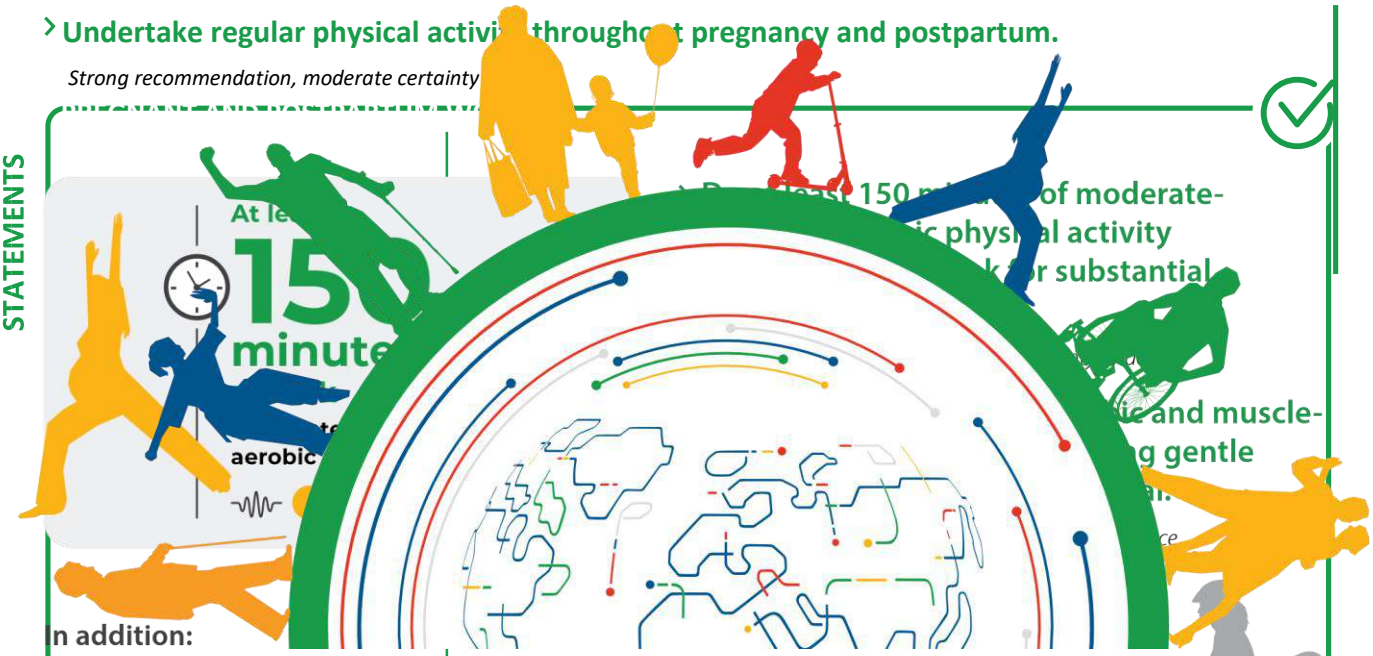


In pregnant and postpartum women, physical activity during pregnancy and postpartum confers benefits on the following maternal and fetal health benefits: decreased risk of pre-eclampsia, gestational hypertension, gestational diabetes, excessive gestational weight gain, delivery complications and postpartum depression, and fewer newborn complications, no adverse effects on birthweight; and no increase in risk of stillbirth.

It is recommended that all pregnant and postpartum women without contraindication should:

› **Undertake regular physical activity throughout pregnancy and postpartum.**

Strong recommendation, moderate certainty



In addition:

› **Women who, before pregnancy, habitually engaged in vigorous-intensity aerobic activity, or who were physically active, can continue these activities during pregnancy and the postpartum period.**

Strong recommendation, moderate certainty evidence

- Doing some physical activity is better than doing none.
- If pregnant and postpartum women are not meeting the recommendations, doing
- Avoid physical activity during considering athletic competition, excessive heat, especially with or exercising significantly above the high humidity.
- Stay hydrated by drinking before, during, and after
- Pregnant and postpartum women should start by doing small amounts of physical activity, and gradually increase frequency, intensity and duration over time.
- Pelvic floor muscle training may be performed on a daily basis to reduce the risk of urinary incontinence.

Additional safety considerations for pregnant women when undertaking physical activity are:

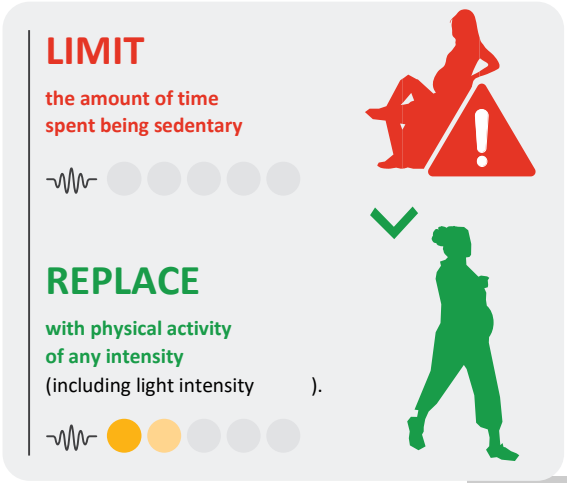
a specialist health-care provider. physical activity.
- Pregnant women should be informed
- Avoid participating in activities by their health-care provider of the which involve physical contact; pose danger signs alerting them as to when a high risk of falling; or might limit to stop; or to limit physical activity and oxygenation (such as activities at consult a qualified health-care provider high altitude, when not immediately should they occur.

normally

living at high altitude).
- Return to physical activity gradually
- Avoid activities in supine position after delivery, and in consultation with after the first trimester of a health-care provider, in the case of pregnancy. delivery by Caesarean section.

In pregnant and postpartum women, as in all adults, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality,

cardiovascular disease mortality and cancer mortality and incidence of cardiovascular



It is recommended that:

- **Pregnant and postpartum women should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.**

  Strong recommendation, low certainty evidence

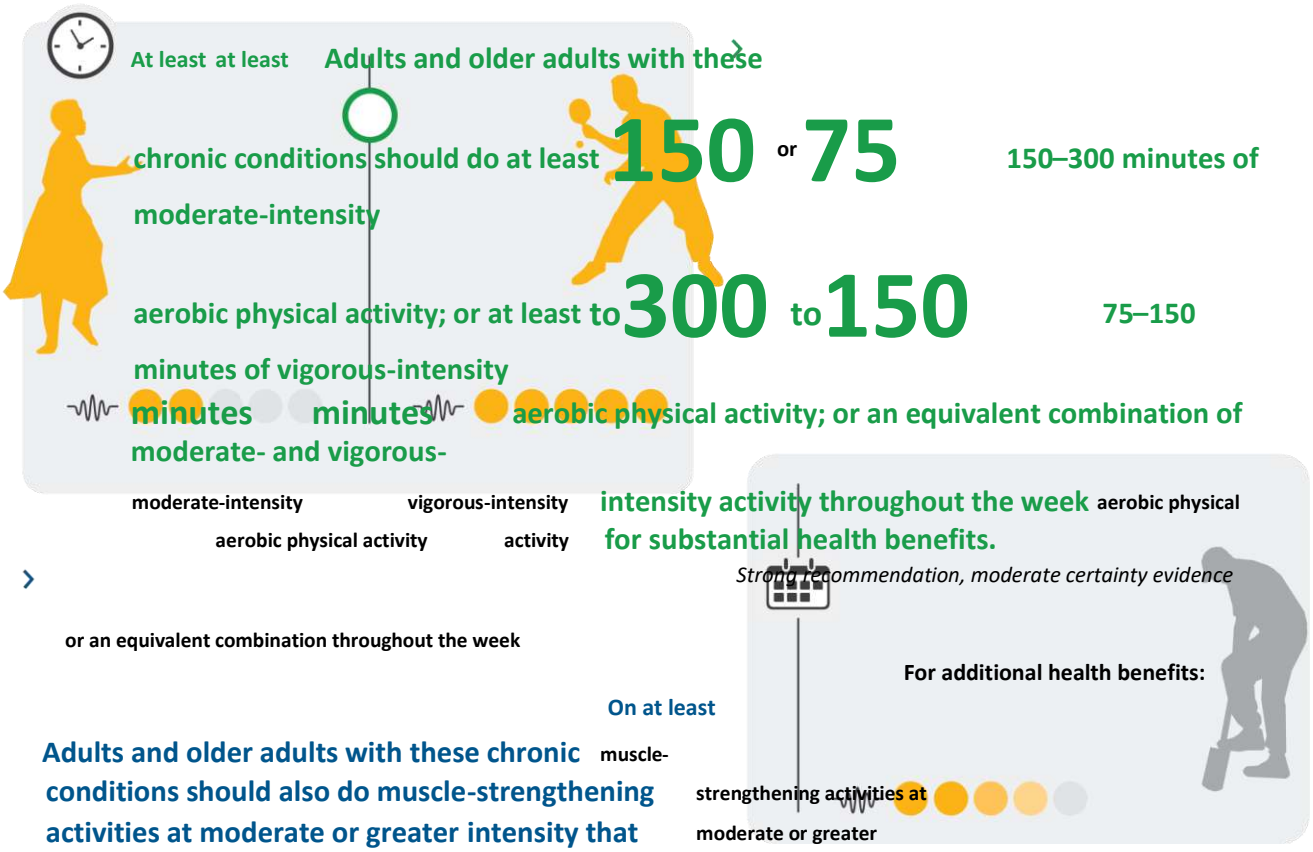
Doing some physical activity is better than doing none.

disease, cancer and incidence of type-2 diabetes.

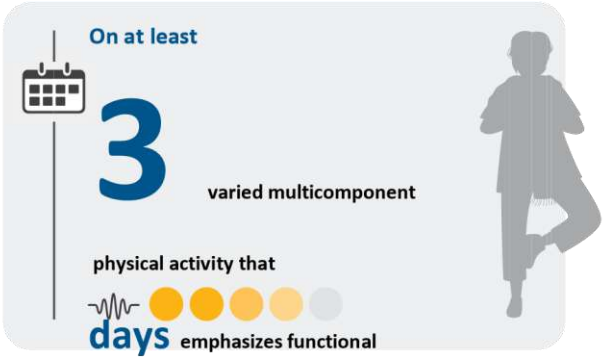
Physical activity can confer health benefits for adults and older adults living with the following chronic conditions: **for cancer survivors** – physical activity improves all-cause mortality, cancerspecific mortality, and risk of cancer recurrence or second primary cancer; **for people living with hypertension** – physical activity improves cardiovascular disease mortality, disease progression, physical function, health-related quality of life; **for people living with type-2 diabetes** – physical activity reduces rates of mortality from cardiovascular disease and indicators disease progression; and **for people living with HIV** – physical activity can improve physical fitness and mental health (reduced symptoms of anxiety and depression), and does not adversely affect disease progression (CD4 count and viral load) or body composition.

It is recommended that:

All adults and older adults with the above chronic conditions should undertake regular physical activity. *Strong recommendation, moderate certainty evidence*



Strong recommendation, moderate certainty evidence



› **minutes** **minutes**

moderate-intensity physical activity | vigorous-intensity aerobic physical activity

or an equivalent combination throughout the week

GOOD PRACTICE STATEMENTS

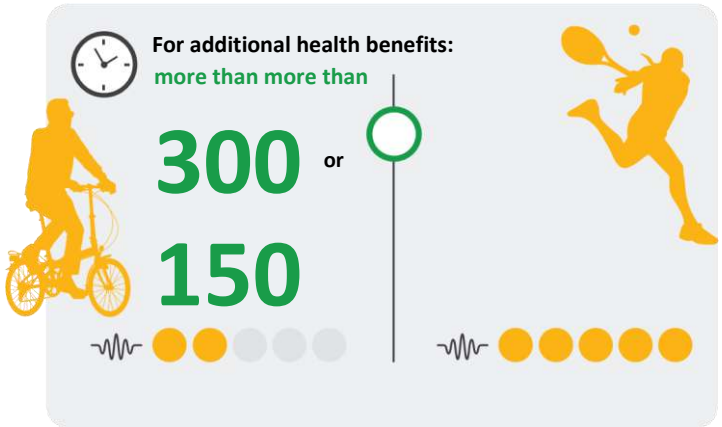
- When not able to meet the above recommendations, adults with these chronic conditions should aim to engage in physical activity according to their abilities.
- Adults with these chronic conditions should start by doing small amounts of physical activity and gradually increase the frequency, intensity and duration over time.
- Adults with these chronic conditions may wish to consult with a physical activity specialist or health-care professional for advice on the types and amounts of activity appropriate for their individual needs, abilities, functional limitations/complications, medications, and overall treatment plan.

As part of their weekly physical activity, older adults with these chronic conditions should do varied multicomponent physical activity that emphasizes functional balance and strength training at moderate or greater intensity on 3 or more days a week, to enhance functional capacity and prevent falls.

When not contraindicated, adults and older adults with these chronic conditions may increase moderateintensity aerobic physical activity to more than 300 minutes; or do more than 150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorousintensity activity throughout the week for additional health benefits.

Strong recommendation, moderate

Conditional recommendation, moderate certainty evidence certainty evidence



› • Pre-exercise medical clearance is generally unnecessary for individuals without contraindications prior to beginning light- or moderate-intensity physical activity not exceeding the

In adults, living with higher amounts with the mortality, cancer mortality, cancer and

including cancer survivors and people hypertension, type-2 diabetes and HIV, of sedentary behaviour are associated following poor health outcomes: all-cause cardiovascular disease mortality and and incidence of cardiovascular disease, incidence of type-2 diabetes.

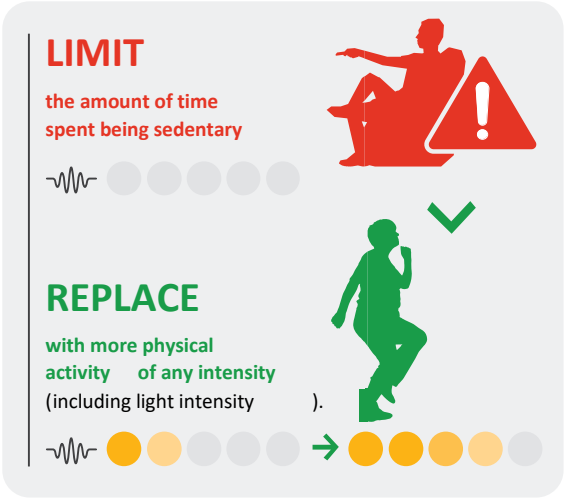
For cancer survivors, and adults living with hypertension, type-2 diabetes and HIV, it is recommended that:

- **Adults and older adults with chronic conditions should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.**

  Strong recommendation, low certainty evidence

- **To help reduce the detrimental effects of high levels of sedentary behaviour on health, adults and older adults with chronic conditions should aim to do more than the recommended levels of moderate- to vigorous-intensity physical activity.**

  Strong recommendation, low certainty evidence



demands of brisk walking or everyday living.

Many of the health benefits of physical activity for children and adolescents, as set out in the section above, also relate to those children and adolescents living with disability. Additional benefits of physical activity to health outcomes for those living with disability include: improved cognition in individuals with diseases or disorders that impair cognitive function, including attention-deficit/ hyperactivity disorder (ADHD); improvements in physical function may occur in children with intellectual disability.

At least 60 It is recommended that: **Children and adolescents**

living
with disability should do at least

minutes a day an average of 60 minutes per day of moderate- to

vigorous moderate- to vigorous-intensity **intensity, mostly aerobic, physical** physical activity across the week;
most of this physical activity **activity, across the week.**
should be aerobic. *Strong recommendation, moderate certainty evidence*

› **Vigorous-intensity aerobic activities, as well as those that strengthen muscle and bone should be incorporated at least 3 days a week.**

Strong recommendation, moderate certainty evidence

Doing some physical activity is better than doing none.

PRACTICE STATEMENTS

- Doing some physical activity is better than doing none.

- If children and adolescents living with disability are not meeting these recommendations, doing some physical activity will bring benefits to health.
- Children and adolescents living with disability should start by doing small amounts of physical activity and gradually increase the frequency, intensity and duration over time.
- There are no major risks for children and adolescents living with disability engaging in physical activity when it is appropriate to an individual's current activity level, health status and physical function; and the health benefits accrued outweigh the risks.
- Children and adolescents living with disability may need to consult a health-care professional or other physical activity and disability specialist to help determine the type and amount of activity appropriate for them.

In children and adolescents, higher amounts of sedentary behaviour are associated with the following poor health outcomes: increased adiposity; poorer cardiometabolic health, fitness, and behavioural conduct/pro-social behaviour; and reduced sleep duration.

It is recommended that:

› Children and adolescents living with disability should limit the amount of time spent being sedentary, particularly the amount of recreational screen time.

Strong recommendation, low certainty evidence

LIMIT

the amount of time spent being sedentary particularly recreational screen time.

Start by doing small amounts of physical activity.

Many of the health benefits of physical activity for adults, as set out in the section above, also relate to adults living with disability. Additional benefits of physical activity to health outcomes for those living with disability include the following: **for adults with multiple sclerosis** – improved physical function, and physical, mental, and social domains of health-related quality of life; **for individuals with spinal cord injury** – improved walking function, muscular strength, and upper extremity function; and enhanced health-related quality of life; **for individuals with diseases or disorders that impair cognitive function** – improved physical function and cognition (in individuals with Parkinson's disease and those with a history of stroke); beneficial effects on cognition, and may improve quality of life (in adults with schizophrenia); and may improve physical function (in adults with intellectual disability); and improves quality of life (in adults

depression)

It is recommended that:

Strong recommendation, moderate certainty evidence

At least at least

All adults living with disability should undertake regular physical activity.

150 or 75 to 300

to 150

2 intensity days that involve all major muscle a week groups.

Adults living with disability should also do muscle-strengthening activities at moderate or greater intensity that involve all major muscle groups on 2 or more days a week, as these provide additional health benefits.

Strong recommendation, moderate certainty evidence

Adults living with disability should do at least 150–300 minutes of moderateintensity aerobic physical activity; or at least 75–150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorousintensity activity throughout the week for substantial health benefits.

Strong recommendation, moderate certainty evidence

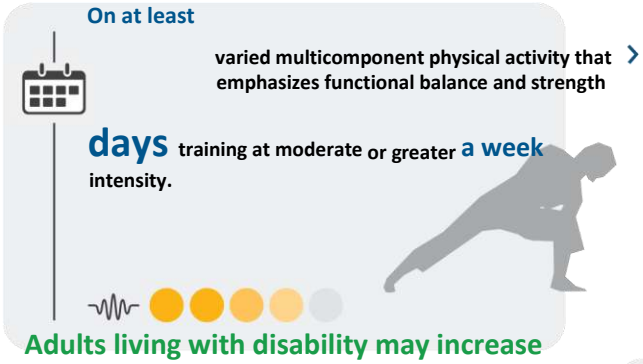
minutes minutes

moderate-intensity vigorous-intensity
aerobic physical aerobic physical activity activity

or an equivalent combination throughout the week

For additional health benefits: On at least

muscle-strengthening activities
at moderate or greater



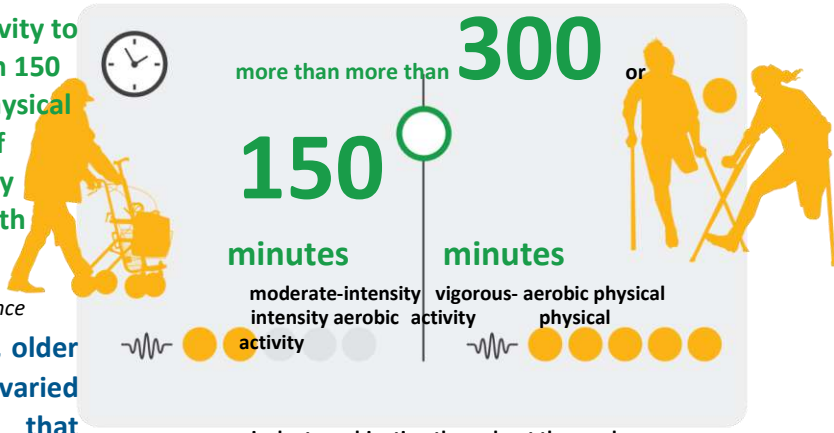
emphasizes functional balance and strength training at moderate or greater intensity on 3 or more days a week, to enhance functional capacity and prevent falls.

Strong recommendation, moderate certainty evidence

For additional health benefits:

Adults living with disability may increase moderate-intensity aerobic physical activity to more than 300 minutes; or do more than 150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous-intensity activity throughout the week for additional health benefits.

Conditional recommendation, moderate certainty evidence



As part of their weekly physical activity, older adults living with disability should do varied multicomponent physical activity that emphasizes functional balance and strength training at moderate or greater intensity on 3 or more days a week, to enhance functional capacity and prevent falls.

or an equivalent combination throughout the week

GOOD PRACTICE STATEMENTS

- Doing some physical activity is better than doing none. If adults living with disability are not meeting these recommendations, doing some physical activity will bring benefits to health.
- There are no major risks to adults living with disability engaging in physical activity when it is appropriate to the individual's current activity level, health status and physical function; and when the health benefits accrued outweigh the risks.
- Adults living with disability should start by doing small amounts of physical activity, and gradually increase the frequency, intensity and duration over time.
- Adults living with disability may need to consult a healthcare professional or other physical activity and disability specialist to help determine the type and amount of activity appropriate for them.

In adults, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality, cardiovascular disease mortality and cancer mortality and incidence of cardiovascular disease, cancer and type-2 diabetes.

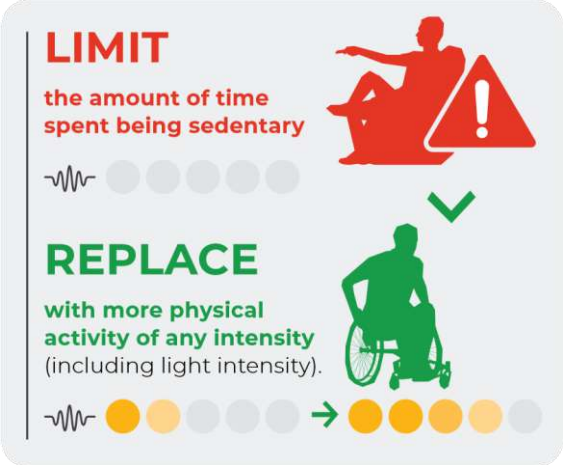
It is recommended that:

- **Adults living with disability should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.**

  Strong recommendation, low certainty evidence

- **To help reduce the detrimental effects of high levels of sedentary behaviour on health, adults living with disability should aim to do more than the recommended levels of moderate- to vigorousintensity physical activity.**

  Strong recommendation, low certainty evidence



Regular physical activity is a known protective factor for the prevention and management of noncommunicable diseases such as cardiovascular disease, type-2 diabetes, breast and colon cancer *(1–3).* Physical activity also has benefits for mental health *(4)*, delays the onset of dementia *(5)*, and can contribute to the maintenance of healthy weight *(1)* and general well-being *(6)*.

Physical activity is defined as any bodily movement produced by skeletal muscles that requires energy expenditure *(1)* and can be performed at a variety of intensities, as part of work, domestic chores, transportation or during leisure time, or when participating in exercise or sports activities. At the low end of the intensity range, sedentary behaviour is defined as any waking behaviour while in a sitting, reclining or lying posture with low energy expenditure *(7)*. Emerging new evidence indicates that high levels of sedentary behaviour are associated with cardiovascular disease and type-2 diabetes as well as cardiovascular, cancer and all-cause mortality *(8–10)*.

Physical inactivity is defined as not meeting the 2010

Global recommendations on physical activity for health (1) and is a leading contributor to global mortality. It is estimated that between four and five million deaths per year could be averted if the global population was more active *(2, 11)*. Global estimates of physical inactivity indicate that in 2016, 27.5% of adults *(12)* and 81% of adolescents *(13)* did not meet the 2010 WHO recommendations *(1)*, and trend data show limited global improvement during the past decade. The data also highlight that women are less active than men in most countries and that there are significant differences in levels of physical activity within and between countries and regions. These differences can be explained by inequities in access to opportunities to be physically active, further amplifying inequalities in health. Currently, there are no global estimates of sedentary behaviour, but technological innovation and the transition towards more sedentary occupations and recreation, and the increasing use of personal motorized transportation are contributing to changing patterns of physical activity and increased sedentary behaviour across the world. The *Global action plan on physical activity 2018–2030 (14)* sets out 4 strategic objectives and 20 policy actions to achieve a 15% relative reduction in the global prevalence of physical inactivity in adults and adolescents by 2030.

In 2010, WHO published the *Global recommendations on physical activity for health (1)*, the first population-based public health guidelines for children and adolescents, adults and older adults. In 2018, the World Health Assembly, in resolution WHA71.6, [1] called for WHO to update the 2010 recommendations.

In 2019, WHO published *Guidelines on physical activity, sedentary behaviour and sleep for children under 5 years of age (15)*. The guidelines were called for by the Commission on Ending Childhood Obesity (recommendation 4.12) *(16)*, and address the omission of this younger age group in the 2010 *Global recommendations on physical activity for health (1)*.

The 2020 WHO *Guidelines on physical activity and sedentary behaviour,* replace the 2010 guidelines and are based on the most recent advances in the evidence for the selected behaviours and associated health consequences. They will form part of the overall set of global recommendations on physical activity and sedentary behaviour.

OTHER KEY WHO GUIDELINES

The importance of physical activity for health is recognized in other WHO guidelines. The *WHO Package of essential noncommunicable disease interventions for primary health care in low-resource settings (17)* provides a protocol for the clinical management of hypertension, type-2 diabetes, raised cardiovascular risk, asthma, and chronic obstructive pulmonary disease, and includes counselling to progressively increase physical activity to moderate levels (such as brisk walking) and at least 150 minutes per week, in line with the 2010 global recommendations. Recent WHO guidance in *Risk reduction of cognitive decline and dementia (18)* states that physical activity should be recommended to adults with normal cognition (strong recommendation) and those with mild cognitive impairment (conditional recommendation) to reduce the risk of cognitive decline. WHO *Integrated care for older people: guidelines on community-level interventions to manage declines in intrinsic capacity (19)* recommend multimodal exercises to prevent falls, and exercises for older adults with declining mobility. *WHO recommendations on antenatal care for a positive pregnancy experience (20)* recommend counselling on healthy eating and being physically active during pregnancy to stay healthy and to prevent excessive weight gain, but do not address the wider health benefits of physical activity during pregnancy and the postpartum period.

The existing WHO guidelines, combined with these updated guidelines, provide an increasingly comprehensive set of global guidance on the

[1] *WHA71.6 WHO Global Action Plan on Physical Activity 2018–2030.*

contribution of physical activity and sedentary behaviours to the prevention and management of key diseases and to the promotion of health and well-being across the life course.

RATIONALE AND PURPOSE

The past 10 years has seen a significant increase in the body of evidence on the health impact of different types, amounts and durations of physical activity, as well as on the impact of sedentary behaviours and its interrelationship with levels of physical activity and health. In addition, the evidence base for physical activity in subpopulations, such as pregnant women and those living with chronic conditions and/or disability now permits the examination of the relationship between physical activity and health outcomes in these groups.

In the *Global action plan on physical activity 2018–2030 (14)*, action 4.1 calls for WHO to develop and disseminate global recommendations for physical activity and sedentary behaviours in children under 5 years of age, young people, adults, older adults and specific subpopulations, such as pregnant women, people living with chronic conditions and disability. Updating and broadening the scope of the guidelines, as requested by the World Health Assembly, ensures that population groups not included in the 2010 recommendations are provided with specific recommendations for physical activity. This aligns with the key principles and goals of the global action plan on physical activity, namely to reduce inequalities and to support all people to be more physically active every day.

The overarching purpose of these guidelines is to provide evidence-based public health recommendations on how much and what type of physical activity

The guidelines have been developed for children and adolescents (aged 5–17 years), adults (aged 18–64 years), older adults (aged 65 years and above), and include for the first time specific recommendations on physical activity for subpopulations such as pregnant women and those living with chronic conditions or disability.

Recommendations are made for each specific age group and subpopulation, to provide those working with particular communities easy access to the relevant information. Providing separate recommendations for subpopulations, especially people living with chronic conditions or with disability, highlights the importance of including these subpopulations in policy and planning of physical activity and sedentary behaviour interventions.

These guidelines do not address sleep as a behaviour. Sleep is an important health-related issue and an emerging topic within population health science. However, it was deemed beyond the scope of the mandate to include sleep in the updated recommendations. Nonetheless, the importance of sleep is recognized and was included as an important health *outcome* when considering

children and adolescents, adults, older adults and subpopulations such as pregnant women and those living with chronic conditions or disability, should do for significant health benefits and mitigation of health risks. The guidelines also provide evidence based recommendations on the associations between sedentary behaviour and health outcomes.

the impact of physical activity and sedentary behaviour.

TARGET AUDIENCE

This document reports the process and summarizes the evidence-base reviewed to develop the recommendations. **The primary audiences are:**

1. Policy-makers in ministries of health, education, youth, sport and/or social or family welfare, working in high as well as low- and middleincome countries, who formulate countryspecific guidelines, and who plan health, education, workplace, residential or communitybased intervention programmes across the life course.
2. Government officials who develop national, subregional or municipal plans to increase physical activity and reduce sedentary behaviours in population groups through guidance documents.
3. Persons working in nongovernmental organizations, education and workplace organizations or research.
4. Persons working in health services and those providing advice and guidance, such as community, family, primary or tertiary nurses or doctors, or allied health and exercise professionals working beyond the health sector. These guidelines can inform the content of their advice on these topics, if national guidance is not available.

The recommendations on physical activity and sedentary behaviour contained within the guidelines should be used to inform pre-service training and professional development courses for health-care workers, physical activity specialists and education professionals.

Derivative products are needed that convey these guidelines to specific end-users, stakeholders in sectors outside of health, and the wider community, that use tailored communications to meet the specific needs of each audience.

These guidelines were developed in accordance with the

WHO Handbook for guideline development (2nd edition)

(21). A WHO Steering Group, led by the Department of Health Promotion, was established, with representation from WHO regional offices and relevant WHO departments. A Guideline Development Group (GDG) was formed, consisting of 27 experts and stakeholders, taking into account gender balance and geographical diversity. The draft guidelines were externally reviewed by seven independent reviewers, who provided feedback on the scientific evidence, its interpretation and content. In addition, an online public consultation was conducted on the draft guidelines, and feedback was received from over 400 contributors. These inputs from scientists, practitioners and the general public were collated and used by the GDG to finalize the guidelines. Full details of the management of the guideline development process are available in Annex 1.

SCOPE OF GUIDELINES AND QUESTIONS OF INTEREST

The GDG reviewed the scope of the guidelines and, at their first meeting, agreed on the most relevant PI/ ECO (**P**opulation, **I**ntervention/**E**xposure, **C**omparison, **O**utcome) questions. The key questions addressed for each subpopulation are summarized as follows: **For physical activity:**

a. What is the association between physical activity and health-related outcomes?

b. Is there a dose-response association (volume, duration, frequency, intensity)?

c. Does the association vary by type or domain of physical activity?

For sedentary behaviour:

a. What is the association between sedentary behaviour and health-related outcomes?

b. Is there a dose-response association (total volume, frequency, duration and intensity of interruption)?

c. Does the association vary by type and domain of sedentary behaviour?

d. In adults only: Does physical activity modify the effect of sedentary behaviour on mortality?

For each population (P), the exposure (E) was greater volume, duration, frequency or intensity of physical activity; for, as comparison (C) no physical activity or lesser volume, frequency, intensity or duration of physical activity. The critical and important outcomes for each population are summarized in Table 1 and the details of each PI/ECO question in the relevant section of the Web Annex: Evidence profiles .

Available online at https://apps.who.int/iris/bitstream/handle/10665/336657/9789240015111eng.pdf

Table 1: ***Summary of critical and important* health outcomes addressed by population groups***

(in alphabetical order) Outcomes	Children and adolescents aged 5–17 years: PA and sedentary behaviour	Adults aged 18–64 years: PA and sedentary behaviour [a]	Adults aged over 65 years: PA and sedentary behaviour [a]	Pregnancy and postpartum [b]	Adults aged 18–64 years: conditions [b]	Chronic conditions	Children and adults with disability [c]
Adiposity (weight gain, weight change, weight control, weight stability, weight status and weight maintenance)	Critical	Critical	Critical	Critical [a]	Critical	Critical – HIV	–
Adverse events	Critical	Critical	–	Critical [a]	Critical (fetal outcomes)	–	–
All-cause and cause-specific mortality	–	Critical (cancer and CVD specific)	Critical	Critical [a]	–	Critical	–
Bone health	Critical	–	Important	–	–	–	–
Cardiometabolic health	Critical	–	–	–	–	–	–
Cognitive outcomes	Critical	Critical	Important	Critical [a]	–	–	Critical – MS, PD, Stk, Sch, ADHD
Delivery complications	–	–	–	–	Important	–	–
Disease progression	–	–	–	–	–	Critical – HT, T2D, HIV, Critical – cancer recurrence	–
Falls and fall-related injuries	–	–	–	Critical	–	–	–
Fetal outcomes (birthweight, preterm birth)	–	–	–	–	Critical	–	–
Functional ability	–	–	–	Critical	–	–	–
Gestational diabetes mellitus	–	–	–	–	Critical	–	–
Gestational hypertension/ preeclampsia	–	–	–	–	Critical	–	–
Health-related quality of life	–	Important	Important	Important [a]	–	Critical – HT, T2D, HIV	Critical – MS, SCI, ID, MCD, Sch
Incidence of cancer	–	Critical	Critical	Critical [a]	–	–	–
Incidence of CVD	–	Critical	Critical	Critical [a]	–	–	–
Incidence of hypertension	–	Important		Important [a]	–	–	–
Incidence of type-2 diabetes	–	Critical	Critical	Critical [a]	–	–	–
Mental health (symptoms of anxiety and depression)	Critical	Critical	Important	Critical [a]	Critical	–	–
Osteoporosis	–	–	–	Critical	–	–	–
Physical fitness	Critical	–	Important	–	–	–	–
Physical function	–	–	Important	–	–	Critical – HT, T2D, HIV	Critical – MS, SCI, ID, PD, Stk

Pro-social behaviour	Important	–	–	–	–	–	–
Psychosocial outcomes	–	–	–	Important	–	–	–
Risk of co-morbid conditions	–	–	–	–	–	Critical – HT, T2D, HIV	Critical – MS, SCI, ID
Sleep	Important	Important	Important	Important [a]	–	–	–

* Critical outcome: an outcome that is critical to decision-making; Important outcome: an outcome that is important, but not critical to decision-making.

[a] The critical and important outcomes considered for the adult population, including older adults. [b] Outcomes are for subpopulation condition as listed: Cancer – cancer survivors; HT – hypertension; T2D – type-2 diabetes; HIV.

[c] Outcomes are for subpopulation condition as listed: MS – muscular sclerosis; SCI – spinal cord injury; ID – intellectual disability; PD – Parkinson's disease; Stk – in stroke survivors; Sch – schizophrenia; ADHD – attention deficit/hyperactivity disorder. Critical and important outcomes for the age-specific population were considered and extrapolated.

THE EVIDENCE

The revision of the 2010 WHO recommendations on physical activity was conducted by identifying, and then updating, the most recent, relevant umbrella reviews related to the scope of these guidelines.

This approach was adopted due to an extensive body of recent systematic reviews which were conducted to inform the development of several national physical activity guidelines. The additional updating was undertaken to ensure the new WHO guidelines reflect the most recent available data in a rapidly developing field of public health.

Umbrella reviews were selected if they met the following three criteria: **i)** the evidence reviews had been conducted according to standard systematic processes that were well documented; **ii)** the assessment of the certainty of the evidence used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method or an equivalent methodology that was clearly described and documented; and **iii)** the evidence reviews addressed the populations of interest with no restrictions to country or country income level.

The PI/ECO questions and the critical and important health outcomes were mapped against existing evidence reviews and, where needed, additional new reviews were commissioned to address gaps. The GDG requested that the evidence reviews be updated, using the same search terms, search languages, and databases as the original reviews.

The following evidence reviews were identified as meeting the above three criteria and were chosen for recency and comprehensiveness:

- A systematic review of the literature conducted by Poitras et al. (2016) on the association between physical activity and health indicators in schoolaged children and youth *(22)* as part of the process for developing the *Canadian 24-hour movement guidelines for children and youth (23)*. This review focused solely on studies that used objective measurements of physical activity. A total of 162 studies were included, representing 204 171 participants from 31 countries.

- A systematic review of the literature of the association between sedentary behaviour and health indicators in school-aged children conducted by Carson et al. (2016) *(24)*, as part of the process for developing the *Canadian 24-hour movement guidelines for children and youth (23)*. A total of 235 studies (194 unique samples) were included representing 1 657 064 unique participants from 71 countries.

- A systematic review conducted by Okely et al. (2019) *(25)* undertaken to update Poitras et al. (2016) *(22)* and Carson et al. (2018) *(24)* as part of the development of the 2019 *Australian 24-hour movement guidelines for children and young people* (aged 5–17 years) *(26)*. This report identified an additional 42 studies on physical activity, and 32 on sedentary behaviour, published through to July 2918 *(25).* The GRADE tables developed by Okely et al. were used as the basis

for the commissioned update conducted for WHO. The GRADE tables along with the evidence profiles

Methods[20]

are presented in the Web Annex: Evidence profiles .

- The 12 systematic reviews conducted and synthesized as part of the development of the *2019 Canadian guideline for physical activity throughout pregnancy (27).* These 12 reviews assessed over 25 000 related studies in English, Spanish and French language on maternal physical activity during pregnancy that reported on maternal, fetal, or neonatal morbidity, or fetal mortality outcomes. Seven of these systematic reviews addressed outcomes deemed critical and important by the GDG *(28–34)* The GRADE tables from these evidence reviews were used as the basis for the literature search conducted to update and inform the development of WHO recommendations. The updated evidence profiles are presented in the Web Annex: Evidence profiles .

- The scientific report of the Physical Activity Guidelines Advisory Group (PAGAC) *(35)* which provides a systematic update of evidence on physical activity and sedentary behaviours and health outcomes published 2008–2016 as part of the development of the 2018

  Physical activity guidelines for Americans, 2nd Edition (36). The evidence summarized addressed a total of 38 main research questions and 104 subquestions selected for their public health relevance. The evidence comprised results from systematic reviews which consisted of a total of 1130 articles, each abstracted to answer the 38 research questions *(35)*. The protocols used a modified version of "A Measurement Tool to Assess Systematic Reviews" (AMSTARExBP) to assess the methodological quality of systematic reviews and meta-analyses. Risk of bias, or internal validity, was assessed for each original study using an adapted version of the USDA NEL Bias Assessment Tool (BAT) *(37)*. The new evidence identified in the updated searches conducted for these WHO guidelines is presented in the evidence profiles in the Web Annex: Evidence profiles ;

Methods for updating the evidence and data extraction

A search for systematic reviews and pooled analyses of cohort studies was conducted for studies published from the date of the last searches carried out for each of the included reviews (listed above) to September 2019; standardized data extraction protocols were developed and employed.

To update the searches conducted by Poitras et al.

(2016)

(22), Carson et al. (2016) *(24)*, and Okely et al. (2019)

(25), the databases MEDLINE, EMBASE, PsycINFO, and SportDiscus were searched to identify reviews that were peer-reviewed, written in English or French. To update the searches conducted by PAGAC *(35),* PubMed, CINAHL and Cochrane databases were searched to identify reviews that were peerreviewed, written in English. A de novo search for important outcomes, where these were not included by PAGAC *(35)*, was not conducted due to resource constraints.

Searches were performed with no restriction by country or country income status, and inclusive of reviews addressing any subjectively or objectively measured physical activity or sedentary behaviour. It was decided not to conduct searches in languages other than those of the original searches, due to resource constraints and previous experience in the field indicating that such searches yielded very few, if any, additional reviews. Reviews were considered that examined an association between physical activity or sedentary behaviour and health-related outcomes (based on levels above or below a threshold of physical activity or sedentary behaviour), and that explored the dose-response

relationship between these and health-related outcomes.

An external team of reviewers used the AMSTAR 2 (Assessment of Multiple Systematic Reviews) instrument to rate the credibility of the systematic reviews under consideration for inclusion *(38).* The AMSTAR 2 tool contains 16 items that relate to the

links are provided to the report and planning and conduct of the review. The overall supplementary materials of PAGAC *(35)*. confidence in the results of each review was rated according to published guidance: a rating of “high”

reflects that the review had zero or one noncritical weakness; "moderate" indicates the review was judged to have more than one noncritical weakness; "low" means the review was judged to have one critical flaw with or without noncritical weaknesses, or multiple noncritical weaknesses; and "critically low" signifies that more than one critical flaw was present. One reviewer completed the AMSTAR 2 tool for all provisionally included reviews. Reviews that were rated critically low by one reviewer were reviewed by a second reviewer using the same tool. Reviews ultimately rated as critically low were excluded because they were judged to be too unreliable to provide an accurate and comprehensive summary of the available evidence, unless it was the only review available for a particular outcome.

This body of evidence also included pooled cohort studies. An external team of reviewers used the NewcastleOttawa Scale to assess the quality of the studies *(39)*. Each study was given a quality rating of "good", "fair", or "poor". In general, a good-quality study met all criteria on the Newcastle-Ottawa scale. A fair-quality study did not meet, or it was unclear whether it met, at least one criterion, but also had no known important limitations that could invalidate its results. A poor-quality study had a single fatal flaw, or multiple important limitations. Poor-quality studies were excluded.

There was an assessment for overlap, recognizing potential for duplication of studies in multiple reviews. Reviews containing redundant bodies of evidence, overviews of reviews, and some pooled cohort studies were excluded, where other more comprehensive and/or recent reviews were identified.

Methods for new reviews

Where gaps in existing evidence were identified, new umbrella reviews were commissioned to examine:

1. the relationship between occupational (i.e. workrelated) physical activity and health-related outcomes

   (40); and

2. the association between leisure-domain physical activity and adverse health outcomes *(41)*.

(For numbers 1 and 2 above, searches were undertaken using

PubMed, SportDiscus and EMBASE for reviews published from 2009 to December 2019.)

3. the association between physical activity and falls prevention; the 2019 Cochrane Collaboration Systematic Review by Sherrington et al. *(42)* was used, and updated with evidence published from the end search date of their original review, through to November 2019.

4. the association between physical activity and osteoporosis and sarcopenia. The search for existing systematic reviews on osteoporosis and sarcopenia, conducted in PubMed for reviews published from 2008 up to November 2019, identified no new reviews and eight new primary studies.

5. the evidence on associations between physical activity and health outcomes in people living with HIV. A scoping review ascertained the availability of evidence on physical activity and health-related outcomes among people living with HIV to support conducting an umbrella review which was conducted for evidence published up to October 2019 with no start date limitation using PubMed, CINAHL and Web of Science.

Summary of characteristics of the evidence and assessment methods of physical activity and sedentary behaviour

Until recently, the primary methods for measuring physical activity and sedentary behaviours in adults has been by self-report (i.e. survey) and, for children, either self-report or parental recall. Although these methods have well-established strengths, limitations include being prone to reporting bias and measurement error *(43)*. In recent years, with digital technology rapidly growing in this area, there has been an increase in the use of device-based measures for assessing physical activity and sedentary time and their associations with health outcomes. However, challenges remain in comparing results between studies due to differences between the technical features and placement of different devices

(accelerometers), and differences in the analyses and reporting of the data. For example, when measuring sedentary time with device-based measures, miscalculation may occur as many of the devices do not currently distinguish between positions (e.g. lying, sitting and standing still). Difficulties also exist when comparing findings from studies using devicebased measures with those reporting results from self-report measures.

Self-report instruments vary in content, in the examples of physical activity, response options and domains covered. Until recently, studies focused primarily on assessing either total physical activity, or physical activity in the leisure/recreation domain only, but now increasingly include other domains such as physical activity for transport (e.g. walking and cycling), at work, and in the household. The majority of evidence reports on associations between aerobic physical activity and health outcomes, however studies are now assessing the benefits of musclestrengthening exercise, as well as combinations of different types of activity and other domains.

Results on the association between physical activity levels and health outcomes are reported and compared in different ways. Many studies report comparisons between quartiles or

quintiles of physical activity, other studies compare those

"meeting" versus "not meeting" national guidelines. Calculation of total physical activity, when reported, is usually estimated in MET-hours per week and some studies compare "highest" versus "lowest", although categories also vary across studies. The literature frequently reports results from analyses that apply data cut points based on an existing guideline, or the current WHO Global recommendation, or metrics from previous research (for example the cut points of 60 minutes per day in research on youth populations, or the frequency of 2–3 times per week for strength training intervention). When such cut points become commonplace the building of evidence on the associations of higher or lower levels of physical activity exposure on health outcomes can be limited.

Most of the evidence assessing the associations between sedentary behaviours and health outcomes for children and adolescents is crosssectional in nature, and a majority of studies rely on self- or parent-reported measures of sedentary time that are subject to measurement errors and recall biases.

Evidence from longitudinal observational studies and intervention trials was prioritized, and reviews that solely or primarily synthesized cross-sectional evidence were not considered. Greater emphasis was given to evidence provided by reviews graded moderate certainty and above, and to those providing evidence from studies using device-based measures of exposure.

Grading the body of evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) method was used to rate the certainty of the evidence for each PI/ECO *(44)*, based on the underlying evidence in the reviews. When available, the GRADE "Evidence Profiles" or "Summary of Findings" tables from each review, were used as a starting point. If no table was available within the existing systematic reviews, "Evidence Profile" tables for each population and outcome of interest were constructed.

The GRADE method was used to rate the certainty of the evidence for each PI/ECO *(44)* with the following criteria considered: study design; risk of bias; consistency of effect; indirectness; precision of effect; and other limitations, including publication bias and factors for upgrading observational evidence (magnitude of effect, dose-response, and effects of confounders). Observational evidence from wellconducted longitudinal studies was also upgraded to reflect more appropriately the increased certainty in findings regarding associations between physical activity or sedentary behaviour and outcomes from such studies. Studies that evaluated intermediate/ indirect outcomes were not necessarily downgraded, as the outcomes (including intermediate outcomes) were prioritized by the GDG; the GRADE rating reflects the certainty in effects on those outcomes. In some cases, the GRADE ratings from existing reviews were modified to ensure consistency in application of

GRADE methods. The certainty in the body of evidence for each outcome was assigned based on the following guidance *(45):*

High	Very confident that the true effect lies close to that of the estimate of the effect.
Moderate	Moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low	Very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Going from evidence to recommendations

The GDG employed the GRADE Evidence to Decisions (EtD) framework for generating question-specific recommendations. The EtD framework is a systematic, structured and transparent approach to decisionmaking. The framework uses explicit criteria for generating guideline recommendations considering research evidence, certainty of evidence and, where required, expert opinion and topical knowledge from the perspective of the target audience. The criteria elicit judgments about the balance between the observed evidence of desirable and undesirable outcomes, overall certainty of evidence, relative values of patients for desirable and undesirable outcomes, resource use (cost considerations) where applicable, potential impact on inequities in health, acceptability and feasibility of recommendations.

The GDG considered the body of evidence in totality for each recommendation for all critical outcomes, and all available important outcomes. For a particular exposure/intervention and outcome link, studies differed widely in the specific exposure/intervention assessed, outcomes assessed, study design, and analytic methods, resulting in heterogeneity in the available evidence. Therefore, it was not possible to apply the classic GRADE approach to each specific exposure/intervention and outcome link; rather, GRADE was applied for the overall body of evidence addressing each exposure/intervention and outcome link, across study design types and variations in exposure/intervention measurements and analyses. When these factors resulted in concerns regarding the coherence of the evidence (i.e. that the evidence for a particular exposure/intervention and outcome link did not correspond when looked at in different ways), the panel downgraded the certainty of evidence *(21)*.

The GDG prioritized the following health outcomes to consider the effects of physical activity and sedentary behaviour: reduced allcause and causespecific mortality (cardiovascular disease and cancer); reduced incidence of cardiovascular disease; cancer (sitespecific); type-2 diabetes; improved physical fitness (e.g. cardiorespiratory, motor development, muscular fitness); improved cardiometabolic health (e.g. blood pressure, dyslipidaemia, glucose, insulin resistance); bone health; mental health (e.g. reduction in depressive symptoms, self-esteem, anxiety symptoms, ADHD); and improved cognitive outcomes (e.g. academic performance, executive function); and reduced adiposity. Adverse effects (e.g. injuries and harms) were

The public health recommendations presented in the *WHO Guidelines on physical activity and sedentary behaviour* are for all populations and age groups ranging from 5 years to 65 years and older, irrespective of gender, cultural background or socioeconomic status, and are relevant for people of all abilities.

The new guidelines are presented by age group and behaviour (physical activity and sedentary). For each set of recommendations, an introductory statement summarizes the health outcomes associated with physical activity and sedentary behaviour respectively; the recommendations then follow. A set of good practice statements is provided to further clarify how the recommendation can be met safely by the target population. These good practice statements are not "graded recommendations" per se, but are derived from scientific evidence and from practical

RECOMMENDATIONS

Additional considerations

For each population and all PI/ECO questions, the GDG also considered values and preferences of those affected by the guidelines; the resource implications of the recommendations; the impact on health equity; and the acceptability and feasibility of the recommendations. As there was considerable duplication in these considerations, and in the GDG's assessment, for each population group, a summary of the discussions regarding assessments for these elements are described in the "Evidence to recommendations" section.

considerations reviewed and recommended by the GDG.

For each set of recommendations, a summary of the supporting scientific evidence is provided, structured by the three PI/ECO questions; presenting first the evidence on the associations with the critical health outcomes, followed by a summary of evidence on dose response. Finally, a summary of evidence on the relationships between different types or domains of exposure and health outcomes is presented, where this exists.

CHILDREN AND ADOLESCENTS
(aged 5–17 years)

PHYSICAL ACTIVITY RECOMMENDATION

For children and adolescents, physical activity can be undertaken as part of recreation and leisure (play, games, sports or planned exercise), physical education, transportation (wheeling, walking and cycling) or household chores, in the context of educational, home, and community settings.

In children and adolescents, physical activity confers benefits for the following health outcomes: improved physical fitness (cardiorespiratory and muscular fitness), cardiometabolic health (blood pressure, dyslipidaemia, glucose, and insulin resistance), bone health, cognitive outcomes (academic performance, executive function), mental health (reduced symptoms of depression); and reduced adiposity.

It is recommended that:

- **Children and adolescents should do at least an average of 60 minutes per day of moderate- to vigorous-intensity, mostly aerobic, physical activity, across the week.**

  Strong recommendation, moderate certainty evidence

- **Vigorous-intensity aerobic activities, as well as those that strengthen muscle and bone, should be incorporated at least 3 days a week.**

  Strong recommendation, moderate certainty evidence

GOOD PRACTICE STATEMENTS

- Doing some physical activity is better than doing none.
- If children and adolescents are not meeting the recommendations, doing some physical activity will benefit their health.
- Children and adolescents should start by doing small amounts of physical activity, and gradually increase the frequency, intensity and duration over time.
- It is important to provide all children and adolescents with safe and equitable opportunities, and encouragement, to participate in physical activities that are enjoyable, offer variety, and are appropriate for their age and ability.

Supporting evidence and rationale

For these guidelines for children and adolescents, systematic reviews *(22, 25, 35)* were used and updated with 16 new reviews identified that met inclusion criteria. Full details of the methods, data extraction and evidence profiles can be found in the Web Annex: Evidence profiles .

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In children and adolescents (aged 5–17 years), what is the association between physical activity and health-related outcomes?

A large body of evidence previously established that greater amounts and higher intensities of physical activity in children and adolescents are associated with multiple beneficial health outcomes *(1).* Recent evidence reaffirms that increased physical activity improves **cardiorespiratory fitness** and **musculoskeletal fitness** in children and adolescents *(22, 35).* For example, positive impacts are obtained when participating in moderate- to vigorousintensity physical activity for 3 or more days per week, for 30 to 60 minutes *(22, 35).*

Regular physical activity, largely aerobic, in children and adolescents is positively associated with beneficial **cardiometabolic health** outcomes, including improved blood pressure, lipid profile, glucose control and insulin resistance *(35)*. Recent reviews examined the effectiveness of school-based physical activity programmes *(46)*, high-intensity interval training *(47)* and resistance training *(48)*, versus no intervention on measures of cardiometabolic health. Within all 3 reviews, there was consistent evidence that interventions were associated with better cardiometabolic outcome measures, although there was varied precision in effect sizes and few individual trials found statistically significant benefits of physical activity across all cardiometabolic outcomes. One review of 19 RCTs (*n*= 11 988) *(46)* reported that school-based physical activity programmes were associated with statistically significant improvements in diastolic blood pressure (ES= 0.21 [95% CI: 0.42 to 0.01]; *p*= 0.04) and fasting insulin (ES= 0.12 [95% CI: 0.42 to 0.04]; *p*= 0.03) compared with no physical activity interventions.

Physical activity has been reported to be favourably associated with **adiposity**, and higher levels of activity may be associated with healthy weight status in children and adolescents *(22, 35)*. The results are generally strongest in cross-sectional studies, while the results are more mixed from prospective observational studies, which limits understanding of the directionality of the reported associations. More recent reviews of physical activity interventions trials (laboratory-based highintensity interval training [HIIT], classroombased active learning, resistance training) reported inconsistent results with the majority of the studies included in the reviews not reporting an effect *(47, 49, 50)*. However, a review of longitudinal and crosssectional studies reported a negative relationship between pedometermeasured physical activity and measures of adiposity, BMI or waist circumference *(51)*. Overall there is low certainty evidence that physical activity is associated with the management of a healthy weight status and more research is needed to determine directionality and strength of association.

There is less evidence examining the association between physical activity and **motor skill development** in children and adolescents, with current reviews demonstrating null findings *(22)*. More research is needed with motor development as an outcome to inform future guidelines.

For children and adolescents, bone-loading activities can be performed as part of playing games, running, turning, or jumping. Physical activity is positively associated with bone mass accrual and/or bone structure, and recent evidence supports that children and adolescents who are more physically active than their peers have greater bone mass, higher bone mineral content or density, and greater bone strength *(35)*. Maximizing **bone health** in

childhood and adolescence can help protect from osteoporosis and related fractures later in life.

Developing and maintaining cognitive function is essential across the entire lifespan. In children and adolescents, physical activity has positive effects on **cognitive function** and **academic outcomes** (e.g. school performance, memory and executive function) *(22, 35)*. One recent review (19 RCTs; *n*= 5038) demonstrated that exercise interventions with multiple sessions per week, for 6 weeks or longer, were associated with greater change in measures of cognitive function such as inhibitory control (SMD 0.26 [95% CI: 0.08 to 0.45], *p*= < 0.01); working memory (SMD 0.10 [95% CI: -0.05 to 0.25], *p*= < 0.02), and cognitive flexibility (SMD 0.14 [95% CI: -0.03 to 0.31], *p*= < 0.04) compared with no exercise interventions *(52)*. Physical activity also reduces the risk of experiencing depression and depressive symptoms in children and adolescents with and without major **depression** *(35)*, and may be comparable to psychological and pharmaceutical therapies in reducing symptoms.

Although all physical activity comes with some **risk of adverse event** *(53)* there is limited evidence reporting harms associated with physical activity levels recommended for health benefit *(35)*. Based on available evidence and expert opinion, the potential risks associated with the amounts and types of physical activity recommended for children and adolescents were considered to be low *(35)* and can be reduced by a progressive increase in the activity level and intensity, especially in children and adolescents who are inactive. It is known that participation in some sports increases the risk of injury, as does increasing exercise intensity *(53)*. More research is needed to strengthen the knowledge base in this area.

The GDG concluded that:

- There is moderate certainty evidence that greater amounts of moderate- and vigorous-intensity physical activity are associated with improved cardiorespiratory fitness and muscular fitness, cardiometabolic health and bone health in children and adolescents.
- There is moderate certainty evidence that both short- and long-term moderate- to vigorousintensity physical activity have positive effects on cognitive function, academic outcomes and mental health.
- There is low certainty evidence that physical activity is favourably associated with the management of healthy weight status in children and adolescents.
- There is low-certainty evidence that the risks for the amounts and types of physical activity recommended for children and adolescents are low and are outweighed by the benefits.

Is there a dose-response association (volume, duration, frequency, intensity)?

Although there is a substantial body of evidence demonstrating a positive association between physical activity and health outcomes in children and adolescents, very few studies have addressed the issue of dose-response. Therefore, the exact shape of the dose-response curve and/or the presence of threshold values (that differentiate lower versus higher risk) for physical activity and specific health outcomes is less well understood in children and adolescents compared with adult populations. Nonetheless, a substantial body of evidence shows that many of the health benefits occur with 60 minutes of physical activity daily *(22, 35)*, and given no contradictory evidence, it was concluded that the updated evidence reaffirms the current WHO recommendation for 60 minutes of moderate- to vigorous-intensity physical activity per day *(1)*.

However, the review of all evidence, including recent results from studies using device-based measures of physical activity, did not support retaining the specification of a "minimum" daily threshold of 60 minutes of moderate- to vigorous-intensity physical activity for health benefits, given that studies broadly used "an average" threshold of 60 minutes per day, not a *minimum* daily threshold of 60 minutes, to assess the benefits of physical activity on health outcomes. The review concluded that the new guideline should be amended to more closely reflect this evidence.

The benefits of regular vigorous-intensity activity on cardiometabolic health outcomes has been previously established *(1)* and recent reviews provided further supporting evidence *(35)*. For example, a recent review *(54)* showed that highintensity interval training, compared with moderate-intensity continuous training, had a moderate beneficial effect on cardiorespiratory

fitness (SMD= 0.51 [95% CI: 0.33 to 0.69], p= < 0.01; I^2= 0%). There was no evidence that intervention duration, exercise modality, exercise and rest ratio, and total bouts modified the effect on cardiorespiratory fitness. These results were consistent overall with other recent reviews *(22, 35, 47)* and provide support to retaining the recommendation that youth and adolescents should do regular vigorous-intensity activity to improve cardiorespiratory fitness.

The GDG concluded that:

- Evidence affirms the previous WHO recommendation for 60 minutes of moderate- to vigorous-intensity physical activity per day.
- Evidence supports amending the previous specification of a minimum daily threshold of 60 minutes of physical activity to an average of 60 minutes per day per week, which more closely reflects the evidence.
- There is moderate certainty evidence that greater amounts of vigorous-intensity physical activity are associated with improved cardiorespiratory fitness.

Does the association vary by type or domain of physical activity?

For children and adolescents, physical activity includes play, games, sports, transportation, recreation, physical education or planned exercise, in the context of family, school, and community activities. However, few studies have directly compared different types or domains of physical activity in children and adolescents and thus there is insufficient evidence to determine if the association between physical activity and health outcomes varies by type of activity (e.g. aerobic versus musclestrengthening exercise) or domain of physical activity (e.g. active transport (walking and cycling) versus physical education, versus sports/recreation).

There is evidence showing that both increased levels of aerobic moderate- to vigorous-intensity physical activity are associated with increased cardiorespiratory fitness, and that increased muscle-strengthening activity increases muscular fitness in children and adolescents. This evidence informed the 2010 WHO *Global recommendations* intensity, largely due to the heterogeneity of exposures assessed in the literature *(22, 35)*. There is less evidence for a protective effect of resistance

on physical activity for health (1) which recommended incorporating activities that strengthen muscles and bones at least 3 days per week. Updated evidence reaffirmed that regular musclestrengthening activity 3 times per week was effective for improving indicators of muscular fitness; however, there is insufficient evidence to state specific details of session duration and duration, it was not possible to specify any further details. Future research should address the health benefits of specific types and domains of physical activity in order to provide more specificity to this component of the guidelines.

The GDG concluded that:

training on cardiometabolic health. Given the absence of new evidence on characteristics other than the frequency of muscle strengthening activities for children and adolescents, such as

- There is moderate certainty evidence that musclestrengthening activities should be incorporated at least 3 days a week.

SEDENTARY BEHAVIOUR RECOMMENDATION

Sedentary behaviour is defined as time spent sitting or lying with low energy expenditure, while awake, in the context of educational, home, and community settings and transportation.

In children and adolescents, higher amounts of sedentary behaviour are associated with the following poor health outcomes: increased adiposity; poorer cardiometabolic health, fitness, behavioural conduct/pro-social behaviour; and reduced sleep duration.

It is recommended that:

Children and adolescents should limit the amount of time spent being sedentary, particularly the amount of recreational screen time.

Strong recommendation, low certainty evidence

Supporting evidence and rationale

Sedentary behaviour was not included in the WHO 2010 recommendations, yet during the past decade, there has been a growing body of research examining the health outcomes associated with different measures and types of sedentary behaviours. Technology and digital communications have influenced how people work, study, travel and spend leisure-time. In most countries, children and adolescents are spending greater time engaged in sedentary behaviours, particularly for recreation, such as screen-based entertainment (television and computers) and digital communications, such as mobile phones.

For these guidelines for children and adolescents, systematic reviews *(24, 25)* were used and updated with seven new reviews identified that met inclusion criteria. Full details of the methods, data extraction and evidence profiles can be found in the Web Annex: Evidence profiles .

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In children and adolescents (aged 5–17 years), what is the association between sedentary behaviour and health-related outcomes?

Evidence indicates that greater time spent in sedentary behaviour, especially recreational screen time, is related to poorer health outcomes *(24, 35)*. For example, higher duration of screen time (including television viewing) is associated with poorer **fitness** and **cardiometabolic health** *(24, 25)* in children and adolescents. Evidence from devicebased assessment of association with sedentary behaviour and interventions studies showed modest effects, although stronger effects for those already living with obesity *(55)*. There is limited evidence suggesting that sedentary behaviour is not related to bone health in children and adolescents.

Despite more mixed results, evidence also suggests that sedentary behaviour may be associated with unfavourable measures of **adiposity** *(24, 25)*. One review of largely cross-sectional studies, reported that sedentary behaviour (measured as total screen time) of more than 2 hours per day was positively associated with childhood overweight/obesity compared with lower levels (< 2 hours/day) *(56)*. However, another review of 20 cross-sectional studies *(57)* found no statistically significant association between sedentary video gaming and body mass index among children or adolescents. A large review of 29 systematic reviews concluded that many studies report unfavourable associations between sedentary behaviour and markers of adiposity in young people when the behaviour is self-reported as some form of screen time *(55)*. However, the review noted that the magnitude of such associations was small and, for studies using device-based assessment of sedentary time, largely zero *(55)*. Intervention studies showed modest effects, although stronger effects for those already living with obesity *(55)*. Further research is needed to inform the association between sedentary behaviours and measures of adiposity.

Although still an emerging area of research, some evidence shows that there may be a negative association between sedentary behaviour and **wellbeing and quality of life**, as well as an unfavourable relationship between **depression** and leisure screen time in children and adolescents *(58, 59)*. For example, higher durations of sedentary behaviour, assessed as screen time, and some aspects of computer use, can be associated with poorer mental health *(24)*. In another recent review, an association between sedentary behaviour and anxiety symptoms was found in 5 of 8 studies, although results were inconsistent across different measures of sedentary behaviour within studies *(60)*. Other evidence demonstrates that higher durations of television viewing and video game use were significantly associated with unfavourable measures of **behavioural conduct/pro-social behaviour** *(24)*; and more screen time and television viewing is associated with shorter **sleep** duration, although there was no association between computer use/gaming and sleep duration *(61)*. Investigations into the relationship between sedentary behaviours and mental health is a rapidly developing field with many unknowns, and reverse causality is likely to be in evidence. Further research is needed to inform on the direction and strength of this association.

The GDG concluded that:

- There is low certainty evidence that higher duration of sedentary behaviour (screen time) is significantly associated with lower physical fitness and cardiometabolic health in children and adolescents.
- There is very low to moderate certainty evidence that higher durations of sedentary behaviour (screen time, television viewing and video game use) are significantly associated with unfavourable measures of mental health and

behavioural conduct/pro-social behaviour in children and adolescents.

- There is low certainty evidence that greater time spent in sedentary behaviour (screen time and television viewing) is associated with detrimental effects on sleep duration in children and adolescents.

- The benefits of limiting the amount of sedentary behaviour for children and adolescents outweigh the harms.

Is there a dose-response association (total volume, duration, frequency, intensity of interruption)?

There is insufficient evidence available to determine whether a dose-response relationship exists between sedentary time (including recreational screen time) and health outcomes in children and adolescents. Most of the evidence assessing the associations between sedentary behaviours and health outcomes in children and adolescents is cross-sectional in nature, with low certainty evidence according to GRADE, and a majority of studies relied on self- or parentreported measures of sedentary time that are subject to measurement errors and recall biases. There is, however, evidence that less time spent in sedentary behaviours appears to be better for health outcomes, and the association between sedentary behaviour and adverse health outcomes is generally stronger for sedentary behaviour when assessed as television viewing or recreational screen time as the exposure variable, than for total sedentary time. However, overall the evidence was considered insufficient to support specifying time limits.

Evidence that sedentary behaviours are linked to adverse health outcomes could be the result of either direct effects of the sedentary behaviours, displacement of time spent in more physically active behaviours, or both. Although there are studies that have reported associations between screen time and adverse health outcomes in children and adolescents, total sedentary time (as assessed in studies using device-based measurements of sedentary behaviour) has consistently not been associated with health outcomes when time in moderate- to vigorousintensity physical activity is taken into account *(62)*. Conversely, the evidence linking moderate- to vigorous-intensity physical activity to positive health outcomes is strong and well documented across diverse settings; replacing some sedentary behaviour with physical activity (especially moderate- to vigorous-intensity physical activity) may improve health outcomes.

Research investigating the associations and interplay between sedentary behaviour, physical activity and health outcomes is rapidly growing, and evidence from device-based measures of sedentary behaviour and cardiometabolic health show the association is attenuated when moderate- to vigorous-intensity physical activity is taken into account (i.e. statistically adjusted for) *(62–64)*. There is therefore a need for further prospective studies using device-based measures of exposure, to advance knowledge of these associations and inform future recommendations.

The GDG concluded that:

- There is low certainty evidence that greater time spent in sedentary behaviour is related to poorer health outcomes.
- There is insufficient evidence to specify time limits on sedentary behaviour.
- Replacing sedentary time with moderate- to vigorousintensity physical activity may provide health benefits.

Does the association vary by type or domain of sedentary behaviour?

The study of health effects of sedentary behaviour is a relatively new field of research. As such the findings are from studies using different instruments and measures of exposure. Exposure assessed as "total time spent doing sedentary behaviours" is frequently used, as is sedentary time spent using "screens" or "television viewing". Available evidence suggests that the association between sedentary behaviour and adverse health outcomes is generally stronger for television viewing or recreational screen time than for total sedentary time *(24, 35)*. The increased use of device-based assessment of sedentary behaviour in the more recent research is advancing knowledge,

activity *(24, 25)*. Sedentary behaviour may include time spent engaged in educational pursuits/study or quiet play, or social interaction without electronic media. These pursuits (e.g. reading, doing puzzles, drawing, crafting, singing, music) are important for child development and have cognitive as well as other benefits.

and when combined with standardized reporting will help inform future guidelines.

It is acknowledged that not all sedentary behaviour is harmful. Evidence suggests certain types of sedentary behaviour, such as reading and doing homework outside of school, are associated with higher academic achievement, indicating that there are differences in outcome depending on the

The GDG acknowledged that:

- Some sedentary activities confer benefits for cognitive function and social interaction in children and adolescents.
- Evidence on the adverse health effects of sedentary behaviour is generally stronger for television viewing or recreational screen time than for total sedentary time.

PHYSICAL ACTIVITY RECOMMENDATION

For adults, physical activity can be undertaken as part of recreation and leisure (play, games, sports or planned exercise), transportation (wheeling, walking and cycling), work or household chores, in the context of daily occupational, educational, home and community settings.

> In adults, physical activity confers benefits for the following health outcomes: improved allcause mortality, cardiovascular disease mortality, incident hypertension, incident sitespecific cancers, [1] incident type-2 diabetes, mental health (reduced symptoms of anxiety and depression); cognitive health, and sleep; measures of adiposity may also improve.

[1] *Site-specific cancers of: bladder, breast, colon, endometrial, oesophageal adenocarcinoma, gastric, and renal.*

It is recommended that:

All adults should undertake regular physical activity.

Strong recommendation, moderate certainty evidence

Adults should do at least 150–300 minutes of moderate-intensity aerobic physical activity; or at least 75–150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous-intensity activity throughout the week, for substantial health benefits.

Strong recommendation, moderate certainty evidence

Adults should also do muscle-strengthening activities at moderate or greater intensity that involve all major muscle groups on 2 or more days a week, as these provide additional health benefits.

Strong recommendation, moderate certainty evidence

Adults may increase moderate-intensity aerobic physical activity to more than 300 minutes; or do more than 150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous-intensity activity throughout the week for additional health benefits.

Conditional recommendation, moderate certainty evidence

- Doing some physical activity is better than doing none.
- If adults are not meeting these recommendations, doing some physical activity will benefit their health.
- Adults should start by doing small amounts of physical activity, and gradually increase the frequency, intensity and duration over time.

Supporting evidence and rationale

For these guidelines, the synthesis of evidence undertaken by the United States Physical Activity Guidelines Advisory Committee (PAGAC) *(35)* was used and updated.

The GDG considered the entire body of evidence, including both the findings reported by PAGAC and the 28 reviews and 3 pooled cohort studies, published from 2017 through to November 2019, that met inclusion criteria, and contributed evidence on the association between physical activity and healthrelated outcomes in adults. In addition, two umbrella reviews were commissioned to address evidence gaps and examine **i)** the relationship between occupational (i.e. work-related) physical activity and health-related outcomes *(40)*; and **ii)** the association between leisure-domain physical activity and adverse health outcomes *(41)*. The umbrella reviews identified 36 and 15 systematic reviews respectively. Evidence from longitudinal observational studies and intervention trials was prioritized, and reviews that solely, or primarily, synthesized cross-sectional evidence were not considered. Greater emphasis was given to evidence provided by reviews graded moderate certainty and above, and to those providing evidence from studies using device-based measures of exposure.

Full details of the methods, data extraction and evidence profiles can be found in the Web Annex: Evidence profiles .

In adults (aged 18–64 years), what is the association between physical activity and health-related outcomes?

The association between physical activity and **allcause mortality and cardiovascular disease mortality** in adults is already well-established *(1)*. Findings from recent reviews reaffirmed that compared with the lowest levels of physical activity, higher levels of physical activity were associated with a lower risk of mortality. New evidence from studies using device-based measures of physical activity reaffirmed and extended the evidence showing that compared with the lowest levels of physical activity, *any* level and *all intensities* (including light intensity) of physical activity, were associated with a lower risk of mortality *(65)*. For example, compared with the least active (referent, 1.00), adjusted HR for quartiles of total physical activity improved across quartiles of physical activity: 2nd quartile (0.48 [95% CI: 0.43 to 0.54]); 3rd quartile (0.34 [95% CI: 0.26 to 0.45]); and 4th quartile (0.27 [95% CI: 0.23 to 0.32]) *(65)*. New evidence also reaffirmed the well-established *(1)* inverse relationship between physical activity and **cardiovascular disease mortality** *(66)*.

The benefits of physical activity for reducing cardiovascular disease and hypertension incidence is well-documented *(1)*. Physical activity promotes many physiological responses that cause beneficial short- and long-term autonomic and haemodynamic adaptations, resulting in lowered risk of **hypertension**, which is a key risk factor for **cardiovascular disease**.

Evidence reaffirmed an inverse relationship between physical activity and incident hypertension among adults with normal blood pressure, and that physical activity reduces blood pressure among adults with prehypertension and normal blood pressure *(35)*.

The inverse association between physical activity and developing **type-2 diabetes** in adults is wellestablished *(1)*. Recent evidence reaffirmed an inverse curvilinear relationship between higher volumes of physical activity and incidence of type-2 diabetes *(35)*, with a decreasing slope at higher levels of physical activity. A new review found that this effect is consistent across individuals of different backgrounds with a reduced risk of developing type2 diabetes in “highest” versus “lowest” levels of physical activity among non-Hispanic whites (RR=

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relationship between a higher volume of physical activity and lower incidence of type2 diabetes exists for people who have normal weight, overweight or obesity *(35)*.

The associations between higher levels of physical activity and reduced risks of **colon cancer and breast cancer** have been well-established *(1)*. In previous reviews of the evidence, higher levels of physical activity have been found to be associated with a 0.71 [95% CI: 0.60 to 0.85]); Asians (RR= 0.76 [95% CI: 0.67 to 0.85]); Hispanics (RR = 0.74 [95% CI 0.64 to 0.84]); and American Indians (RR = 0.73 [95% CI: 0.60 to 0.88]), although the effect among non-Hispanic blacks was not significant (RR = 0.91 [95% CI: 0.76 to 1.08]) *(67)*. Evidence suggests there is no effect modification by weight status and that the inverse reduced risk of developing breast cancer and colon cancer *(1)*. Following an extensive increase in physical activity and cancer research, there is new evidence demonstrating higher levels of physical activity are also associated with reduced risk of developing bladder, endometrial, oesophageal adenocarcinoma, gastric and renal cancers, as well as reaffirming that physical activity is protective for breast cancer and colon cancer *(35)*. Higher levels of physical activity are associated with risk reductions ranging from approximately 10–20% *(35)*. For example, one review reported an inverse association with liver cancer risk when comparing high levels of physical activity to low levels of physical activity (HR= 0.75 [95% CI: 0.63 to 0.89]) *(68)*. There is insufficient evidence on the association between increased physical activity and decreased risks of hematologic, head and neck, ovary, pancreas, prostate, thyroid, rectal and brain cancer *(35)*. While evidence suggests a reduction in risk of lung cancer between the highest versus lowest levels of physical activity, these findings may be confounded by of weight gain in adults *(35)*. Further research is needed to establish consistent results and strength of associations.

Research on physical activity and **mental health, cognition and sleep** has increased substantially since the development of the 2010 *Global recommendations on physical activity for health (1).* At that time, there was sufficient evidence to conclude only that physical activity may reduce the risk of depression and cognitive decline in adults. tobacco use and it was determined that overall there is insufficient evidence to establish an association.

The association between physical activity and **adiposity** in adult populations is less well established despite a large, but heterogenous, body of evidence assessing this relationship across various outcome measures (weight gain, weight change, weight control, weight stability, weight status and weight maintenance) *(35, 69, 70)*. Overall the evidence shows that higher levels of physical activity may be associated with more favourable measures of adiposity and attenuation New evidence reviewed for these guidelines showed that adults engaging in higher versus lower physical activity are at reduced risk of developing anxiety and depression. For example, adults with high, versus low, levels of physical activity were at reduced odds of developing anxiety (AOR= 0.81 [95% CI: 0.69 to 0.95]) *(71)* or depression (AOR= 0.78 [95% CI: 0.70 to 0.87) *(72)*. Greater amounts of moderate- to vigorous-intensity physical activity are associated with improvements in cognition (e.g. processing speed, memory, and executive function) *(35)*, brain function and structure, and a reduced risk of developing **cognitive impairment**, including Alzheimer's disease *(73–76)*. The evidence included several adult populations representing a gradient of normal to impaired cognitive health status and the beneficial effects of physical activity were reported

across a variety of types, including aerobic activity, walking, muscle-strengthening activity, and yoga *(74)*. There is evidence that both acute bouts and regular physical activity improve **sleep and healthrelated quality of life** outcomes in adults *(35)*.

Evidence examining physical activity and **symptoms of depression, symptoms of anxiety, and the development of anxiety and depression** indicated that physical activity was associated with reduced symptoms of anxiety *(77, 78)* and reduced symptoms of depression

(77, 79).

All physical activity comes with some risk. Evidence from a commissioned review on the adverse effects,

cardiovascular disease and type-2 diabetes.

evidence *(35)* indicates sudden cardiac adverse events are rare and associated with acute sessions of relatively vigorousintensity physical activity. Generally, the risks of adverse events are very low with moderate-intensity physical activity and when increases in physical activity frequency, intensity and duration are gradual *(35)*.

The GDG concluded that:

- There is high certainty evidence that any level and any intensity of physical activity is associated with lower risk of all-cause mortality and cardiovascular disease mortality, incidence of hypertension,

  the associations between higher levels of physical activity and lower risk of incidence of site-specific

as all-cause mortality, cardiovascular disease mortality, incident type-2 diabetes *(67)*, and incident

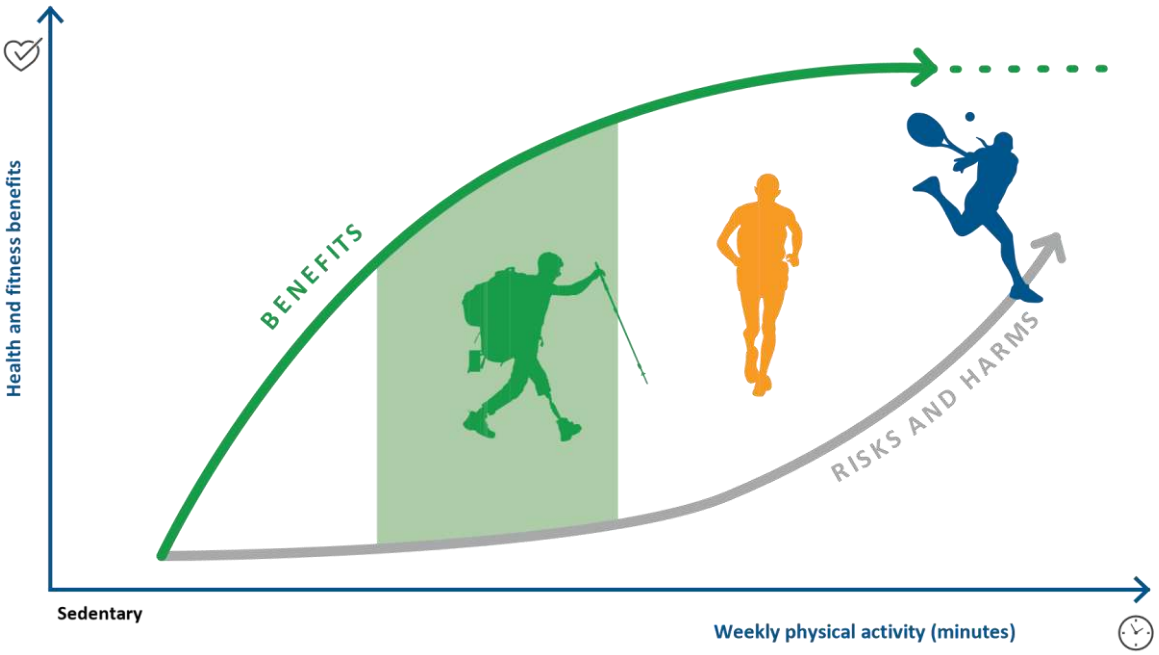

Figure 1: ***Dose response curve***

- There is moderate to high certainty evidence on injuries and harms associated with leisure physical

site-specific cancers in adults. As described in **Figure** cancers.

activity in adults *(41)* suggests an unfavourable association between levels of leisure-time physical activity and musculoskeletal injuries, and a favourable relationship between leisuretime physical activity and risk of fracture and onset of knee or hip osteoarthritis. Additional existing

- There is moderate certainty evidence supporting an association between physical activity and improvements in mental health, cognitive health and sleep outcomes.
- There is evidence of an association between higher levels of physical activity and more

favourable measures of adiposity and attenuation of weight gain in adults.

- There is low certainty evidence that physical activity recommended for adults will not be harmful and that the health benefits from such activity outweigh the risks.

Is there a dose-response association (volume, duration, frequency, intensity)?

Overall the evidence across cardiovascular and metabolic health outcomes shows a consistent curvilinear inverse dose-response relationship between physical activity and major outcomes such

, the shape of the dose-response curve indicates that there is no lower threshold for benefit, and the greatest benefits are seen at the lower end of the dose-response curve *(65)*. The curvilinear inverse association is consistently reported and across studies using different measures of physical activity. Important new evidence was provided in a metaanalysis of eight prospective cohort studies, with mean follow-up of 5.8 years (range 3–14.5 years) *(65)* that reported the adjusted HR for quartiles of total physical activity using device-based measures of exposure and **all-cause mortality**. The results showed a doseresponse with increasing volume of physical activity and benefits of higher levels of *any* intensity of physical activity compared with the least active (referent, 1.00): 2nd quartile (adjusted HR= 0.48 [95% CI: 0.43 to 0.54]); rd quartile (adjusted HR= 0.34 [95% CI: 0.26 to 0.45]); and 4th quartile (adjusted HR= 0.27 [95% CI: 0.23 to 0.32]). Maximal risk reductions for moderate- to vigorousintensity physical activity were observed at 24 minutes per day (equivalent to 168 minutes per week), which closely reflects the recommendation of 150 minutes per week, and provides new device-based evidence reinforcing the existing global guidance to adults of 150–300 minutes of physical activity per week *(65)*. These findings are consistent with the evidence from existing reviews *(35)* and the other new identified reviews *(66)*.

At the upper end, higher levels of physical activity continue to provide benefits in terms of reduced risk of mortality with no increased risk of harms. For example, evidence from a new review with findings from a metaanalysis of individual data from device-based measures of exposure *(65)*, indicates that although reduced risk of mortality is observed up to 750 minutes of moderate- to vigorous-intensity physical activity per week, the relative risk of mortality levels off beyond 300 minutes per week. These results accord with previous evidence which consistently showed that more physical activity is associated with further health benefits, although the relative benefits are reduced at higher levels of physical activity *(35, 80, 81)*. There is, however, insufficient evidence to identify the exact physical activity level where diminished returns of health benefits begin for adults.

Evidence also reaffirmed the well-established inverse relationship between physical activity and **cardiovascular disease mortality**, providing additional evidence of a dose-response relationship well beyond current recommended volumes of physical activity.

A meta-analysis of 48 prospective studies assessing physical activity (total, leisure, and occupational) provided additional evidence of a dose-response relationship *(66)* well beyond current recommended volumes of physical activity. Compared with the recommended level of 750 MET minutes per week, participation in 5000 MET minutes per week (1000 minutes of moderate-intensity activity) resulted in a significantly lower risk for cardiovascular disease mortality (HR= 0.73 [95% CI: 0.56 to 0.95]) *(66)*.Previous WHO recommendations *(1)* concluded that aerobic activity should be performed in bouts of at least 10 minutes duration. However, new

evidence, using device-based assessments, demonstrates that physical activity of *any* duration, without a minimum threshold, is associated with improved health outcomes, including all-cause mortality *(65, 82)*. For example, new evidence from reviews of studies assessing physical activity by accelerometry reaffirms similar associations between all indices of physical activity and all-cause mortality, with hazard ratios of 0.27 for total physical activity, 0.28 for 5-minute bouts, and 0.35 for 10-minute bouts, comparing the highest versus lowest quartiles *(83)*. These results, reaffirmed by findings in the new review by Ekelund et al. 2019 *(65)*, provide evidence that physical activity of any bout duration is associated with improved health outcomes, including all-cause mortality *(82)*. Based on new evidence, the recommendation for bouts of least 10 minutes duration has been removed.

Although evidence showing the associations between higher levels of physical activity and lower risk of incidence of **site-specific cancers** was deemed to be consistent overall, there is insufficient evidence to determine the specific levels of physical activity that correspond to the reported risk reduction due to the large heterogeneity in the assessment and classification of exposure across studies. There is however, no evidence to suggest that there is a lower threshold below which no beneficial effect of physical activity is evident, thus suggesting that any level of physical activity can confer benefit on reducing the risk of site-specific cancers. Future research assessing the nature of the doseresponse and using more consistent measures and reporting is needed to inform future guidelines.

Although there is a large body of evidence on the associations between physical activity and various measures of adiposity, weight gain and the management of a healthy weight status *(35)*, currently there is insufficient evidence to describe more specifically the dose-response relationship or identify a threshold of effect. Further research is needed to inform future guidelines.

Greater amounts of moderate- to vigorous-intensity physical activity are associated with improvements in **cognition** (e.g. processing speed, memory, and executive function) *(35)*, brain function and structure, and a reduced risk of developing **cognitive impairment**, including Alzheimer's disease *(73–76)*. There is evidence that both acute bouts and regular physical activity improve **sleep and health-related quality of life** outcomes in adults *(35)*. There is however insufficient evidence to describe more specifically the dose-response relationship between physical activity and individual mental and cognitive health outcomes. Similarly, more evidence is needed to further describe the dose-response relationship between volume and/or intensity of aerobic physical activity and muscle-strength training and specific health outcomes. Such information is key to establishing minimal effective doses and maximum safety thresholds of physical activity for different population subgroups.

The GDG concluded that:

- There is evidence that more physical activity is associated with larger effects on health outcomes, although the relative benefits level off at higher levels of physical activity. There was insufficient evidence to identify the exact level where diminished returns start to occur.
- There is high certainty evidence that higher levels of physical activity are associated with lower risk of allcause mortality, cardiovascular disease mortality, cancer mortality, cardiovascular disease incidence, and incidence of hypertension and type-2 diabetes, with no increased risk of harms.
- There is moderate certainty evidence that physical activity of any duration is associated with

improved health outcomes, and prior specification that aerobic activity should be performed in bouts of at least 10 minutes duration should be removed.

- There is evidence that higher amounts of physical activity may be associated with more favourable measures of adiposity and attenuation of weight gain in adults and there is a low risk that physical activity will be harmful for the management of healthy weight status in adults.

- There is moderate certainty evidence that 150–300 minutes of moderate intensity aerobic physical activity or equivalent, per week, reduces risk for multiple health outcomes, and risk reduction continues, but starts to plateau, beyond 300 minutes per week.

Does the association vary by type or domain of physical activity?

Evidence shows that different types of physical activity and physical activity undertaken in different domains (i.e. occupation, transport, or leisure) can provide favourable health outcomes. For all-cause and cardiovascular disease mortality, undertaking aerobic physical activity alone, or combining with strength-promoting exercise shows beneficial associations, although performing recommended levels of both types is optimal *(84)*.

More recent moderate certainty evidence indicates that muscle-strengthening physical activity, independent of aerobic physical activity, is also associated with lower risk of all-cause mortality. Results reported by Stamatakis et al. (2018), from a pooled analysis of 11 cohorts examining the 2 days per week muscle-strengthening exercise recommendation against all-cause mortality, showed that undertaking both aerobic and musclestrengthening physical activity at recommended levels *(1)* versus not meeting either recommendation (adjusted HR= 0.71 [95% CI: 0.57 to 0.87]) as well as adherence to just the strength exercise recommendation versus not adhering (HR= 0.80 [95% CI: 0.70 to 0.91]) was associated with significantly lower risk of all-cause mortality *(84)*. These data affirm that health benefits associated with muscle-strengthening exercise were independent of aerobic physical activity and also provide evidence to support recommending a frequency of 2 days per week of musclestrengthening exercise. Other findings reported by Dinu et al. (2019) provided supporting evidence reaffirming that physical activity undertaken in domains other than leisure (or recreation) can be beneficial and specifically showed that active commuting (i.e. walking and cycling for transport) can significantly lower risk of all-cause mortality (RR= 0.92 [95% CI: 0.85–0.98]) *(85)*.

Recent research provides evidence demonstrating that for those who participate in active commuting (i.e. walking or cycling for transport), there is reduced risk of cardiovascular disease (coronary heart disease, stroke and heart failure) compared with those participating in no active commuting (RR= 0.91 [95% CI 0.83 to 0.99]) *(85)*; and that there is sufficient evidence from these health outcomes to conclude that activity in different domains can be beneficial. However, there is insufficient evidence to differentiate the effect of different domains of physical activity on every health outcome. For example, there is insufficient evidence to determine if the association between physical activity and cancer risk or type-2 diabetes incidence varies by type or domain of physical activity. For mental health outcomes, evidence *(35)* shows that a variety of types of physical activity, including aerobic activity, walking, muscle-strengthening activity, and yoga can provide beneficial effects for reducing symptoms of depression and development of anxiety *(74, 79, 86)*. For example recent evidence for the beneficial effects of resistance exercise interventions and mental health was provided by two reviews reporting moderately large reductions in symptoms of depression (77) and small reductions in symptoms of anxiety *(78)* compared with control conditions.

Evidence from a new review affirmed that high levels of occupational physical activity is associated with reduced risk of many cancers, coronary heart disease, and type2 diabetes *(40)*. However, higher levels of occupational physical activity may also be associated with an increased risk of osteoarthritis, poor sleep quality, and all-cause mortality among males (but not among females). There is insufficient evidence to determine the relationship between occupational physical activity and adiposity, prevention of body weight gain, mental health, and health-related quality of life *(40)*. There is also insufficient evidence to determine if the association between physical activity and cancer risk varies by type or domain of physical activity. There is less evidence on associations by different domains of physical activity, and therefore it was difficult to differentiate the effect of different domains of physical activity on various health outcomes.

The GDG concluded that:

- There is moderate certainty evidence that musclestrengthening activities undertaken on 2 or more days a week, provide additional health benefits, but there is insufficient evidence to specify a specific duration for optimal health benefits.

- There is moderate certainty evidence that physical activity undertaken in different domains (e.g. leisure, transport, occupational) can provide health benefits, although currently it is not possible to differentiate the effect of different domains of physical activity on various health outcomes.

- Although higher levels of occupational physical activity may be associated with an increased risk of osteoarthritis, poor sleep quality, and all-cause mortality among males (but not among females), overall there is moderate certainty evidence that occupational physical activity can provide health benefits.

SEDENTARY BEHAVIOUR RECOMMENDATION

For adults, sedentary behaviour is defined as time spent sitting or lying with low energy expenditure, while awake, in the context of occupational, educational, home and community settings, and transportation.

In adults, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality, cardiovascular disease mortality and cancer mortality and incidence of cardiovascular disease, cancer and type-2 diabetes.

It is recommended that:

› **Adults should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.**

Strong recommendation, moderate certainty evidence

› **To help reduce the detrimental effects of high levels of sedentary behaviour on health, adults should aim to do more than the recommended levels of moderate- to vigorousintensity physical activity.**

Strong recommendation, moderate certainty evidence

Supporting evidence and rationale

For these guidelines, the synthesis of evidence undertaken by PAGAC *(35)* was used and updated. The GDG considered the entire body of evidence, including both the findings reported by PAGAC and the 13 new reviews that met inclusion criteria, to contribute evidence on the association between sedentary behaviour and healthrelated outcomes in adults. Investigating the association between sedentary behaviour and health outcomes is a relatively new field of public health compared with that of physical inactivity, yet it has developed rapidly in the past decade. Studies have typically measured sedentary behaviour using either **i)** self-report questionnaires which ask about "total time" spent in sedentary behaviours, or time spent in specific behaviours, such as television viewing, computer/screen use, and sitting; or **ii)** device-based assessments. There are no standardized measures or analytical protocols for sedentary behaviour and thus the reporting of results is heterogeneous. Recent methodological developments include the use of device-based assessment of time spent sedentary which can reduce measurement error and other biases inherent in self-reported recall.

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In considering the total body of evidence, the GDG gave greater emphasis to evidence provided by reviews graded moderate and above, taken from reviews providing evidence from studies using measures of total sedentary or sitting time, or device-based measures of sedentary behaviour where available.

Full details of the methods, data extraction and evidence profiles can be found in the Web Annex: Evidence profiles .

Research on the potential adverse health effects associated with sedentary behaviour has rapidly accumulated during the past decade. In more recent studies, notable developments include an increase in evidence reporting on dose-response relationships between sedentary behaviour and multiple health outcomes, and on the interplay between sedentary behaviour and physical activity.

Available online at https://apps.who.int/iris/bitstream/handle/10665/336657/9789240015111-eng.pdf

In adults (aged over 18 years), what is the association between sedentary behaviour and health-related outcomes?

Overall, there is evidence of an association between greater time spent in sedentary behaviour (examined mostly via self-reporting or device-based assessments of sitting or television viewing time) and higher all-cause mortality, cardiovascular mortality, cardiovascular disease incidence and type-2 diabetes incidence *(8, 35, 65, 87)*. For example, supporting evidence includes results from a recent large meta-analysis (*n*= 36 383; mean age 62.6 years; 72.8% women) of accelerometer assessed total sedentary time and **all-cause mortality** *(65)* and showed that increasing time spent in sedentary behaviour was significantly associated with all-cause mortality. Similar findings from a meta-analysis comprising more than 1 million participants *(87)* showed associations for total sedentary behaviour with **all-cause mortality**, and **cardiovascular disease mortality**, after adjustment for physical activity *(87)*, although in this study the associations with **cancer mortality** were not statistically significant after adjustment for physical activity *(87)*.

Another recent meta-analysis *(8)* reported significant associations between sedentary behaviour (assessed as sitting) and **cardiovascular disease and cancer mortality**, with results indicating a 9–32% (*p* for trend < 0.001) higher risk of cardiovascular disease mortality with higher levels of sedentary behaviour when measured as sitting time in the "inactive", lowest quartile of physical activity (~ 5 min/day). The study reported that adults who were sedentary (sitting) for more than 8 hours per day had a higher risk of cardiovascular disease mortality, except for those who were "most active" (i.e. > 35.5 METhours/week, or ~ 60–75 mins/ day), where the association was mitigated. Results on the associations between sedentary behaviours and **cancer mortality** were generally weaker, although a 6–21% higher dose-related risk was observed with longer sitting time (particularly > 8 hours/day), but only among those in the lowest quartile of physical activity (< 2.5 METhours/week) *(8)*.

Evidence supports an association between sedentary behaviour (measured as total sitting time) and increased **incident cardiovascular disease** (HR= 1.29 [95% CI: 1.27 to 1.30]) which was attenuated following adjustment for potential covariates, including level of physical activity (HR= 1.14 [95% CI: 1.04 to 1.23]) *(88)*. A review of studies in south-east Asian populations provided evidence of low certainly that greater sedentary time was associated with an increased likelihood of unfavourable

cardiometabolic indicators (including type-2 diabetes, higher BMI, higher blood pressure) *(89)*.

Two recent reviews report on the association of total daily sitting time *(88)* and total sedentary behaviour and television viewing *(87)* with **type-2 diabetes incidence**. Both studies found a higher level of sedentary behaviour was associated with increased risk of type-2 diabetes incidence. For example, a linear association with type-2 diabetes was observed for total sedentary behaviour (RR= 1.01 [95% CI: 1.00 to 1.01] p= < 0.001) and television viewing (RR= 1.09 [95% CI: 1.07 to 1.12] p= < 0.001), when adjusted for physical activity *(87)*.

There is also supporting evidence for a significant association between sedentary behaviour (when measured as time spent viewing television) and **cancer mortality** *(35, 87)*. Several more recent reviews, of low and very low certainty, provide supporting evidence for an association between sedentary behaviours and colorectal cancer *(90)*, but no associations with incident prostate, breast or rectal cancer *(90–93)*. Additional evidence *(35)* reported significant associations between greater time spent in sedentary behaviour and higher risk of developing endometrial, colon and lung cancers *(35)*.

There is low certainty evidence of an unfavourable relationship between time spent in sedentary behaviour and **adiposity** and other indicators of weight status, and whether the relationship between sedentary behaviour and weight status varies by amount of moderate- to vigorous-intensity physical activity. Overall, it was concluded that there was insufficient evidence to inform these recommendations/guidelines and that further research is needed.

There is limited evidence assessing adverse effects of reducing sedentary time. Expert opinion informed the conclusion that recommending the reduction in sedentary time would be unlikely to increase risk of injury, especially if replaced with light-intensity physical activity.

The GDG concluded that:

- Overall there is sufficient evidence to support the development of a new WHO recommendation to limit sedentary behaviour to reduce health risks.
- There is moderate certainty evidence of an association between greater time spent in sedentary behaviour and higher all-cause mortality, cardiovascular disease mortality, cancer mortality and incidence of cardiovascular disease and type-2 diabetes.
- There is low to moderate certainty evidence of an association between greater time spent in sedentary behaviour and higher risk of incident endometrial, colon, and lung cancers.
- There is insufficient evidence on the association between sedentary behaviour and measures of adiposity and further research is needed.
- The benefits of limiting sedentary behaviour outweigh any potential risks.

Is there a dose-response association (total volume, frequency, duration, intensity of interruption)?

Overall, moderate certainty evidence indicates a nonlinear dose-response relationship between sedentary time (sitting or television viewing time assessed by self-reporting, or by device-based assessments) and allcause mortality, cardiovascular disease mortality, cancer mortality, and incident cardiovascular disease *(8, 35, 87)*.

A recent meta-analysis provided high certainty evidence on the dose-response relationship between accelerometer assessed total sedentary time and **all-cause mortality** *(65)* reporting that increasing time spent in sedentary behaviour was significantly associated with all-cause mortality. The hazard ratios for increasing quartiles of sedentary time were 1.00 (referent; least sedentary); 1.28 (1.09– 1.51); 1.71 (1.36–2.15); and 2.63 (1.94–3.56), after adjustment for potential confounders including time spent in moderate- to vigorousintensity physical activity *(65)*. This analysis of doseresponse relations between sedentary time and mortality showed risk increased gradually from about 7.5–9 hours and was more pronounced at greater than 9.5 hours. Sedentary behaviour of 10 hours and 12 hours each day were associated with 1.48 (1.22–1.79) and 2.92 (2.24–3.83) higher risk of death, respectively *(65)*.

Another recent meta-analysis assessed doseresponse and reported non-linear associations for

total sedentary time and **all-cause mortality** (RR per 1 hour/day = 1.01 (1.00–1.01) for ≤ 8 hours/day; and 1.04 (1.03–1.05) for > 8 hours/day of exposure); and **cardiovascular disease mortality** (RR= 1.01 (0.99–1.02) for ≤ 6 hours/day; and RR= 1.04 (1.03– 1.04) for > 6 hours/day) after adjustment for physical activity *(87)*. In this same study, a small linear dose-response association between **type-2 diabetes** was observed for total sedentary behaviour (1.01 (1.00–1.01)) when adjusted for physical activity and television viewing (1.09 (1.07– 1.12)) *(87).*

Overall, evidence supports that higher amounts of sedentary behaviour are associated with less favourable health outcomes and it was concluded that there is sufficient evidence to support minimizing sedentary time to reduce health risks. However, given the considerable variations in how sedentary behaviour was assessed across reviews (via self-reported sitting time, television viewing time, or device-based (accelerometer) assessments) and the probability that thresholds for sedentary time might vary across health outcomes, by levels of moderate- to vigorous-intensity physical activity, and among population subgroups, there is insufficient evidence to set a time-based (quantified) recommendation.

In addition to overall volume of sedentary behaviour, evidence on the patterns by which sedentary behaviour is accrued was reviewed. However, there was limited evidence to make recommendations on the frequency and/or duration of breaks in sedentary behaviour.

The GDG concluded that:

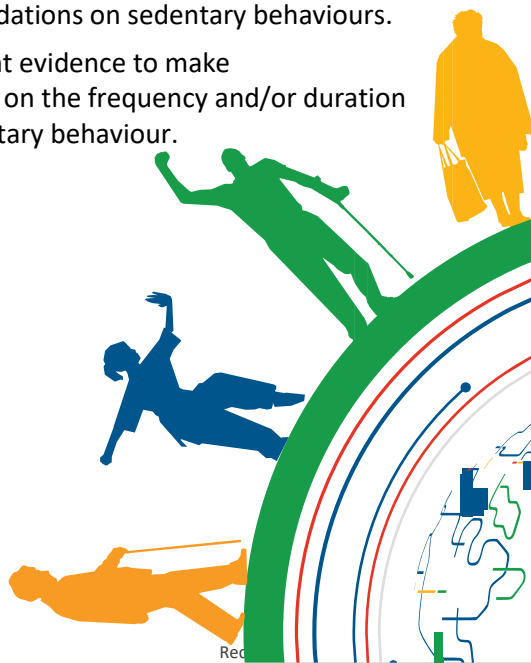
Does the association vary by type and domain of sedentary behaviour?

Some domains or different types of sedentary behaviour may be more detrimental than others, both in terms of their direct associations and in their potential to displace time spent in more healthful physical activity. Although there has been a rapid growth in research on sedentary behaviour, there is limited evidence available directly comparing the association between different types of sedentary behaviour and different health outcomes. For example, some studies report stronger results with sedentary behaviour measured as television viewing compared with total sitting time *(87)*. This may be due to the differential measurement error or residual confounding associated with self-report measures and instruments. Currently, there is insufficient evidence to determine the different associations with different health outcomes and how these may vary by subpopulation.

A growing number of studies are using devicebased measures of physical activity and sedentary time in relation to health outcomes. However, some misclassification may occur from device-based measures of sedentary time as many of these device placements (e.g. wrist, waist) do not currently distinguish between positions (e.g. lying, sitting and standing still). Future research using harmonized reporting, and methods that distinguish between positions, will help to strengthen the knowledge on the patterns of sedentary behaviour.

The GDG concluded that:

- There is insufficient evidence to set quantified (time based) recommendations on sedentary behaviours.
- There is insufficient evidence to make recommendations on the frequency and/or duration of breaks in sedentary behaviour.



- There is insufficient evidence to make recommendations on different types or domains of sedentary behaviour.

Does level of physical activity modify the effect of sedentary behaviour on mortality?

The increased interest in the impact of sedentary behaviour on health outcomes has stimulated investigation into the potential interplay between different levels of physical activity and levels of sedentary behaviour. Based on available research, there is moderate certainty evidence that the relationship between sedentary behaviour and **all-cause mortality**, **cardiovascular disease mortality** and **cancer mortality** varies by amount of moderate- to vigorous-intensity physical activity *(8, 9, 35)*. Overall findings show that the effect of sedentary behaviour is stronger in those who do low amounts of moderate- to vigorous-intensity physical activity or, phrased conversely, that higher amounts of moderate- to vigorousintensity physical activity can mitigate the unfavourable health outcomes associated with higher levels of sedentary behaviours.

The risk associated with sedentary time and allcause mortality has been shown to be more pronounced at lower levels of physical activity than at higher levels *(35)*. In a harmonized meta-analysis, Ekelund et al. investigated the joint and stratified effects of sedentary behaviour and physical activity with **all-cause mortality** in more than 1 million men and women, and showed that the associations differed depending on the level of physical activity *(9)*. The analyses used quartiles of sedentary behaviour (sitting) and quartiles of moderate- to vigorous-intensity physical activity, and found that compared with the referent (< 4 hours of sitting per day and highest quartile of moderate- to vigorousintensity physical activity [> 35.5 MET-hours/ week]), there was no increased risk of dying during follow-up in those who sat for more than 8 hours per day but who also reported more than 35.5 METhours per week of activity (HR= 1.04 [95% CI: 0.99 to 1.10]) . In contrast, those who sat the least (< 4 hours/ day) and were in the lowest (< 2.5 METhours/week) physical activity quartile had a significantly increased risk of dying during follow-up (HR= 1.27 [95% CI: 1.22 to 1.31]). The study concluded that levels of moderate- to vigorousintensity physical activity of about 60–75 minutes per day (the highest quartile) can attenuate, and even eliminate, the detrimental association between sedentary behaviour and health outcomes *(9)*.

behaviour and moderate- to vigorous-intensity physical activity was summarized in the systematic review by PAGAC *(35)* as shown in **Figure 2**.

Another recent study provided new evidence investigating the same associations with causespecific mortality and showed similar findings *(8)*. In a large harmonized meta-analysis (9 studies, *n*= 850 000, CVD mortality; 8 studies, *n*= 777 000, cancer mortality), results showed that higher levels of moderate- to vigorousintensity physical activity mitigated the increased risk of **cardiovascular disease mortality** with high levels of sedentary behaviour, whether measured as time spent sitting or time spent viewing television *(8)*. The study showed that in individuals who were sitting for more than 8 hours per day, there was an association with higher risk of death, except in the most active quartile, where the association was mitigated. More specifically, the hazard of cardiovascular disease mortality was 32% higher in those who sat for more than 8 hours per day compared with the reference group (< 4 hours/day) *(p* for trend < 0.001). The results were less pronounced but remained significant compared with the reference group for HR= 1.11 [95% CI: 1.03 to 1.20]; 3rd quartile, HR= 1.14 [95% CI: 1.03 to 1.26]). Similar associations were observed for television time and cardiovascular disease mortality across strata of moderate- to vigorousintensity physical activity *(8)*. The associations for **cancer mortality** were more mixed, although generally showed that higher levels of physical activity attenuated the detrimental effects of sedentary behaviour when assessed as total sitting time.

Based on this evidence, it was agreed that higher levels of moderate- to vigorous-intensity physical activity should be recommended for those the other quartiles of physical activity (2nd quartile, individuals who undertake high levels of sedentary

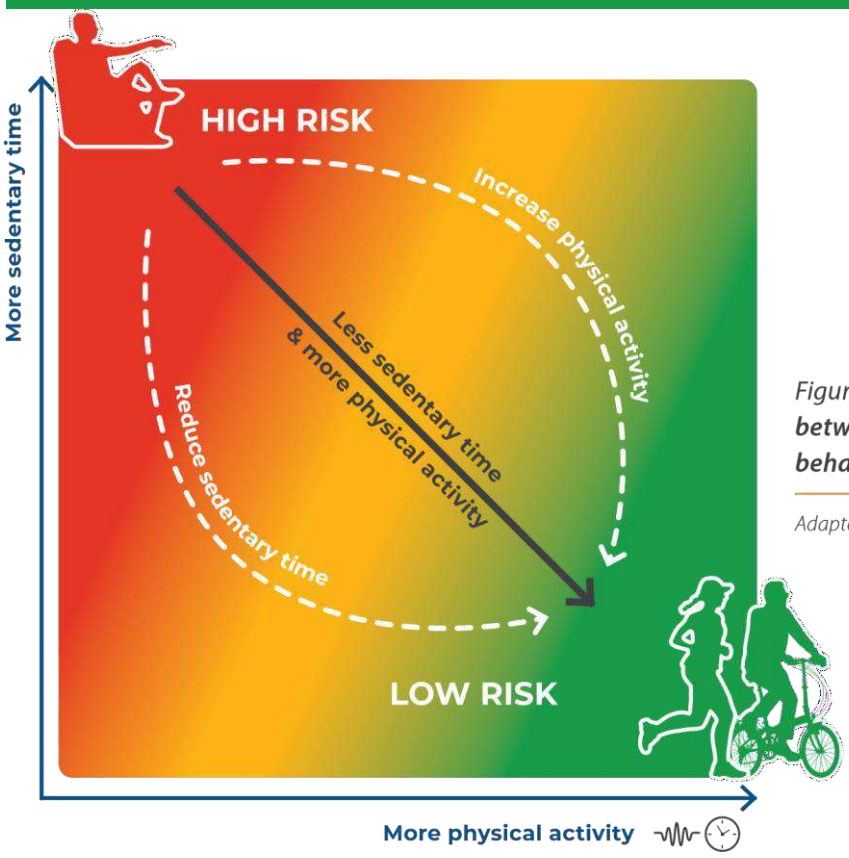


Figure 2: ***The relationship between levels of sedentary behaviour and physical activity***

Adapted from PAGAC

This relationship between levels of sedentary

behaviour and that the benefits would outweigh the risks.

The GDG concluded that:

- There is moderate certainty evidence that the relationship between sedentary behaviour and all-cause mortality, cardiovascular disease and cancer mortality varies by amount of moderate- to vigorous-intensity physical activity.
- Higher amounts of moderate- to vigorousintensity physical activity can attenuate the detrimental association between sedentary behaviour and health outcomes.

PHYSICAL ACTIVITY RECOMMENDATION

For older adults, physical activity can be undertaken as part of recreation and leisure (play, games, sports or planned exercise), transportation (wheeling, walking and cycling), work, or household chores, in the context of daily occupational, educational, home or community settings.

In older adults, physical activity confers benefits for the following health outcomes: improved all-cause mortality, cardiovascular disease mortality, incident hypertension, incident sitespecific cancers, incident type-2 diabetes, mental health (reduced symptoms of anxiety and depression), cognitive health, and sleep; measures of adiposity may also improve. In older adults, physical activity helps prevent falls and falls-related injuries and declines in bone health and functional ability.

It is recommended that:

- **All older adults should undertake activity.** *Strong recommendation, moderate certainty evidence*
- **As part of their weekly physical activity, older adults should do varied multicomponent physical activity that emphasizes functional balance and strength training at moderate intensity, on 3 or more days a week, to enhance functional capacity and prevent falls.** *Strong recommendation, moderate certainty evidence*
- **Older adults should do at least 150–300 minutes of moderate-intensity aerobic physical activity; or at least 75–150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous- intensity activity throughout the week, for substantial health benefits.** *Strong recommendation, moderate certainty evidence*
- **Older adults may increase moderate intensity aerobic physical activity to more than 300 minutes; or do more than 150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous- intensity activity throughout the week, for additional health benefits.** *Conditional recommendation, moderate certainty evidence*
- **Older adults should also do muscle strengthening activities at moderate or greater intensity that involve all major muscle groups on 2 or more days a week, as these provide additional health benefits.** *Strong recommendation, moderate certainty evidence*

- Doing some physical activity is better than doing none.
- If older adults are not meeting the recommendations, doing some physical activity will bring benefits to health.
- Older adults should start by doing small amounts of physical activity, and gradually increase the frequency, intensity and duration over time.
- Older adults should be as physically active as their functional ability allows, and adjust their level of effort for physical activity relative to their level of fitness.

Supporting evidence and rationale

For these guidelines, for older adults, the comprehensive synthesis of evidence undertaken by PAGAC *(35)* was used and updated. Fifteen reviews met the inclusion criteria and informed the examination of the association between physical activity and health-related outcomes specific to older adults (falls prevention, fall-related injuries, physical function, frailty, and osteoporosis).

The evidence for falls prevention used and updated the 2019 Cochrane Collaboration Systematic Review by

Sherrington et al. *(42)*, with evidence published from the end search date of their original review, to November 2019 (9 new studies). A search for existing systematic reviews on osteoporosis and sarcopenia was conducted in PubMed for reviews published from 2008 through to November 2019 and identified no new reviews and 8 new studies.

Full details of the methods, data extraction and evidence profiles can be found in the Web Annex: Evidence profiles .

A further review of evidence was conducted to examine and inform on the association between physical activity and health-related outcomes specific to older adults, including falls prevention, fall-related injuries, physical function, frailty and osteoporosis.

Declining physical capacity in older people often manifests in falls and fall-related injuries that can have serious consequences. Accidental falls are due to a combination of extrinsic (environmental) and intrinsic (e.g. musculoskeletal or nervous system abnormalities affecting postural control) factors. Evidence demonstrates that physical activity – in particular multicomponent physical activity programmes that include combinations of balance, strength, endurance, gait, and physical function training – is associated with a reduced rate of **falls**

In older adults (aged 65 years and over), what is the association between physical activity and health-related outcomes?

The primary evidence base for assessing the associations between physical activity and health outcomes, such as all-cause and cause-specific mortality, cardiovascular disease, type-2 diabetes, cancer incidence, adiposity, mental health, and cognitive outcomes in older adult populations was the same scientific literature collated and reviewed for adult populations. This same body of evidence was accepted and extrapolated to older adults because the majority of studies stated no upper age limit criterion and therefore included adults over the age of 65 years.

and risk of **injury from falls** in older adults. Recent evidence demonstrates that exercise may reduce the rate of falls by as much as 23% (pooled rate ratio (RaR) 0.77 [95% CI: 0.71 to 0.83]) in older adults, which can significantly reduce the risk of injury from falls, including severe falls that result in bone fracture, head trauma, open wound, soft tissue injury, or any other injury requiring medical care or admission to hospital *(42)*. This evidence was consistent with, and reaffirmed findings in, other reviews *(35).*

After reaching a peak in early adulthood, muscle and bone mass tends to decline with increasing age (i.e. sarcopaenia and osteopaenia/osteoporosis), and this can be associated with declining strength and physical function. Evidence demonstrates that regular physical activity improves **physical function** and reduces the risk of age-related loss of physical function in older adults. Findings show beneficial effects on dynamic balance

(SMD= 1.10 [95% CI: 0.29 to 1.90]); muscle strength

(SMD= 1.13 [95% CI: 0.30 to 1.96]); flexibility (SMD= 1.22

[95% CI: 0.39 to 2.04]); and cardiorespiratory fitness (SMD= 1.48 [95% CI: 0.42 to 2.54]) *(94)*. Evidence also shows that higher levels of physical activity may improve bone health and thus prevent **osteoporosis** in older adults (pooled standardized effect size 0.21 [95% CI: 0.06 to 0.36]) *(95)*. Physical activity interventions may improve lumbar spine and femoral neck (hip) bone mineral density.

The GDG concluded that:

- There is moderate certainty evidence that physical activity improves physical function and reduces risk of age-related loss of physical function in the general ageing population.
- There is low-certainty evidence that the risks for the amounts and types of physical activity recommended for older adults are low and are outweighed by the benefits.

Is there a dose-response association (volume, duration, frequency, intensity)?

Evidence shows an inverse relationship between the amount of physical activity performed by older adults and the risk of physical function limitations. In general, more physical activity (frequency, duration and/or volume) is associated with greater benefits *(35)*. Evidence suggests that fast-intended velocity resistance training may be superior to moderate-velocity resistance training for improvements in general functional capacity (SMD= 0.41 [95% CI: 0.18 to 0.65]; and SPPB (SMD= 0.52 [95% CI: 0.10 to 0.94])) *(96)*.

There is limited evidence examining the doseresponse relationship between physical activity and prevention of falls; however the majority of studies providing supportive evidence show testing a programme consistent with 3 days per week.

The GDG concluded that:

- There is high certainty evidence of an inverse doseresponse relationship between volume of aerobic physical activity and risk of physical functional limitations in the general older adult population.

Does the association vary by type or domain of physical activity?

Physical activity programmes that include combinations of balance, strength, endurance, gait, and physical function training are associated with a reduced rate of falls and risk of injury from falls in older adults.

Evidence from a review of 11 RCT showed that by engaging in a variety of different physical activity interventions (commonly balance and functional

exercises plus resistance exercises), older adults can reduce rate of falls by up to 28% (RaR= 0.72 [95% CI:

0.56 to 0.93]) *(42)*. The effect of resistance exercises was uncertain and based on limited data (RR= 0.97 [95% CI:

0.14 to 6.49]; 1 trial; *n*= 73) *(42)*.

Evidence also suggests that programmes which include multiple exercise types have greater positive effects on bone health (standardized effect size 0.45 [95% CI: 0.20 to 0.71]; *p*= 0.001), compared with those which do not *(95)*.

The GDG concluded that:

- There is high certainty evidence that higher levels of physical activity that combines balance, strength, gait, and functional training (e.g. multicomponent physical activity) are associated with a reduced rate of falls and risk of injury from falls in older adults.

For older adults, sedentary behaviour is defined as time spent sitting or lying with low energy expenditure, while awake, in the context of occupational, educational, home and community settings and

• There is moderate certainty evidence that

involving multiple exercise types may have significant effects on bone health and osteoporosis prevention.

programmes

SEDENTARY BEHAVIOUR RECOMMENDATION

transportation.

Older adults should limit the amount of time spent being sedentary.

In older adults, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality, cardiovascular disease mortality and cancer mortality, and incidence of cardiovascular disease, cancer and incidence of type-2 diabetes.

It is recommended that:

›

Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.

Strong recommendation, moderate certainty evidence

To help reduce the detrimental effects of high levels of sedentary behaviour on health, older adults should aim to do more than the recommended levels of moderate- to vigorousintensity physical activity.

Strong recommendation, moderate certainty evidence

Supporting evidence and rationale

Sedentary behaviour was not included in the 2010 *Global recommendations on physical activity for health (1)*. Due to a lack of population-specific evidence, the primary evidence base for assessing the associations between sedentary behaviour and health outcomes in older adult populations was the same scientific literature collated and reviewed for adult populations because the majority of studies stated no upper age limit criterion and therefore included adults over the age of 65 years. The findings from evidence on sedentary behaviours in the general adult population were reviewed, including assessing if there was evidence that the outcomes would be any different, or would not apply to, or would be contraindicated, for older adults.

Full details of the methods, data extraction and evidence profiles can be found in the Web Annex: Evidence profiles .

These guidelines address physical activity and maternal and fetal health outcomes during pregnancy and the postpartum period. They are for all pregnant and postpartum women, irrespective of age, cultural background, or socioeconomic status. Pregnancy and the period after delivery are stages in a woman's life, and the benefits of being physically active throughout adulthood are detailed in the recommendations provided for adults.

Pregnant and postpartum women should be under the care of a health-care provider for antenatal and postnatal care who can advise on special considerations given their medical history and any contraindications to participating in physical activity during pregnancy or in the postpartum period. These guidelines are public health and populationbased. Clinical guidance should be sought for women with complications associated with pregnancy or delivery. Pregnant and postpartum women should try to meet these recommendations where possible, as able, and without contraindication.

PHYSICAL ACTIVITY RECOMMENDATION

For pregnant and postpartum women, physical activity can be undertaken as part of recreation and leisure (play, games, sports or planned exercise), transportation (wheeling, walking and cycling), work, household chores, in the context of daily occupational, educational, home and community settings.

In pregnant and postpartum women, physical activity during pregnancy and postpartum confers benefits on the following maternal and fetal health benefits: decreased risk of preeclampsia, gestational hypertension, gestational diabetes, excessive gestational weight gain, delivery complications and postpartum depression, and fewer newborn complications, no adverse effects on birthweight; and no increase in risk of stillbirth.

It is recommended that all pregnant and postpartum women <u>without contraindication</u> should:

- **undertake regular physical activity throughout pregnancy and postpartum;**

  Strong recommendation, moderate certainty evidence

- **do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week for substantial health benefits; and**

  Strong recommendation, moderate certainty evidence

- **incorporate a variety of aerobic and muscle-strengthening activities. Adding gentle stretching may also be beneficial.**

  Strong recommendation, moderate certainty evidence

In addition:

-

Women who, before pregnancy, habitually engaged in vigorous-intensity aerobic activity, or who were physically active, can continue these activities during pregnancy and the postpartum period.

Strong recommendation, moderate certainty evidence

GOOD PRACTICE STATEMENTS

- Doing some and duration over time. physical may be performed on a daily basis to reduce the risk of urinary better than incontinence. doing none.
- If pregnant postpartum humidity; not meeting the physical activity;
- Avoid participating in activities which involve physical contact; pose a high risk of falling; or might limit oxygenation such as activities at high altitude, when not normally living at high altitude);
- Avoid activities in supine position after the first trimester of pregnancy;
- Pregnant and postpartum women should start by doing recommendations, doing some physical activity will benefit their health.
- When considering athletic competition, or exercising
- Pelvic floor muscle training activity is

Additional safety considerations for pregnant women when undertaking physical activity are: and

- Avoid physical activity during excessive heat, especially with high women are
- Stay hydrated by drinking water before, during, and after
- significantly above the recommended guidelines pregnant women should seek supervision from a specialist health-care provider;
- Pregnant women should be informed by their health-care provider of the danger signs alerting them as to when to stop; or to limit physical activity and consult a qualified health-care provider immediately should they occur;

WHO guidelines on physical activity and sedentary behaviour

Supporting evidence and rationale

For these *Guidelines on physical activity and sedentary behaviour* (2020) for pregnant and postpartum women, the evidence syntheses from 7 systematic reviews addressing the critical and important outcomes *(28–34)* were used and updated. Four of the 7 reviews met inclusion criteria.

Full details of the methods, data extraction and evidence profiles can be found in the Web Annex: Evidence profiles .

small amounts of activity, and increase by

- Return to physical activity gradually after delivery, and in consultation with a health-care provider, in the case of Caesarean section.

physical activity gradually frequency, intensity

In pregnant and postpartum women, what is the association between physical activity and health-related outcomes?

Physical activity before and during pregnancy can help reduce the risk of common complications of pregnancy. Engaging in physical activity during pregnancy is significantly associated with reduced **gestational weight gain** (MD= 1.14 kg [95% CI: 1.67 to 0.62]) *(97)*, and a reduced risk of **gestational diabetes** (RR= 0.71 [95% CI: 0.57 to 0.89]) *(97)*, as is being physically active before pregnancy (OR= 0.70 [95% CI: 0.57 to 0.85]) *(31, 34, 97)*, including in women with overweight or obesity *(97)*.

Physical activity during pregnancy does not appear to increase the incidence of **gestational hypertension or preeclampsia** *(31)*. Evidence suggests that among pregnant women with overweight or obesity, there is no significant difference in the incidence of gestational hypertension (RR= 0.63 [95% CI: 0.38 to 1.05]) or in preeclampsia (RR= 1.39 [95% CI: 0.66 to 2.93]) between physical activity intervention groups versus standard antenatal care *(97)*.

There have been long-standing concerns about potential adverse effects of maternal physical activity on the developing fetus and delivery. However, recent evidence demonstrates that physical activity is not associated with increased risk of the incidence of **miscarriage, stillbirth or delivery complications** *(32)*. Evidence suggests no difference in the incidence of Caesarean delivery among pregnant women with overweight or obesity between physical activity intervention groups versus standard antenatal care *(97)*.

Physical activity during pregnancy is not associated with increased risk of adverse effects on **birthweight** *(98)* or preterm birth *(32)*, and may even be protective, reducing the overall risk *(98)*, even among pregnant women with overweight or obesity (RR= 1.02 [95% CI: 0.54 to 1.92]) or large-for-gestational-age babies (RR= 0.90 [95% CI: 0.65 to 1.25]) between physical activity intervention groups versus standard antenatal care) *(97)*.

In the postpartum period, mothers can experience many physical and emotional changes. Evidence demonstrates that physical activity during pregnancy may be inversely associated with **postpartum depression** *(29)*. Evidence from a metaanalysis of 6 trials and 11 observational studies of physical activity during pregnancy *(99)* showed a significant inverse relationship between physical activity during pregnancy and postpartum depression (SMD= 0.58 [95% CI: 1.09 to 0.08]). The effect was stronger when limited to 5 studies with at least moderate-intensity interventions (SMD= 0.70 [95% CI:

1.19 to 0.22]) *(99)*.

The GDG concluded that:

- There is high certainty evidence that physical activity during pregnancy may reduce gestational weight gain and risk of gestational diabetes mellitus.
- There is moderate to high certainty evidence that physical activity does not increase the incidence of gestational hypertension.
- There is moderate certainty evidence that physical activity does not increase the incidence of miscarriage, stillbirth or delivery complications; and moderate certainty evidence of a reduced risk of preterm birth for mothers engaged in vigorous-intensity physical activity.

- There is low to moderate certainty evidence that physical activity does not increase the risk of low birth weight, or small-for-gestational-age, or large-forgestational-age babies.
- There is low certainty evidence that physical activity during pregnancy is associated with lower levels of postpartum depression.
- The risks for the amounts and types of physical activity recommended for pregnant and postpartum women are low and are outweighed by the benefits.

Is there a dose-response association (volume, duration, frequency, intensity)?

Across the evidence on physical activity during pregnancy and the postpartum period, the interventions varied in the amount (i.e. dose) of physical activity, both in duration in minutes and frequency per week. In general, the evidence available reflected a frequency of aerobic physical activity of at least 3 times per week, typically for between 30 and 60 minutes. This evidence is taken from studies assessing the health impact of a dose broadly consistent with the amount of activity recommended for the general adult population – namely 150 minutes of moderate-intensity physical activity per week.

While more physical activity (frequency, duration and/or volume) is generally found to be associated with greater benefits, further research is needed to understand in more detail the dose-response relationship. Participating in higher versus lower amounts of leisure time physical activity prepregnancy is associated with a significantly lower risk of gestational diabetes (OR= 0.54 [95% CI: 0.34 to 0.87]) *(100)*. There is also evidence of a small, but significant, reduced risk of preterm birth in babies of mothers who engaged in vigorousintensity physical activity (RR= 0.20 [95% CI: 0.36 to 0.03]) *(98)*. No evidence was identified regarding the safety or additional benefit of exercising at levels significantly above the recommendations.

The GDG concluded that:

- There is insufficient evidence to determine a doseresponse association between physical activity and specific critical health outcomes during pregnancy and the postpartum period.

- The overall evidence shows benefits to critical health outcomes and is based on interventions that are broadly consistent with the amount of physical activity recommended for the general adult population, namely 150 minutes of moderate-intensity physical activity per week.
- There was no reason to alter the amount or frequency of recommended moderate-intensity physical activity for pregnant and postpartum women compared with the general adult population.
- There is moderate certainty evidence of a reduced risk of preterm birth for mothers engaged in vigorousintensity physical activity.

Does the association vary by type or domain or timing (pre-pregnancy, antenatal or postnatal) of physical activity?

Evidence is available from studies that mostly assessed leisure domain physical activity; the type of activity was mostly aerobic (such as walking or swimming), although there is some evidence from or domain or timing (pre-pregnancy, antenatal or postnatal) of physical activity. **The GDG concluded that:**

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studies assessing interventions that also included strength training (e.g. circuit training), or combinations of aerobic and muscle-strengthening exercise. However, overall there is insufficient evidence to determine if the associations between physical activity and health outcomes vary by type

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SEDENTARY BEHAVIOUR RECOMMENDATION

For pregnant and postpartum women, sedentary behaviour is defined as time spent sitting or lying with low energy expenditure while awake, in the context of occupational, educational, home and community settings and transportation.

In pregnant and postpartum women, as in all adults, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality, cardiovascular disease mortality and cancer mortality and incidence of cardiovascular disease, cancer and incidence of type-2 diabetes.

It is recommended that:

Pregnant and postpartum women should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.

Strong recommendation, low certainty evidence

Supporting evidence and rationale

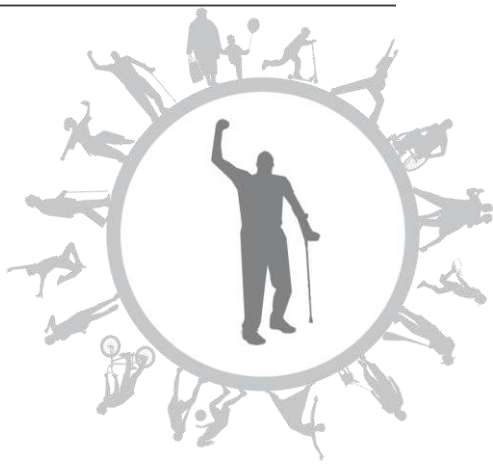
Sedentary behaviour was not included in the 2020 *Global recommendations on physical activity for health (1).* Due to a lack of population-specific evidence, the primary evidence base for assessing the associations between sedentary behaviour and health outcomes in pregnant and postpartum women was the scientific literature collated and reviewed for adult populations.

The findings from evidence on sedentary behaviours in the general adult population were reviewed, including assessing whether the outcomes would be any different, or would not apply to, or would be contraindicated, for pregnant and postpartum women.

Based on available evidence and expert opinion, the evidence was extrapolated to inform the new WHO recommendations on sedentary behaviour for pregnant and postpartum women for the

common set of critical health outcomes. Due to indirectness of the evidence, the level of certainty was downgraded.
Given the lack of evidence specific to this population, and that pregnant women were excluded from studies, the recommendation to increase levels of physical activity beyond recommended levels to counter the detrimental effect of high sedentary behaviour was not extrapolated for women during pregnancy and the postpartum period. **The GDG concluded that:**

- The evidence on sedentary behaviours in the general adult population could be extrapolated to inform recommendations for pregnant and postpartum women for the common set of critical health outcomes.
- The benefits of minimizing sedentary behaviour outweigh the risks for pregnant and postpartum women.
- The certainty of the evidence should be downgraded due to indirectness.



To date, most physical activity guidelines for people with chronic conditions have been limited to clinical or therapeutic guidance. For example, there are clinical practice recommendations and resources developed by the professional medical associations for oncology (101), type-2 diabetes (102), hypertension (103), and other chronic diseases (104). WHO also has clinical practice guidance which includes recommending physical activity to patients with chronic disease (17).

These guidelines are the first WHO population-based guidelines on physical activity for people living with chronic conditions, specifically those living with cancer (from here on referred to as "cancer survivors"), hypertension, type-2 diabetes, and HIV.

Given the advances of effective and widely available antiretroviral treatment for HIV, this condition is now also considered a chronic condition. For patients undergoing acute treatment (e.g. chemotherapy), or not yet stabilized on their chronic medication, health-care providers should also refer to clinical practice guidelines relevant to each chronic condition.

PHYSICAL ACTIVITY RECOMMENDATION

For adults living with chronic conditions, physical activity can be undertaken as part of recreation and leisure (play, games, sports or planned exercise), transportation (wheeling, walking and cycling), work or household chores, in the context of daily occupational, educational, home or community settings.

All adult cancer survivors and those living with hypertension, type-2 diabetes and HIV, should try to meet these recommendations where possible, as able and without contraindication.

> Physical activity can confer health benefits for adults and older adults living with the following chronic conditions: for **cancer survivors** – physical activity improves all-cause mortality, cancer-specific mortality, and risk of cancer recurrence or second primary cancer; **for people living with hypertension** – physical activity improves cardiovascular disease mortality, disease progression, physical function, health-related quality of life; **for people living with type-2 diabetes** – physical activity reduces rates of mortality from cardiovascular disease and indicators disease progression; and **for people living with HIV** – physical activity can improve physical fitness and mental health (reduced symptoms of anxiety and depression), and does not adversely affect disease progression (CD4 count and viral load) or body composition.
>
> Recommendations[62]

It is recommended that:

All adults and older adults with these chronic conditions should undertake regular physical activity.

Strong recommendation, moderate certainty evidence

Adults and older adults with these chronic conditions should do at least 150–300 minutes of moderate-intensity aerobic physical activity; or at least 75–150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous-intensity activity throughout the week for substantial health benefits.

Strong recommendation, moderate certainty evidence

Adults and older adults with these chronic conditions should also do musclestrengthening activities at moderate or greater intensity that involve all major muscle groups on 2 or more days a week, as these provide additional benefits.

Strong recommendation, moderate certainty evidence

As part of their weekly physical activity, older adults with these chronic conditions should do varied multicomponent physical activity that emphasizes functional balance and strength training at moderate or greater intensity on 3 or more days a week, to enhance functional capacity and prevent falls.

Strong recommendation, moderate certainty evidence

When not contraindicated, adults and older adults with these chronic conditions may increase moderate-intensity aerobic physical activity to more than 300 minutes; or do more than 150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous-intensity activity throughout the week for additional health benefits.

Conditional recommendation, moderate certainty evidence

GOOD PRACTICE STATEMENTS

- When not able to meet the above recommendations, adults with these chronic conditions should aim to engage in physical activity according to their abilities.
- Adults with these chronic conditions should start by doing small amounts of physical activity and gradually increase the frequency, intensity and duration over time.
- Adults with these chronic conditions may wish to consult with a physical activity specialist or health-care professional for advice on the types and amounts of activity appropriate for their individual needs, abilities, functional limitations/ complications, medications, and overall treatment plan.
- Pre-exercise medical clearance is generally unnecessary for individuals without contraindications prior to beginning light- or moderate-intensity physical activity not exceeding the demands of brisk walking or everyday living.

Supporting evidence and rationale

The scope of these guidelines assessed the associations between physical activity and the following health outcomes: **for cancer survivors** – all-cause mortality, cancer-specific mortality, and risk of cancer recurrence or second primary cancer; **for people living with hypertension** – cardiovascular disease mortality, risk of co-morbid conditions, physical function, health-related quality of life, and disease progression (here defined as the blood pressure response to physical activity); **for people living with type-2 diabetes** – cardiovascular disease mortality, risk of co-morbid conditions, physical function, healthrelated quality of life, and disease progression; and **for people living with HIV**

– physical function (physical fitness, exercise tolerance and strength), health-related quality of life, mental health (symptoms of anxiety and depression), cardiometabolic disease risk indicators (blood lipids, blood glucose and body composition) and adverse effects on disease progression (namely CD4 count and viral load).

The evidence informing these guidelines was the report of PAGAC *(35)* which was updated with 16 new reviews identified from 2017 to 2019 for cancer (*n*= 1), hypertension (*n*= 2) and type-2 diabetes (*n*= 13). In addition, a commissioned umbrella review on physical activity and health-related outcomes among people living with HIV provided evidence from 19 eligible reviews published 2002–2018. Full details of the methods, data extraction and evidence profiles can be found in the Web Annex: Evidence profiles .

Available online at https://apps.who.int/iris/bitstream/handle/10665/336657/9789240015111-eng.pdf

In adults and older adults (aged 18 years and over) living with cancer (cancer survivors), hypertension, type-2 diabetes, or HIV, what is the association between physical activity and health-related outcomes?

Physical activity promotes beneficial short- and longterm changes in metabolic, hormonal, and inflammatory pathways, which are thought to be protective for **cancer** incidence and survival *(35)*. Evidence shows that higher levels of physical activity after cancer diagnosis were found to be protective for all-cause mortality following breast cancer (HR= 0.58 [95% CI: 0.52 to 0.65], 17 studies); colorectal cancer (HR= 0.63 [95% CI: 0.50 to 0.78], 10 studies), female reproductive cancer (HR= 0.66 [95% CI: 0.49 to 0.88], 4 studies); glioma (HR= 0.64 [95% CI: 0.46 to 0.91], 1 study); hematologic cancer (HR= 0.60 [95% CI: 0.51 to 0.69], 2 studies); kidney cancer (HR= 0.60 [95% CI: 0.38 to 0.95], 1 study); lung cancer (HR= 0.76 [95% CI: 0.60 to 0.97], 2 studies); prostate cancer (HR= 0.60 [95% CI: 0.46 to 0. 79], 5 studies); and stomach cancer (HR= 0.75 [95% CI: 0.61 to 0.93], 1 study) *(105)*.

Greater amounts of physical activity after cancer diagnosis are also associated with lower risks of cause-specific mortality in breast cancer, colorectal cancer, and prostate cancer survivors. The metaanalysis found reduced hazards of mortality for those in the highest versus the lowest levels of postdiagnosis total physical activity for all cancers combined (HR= 0.63 [95% CI: 0.53 to 0.75], 4 studies); breast cancer (HR= 0.63 [95% CI: 0.50 to 0.78], 13 studies); colorectal cancer (HR= 0.62 [95% CI: 0.44 to 0.86], 6 studies); and prostate cancer (HR= 0.70 [95% CI: 0.55 to 0.90], 4 studies) *(105)*. There was, however, insufficient evidence to determine if physical activity is associated with cancer recurrence or second primary cancer.

Physical activity is important for both the primary prevention and management of **hypertension**, with evidence showing that physical activity improves physical function, cardiovascular disease progression (i.e. blood pressure response to physical activity), and cardiovascular disease mortality in people living with hypertension *(35)*. For example, compared with no exercise control groups, people with hypertension who are physically active can reduce systolic blood pressure by approximately 12mm Hg and diastolic blood pressure by approximately 6mm Hg (SBP MD= 12.26 mm Hg [95% CI: 15.17 to 9.34], *p*= < 0.05; DBP MD= 6.12 mm Hg [95% CI: 7.76 to 4.48], *p*= < 0.05) *(106)*. Emerging evidence demonstrates that people with hypertension who are physically active can significantly improve their health-related quality of life compared with those with hypertension who are inactive *(54)*.

Physical activity, including aerobic activity, musclestrengthening activity, and aerobic plus musclestrengthening activity, is associated with improved secondary indicators of risk of progression (HbA1c, blood pressure, BMI, and lipids) in adults with **type-2 diabetes** *(35)*. For example, recent research found that resistance training was associated with greater reduction in HbA1c versus control groups, and that highintensity resistance training has significant positive effects on fasting insulin *(107)*. There is insufficient evidence to assess the effects of physical activity on health-related quality of life and physical function in adults with type-2 diabetes.

Physical activity in people living with **HIV** improves cardiorespiratory fitness. The interventions studied involved either aerobic exercise, or exercise combined with progressive muscle-strengthening exercise, for at least 30 minutes, 3 times per week *(108, 109)*. There is also evidence that physical activity interventions can improve markers of cardiometabolic risk (e.g. lipids) although results are mixed; no effects were established on insulin concentration, although glucose was lowered after aerobic training *(110)*. Physical activity, whether aerobic, or combined with muscle-strengthening exercise, in people living with HIV is positively associated with health-related quality of life *(111)* and a reduction in symptoms of depression and anxiety *(112)*. The metaanalysis for depression (9 studies) showed an SMD of 0.84 (95% CI: 1.57 to 0.11) favouring the intervention groups (p= 0.02). The SMD for reduction in anxiety (5 studies) was also statistically significant, favouring the intervention (1.23 [95% CI: 2.42 to 0.04], p= 0.04) *(112)*. Physical activity is also associated with significant standardized mean increases in lean body mass of 1.75 kg and a significant decrease in percent body fat of 1.12% for participants in the exercising control groups, as well as an increase in peripheral leg and arm muscle area, compared with participants in the non-exercising control groups *(111)*, but is not associated with changes in BMI or waist circumference in people living with HIV *(111)*. Physical activity does not adversely influence markers of HIV disease progression, such as CD4 count (cells/mm^3) or viral load *(111)*. Importantly, this evidence suggests that HIV as a chronic disease will not be adversely affected by physical activity.

The GDG concluded that:

- There is moderate certainty evidence that greater amounts of physical activity after cancer diagnosis are associated with lower risks of all-cause, causespecific, and cancer-specific mortality in cancer survivors.
- There is high certainty evidence that physical activity reduces the risk of cardiovascular disease progression in adults with hypertension.
- There is moderate certainty evidence that physical activity improves physical function and health-related quality of life outcomes in adults with hypertension.
- There is high certainty evidence that physical activity improves markers of disease progression (HbA1c, blood pressure, BMI, and lipids) in adults with type-2 diabetes.
- There is moderate certainty evidence of an association between physical activity and improvements in fitness (maximal oxygen consumption, exercise tolerance) and muscular strength for people living with HIV, and favourable associations between physical activity and body composition, health-related quality of life, reduced symptoms of depression and anxiety, and no change in viral load or CD4 count in people living with HIV.

- The benefits associated with engaging in regular physical activity in cancer survivors and people living with hypertension, type-2 diabetes, and HIV in relation to specific health outcomes, outweigh the risks. ***Is there a dose-response association (volume, duration, frequency, intensity)?***

Greater amounts of physical activity after **cancer** diagnosis have been linked with lower risks of allcause, and cancerspecific mortality. Evidence demonstrates a non-linear relationship between increasing levels of post-diagnosis physical activity and breast cancer-specific and all-cause mortality up to 10–15 MET-hours per week (consistent with 150 mins/week of moderate- to vigorous-intensity physical activity) with no evidence for harms at higher levels *(105)*. There is a suggestion of similar dose-response association for other cancer sites however there were too few studies to permit a formal meta-analysis. Further research is needed to determine strength of association.

There is a clear dose-response relationship between physical activity and cardiovascular disease mortality for people living with **hypertension** *(35)*. Findings show that as systolic blood pressure increases within hypertensive ranges, the risk of cardiovascular disease mortality increases, but this increased risk is attenuated with higher levels of physical activity *(35)*. Similar to recommendations for the general population, most of the traditional interventions are based around 30–60 minutes of moderateintensity aerobic activity, 3 days per week,

and/or 2–3 sessions of resistance training per week.

There is substantial evidence of an inverse curvilinear association between volume of physical activity and risk of cardiovascular mortality in adults with **type-2 diabetes** *(113–115)*. Higher amounts of physical activity (from both below and at, or above the recommended levels of 150 mins/week of moderate-intensity activity) progressively reduce risk. For example, compared with doing no activity, engaging in some activity was associated with a 32% reduction in risk of cardiovascular disease mortality (adjusted HR= 0.68 [95% CI: 0.51 to 0.92]), while engaging in amounts of activity meeting physical activity guidelines or above was associated with a larger 40% reduction in risk of cardiovascular disease mortality (adjusted HR= 0.60 [95% CI: 0.44 to 0.82]) *(115)*. Most interventions are based around 150–300 minutes of moderate-intensity aerobic activity or 75 minutes of vigorous-intensity activity, and/or 2–3 sessions of resistance training per week. For some outcomes (e.g. HBA1c and blood pressure) in adults with type-2 diabetes, there is evidence for a stronger effect with more aerobic activity (i.e. greater than 150 mins/week versus less than 150 mins/week), but limited evidence for intensity *(35)*.

In people living with **HIV**, there is insufficient evidence to establish a doseresponse relationship between physical activity and body composition, or for intermediate markers of cardiometabolic diseases (such as blood lipid profiles, insulin resistance, fasting glucose concentrations or blood pressure). The majority of studies providing evidence involved physical activity interventions conducted at least 3 times a week for 12–48 weeks, and involved at least 30 minutes of moderate- to vigorous-intensity aerobic exercise alone or in combination with progressive resistance training. There is also insufficient evidence to establish more precisely the dose-response relationship for mental health and health-related quality of life outcomes. The available evidence is from studies typically assessing physical activity interventions of 3 or more times weekly.

Overall there was evidence ranging from moderate to high certainty to support a physical activity recommendation of 150–300 minutes of moderateintensity physical activity (or equivalent) for the specified populations of people living with chronic disease and the specific set of health outcomes. There was clearer evidence of higher levels of activity being associated with greater benefits in the evidence addressing people living with hypertension, type-2 diabetes and cancer survivors. The variations in the certainty and directness of the evidence according to the specific chronic condition and specific outcomes examined was acknowledged. Where evidence showed positive outcomes from strength training exercise, the frequency of activity was 2 or 3 sessions of resistance training per week.

The GDG concluded that:

- There is moderate certainty evidence of a doseresponse relationship between physical activity and decreased allcause mortality and cancerspecific mortality in cancer survivors.
- There is high certainty evidence of a doseresponse relationship between physical activity and cardiovascular disease mortality for adults with hypertension.
- There is evidence of an inverse, curvilinear doseresponse relationship between activity volume and risk of cardiovascular mortality among adults with type-2 diabetes.
- There is insufficient evidence for a dose-response relationship between physical activity and intermediate markers of cardiometabolic diseases, body composition, and health-related quality of life symptoms of anxiety and depression in people living with HIV.

- Interventions in the range of 150–300 minutes of moderate-intensity aerobic activity (or equivalent) provided favourable health outcomes, and positive outcomes from strength training exercise, where noted, with 2 or 3 sessions of resistance training per week.

Does the association vary by type or domain of physical activity?

There is evidence that different types and domains of physical activity provide favourable health outcomes. **Cancer survivors** who are meeting recommended levels of aerobic and muscle-strengthening physical activity, versus not meeting either recommendation, have significantly lower risk of cancer mortality (adjusted HR= 0.70 [95% CI: 0.50 to 0.98]) *(84)*. Evidence demonstrates that adhering solely to musclestrengthening physical activity recommendations versus not adhering is also beneficial in improving cancer mortality outcomes (HR= 0.66 [95% CI: 0.48 to 0.92]) *(84)*. A metaanalysis also reported these associations by physical activity domain and found the most consistent reductions in mortality for all cancers, breast cancer, and colorectal cancer-specific mortality for recreational physical activity *(105)*. For adults living with **hypertension**, evidence supports aerobic activity, muscle-strengthening activity, and combinations of the two for improving cardiovascular disease progression. The blood pressure lowering effects between traditional modes of physical activity (i.e. aerobic and resistance activity) do not appear to vary significantly among people with hypertension *(35)*; however, this evidence is not based on direct comparisons between activity types. There is also emerging evidence to support beneficial effects of other forms of exercises in people living with hypertension (e.g. Tai Chi, yoga, Qigong), however further research is needed to explore these specific types of activity to determine strength of association.

Aerobic activity, muscle-strengthening activity, or a combination of both, is associated with improved secondary indicators of risk of progression (HbA1c, blood pressure, BMI, and lipids) among adults with **type-2 diabetes** *(35, 107)*. One review of 24 RCTs (*n*= 962) reported that resistance training was associated with greater reduction in HbA1c versus control groups (MD= 0.45 [95% CI: 0.65 to 0.25], 20 trials; *n*= 824). Statistically significant effects were found for highintensity resistance training versus control groups on fasting insulin (MD= 4.60 [95% CI: 7.53 to 1.67], 5 trials; *n*= 174) *(107)*. Another review of 7 RCTs (*n*= 189) reported that interval training (2–5 times/week; intervals 1–4 mins duration; total session lengths 20–60 mins) was associated with statistically significantly decreased HbA1c by 0.26% (95% CI: 0.46 to 0.07%, 5 RCTs) compared with MICT, and by 0.83% (95% CI: 1.39% to 0.27%, 4 RCTs) compared with no-exercise control groups *(116)*. As with recommendations for the general population, most of these interventions are based around aerobic activity consistent with the recommendation of 150–300 minutes of moderateintensity aerobic activity (or 75 minutes of vigorousintensity activity) and muscle-strengthening activity conducted 2–3 sessions per week. For some outcomes (e.g. HBA1c and blood pressure), there is evidence for a stronger effect with more aerobic activity (i.e. greater than 150 mins/week versus less than 150 mins/ week), but limited evidence for intensity. More recent studies provide evidence that traditional Chinese exercise, such as Tai Chi may have glycaemic benefits, but these were of moderate and variable certainty (i.e. risk of bias or inconsistency). Further research is needed to determine these associations.

Multiple types of physical activity, including aerobic and resistance-training, have been shown to have positive effects on health-related quality of life in people living with **HIV** *(111).* Recent research examining changes in health-related quality of life in response to aerobic, progressive resistance exercise, or a combination of both, demonstrates significant improvements in general health, and mental health. There is also evidence that both aerobic and multicomponent activity is related to a reduction in symptoms of depression and anxiety in people living with HIV *(112)*. Evidence for the effects of physical

activity on mental health symptoms has involved aerobic or aerobic combined with progressive muscle-strengthening activity, or yoga. Evidence also demonstrates that aerobic exercise alone, or when combined with resistance exercise, does not result in any significant change in viral load or CD4 count in people living with HIV *(111)*.

Direct evidence, from both the existing and updated literature, supports the inclusion of the recommendations for people living with type-2 diabetes and hypertension to undertake aerobic and muscle-strengthening physical activity. Although there is a lack of published evidence, there is biological plausibility for the benefits of aerobic and muscle-strengthening physical activity for adults living with HIV and cancer survivors. Furthermore, as noted by the GDG, established international clinical practice guidelines recommend aerobic and musclestrengthening physical activity for these populations (for example ACSM "Moving Through Cancer" guidelines *(101)* based on a systematic review of evidence *(3)*). Recognizing this evidence base is still emerging, the level of certainty was downgraded.

The GDG concluded that:

- There is moderate certainty evidence for combined or additive effects of aerobic or muscle-strengthening activity for reduced cancer mortality, improvements in blood pressure among those with hypertension.
- There is high certainty evidence that aerobic activity, muscle-strengthening activity, and aerobic plus musclestrengthening activity improve markers of disease progression (HbA1C, blood pressure, BMI, and lipids) in adults with type-2 diabetes.
- There is moderate certainty evidence that regular aerobic exercise alone, or combined with resistance exercise, does not result in any significant change in viral load or CD4 count in people living with HIV.

- There is insufficient evidence for an effect of strength training alone on health-related quality of life in people living with HIV.

SEDENTARY BEHAVIOUR RECOMMENDATION

Sedentary behaviour was not included in the 2010 *Global recommendations on physical activity for health (1).* The scope of this new recommendation on sedentary behaviours in cancer survivors and those people living with hypertension, type-2 diabetes and HIV.

Sedentary behaviour is defined as time spent sitting or lying with low energy expenditure, while awake, in the context of occupational, educational, home and community settings, and transportation.

In adults, including **cancer survivors** and people living with **hypertension**, **type-2 diabetes** and **HIV**, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality; cardiovascular disease mortality; cancer mortality; incidence of cardiovascular disease; cancer; and type-2 diabetes.

For cancer survivors, and adults living with hypertension, type-2 diabetes and HIV, it is recommended that:

› **Adults and older adults with chronic conditions should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including light intensity) provides health benefits.**

Strong recommendation, low certainty evidence

› **To help reduce the detrimental effects of high levels of sedentary behaviour on health, adults and older adults with chronic conditions should aim to do more than the recommended levels of moderate- to vigorous-intensity physical activity.**

Strong recommendation, low certainty evidence

Supporting evidence and rationale

Due to a lack of population-specific evidence, the primary evidence base for assessing the associations between sedentary behaviour and health outcomes in adults and older adult cancer survivors and those adults and older adults living with hypertension, type-2 diabetes, and HIV, was the scientific literature collated and reviewed for adult populations.

The findings from evidence on sedentary behaviours in the general adult population were reviewed, including assessing if there was evidence that the outcomes would be any different, or would not apply to, or would be contraindicated, for adults and older adults living with chronic conditions.

Based on available evidence and expert opinion, the evidence was extrapolated to inform the new WHO recommendations on sedentary behaviour for adults living with chronic conditions for the common set of critical health outcomes. The extrapolation of evidence is supported largely by the assessment that the majority of studies imposed no upper age limit criterion, included adults over the age of 65 years and may have included adults with chronic conditions, such as cancer survivors, those living with hypertension or type-2 diabetes. For people living with HIV, no reasons were identified as to why the evidence on the health impacts of sedentary behaviours would not apply. Due to indirectness of the evidence to develop these recommendations, the level of certainty was downgraded.

The applicability of evidence on the benefit of undertaking more moderate- and vigorousintensity physical activity to help counteract the potential risks of high levels of sedentary behaviour was also considered and was also extrapolated to inform recommendations for adults with chronic conditions for the common set of critical health outcomes. Given the indirectness, the certainty of the evidence was downgraded.

The GDG concluded that:

- The evidence on sedentary behaviours in the general adult population could be extrapolated to inform recommendations for adult and older adult cancer survivors and those adults and older adults living with hypertension, type-2 diabetes, and HIV for the common set of critical outcomes, with the level of certainty of the evidence downgraded due to indirectness.
- The evidence on the benefits of undertaking more moderate- and vigorous-intensity physical activity to help counteract the potential risks of high levels of sedentary behaviour in the general adult population could be extrapolated to inform recommendations for adult and older adult cancer survivors and those adults and older adults living with hypertension, type-2 diabetes, and HIV for the common set of critical outcomes, with the level of certainty of the evidence downgraded due to indirectness.

behaviours outweigh the harms for cancer

hypertension, type-2 diabetes, and HIV.

PHYSICAL ACTIVITY RECOMMENDATION

Children, adolescents and adults living with disability can achieve important health benefits from physical activity. Children, adolescents

- The benefits for minimizing sedentary

survivors and those people living with

and adults with disability should try to meet these recommendations where possible and as able.

For children, adolescents and adults living with disability, physical activity can be undertaken as part of recreation and leisure (play, games, sports or planned exercise), physical education, transportation (wheeling, walking and cycling) or household chores, in the context of home, educational, occupational and community settings. It is important to provide all children, adolescents and adults living with

disability with opportunities and encouragement to participate in physical activities appropriate for their age and ability, that are enjoyable, and that offer variety.

benefits of physical activity to health outcomes for those living with disability include:

improved cognition in individuals with diseases or disorders that impair cognitive function, including attention-deficit/hyperactivity disorder (ADHD); improvements in physical function may occur in children with intellectual disability.

It is recommended that:

Children and adolescents living with should do at least an average day of moderate- physical activity, across the week. *Strong recommendation, moderate certainty evidence*

Vigorous-intensity aerobic activities, disability as well as those that strengthen muscle and bone should be incorporated to of 60 minutes per vigorous-intensity, mostly aerobic, at least 3 days a week. *Strong recommendation, moderate certainty evidence*

- Doing some physical activity is better than doing none.
- If children and adolescents living with disability are not meeting these recommendations, doing some physical activity will bring benefits to health.
- Children and adolescents living with disability should start by doing small amounts of physical activity and gradually increase the frequency, intensity and duration over time.
- There are no major risks for children and adolescents living with disability engaging in physical activity when it is appropriate to an individual's current activity level, health status and physical function; and the health benefits accrued outweigh the risks.
- Children and adolescents living with disability may need to consult a health-care professional or other physical activity and disability specialist to help determine the type and amount of activity appropriate for them.

Many of the health benefits of physical activity for children and adolescents, as set out in the section above, also relate to those children and adolescents living with disability. Additional

Many of the health benefits of physical activity for adults, as set out in the section above, also relate to adults living with disability. Additional benefits of physical activity to health outcomes for those living with disability include the following: **for adults with multiple sclerosis** – improved physical function, and physical, mental, and social domains of healthrelated quality of life; **for individuals with spinal cord injury** – improved walking function, muscular strength, and upper extremity function; and enhanced health-related quality of life; **for individuals with diseases or disorders that impair cognitive function** – improved physical function and cognition (in individuals with Parkinson's disease and those with a history of stroke); beneficial effects on cognition; and may improve quality of life (in adults with schizophrenia); and may improve physical function (in adults with intellectual disability); and improves quality of life (in adults with major clinical depression).

It is recommended that:

› **All adults living with disability should regular physical activity.** *Strong recommendation, moderate certainty evidence*

› **Adults living with disability should do balance and strength training at at least 150–300 minutes of moderate moderate or greater intensity on 3 or intensity aerobic physical activity; or more days a week, to enhance functional at least 75–150 minutes of vigorous capacity and prevent falls.**

› **As part of their weekly physical activity, undertake older adults living with disability should do varied multicomponent physical activity that emphasizes functional**

intensity aerobic physical activity; or an *Strong recommendation, moderate certainty evidence* **equivalent combination of moderate- and**

vigorous-intensity activity throughout Adults living with disability may increase the week for substantial health benefits. moderate-intensity aerobic physical

› *Strong recommendation, moderate certainty evidence* **activity to more than 300 minutes; or do more than 150 minutes of vigorous Adults living with disability should intensity aerobic physical activity; or an also do muscle-strengthening activities equivalent combination of moderate- and at moderate or greater intensity that vigorous-intensity activity throughout involve all major muscle groups on 2 the week for additional health benefits. or more days a week, as these provide** *Conditional recommendation, moderate certainty evidence* **additional health benefits.**

Strong recommendation, moderate certainty evidence

GOOD PRACTICE STATEMENTS

- Doing some physical activity is better than doing none.
- If adults living with disability are not meeting these recommendations, doing some physical activity will bring benefits to health.
- Adults living with disability should start by doing small amounts of physical activity, and gradually increase the frequency, intensity and duration over time.
- There are no major risks to adults living with disability engaging in physical activity when it is appropriate to the individual's current activity level, health status and physical function; and when the health benefits accrued outweigh the risks.

- Adults living with disability may need to consult a health-care professional or other physical activity and disability specialist to help determine the type and amount of activity appropriate for them.

Recommendations

Supporting evidence and rationale

For these guidelines for children, adolescents and adults living with disability, the comprehensive evidence synthesis undertaken by PAGAC *(35)* was used and updated. Full details of the methods, data extraction and summary evidence tables of this existing evidence on physical activity and health outcomes is available *(35)* and was reviewed by the GDG in addition to the findings of the updated search.

The update conducted for these guidelines identified 39 reviews published from 2017 to 2019. Of these, 27 met the inclusion criteria and informed the examination of the association between physical activity and health-related outcomes among children, adolescents and adults living with disability.

Full details of the methods, data extraction and summary evidence portfolios can be found in the Web profile s .

Annex: Evidence

The evidence reviewed considered the association between physical activity and health-related outcomes in children, adolescents and adults living with disability resulting from the following health conditions: multiple sclerosis, spinal cord injury, intellectual disability, Parkinson's disease, stroke, major clinical depression, schizophrenia, and attention-deficit/hyperactivity disorder (ADHD). The four health-related outcomes examined included risk of co-morbid conditions, physical function, cognitive function and health-related quality of life, although not all outcomes were explored for each condition. The impact of environmental factors on disability in the context of physical activity was beyond the scope of these guidelines and was not analysed.

In children and adolescents (aged 5–17 years) and adults (aged over 18 years) living with disability, what is the association between physical activity and health-related outcomes?

For people living with **multiple sclerosis**, physical activity improves physical function, functional mobility, walking speed and endurance, and cardiorespiratory fitness, strength and balance. For example, high-intensity interval training over 3–12 weeks demonstrated improvements in cardiorespiratory fitness or muscle strength *(117)* and lower limb strength training found strength increased by 23.1% (95% CI: 11.8 to 34.4) over an average training period of 13.2 weeks *(118)* over an average of 13 weeks resulted in increases in strength, and dance interventions studies reported improvements in functional mobility and balance *(119)*. As well as physical health benefits, existing evidence demonstrates that physical activity can benefit cognition in people living with multiple sclerosis *(35)*. Newer research reveals that aerobic exercise has a small yet significant effect on physical, mental and social domains of health-related quality of life (including symptoms of fatigue and depressive symptoms) *(35, 120)*.

For people living with **spinal cord injury**, physical activity can improve walking function, muscular strength and upper extremity function *(35)*. Physical activity may also reduce shoulder pain, improve vascular function and enhance health-related quality of life *(35)*.

For people living with **Parkinson's disease**, physical activity can improve motor symptoms, functional mobility and performance, endurance, freezing of gait and velocity of forward and backward movement *(35, 121, 122)*. New

evidence suggests that exercise can also help global cognitive function in individuals with Parkinson's disease *(123)*.

For people with a history of **stroke**, physical activity can improve physical function, notably upper limb function, sensory motor function of the lower limb, balance, walking speed, distance, ability and endurance, cardiorespiratory fitness, mobility and activities of daily living. Existing evidence suggests that physical activity may also have beneficial effects on cognition *(35)*.

For people with **major clinical depression**, new reviews *(124, 125)* supported existing evidence *(35)* that physical activity can improve health-related quality of life *(35, 124, 125).*

For individuals with **diseases or disorders that impair cognitive function, including schizophrenia** –physical activity can have beneficial effects on cognition, working memory, social cognition and attention/vigilance *(35, 126)*. One review found that moderate- to vigorous-intensity physical activity delivered significant improvements in health-related quality of life and disability *(35, 124)*. For people living with **intellectual disability**, physical activity has been shown to improve physical function. The interventions reviewed largely focused on balance and strength activities over 6–24 weeks and reported significant improvement in static balance, dynamic balance and static-dynamic balance compared with controls *(35, 127, 128).*

For children with **attention-deficit/hyperactivity disorder**, evidence, including one review of 5 RCTs involving ADHD *(129)*, demonstrates a positive association between exercise and attention, executive function and social disorders *(35, 129).*

The GDG considered the evidence from the general population of children, adolescents and adults and concluded that as there is no reason to believe that there would be an effect modification due to impairment and that the same health physiological benefits will be conferred by being physically active. The GDG acknowledged that few studies include people living with disability, and that effect modification is seldom tested.

This evidence in the area disability, combined with the broader evidence for the general population, supported the general population recommendation being inclusive of people with disability, noting reference to "all adults", "all older adults" and "people of all abilities".

The GDG concluded that:

In individuals with spinal cord injury, there is:

- low certainty evidence that physical activity reduces shoulder pain and improves vascular function in paralysed limbs and enhances healthrelated quality of life; and
- moderate certainty evidence that physical activity improves walking function, muscular strength, and upper extremity function.

In individuals with diseases or disorders that impair cognitive function, including Parkinson's disease, there is:

- high certainty evidence that physical activity improves a number of functional outcomes including walking, balance, strength, and disease specific motor scores; and
- moderate certainty evidence that moderate- to vigorous-intensity physical activity can have beneficial effects on cognition.

In individuals with a history of stroke, there is:

- moderate certainty evidence that mobilityoriented physical activity can have beneficial effects on physical function and cognition.

Available online at https://apps.who.int/iris/bitstream/handle/10665/336657/9789240015111-eng.pdf

In individuals with diseases or disorders that impair cognitive function, including schizophrenia, there is:

- moderate certainty evidence that physical activity improves quality of life; and
- high certainty evidence that moderate- to vigorousintensity physical activity can have beneficial effects on cognition, working memory, social cognition and attention.

In adults with major clinical depression there is:

- moderate certainty evidence that physical activity improves quality of life.

In adults with multiple sclerosis, there is:

- high certainty evidence that physical activity, particularly aerobic and muscle-strengthening activities, improves physical function, functional mobility, walking speed and endurance, and cardiorespiratory fitness, strength and balance;
- moderate certainty evidence that physical activity can have a beneficial effect on cognition; and
- low certainty evidence that physical activity improves quality of life including symptoms of fatigue and depressive symptoms.

In children and adults with intellectual disability, there is:

- low certainty evidence that physical activity improves physical function.

In children and adolescents with ADHD, there is:

- moderate certainty evidence that moderate- to vigorous-intensity physical activity can have beneficial effects on cognition, including attention, executive function, and social disorders.

The GDG further concluded that there is sufficient scientific evidence on the positive impact of physical activity on a variety of health outcomes across a broad range of impairment areas, and that the benefits of physical activity for people living with disability outweigh the potential harms.

Due to indirectness of the evidence to develop these recommendations, the level of certainty was downgraded.

Recommendations

SEDENTARY BEHAVIOUR RECOMMENDATION

For children, adolescents and adults living with disability, sedentary behaviour is defined as time spent sitting or lying with low energy expenditure, while awake, in the context of educational, home and community settings, and transportation. It is possible to avoid sedentary behaviour and be physically active while sitting or lying, through, for example, upper body led activities, inclusive and/or wheelchair-specific sport and activities.

In children and adolescents, higher amounts of sedentary behaviour are associated with the following poor health outcomes: increased adiposity; poorer cardiometabolic health, fitness, and behavioural conduct/pro-social behaviour; and reduced sleep duration.

It is recommended that:

› **Children and adolescents living with disability should limit the amount of time spent being sedentary, particularly the amount of recreational screen time.**

Strong recommendation, low certainty evidence

In adults, higher amounts of sedentary behaviour are associated with the following poor health outcomes: all-cause mortality, cardiovascular disease mortality and cancer mortality, and incidence of cardiovascular disease, cancer and type-2 diabetes.

It is recommended that:

› **Adults living with disability should limit the amount of time spent being sedentary. Replacing sedentary time with physical activity of any intensity (including lightintensity) provides health benefits.**

Strong recommendation, low certainty evidence

› **To help reduce the detrimental effects of high levels of sedentary behaviour on health, adults living with disability should aim to do more than the recommended levels of moderate- to vigorous-intensity physical activity.**

Strong recommendation, low certainty evidence

Supporting evidence and rationale

Sedentary behaviour was not included in *The Global recommendations on physical activity for health (2010).*

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Due to a lack of population-specific evidence, the primary evidence base for assessing the associations between sedentary behaviour and health outcomes in children, adolescents and adults living disability was the scientific literature collated and reviewed for populations without disability.

The findings from evidence on sedentary behaviours in the general population were reviewed including assessing if there was evidence that the outcomes would be any different, or would not apply to, or would be contraindicated for children, adolescents and adults living with disability.

Based on available evidence and expert opinion, the evidence was extrapolated to inform new WHO recommendations on sedentary behaviour for individuals living with disability for the common set of critical health outcomes, recognizing that certain population groups, such as wheelchair users, unavoidably sit for long periods of time and sitting may therefore be the norm. For these groups, sedentary behaviour should be defined as time spent with low energy expenditure, e.g. moving in a power chair or being pushed while sitting in a manual

wheelchair. There is a lack of research on the association between sedentary behaviour and health outcomes in individuals living with disability. However, based on expert opinion, there are no reasons to believe that there would be an effect modification due to impairment, and therefore the same physiological health benefits will be conferred by limiting sedentary behaviour in individuals living with disability. Due to indirectness of the evidence

to develop these recommendations, the level of certainty was downgraded.

The applicability of evidence on the benefit of adults undertaking more moderate- and vigorous-intensity physical activity to help counteract the potential risks of high levels of sedentary behaviour was also considered and was also extrapolated to inform recommendations for adults living with disability

for the common set of critical health outcomes. Given the indirectness, the certainty of the evidence was downgraded. **The GDG concluded that:**

- The evidence on sedentary behaviours in child and adolescent populations could generally be extrapolated to children and

adolescents living with disability, according to their specific ability.

- The evidence on sedentary behaviours in the general adult population, including the benefit for adults of undertaking more moderate- to vigorousintensity physical activity to help counteract the potential risks of high levels of sedentary behaviour, could generally be extrapolated to adults and older adults living with disability, according to their specific ability. However, the certainty of the evidence was downgraded due to indirectness.
- The benefits of minimizing sedentary behaviour in children, adolescents, adults and older adults living with disability outweigh the harms.

EVIDENCE TO RECOMMENDATIONS

In accordance with the GRADE process, the proposed wording of the updated recommendations, and the rating of their strength ("strong" or "conditional"), were based on consideration of the balance of benefits to harms; the certainty of evidence; sensitivity to the values and preferences of those affected by the guidelines; the potential impact on gender, social and health equity; and acceptability, feasibility and resource implications. These were considered for each population group, but given the similarity of issues and considerations discussed, are consolidated and presented here.

The strength of the recommendation was primarily based on the assessed balance of benefits to harms. Recommendations were graded "strong" if the balance of benefits to harms was assessed as substantial for the target population for the recommendation, and "conditional" if the balance of benefits to harms was small or there was important likely variability in benefits in the target population. The evidence on harms was specifically sought through the commissioning of a new systematic review. However, this was limited, as most evidence focuses on injuries and harms to elite and competitive athletes, rather than the general population. Overall, despite the limited evidence, and informed by expert opinion, it was concluded that the risk was no greater than small. The evidence generally indicated that the benefits of physical activity far outweighed the harms, and that physical activity can be an important intervention to support closing an existing health gap, particularly for disadvantaged populations.

Issues of health equity, feasibility and acceptability were also considered by the GDG and formed part of the online public consultation on the draft recommendations held between 31 March 2020 and 17 April 2020. The survey for the public consultation asked specific questions on the balance between the costs to individuals and governments of implementing the recommendations, and the potential health benefits, and whether the guidelines would improve health equity. In addition, the draft recommendations and the feedback form were sent to countries that had recently expressed an interest in developing, or had initiated the process of drafting, national guidelines on physical activity. Feedback was received from more than 420 submissions to the online consultation, and additional collation of feedback from the WHO European Regional Office, incorporating comments from WHO Collaborating Centres and Member States. The feedback from this consultation was collated, reviewed by the GDG, and used to further inform the consideration on feasibility, resource implications, and health equity through consultation with the Steering Group and the GDG.

Decisions were reached by consensus through discussion. The GDG came to consensus on each recommendation and on the strength of the recommendation; ratings and voting were not required.

ASSESSMENT OF THE CERTAINTY OF EVIDENCE

The GRADE framework was used by the GDG to examine the certainty of primary research

contributing to each outcome identified in the PI/ECOs, and assessed the overall certainty of evidence taking into consideration the risk of bias, inconsistency, imprecision, indirectness of the evidence and publication bias across each outcome. GRADE tables detailing this information for each PI/ECO are available in the Web Annex: Evidence profiles ↓ . The assessment of the certainty of the evidence was based on an overall assessment across all evaluated outcomes and prioritized all-cause mortality and cardiovascular mortality as the most critical outcomes, followed by other clinical outcomes (falls, depression, cognition, health-related quality of life, etc), then intermediate outcomes (e.g. cardiometabolic markers, other metabolic markers), as well as harms. Where the evidence had not been specifically reviewed, such as for sedentary behaviour in subpopulations primarily due to a lack of evidence for these groups, the evidence for the general population was extrapolated and downgraded where this was deemed appropriate, due to indirectness.

BENEFITS AND HARMS

The development of the recommendations included an assessment of adverse impacts or risks. Where there was limited evidence, decisions were based on the expertise of the GDG. Overall, for all populations it was concluded that the benefits of physical activity and limiting sedentary behaviour outweighed the potential harms. These guidelines are for the general population and do not address the benefits and harms experienced by athletes undertaking the types and amounts of activity necessary to improve performance-related fitness for participation in competition.

Doing some physical activity is better than doing none. If individuals are not currently meeting these recommendations, doing some physical activity will bring benefits to their health. They should start by doing small amounts of physical activity, gradually increasing frequency, intensity and duration over time. Pre-exercise medical clearance is generally unnecessary. Inactive individuals who gradually progress to undertaking moderate-intensity activity have no known risk of sudden cardiac events and very low risk of bone, muscle, or joint injuries. An individual who is habitually engaging in moderateintensity activity can gradually increase to vigorousintensity without needing to consult a healthcare provider. Those who develop new symptoms when increasing their levels of activity should consult a healthcare provider.

The choice of appropriate types and amounts of physical activity can be affected by pregnancy, chronic conditions, and disability, and should be undertaken as able and without contraindication. These individuals may wish to consult with a physical activity specialist or health-care professional for advice on the types and amounts of activity appropriate for their individual needs, abilities, functional limitations/complications, medications, and overall treatment plan. Light- and moderate-intensity physical activity are generally low risk and are recommended for all.

VALUES AND PREFERENCES

The values and preferences of those affected by the guidelines (in this case parents and caregivers, children and adolescents, adults, older adults, pregnant and postpartum women, people living with chronic conditions and/or disability) were considered. Overall it was concluded that there was little or no uncertainty about preferences regarding the main outcomes, including mortality and cardiovascular mortality. The estimated potential benefits greatly outweighed any potential harms, and as such, the GDG considered the recommendations to be not preference-sensitive.

RESOURCE IMPLICATIONS

The expert opinion of the GDG, and a small body of evidence reporting on economic analyses of interventions and savings to the health-care systems from increasing levels of physical activity, informed discussion on the resource implications of the recommendations in different settings. In addition, results from the online public consultation showed that over 75% of respondents agreed, or strongly agreed, that the benefits of implementing the guidelines would outweigh the cost to the individual, and 81% agreed, or strongly agreed, that the benefits of implementing the guidelines would outweigh the cost to government.

Available evidence and expert opinion recognize that substantial health benefits can be achieved at low risk through activities such as walking, that require no specific equipment or cost to the individual. Further, it was acknowledged that other forms of physical activities, for example structured sports, cycling and exercise classes, may incur costs, which can be a barrier for some individuals, particularly those with lower incomes. Government implementation of policy and programmes to promote and enable physical activity also requires investments in areas such as human resources, policy development, provision of facilities and services and potentially, equipment, some of which is incurred by

ministries of health, but also in sectors outside of health, such as sport, education, transport and urban planning. The resources required may be at more than one level of government (national, subnational and local levels) to ensure all communities have equal access to physical activity opportunities.

These investments may involve new resources, but also can be addressed by reallocation of existing budgets to reflect the prioritization of facilities and programmes towards increasing population levels of physical activity. Examples of budget reallocation include towards infrastructure for walking and cycling from the existing transport budget, and towards "sports for all" from the sports budgets. In key settings, such as schools and workplaces, low-cost interventions, combined with changes to the physical environment, can support participation in physical activity and would also contribute to reducing inequities in opportunities to be active,

experienced by some subpopulation groups. Overall, it was assessed that while there are resource implications to achieve these draft recommendations, implementation of actions is possible within current governance structures.

Further, evidence supports that substantial health savings are possible for the health-care system resulting from increasing levels of physical activity. In 2013 the global annual cost of physical inactivity was estimated at INT$ 54 billion due to direct health costs alone *(130)*; and at a national level, inactivity is estimated to cost between 1–3 % of health-care budgets *(131)*.

Within the wider context of noncommunicable disease (NCD) prevention, additional costs to government and nongovernmental organizations of guideline implementation may be minimized if recommended physical activity can be relatively easily incorporated by individuals into their lives; likewise if existing resources in primary and secondary care, schools, workplaces or transportation can be shifted, resulting in increased physical activity.

Analysis of the cost and benefits of physical activity promotion indicate positive returns on investment over 15 years, in terms of NCD prevention, in many countries where the investment cases have been conducted *(132)*. Interventions such as public education and awareness campaigns and physical activity counselling and referral are a "best buy" and a "good buy" respectively, of recommended interventions to address NCDs based on an update of Appendix 3 of the *Global action plan for the prevention and control of NCDs 2013–2020 (133).* Overall, the GDG concluded that the benefits of implementing the recommendations outweigh the costs.

Delivering on physical activity guidelines for people with disability may require investment, such as the training of activity specialists, adapted equipment where needed, and facilities that need to be made accessible. These investments can facilitate the needs of a wide range of population groups. Evidence demonstrates a significant participation gradient between people with and without disability in relation to physical activity, due to multiple barriers regarding access, choice of activities offered, and the attitudes of others. Universal design principles should be applied to ensure full and effective participation by people living with disability. With innovation, it is possible to address many of these resource implications. Adopting universal design approaches would mitigate against these costs in the future.

EQUITY, ACCEPTABILITY AND FEASIBILITY

In updating the 2010 recommendations the decision was taken to explicitly include consideration of vulnerable populations, such as those living with chronic conditions and/or disability. The GDG and Steering Group included members representing such groups. The GDG discussed each recommendation at length, considering whether implementing the recommendations would decrease health equity, and the issues related to implementation, to ensure that the recommendations did not worsen equity issues (for example, ensuring that there are safe facilities and

opportunities accessible for all, including people living with disability, and socioeconomically and other disadvantaged people, to engage in physical activity; addressing gender and other cultural biases that could restrict access and opportunity to participate in physical activity, etc.). Of respondents to the online public consultation, 76% agreed, or strongly agreed, that implementing the guidelines

RESEARCH NEEDS

can achieve a reduction in health inequity by increasing opportunities for all to be active and improve health outcomes. It was noted that supporting environments are key to enabling participation in physical activity. A comprehensive approach to the design and implementation of policies across a number of sectors will be required to address barriers to physical activity for vulnerable groups, such as socioeconomically disadvantaged women and girls, and people with disability.

People with disability experience worse health outcomes than people without disability, yet the benefits of physical activity far outweigh the harms and can be an important intervention to close this health gap. Evidence demonstrates a significant participation gradient between people with and without disability in relation to physical activity, due to multiple barriers regarding access, choice of activities offered, and the attitudes of others. For many people with disability, it should be possible to engage in various forms of physical activity without the need for adapted equipment or facilities. However, in order for people with disability to engage in physical activity on an equal basis with others, adapted equipment may need to be obtained, facilities may need to be made accessible, and activity specialists may need to be trained. Despite the large quantity of data relating physical activity and, increasingly, sedentary behaviours to health outcomes across the life span, the GDG discussions revealed important evidence gaps, which should be prioritized to inform future guidelines. Evidence gaps across population subgroups included a lack of information on:

1) the more precise details on the dose-response relationship between physical activity and/or sedentary behaviour and several of the health outcomes studied;

2) the health benefits of light-intensity physical activity and of breaking up sedentary time with lightintensity activity;

3) differences in the health effects of different types and domains of physical activity (leisure time; occupational; transportation; household; education) and of sedentary behaviour (occupational; screen time; television viewing); and

4) the joint association between physical activity and sedentary time with health outcomes across the life course. It was also noted that there remains limited evidence from low- and middle-income countries, economically disadvantaged or underserved communities, and in people living with disability and/or chronic disease. Many studies are not designed or powered to test for effect modification by various sociodemographic factors (age, sex, race/ethnicity, socioeconomic status) that may modify the health effects of physical activity. Such information is important for making more specific public health recommendations and for reducing health disparities in more vulnerable sectors of the population. Further details on the research gaps arising from these new guidelines can also be found in published literature *(134)*.

ADOPTION

WHO undertakes a rigorous and extensive process to develop globally relevant guidelines *(21)* for use by all countries. These *Guidelines on physical activity and sedentary behaviour* provide evidencebased recommendations on the health impacts of physical activity and sedentary behaviour that national governments can adopt and use as part of their national policy frameworks. The development of global guidelines, with extensive consultation, should largely remove the need for individual countries to use resources to undertake the lengthy scientific process. Reviewing and adopting these global physical activity and sedentary behaviour guidelines provides a rapid and cost-effective method to develop guidelines tailored to local context.

Adopting the WHO guidelines at regional or national level will ensure countries provide consistent recommendations on physical activity and sedentary behaviour, which are informed by the latest and best available scientific evidence. In addition, consistency of the recommendations

ADOPTION, DISSEMINATION, IMPLEMENTATION AND EVALUATION

across countries will facilitate national

surveillance, global estimates of physical activity

Research needs

and sedentary behaviour, and crosscountry

The goal of these guidelines is to provide comparisons. Throughout the adoption process,
policymakers, and those who develop health-care, consideration should be given to the need to
education, workplace and community intervention contextualize and tailor the guidelines. Translation
programmes, with recommendations on how into the local language is one element of adoption
much time children, adolescents, adults and older and contextualization. Examples of physical
adults should spend each day being physically activities may need to be changed to be locally
active, and recommendations on limiting time relevant and the use of images tailored to reflect
spent being sedentary. However, developing local cultures, norms and values.
global guidelines is not an end in itself: without

A step-by-step framework to support country

dissemination and implementation, changes in adoption of the Global guidelines is under
physical activity levels will not be achieved.

development, following a series of regional workshops with relevant stakeholders. This framework can be populated with relevant national data (for example physical activity prevalence estimates), and will provide a fast-track approach to the development of a national guidelines document. These supporting resources will be available in 2021 through the WHO website.

When considering adopting the guidelines it is recommended that the following ten-step process is applied:

1. Advocate for a review of current national guidelines on physical activity and the adoption of the WHO guidelines to secure government authorization.
2. Engage key stakeholders both within the health sector and other relevant sectors, such as sport, education, transport; engage relevant professional associations and scientists, with topic expertise.
3. Assess the applicability, acceptability and feasibility of the recommendations.
4. Adapt guidelines to the local context, including language, examples, and other cultural considerations.
5. Conduct an external review with target users, including policy-makers, practitioners, and the general public.
6. Establish a budget and clear plan for dissemination and communication.

7. Publish and promote the national guidelines, ideally alongside a launch event to generate publicity and interest.

8. Engage relevant professional bodies or organizations and support policy alignment and/or endorsement.

9. Implement national policies and practices to support implementation of national guidelines and behaviour change.

10. Agree a timeline for evaluation, review, and update of the guidelines.

DISSEMINATION

National physical activity guidelines are a core component of the governance structures for a comprehensive approach to increasing population levels of physical activity. National guidelines inform the development and priorities of national and subnational strategy planning and require dissemination of the correct information, to the relevant groups of people, in an appropriate way. Unfortunately, too often, national guidelines are not disseminated, and so awareness of recommendations among both professional audiences and the wider community can remain very low. Securing dedicated resources to support wide-scale dissemination is an important first step to changing awareness and knowledge about the importance of increasing physical activity and reducing sedentary behaviours.

Key audiences for dissemination of national guidelines on physical activity and sedentary behaviour include:

- **Policy-makers within and outside the health sector** (including transport, planning, education, workplaces, sport, parks and recreation), to increase:
  a. knowledge of the contribution that increasing physical activity and reducing sedentary behaviour can have in improving not only health, but also a range of diverse yet related agendas, including gender equity, human rights obligations, and sustainable development;
  b. integration of policy and programmes on physical activity and sedentary behaviour into all relevant policies; and
  c. investment in scaled-up and coordinated national and local actions.
- **Non-state actors** (including nongovernmental organizations, academic and research organizations, the private sector as well as the media and research funding agencies), to: a. raise awareness of the importance of increasing physical activity and reducing sedentary behaviours across all ages;
  b. encourage and ensure policy alignment; and
  c. increase collaboration and investment in policy implementation and local action.
- **Practitioners in health and non-health sectors** (including sport, education, transport, and planning) to increase:
  a. awareness and knowledge of national guidelines on physical activity and sedentary behaviours;
  b. knowledge, skills and confidence in promoting increased physical activity and reduction in sedentary behaviours; and
  c. integration of physical activity promotion into routine practice where applicable.
- **The general public and specific population subgroups**, to increase:
  a. awareness and knowledge of the guidelines on physical activity and sedentary behaviour;
  b. knowledge of how to achieve the physical activity and sedentary behaviour guidelines;
  and c. intentions and motivation to be more physically

active and to reduce sedentary behaviour.

COMMUNICATION CAMPAIGNS

Different stakeholders will benefit from different materials; therefore to communicate guidelines to multiple audiences effectively, consideration must be given to the content, format, and delivery channels for guideline communication. When developing a guideline communication strategy, formative research can help determine the key audiences and understand the values, needs and preferences that influence levels of physical activity and sedentary behaviour. This should include exploration of the barriers to physical activity or to the integration of physical activity into policy and practice, as well as testing of draft messages and materials with different groups. This will help inform the key messages that are used, as well as the appropriate format(s) and channel(s) for communication. A comprehensive communication strategy will include a range of communications aimed at different audiences. Countries may need to prioritize specific groups depending on available resources (human and financial).

Communication campaigns on physical activity targeting the general public or specific subpopulations are a costeffective intervention *(133)* and recommended in the WHO *Global action plan on physical activity 2018–2030 (14)*. National and subnational campaigns on physical activity typically establish an overarching campaign slogan (for example “Be Active” or “Move More”), and develop design elements or characters, which may include tailored messages for different audiences

(such as for young children, adolescents, adults or older adults, the less active, people living with disability or chronic conditions). Campaign messages and resources that are tailored to specific population groups are likely to be more effective than generic materials. Communication campaigns should consider the reach and effectiveness of both traditional media channels (such as television, radio, billboards, printed resources) as well as digital media channels (websites, mobile phones, Apps). Providing information on the national guidelines in a variety of formats is also useful. For example, a relatively new but increasingly common approach to communicating physical activity guidelines is through the use of infographics or short animated videos. WHO has supporting materials for developing and implementing such communication campaigns *(135)*.

The academic and research community are likely to be interested in the scientific report which details the epidemiological evidence on which the guidelines are based. However the specific details of the underlying research is unlikely to be of interest to other more general audiences. Policy-makers may prefer a summary of the science, or even a short briefing document. Other audiences, such as health and non-health professionals, are more likely to favour different types of resources, for example a brochure or factsheet about the guidelines, or about how to integrate physical activity promotion into routine practice (for example in patient consultations in a health-care setting, or when developing building or transport plans for urban environments). Different professionals will require resources that are tailored to their role. Health professions, in particular, may benefit from a suite of resources to reflect the diverse population groups that they work with.

IMPLEMENTATION OF POLICY AND PROGRAMMES

National guidelines on physical activity and sedentary behaviour, in isolation, are unlikely to lead to increases in population levels of physical activity and should therefore be seen as one element of a policy and planning framework. It is critical that national guidelines are disseminated to key audiences and supported by a sustained national communication strategy that will lead to

increased awareness and knowledge about the multiple benefits of regular physical activity and reducing sedentary behaviours. However, in order to achieve sustained behaviour change, these actions must be supported by policies that create supportive environments that enable and encourage people to be active, along with increased local, appropriate opportunities for people to participate in physical activity. Policies and programmes must consider and be adapted to the local context, in terms of both the health system and the complex multisector institutions that have an interest in, or opportunity to support, physical activity promotion. Action should be taken using a "whole of government" approach and consider the "system" of policies and multiple actions that can, through engagement of a wide range of stakeholders, support more people to be physical active across multiple sectors and settings. Using a "systems" approach that is aligned with a sustained communication strategy ensures that increased demand for physical activity, generated through effective communication, is matched by the provision of environments and opportunities for people to be physically active. The WHO *Global action plan on physical activity 2018–2030* set a target to reduce physical inactivity by 15% by 2030, and outlined 20 recommended policy actions and interventions *(14)*. These included recommending that all countries implement sustained national public education and awareness campaigns and the integration of physical activity counselling programmes into primary and secondary health care. Other recommendations included the creation of appropriate environments for physical activity, including walking, cycling and wheeling, for all population groups and the provision of more opportunities and programmes for physical activity in schools, workplaces and sports clubs and venues. Implementation across all 20 recommendations may not be feasible in the short term in all countries, but should be viewed as a long-term goal. To identify an appropriate and feasible set of immediate actions, WHO Member States should conduct a situational analysis of current policy and practice. This will enable multisector collaboration and help identify areas of strength as well as gaps and opportunities, and can be used as the basis for developing or updating national and subnational plans.

These new WHO guidelines support expanding the scope of actions to include additional groups, such as people living with disability or chronic conditions, and women who are pregnant or postpartum. Policy will need to support appropriate programme delivery and practice that recognizes community needs and the diversity of groups and contexts. A number of sector-specific toolkits are under development to support implementation of the ACTIVE technical package *(135)*; these will provide

each sector with guidance on how to promote physical activity, for example through schools, through primary health care, or by improving provision for walking and cycling. The ACTIVE toolkit, as well as other WHO regional and national resources will support implementation of these physical activity and sedentary behaviour guidelines.

SURVEILLANCE AND EVALUATION

The WHO *Global recommendations for physical activity for health* have been used as benchmarks for population health monitoring and surveillance since 2010. The changes introduced to the recommendations in these updated guidelines will have some implications for surveillance systems and assessment instruments currently used to monitor national levels of physical activity. The publication of these new guidelines will call for a review of current instruments and reporting protocols to inform any adjustments and recommendations on future reporting against the new guidelines. Instruments, such as the Global Physical Activity Questionnaire and Global Student Health Survey, will be reviewed and protocols updated to align with these new guidelines; supporting guidance to all countries will be provided in 2021.

The WHO NCD Country Capacity Survey (CCS) is the main instrument used to monitor global progress on NCD policy implementation, and is conducted every two years. The CCS includes specific questions on population surveillance systems on physical activity for each age group covered by these WHO guidelines on physical activity and sedentary behaviour, and since 2019, on the existence of national physical activity guidelines. WHO Member States are requested to upload documentation to support their response. In 2019, of the 194 WHO Member States, 78 (40%) reported having physical activity guidelines *(136)*. A detailed document analysis of responses to the CCS in 2019 was carried out, and identified that only two thirds of the 78 Member States (52/78) with national guidelines include statements on how much physical activity their populations should do; and of these, only 42 countries aligned fully with the 2010 WHO *Global recommendations on physical activity for health (1)*. Data from the 2021 and subsequent surveys will provide information on uptake of these updated guidelines.

UPDATING

These guidelines will be updated after ten years, unless advances in the science of how physical activity is assessed using device-based measurement, and the rapidly evolving science on sedentary behaviour, prompt an earlier update.

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ANNEX 1:

MANAGEMENT OF GUIDELINE DEVELOPMENT

PROCESS

Contributors to guideline development

WHO Steering Group

The Steering Group included experts in the areas of physical activity, adolescent health, ageing disability, mental health, injury prevention, cancer, pregnancy and surveillance from both headquarters and regional offices.

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The Steering Group drafted the scope of the guidelines, and the PI/ECOs. They reviewed the declaration of interests; and drafted, reviewed and finalized the guidelines.

Guideline Development Group (GDG)

The Guideline Development Group consisted of a broad group of relevant experts in the field and end users of, and persons affected by, the recommendations. The members of the Guideline Development Group included:

Dr Salih Saad Al-Ansari (advocate in health promotion and education to combat NCDs through physical activity and walking); **Dr Stuart Biddle** (physical activity and sedentary behaviour, and behaviour change); **Dr Katja Borodulin** (physical activity in pregnancy and older adults); **Dr Matthew Buman** (sleep, sedentary behaviour, and physical activity in people living with chronic conditions); **Dr Greet Cardon** (physical activity in children and adolescents); **Ms Catherine Carty** (physical activity in people living with disability); **Dr Jean-Philippe Chaput** (sleep, sedentary behaviour and physical activity in children and adolescents); **Dr Sebastien Chastin** (physical activity, sedentary behaviour and health, objective measurement of physical activity and sedentary behaviour); **Dr Paddy Dempsey** (physical activity and sedentary behaviour in adults and people living with chronic conditions); **Dr Loretta DiPietro** (physical activity in pregnancy and older adults); **Dr Ulf Ekelund** (sedentary behaviour and physical activity, physical activity in children and adolescents); **Dr Joseph Firth** (physical activity and mental health); **Dr Christine Friedenreich** (physical activity in people living with chronic conditions, physical activity and cancer risk); **Dr Leandro Garcia** (physical activity and health in adults); **Dr Muthoni Gichu** (policy implementation, national government); **Dr Russ Jago** (physical activity in children and adolescents); **Dr Peter Katzmarzyk** (physical activity and sedentary behaviour); **Dr Estelle V. Lambert** (physical activity and obesity); **Dr Michael Leitzmann** (sedentary behaviour and physical activity in people living with chronic conditions); **Dr Karen Milton** (translating recommendations into practice); **Dr Francisco B. Ortega** (physical activity in children and adolescents, mental health and objective measurement); **Dr Chathuranga Ranasinghe** (promotion of physical activity and health in the community, workplace and school settings); **Dr Emmanuel Stamatakis** (physical activity and sedentary behaviour and multiple health outcomes in adults); **Dr Anne Tiedemann** (physical activity in older adults); **Dr Richard Troiano** (policy development); **Dr Hidde van der Ploeg** (physical activity and sedentary behaviour in adults); **Ms Vicky Wari** (policy implementation – national government); **Dr Roger Chou** (Pacific Northwest Evidencebased Practice Center and Professor of Medicine, Departments of Medicine, Medical Informatics and Clinical Epidemiology of the Oregon Health and Science University) served as GRADE methodologist. Further details of the GDG are available in Annex 2.

A first GDG meeting was held 2–4 July 2019, at which the GDG decided on the PI/ECO questions, reviewed the existing systematic reviews, and identified updates required. The Group agreed on the process for decision-making on recommendations and the strength of the evidence to be applied at the second GDG meeting. The second meeting was held 11–14 February 2020; updated evidence was reviewed and final recommendations agreed upon by consensus.

External Review Group (ERG)

Seven peer reviewers were drawn from a list of individuals suggested by the GDG and Steering Group. They provided relevant expertise, including programme implementation and represented all six WHO regions. The ERG reviewed the draft guidelines and provided feedback to the Steering Group on issues of clarity and implementation, which was incorporated, as appropriate. External peer reviewers did not make changes to the recommendations. External peer reviewers are listed in Annex 2.

Declarations of Interest

All GDG members and external peer reviewers completed and submitted a WHO Declaration of Interests form and signed confidentiality undertakings prior to attending any GDG meetings. The Steering Group reviewed and assessed the submitted curriculum vitae and declarations of

interest and performed an internet and publications search to identify any obvious public controversies or interests that may lead to compromising situations. The names and brief biographies of all proposed GDG members were published on the WHO Physical Activity webpage for public consultation for a period of 14 days. No comments were received. If additional guidance on management of any declaration or conflicts of interest had been required, the Steering Group would have consulted with colleagues in Office of Compliance, Risk Management and Ethics. If deemed necessary, individuals found to have conflicts of interest, financial or non-financial, would have been excluded from participation on any topics where interests were conflicting. The management of conflicts of interest was reviewed throughout the process. GDG members were required to update their Declaration of Interest, if necessary, before each meeting and a verbal declaration of interest was solicited at the beginning of each GDG meeting. Declared interests of the GDG and of the external peer reviewers are summarized in Annex 3.

No conflict of interest was identified.

Peer review

The draft guidelines were reviewed by seven external peer reviewers identified by the GDG and Steering Group. External peer reviewers were requested to provide comments on issues of clarity, presentation of the evidence, and implementation; comments were incorporated as appropriate. External peer reviewers could not change the recommendations decided upon by the GDG. External peer reviewers are listed in Annex 2; a summary of declarations of interest are provided in Annex 3. In addition, inputs were actively sought from WHO regional offices.

ANNEX 2:

GUIDELINE DEVELOPMENT GROUP, EXTERNAL PEER REVIEWERS, AND WHO STAFF INVOLVED IN THE DEVELOPMENT OF THESE GUIDELINES

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ANNEX 3:

SUMMARY OF DECLARATION OF INTEREST AND HOW THESE WERE MANAGED

Guideline Development Group members

Name	Gender	Expertise	Disclosure of interest	Conflict of interest and management
Dr Salih Saad Al-Ansari	Male	Advocate in health promotion and education to combat NCDs through physical activity and walking	Owner and Chief Executive Officer of the Health Promotion Center	No conflict of interest identified
Dr Stuart Biddle	Male	Physical activity in youth	Research funds and paid consultancy	No conflict of interest identified
Dr Katja Borodulin	Female	Physical activity in pregnancy	Employment at National Institute for Health and Welfare and Age Institute; research funds	No conflict of interest identified
Dr Matthew Buman	Male	Sleep and physical activity in people living with chronic conditions	None declared	No conflict of interest identified
Dr Greet Cardon	Female	Physical activity in youth	None declared	No conflict of interest identified
Ms Catherine Carty	Female	Physical activity in people living with disability	Research funds	No conflict of interest identified
Dr Jean-Philippe Chaput	Male	Sleep	None declared	No conflict of interest identified

Dr Sebastien Chastin	Male	Physical activity and health, objective measurement of physical activity	Research funds	No conflict of interest identified
Dr Paddy Dempsey	Male	Physical activity and sedentary behaviour in adults and people living with chronic conditions	Employment and research funds	No conflict of interest identified
Dr Loretta DiPietro	Female	Physical activity in older adults	None declared	No conflict of interest identified
Dr Ulf Ekelund	Male	Sedentary behaviour and physical activity in youth	None declared	No conflict of interest identified
Dr Joseph Firth	Male	Physical activity and mental health	None declared	No conflict of interest identified
Dr Christine Friedenreich	Female	Physical activity in people living with chronic conditions, physical activity and cancer risk	None declared	No conflict of interest identified
Dr Leandro Garcia	Male	Physical activity and mental health	Employment and paid consultancy	No conflict of interest identified
Dr Muthoni Gichu	Female	Policy implementation (national government)	None declared	No conflict of interest identified
Dr Russ Jago	Male	Physical activity in youth	None declared	No conflict of interest identified
Name	**Gender**	**Expertise**	**Disclosure of interest**	**Conflict of interest and management**
Dr Peter Katzmarzyk	Male	Physical activity and sedentary behaviour in youth	Travel support to assist guideline committees	No conflict of interest identified
Dr Estelle V. Lambert	Female	Physical activity and obesity	None declared	No conflict of interest identified
Dr Michael Leitzmann	Male	Sedentary behaviour and chronic conditions	None declared	No conflict of interest identified
Dr Karen Milton	Female	Translating recommendations into practice	Travel support to assist guideline committee	No conflict of interest identified

Dr Francisco Ortega	Male	Physical activity in youth, mental health and objective measurement	None declared	No conflict of interest identified
Dr Chathuranga Ranasinghe	Male	Promotion of physical activity and health in the community, workplace and school settings	Research funds	No conflict of interest identified
Dr Emmanuel Stamatakis	Male	Physical activity and multiple health outcomes in adults	Grant for technology company for objective measurement of physical activity	No conflict of interest identified
Dr Anne Tiedemann	Female	Physical activity and health outcomes in older adults	None declared	No conflict of interest identified
Dr Richard Troiano	Male	Policy development	None declared	No conflict of interest identified
Dr Hidde van der Ploeg	Male	Physical activity, sedentary behaviour and health outcomes in adults	Travel support to assist 2017 Dutch Physical Activity Guidelines committee and research funds	No conflict of interest identified
Ms Vicky Wari	Female	Policy implementation (national government)	Shares (not relevant to guideline)	No conflict of interest identified

External peer re viewers

Name	Gender	Expertise	Disclosure of interest	Conflict of interest and management
Kingsley Akinroye	Male	Advocacy, noncommunicable diseases	None declared	No conflict of interest identified
Dr Huda Alsiyabi	Female	Policy and programme implementation	None declared	No conflict of interest identified
Dr Alberto FlórezPregonero	Male	Physical activity and sedentary behaviour measurement and surveillance	None declared	No conflict of interest identified

Dr Shigeru Inoue	Male	Epidemiology and physical activity promotion	None declared	No conflict of interest identified
Dr Agus Mahendra	Male	Physical activity and movement skills in children	None declared	No conflict of interest identified
Dr Deborah Salvo	Female	Health and social disparities, with a particular emphasis on chronic disease prevention	None declared	No conflict of interest identified
Dr Jasper Schipperijn	Male	Physical activity and the built environment	President-Elect of the International Society for Physical Activity and Health (ISPAH)	No conflict of interest identified

Annex 3

ISBN 978-92-4-001512-83 5


LET'S
Be active
Everyone
Everywhere
Everyday


World Health
Organization


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Should I wear a mask while exercising?

Even when you're in an area of COVID-19 transmission, masks should not be worn during vigorous physical activity because of the risk of reducing your breathing capacity. No matter how intensely you exercise, keep at least 1 metre away from others, and if you're indoors, make sure there is adequate ventilation.

Mask use in the context of COVID-19

Interim guidance

1 December 2020

World Health Organization

This document, which is an update of the guidance published on 5 June 2020, includes new scientific evidence relevant to the use of masks for reducing the spread of SARS-CoV-2, the virus that causes COVID-19, and practical considerations. It contains updated evidence and guidance on the following:

- mask management;
- SARS-CoV-2 transmission;
- masking in health facilities in areas with community, cluster and sporadic transmission;
- mask use by the public in areas with community and cluster transmission;
- alternatives to non-medical masks for the public;
- exhalation valves on respirators and non-medical masks;
- mask use during vigorous intensity physical activity;
- essential parameters to be considered when manufacturing non-medical masks (Annex).

Key points

- The World Health Organization (WHO) advises the use of masks as part of a comprehensive package of prevention and control measures to limit the spread of SARS-CoV-2, the virus that causes COVID-19. A mask alone, even when it is used correctly, is insufficient to provide adequate protection or source control. Other infection prevention and control (IPC) measures include hand hygiene, physical distancing of at least 1 metre, avoidance of touching one's face, respiratory etiquette, adequate ventilation in indoor settings, testing, contact tracing, quarantine and isolation. Together these measures are critical to prevent human-to-human transmission of SARS-CoV-2.
- Depending on the type, masks can be used either for protection of healthy persons or to prevent onward transmission (source control).
- WHO continues to advise that anyone suspected or confirmed of having COVID-19 or awaiting viral laboratory test results should wear a medical mask when in the presence of others (this does not apply to those awaiting a test prior to travel).
- For any mask type, appropriate use, storage and cleaning or disposal are essential to ensure that they are as effective as possible and to avoid an increased transmission risk.

<u>Mask use in health care settings</u>

- WHO continues to recommend that health workers (1) providing care to suspected or confirmed COVID-19 patients wear the following types of mask/respirator in addition to other personal protective equipment that are part of standard, droplet and contact precautions:
  - medical mask in the absence of aerosol generating procedures (AGPs)
  - respirator, N95 or FFP2 or FFP3 standards, or equivalent in care settings for COVID-19 patients where AGPs are performed; these may be used by health workers when providing care to COVID-19 patients in other settings if they are widely available and if costs is not an issue.
- In areas of known or suspected community or cluster SARS-CoV-2 transmission WHO advises the following:
  - universal masking for all persons (staff, patients, visitors, service providers and others) within the health facility (including primary, secondary and tertiary care levels; outpatient care; and long-term care facilities)
  - wearing of masks by inpatients when physical distancing of at least 1 metre cannot be maintained or when patients are outside of their care areas.
- In areas of known or suspected sporadic SARS-CoV-2 transmission, health workers working in clinical areas where patients are present should continuously wear a medical mask. This is known as targeted continuous medical masking for health workers in clinical areas;
- Exhalation valves on respirators are discouraged as they bypass the filtration function for exhaled air by the wearer.

<u>Mask use in community settings</u>

- Decision makers should apply a risk-based approach when considering the use of masks for the general public.
- In areas of known or suspected community or cluster SARS-CoV-2 transmission:
  - WHO advises that the general public should wear a non-medical mask in indoor (e.g. shops, shared workplaces, schools - see Table 2 for details) or outdoor settings where physical distancing of at least 1 metre cannot be maintained.
  - If indoors, unless ventilation has been be assessed to be adequate[1], WHO advises that the general public should wear a non-medical mask, regardless of whether physical distancing of at least 1 metre can be maintained.

[1] For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies enacting ventilation requirements. If not available or applicable, a recommended ventilation rate of 10 l/s/person should be met (except healthcare facilities which have specific requirements). For more information consult "Coronavirus (COVID-19) response

  - Individuals/people with higher risk of severe complications from COVID-19 (individuals ≥ 60 years old and those with underlying conditions such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease or immunosuppression) should wear medical masks when physical distancing of at least 1 metre cannot be maintained.
- In any transmission scenarios:
  - Caregivers or those sharing living space with people with suspected or confirmed COVID-19, regardless of symptoms, should wear a medical mask when in the same room.

Mask use in children (2)

- Children aged up to five years should not wear masks for source control.
- For children between six and 11 years of age, a risk-based approach should be applied to the decision to use a mask; factors to be considered in the risk-based approach include intensity of SARS-CoV-2 transmission, child's capacity to comply with the appropriate use of masks and availability of appropriate adult supervision, local social and cultural environment, and specific settings such as households with elderly relatives, or schools.
- Mask use in children and adolescents 12 years or older should follow the same principles as for adults.
- Special considerations are required for immunocompromised children or for paediatric patients with cystic fibrosis or certain other diseases (e.g., cancer), as well as for children of any age with developmental disorders, disabilities or other specific health conditions that might interfere with mask wearing.

Manufacturing of non-medical (fabric) masks (Annex)

- Homemade fabric masks of three-layer structure (based on the fabric used) are advised, with each layer providing a function: 1) an innermost layer of a hydrophilic material 2) an outermost layer made of hydrophobic material 3) a middle hydrophobic layer which has been shown to enhance filtration or retain droplets.
- Factory-made fabric masks should meet the minimum thresholds related to three essential parameters: filtration, breathability and fit.
- Exhalation valves are discouraged because they bypass the filtration function of the fabric mask rendering it unserviceable for source control.

Methodology for developing the guidance

Guidance and recommendations included in this document are based on published WHO guidelines (in particular the WHO Guidelines on infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care) (2) and ongoing evaluations of all available scientific evidence by the WHO ad hoc COVID-19 Infection Prevention and Control Guidance Development Group (COVID-19 IPC GDG) (see acknowledgement section for list of GDG members). During emergencies WHO publishes interim guidance, the development of which follows a transparent and robust process of evaluation of the available evidence on benefits and harms. This evidence is evaluated through expedited systematic reviews and expert consensus-building through weekly GDG consultations, facilitated by a methodologist and, when necessary, followed up by surveys. This process also considers, as much as possible, potential resource implications, values and preferences, feasibility, equity, and ethics. Draft guidance documents are reviewed by an external review panel of experts prior to publication.

Purpose of the guidance

This document provides guidance for decision makers, public health and IPC professionals, health care managers and health workers in health care settings (including long-term care and residential), for the public and for manufactures of non-medical masks (Annex). It will be revised as new evidence emerges.

WHO has also developed comprehensive guidance on IPC strategies for health care settings (3), long-term care facilities (LTCF) (4), and home care (5).

Background

The use of masks is part of a comprehensive package of prevention and control measures that can limit the spread of certain respiratory viral diseases, including COVID-19. Masks can be used for protection of healthy persons (worn to protect oneself when in contact with an infected individual) or for source control (worn by an infected individual to prevent onward transmission) or both.

However, the use of a mask alone, even when correctly used (see below), is insufficient to provide an adequate level of protection for an uninfected individual or prevent onward transmission from an infected individual (source control). Hand hygiene, physical distancing of at least 1 metre, respiratory etiquette, adequate ventilation in indoor settings, testing, contact tracing, quarantine, isolation and other infection prevention and control (IPC) measures are critical to prevent human-to-human transmission of SARS-CoV-2, whether or not masks are used (6).

Mask management

For any type of mask, appropriate use, storage and cleaning, or disposal are essential to ensure that they are as effective as possible and to avoid any increased risk of transmission. Adherence to correct mask management practices varies, reinforcing the need for appropriate messaging (7).

WHO provides the following guidance on the correct use of masks:

- Perform hand hygiene before putting on the mask.
- Inspect the mask for tears or holes, and do not use a damaged mask.
- Place the mask carefully, ensuring it covers the mouth and nose, adjust to the nose bridge and tie it securely to minimize any gaps between the face and the mask. If using ear loops, ensure these do not cross over as this widens the gap between the face and the mask.

resources from ASHRAE and others''
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- Avoid touching the mask while wearing it. If the mask is accidently touched, perform hand hygiene.
- Remove the mask using the appropriate technique. Do not touch the front of the mask, but rather untie it from behind.
- Replace the mask as soon as it becomes damp with a new clean, dry mask.
- Either discard the mask or place it in a clean plastic resealable bag where it is kept until it can be washed and cleaned. Do not store the mask around the arm or wrist or pull it down to rest around the chin or neck.
- Perform hand hygiene immediately afterward discarding a mask.
- Do not re-use single-use mask.
- Discard single-use masks after each use and properly dispose of them immediately upon removal.
- Do not remove the mask to speak.
- Do not share your mask with others.
- Wash fabric masks in soap or detergent and preferably hot water (at least 60° Centigrade/140° Fahrenheit) at least once a day. If it is not possible to wash the masks in hot water, then wash the mask in soap/detergent and room temperature water, followed by boiling the mask for 1 minute.

Scientific evidence

Transmission of the SARS-CoV-2 virus

Knowledge about transmission of the SARS-CoV-2 virus is evolving continuously as new evidence accumulates. COVID-19 is primarily a respiratory disease, and the clinical spectrum can range from no symptoms to severe acute respiratory illness, sepsis with organ dysfunction and death.

According to available evidence, SARS-CoV-2 mainly spreads between people when an infected person is in close contact with another person. Transmissibility of the virus depends on the amount of viable virus being shed and expelled by a person, the type of contact they have with others, the setting and what IPC measures are in place. The virus can spread from an infected person's mouth or nose in small liquid particles when the person coughs, sneezes, sings, breathes heavily or talks. These liquid particles are different sizes, ranging from larger 'respiratory droplets' to smaller 'aerosols.' Close-range contact (typically within 1 metre) can result in inhalation of, or inoculation with, the virus through the mouth, nose or eyes (8-13).

There is limited evidence of transmission through fomites (objects or materials that may be contaminated with viable virus, such as utensils and furniture or in health care settings a stethoscope or thermometer) in the immediate environment around the infected person (14-17). Nonetheless, fomite transmission is considered a possible mode of transmission for SARS-CoV-2, given consistent finding of environmental contamination in the vicinity of people infected with SARS-CoV-2 and the fact that other coronaviruses and respiratory viruses can be transmitted this way (12).

Aerosol transmission can occur in specific situations in which procedures that generate aerosols are performed. The scientific community has been actively researching whether the SARS-CoV-2 virus might also spread through aerosol transmission in the absence of aerosol generating procedures (AGPs) (18, 19). Some studies that performed air sampling in clinical settings where AGPs were not performed found virus RNA, but others did not. The presence of viral RNA is not the same as replication- and infection-competent (viable) virus that could be transmissible and capable of sufficient inoculum to initiate invasive infection. A limited number of studies have isolated viable SARS-CoV-2 from air samples in the vicinity of COVID-19 patients (20, 21).

Outside of medical facilities, in addition to droplet and fomite transmission, aerosol transmission can occur in specific settings and circumstances, particularly in indoor, crowded and inadequately ventilated spaces, where infected persons spend long periods of time with others. Studies have suggested these can include restaurants, choir practices, fitness classes, nightclubs, offices and places of worship (12).

High quality research is required to address the knowledge gaps related to modes of transmission, infectious dose and settings in which transmission can be amplified. Currently, studies are underway to better understand the conditions in which aerosol transmission or superspreading events may occur.

Current evidence suggests that people infected with SARS-CoV-2 can transmit the virus whether they have symptoms or not. However, data from viral shedding studies suggest that infected individuals have highest viral loads just before or around the time they develop symptoms and during the first 5-7 days of illness (12). Among symptomatic patients, the duration of infectious virus shedding has been estimated at 8 days from the onset of symptoms (22-24) for patients with mild disease, and longer for severely ill patients (12). The period of infectiousness is shorter than the duration of detectable RNA shedding, which can last many weeks (17).

The incubation period for COVID-19, which is the time between exposure to the virus and symptom onset, is on average 5-6 days, but can be as long as 14 days (25, 26).

Pre-symptomatic transmission – from people who are infected and shedding virus but have not yet developed symptoms – can occur. Available data suggest that some people who have been exposed to the virus can test positive for SARS-CoV-2 via polymerase chain reaction (PCR) testing 1-3 days before they develop symptoms (27). People who develop symptoms appear to have high viral loads on or just prior to the day of symptom onset, relative to later on in their infection (28).

Asymptomatic transmission – transmission from people infected with SARS-CoV-2 who never develop symptoms – can occur. One systematic review of 79 studies found that 20% (17–25%) of people remained asymptomatic throughout the course of infection. (28). Another systematic review, which included 13 studies considered to be at low risk of bias, estimated that 17% of cases remain asymptomatic (14%–20%) (30). Viable virus has been isolated from specimens of pre-symptomatic and asymptomatic individuals, suggesting that people who do not have symptoms may be able to transmit the virus to others. (25, 29-37)

Studies suggest that asymptomatically infected individuals are less likely to transmit the virus than those who develop symptoms (29). A systematic review concluded that individuals who are asymptomatic are responsible for transmitting fewer infections than symptomatic and pre-symptomatic cases (38). One meta-analysis estimated that there is a 42% lower relative risk of asymptomatic transmission compared to symptomatic transmission (30).

Guidance on mask use in health care settings

Masks for use in health care settings

Medical masks are defined as surgical or procedure masks that are flat or pleated. They are affixed to the head with straps that go around the ears or head or both. Their performance characteristics are tested according to a set of standardized test methods (ASTM F2100, EN 14683, or equivalent) that aim to balance high filtration, adequate breathability and optionally, fluid penetration resistance (39, 40).

Filtering facepiece respirators (FFR), or respirators, offer a balance of filtration and breathability. However, whereas medical masks filter 3 micrometre droplets, respirators must filter more challenging 0.075 micrometre solid particles. European FFRs, according to standard EN 149, at FFP2 performance there is filtration of at least 94% solid NaCl particles and oil droplets. US N95 FFRs, according to NIOSH 42 CFR Part 84, filter at least 95% NaCl particles. Certified FFRs must also ensure unhindered breathing with maximum resistance during inhalation and exhalation. Another important difference between FFRs and other masks is the way filtration is tested. Medical mask filtration tests are performed on a cross-section of the masks, whereas FFRs are tested for filtration across the entire surface. Therefore, the layers of the filtration material and the FFR shape, which ensure the outer edges of the FFR seal around wearer's face, result in guaranteed filtration as claimed. Medical masks, by contrast, have an open shape and potentially leaking structure. Other FFR performance requirements include being within specified parameters for maximum CO_2 build up, total inward leakage and tensile strength of straps (41, 42).

A. Guidance on the use of medical masks and respirators to provide care to suspected or confirmed COVID-19 cases

Evidence on the use of mask in health care settings

Systematic reviews have reported that the use of N95/P2 respirators compared with the use of medical masks (see mask definitions, above) is not associated with statistically significant differences for the outcomes of health workers acquiring clinical respiratory illness, influenza-like illness (risk ratio 0.83, 95%CI 0.63-1.08) or laboratory-confirmed influenza (risk ratio 1.02, 95%CI 0.73-1.43); harms were poorly reported and limited to discomfort associated with lower compliance (43, 44). In many settings, preserving the supply of N95 respirators for high-risk, aerosol-generating procedures is an important consideration (45).

A systematic review of observational studies on the betacoronaviruses that cause severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS) and COVID-19 found that the use of face protection (including respirators and medical masks) is associated with reduced risk of infection among health workers. These studies suggested that N95 or similar respirators might be associated with greater reduction in risk than medical or 12–16-layer cotton masks. However, these studies had important limitations (recall bias, limited information about the situations when respirators were used and limited ability to measure exposures), and very few studies included in the review evaluated the transmission risk of COVID-19 (46). Most of the studies were conducted in settings in which AGPs were performed or other high-risk settings (e.g., intensive care units or where there was exposure to infected patients and health workers were not wearing adequate PPE).

WHO continues to evaluate the evidence on the effectiveness of the use of different masks and their potential harms, risks and disadvantages, as well as their combination with hand hygiene, physical distancing of at least 1 metre and other IPC measures.

Guidance

WHO's guidance on the type of respiratory protection to be worn by health workers providing care to COVID-19 patients is based on 1) WHO recommendations on IPC for epidemic- and pandemic-prone acute respiratory infections in health care (47); 2) updated systematic reviews of randomized controlled trials on the effectiveness of medical masks compared to that of respirators for reducing the risk of clinical respiratory illness, influenza-like illness (ILI) and laboratory-confirmed influenza or viral infections. WHO guidance in this area is aligned with guidelines of other professional organizations, including the European Society of Intensive Care Medicine and the Society of Critical Care Medicine, and the Infectious Diseases Society of America (48, 49).

The WHO COVID-19 IPC GDG considered all available evidence on the modes of transmission of SARS-CoV-2 and on the effectiveness of medical mask versus respirator use to protect health workers from infection and the potential for harms such as skin conditions or breathing difficulties.

Other considerations included availability of medical masks versus respirators, cost and procurement implications and equity of access by health workers across different settings.

The majority (71%) of the GDG members confirmed their support for previous recommendations issued by WHO on 5 June 2020:

1. In the absence of aerosol generating procedures (AGPs)[2], WHO recommends that health workers providing care to patients with suspected or confirmed COVID-19 should wear a medical mask (in addition to other PPE that are part of droplet and contact precautions).
2. In care settings for COVID-19 patients where AGPs are performed, WHO recommends that health workers should wear a respirator (N95 or FFP2 or FFP3 standard, or equivalent) in addition to other PPE that are part of airborne and contact precautions.

In general, health workers have strong preferences about having the highest perceived protection possible to prevent COVID-19 infection and therefore may place high value on the potential benefits of respirators in settings without AGPs. WHO recommends respirators primarily for settings where AGPs are performed; however, if health workers prefer them and they are sufficiently available and cost is not an issue, they could also be used during care for COVID-19 patients in other settings. For additional guidance on PPE, including PPE

[2] The WHO list of AGPs includes tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, bronchoscopy, sputum induction using nebulized hypertonic saline, and dentistry and autopsy procedures.

beyond mask use by health workers, see WHO IPC guidance during health care when COVID-19 infection is suspected (3) and also WHO guidance on the rational use of PPE (45).

Exhalation valves on respirators are discouraged as they bypass the filtration function for exhaled air.

B. Guidance on the use of mask by health workers, caregivers and others based on transmission scenario

Definitions

Universal masking in health facilities is defined as the requirement for all persons (staff, patients, visitors, service providers and others) to wear a mask at all times except for when eating or drinking.

Targeted continuous medical mask use is defined as the practice of wearing a medical mask by all health workers and caregivers working in clinical areas during all routine activities throughout the entire shift.

Health workers are all people primarily engaged in actions with the primary intent of enhancing health. Examples are: nursing and midwifery professionals, doctors, cleaners, other staff who work in health facilities, social workers, and community health workers.

Evidence on universal masking in health care settings

In areas where there is community transmission or large-scale outbreaks of COVID-19, universal masking has been adopted in many hospitals to reduce the potential of transmission by health workers to patients, to other staff and anyone else entering the facility (50).

Two studies found that implementation of a universal masking policy in hospital systems was associated with decreased risk of healthcare-acquired SARS-CoV-2 infection. However, these studies had serious limitations: both were before-after studies describing a single example of a phenomenon before and after an event of interest, with no concurrent control group, and other infection control measures were not controlled for (51, 52). In addition, observed decreases in health worker infections occurred too quickly to be attributable to the universal masking policy.

Guidance

Although more research on universal masking in heath settings is needed, it is the expert opinion of the majority (79%) of WHO COVID-19 IPC GDG members that universal masking is advisable in geographic settings where there is known or suspected community or cluster transmission of the SARS-CoV-2 virus.

1. In areas of known or suspected community or cluster SARS-CoV-2 transmission, universal masking should be advised in all health facilities (see Table 1).

- All health workers, including community health workers and caregivers, should wear a medical mask at all times, for any activity (care of COVID-19 or non-COVID-19 patients) and in any common area (e.g., cafeteria, staff rooms).
- Other staff, visitors, outpatients and service providers should also wear a mask (medical or non-medical) at all times
- Inpatients are not required to wear a mask (medical or non-medical) unless physical distancing of at least 1 metre cannot be maintained (e.g., when being examined or visited at the bedside) or when outside of their care area (e.g., when being transported).
- Masks should be changed when they become soiled, wet or damaged or if the health worker/caregiver removes the mask (e.g., for eating or drinking or caring for a patient who requires droplet/contact precautions for reasons other than COVID-19).

2. In the context of known or suspected sporadic SARS-CoV-2 virus transmission, WHO provides the following guidance:

- Health workers, including community health workers and caregivers who work in clinical areas, should continuously wear a medical mask during routine activities throughout the entire shift, apart from when eating and drinking and changing their medical masks after caring for a patient who requires droplet/contact precautions for other reasons. In all cases, medical masks must be changed when wet, soiled, or damaged; used medical masks should be properly disposed of at the end of the shift; and new clean ones should be used for the next shift or when medical masks are changed.
- It is particularly important to adopt the continuous use of masks in potentially high transmission risk settings including triage, family physician/general practitioner offices; outpatient departments; emergency rooms; COVID-19 designated units; haematology, oncology and transplant units; and long-term health and residential facilities.
- Staff who do not work in clinical areas (e.g., administrative staff) do not need to wear a medical mask during routine activities if they have no exposure to patients.

Whether using masks for universal masking within health facilities or targeted continuous medical mask use throughout the entire shift, health workers should ensure the following:

- Medical mask use should be combined with other measures including frequent hand hygiene and physical distancing among health workers in shared and crowded places such as cafeterias, break rooms, and dressing rooms.
- The medical mask should be changed when wet, soiled, or damaged.
- The medical mask should not be touched to adjust it or if displaced from the face for any reason. If this happens, the mask should be safely removed and replaced, and hand hygiene performed.
- The medical mask (as well as other personal protective equipment) should be discarded and changed after caring for any patient who requires contact/droplet precautions for other pathogens, followed by hand hygiene.
- Under no circumstances should medical masks be shared between health workers or between others wearing them. Masks should be appropriately disposed of whenever removed and not reused.

- A particulate respirator at least as protective as a United States of America (US) National Institute for Occupational Safety and Health-certified N95, N99, US Food and Drug Administration surgical N95, European Union standard FFP2 or FFP3, or equivalent, should be worn in settings for COVID-19 patients where AGPs are performed (see WHO recommendations below). In these settings, this includes continuous use by health workers throughout the entire shift, when this policy is implemented.

Note: Decision makers may consider the transmission intensity in the catchment area of the health facility or community setting and the feasibility of implementing a universal masking policy compared to a policy based on assessed or presumed exposure risk. Decisions need to take into account procurement, sustainability and costs of the policy. When planning masks for all health workers, long-term availability of adequate medical masks (and when applicable, respirators) for all workers should be ensured, in particular for those providing care for patients with confirmed or suspected COVID-19. Proper use and adequate waste management should be ensured.

The potential harms and risks of mask and respirator use in the health facility setting include:

- contamination of the mask due to its manipulation by contaminated hands (53, 54);
- potential self-contamination that can occur if medical masks are not changed when wet, soiled or damaged; or by frequent touching/adjusting when worn for prolonged periods (55);
- possible development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours (56-58);
- discomfort, facial temperature changes and headaches from mask wearing (44, 59, 60);
- false sense of security leading potentially to reduced adherence to well recognized preventive measures such as physical distancing and hand hygiene; and risk-taking behaviours (61-64);
- difficulty wearing a mask in hot and humid environments
- possible risk of stock depletion due to widespread use in the context of universal masking and targeted continuous mask use and consequent scarcity or unavailability for health workers caring for COVID 19 patients and during health care interactions with non-COVID-19 patients where medical masks or respirators might be required.

Alternatives to medical masks in health care settings

The WHO's disease commodity package (DCP) for COVID-19 recommends medical masks for health workers to be type II or higher (65). Type II medical masks provide a physical barrier to fluids and particulate materials and have bacterial filtration efficiency of ≥98% compared to Type I mask, which has bacterial filtration efficiency of ≥95% and lower fluid resistance (66) In case of stock outs of type II or higher medical masks, health workers should use a type I medical mask as an alternative. Other alternatives such as face shields or fabric masks should be carefully evaluated.

Face shields are designed to provide protection from splashes of biological fluid (particularly respiratory secretions), chemical agents and debris (67, 68) into the eyes. In the context of protection from SARS-CoV-2 transmission through respiratory droplets, face shields are used by health workers as personal protective equipment (PPE) for eye protection in combination with a medical mask or a respirator (69, 70) While a face shield may confer partial protection of the facial area against respiratory droplets, these and smaller droplets may come into contact with mucous membranes or with the eyes from the open gaps between the visor and the face (71,67).

Fabric masks are not regulated as protective masks or part of the PPE directive. They vary in quality and are not subject to mandatory testing or common standards and as such are not considered an appropriate alternative to medical masks for protection of health workers. One study that evaluated the use of cloth masks in a health care facility found that health care workers using 2 ply cotton cloth masks (a type of fabric mask) were at increased risk of influenza-like illness compared with those who wore medical masks (72).

In the context of severe medical mask shortage, face shields alone or in combination with fabric mask may be considered as a last resort (73). Ensure proper design of face shields to cover the sides of the face and below the chin.

As for other PPE items, if production of fabric masks for use in health care settings is proposed locally in situations of shortage or stock out, a local authority should assess the product according to specific minimum performance standards and required technical specifications (see Annex).

Additional considerations for community care settings

Like other health workers, community health workers should apply standard precautions for all patients at all times, with particular emphasis regarding hand and respiratory hygiene, surface and environmental cleaning and disinfection and the appropriate use of PPE. When a patient is suspected or confirmed of having COVID-19, community health workers should always apply contact and droplet precautions. These include the use of a medical mask, gown, gloves and eye protection (74).

IPC measures that are needed will depend on the local COVID-19 transmission dynamics and the type of contact required by the health care activity (see Table 1). The community health workforce should ensure that patients and workforce members apply precautionary measures such as respiratory hygiene and physical distancing of at least 1 metre (3.3 feet). They also may support set-up and maintenance of hand hygiene stations and community education (74). In the context of known or suspected community or cluster transmission, community health workers should wear a medical mask when providing essential routine services (see Table 1).

Table 1. Mask use in health care settings depending on transmission scenario, target population, setting, activity and type*

Transmission scenario	Target population (who)	Setting (where)	Activity (what)	Mask type (which one) *
Known or suspected community or cluster transmission of SARS-CoV-2	Health workers and caregivers	Health facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities)	For any activity in patient-care areas (COVID-19 or non-COVID-19 patients) or in any common areas (e.g., cafeteria, staff rooms)	Medical mask (or respirator if aerosol generating procedures performed)
	Other staff, patients, visitors, service suppliers		For any activity or in any common area	Medical or fabric mask
	Inpatients	In single or multiple-bed rooms	When physical distance of at least 1 metre cannot be maintained	
	Health workers and caregivers	Home visit (for example, for antenatal or postnatal care, or for a chronic condition)	When in direct contact with a patient or when a distance of at least 1 metre cannot be maintained.	Medical mask
		Community	Community outreach programmes/essential routine services	
Known or suspected sporadic transmission of SARS-CoV-2 cases	Health workers and caregivers	Health facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities)	In patient care area- irrespective of whether patients have suspected/confirmed COVID-19	Medical mask
	Other staff, patients, visitors, service suppliers and all others		No routine activities in patient areas	Medical mask not required. Medical mask should be worn if in contact or within 1 metre of patients, or according to local risk assessment
	Health workers and caregivers	Home visit (for example, for antenatal or postnatal care, or for a chronic condition)	When in direct contact or when a distance of at least 1metre cannot be maintained.	Medical mask
		Community	Community outreach programs (e.g., bed net distribution)	
No documented SARS-CoV-2 transmission	Health workers and caregivers	Health facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities)	Providing any patient care	Medical mask use according to standard and transmission-based precautions
		Community	Community outreach programs	
Any transmission scenario	Health workers	Health care facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities), in settings where aerosol generating procedures (AGP) are performed	Performing an AGP on a suspected or confirmed COVID-19 patient or providing care in a setting where AGPs are in place for COVID-19 patients	Respirator (N95 or N99 or FFP2 or FFP3)

**This table refers only to the use of medical masks and respirators. The use of medical masks and respirators may need to be combined with other personal protective equipment and other measures as appropriate, and always with hand hygiene.*

Guidance on mask use in community settings

Evidence on the protective effect of mask use in community settings

At present there is only limited and inconsistent scientific evidence to support the effectiveness of masking of healthy people in the community to prevent infection with respiratory viruses, including SARS-CoV-2 (75). A large randomized community-based trial in which 4862 healthy participants were divided into a group wearing medical/surgical masks and a control group found no difference in infection with SARS-CoV-2 (76). A recent systematic review found nine trials (of which eight were cluster-randomized controlled trials in which clusters of people, versus individuals, were randomized) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness. Two trials were with healthcare workers and seven in the community. The review concluded that wearing a mask may make little or no difference to the prevention of influenza-like illness (ILI) (RR 0.99, 95%CI 0.82 to 1.18) or laboratory confirmed illness (LCI) (RR 0.91, 95%CI 0.66-1.26) (44); the certainty of the evidence was low for ILI, moderate for LCI.

By contrast, a small retrospective cohort study from Beijing found that mask use by entire families before the first family member developed COVID-19 symptoms was 79% effective in reducing transmission (OR 0.21, 0.06-0.79) (77). A case-control study from Thailand found that wearing a medical or non-medical mask all the time during contact with a COVID-19 patient was associated with a 77% lower risk of infection (aOR 0.23; 95% CI 0.09–0.60) (78). Several small observational studies with epidemiological data have reported an association between mask use by an infected person and prevention of onward transmission of SARS-CoV-2 infection in public settings. (8, 79-81).

A number of studies, some peer reviewed (82-86) but most published as pre-prints (87-104), reported a decline in the COVID-19 cases associated with face mask usage by the public, using country- or region-level data. One study reported an association between community mask wearing policy adoption and increased movement (less time at home, increased visits to commercial locations) (105). These studies differed in setting, data sources and statistical methods and have important limitations to consider (106), notably the lack of information about actual exposure risk among individuals, adherence to mask wearing and the enforcement of other preventive measures (107, 108).

Studies of influenza, influenza-like illness and human coronaviruses (not including COVID-19) provide evidence that the use of a medical mask can prevent the spread of infectious droplets from a symptomatic infected person to someone else and potential contamination of the environment by these droplets (75). There is limited evidence that wearing a medical mask may be beneficial for preventing transmission between healthy individuals sharing households with a sick person or among attendees of mass gatherings (44, 109-114).

A meta-analysis of observational studies on infections due to betacoronaviruses, with the intrinsic biases of observational data, showed that the use of either disposable medical masks or reusable 12–16-layer cotton masks was associated with protection of healthy individuals within households and among contacts of cases (46). This could be considered to be indirect evidence for the use of masks (medical or other) by healthy individuals in the wider community; however, these studies suggest that such individuals would need to be in close proximity to an infected person in a household or at a mass gathering where physical distancing cannot be achieved to become infected with the virus. Results from cluster randomized controlled trials on the use of masks among young adults living in university residences in the United States of America indicate that face masks may reduce the rate of influenza-like illness but showed no impact on risk of laboratory-confirmed influenza (115, 116).

Guidance

The WHO COVID-19 IPC GDG considered all available evidence on the use of masks by the general public including effectiveness, level of certainty and other potential benefits and harms, with respect to transmission scenarios, indoor versus outdoor settings, physical distancing and ventilation. Despite the limited evidence of protective efficacy of mask wearing in community settings, in addition to all other recommended preventive measures, the GDG advised mask wearing in the following settings:

1. In areas with known or suspected community or cluster transmission of SARS-CoV-2, WHO advises mask use by the public in the following situations (see Table 2):

   Indoor settings:

- in public indoor settings where ventilation is known to be poor regardless of physical distancing: limited or no opening of windows and doors for natural ventilation; ventilation system is not properly functioning or maintained; or cannot be assessed;
- in public indoor settings that have adequate[3] ventilation if physical distancing of at least 1 metre cannot be maintained;
- in household indoor settings: when there is a visitor who is not a household member and ventilation is known to be poor, with limited opening of windows and doors for natural ventilation, or the ventilation system cannot be assessed or is not properly functioning, regardless of whether physical distancing of at least 1 metre can be maintained;
- in household indoor settings that have adequate ventilation if physical distancing of at least 1 metre cannot be maintained.

[3] For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies enacting ventilation requirements. If not available or applicable, a recommended ventilation rate of 10 l/s/person should be met (except healthcare facilities which have specific requirements). For more information consult "Coronavirus (COVID-19) response resources from ASHRAE and others'' https://www.ashrae.org/technical-resources/resources

Table 2. Mask use in community settings depending on transmission scenario, setting, target population, purpose and type*

Transmission scenario	Situations/settings (where)	Target Population (who)	Purpose of mask use (why)	Mask type (which one)
Known or suspected community or cluster transmission of SARS-CoV-2	Indoor settings, where ventilation is known to be poor or cannot be assessed or the ventilation system is not properly maintained, regardless of whether physical distancing of at least 1 meter can be maintained	General population in public* settings such as shops, shared workplaces, schools, churches, restaurants, gyms, etc. or in enclosed settings such as public transportation. For households, in indoor settings, when there is a visitor who is not a member of the household	Potential benefit for source control	Fabric mask
	Indoor settings that have adequate [4] ventilation if physical distancing of at least 1 metre cannot be maintained			
	Outdoor settings where physical distancing cannot be maintained	General population in settings such as crowded open-air markets, lining up outside a building, during demonstrations, etc.		
	Settings where physical distancing cannot be maintained, and the individual is at increased risk of infection and/or negative outcomes	Individuals/people with higher risk of severe complications from COVID-19: • People aged ≥60 years • People with underlying comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease, immunosuppression, obesity, asthma	Protection	Medical mask
Known or suspected sporadic transmission, or no documented SARS-CoV-2 transmission	Risk-based approach	General population	Potential benefit for source control and/or protection	Depends on purpose (see details in the guidance content)
Any transmission scenario	Any setting in the community	Anyone suspected or confirmed of having COVID-19, regardless of whether they have symptoms or not, or anyone awaiting viral test results, when in the presence of others	Source control	Medical mask

**Public indoor setting includes any indoor setting outside of the household*

[4] For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies enacting ventilation requirements. If not available or applicable, a recommended ventilation rate of 10l/s/person should be met (except healthcare facilities which have specific requirements).). For more information consult "Coronavirus (COVID-19) response resources from ASHRAE and others'' https://www.ashrae.org/technical-resources/resources

In outdoor settings:

- where physical distancing of at least 1 metre cannot be maintained;
- individuals/people with higher risk of severe complications from COVID-19 (individuals ≥ 60 years old and those with underlying conditions such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease or immunosuppression) should wear medical masks in any setting where physical distance cannot be maintained.

2. In areas with known or suspected sporadic transmission or no documented transmission, as in all transmission scenarios, WHO continues to advise that decision makers should apply a risk-based approach focusing on the following criteria when considering the use of masks for the public:

- **Purpose of mask use**. Is the intention source control (preventing an infected person from transmitting the virus to others) or protection (preventing a healthy wearer from the infection)?
- **Risk of exposure to SARS-CoV-2**. Based on the epidemiology and intensity of transmission in the population, is there transmission and limited or no capacity to implement other containment measures such as contact tracing, ability to carry out testing and isolate and care for suspected and confirmed cases? Is there risk to individuals working in close contact with the public (e.g., social workers, personal support workers, teachers, cashiers)?
- **Vulnerability of the mask wearer/population**. Is the mask wearer at risk of severe complications from COVID-19? Medical masks should be used by older people (≥ 60 years old), immunocompromised patients and people with comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer and cerebrovascular disease (117).
- **Setting in which the population lives**. Is there high population density (such as in refugee camps, camp-like settings, and among people living in cramped conditions) and settings where individuals are unable to keep a physical distance of at least 1 metre (for example, on public transportation)?
- **Feasibility**. Are masks available at an affordable cost? Do people have access to clean water to wash fabric masks, and can the targeted population tolerate possible adverse effects of wearing a mask?
- **Type of mask**. Does the use of medical masks in the community divert this critical resource from the health workers and others who need them the most? In settings where medical masks are in short supply, **stocks should be prioritized for health workers and at-risk individuals.**

The decision of governments and local jurisdictions whether to recommend or make mandatory the use of masks should be based on the above assessment as well as the local context, culture, availability of masks and resources required.

3. In any transmission scenario:

- Persons with any symptoms suggestive of COVID-19 should wear a medical mask and (5) additionally:
  - self-isolate and seek medical advice as soon as they start to feel unwell with potential symptoms of COVID-19, even if symptoms are mild);
  - follow instructions on how to put on, take off, and dispose of medical masks and perform hand hygiene (118);
  - follow all additional measures, in particular respiratory hygiene, frequent hand hygiene and maintaining physical distance of at least 1 metre from other persons (46). If a medical mask is not available for individuals with suspected or confirmed COVID-19, a fabric mask meeting the specifications in the Annex of this document should be worn by patients as a source control measure, pending access to a medical mask. The use of a non-medical mask can minimize the projection of respiratory droplets from the user (119, 120).
  - Asymptomatic persons who test positive for SARS-CoV-2, should wear a medical mask when with others for a period of 10 days after testing positive.

Potential benefits/harms

The potential advantages of mask use by healthy people in the general public include:

- reduced spread of respiratory droplets containing infectious viral particles, including from infected persons before they develop symptoms (121);
- reduced potential for stigmatization and greater of acceptance of mask wearing, whether to prevent infecting others or by people caring for COVID-19 patients in non-clinical settings (122);
- making people feel they can play a role in contributing to stopping spread of the virus;
- encouraging concurrent transmission prevention behaviours such as hand hygiene and not touching the eyes, nose and mouth (123-125);
- preventing transmission of other respiratory illnesses like tuberculosis and influenza and reducing the burden of those diseases during the pandemic (126).

The potential disadvantages of mask use by healthy people in the general public include:

- headache and/or breathing difficulties, depending on type of mask used (55);
- development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours (58, 59, 127);
- difficulty with communicating clearly, especially for persons who are deaf or have poor hearing or use lip reading (128, 129);
- discomfort (44, 55, 59)
- a false sense of security leading to potentially lower adherence to other critical preventive measures such as physical distancing and hand hygiene (105);
- poor compliance with mask wearing, in particular by young children (111, 130-132);
- waste management issues; improper mask disposal leading to increased litter in public places and environmental hazards (133);
- disadvantages for or difficulty wearing masks, especially for children, developmentally challenged persons, those with mental illness, persons with cognitive impairment, those with asthma or chronic respiratory or breathing problems, those who have had facial trauma or recent oral maxillofacial surgery and those living in hot and humid environments (55, 130).

Considerations for implementation

When implementing mask policies for the public, decision-makers should:

- clearly communicate the purpose of wearing a mask, including when, where, how and what type of mask should be worn; explain what wearing a mask may achieve and what it will not achieve; and communicate clearly that this is one part of a package of measures along with hand hygiene, physical distancing, respiratory etiquette, adequate ventilation in indoor settings and other measures that are all necessary and all reinforce each other;
- inform/train people on when and how to use masks appropriately and safely (see mask management and maintenance sections);
- consider the feasibility of use, supply/access issues (cleaning, storage), waste management, sustainability, social and psychological acceptance (of both wearing and not wearing different types of masks in different contexts);
- continue gathering scientific data and evidence on the effectiveness of mask use (including different types of masks) in non-health care settings;
- evaluate the impact (positive, neutral or negative) of using masks in the general population (including behavioural and social sciences) through good quality research.

Mask use during physical activity

Evidence

There are limited studies on the benefits and harms of wearing medical masks, respirators and non-medical masks while exercising. Several studies have demonstrated statistically significant deleterious effects on various cardiopulmonary physiologic parameters during mild to moderate exercise in healthy subjects and in those with underlying respiratory diseases (134-140). The most significant impacts have been consistently associated with the use of respirators and in persons with underlying obstructive airway pulmonary diseases such as asthma and chronic obstructive pulmonary disease (COPD), especially when the condition is moderate to severe (136). Facial microclimate changes with increased temperature, humidity and perceptions of dyspnoea were also reported in some studies on the use of masks during exercise (134, 141). A recent review found negligeable evidence of negative effects of mask use during exercise but noted concern for individuals with severe cardiopulmonary disease (142).

Guidance

WHO advises that people should not wear masks during vigorous intensity physical activity (143) because masks may reduce the ability to breathe comfortably. The most important preventive measure is to maintain physical distancing of at least 1 meter and ensure good ventilation when exercising.

If the activity takes place indoors, adequate ventilation should be ensured at all times through natural ventilation or a properly functioning or maintained ventilation system (144). Particular attention should be paid to cleaning and disinfection of the environment, especially high-touch surfaces. If all the above measures cannot be ensured, consider temporary closure of public indoor exercise facilities (e.g., gyms).

Face shields for the general public

At present, face shields are considered to provide a level of eye protection only and should not be considered as an equivalent to masks with respect to respiratory droplet protection and/or source control. Current laboratory testing standards only assess face shields for their ability to provide eye protection from chemical splashes (145).

In the context of non-availability or difficulties wearing a non-medical mask (in persons with cognitive, respiratory or hearing impairments, for example), face shields may be considered as an alternative, noting that they are inferior to masks with respect to droplet transmission and prevention. If face shields are to be used, ensure proper design to cover the sides of the face and below the chin.

Medical masks for the care of COVID-19 patients at home

WHO provides guidance on how to care for patients with confirmed and suspected COVID-19 at home when care in a health facility or other residential setting is not possible (5).

- Persons with suspected COVID-19 or mild COVID-19 symptoms should wear a medical mask as much as possible, especially when there is no alternative to being in the same room with other people. The mask should be changed at least once daily. Persons who cannot tolerate a medical mask should rigorously apply respiratory hygiene (i.e., cover mouth and nose with a disposable paper tissue when coughing or sneezing and dispose of it immediately after use or use a bent elbow procedure and then perform hand hygiene).
- Caregivers of or those sharing living space with people with suspected COVID-19 or with mild COVID-19 symptoms should wear a medical mask when in the same room as the affected person.

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Acknowledgments

This document was developed based on advice by the Strategic and Technical Advisory Group for Infectious Hazards (STAG-IH), and in consultation with the following members of:

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WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 1 year after the date of publication.

Annex: Updated guidance on non-medical (fabric) masks

Background

A non-medical mask, also called fabric mask, community mask or face covering, is neither a medical device nor personal protective equipment. Non-medical masks are aimed at the general population, primarily for protecting others from exhaled virus-containing droplets emitted by the mask wearer. They are not regulated by local health authorities or occupational health associations, nor is it required for manufacturers to comply with guidelines established by standards organizations. Non-medical masks may be homemade or manufactured. The essential performance parameters include good breathability, filtration of droplets originating from the wearer, and a snug fit covering the nose and mouth. Exhalation valves on masks are discouraged as they bypass the filtration function of the mask.

Non-medical masks are made from a variety of woven and non-woven fabrics, such as woven cotton, cotton/synthetic blends, polyesters and breathable spunbond polypropylene, for example. They may be made of different combinations of fabrics, layering sequences and available in diverse shapes. Currently, more is known about common household fabrics and combinations to make non-medical masks with target filtration efficiency and breathability (119, 146-150). Few of these fabrics and combinations have been systematically evaluated and there is no single design, choice of material, layering or shape among available non-medical masks that are considered optimal. While studies have focussed on single fabrics and combinations, few have looked at the shape and universal fit to the wearer. The unlimited combination of available fabrics and materials results in variable filtration and breathability.

In the context of the global shortage of medical masks and PPE, encouraging the public to create their own fabric masks may promote individual enterprise and community integration. Moreover, the production of non-medical masks may offer a source of income for those able to manufacture masks within their communities. Fabric masks can also be a form of cultural expression, encouraging public acceptance of protection measures in general. The safe re-use of fabric masks will also reduce costs and waste and contribute to sustainability (151-156).

This Annex is destined intended for two types of readers: homemade mask makers and factory-made masks manufacturers. Decision makers and managers (national/sub-national level) advising on a type of non-medical mask are also the focus of this guidance and should take into consideration the following features of non-medical masks: breathability, filtration efficiency (FE), or filtration, number and combination of fabric layers material used, shape, coating and maintenance.

Evidence on the effectiveness of non-medical (fabric) masks

A number of reviews have been identified on the effectiveness of non-medical masks (151-156). One systematic review (155) identified 12 studies and evaluated study quality. Ten were laboratory studies (157-166), and two reports were from a single randomized trial (72, 167). The majority of studies were conducted before COVID-19 emerged or used laboratory generated particles to assess filtration efficacy. Overall, the reviews concluded that cloth face masks have limited efficacy in combating viral infection transmission.

Homemade non-medical masks

Homemade non-medical masks made of household fabrics (e.g., cotton, cotton blends and polyesters) should ideally have a three-layer structure, with each layer providing a function (see Figure 1) (168). It should include:

1. an innermost layer (that will be in contact with the face) of a hydrophilic material (e.g., cotton or cotton blends of terry cloth towel, quilting cotton and flannel) that is non-irritating against the skin and can contain droplets (148)
2. a middle hydrophobic layer of synthetic breathable non-woven material (spunbond polypropylene, polyester and polyaramid), which may enhance filtration, prevent permeation of droplets or retain droplets (148, 150)
3. an outermost layer made of hydrophobic material (e.g. spunbond polypropylene, polyester or their blends), which may limit external contamination from penetrating through the layers to the wearer's nose and mouth and maintains and prevents water accumulation from blocking the pores of the fabric (148).

Although a minimum of three layers is recommended for non-medical masks for the most common fabric used, single, double or other layer combinations of advanced materials may be used if they meet performance requirements. It is important to note that with more tightly woven materials, breathability may be reduced as the number of layers increases. A quick check may be performed by attempting to breathe, through the mouth, through the multiple layers.

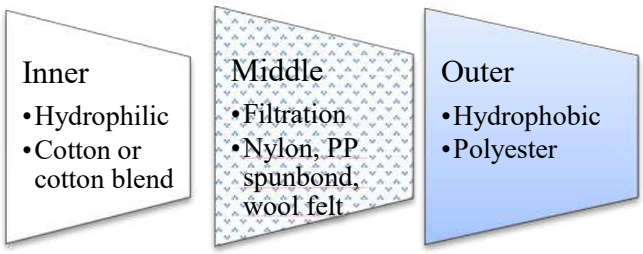

Figure 1. Non-medical mask construction using breathable fabrics such as cotton, cotton blends, polyesters, nylon and polypropylene spunbond that are breathable may impart adequate filtration performance when layered. Single- or double-layer combinations of advanced materials may be used if they meet performance requirements (72).

Assumptions regarding homemade masks are that individual makers only have access to common household fabrics and do not have access to test equipment to confirm target performance (filtration and breathability). Figure 1 illustrates a multi-layer mask construction with examples of fabric options. Very porous materials, such as gauze, even with multiple layers, may provide very low filtration efficiency (147). Higher thread count fabrics offer improved filtration performance (169). Coffee filters, vacuum bags and materials not meant for clothing should be avoided as they may contain injurious content when breathed in. Microporous films such as Gore-Tex are not recommended (170).

Factory-made non-medical masks: general considerations for manufacturers

The non-medical mask, including all components and packaging, must be non-hazardous, non-toxic and child-friendly (no exposed sharp edges, protruding hardware or rough materials). Factory-made non-medical masks must be made using a process that is certified to a quality management system (e.g., ISO 9001). Social accountability standards (e.g., SAI SA8000) for multiple aspects of fair labour practices, health and safety of the work force and adherence to UNICEF's Children's Rights and Business Principles are strongly encouraged.

Standards organizations' performance criteria

Manufacturers producing masks with consistent standardized performance can adhere to published, freely available guidance from several organizations including those from: the French Standardization Association (AFNOR Group), The European Committee for Standardization (CEN), Swiss National COVID-19 Task Force, the American Association of Textile Chemists and Colorists (AATCC), the South Korean Ministry of Food and Drug Safety (MFDS), the Italian Standardization Body (UNI) and the Government of Bangladesh.

Essential parameters

The essential parameters presented in this section are the synthesis of the abovementioned regional and national guidance. They include filtration, breathability and fit. Good performance is achieved when the three essential parameters are optimized at the preferred threshold (Figure 2).

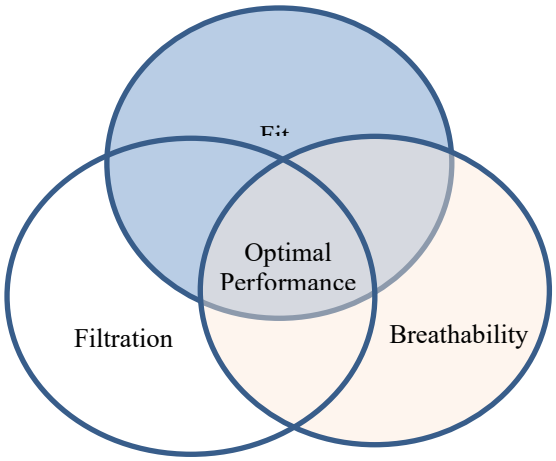

Figure 2. Illustration of the three essential parameters of filtration, breathability and fit.

The summary of the three essential parameters can be found in Table 1 and the additional performance considerations in Table 2. The minimum threshold is the minimum acceptable parameter, while the preferred threshold is the optimum.

Filtration and breathability

Filtration depends on the filtration efficiency (in %), the type of challenge particle (oils, solids, droplets containing bacteria) and the particle size (see Table 1). Depending on the fabrics used, filtration and breathability can complement or work against one another. The selection of material for droplet filtration (barrier) is as important as breathability. Filtration is dependent on the tightness of the weave, fibre or thread diameter. Non-woven materials used for disposable masks are manufactured using processes to create polymer fibres that are thinner than natural fibres such as cotton and that are held together by partial melting.

Breathability is the difference in pressure across the mask and is typically reported in millibars (mbar) or Pascals (Pa) or, normalized to the cm^2 in $mbar/cm^2$ or Pa/cm^2. Acceptable breathability of a medical mask should be below 49 Pa/cm^2. For non-medical masks, an acceptable pressure difference, over the whole mask, should be below 60 Pa/cm^2, with lower values indicating better breathability.

Non-medical fabric masks consisting of two layers of polypropylene spunbond and two layers of cotton have been shown to meet the minimum requirements for droplet filtration and breathability of the CEN CWA 17553 guidance. It is preferable not to select elastic material to make masks as the mask material may be stretched over the face, resulting in increased pore size and lower filtration through multiple usage. Additionally, elastic fabrics are sensitive to washing at high temperatures thus may degrade over time.

Coating the fabric with compounds like wax may increase the barrier and render the mask fluid resistant; however, such coatings may inadvertently completely block the pores and make the mask difficult to breathe through. In addition to decreased breathability unfiltered air may more likely escape the sides of the mask on exhalation. Coating is therefore not recommended.

Valves that let unfiltered air escape the mask are discouraged and are an inappropriate feature for masks used for the purpose of preventing transmission.

Table 1. Essential parameters (minimum and preferred thresholds) for manufactured non-medical mask

Essential Parameters	Minimum threshold	Preferred threshold
1. Filtration*		
1.1. filtration efficiency	70% @ 3 micron	> 70%, without compromising breathability
1.2. Challenge particle	Solid: sodium chloride (NaCl), Talcum powder, Holi powder, dolomite, Polystyrene Latex spheres Liquid: DEHS Di-Ethyl-Hexyl-Sebacat, paraffin oil	Based on availability
1.3. Particle size	Choose either sizes: 3 µm, 1 µm, or smaller	Range of particle sizes
2. Breathability		
2.1. Breathing resistance**	≤60 Pa/cm^2	Adult: ≤ 40 Pa/cm^2 Paediatric: ≤ 20 Pa/cm^2
2.2 Exhalation valves	Not recommended	N/A
3. Fit		
3.1. Coverage	Full coverage of nose and mouth, consistent, snug perimeter fit at the nose bridge, cheeks, chin and lateral sides of the face; adequate surface area to minimize breathing resistance and minimize side leakage	Same as current requirements
3.2 Face seal	Not currently required	Seal as good as FFR (respirator): Fit factor of 100 for N95 Maximum Total Inward Leakage of 25% (FFP1 requirement)
3.2. Sizing	Adult and child	Should cover from the bridge of the nose to below the chin and cheeks on either side of the mouth Sizing for adults and children (3-5, 6-9, 10-12, >12)
3.3Strap strength		> 44.5 N

* Smaller particle may result in lower filtration.
** High resistance can cause bypass of the mask. Unfiltered air will leak out the sides or around the nose if that is the easier path.

Fit: shape and sizing

Fit is the third essential parameter, and takes into consideration coverage, seal, sizing, and strap strength. Fit of masks currently is not defined by any standard except for the anthropometric considerations of facial dimensions (ISO/TS 16976-2) or simplified to height mask (South Korean standard for KF-AD). It is important to ensure that the mask can be held in place comfortably with as little adjustment of the elastic bands or ties as possible.

Mask shapes typically include flat-fold or duckbill and are designed to fit closely over the nose, cheeks and chin of the wearer. Snug fitting designs are suggested as they limit leaks of unfiltered air escaping from the mask (148). Ideally the mask should not have contact with the lips, unless hydrophobic fabrics are used in at least one layer of the mask (148). Leaks where unfiltered air moves in and out of the mask may be attributed to the size and shape of the mask (171).

Additional considerations

Optional parameters to consider in addition to the essential performance parameters include if reusable, biodegradability for disposal masks, antimicrobial performance where applicable and chemical safety (see Table 2).

Non-medical masks intended to be reusable should include instructions for washing and must be washed a minimum of five cycles, implying initial performance is maintained after each wash cycle.

Advanced fabrics may be biodegradable or compostable at the end of service life, according to a recognized standard process (e.g., UNI EN 13432, UNI EN 14995 and UNI / PdR 79).

Manufacturers sometimes claim their NM masks have antimicrobial performance. Antimicrobial performance may be due to coatings or additives to the fabric fibres. Treated fabrics must not come into direct contact with mucous membranes; the innermost fabric should not be treated with antimicrobial additives, only the outermost layer. In addition, antimicrobial fabric standards (e.g., ISO 18184, ISO 20743, AATCC TM100, AATCC 100) are generally slow acting. The inhibition on microbial growth may take full effect after 2- or 24-hour contact time depending on the standard. The standards have generally been used for athletic apparel and substantiate claims of odour control performance. These standards are not appropriate for non-medical cloth masks and may provide a false sense of protection from infectious agents. If claims are maid, manufacturers should specify which standard supports antimicrobial performance, the challenge organism and the contact time.

Volatile additives are discouraged as these may pose a health risk when inhaled repeatedly during wear. Certification according to organizations including OEKO-TEX (Europe) or SEK (Japan), and additives complying with REACH (Europe) or the Environmental Protection Agency (EPA, United States of America) indicate that textile additives are safe and added at safe levels.

Table 2. Additional parameters for manufactured non-medical masks

Additional parameters	Minimum thresholds
If reusable, number of wash cycles	5 cycles
Disposal	Reusable If biodegradable (CFC-BIO), according to UNI EN 13432, UNI EN 14995
Antimicrobial (bacteria, virus, fungus) performance	ISO 18184 (virus) ISO 20743 (bacteria) ISO 13629 (fungus) AATCC TM100 (bacteria)
Chemical safety	Comply with REACH regulation, including inhalation safety

WHO reference number: WHO/2019-nCoV/IPC_Masks/2020.5

- **FDA DOES NOT GIVEN APPROVEL TO MASK (ref page no :7)**
- **If you have any problems due to wear mask please reporting to FDA or your nearest helth center . (ref page no: 11 & 13)**

- **https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-barrier-face-coverings-surgical-masks-and-respirators-covid-19**

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Face Masks, Barrier Face Coverings, Surgical Masks, and Respirators for COVID-19

Español (/medical-devices/coronavirus-covid-19-and-medical-devices/mascarillas-faciales-cubiertas-faciales-de-barrera-mascarillas-quirurgicas-y-respiradores-para-el) 简体中文 (/medical-devices/coronavirus-covid-19-and-medical-devices/yongyu2019xinguanfeiyandemianzhaozugexingmianzhaowaikekouzhaohehuxiqi)

This page provides information on face masks, barrier face coverings, surgical masks, and respirators (filtering facepiece respirators, such as N95 respirators) intended for a medical purpose to assist in preventing the spread of infectious materials during the COVID-19 pandemic.

This page does not cover:

- Powered respirators, such as powered air purifying respirators (PAPRs)
- Face shields
- Non-healthcare use of face masks and respirators intended to limit industrial or general exposure to non-infectious particles, such as during construction or other industrial use.

The information provided may be useful to manufacturers and importers of face masks, barrier face coverings, surgical masks, and respirators, as well as healthcare facilities and health care personnel.

To help expand the availability of face masks, barrier face coverings, surgical masks, and respirators, the FDA is providing certain regulatory flexibility for the duration of the COVID-19 public health emergency, as described in the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) (/regulatory-information /search-fda-guidance-documents/enforcement-policy-face-masks-barrier-face-coverings-face-shields-surgical-masks-andrespirators), and has issued emergency use authorizations (/medical-devices/emergency-use-authorizations-medical-devices /coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices) (EUAs) for face masks, surgical masks, and respirators that meet certain criteria. The FDA regularly updates its communications about face masks, surgical masks, and respirators, including the answers to frequently asked questions on this page.

On this page:

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- Shortages of face masks, surgical masks, and respirators during the COVID-19 pandemic
- Emergency Use Authorizations for face masks, surgical masks, and respirators
- Manufacturing and importing face masks, barrier face coverings, surgical masks, and respirators during the COVID-19 pandemic
- Purchasing face masks, barrier face coverings, surgical masks, and respirators during the COVID-19 pandemic
- Reporting shortages of or problems with face masks, surgical masks, or respirators

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The Basics on Face Masks, Barrier Face Coverings, Surgical Masks, and Respirators

Q: Q: Is there a difference between a face mask, a barrier face covering, a surgical mask, and a respirator?

A: Face masks, barrier face coverings, surgical masks, and respirators (https://www.fda.gov/medical-devices/personalprotective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks#s4) all cover a wearer's nose and mouth, but they differ in several aspects.

- **Face masks:** A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks should be used by the general public and health care personnel as

  source control in accordance with CDC recommendations on Interim Infection Prevention and Control (https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Finfection-control%2Fcontrol-recommendations.html).
- **Barrier face coverings:** As described in ASTM F3502-21, a barrier face covering is a product worn on the face, specifically covering at least the wearer's nose and mouth, with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter.
- **Surgical masks:** A mask intended for medical purposes that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks are Class II medical devices. These masks meet certain fluid barrier protection standards and flammability requirements (that is, Class I or Class II, per 16 CFR 1610.4). Surgical masks are also tested for particulate and bacterial filtration efficiencies and biocompatibility and are considered personal protective equipment (PPE). While surgical masks may be effective in blocking splashes and large-particle droplets, they do not provide a reliable level of protection from aerosolized particles because of the loose fit between the surface of the mask and your face. Surgical masks are not respiratory protective devices, such as respirators.
- **Respirators:** Air purifying respirators, known as respirators, including filtering facepiece respirators (FFRs) such as N95s and surgical N95s, filter at least 95 percent of airborne particles. They are PPE that tightly fit the face and provide certain filtration efficiency levels to help reduce wearer exposure to pathogenic particles in a health care setting. They provide a higher level of protection against viruses and bacteria when properly fit-tested (https://blogs.cdc.gov/nioshscience-blog/2020/03/16/n95-preparedness/).

This CDC infographic (https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf) (PDF - 227KB) explains the differences between surgical masks and N95 respirators.

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Q: Which face masks, barrier face coverings, and surgical masks are medical devices regulated by the FDA?

A: The FDA regulates face masks, including cloth face coverings, barrier face coverings, and surgical masks as medical devices **when they are intended for a medical purpose**. Medical purposes include uses related to helping prevent the spread of COVID-19. Face masks intended for use by the general public for non-medical purposes, such as for use in construction and other industrial applications, are not medical devices.

Using Face Masks, Barrier Face Coverings, Surgical Masks, and Respirators

Q: Do face masks and barrier face coverings provide protection from coronavirus?

A: Face masks and barrier face coverings should generally be used for source control, meaning they may help prevent people who have COVID-19 from spreading the virus to others. These products may also help limit exposure to respiratory droplets and large particles but are not a substitute for filtering facepiece respirators or surgical masks. Please refer to CDC's webpage for recommendations regarding use of masks (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-facecoverings.html).

Q: Are face masks, barrier face coverings, surgical masks, and respirators safe to wear?

A: If worn properly, face masks, barrier face coverings, surgical masks, or respirators may reduce the chance of spreading a COVID-19 infection between you and those around you. The CDC provides information on Using PPE (https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html), How to Protect Yourself and Others (https://www.cdc.gov/coronavirus/2019ncov/prevent-getting-sick/prevention.html), and When You've Been Fully Vaccinated (https://www.cdc.gov/coronavirus /2019-ncov/vaccines/fully-vaccinated.html).

FDA-cleared surgical masks and respirators have been used by health care personnel for years and have been worn in health care facilities during extended procedures without harm to the wearer. Health care personnel with medical conditions should discuss concerns they may have with wearing respirators with their own health care providers. Health care personnel should follow the manufacturer's instructions and their facility's policies for use of all PPE

Q: What does wearing a face mask or a barrier face covering for 'source control' mean?

A: Source control refers to a person's use of barrier face coverings or face masks, including cloth face coverings, to cover the person's mouth and nose when they are talking, sneezing, or coughing to reduce the likelihood of transmission of infection by preventing the spread of respiratory secretions and large particles. COVID-19 may be spread by individuals who may or may not have symptoms of COVID-19.

The general public's use of cloth face coverings made from common, easily accessible materials, are an additional public health approach to help slow the spread of COVID-19. The CDC has information on Types of Masks and Respirators (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html) for the general public.

Barrier face coverings and face masks, including cloth face coverings, intended for a medical purpose, such as prevention of infectious disease transmission, are subject to FDA regulation. The FDA has issued a policy of regulatory flexibility for such products, as well as an emergency use authorization (EUA) for face masks. For more information, see "I'm interested in manufacturing face masks or surgical masks for the COVID-19 pandemic. What do I need to do?"

For more information on source control, see the CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic (https://www.cdc.gov/coronavirus/2019ncov/hcp/infection-control-recommendations.html).

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Q: During the COVID-19 public health emergency, when should health care personnel wear face masks, barrier face coverings, or respirators?

A: During the COVID-19 public health emergency, the CDC recommends healthcare personnel wear well-fitting source control at all times while they are in the healthcare facility, including in breakrooms or common areas where they might encounter co-workers or visitors.

When available, surgical masks (a specific type of face mask) are preferred over cloth face coverings for healthcare personnel as surgical masks offer both source control and protection for the wearer against exposure to splashes and sprays of infectious material from others.

- Non-surgical face masks, including cloth face coverings, should NOT be worn instead of a respirator or surgical mask if more than source control is needed.
- Wear an N95 or equivalent or higher-level respirator, instead of a face mask or barrier face covering, for:
  - Aerosol generating procedures (refer to "Which procedures are considered aerosol generating procedures in healthcare settings?" on the CDC's Clinical Questions about COVID-19: Questions and Answers (https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html) page).
  - Surgical procedures that might pose a higher risk for transmission if the patient has COVID-19 (for example, that generate potentially infectious aerosols or involve anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, or respiratory tract). Refer to "During the COVID-19 pandemic, are there special considerations for surgical and other procedural care settings, including performance of aerosol-generating procedures (AGPs)?" on the CDC's Clinical Questions about COVID-19: Questions and Answers (https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html) page.

Health care personnel should consult their institutional policies for further guidance on what type of face mask or respirator to use.

The CDC provides information on infection control measures for COVID-19 on its Clinical Questions about COVID-19: Questions and Answers (https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html) page.

Shortages of Face Masks, Surgical Masks, and Respirators During the COVID-19 Pandemic

Q:How can health care facilities know if there may be a shortage of face masks, surgical masks, or respirators so they can prepare?

A: The FDA provides information on medical device shortages during the COVID-19 public health emergency (/medicaldevices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency) and maintains a list of devices that it has determined to be either in shortage (https://www.fda.gov/medical-devices/coronaviruscovid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage) or permanently discontinued. (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medicaldevice-shortages-during-covid-19-public-health-emergency#discontinuance)

The FDA is interested in hearing from health care facilities and other stakeholders about shortages and potential shortages they may be experiencing. You may email the FDA at deviceshortages@fda.hhs.gov (mailto:deviceshortages@fda.hhs.gov) .

Q: My supply of surgical masks is running low. What are the best strategies to conserve surgical masks during COVID-19?

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A: The FDA issued a Letter to Health Care Providers on Surgical Mask and Gown Conservation Strategies (/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers) that describes these recommended strategies:

- Conventional capacity strategies
- Contingency capacity strategies
- Crisis or alternate strategies if surgical masks are running low or not available

The CDC provides additional information on Strategies for Optimizing the Supply of Facemasks (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html), including surgical masks.

Q: Can we use expired face masks, barrier face coverings, or surgical masks? Do they offer the protection needed?

A: Face masks, barrier face coverings, and surgical masks are designed to serve as protective barriers and may still offer some protection even if they are used beyond the manufacturer's designated shelf life or expiration date. If there is no date available on the product label or packaging, facilities should contact the manufacturer. The user should inspect all masks prior to use and, if there are concerns such as degraded materials (such as elastic) or visible tears, the product should be discarded. For additional information please refer to the CDC's Strategies for Optimizing the Supply of Facemasks (https://www.cdc.gov /coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html).

Q: How do I know what the manufacturer-designated shelf life is?

A: The manufacturer-designated shelf life or expiration date may be found on the product labeling or packaging, or you can contact the manufacturer directly.

Q: Can we reuse disposable surgical masks during COVID-1 9?

A: The CDC does not recommend the reuse of disposable surgical masks (https://www.cdc.gov/coronavirus/2019-ncov/hcp /non-us-settings/emergency-considerations-ppe.html) that are intended to be used once. The FDA recognizes that there may be availability concerns with surgical masks during the COVID-19 public health emergency, but there are strategies to conserve surgical masks. (/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategiesletter-health-care-providers)

Q: Can face masks and barrier face coverings be cleaned and reused during COVID-19?

A: The CDC recommends reusable face masks be washed after each use and provides information on the washing of cloth face masks. (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wash-cloth-face-coverings.html)

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The reuse of barrier face coverings should be determined based upon the manufacturer's instructions, which may include washing and subsequent wear.

Q: My supply of respirators is running low. What are the best strategies to conserve respirators during COVID-19? Can filtering facepiece respirators (FFRs) such as N95s be reused during COVID-19?

A: The CDC provides additional information on Strategies for Optimizing the Supply of N95 Respirators (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html). As of May 2021, the CDC states that "the supply and availability of NIOSH-approved respirators have increased significantly over the last several months. Healthcare facilities should not be using crisis capacity strategies at this time and should promptly resume conventional practices." Reuse of FFRs is currently not recommended.

Q: Can I still use non-NIOSH-approved FFRs that are no longer authorized by FDA?

A: The FDA realizes that stakeholders such as healthcare facilities and states may continue to have a supply of non-NIOSHapproved FFRs that were authorized prior to FDA's July 6, 2021 revocation of both EUAs concerning non-NIOSH-approved FFRs (/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-ordecontaminated-disposable-respirators). The Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) (/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-barrier-face-coverings-faceshields-surgical-masks-and-respirators) explains that the FDA generally does not intend to object, for the duration of the public health emergency, to the further distribution and use of existing stockpiles of non-NIOSH-approved disposable FFRs for use as face masks for source control by the general public and HCP without compliance with certain regulatory requirements, where such use does not create an undue risk in light of the public health emergency. More information is included in the guidance.

Emergency Use Authorizations for Face Masks, Surgical Masks, and Respirators

Q: Why does the FDA issue Emergency Use Authorizations (EUAs)?

A: EUAs authorize the emergency use of unapproved medical devices. The EUA authority allows the FDA to help strengthen the nation's public health protections against emerging infectious disease threats by facilitating the availability and use of medical devices needed during public health emergencies.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act (/regulatory-information/laws-enforced-fda/federal-food-drugand-cosmetic-act-fdc-act)), the FDA Commissioner may authorize the emergency use of an unapproved or uncleared medical product or an unapproved / uncleared use of an approved/cleared medical product (/medical-devices/coronavirus-disease2019-covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devicesduring-covid-19-pandemic) for certain emergency circumstances after the HHS Secretary has made a declaration of

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emergency or threat justifying emergency use. The FDA Commissioner may issue an EUA to authorize a medical product for use in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, or available alternatives when certain criteria for issuance are met. The Emergency Use Authorizations (EUAs) (/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergencyuse-authorizations-medical-devices) for diagnostic, non-diagnostic, and therapeutic medical devices that the FDA has issued related to COVID-19 may be revised, terminated, or revoked as appropriate.

For details on the Emergency Use Authorizations for these devices, see:

- Personal Protective Equipment EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-useauthorizations-medical-devices/personal-protective-equipment-euas)
- Face Mask EUA (/media/137121/download) (PDF - 98KB)

If you need help with the EUA process for face masks, surgical masks, or respirators, contact CDRH-NonDiagnosticEUATemplates@fda.hhs.gov (mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov) .

To identify FDA-cleared surgical masks and respirators, search the 510(k) Premarket Notification database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm).

Q: What is a pre-EUA?

A: To help prepare for potential and current emergencies, the FDA works with medical device developers to prepare pre-EUA packages when appropriate. A pre-EUA package contains data and information about the safety, quality, and effectiveness of the product, its intended use, and information about the emergency or potential emergency. The pre-EUA process allows the FDA's scientific and technical subject matter experts to begin a review of information and consideration of the EUA statutory criteria, assist in the development of conditions of authorization, fact sheets, and other documentation that would be needed for an EUA, and also helps to facilitate completion of EUA requests during a current emergency declaration.

If you need help with the pre-EUA process for face masks, surgical masks, or respirators, contact CDRH-NonDiagnosticEUATemplates@fda.hhs.gov (mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov) .

For additional information, refer to Emergency Use Authorization of Medical Products and Related Authorities (/regulatoryinformation/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities).

Q: What is an Umbrella EUA?

A: Many EUAs apply only to a specific medical device. Generally, an *umbrella* EUA authorizes many devices that meet specific criteria for that device type, helping to facilitate access to those devices by streamlining the process associated with EUAs (for example, EUA request submission and FDA authorization) for any medical devices that meet the requirements within the EUA.

Q: What type of mask is authorized under the umbrella EUA for surgical masks?

A: The FDA issued an umbrella EUA (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergencyuse-authorizations-medical-devices/personal-protective-equipment-euas#surgicalmasks) in response to insufficient availability of disposable, single-use surgical masks. Surgical masks within the Scope of Authorization of this EUA are authorized for emergency use in health care settings by health care personnel as PPE.

The Scope of Authorization includes performance metrics that must be met including liquid barrier performance, particulate filtration efficiency, air flow resistance, and use of biocompatible, non-cytotoxic, non-irritating, and non-

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sensitizing materials. Surgical masks that have been confirmed by the FDA to be within the Scope of Authorization are listed in Appendix A

(https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices /personal-protective-equipment-euas#appendixasurgicalmasks) of the EUA as authorized surgical masks.
To be added to Appendix A (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medicaldevices/personal-protective-equipment-euas#appendixasurgicalmasks), test reports must be submitted to the FDA demonstrating that the surgical mask meets the performance criteria. Requests can be submitted to the FDA with the subject

line "Surgical Masks EUA" to CDRH-nondiagnosticEUA-templates@fda.hhs.gov (mailto:CDRH-nondiagnosticEUAtemplates@fda.hhs.gov). The Surgical Masks EUA Template for Addition to Appendix A (/media/140896/download) (DOCX 56 KB) can be used to provide the required information.

Manufacturers, importers, and distributors must also comply with the conditions of authorization found in Section IV of the EUA Letter of Authorization (/media/140894/download) (PDF - 101KB).

The following surgical masks are not within the scope of this EUA:

- Surgical masks that are FDA-cleared
- Surgical masks that are manufactured in China
- Surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents

Q. What types of respirators are authorized under the umbrella EUA for NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency?

A: Respirators authorized by this EUA (/media/135763/download) (PDF - 176KB) include :

1. Non-powered air-purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH in accordance with 42 CFR Part 84 and listed on the NIOSH Certified Equipment list (CEL) for non-powered air purifying respirators with particulate protection; and
2. Other powered air purifying respirators (PAPRs) approved by NIOSH, in accordance with 42 CFR Part 84, and that are listed on the NIOSH CEL for PAPRs with particulate protection

Q. If I am producing surgical masks or respirators under an EUA during COVID-19, what do I need to do to continue marketing my product after the emergency is over?

A: Unapproved devices or unapproved uses of FDA-approved or cleared devices must submit marketing applications under the traditional premarket pathways in order to continue marketing their products if the applicable emergency use authorization is revoked.

Device manufacturers are encouraged to pursue marketing applications through the appropriate regulatory pathway (such as 510(k) , De Novo request, or PMA) during the emergency so that devices can remain on the market once the EUA is no longer in effect. For more information, see FAQs on Emergency Use Authorizations (EUAs) for Medical Devices During the COVID-19 Pandemic (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic).

Manufacturing and Importing Face Masks, Barrier Face Coverings, Surgical Masks, and Respirators During the COVID-19 Pandemic

Q: I'm interested in manufacturing face masks, barrier face coverings, or surgical masks for the COVID-19 pandemic. What do I need to do?

A: Face masks and barrier face coverings intended for a medical purpose, such as prevention of infectious disease transmission, are subject to FDA regulation. The FDA has issued guidance on regulatory flexibility (/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-barrier-face-coverings-face-shields-surgical-masks-

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andrespirators) for such products, as well as EUAs for face masks and surgical masks (/medical-devices/coronavirus-disease2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas).

The guidance provides an enforcement discretion policy for face masks and barrier face coverings intended for a medical purpose for use during the COVID-19 public health emergency, such as for use as source control.

Face masks, intended for use by health care personnel and the general public as source control to help stop the spread, may be
authorized under the umbrella EUA for face masks (/media/137121/download) (PDF - 92KB) without submitting documentation to the FDA if the face mask is within the Scope of the EUA. A face mask authorized under this EUA must comply with the Conditions of Authorization (Section IV) of the EUA.

For a surgical mask to be added to the Surgical Mask EUA Appendix A (https://www.fda.gov/medical-devices/coronavirusdisease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-
euas#appendixasurgicalmasks), test reports must be submitted to the FDA demonstrating that the surgical mask meets the performance criteria for liquid barrier protection. Requests can be submitted to the FDA with the subject line "Surgical Masks EUA" to CDRH-nondiagnosticEUA-templates@fda.hhs.gov (mailto:CDRH-nondiagnosticEUA-templates@fda.hhs.gov) . The Surgical Masks EUA Template for Addition to Appendix A (/media/140896/download) (PDF - 176KB) can be used to provide the required information.

Manufacturers, importers, and distributors of surgical masks must also comply with the conditions of authorization found in Section IV of the EUA Letter of Authorization (/media/140894/download) (PDF - 101KB).

The following surgical masks are not covered in the scope of this EUA:

- Surgical masks that are FDA-cleared
- Surgical masks that are manufactured in China
- Surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents.

Q: I'm interested in manufacturing respirators for the COVID-19 pandemic. What do I need to do?

A: Respirators require NIOSH approval. Once NIOSH approval is obtained, the respirator is authorized under the EUA for NIOSH-approved air-purifying respirators (/media/135763/download) (PDF - 176KB). In some cases (for example, if the respirator claims to prevent specific diseases or infection, or if it includes antimicrobials or other additives), obtaining FDA clearance may be the appropriate pathway (see 21 CFR 878.4040).

Additional information is available in the Manufacturing and Distributing Respirators for Health Care Use in the United States Under an Existing Emergency Use Authorization (EUA) During the COVID-19 Pandemic (/medical-devices/coronavirus-covid-19-and-medical-devices/manufacturing-and-distributing-respirators-health-care-use-united-statesunder-existing-emergency) flowchart.

Q: Who can I contact at the FDA if I have questions about manufacturing or importing face masks, barrier face coverings, surgical masks, and respirators?

A: The Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the
Coronavirus Disease (COVID-19) Public Health Emergency (/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-barrier-face-coverings-face-shields-surgical-masks-and-respirators) provides guidance on manufacturing or importing face masks, barrier face coverings, surgical masks, and respirators. Device Advice (/medicaldevices/device-advice-comprehensive-regulatory-assistance) provides comprehensive regulatory assistance to manufacturers and importers. If you have additional questions, you may send an email to CDRH-COVID19-PPE@fda.hhs.gov (mailto:CDRHCOVID19-PPE@fda.hhs.gov).

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Q: I'm having trouble importing face masks, barrier face coverings, surgical masks, or respirators into the United States. What do I do?

A: To help avoid shipment delays, review Importing COVID-19 Supplies (/industry/import-program-food-and-drugadministration-fda/importing-covid-19-supplies) and Information for Filing Personal Protective Equipment and Medical Devices During COVID-19 (https://imports.cbp.gov/s/article/CSMS-42448725-Information-for-Filing-Personal-ProtectiveEquipment-and-Medical-Devices-During-COVID-19) for important information from the FDA on importing products, including face masks, barrier face coverings, surgical masks, and respirators to ensure that the proper documentation is submitted at the time of entry.

The FDA is ready and available to engage with importers to help minimize disruptions during the importing process. If you have any specific import questions related to COVID-19, you may email COVID1 9 FDAIMPORTIN Q UIRIES @ fda.hhs. g ov (mailto:COVID19FDAIMPORTINQUIRIES@fda.hhs.gov) .

Purchasing Face Masks, Barrier Face Coverings, Surgical Masks, and Respirators During the COVID-19 Pandemic

Q: I would like to purchase face masks, barrier face coverings, surgical masks, or respirators for health care personnel. Where can I find ones that can be used in health care?

A: The FDA does not maintain a list of face mask, barrier face covering, surgical mask, or respirator suppliers. If you are a health care facility, check with your supplier, distributor, or your local health department.

You may also want to check with the Association for Health Care Resource & Materials Management (https://www.ahrmm.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (AHRMM) of the American Hospital Association, which maintains the AHRMM Novel Coronavirus (COVID-19) Update (https://www.ahrmm.org/ahrmm-covid-19) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) on health care supply chain issues and includes vetted non-traditional supplies, companies offering supplies at no cost, and alternate supply channels.

Q: How can I tell if the face masks, barrier face coverings, surgical masks, or respirators I want to purchase are counterfeit or fraudulent?

A: The FDA does not have a list of all counterfeit or fraudulent products. To report fraudulent COVID-19 products to the FDA, email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov (mailto:FDA-COVID-19-Fraudulent-Products@fda.hhs.gov) . The CDC provides information on identifying counterfeit respirators at Counterfeit Respirators / Misrepresentation of NIOSHApproval (https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html).

Reporting Shortages of or Problems with Face Masks, Barrier Face Coverings, Surgical Masks, or Respirators

Q: How do I report a shortage of face masks, surgical masks, or respirators?

The FDA encourages health care facilities which anticipate a potential shortage or are experiencing an actual shortage to notify the FDA. For potential or actual supply issues, e-mail information to the FDA at deviceshorta g es @ fda.hhs. g ov (mailto:deviceshortages@fda.hhs.gov) .

For manufacturers:

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Certain device manufacturers are now required under section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to notify the FDA of an interruption or permanent discontinuance in manufacturing. Section 506J of the FD&C Act (/medicaldevices/medical-device-safety/contact-fda-about-medical-device-supply-chain-issue) requires manufacturers to notify the FDA of a permanent discontinuance in the manufacture of certain devices or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States.

The FDA has issued a guidance (/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanentdiscontinuance-or-interruption-manufacturing-device-under-section-506j-fdc) to assist manufacturers in providing the FDA with timely and informative notifications about these changes in the production of certain medical device products. These notifications will help the FDA prevent or mitigate shortages of such devices during the COVID-19 public health emergency.

The FDA has prepared a list of medical device types (/medical-devices/coronavirus-covid-19-and-medical-devices/medicaldevice-types-help-determine-section-506j-notification-obligations) and corresponding product codes identifying devices that the FDA believes are critical to the public health during the COVID-19 pandemic. This list is not exhaustive, and the FDA intends to update this list as the COVID-19 pandemic evolves.

Manufacturers of device types that are included on this list should review section 506J of the FD&C Act and FDA's guidance,
Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device under Section 506J of the
FD&C Act During the COVID-19 Public Health Emergency (/regulatory-information/search-fda-guidance-documents /notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc), to determine whether they are required to notify the FDA.

Manufacturers should submit their notifications by email to CDRHManufacturerShorta g e @ fda.hhs. g ov (mailto:CDRHManufacturerShortage@fda.hhs.gov) during the COVID-19 Public Health Emergency. Please begin the email subject line with the word "Notification."

Q: How do I report a problem with face masks, barrier face coverings, surgical masks, or respirators?

A: The FDA encourages reporting of any adverse events or suspected adverse events experienced with face masks, barrier face coverings, surgical masks, or respirators.

- In general, device manufacturers, importers, and device user facilities (health care facilities) must comply with the applicable medical device Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importersand-device-user-facilities).
- Voluntary reports from health care personnel and users can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-eventreporting-program/reporting-serious-problems-fda).
- Health care personnel employed by organizations that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their organizations.

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Face Masks, Barrier Face Coverings, Surgical Masks, and Respirators fo... https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical...

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- **WHO SAID** :- **disadvantages for or difficulty wearing masks, especially for children, developmentally challenged persons, those with mental illness, persons with cognitive impairment, those with asthma or chronic respiratory or breathing problems, those who have had facial trauma or recent oral maxillofacial surgery and those living in hot and humid environments (55, 130).**

  - https://apps.who.int/iris/bitstream/handle/10665/337199/WHO-2019-nCov-IPC_Masks-2020.5-eng.pdf?sequence=1&isAllowed=y

- **NCBI (NATIONAL CENTER OF BIOTECHNOLOGY INFORMATION) (USA)**

  - The effect of N95 and surgical masks on mucociliary clearance function and sinonasal complaints According NCBI

  - **The effect of N95 and surgical masks on mucociliary clearance function and sinonasal complaints (nih.gov)**

- **Risks of Face MasK**

  - **Risks of N95 Face Mask Use in Subjects With COPD | Respiratory Care (rcjournal.com)**

- **Side-Effects of Public Health Policies Against Covid-19: The Story of an Over-Reaction**

  - https://internal-journal.frontiersin.org/articles/10.3389/fpubh.2021.696818/full

❖ Discomfort and Exertion Associated with Prolonged Wear of Respiratory Protection in a Health Care Setting

- https://www.researchgate.net/publication/51877195_Discomfort_and_Exertion_Associated_with_Prolonged_Wear_of_Respiratory_Protection_in_a_Health_Care_Setting

Eur Arch Otorhinolaryngol. 2022; 279(2): 759–764. PMCID: PMC8081280
Published online 2021 Apr 28. doi: 10.1007/s00405-021-06838-x PMID: 33912995

The effect of N95 and surgical masks on mucociliary clearance function and sinonasal complaints

Ceyhun Cengiz and İlknur Haberal Can

Abstract

Purpose

The aim of this study was to reveal the effect of N95 and surgical masks on mucociliary clearance function and sinonasal complaints.

Methods

Sixty participants were enrolled in this study, including 30 people in N95 mask group and 30 people in surgical mask group. Two interviews, three days apart, were performed with all participants. The participants were asked not to use any mask before the first interview while they were asked to use the determined mask just before the second interview for 8 h. In both interviews, the mucociliary clearance times (MCTs) were measured and participants were asked to score ten distinct sinonasal complaints using visual analog scale (VAS). Data obtained from first interview were named pre-mask data, data obtained from second interview were called after-mask data. In both groups, pre-mask MCTs and VAS scores were compared with after-mask MCTs and VAS scores.

Results

After-mask MCTs (mean = 13.03 ± 6.05 min) were significantly longer than pre-mask MCTs (mean = 10.19 ± 4.21 min) in N95 mask group ($p = 0.002$). No significant difference was found between after-mask and pre-mask MCTs (mean = 12.05 ± 5.21 min, mean = 11.00 ± 5.44 min, respectively) in surgical mask group ($p = 0.234$). When after-mask VAS scores were compared with pre-mask VAS scores, it was found that N95 mask use increased nasal blockage and postnasal discharge, surgical mask usage increased nasal blockage.

Conclusion

While the use of N95 mask leads to nasal blockage and postnasal discharge, surgical mask use results in nasal blockage. N95 masks cause impairment in mucociliary clearance function. But all these effects are mild. Surgical masks have not been found to have any effect on mucociliary clearance function.

Keywords: N95 mask, Surgical mask, Mucociliary clearence, Sinonasal complaints

Introduction

N95 and surgical masks are among the personal protective equipment that are commonly used. The importance of these equipment is better appreciated in the COVID-19 pandemic. During this pandemic, healthcare professionals had to wear the N95 and surgical mask for long hours. It is also recommended that the masks be used by the people in public areas due to the pandemic. During the use of these masks, the breathing takes place through the pores on the masks. Since respiration made in this way is not a physiological respiration, some effects in the body are inevitable. The literature review revealed that there are many studies on how masks affect the systems in the body [1, 2]. On the other hand, there are small number studies on how the various types of masks affect the upper respiratory tract physiology and complaints related to the upper respiratory tract.

Mucociliary clearance function is a crucial defense mechanism of the nose and paranasal sinuses. Disruption of this function causes accumulation of secretions and secondary infections [3]. Temperature, humidity, pH and partial oxygen pressure are factors that affect this function [4]. Furthermore, it has been found that this function is impaired in many pathologies that affect the upper respiratory tract directly or indirectly [5, 6]. During breathing through masks, the humidity, temperature, and resistance of inhaled air are altered [7]. Changes in all these parameters may affect mucociliary clearance function. In addition, breathing through these masks for a long time may cause an increase in complaints related to the upper respiratory tract.

In this study, the effect of N95 and surgical masks on mucociliary clearance function and sinonasalcomplaints was investigated.

Materials and methods

This study was conducted in the Department of Otorhinolaryngology of XXXXXXX Yozgat Bozok University after the approval of the local ethics committee. Sixty participants were enrolled in the study, including 30 individuals in N95 mask group and 30 individuals in surgical mask group. Written informed consent was obtained from all participants before enrollment in the study. Those with a diagnosis of nasal polyposis, sinusitis, allergic rhinitis, vasomotor rhinitis, diabetes, kidney failure, smokers, a history of nasal surgery and those younger than 18 and older than 65 years were excluded from the study. Participants were randomly allocated to the groups. Fifteen of the N95 mask group were women and 15 were men. Of the surgical mask group, 16 were women and 14 were men. The mean age of the N95 mask group was 29.17 ± 3.98, while the average age of the surgical mask group was 28.03 ± 4.30. There was no difference between the two groups in terms of age and gender (For gender $p = 0.796$, for age $p = 0.294$). Two interviews were performed with all participants, three days apart. Before the first interview, the participants were asked not to use any type of mask. Just before the second interview, they were asked to wear the specified mask type (N95 or surgical mask) for 8 h. In both interviews, the mucociliary clearance function of the participants was evaluated and they were asked to score determined sinonasal complaints according to their feelings during the interview using VAS (0 = No complaints, 10 = the worst possible level). The data obtained from the first interview were named pre-mask data, and the data obtained from the second interview were called after-mask data. Mucociliary clearance function was evaluated using the saccharin test. This test was carried out by the

same otorhinolaryngologist. The saccharin test was applied from the same nasal passage in both interviews. Participants were asked not to eat or drink within one hour before the test. During the test, the participants were told to stay in an upright position, not to blow their nose or sniff. A 1-mm-wide piece of sodium saccharin was placed on the antero-medial surface of the inferior concha. MCT was accepted as the time from tablet insertion until the sugar was tasted. In addition, the participants were asked to rate their complaints of need to blow nose, nasal blockage, sneezing, runny nose, cough, postnasal discharge, thick nasal discharge, ear fullness, ear pain, facial pain/pressure using VAS, according to what they felt during the first and second interviews. The mean MCT and the mean VAS score for each complaint in the N95 and surgical mask group at the second interview (after-mask) were compared with those obtained in the first interview (pre-mask). The aim of the study was to reveal the effect of N95 and surgical mask on mucociliary clearance function and sinonasal complaints.

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 15. The variables were investigated using visual (histograms, probability plots) and analytical methods (Kolmogorov–Smirnov test) to determine whether or not they are normally distributed. Paired samples t test/Wilcoxon signed-rank test was run to compare the data at two time points (pre-mask and after-mask) for MCT and VAS scores of sinonasal complaints in N95 mask group and surgical mask group. A p value of less than 0.05 was considered to show a statistically significant result.

Results

In the N95 mask group, pre-mask mean MCT was 10.19 ± 4.21 min. and aftermask mean MCT was 13.03 ± 6.05 min. This difference was statistically significant ($p = 0.002$, Table 1). There was no statistically significant difference between the pre-mask mean MCT (11.00 ± 5.44 min.) and after-mask mean MCT (12.05 ± 5.21 min.) in the surgical mask group ($p = 0.234$, Table 1).

Table 1

Comparison of after-mask mucociliary clearence times with pre-mask mucociliary clearence times in groups

	Mucociliary Clearence time(minutes)		***p***
	Pre-mask	**After-mask**	
N95 Mask group	10.19 ± 4.21 min	13.03 ± 6.05 min	0.002[a]*
Surgical mask group	11.00 ± 5.44 min	12.05 ± 5.21 min	0.234[b]

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[a]Wilcoxon signed-rank test

[b]Paired samples *t* test

*Statistically significant

After-mask mean VAS scores of nasal blockage and postnasal discharge complaints (3.27 ± 2.97, 2.90 ± 2.88, respectively) were higher than pre-mask mean VAS scores (1.97 ± 2.18, 2.13 ± 2.44, respectively) in the N95 mask group. These differences were also statistically significant ($p = 0.010$, $p = 0.015$, respectively, Table 2). Similarly, in the surgical mask group, after-mask mean VAS score of the nasal blockage complaint (3.97 ± 2.48) was statistically significantly higher than pre-mask mean VAS score of this complaint (3.67 ± 2.38, $p = 0.037$, Table 2).

Table 2

Comparison of after-mask sinonasal complaints VAS scores with pre-mask sinonasal complaints VAS scores in groups

Complaints	N95 mask group		*p*	Surgical mask group		*p*
	Pre-mask VAS	After-mask VAS		Pre-mask VAS	After-mask VAS	
Need to blow nose	2.43 ± 2.35	2.83 ± 2.60	0.372[a]	3.13 ± 2.95	2.60 ± 2.94	0.174[a]
Nasal blockage	1.97 ± 2.18	3.27 ± 2.97	0.010[a]*	3.67 ± 2.38	3.97 ± 2.48	0.037[b]*
Sneezing	2.10 ± 2.29	1.53 ± 2.12	0.159[a]	3.07 ± 2.55	2.67 ± 2.74	0.080[a]
Runny nose	2.10 ± 2.38	2.77 ± 3.27	0.320[a]	3.20 ± 2.92	2.43 ± 2.89	0.069[a]
Cough	0.90 ± 1.42	0.80 ± 1.40	0.377[a]	1.67 ± 1.98	1.30 ± 1.68	0.252[a]
Postnasal discharge	2.13 ± 2.44	2.90 ± 2.88	0.015[a]*	2.27 ± 2.58	1.87 ± 2.50	0.117[a]
Thick nasal discharge	1.47 ± 2.72	1.50 ± 2.14	0.757[a]	1.60 ± 2.82	1.43 ± 2.47	0.857[a]
Ear fullness	0.70 ± 1.91	1.00 ± 2.15	0.750[a]	2.53 ± 3.48	2.10 ± 3.13	0.204[a]
Ear pain	0.80 ± 2.45	0.83 ± 1.82	0.673[a]	1.73 ± 2.70	1.60 ± 2.50	0.631[a]
Facial pain/pressure	0.90 ± 2.35	1.73 ± 2.82	0.234[a]	1.77 ± 3.12	2.23 ± 3.20	0.119[a]

Open in a separate window

[a]Wilcoxon signed-rank test

[b]Paired samples *t* test

*Statistically significant

In the N95 mask group, there was no statistically significant difference between pre-mask mean VAS scores of need to blow nose, sneezing, runny nose, cough, thick nasal discharge, ear fullness, ear pain, facial pain/pressure and after-mask mean VAS scores of these complaints (Table 2).

There was no statistically significant difference between pre-mask mean VAS scores of need to blow nose, sneezing, runny nose, cough, postnasal discharge, thick nasal discharge, ear fullness, ear pain, facial pain/pressure complaints and after-mask mean VAS scores of these complaints in the surgical mask group (Table 2).

Discussion

N95 and surgical mask types have multiple overlapping layers of polypropylene [8, 9]. These fiber structures not only provide mechanical filtration, but also contribute to filtration by creating an electrostatic charge [10, 11]. N95 and surgical masks can be used separately or by wearing a surgical mask on the N95 mask to prevent surface contamination [12]. A surgical mask protects the patient and the surgical area from contamination, however, it does not protect the person from infectious aerosols. The N95 mask is designed to protect the person from infectious agents [13]. During the use of masks, air passes through a narrow passage and breathing pressure, breathing resistance and breathing quality are affected [14]. Therefore, besides the filtration capacity, the breathability of the masks is also crucial [15]. It has been suggested that breathability will not be altered if the flow rate of the air passing through the mask is above 85 L/min [16]. Lee et al. performed rhinomanometry and nasal spirometry on 14 participants using N 95 masks in their study and found 126% increase in inspiratory flow resistance and 122% increase expiratory flow resistance [17]. In the same study, it is also emphasized that there is an average decrease of 37% in air exchange volume due to the use of N95 masks. In their study, Yang et al. used surface EMG signals and respiratory signals to reveal the breathing resistance that occurs due to the N95 mask [18]. All these studies prove that breathing performed through masks differs from physiological respiration.

There are various studies investigating the effect of this non-physiological breathing pattern through masks on the body systems. In a study investigating the effects of masks, an increase in perceived exertion, perceived shortness of air, complaints of headache, lightheadedness, difficulty in communicating due to prolonged use of mask was found [19]. It has been shown that the use of N95 mask in patients with chronic obstructive pulmonary disease affects breathing frequency, blood oxygen saturation, and carbon dioxide level in exhaled air [20]. Bharatendu et al. suggested that the use of N95 mask may alter cerebral hemodynamics [21]. It was stated in the literature that using personal protective equipment, including the N95 mask, may cause headache [22]. Headache following the use of N95 mask may be due to changes in cerebral hemodynamics. Lässing et al. evaluated the cardiopulmonary and metabolic responses due to the use of surgical masks with impedance cardiography and ergo-spirometry and found that the use of surgical masks increased airway resistance and heart rate [23]. In another study conducted on healthcare professionals working in intensive care, it was shown that the use of personel protective equipment along with a mask caused changes in heart rate, oxygen saturation and perfusion index [24]. Breathing through masks is not a physiological respiration and this type of respiration affects several systems in the body.

It is inevitable that the masks will affect the physiology of the upper respiratory tract since the masks completely cover the mouth and nose, which constittue the opening to the upper respiratory tract, and the air inhaled through the masks comes into direct contact with the upper respiratory tract. However, there are small numbers of studies in the literature on how mask types affect sinonasal physiology. There are changes in the temperature and humidity of the inhaled air due to the use of face mask [25]. Furthermore, changes in the temperature, humidity, and pH of the inhaled air affect the cilia functions in the upper respiratory tract. Klimek et al. described a new form of irritant rhinitis due to the use of N95 mask [26]. It is suggested that the irritation here may be due to polypropylene fibers seen in the nasal passage due to the use of N95 mask. In addition, in this study, an increase in complaints of sneezing, itching, nasal blockage and rhinorrhea was observed due to the use of the N95 mask. In a study conducted with 87 participants, who used a N95 mask in the first session and a surgical mask in the second session, received acoustic rhinometry and rhinomanometry tests before and after the mask. No difference was found in terms of mean minimum cross-sectional area values obtained before and after the mask in both sessions [27]. However, in this study, the duration of use of masks was three hours. In another study conducted with 250 participants, the effects of the masks were investigated.

Excessive sweating around the mouth was found in 67.6% of the participants, difficulty in breathing on exertion at 58.2%, acne in 56.0%, and itchy nose in 52.0% [28]. In our study, a statistically significant prolongation was noted in MCT in the N95 mask group, whereas no statistically significant prolongation was observed in MCT in the surgical mask group (Table 1, Fig. 1). This elongation detected in the N95 mask group may be due to changes in the temperature, humidity, pH of the breathing air or irritant rhinitis. In addition, this type of mask creates higher resistance to inhaled air, which results in negative pressure on the nasal mucosa. This negative pressure may lead to edema of the nasal mucosa, impaired mucociliary clearance function and increased complaints of nasal blockage. Increasing the temperature of the inhaled air may be associated with the thickening of the postnasal discharge and the increased complaints of postnasal discharge. There was no increase in sinonasal complaints other than nasal blockage in the surgical mask group and mucociliary clearance function was not affected (Tables 1, 2). This can be attributed to a more physiological respiration, due to the open edges of the surgical mask.

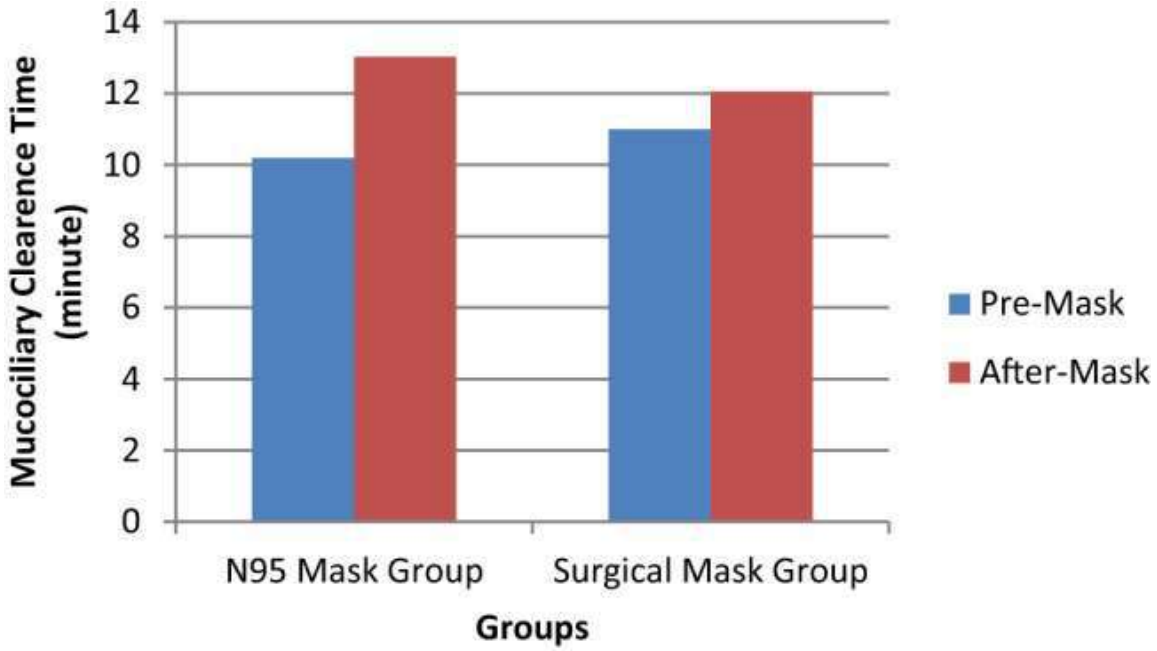
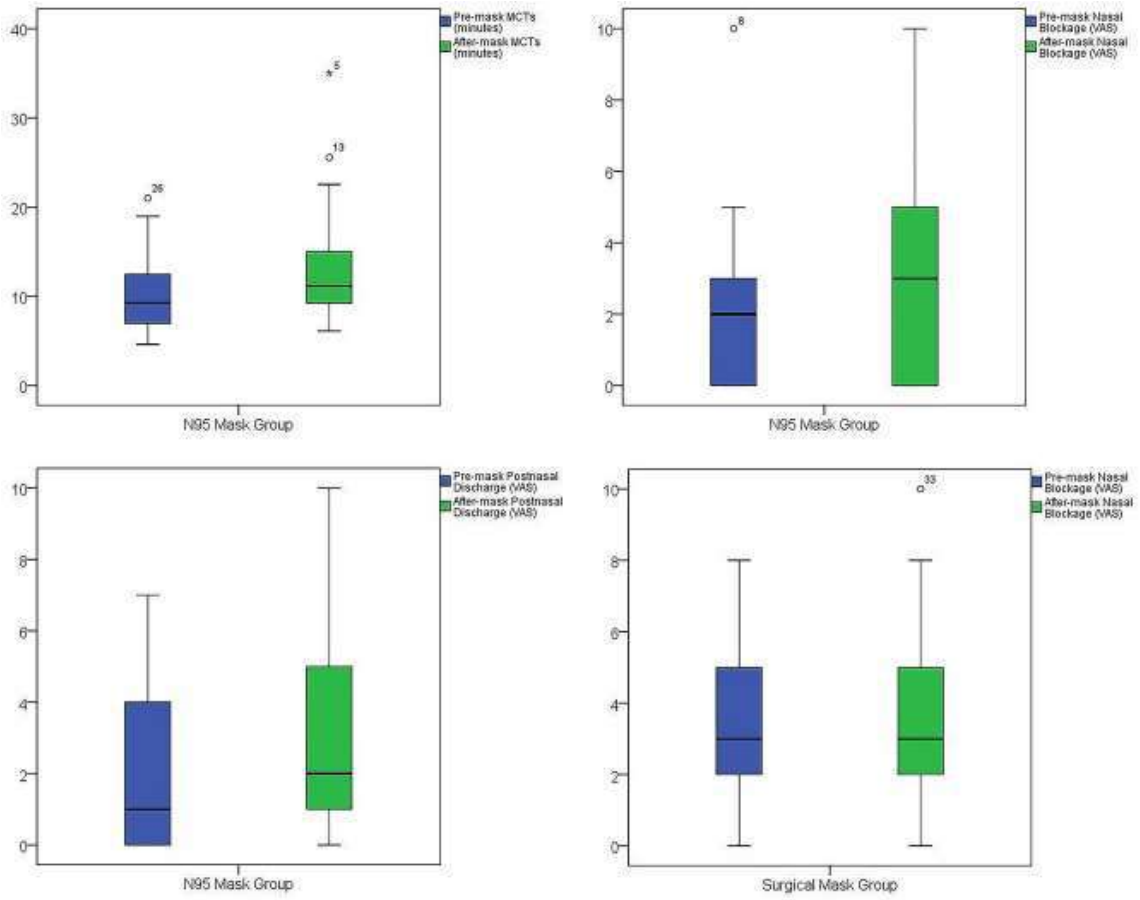


Fig. 1

Graphical illustration of pre-mask and after-mask mean mucociliary clearence times in groups

In the literature, similar to our study, mucociliary clearance function and sinonasal complaints were evaluated in pathologies that directly affect the nasal mucosa, such as acute rhinitis and chronic rhinosinusitis. More significant changes were found in these studies compared to those obtained in our study [29, 30]. This suggests that increases in MCT, nasal blockage and postnasal discharge complaints detected in the N95 mask group and the increase in nasal blockage complaint seen in the surgical mask group were mild. Furthermore, N95 and surgical masks have been frequently used during the COVID-19 pandemic. However, no increase in number of patients with acute rhinosinusitis was noted both in our practice and in the literature review, and these masks are well tolerated by users. Although the increases in the MCT, nasal blockage and postnasal discharge were statistically significant in our study, these differences did not reach clinically significant level. In the N95 mask group, a slight increase in

MCT due to the use of the mask was observed in most of the participants (Fig. 2). On the other hand, it was determined that the increase in nasal blockage complaint in the surgical mask group and the increase in nasal blockage and postnasal discharge complaints in the N95 mask group were more common in some participants (Fig. 2). This may be associated with the VAS being more subjective than the saccharine test, or more frequent occurrence of nasal blockage and postnasal discharge complaints due to irritant rhinitis in some participants.



Open in a separate window

Fig. 2

Boxplot graphs of significantly changing parameters in groups

In this study, there was a short period of 3 days between the first and the second interview to prevent the intervention of other factors that may affect mucociliary clearance. Furthermore, pre-mask and after-mask mucociliary clearance measurements were not performed on the same day, as this may affect the results. These are the strengths of this study. On the other hand, in this study, the effects of using the masks for eight hours were investigated. Especially healthcare professionals have to use these masks for much longer hours and months. Therefore, further studies are needed to investigate the effects of prolonged mask use.

Conclusion

The use of N95 mask causes complaints of nasal blockage and postnasal discharge, while the use of surgical mask causes nasal blockage. N95 masks lead to impairment in mucociliary clearance function. But all these effects are mild and these masks are well tolerated by users. Surgical masks have not been found to have any effect on mucociliary clearance function.

Declarations

Conflict of interest

The authors declare that they have no conflict of interest.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Yozgat Bozok University Clinical Researches Ethic Committee Ref No: 2017-KAEK-189_2020.09.16_02) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Footnotes

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Risks of N95 Face Mask Use in Subjects With COPD

Sun Young Kyung, Yujin Kim, Hyunjoong Hwang, Jeong-Woong Park, and Sung Hwan Jeong

BACKGROUND: The N95 filtering facepiece respirator (FFR) is the most popular individual protective device to reduce exposure to particulate matter. However, concerns have been raised with regard to its use because it can increase respiratory resistance and dead space. Therefore, this study assessed the safety of N95 use in patients with COPD and air-flow limitation. METHODS: This prospective study was performed at a tertiary hospital and enrolled 97 subjects with COPD. The subjects were monitored for symptoms and physiologic variables during a 10-min rest period and 6-min walking test while wearing an N95. RESULTS: Of the 97 subjects, 7 with COPD did not wear the N95 for the entire test duration. This mask-failure group showed higher British modified Medical Research Council dyspnea scale scores and lower FEV_1 percent of predicted values than did the successful mask use group. A modified Medical Research Council dyspnea scale score $\geq$ 3 (odds ratio 167, 95% CI 8.4 to >999.9; $P = .008$) or a $FEV_1 < 30\%$ predicted (odds ratio 163, 95% CI 7.4 to >999.9; $P = .001$) was associated with a risk of failure to wear the N95. Breathing frequency, blood oxygen saturation, and exhaled carbon dioxide levels also showed significant differences before and after N95 use. CONCLUSIONS: This study demonstrated that subjects with COPD who had modified Medical Research Council dyspnea scale scores $\geq$ 3 or $FEV_1 < 30\%$ predicted wear N95s only with care. *Key words: Air pollution; COPD; particulate matter; respirators; respiratory protective devices; safety.* [Respir Care 2020;65(5):658–664. © 2020 Daedalus Enterprises]

Introduction

Particulate matter (PM) consists of a complex mixture of solid and liquid organic and inorganic particles suspended in the air.[1] The most harmful particles are those with diameters $\leq$ 2.5 μm, which can penetrate and lodge deep inside the lungs.[1,2] Exposure to air pollutants, including PM, is associated with negative health impacts, and PM is considered one of the most important air pollutants associated with adverse health problems worldwide.[2,3] For example, many epidemiological studies have shown that PM has noxious effects in respiratory, cardiovascular, cerebrovascular, metabolic, and neuropsychiatric disorders as well as during pregnancy.[4-7] PM exposure is also associated with increased exacerbation in patients with COPD, asthma, and several other respiratory diseases, which thus results in increased hospitalization and mortality.[4,7-11] In addition, PM exposure increases the incidence of lung cancer and pneumonia.[12,13]

The best solution for reducing the health hazards associated with PM exposure is to remove the sources of PM via environmental interventions; however, this is very expensive and takes time. Therefore, individual interventions to protect against the adverse health effects of PM are required. The most popular practical solution to reduce individual exposure is the use of an N95 filtering facepiece respirator (N95 FFR), which is a respiratory protective device designed to achieve a very close facial fit and efficient filtration of airborne particles, blocking at least 95% of small particles (0.3 μm).[14] N95s are most commonly used by health-care and industrial workers to minimize exposure to microorganisms or airborne

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This study was supported by a Korea Centers for Disease Control and Prevention grant [HD15A1482].

The authors have disclosed no conflicts of interest.

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DOI: 10.4187/respcare.06713

dust.[15-17] They are also frequently used in areas with high concentrations of air pollutants to protect against PM.[15,18,19] The use of face masks to decrease personal PM exposure has been shown to reduce systolic blood pressure in healthy volunteers during a 2-h walk.[15] Furthermore, N95 use during walking in areas with high atmospheric PM concentrations is associated with improvements in objective measures of myocardial ischemia, exercise-related increases in blood pressure, and heart rate variability in patients with coronary heart disease.[20]

However, the adverse physiologic impacts of N95 are a concern because N95 use can cause increased inspiratory and expiratory flow resistance and dead space.[14] The increased flow resistance can cause an increase in tidal volume, a decrease in breathing frequency, and a decrease in minute ventilation, with a concomitant decrease in alveolar ventilation.[14] In healthy subjects, wearing a gas mask increases breathing effort by ~1.5-fold.[21] In healthy healthcare workers, N95 use did not cause any important physiologic burden during 1 h of use.[22] However, continuous use of the N95 that exceeded 4 h was associated with the development of headaches.[23] According to respiratory protection guidelines for the workplace, N95-induced increases in respiratory flow resistance, dead space, and physiologic load are small and generally well tolerated in healthy individuals and persons with impaired lung function.[14] Nevertheless, when the elderly or patients with respiratory disease, heart disease, or stroke wear an N95 to reduce PM exposure, they should consult their physician about the safety of N95 use.[24] The balance between the risks and benefits of N95 use in these patients, particularly patients with chronic pulmonary function impairment, is unclear. Therefore, we evaluated the safety and risk of N95 use in subjects with COPD, which is associated with chronic air-flow limitation and is substantially affected by PM exposure.

QUICK LOOK

Current knowledge

Previous studies indicate that the use of the N95 face mask in patients with mild respiratory disease ($FEV_1 \geq 50\%$) did not induce significant adverse effects. However, the use of the N95 face mask could induce an increase in flow resistance and dead space.

What this paper contributes to our knowledge

In this prospective study, we evaluated the physiologic impacts of N95 face mask use in subjects with COPD and severe air-flow obstruction. Patients with COPD and with modified Medical Research Council dyspnea scale scores ≥ 3 or $FEV_1 < 30\%$ predicted should be careful when using N95 face masks because these may increase the risk of dyspnea and breathing discomfort.

Methods

Study Design and Subjects

A prospective panel study was performed between March and May 2015 at a tertiary hospital of Incheon, South Korea. In total, 97 patients were recruited from the Gachon University Gil Medical Center (Incheon, South Korea). All the subjects were diagnosed with COPD and were treated in the pulmonary division, with regular visits to the out-patient department. The inclusion criteria were age 19–80 y old, smoking history > 10 pack-years, and adequate physical activity to allow for hospital visitation via unassisted walking. The exclusion criteria were severe respiratory failure with long-term oxygen therapy; history of hospital admission within the previous 3 months due to COPD exacerbation; a history of invasive mechanical ventilation or noninvasive ventilation; severe renal or hepatic failure; history of heart failure; history of acute cardiovascular or cerebrovascular event within the previous 2 months; advanced stage of malignancy, with an expected survival within 6 months; or other severe pulmonary diseases (eg, tuberculosis-destroyed lung and severe bronchiectasis). Baseline data, including smoking history, the British modified Medical Research Council dyspnea scale (mMRC) questionnaire results, COPD Assessment Test (CAT) score, and spirometry and laboratory measurements were recorded in the case report forms.

All the subjects provided written informed consent, and the study was reviewed and approved by the institutional review board of Gachon University Gil Medical Center (GBIRB2015-300). The subjects were monitored for symptoms and safety during a 10-min rest period and 6-min walk test (6MWT) while wearing an N95 (3M 9210, 3M, St. Paul, Minnesota). We purchased the 3M 9210 face mask for this study; however, this device is no longer being manufactured (since 2014). Electrocardiogram and S_{pO_2} monitoring were continuous during the study. Systolic blood pressure, diastolic blood pressure, heart rate, breathing frequency, S_{pO_2}, and exhaled carbon dioxide (P_{ETCO_2}) were measured at baseline and during the 6MWT without a mask, 10 min rest with a mask, and 6MWT with a mask. If the subjects felt too uncomfortable to wear the N95 or their physiologic variables became unstable, they removed the mask immediately; these subjects were included in the mask failure group. Investigators (SYK, YJK, HJH) attended to these subjects and monitored them carefully until recovery.

Baseline Data Collection and Classification of COPD

The severity of COPD was evaluated by using the mMRC score, CAT score, and postbronchodilator FEV_1 percent of predicted according to the Global Initiative for Chronic Obstructive Lung Disease guidelines.[25] The mMRC dyspnea scale is a simple measure of breathlessness in COPD: grade 0, only experiences breathlessness on strenuous exercise; grade 1, experiences shortness of breath when hurrying on level ground or walking up a slight hill; grade 2, walks on level ground slower than people of the same age due to breathlessness or stops to catch breath when walking at a comfortable pace on level ground; grade 3, stops to catch breath after walking ~100 m or after a few minutes on level ground; and grade 4, too breathless to leave the house or breathless when dressing or undressing. The CAT is an 8-item unidimensional measure of health status impairment in patients with COPD. The score ranges from 0 to 40 and is closely correlated with the quality of life. The severity of air-flow obstruction in COPD was categorized by using postbronchodilator FEV_1 percent of predicted: $FEV_1 \geq 80\%$ predicted; FEV_1, 50–79% predicted; FEV_1, 30–49% predicted; and $FEV_1 < 30\%$ predicted.

Physiologic Variables and Symptom Questionnaire

Heart rate, breathing frequency, and S_{pO_2} were continuously monitored by using electrocardiogram monitoring and pulse oximetry during the study. Systolic blood pressure, diastolic blood pressure, and P_{ETCO_2} were measured at baseline and during the 6MWT without a mask, 10-min rest with a mask, and 6MWT with a mask. P_{ETCO_2} was measured by using capnography and was expressed as the mean (mm Hg) of 3 respirations. Symptoms associated with N95 use were evaluated by using a symptom questionnaire that included the presence of dyspnea, headache, dizziness, anxiety, facial pressure, and skin irritation.

Statistical Analyses

We used IBM SPSS Statistics for Windows/Macintosh, Version 23.0 (IBM, Armonk, New York) and SAS version 9.4 (SAS Institute, Cary, North Carolina) for statistical analyses. Categorical variables were compared by using the Fisher exact test, and continuous variables were compared by using the Mann–Whitney test, between the successful mask use group and mask failure group. To identify differences in the physiologic variables, repeated-measures analysis of variance was performed for blood pressure, heart rate, breathing frequency, S_{pO_2}, and P_{ETCO_2} by using the values from the baseline data without a mask as the covariant. The impacts of potential risk factors of the failure to wear a mask were analyzed by using univariate logistic regression analyses. Significant variables in the univariate analyses were included in the multivariate logistic regression analyses by using the Firth method to identify independent risk factors of N95 safety. The Firth method was used because one cell had a value of zero. Independent influences of risk factors of N95 safety were expressed as the odds ratio with 95% CI. Significance was considered as $P < .05$.

Results

Subject Characteristics

The mean ± SD age of the subjects was 68 ± 6.5 y and 94% were male subjects. The mean ± SD mMRC score was 1.5 ± 0.9 and the mean ± SD CAT score was 15.1 ± 8.2. The mean FEV_1 was 57.1% predicted and the most common air-flow obstruction category was moderate (FEV_1, 50–79% predicted; $n = 58$). Seven of the 97 subjects with COPD (7.2%) failed to wear the N95 during the test (Table 1). The mask failure group ($n = 7$) showed significantly higher mMRC scores and CAT scores as well as lower FEV_1/FVC, FEV_1, FVC, and S_{pO_2} values than did the successful mask use group ($n = 90$). The subjects who failed to wear the mask had an mMRC score ≥ 3 and $FEV_1 < 50\%$ predicted. The most common mask-associated symptom was dyspnea ($n = 8$); however, the subjects who failed to wear the mask had dizziness or headache as well as dyspnea.

Risk Factors for the Development of N95–Associated Complications

According to the multivariate logistic regression analyses, the independent risk factors for the failure to wear the mask included a high mMRC score, with an odds ratio of 12.58, 95% CI 1.49–105.95 ($P = .02$) (Table 2). In particular, an mMRC score of 3 was associated with a 167-fold increased risk of failure to wear the mask (95% CI 8.43 to >999.99; $P < .001$) (Table 3). In addition, $FEV_1 < 30\%$ predicted was associated with a 162.5-fold increased risk of failure to wear the mask (95% CI 7.36 to >999.99; $P = .001$).

Characteristics of the Mask Failure Group

Only one subject failed to wear the mask after 8 min during the rest period and showed increased P_{ETCO_2} and mask-associated symptoms, such as headache, dizziness, and facial pressure (Table 4). Most of the subjects ($n = 6$) in the mask failure group removed the mask during the 6MWT due to low S_{pO_2} or CO_2 retention. All the subjects exhibited decreased S_{pO_2}, increased P_{ETCO_2}, and dyspnea.

Table 1. Characteristics of the Subjects and Differences According to N95 Safety Outcome

Variable	All Subjects	Use of Mask		*P*
		Safe	Fail	
Subjects, *n*	97	90	7	
Age, mean ± SD y	68.0 ± 6.5	67.9 ± 6.4	68.6 ± 8.1	.81
Male, *n* (%)	91 (93.8)	85 (94.4)	6 (85.7)	.37
Current smoker, *n* (%)	26 (26.8)	25 (27.8)	1 (14.3)	.39
mMRC				
Score, mean ± SD	1.5 ± 0.9	1.4 ± 0.7	3.3 ± 0.5	<.001
Grade, *n* (%)				
0	6	6	0	
1	54	54	0	
2	23	23	0	
3	11	6	5 (45.5)	
4	3	1	2 (66.7)	
CAT score, mean ± SD	15.1 ± 8.2	14.3 ± 7.8	26.1 ± 3.7	<.001
Pulmonary function test				
FEV_1/FVC, mean ± SD	55.0 ± 13.1	56.3 ± 12.2	38.9 ± 13.5	.006
FVC, mean ± SD L	3.1 ± 0.7	3.2 ± 0.7	2.1 ± 0.7	.003
FVC % predicted, mean ± SD	73.5 ± 15.4	75.0 ± 14.6	54.6 ± 13.0	.002
FEV_1, mean ± SD L	1.7 ± 0.6	1.8 ± 0.6	0.8 ± 0.2	<.001
FEV_1 % predicted, mean ± SD	57.1 ± 18.9	59.3 ± 17.6	28.7 ± 9.2	<.001
FEV_1 % predicted, *n*				
≥80%	8	8	0	
50–79%	58	58	0	
30–49%	22	20	2	
<30%	9	4	5	
Physiologic variables, mean ±SD				
S_{pO_2}, %	96.4 ± 1.6	96.5 ± 1.5	94.9 ± 2.0	.02
P_{ETCO_2}, mm Hg	24.8 ± 6.8	24.4 ± 6.5	29.7 ± 8.6	.06
Mask-associated symptoms, *n*				
Dyspnea	8	2	6	
Dizziness/headache	3/1	0/0	3/1	
Facial pressure	5	4	1	

mMRC = modified Medical Research Council dyspnea scale
CAT = COPD Assessment Test
P_{ETCO_2} = end-tidal PCO_2

Table 2. Risk Factors for the Development of N95 Complications

Variable	Univariate Analysis			Multivariate Analysis		
	OR	95% CI	*P*	OR	95% CI	*P*
mMRC score	15.05	1.90–118.98	.01	12.58	1.49–105.95	.02
FEV_1% predicted	1.13	0.78–0.99	.03	1.09	0.83–1.00	.06

Risk factor analysis (Nagelkerke R^2 value = 0.732, Hosmer-Lemeshow goodness of fit with a χ^2 value = 0.779).
OR = odds ratio
mMRC = modified Medical Research Council dyspnea scale

Table 3. Risk of N95 Failure According to Binary Values of mMRC and FEV_1%

Variable	OR	95% CI	*P*
mMRC score ≥ 3	167.0	8.43–999.99	<.001
FEV_1% predicted < 30%	162.5	7.36–999.99	.001

Firth method was used for the logistic regression analysis because there was a cell with a value of zero.
mMRC = modified Medical Research Council dyspnea scale
OR = odds ratio

Physiologic Variables before and after Mask Use in the Successful Mask Use Group

In the mask-safe group, the breathing frequency, S_{pO_2}, and P_{ETCO_2} significantly differed before and after N95 use for 10 min in a resting state (Table 5). The heart rate, breathing frequency, and P_{ETCO_2} were significantly higher after the 6MWT with a mask than after the 6MWT without a mask. The S_{pO_2} levels were significantly lower after the 6MWT with a mask than after the 6MWT without a mask.

Table 4. Characteristics and Mask-Associated Symptoms in Subjects in the Mask Failure Group

Subject No.	Age, y/Sex	mMRC Score	FEV_1, % Predicted	Time of Recording	Respiratory Variables, Baseline/Final		Mask-Associated Symptoms
					Percentages	P_{ETCO_2}, mm Hg	
1	65/M	3	22	At rest with mask at 8 min	97/96	26/34	Headache, dizziness, facial pressure
2	76/M	3	26	During 6MWT without mask at 4 min	92/85	34/31	Dyspnea
3	69/F	3	35	During 6MWT without mask at 2 min, 43 s	96/83	26/42	Dyspnea, dizziness, anxiety
4	53/M	3	23	During 6MWT with mask at 5 min, 12 s	96/83	43/54	Dyspnea, dizziness, anxiety, cold sweating
5	78/M	3	48	During 6MWT with mask at 1 min 3 s	95/83	14/28	Dyspnea, dizziness, anxiety
6	75/M	4	28	During 6MWT with mask at 2 min 15 s	96/90	36/48	Dyspnea
7	65/M	4	19	During 6MWT without mask at 40 s	93/90	27/31	Dyspnea, anxiety

$n = 7$.
mMRC = modified Medical Research Council dyspnea scale
P_{ETCO_2} = end-tidal PCO_2
6MWT = 6-min-walk test

Table 5. Physiologic Variables after Use of N95 in Subjects Who Successfully Used a Mask

Parameter	Baseline without FFR	After 10-Min Rest with FFR	*P*	After 6MWT without FFR	After 6MWT with FFR	*P*
SBP, mm Hg	127.7 ± 15.0	129.6 ± 14.9	.30	133.8 ± 16.1	134.2 ± 16.5	.56
DBP, mm Hg	77.4 ± 11.1	80.1 ± 10.1	.003	79.4 ± 11.3	78.6 ± 11.5	.19
Heart rate, beats/min	77.6 ± 13.8	78.0 ± 14.0	.18	87.7 ± 17.0	92.4 ± 17.2	<.001
f, breaths/min	19.7 ± 1.2	20.7 ± 2.3	<.001	23.3 ± 2.6	25.7 ± 7.5	.002
S_{pO_2}, %	96.4 ± 1.6	96.0 ± 1.5	<.001	93.8 ± 2.6	93.0 ± 2.6	<.001
P_{ETCO_2}, mm Hg	24.8 ± 6.8	25.7 ± 7.3	<.001	34.0 ± 6.8	35.5 ± 7.6	<.001

$n = 90$.
Values are as mean ± standard deviation.
FFR = filtering facepiece respirator
6MWT = 6-min-walk test
SBP = systolic blood pressure
DBP = diastolic blood pressure
f = breathing frequency
P_{ETCO_2} = end-tidal PCO_2

Discussion

To our knowledge, this was the first study on the safety of N95 use in subjects with COPD and severely limited air flow. Patients with COPD are sensitive to PM, which can induce exacerbation of COPD, and experience respiratory failure, which can increase the risk of N95 use. The results of this study indicated that the subjects with COPD and with mMRC scores ≥ 3 or $FEV_1 < 30\%$ predicted should be careful to use N95s due to the increased risk for inducing hypoxic or hypercapnic respiratory failure.

The mean FEV_1 of the subjects enrolled in this study was 57.1% predicted, and 31 of the 97 subjects had an $FEV_1 < 50\%$ predicted. All the subjects were able to walk during regular out-patient clinic visits and showed stable baseline respiratory variables. The subjects were monitored continuously via electrocardiograms as well as for breathing frequency, S_{pO_2}, and subjective response by a respiratory physician (SYK, YJK, HJH) throughout the experiment. A number of studies examined the physiologic effects of face masks in subjects with mild respiratory disease (eg, asthma, COPD, and chronic rhinitis) while performing simulated work tasks.[26-29] For example, Harber et al[26] reported that subjects with mild COPD or asthma experienced adverse effects on ventilation while wearing half-mask respirators, which differ from N95s. In their study, the subjects with severe COPD and with an $FEV_1 < 50\%$ predicted were excluded.[27] They concluded that the respirator significantly affected

several physiologic variables and subjective responses, and that the type of lung disease (eg, mild asthma or COPD) did not significantly affect the results.[27] In contrast, we enrolled and performed close monitoring of subjects with severe COPD, and these subjects showed significant adverse effects in terms of respiratory variables and subjective symptoms while resting or walking for 6 min and wearing an N95.

The adverse effects of N95 use in healthy people were originally studied in workers while the workers were wearing required respirators and showed elevated CO_2 levels and decreased O_2 levels during a qualitative respirator fit test.[30] In addition, the physiologic impact of the N95 has been studied in health-care workers.[22,23] Although the mask did not cause any adverse physiologic effects during 1 h of use, continuous use of the N95 for >4 h was associated with headaches and two subjects showed peak transcutaneous CO_2 levels > 50 mm Hg.[23] The effects of N95 use have also been assessed in pregnant women.[31-33] No differences were observed between pregnant and nonpregnant women in terms of physiologic variables (eg, heart rate, breathing frequency, O_2 saturation, or transcutaneous CO_2 level) after wearing an N95 for 1 h during sedentary activity or exercise.[31] However, exercising at 3 Metabolic Equivalent of Task while breathing through an N95 reduced the tidal volume, minute ventilation, and exhaled O_2 concentration but increased exhaled CO_2 concentration in pregnant women.[32] These results suggest that breathing through an N95 impedes gas exchange in pregnant women, and these factors should be considered when recommending N95 use.

According to the respiratory protection guideline of the American Thoracic Society,[14] FFRs generally induce minimum adverse physiologic effects and are tolerated by both healthy individuals and persons with impaired lung function. However, the American Thoracic Society agrees that FFR use can increase breathing resistance, dead space, and physiologic load. In particular, Lee and Wang[34] reported that N95 (model 8210; 3M) use yielded mean increments of 126% and 122% in inspiratory and expiratory flow resistance, respectively, measured by using rhinomanometry. Moreover, they reported that N95 use induced a mean 37% reduction in air-exchange volume.[34] According to the guideline for physicians of the Hong Kong Medical Association, the elderly, people with illness (eg, chronic lung disease, heart disease, or stroke), and pregnant women should consult their physician to determine whether they can use N95s because they may already have reduced lung volumes.[24]

In a study on the efficacy of N95s in subjects with coronary heart disease, the subjects walked for 2 h while wearing an N95.[20] All 96 subjects enrolled in that study tolerated the mask intervention well. Moreover, the mean ambulatory arterial blood pressure and heart rate were more stable in the subjects who used masks than in those who did not use a mask. Although patients with uncontrolled heart failure were excluded from that study, the results indicate that N95 use for <2 h is safe for people with coronary heart disease in a stable state.[20] Unlike that study, we found that subjects with COPD enrolled in this study showed significant differences in physiologic variables, depending on whether they used a mask. The subjects showed worsening of respiratory variables when they wore an N95, including increased breathing frequency, P_{ETCO_2}, and decreased S_{pO_2}. When considering the increase in respiratory resistance with N95 use, patients with COPD and low baseline pulmonary function may be considered to have a greater physiologic impact with mask use.

A major limitation of this study was that it was performed at a single center with a relatively small mask failure group. Nevertheless, the results are sufficient for informing guidelines on safe N95 use in patients with COPD. In the future, a larger population should be recruited from multiple institutes. Another limitation is that we used the 6MWT to evaluate the safety of N95 use during exercise. The 6MWT is simple and is often used to evaluate exercise tolerance. However, the safety of N95 use during 6 min of walking may not adequately reflect safety under real outdoor conditions; outdoor activities may last for varying durations of time and may involve varying levels of exertion. Most of the subjects in the mask failure group showed hypoxemia or hypercapnia and mask-associated symptoms during the 6MWT. Furthermore, other susceptible patients, such as those with asthma or severe heart failure, should be included in future studies of N95 use safety.

Conclusions

We generally recommend the use of N95s for patients with COPD for protection against PM exposure during outdoor activity under high PM conditions. However, patients with very severe COPD, mMRC scores ≥ 3, or FEV_1 < 30% predicted should be careful when using N95s. Performance of the 6MWT while wearing the N95 may predict mask-associated risks in patients with severe COPD. Also, patients should be warned to remove the N95s immediately on the onset of dyspnea, headache, or dizziness.

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Legal notice under Section 60 of Disaster Management Act, 2005

Subject :-

1. To forthwith stop the offence under section 51 (b) of Disaster Management Act section 52, 166, 188, 120 (B) 34 etc., of Indian Penal Code, which are being committed by you issuing circulars orders sop editing vaccinations against Central governments decisions and policy.
2. To forthwith stop the Contempt of the Honorable Supreme Court and Honorable High Court.

Sir,

1. That, you noticee No. P.R.CH.-102020-501-T, Dt-31-12-2021 & Kramank GP_20_NCV_102020/SFS-1/G dt-30-05-2020, I have issued following directions circulars/SOP.

2. That, your circulars/directions are against Central government policy decision/policy/direction;

(i) P.R.CH.-102020-501-T, Dt-31-12-2021 & Kramank GP_20_NCV_102020/SFS-1/G dt-30-05-2020

3. It is also Contempt of the following judgements of Honorable Supreme Court and Honorable High Court which mandates that, State authority or any authority cannot issue any direction/circulars/order/SOP thereby restricting the movment, Livelihood etc. of citizen based on his vaccination status.

4. That as per **Article 14, 19, 21** of Constitution of India and more particularly as per law laid down in the case of **(i) Registrar General Vs. State of Meghalaya 2021 SCC OnLine Megh 130, (ii) Re Dinthar Incident Vs. State of Mizoram 2021 SCC OnLine Gau 1313** and other verious

landmark judgments it is clear that, there is no difference between vaccinated and non-vaccinated people. The vaccinated people can get corona, they can spread infection and they can die due to corona. Vaccinated people can also be a super spreader.

5. That, Union of India made it clear that, there cannot be any discrimination on the basis of vaccination status. The relevant RTI dated **19.03.2021** is annexed herewith at **'Annexure- A'.** Said RTI is also taken note by Hon'ble High Court in the **Madan Mili Vs. Union of India 2021 SCC OnLine Gau 1503.**

6. That, Honorable Supreme Court made it clear that, when State authority is prevented or prohibited from doing any act then it cannot be done indirectly. **[Noida Vs Noida (2011) 6 SCC 527]**

7. Section **52 of IPC** says that;
   *52. "**Good faith".** —Nothing is said to be done or believed in "good faith" which is done or believed without due care and attention.*

8. Therefore, your circular/SOP are unconstitutional, arbitrary and actuated with ulterior purposes.

9. That your act is an offence under section 51(B), 55 of the **Disaster Management Act,** said section reads thus:

   51 (b) refuses to comply with any direction given by or on behalf of the Central Government or the State Government or the National Executive Committee or the State Executive Committee or the District Authority under this Act.

   55. (1) Where an offence under this Act has been committed by any Department of the Government, the head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded

against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Department of the Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the head of the Department, such officer shall be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

10. Also an offence under section 166, 167, 188, 120 (B) & 34 of Indian Penal Code said **section read thus:**

166. Public servant disobeying law, with intent to cause injury to any person.—Whoever, being a public servant, knowingly disobeys any direction of the law as to the way in which he is to conduct himself as such public servant, intending to cause, or knowing it to be likely that he will, by such disobedience, cause injury to any person, shall be punished with simple imprisonment for a term which may extend to one year, or with fine, or with both. Illustration A, being an officer directed by law to take property in execution, in order to satisfy a decree pronounced in Z's favour by a Court of Justice, knowingly disobeys that direction of law, with the knowledge that he is likely thereby to cause injury to Z. A has committed the offence defined in this section.

167. Public servant framing an incorrect document with intent to cause injury.—Whoever, being a public servant, and being, as 1[such public servant, charged with the preparation or translation of any

document or electronic record, frames, prepares or translates that document or electronic record] in a manner which he knows or believes to be incorrect, intending thereby to cause or knowing it to be likely that he may thereby cause injury to any person, shall be punished with imprisonment of either description for a term which may extend to three years, or with fine, or with both.

188. Disobedience to order duly promulgated by public servant.— Whoever, knowing that, by an order promulgated by a public servant lawfully empowered to promulgate such order, he is directed to abstain from a certain act, or to take certain order with certain property in his possession or under his management, disobeys such direction, shall, if such disobedience causes or tends to cause obstruction, annoyance or injury, or risk of obstruction, annoyance or injury, to any person lawfully employed, be punished with simple imprisonment for a term which may extend to one month or with fine which may extend to two hundred rupees, or with both; and if such disobedience causes or trends to cause danger to human life, health or safety, or causes or tends to cause a riot or affray, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both. Explanation.—It is not necessary that the offender should intend to produce harm, or contemplate his disobedience as likely to produce harm. It is sufficient that he knows of the order which he disobeys, and that his disobedience produces, or is likely to produce, harm. Illustration An order is promulgated by a public servant lawfully empowered to promulgate such order, directing that a religious procession shall not pass down a certain street. A knowingly

disobeys the order, and thereby causes danger of riot. A has committed the offence defined in this section.

120B. Punishment of criminal conspiracy.—

(1) Whoever is a party to a criminal conspiracy to commit an offence punishable with death, 2[imprisonment for life] or rigorous imprisonment for a term of two years or upwards, shall, where no express provision is made in this Code for the punishment of such a conspiracy, be punished in the same manner as if he had abetted such offence.

(2) Whoever is a party to a criminal conspiracy other than a criminal conspiracy to commit an offence punishable as aforesaid shall be punished with imprisonment of either description for a term not exceeding six months, or with fine or with both.]

34. Acts done by several persons in furtherance of common intention.— When a criminal act is done by several persons in furtherance of the common intention of all, each of such persons is liable for that act in the same manner as if it were done by him alone.

11. That, **(my client)/** I/we, have decided to initiate proceedings against you in the Court of law.

12. That, as per **section 60** of the Disaster Management Act, 2005, **30 days' notice** is required to be given before initiating prosecution against you.

Said section read thus:

"60. No court shall take cognizance of an offence under this Act except on a complaint made by

(a) the National Authority, the State Authority, the Central Government, the State Government, the District Authority or any other authority or officer authorised in this behalf by that Authority or Government, as the case may be; or

(b) any person who has given notice of not less than thirty days in the manner prescribed, of the alleged offence and his intention to make a complaint to the National Authority, the State Authority, the Central Government, the State Government, the District Authority or any other authority or officer authorised as aforesaid.".

13. That, so far as prosecution on under other sections of IPC is concerned, it is to remind you that, as being Public Servant you are being given salary to act as per law and in good faith take decision for larger interest of society and not to work for benefit of vaccine companies it is not a part to your official duty to get involved in the conspiracy with ulterior purposes of giving undue profit to vaccine companies and to violates the fundamental rights of the citizen and to pay with their life.

These offences can never be part of your duty and therefore no sanction is required to prosecute you **[See: Punjab State Warehousing Corporation Vs. Bhushan Chander (2016) 13 SCC 44]**

14. That because of your unlawful acts of commission and omission many people were compelled to take vaccine and their life is put in danger.

15. That, you are well aware that vaccine are not required prohibited for following people:

(i) Persons cured from Covid – 19 or who have developed anti – bodies due to their contract with corona virus.

(ii) Persons having allergies to the contents of the vaccines;

(iii) People which were not included in the clinical trials such as pregnant women etc.

(iv) People who are warned by the vaccine companies itself such as;

COVAXIN

The fact sheet available on the website of the Covaxin states that certain categories of persons should not be administered the vaccine. The fact sheet can be found at https://www.bharatbiotech.com/images/covaxin/covaxin-factsheet.pdf

The relevant part of the fact sheet is asunder:

"What should you mention to your vaccine provider before you get Covaxin? Tell the Vaccintor/officer supervising your vaccination about all of your medical conditions, including if you: ·

Are on regular medication for any illness,

for how long and for which condition.

It is not advisable to take the vaccine in any of these conditions - have any allergies

have fever ·

have a bleeding disorder or a blood thinner ·

are immunocompromised or

are on a medicine that affects your immune system ·

Are pregnant ;·

Are breast feeding ·

Have received another Covid-19 vaccine

WHO SHOULD NOT GET COVAXIN -

You should not get Covaxin if you :

1. Had a severe allergic reaction to any ingredients of the vaccine

2. Had a severe allergic reaction after a previous dose of the vaccine

3. Currently have an acute infection or fever

4. Further in a document released by Bharat Biotech titled "SUMMARY OF PRODUCT CHARACTERISTICS" dated 15 Jan 2021, the effect of the vaccine has been explained for certain categories of work and exercise. The relevant part of the report is as under:

> 4.1 Interaction with other medicinal products. Chloroquine and Corticosteroids as they may impair the antibody response.
>
> 4.2 Effects on ability to drive and use machines

No studies on the effect of COVAXINTM on the ability to drive and use machines have been performed. The link of the report titled "SUMMARY OF PRODUCT CHARACTERISTICS" dated 15 Jan 2021 can be found at:

https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/en/COVAXIN-SMPC_-BBIL.pdf

It is submitted that Chloroquine is a medication primarily used to prevent and treat malaria in areas where malaria remains sensitive to its effects. Corticosteroids are a class of drug that lowers inflammation in the body. They also reduce immune system activity. Because corticosteroids ease swelling, itching, redness, and allergic reactions, doctors often prescribe them to help treat diseases like: asthma.

As can be seen from the above there are many diseases for which vaccine should not be taken/given.

Immunocompromised can be due to many causes, such as · chronic medical conditions, such as heart disease, lung disease, diabetes, HIV, and cancer · autoimmune diseases, such as lupus, multiple sclerosis, and rheumatoid arthritis· medications or treatments, such as radiation therapy · transplants, such as bone marrow or solid organ This can be found at:

https://www.healthline.com/health/immunocompromised-how-toknow-if-you-have-a-weakened-immune-system

COVISHIELD:-

Similarly the fact sheet of Covishield Vaccine states the categories who should not take the vaccine. The fact sheet can be accesses at:

https://www.seruminstitute.com/pdf/covishield_fact_sheet.pdf

The relevant part of the Fact sheet is as under:

> *"What you should mention to your health care provider before you get the Covishield vaccine: Tell the healthcare provider about all of your medical conditions, including; ·*
>
> *If you have ever had a severe allergic reaction (anaphylaxis) after any drug, food, any vaccine or any ingredients of Covishield vaccine*
>
> *If you have fever ·*
>
> *If you have a bleeding disorder or on a blood thinner ·*
>
> *If you are immunocompromised or are on a medicine which affects the immune system ·*
>
> *If you are pregnant or plan to become pregnant ·*
>
> *If you are breast feeding ·*
>
> *If you have received another covid-19 vaccine*
>
> *You should not get the covishield if you ·*
>
> *Had a severe allergic reaction after a previous dose of this vaccine Had a severe allergic reaction to any ingredients of this vaccine"*

The insert sheet of Covishield Vaccine gives warnings against the use of Covid-19 vaccine for certain categories of persons. The product sheet can be found at:

https://www.seruminstitute.com/pdf/covishield_ChAdOx1_nCoV19_corona_virus_vaccine_insert.pdf

The relevant part of the product sheet is asunder:

"4.4 Special warnings & Special precautions for use - Hypersensitivity As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Concurrent illness As with other vaccines, administration of Covishield should be postponed in individuals suffering from an acute severe fibrile illness. However the presence of a minor infection such as cold and/or low grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders As with other intramuscular injections Covishield should be given with caution to individuals with Thrombocytopenia, any coagulation disorders or to persons on anti-coagualation therapy, because bleeding/bruising may occur following an intramuscular administration in these individuals.

Immunocompromised Individuals It is not known whether individuals with impaired immune responsiveness, including individuals receiving immune suppressant therapy, will elicit the same response as immune competent individuals to the vaccine regimen.

Immunocompromised Individuals may have relatively weaker immune response to the vaccine regimen.

4.5 Interactions with other medicinal products and other forms of interaction. No interaction studies have been performed. Concomitant administration of Covishield with other vaccines has not been studied. 4.6 Fertility, pregnancy and lactation Fertility Preliminary animal studies do not indicate direct or indirect harmful effects with respect to fertility.

Pregnancy There is a limited experience with the use of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) in pregnant women. ... Breastfeeding It is unknown whether covishield is excreted in human milk."

Thrombocytopenia is a dangerous drop in the number of platelets in the blood. This decrease can increase the risk of bleeding.

Thrombocytopenia occurs in people without cancer as well. Coagulation disorders are disruptions in the body's ability to control blood clotting. Coagulation disorders can result in either a hemorrhage (too little clotting that causes an increased risk of bleeding) or thrombosis (too much clotting that causes blood clots to obstruct blood flow). As with other intramuscular injections,

COVISHIELD should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulation therapy, because bleeding or bruising may occur following an intramuscular administration in these individuals.

Re interaction with other medicinal products, it is important to note that patients who are on regular medications for Diabetes, heart issues, other lifestyle diseases where daily medication is required, no studies have been done.

Re Breast feeding- It is unknown whether Covishield is excreted in human milk. - Since this vaccine is not a live attenuated or inactivated virus technology but an Recombinant DNA technology in which Adeno Viruses carry a spike protein DNA molecule of Sarscov 2 which enters into human cells nucleus and instructs the DNA of the human cell to produce mRNA which instructs the ribosomes to produce spike proteins, and then our immune system responds to the proteins. This is very alarming as we don't know what reaction it will create in newborn babies when the human milk is consumed. The link to a news article explaining recombinant DNA vaccine of Covishield can be found at:

https://www.nytimes.com/interactive/2020/health/oxford astrazeneca-covid-19-vaccine.html

Further re Duration and level of protection, it has not yet been established. Vaccinating with Covishield may not protect all vaccine recipients. As can be seen from the above there are many diseases for which vaccine should not be taken/given. People can be immunocompromised due to many reasons- diabeties, heart issues, thyroid gland problem, arthritis, crohns disease, psoriasis, eczema IIII etc and a high percentage of people with various comobordities are using blood thinners.

Hence the Government & vaccine manufacturers should give more clarity on these issues, & if these implications are correct, then the Government must stop recommending people with comorbidities to get vaccinated.

It is further submitted that being immunocompromised can be due to many causes: · chronic medical conditions, such as heart

disease, lung disease, diabetes, HIV, and cancer · autoimmune diseases, such as lupus, multiple sclerosis, and rheumatoid arthritis · medications or treatments, such as radiation therapy · transplants, such as bone marrow or solid organ · pregnancy · a combination of any of the above This explanation can be found at:

https://www.healthline.com/health/immunocompromised-how-toknow-if-you-have-a-weakened-immune-system

There are some additional data of side effects of vaccines:

Link:
https://drive.google.com/file/d/1uikc1a_KDzUx7HNLrfwaI1NJRt0D_YP/view?usp=sharing

16. But you have issued the circulars by ignoring the abovesaid facts and therefore you are guilty of not acting in good faith or acting in bad faith.

[Section 52 of IPC]

17. Forced vaccination is an offence u/s 323, 336 etc., of IPC. If the person dies then it is an offence u/s 305, 304 etc., of IPC.

18. That, for the above said reason you should also be held responsible for offences of mass murders of those people who died because of vaccination against their will and without disclosing them the side effects of vaccines and also the other available remedies such as; Covid cure immunity, Naturopathy, Ayurvedic, Anandia's herbal composition which is approved by Hon'ble Andhra Pradesh High Court in **Ponnekanti Mallikarjuna Rao Vs. State of Andhra Pradesh, rep. by its Chief Secretary to Government 2021 SCC OnLine AP 2171.**

19. That, as being responsible public servant holding a post to take decision regarding vaccination of public you, your office and medical officers attached with your office were duty bound to tell public about side effects of vaccines and also about the other alternate remedies.

But you failed to do so and you misused your position and public property for giving undue profit of vaccine companies. This is an offence u/s 409 of IPC.

Section 409 read thus;

> **409. Criminal breach of trust by public servant, or by banker, merchant or agent.**—Whoever, being in any manner entrusted with property, or with any dominion over property in his capacity of a public servant or in the way of his business as a banker, merchant, factor, broker, attorney or agent, commits criminal breach of trust in respect of that property, shall be punished with 1[imprisonment for life], or with imprisonment of either description for a term which may extend to ten years, and shall also be liable to fine.

20. But you have not performed that, duty and therefore you are having no protection from prosecution.

21. That, as being vigilant citizen of this country, it is my duty under article 51a to save the property and life of citizen office country and stop the commission of offence is being committed by you

21. Hence, I am issuing this notice is hereby calling you forthwith stop all your unlawful activities

Subject:- LEGAL NOTICE FOR MAKE MANDATORY WEAR MASK

(i) Avoidance of illegal enforcement of mask mandates through violation of sections 38 and 39 of the Disaster Management Act, 2005 by the Government of Maharashtra despite advisory by the Central Government that wearing of masks is not mandatory. Prevention of offences under Sections 166, 120 (B), 34 and Sections 51 (B), 55 of the said Disaster Management Act;

(ii) Filing of offenses under Sections 341, 342, 220, 385, 120 (B), 34 and 109 on marshals / officers / employees for illegally detaining citizens and imposing penalty for not wearing masks.

OR

(iii) If the orders and evidence of the Central Government are wrong and the Government of Maharashtra has the right to go against the Central Government and make rules, then to take appropriate legal action against me for not wearing a mask.

References**:-** **(i)** Central Government's letter dt. **19.05.2021** and dt**. 27.05.2021.**

(ii) Hon. High Court and Hon. Supreme Court order

Re Dinthar Incident Vs. State of Mizoram 2021 SCC OnLine Gau 1313, Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503, Common Cause Vs. Union of India (2018) 5 SCC 1, Nandini Satpathy Vs. P.L. Dani (1978) 2 SCC 42.

Respected Sir,

1. The reply given by the Central Government's Ministry of Health on **19.05.2021** clarifies that there is no scientific evidence that wearing masks benefits healthy people. Also, people who do not have Covid-19 symptoms should not wear a mask.

"In reply dated ***19.05.2021 to Shri. Amit Chauhan RTI Application No. INCMR/R/E/21/00355****, it is specifically pointed out as under;*

4. Use of masks by general public

4.1. Persons having no symptoms are not to use mask

Medical masks should not be used by healthy persons who are not having any symptoms because it create a false sense of security that can lead to neglecting other essential measures such as washing of hands.

Further, ***there is no scientific evidence to show health benefit of using masks for non-sick persons in the community****. In fact erroneous use of masks or continuous use of a disposable mask for longer than 6 hours or repeated use of same mask may actually increase risk of getting an infection. It also incurs unnecessary cost."*

Link:-https://drive.google.com/file/d/1wacZL6qyo-5McYEStO0cH4i9pZONg5xg/view?usp=sharing

A copy of that letter is attached.

2. In its reply dated **27.05.2021**, the Central Government has made it clear that wearing a mask is optional and not mandatory. Mask wearers should not wear the mask for more than **eight hours**.

> *"In reply dated* ***27th May, 2021 to Mr. Sourav Bysack Being RTI Application No. F.No. Z.28016/133/2021-DM CELL*** *it is made clear that mask are not mandatory.*
>
> > *"Use of mask/face cover has been advised to all in various SOPs/Guidelines issued by MoHFW.* ***However as per these guidelines/SOPs its use has not been explicitly made mandatory."***
>
> **Link**:- **https://drive.google.com/file/d/1qNZGh4DMCWQUVPQ4_Di-D7f3nhdBi9Nq/view?usp=sharing**

A copy of that letter is attached.

3. Research by 47 different world renowned experts has shown that there is no evidence that wearing a mask stops the spread of corona virus but there is enough scientific evidence that wearing a mask causes respiratory diseases and lung diseases (lungs damage).

Link:https://m.facebook.com/story.php?story_fbid=410683863978040&id=100051092899107

> **"**The mask is unscientific, dangerous and useless. Forcing it is deteriorating health. The situation gets more serious.
>
> ***47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effect"***

4. The central government, in a letter dated **17.07.2021**, has clarified that the size of the pores of a high quality Surgical Mask is between 0.3 - 10 µm & 0.1 - 0.3 µm and the corona virus is many times smaller than that. This means that even after wearing a mask, thousands of corona virus particles can pass through it and spread the infection.

The central government's answer is as follows:

> ***"1. SARS-CoV-2 virus is round shaped virus with an average size of 70-80 nm.***
>
> ***2. Pore size of standard surgical mask and N95 mask is 0.3 – 10 µm & 0.1 – 0.3 µm respectively."***

5. One study also found that a 15-layer mask could allow a virus particle to pass through with ease.

6. But the corrupt, ignorant and incompetent members of the Maharashtra Task Force, such as Shri. Rahul Pandit and Shri. Sanjay Oak are advocating wearing a mask.

7. It is clear from this that the imposition of wearing of masks has been issued with a malafide and misguided motive and for this the members of the task force are co-accused under Section 409, 52, 120 (B), 34 and Section 10 of the Evidence Act and are required to be severely punished. .

8. In addition, the government is obligated to exempt those who suffer from respiratory problems and asthma from wearing a mask if they obtain a certificate from a doctor. Sections 52, 115, 304, 304-A, 302 provide that the officers concerned will be responsible for the death and other injuries caused to the person otherwise.

9. This shows that the government is not acting in the best interests of the people but is conspiring to make the people even sicker in order to benefit the vaccine manufacturers and pharmaceutical companies by tens of thousands of crores of rupees and enslave humanity.

10. Given clarifications by the Central Government, the order issued by the Chief Secretary of Maharashtra, Sitaram Kunte on November 27, 2021, and orders and restrictions issued by any official in the state to this effect are illegal and void ab initio. Under Sections 38 (a) and 39 (c) of the Disaster Prevention Act, 2005, the State Government or any District Level Collector or any officer has no power to issue decrees in violation of the clarifications of the Central Government.

"39. Responsibilities of State Government Departments,

It will be the responsibility of every department of the state government to ensure that

> ***(A)*** The measures required for disaster prevention, mitigation, preparedness and capacity building should be planned in accordance with the guidelines laid down by the National Authority and the State Authority; "

10.1. As per **section 38(1), 39(a) of Disaster Management Act, 2005,** the State Government has to act in line of the guidelines laid down by the National Authority.

Section 38(1) reads thus;

> "***38. State Government to take measures.-***
>
> *(1) Subject to the provisions of this Act,* ***each State Government shall take all measures specified in the guidelines laid down by the National Authority*** *and such further measures as it deems necessary or expedient, for the purpose of disaster management."*

10.2. Section 39(a) reads thus;

> ***"39. <u>Responsibilities of departments of the State Government.</u> - <u>It shall be the responsibility of every department of the Government of a State to</u>-***
>
> ***(a) <u>take measures necessary for prevention of disasters, mitigation, preparedness and capacity-building in accordance with the guidelines laid down by the National Authority and the State Authority;"</u>***

10.3. Section 78(3) of Disaster Management Act, 2005 makes it mandatory for State Authority that every rule made by the state should be laid before House of State Legislature.

It reads thus;

> ***"78.3.* <u>**The State Government may, by notification in the Official Gazette, make rules to carry out the provisions of this Act. -**</u>**
>
> *Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before each House of the State Legislature where it consists of two Houses, or where such Legislature consists of one House before that House."*

11. Under Article 19 (6) of the Indian Constitution, simply by coming out with a circular or a G.R., personal freedom and freedom to earn a living of the citizens cannot be trampled upon as per The Hon'ble High Court <u>in Re: Dinthar 2021 SCC OnLine Gau 1313</u> and <u>Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503.</u> In the case mentioned above, the orders of the Collector and the Chief Secretary, mandating immunization, have been revoked. Links to that command are available below.

(i) <u>Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503</u>

https://drive.google.com/file/d/1vuwmYwPu2zqony8An-7X5cQn9_yNHEZ2/view

(ii) In Re: Dinthar 2021 SCC OnLine Gau 1313

https://drive.google.com/file/d/1R26lX2FWuxwdYpzmrTqMN_RcBiA4Guw9/view?usp=sharing

(iii) Osbert Khaling Vs. State of Manipur and Ors. 2021 SCC OnLine Mani 234

https://drive.google.com/file/d/1cLKR3LutxomKX3BbmaIBwQ9SfUhdvIJQ/view

12. Twice the rules brought by the Government of Maharashtra against the instructions of the Central Government were declared illegal by the Central Government and the orders were later withdrawn by the Government of Maharashtra. For example, on 30.11.2021 the Government of Maharashtra had issued an order stating RT-PCR would be binding on the people entering Maharashtra. This order was later withdrawn as it was against the guidelines given by the Central Government. The news regarding this has been published in 'Free Press Journal' and 'Dainik Sakal' today.

i) Centre raps state govt, asks it to align with national norms; vaccinated domestic passenger can travel without test, Anow OVERRULED

Links:

(i) https://epaper.freepressjournal.in/c/64692765

(ii)https://epaper.esakal.com/FlashClient/Client_Panel.aspx#currPage=1

13. Rajesh Bhushan, Chief Secretary, Ministry of Health, Central Government sent a letter to Chief Secretary of Maharashtra Dr. Pradip Vyas . The text of the letter was as follows.

"This is with reference to the ***Govt. Of Maharashtra Order No. DMU/20201CR.92lDisM-1 dated 30th Nov. 2020****, vide which the following restrictions have been imposed:*

i. Mandatory RTPCR testing of all international travellers at the Mumbai airport, irrespective of country of origin

ii. Mandatory 14-day home quarantine for all international passengers, despite being tested RTPCR Negative upon arrival

iii. Mandatory RTPCR test for passengers planning to undertake connecting flights after disembarking at Mumbai and further travel subject to a negative RTPCR result

iv. Requirement of negative RTPCR test 48 hours prior to date of journey, for domestic passengers travelling from other States to Maharashtra

2. ***This is in divergence with the SoPs & Guidelines issued by Ministry of Health & Family Welfare, Govt. of lndia. I would, therefore, urge you to align the Orders issued by the State with the Guidelines issued by the Ministry of Health & Family Welfare, Govt. Of lndia, so that uniform implementation of the guidelines may be ensured across all States/UTs. I would also advise that such modified orders of***

the State Government are given wide publicity to obviate any inconvenience to travellers"

Link:**https://drive.google.com/file/d/1OTvnR04kQv7LwYGFru8IajJblBTII1wN/view?usp=sharing**

14. However, some officials and employees are illegally endangering the lives of healthy citizens by forcing them to wear masks and this is a crime under sections 327, 329, 323, 336, 109, 52, 120 (B), 34 of the Constitution.

Section 323 in the Indian Penal Code:-

***"323. Punishment for voluntarily causing hurt**.- Whoever, except in the case provided for by section 334, voluntarily causes hurt, shall be punished with imprisonment of either description for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both."*

Section 327 in tIndian Penal Code:-

***"327. Voluntarily causing hurt to extort property, or to constrain to an illegal act.-** Whoever voluntarily causes hurt, for the purpose of extorting from the sufferer, or from any person inter¬ested in the sufferer, any property or valuable security, or of constraining the sufferer or any person interested in such suf¬ferer to do anything which is illegal or which may facilitate the commission of an offence, shall be punished with imprisonment of either description for a term which may extend to ten years, and shall also be liable to fine."*

Section 329 in the Indian Penal Code:-

"329. Voluntarily causing grievous hurt to extort property, or to constrain to an illegal act.- *Whoever voluntarily causes grievous hurt for the purpose of extorting from the sufferer or from any person interested in the sufferer any property or valuable secu¬rity, or of constraining the sufferer or any person interested in such sufferer to do anything that is illegal or which may facili¬tate the commission of an offence, shall be punished with 1[imprisonment for life], or imprisonment of either description for a term which may extend to ten years, and shall also be liable to fine."*

Section 336 in the Indian Penal Code:-

"336. Act endangering life or personal safety of others.- *Whoever does any act so rashly or negligently as to endanger human life or the personal safety of others, shall be punished with impris¬onment of either description for a term which may extend to three months, or with fine which may extend to two hundred and fifty rupees, or with both."*

Section 109 in the Indian Penal Code:-

"109. Punishment of abetment if the act abetted is committed in consequence and where no express provision is made for its punishment.- *Whoever abets any offence shall, if the act abetted is committed in consequence of the abetment, and no express provision is made by this Code for the punishment of such abet¬ment, be punished with the punishment provided for the offence. Explanation.—An act or*

offence is said to be committed in conse¬quence of abetment, when it is committed in consequence of the instigation, or in pursuance of the conspiracy, or with the aid which constitutes the abetment."

Section 52 in the Indian Penal Code:-

"52. "Good faith".- *Nothing is said to be done or believed in "good faith" which is done or believed without due care and attention."*

Section 120B in the Indian Penal Code:-

"120B. Punishment of criminal conspiracy.-

(1) Whoever is a party to a criminal conspiracy to commit an offence punishable with death, 2[imprisonment for life] or rigorous imprisonment for a term of two years or upwards, shall, where no express provision is made in this Code for the punishment of such a conspiracy, be punished in the same manner as if he had abetted such offence.

(2) Whoever is a party to a criminal conspiracy other than a criminal conspiracy to commit an offence punishable as aforesaid shall be punished with imprisonment of either description for a term not exceeding six months, or with fine or with both."

Section 34 in the Indian Penal Code:-

"34. Acts done by several persons in furtherance of common intention.- *When a criminal act is done by several persons in furtherance of the common intention of all, each of such*

persons is liable for that act in the same manner as if it were done by him alone."

15. It is a criminal offense under Sections 341, 342 for an officer to stop or obstruct a person's movement in order to recover an unlawful penalty.

Section 341 in the Indian Penal Code:-

"341. Punishment for wrongful restraint.- *Whoever wrongfully restrains any person shall be punished with simple imprisonment for a term which may extend to one month, or with fine which may extend to five hundred rupees, or with both.*

Section 342 in the Indian Penal Code:-

"342. Punishment for wrongful confinement.- *Whoever wrongfully confines any person shall be punished with imprisonment of either description for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both."*

16. Illegally levying fines that go against Central Government directives, by threatening citizens of legal action fall into the category of extortion and are punishable under sections 384 and 385 of the IPC.

Section 384 in the Indian Penal Code:-

"384. Punishment for extortion.- *Whoever commits extortion shall be punished with imprisonment of either description for*

a term which may extend to three years, or with fine, or with both."

Section 385 in the Indian Penal Code:-

"385. Putting person in fear of injury in order to commit extor¬tion.- *Whoever, in order to the committing of extortion, puts any person in fear, or attempts to put any person in fear, of any injury, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both."*

17. Details of legal action to be taken against the police for illegal activities related to masks: -

17.1. The following clauses are imposed by the police on persons who do not wear masks:

(a) *"**188. Disobedience to order duly promulgated by public servant**.- Whoever, knowing that, by an order promulgated by a public servant lawfully empowered to promulgate such order, he is directed to abstain from a certain act, or to take certain order with certain property in his possession or under his management, disobeys such direction, shall, if such disobedience causes or tends to cause obstruction, annoyance or injury, or risk of obstruction, annoyance or injury, to any person lawfully employed, be punished with simple imprisonment for a term which may extend to one month or with fine which may extend to two hundred rupees, or with both; and if such disobedience causes or trends to cause danger to human life, health or*

safety, or causes or tends to cause a riot or affray, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both.

(ii) 269. Negligent act likely to spread infection of disease dangerous to life.*—Whoever unlawfully or negligently does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both."*

(b) Section of Disaster Management Act **51(b):-**

"51. Punishment for obstruction, etc.-

Whoever without reasonable cause-

(b) ***refuses to comply with any direction given by or on behalf of the Central Government*** *or the State Government or the National Executive Committee or the State Executive Committee or the District Authority under this Act,* ***shall on conviction be punishable with imprisonment for a term which may extend to one year or with fine, or with both, and if such obstruction or refusal to comply with directions results in loss of lives or imminent danger thereof, shall on conviction be punishable with imprisonment for a term which may extend to two years****."*

17.2. To begin with, the police have no authority to impose or take any action under section 188 of the IPC. This is because under Section 195 of the Code of Criminal Procedure (Cr.P.C.), only the officer who issued the order, the Chief Secretary for

instance, can lodge a complaint. The court does not have the power to hear complaints from other people or the police. Also, even if any other clause has been added along with section 188, the police do not have the authority to take action as they are still bound by restrictions under Cr.P.C. 195.

[Bandekar Brothers Pvt. Ltd. v. Prasad Vassudev Keni, 2020 SCC OnLine SC 707]

17.3. Article 269 of the Act is aimed at those who deliberately spread the disease. It cannot be used in the case of masks and against healthy people. This is because there is no evidence that wearing a mask stops spread of the disease or that everyone who does not wear a mask spreads the disease. If the police impose that clause, they could face severe action. In case of unlawful arrest or forced bail or filing of chargesheet under false clause, the concerned police officer is guilty under Sections 211, 192, 193, 220, 120 (B), 34, 52, 109 and Sections 145 (2) of Maharashtra Police Act and are subject to internal punishment.

17.4. Section 51 (B) of the Disaster Management Act cannot apply to a person who does not wear a mask, as the Government of Maharashtra rules are against the rules of the Central Government. .

17.5. Section 211 of the Indian Penal Code:-

> ***"211. False charge of offence made with intent to injure.-*** *Whoever, with intent to cause injury to any person, institutes or causes to be instituted any criminal proceeding against that person, or falsely charges any person with having committed an offence, knowing that there is no just or lawful ground for such proceeding or charge against that person, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both; and if such criminal proceeding be instituted on a false charge of an offence punishable with death, 1[imprisonment for life], or imprisonment for seven*

years or upwards, shall be punishable with imprisonment of either description for a term which may extend to seven years, and shall also be liable to fine."

17.6. Section 192 of the Indian Penal Code:-

"192. Fabricating false evidence.- *Whoever causes any circumstance to exist or 1[makes any false entry in any book or record, or electronic record or makes any document or electronic record containing a false statement], intending that such circumstance, false entry or false statement may appear in evidence in a judicial proceeding, or in a proceeding taken by law before a public servant as such, or before an arbitrator, and that such circumstance, false entry or false statement, so appearing in evidence, may cause any person who in such proceeding is to form an opinion upon the evidence, to entertain an erroneous opinion touching any point material to the result of such proceeding, is said "to fabricate false evidence".*

17.7. Section 193 of the Indian Penal Code:-

"193. Punishment for false evidence.- *Whoever intentionally gives false evidence in any stage of a judicial proceeding, or fabricates false evidence for the purpose of being used in any stage of a judicial proceeding, shall be punished with imprisonment of either description for a term which may extend to seven years, and shall also be liable to fine, and whoever intentionally gives or fabricates false evidence in any*

other case, shall be punished with imprisonment of either description for a term which may extend to three years, and shall also be liable to fine."

17.8. Section 220 of the Indian Penal Code:-

***"220. Commitment for trial or confinement by person having authority who knows that he is acting contrary to law**.- Whoever, being in any office which gives him legal authority to commit persons for trial or to confinement, or to keep persons in confinement, corruptly or maliciously commits any person for trial or to confinement, or keeps any person in confinement, in the exercise of that authority knowing that in so doing he is acting contrary to law, shall be punished with imprisonment of either description for a term which may extend to seven years, or with fine, or with both."*

17.9. Section 120(B) of the Indian Penal Code:-

***"120(B). Punishment of criminal conspiracy**.- (1) Whoever is a party to a criminal conspiracy to commit an offence punishable with death, 2[imprisonment for life] or rigorous imprisonment for a term of two years or upwards, shall, where no express provision is made in this Code for the punishment of such a conspiracy, be punished in the same manner as if he had abetted such offence.*

(2) Whoever is a party to a criminal conspiracy other than a criminal conspiracy to commit an offence

punishable as aforesaid shall be punished with imprisonment of either description for a term not exceeding six months, or with fine or with both.

17.11. Section 34 of the Indian Penal Code:-

"34. Acts done by several persons in furtherance of common intention.- *When a criminal act is done by several persons in furtherance of the common intention of all, each of such persons is liable for that act in the same manner as if it were done by him alone."*

17.12. Section 52 of the Indian Penal Code:-

"52. Good faith. **-** *Nothing is said to be done or believed in "good faith" which is done or believed without due care and attention."*

17.13. Section 109 of the Indian Penal Code:-

"109. Punishment of abetment if the act abetted is committed in consequence and where no express provision is made for its punishment.- *Whoever abets any offence shall, if the act abetted is committed in consequence of the abetment, and no express provision is made by this Code for the punishment of such abetment, be punished with the punishment provided for the offence."*

17.14. Section 145(2) of the Bombay Police Act:-

"145(2) *Any Police officer who (a) is guilty of cowardice, or (b) resgins his office or withdraws himself from duties thereof in contravention of section 29, or (c) is guilty of any wilful-breach or neglect of any*

provision of law or of any rule or order which as such Police officer, it is his duty to observe or obey, or (d) is guilty of any violation of duty for which no punishment is expressly provided by any other law in force, shall, on conviction, be punished with imprisonment for a term which may extend to three months, or with fine which may extend to one hundred rupees, or with both."

18. The body needs enough oxygen to protect itself from Covid. But wearing a mask does not allow enough oxygen to enter the body. As a result, many doctors are advising people not to wear masks as this may endanger their lives and medical exemption certificates stating the same are available with many people.

"1. Preliminary report on surgical mask induced deoxygenation during major surgery.

Face mask side effects include lowered oxygen levels.

This study proved that surgeons that wore a mask in surgery for an hour + had significant reductions in blood oxygen saturation.

This is relevant because most of us are being made to wear face masks at work for the whole shift, long journeys on public transport, and when we are in a public places doing shopping etc. and this requires a degree of exertion that is not taken into account.

"Considering our findings, pulse rates of the surgeon's increase and SpO2 decrease after the first hour."

Decreasing oxygen and increasing carbon dioxide in the bloodstream stimulates a compensatory response in the respiratory centers of the brain. These changes in blood gases result in increases in both frequency and depth of breaths. This exposes another risk – if your mask traps some virus you are breathing more hence increasing viral load and exposure."

Link:**https://www.sciencedirect.com/science/article/abs/pii/S1130147308702355?via%3Dihub**

Study article: **https://pubmed.ncbi.nlm.nih.gov/18500410/**

19. It is clear the Maharashtra government has imposed restrictions with intentions to create fear among the citizens without considering if they can be detrimental to life.

19.1 At Sanjay Raut's daughter's wedding on 29.11.2021 many people had turned up Including Mumbai Mayor Kishori Pednekar, various District Collectors, Ministers etc. Most people were seen without a mask and did not observe any social distancing. It is clear from this that the ministers and officials are aware masks and social distancing have no scientific basis, but are merely fooling the people and treating them like slaves and breaking their own rules. The question is why no charges have been filed against them.

Link: https://youtu.be/3aMpOrhR7Cc

19.2. Today, there is no serious outbreak of corona anywhere in the entire state. People are happily going on with their business. More than 10,000 state transport (S.T.) employees were on a hunger strike at Azad Maidan in Mumbai. The farmers' agitation went on for a year and all the MLAs, MPs, ministers were holding their social, political programs, their employees holding their meetings. They did not find it dangerous to do so. Every official should be answerable to the citizens as to why

and for what purpose these restrictions have been imposed on the common man and no one else.

19.3. Even after the new rules set by the government, a state minister, Shri. Nawab Malik and Shri. Mohit Kamboj while appearing for a court case, were found to be not observing any social distancing regulations. Same goes for their activists who were present in thousands.

19.4. Government officials and leaders are harassing citizens and forcing them to follow rules whereas they themselves break them. From all the above mentioned evidence and the provisions of law, it is clear that the government does not seem to be working in the best interest of people and has a motive of benefiting vaccine manufacturers.

20. Request: However, I humbly request you that,

(i) The Government of Maharashtra, in violation of Sections 38 and 39 of the Disaster Management Act and Sections 166, 120 (B), 34 has made it mandatory to wear a mask for every citizen. These crimes should be immediately stopped under the Sections 52(B) and 55 of the Disaster Management Act.

(ii) Crimes under Sections 341, 342, 220, 385, 120 (B), 34, 109 should be filed against the marshals / officers / employees for illegally stopping the citizens and collecting fines from them.

OR

(i) If the orders and evidence of the Central Government are not up to the mark and the Government of Maharashtra has the right to go against the Central Government and make rules, then appropriate legal action should be taken against me for not wearing a mask.

Yours sincerely,