SANDIPAN DAS
ADVOCATE
HIGH COURT, CALCUTTA

CHAMBER : 43/2B SUBHASINI GANGULI SARANI,
KOLKATA 700025
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6. The Secretary Law,
to the Government of West Bengal,
having his at Writer's Building,
BBD Bagh, Kolkata- 700001;

7. The State Commissioner,
Disabilities Government of West Bengal,
having its office at Subhanna,
2nd Floor Saltlake, Kolkata-700061.

Ref ; W.P.A (P) No. 159 of 2021
Covid Crisis Support Network & Ors ...Petitioners

-Versus-

The Union of India & Ors ...Respondents

Dear Sir,

Enclosed please find herewith a copy of the writ application with all annexure and take notice that the above matter filled before Hon'ble High Court At ,Calcutta and the above mentioned matter shall appear before the Hon'ble Justice Rajesh Bindal (Acting) & Hon'ble Justice Arijit Banerjee on 04.06.2021 or so soon thereafter as and when the business of the Hon'ble Court will permit.

Yours sincerely,

(SANDIPAN DAS)
Advocate

DISTRICT: KOLKATA

IN THE HIGH COURT AT CALCUTTA
CONSTITUTIONAL WRIT JURISDICTION
(APPELLATE SIDE)

W.P.A (P). 159 of 2021

In the matter of:
An application under Article 226 of the Constitution of India.
And
Subject matter relating to
Under Group - Head
Of the Classification of List.
Cause Title
In the matter of:
Covid Crisis Support Network & Ors
...Petitioners
-Versus-
The Union of India & Ors
...Respondents

Advocate-on-Record

SANDIPAN DAS
Advocate
High Court, Calcutta
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LIST OF DATES AND SHORT FACTS

Dates	Short facts
01.03.2021	Persons over the age of 60 years, and,Mwith comorbiditics between the ages of 59 to 45 were eligible for the vaccine as per govt. guidelines
23.03.2021	Government decision to vaccinate all over 45years
01.05.2019	Beginning of Phase 3 Strategy of COVID 19 vaccination for persons over 18 years
19.04.2021	The High Court at Madras directs for endeavours to bc made by the State to enable expeditious vaccination to persons with disabilities.
26.04.2021	Department of Empowerment of Persons with Disabilities has requested the GOI to prirotise testing, vaccination and treatment of PwDs at Covid centres.
27.04.2021	High Court at Karnatak directs priortising vaccination to PwDs with doorstep vaccination to some category.
30.04.2021	The Hon'ble Supreme Court Suo Moto recognized the shortage of vaccines and, that the age group of 18-45 also consists of persons who suffer from vulnerabilities.
	Instant Writ Petition is filed

SYNOPSIS

The surging COVID-19 crisis has cornered Persons with Disabilites (PwDs) to a postion of extreme vulnerability. Special focus on vaccination of PwDs on a priority basis needs urgent addressal from the Respondents. The Government of india while announcing vaccination for all above the age of 45 years and between the age of 18-45years in not specially mentioning PwDs, has put this vulnerable community on the same footing as all. The same is arbitrary and counter productive of the international protocols for providing disabled persons with treatment and safety and treating them equally.

That, further, recognition by the Respondent of the types of disabilities as under the Rights of Persons with Disabilties Act, 2016 is necessary for vaccinating PwDs on a priority basis; wherein, persons with benchmark disabilities and High Support Needs, among various other forms of severe disabilities including mental/intellectual disability would endanger themselevs in travelling to Covid Vaccination Centres (CVC).

That Department of Empowerment of Persons with Disabilities has requested the GOI to prirotise testing, vaccination and treatment of PwDs at CVC's. There is an urgent need for the Centre and State Governments to speedily work out the request and come with an action plan to prioritise vaccination drives amongst consenting PwDs and their caregivers at not just CVC's, but also at the homes of PwD's, mental health institutions, NGO's and organizations supporting PwDs.

That this instant Writ Petition is filed praying for the protection of lives of the PwD's alongwith their caregivers through prioritised vaccination drives; simultaneously, prayer for vaccination drives in leprosy colonies in thee State of West Bengal is made.

POINTS OF LAW

1. Whether the Persons with Disabilities (PWDs are the most vulnerable group to the ongoing COVID-19 pandemic or not?

2. Whether the Respondent Authorities have taken any steps to ensure 100% vaccination of the Persons with Disabilities (PWDs) in the state or not?

3. Whether the safe, unhindered, access to vaccination for Persons with Disabilities (PWDs) comes within the purview of the Article 21 of the Constitution of India or not?

4. Whether the Respondent Authorities have failed to take appropriate steps in consonance with the provisions of Section 8 and Section 25(1) of the Rights of Persons with Disabilities Act, 2016 or not?

5. Whether the respondent has failed to see WHO guidelines and the Policy Brief -UN Secretary General- Disability Inclusive Response to COVID-19 and to include safety of persons with disabilities in providing healthcare during COVID-19, in light of the risks associated with PwDs?

DISTRICT: KOLKATA

IN THE HIGH COURT AT CALCUTTA
CONSTITUTIONAL WRIT JURISDICTION
(APPELLATE SIDE)

W.P.A(P)No. 159 of 2021

In the matter of:
An application under Article 226 of the Constitution of India.

And

In the matter of:

1. Covid Crisis Support Network Through Joint Convenor Shri. Soumen Upadhaya, having its office at 9E BaishnabGhata Lane, Kolkata-700047..

2. Shri. Soumen Upadhaya, son of Shibdas Upadhyay, residing at 2/3 Central Park Second Street, City Centre Durgapur, Barddhaman pin-713216.

3. Smt. Snigdha Sarkar Daughter of Sudhindra Chandra, residing at Flat No.21 J 374 B. P. Township, Patuli kolkata-700094.

...Petitioners

-Versus-

1. The Union of India, service through the Ministry of Law and Justice, having office at 11, Strand Road, Kolkata 700001;

2. The State of West Bengal through the Chief Secretary, Nabanna (13th Floor), 325, Sarat Chatterjee Road, Shibpur, Howrah-711102.

3. Department of Home and Hill Affairs, through the Additional Chief Secretary, Nabanna, 13th Floor,325, Sarat Chatterjee Road,Mandirtala, Shibpur, Howrah-711102

4. Department of Health and Family Welfare through the Secretary, Swasthya Bhawan, GN-29, Sector V, Salt Lake, Kolkata-700091.

5. Department of Disaster Management and Civil Defence, through the Principal Secretary, Nabanna, 2nd Floor, 325 Sarat Chatterjee Road, Mandirtala, Shibpur, Howrah-711102.

6. The Secretary Law, to the Government of West Bengal, having his at Writer's Building, BBD Bagh, Kolkata- 700001;

7. The State Commissioner, Disabilities Government of West Bengal, having its office at Subhanna, 2nd Floor Saltlake, Kolkata-700061.

...Respondents.

To

The Hon'ble Rajesh Bindal, ~~Acting~~ (Acting) Chief Justice, and His Companion Justices of the said Hon'ble Court.

The humble petition of the petitioner above-named;

Most Respectfully Sheweth:-

1. That your Petitioners are citizens of India and are hence amenable to the writ jurisdiction of this Hon'ble Court.

2. That the Petitioner no.1 organization being COVID 19 Crisis Support Network for PWDs is a network formed by members of Disability Activists Forum, PARIVAAR Bengal (an accredited State Federation of PARIVAAR), National Confederation of Parents Organizations (NCPO) for the Persons with Intellectual & Developmental Disability, together with another cross disability federal network organization- Disability Activists Forum, West Bengal. Petitioner no. 1 is represented by its joint convenor Sh. Soumen Upadhaya, son of Shibdas Upadhyay, residing at 2/3 Central

Park Second Street, City Centre Durgapur, Barddhaman, Pin-713216. The prime objective of the network is to support PWDs, their families during the current Covid 19 pandemic crisis by extensively working to provide them with necessities. A brief introduction of the Petitioner no.1 alongwith activities undertaken in the past year is annexed herein as ANNEXURE "P/1".

3. That petitioner no.2, Shri Soumen Upadhaya, son of Shibdas Upadhyay, residing at 2/3 Central Park Second Street, City Centre Durgapur, Barddhaman, Pin-713216 and Petitioner no. 3, Smt. Snigdha Sarkar, daughter of Sudhindra Chandra, residing at Flat No.21 J 374 B. P. Township, Patuli, Kolkata-700094, are public spirited persons working ceaselessly for the cause of Persons Living with Disabilities (PwDs) since the past 2 decades. Adhaar identification cards of the petitioners is attached herein as ANNEXURE P/2- Colly.

4. That the Covid Crisis Support Network have filed representations before the Director of Health Services, West Bengal dated 28.04.2020 seeking priority in vaccination of PwDs, earmarking of waiting rooms, banners/posters in CVCs to escort PwDs, among other requests. A subsequent representation dated 30.04.2021 to the State Commissioner of Disabilities was made intimating about the representation of 28.04.2021 and seeking the monitoring of vaccination process within Kolkata and at the districts by engaging administration and the LLCs. Copy of the represenations dated 28.04.2020 and 30.04.2021 is annexed herein as ANNEXURE P/3 Colly.

5. This Writ Petition is a Public Interest Writ Petition and is filed to espouse the cause of persons with disabilities and ensure that persons with disabilities from the age of 18 and upwards, and their caregivers are

administered the vaccine against the novel Corona virus (COVID 19) irrespective of the category or type of disability on a priority basis not just at the centres for vaccination, but keeping the vulnerability of PwDs in mind, initiate doorstep vaccination to this high-risk group.

6. It is submitted that the world is going through the second wave of COVID 19 and in spite of the availability of vaccines like Covishield and Covaxin and vaccination drives on a war footing, the second wave appears to be lethal and dangerous. It is submitted that all persons over the age of 60 years were administered the vaccine in the first round of vaccinations from 01.03.2021, and persons with comorbidities between the ages of 59 to 45 were also eligible for the vaccine in the first round of vaccinations as per Guidelines under COWIN 2.0 for the first round of vaccination.

7. That during the first round of vaccinations, persons with comorbidities were administered the vaccine even if they were of the age group of 59 years to 45 years if they had certain comorbidities. For reasons best known to the Ministry of Health, certain persons with disabilities were classified as persons with comorbidities. Eligible Beneficiary according to these guidelines issued by the Union Ministry of Health and Family Welfare were:

"C. All such citizens that are aged, or will attain the age of 45 years to 59 years as on 1st January 2022, and have any of the specified comorbidities, which have been recommended by National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) and approved by Government of India from time to time, subject to certification to that effect by a Registered Medical Practitioner. The list of specified co-morbidities (20) and the form for comorbidity certificate are annexed at Annexure I(A) and I(B) respectively."

Entry 20 of the comorbidities in Annexure 1(A) and 1(B)reads as follows:

"Persons with disabilities due to Intellectual disabilities/ Muscular Dystrophy/Acid attack with involvement of respiratory system/ Persons with disabilities having high support needs/ Multiple disabilities including deaf-blindness."

Copy of the Guidance note for COWIN 2.0 dated 24.02.2021 is annexed as ANNEXURE P/4.

8. It is relevant to mention that to consider disability as a comorbidity is faulty. Further exclusion of other forms of disability qualifying under the Rights of Persons with Disabilities Act, 2016 is arbitrary and does not appear to be based on any rational nexus with the vaccination drive to bring the COVID 19 pandemic under control.

9. That it is submitted that the Government began vaccinating all persons over the age of 45years. The Government's decision is reflected in the Press and Information Bureau's release by the Ministry of Health and family welfare dated 01.04.2021 which is annexed to this writ petition as ANNEXURE P/5.. It is to be noted that the vaccination of comorbid persons who were prioritised earlier, are completely excluded with age being the only criterion now.

10. That, further, with the colossal suffering due to the ongoing second wave, Central Government launches the Liberalised and Accelerated Phase 3 Strategy of COVID 19 vaccination from 01.05.2021; wherein everyone above the age of 18 will be eligible to be administered the

COVID-19 vaccine from May 1. No specific mention is made of special preference to persons with disabilities.

11. It is submitted that the exclusion of persons with disabilities who form a separate class, have no reasonable nexus to the vaccination drive aimed at controlling the pandemic. The same is arbitrary, violative of fundamental rights of persons with disabilities and go against statutory protections guaranteed to persons with disabilities in the United Nations Convention on the Rights of Persons with Disabilities and the Rights of Persons with Disabilities Act, 2016. Infact, the Rights of Persons with Disabilities Act, 2016, was enacted by the Parliament in accordance with the Convention of Rights of Persons with Disabilities, 2006.

12. Mortality in Persons with Disability due to COVID-19: It is submitted that according to a report published by Public Health England earlier in November,2020 based on the early months of the pandemic, people with learning disabilities are over six times more likely to die from COVID-19 than the general population. Young people with learning disabilities aged 18-34 are a staggering thirty times more likely to die from COVID-19 than their neurotypical peers. Further, according to data published by the UK Government on "Coronavirus (COVID-19) related deaths by disability status, England and Wales: 2 March to 14 July 2020" indicates that disabled people (as defined) made up almost 6 in 10 (59%) of all deaths involving COVID-19 in this period; while they constitute 16% of the population. Copy of Report by Public health England dated 12.11.2020 and UK Government dated 18.09.2021 is annexed herein as ANNEXURE P/6 Colly.

13. That persons of disabilities by reason of unique characteristics, are incapable of maintaining social distancing and wearing masks, and face three increased risks with devastating consequences: the risks of

contracting COVID-19, developing severe symptoms from COVID-19 or dying from the disease, as well as having poorer health during and after the pandemic, whether or not they are infected with COVID-19.

14. That the persons with disabilities require specific support services including habilitation and rehabilitation services and the nature of the services required also compromise the various safety norms prescribed for protection against COVID-19. Persons with disability are already at a position of disadvantage owing to multiple barriers including access to information regarding health services, inaccessibility of health services and health infrastructure, increased financial burden due to loss of income/reduced income of the individual and the family providing primary care. They also suffer due to the lack of adequate social protection and income security due to the pre-existing inequalities in access to education and employment of persons with disabilities.

15. That the persons with disabilities experience unique challenges in maintaining safety and adherence to safety measures to avoid infection. Persons with disabilities include those with the visual impairments, locomotor disabilities, cerebral palsy, autism etc. Each of these disabilities present a unique challenge in ensuring safe practices to avoid infection. Moreover, some persons with disabilities such as those with disabling health conditions such as multiple sclerosis, persons with hemophilia, thalassemia and those persons with disabilities having comorbid conditions in addition to their impairments and their associated risk factors tend to have a weak immune system which makes them more susceptible to various infections and raises risk of COVID-19 exposure manifold leading to complications and death. People with disabilities despite their susceptibility, are often invisible largely due to lack of adequate data on persons with disabilities across sectors and owing to the

higher rate of poverty, persons with disability remain in vulnerable situations and experience heightened marginalization and must be considered at risk in during COVID-19-related decision- and policy-making processes. As in any crisis, people with disability/impairment must be regarded as an at risk population.

16. That the persons with benchmark disabilities as such blind persons are more reliant on their sense of touch as a substitute for impaired vision. One of the major routes of the virus transmission is believed to be via contact and hence this group is at a higher risk of contracting COVID-19. People with neurological disability also have associated underlying medical conditions that place them at higher risk than others Eg. those with kyphosis and scoliosis live with diminished lung volumes in addition to their disability caused by curvature of the spine. Because of differences in their immune systems, those with Down syndrome are at increased risk of contracting infectious diseases, usually of the upper respiratory tract. Global evidence indicates higher rate of deaths among persons with developmental disabilities.

17. That it is further submitted that wearing masks is not an option for those with cerebral palsy, autism or any developmental disability as it is not an object they are used to, and drooling makes masks unusable. Persons with disabilities experience higher risk of contracting the virus as they require close contact with others as a result of personal care needs (activities of daily living), and/or many live in shared settings like a group home. Persons with disabilities experience greater challenges as a result of public health measures such as physical distancing. This can create greater social isolation and interruption of vital, irreplaceable support networks. Family members / care givers are also at risk of contracting the virus from persons with disabilities and vice versa.

18. That, accordingly, it is submitted vide office memorandum dated 26.04.2021 the Department of Empowerment of Persons with Disabilities has requested the Government of india to prioritize testing, vaccination and COVID-19 related treatment at centres on a priority basis. Excerpt from the notification is as follows,

"...special provisions be made in COVID-19 testing, vaccination and treatment centres for priority in attending to and treatment of PwDs."

Corollary to the limitations faced by PWDs as aforementioned in submissions above, it is submitted that prioritization just at centres is insufficient in protecting disabled persons from contracting infection; it is crucial that prioritised doorstep vaccination drives be conducted for the varied classes of disability hindering PWDs, especially ones with High Support Needs, from approaching these centres in the first place. Failure to do so has resulted in a situation where a person over 18, otherwise fit, who is also entirely capable of following and understanding social distancing guidelines, is given priority over the health of a disabled person with high support needs and co-morbidities. Copy of the office memorandum dated 26.04.2021 the Department of Empowerment of Persons with Disabilities is annexed herein as ANNEXURE P/7.

19. It is submitted that going by the 2011 census wherein some disabilities were counted as disabilities in the census, the population of disabled persons in West Bengal stands at 2.21 %. The population of disable person is 20,17,406. This information is also reflected in the official website http://wbcommissionerdisabilities.gov.in/User/census. There is no doubt that this figure would have gone up with the addition of disabilities and keeping in mind the fact that world-over estimates of disabled population may go up to 10% of the total population.

20. That it is submitted that as on 4th April, 2021, the official figures for COVID 19 infections in the country crossed the 2 crore mark, 2,22,408 lakh deaths as per the Union Health Ministry data. Presently, the covid infection is rising at alarming rate in West Bengal with 8,81, 000 confirmed cases and 11,637 deaths due to COVID 19 as on 04.05.2021.

21. Inclusion of persons with disabilities as a priority / at risk group in other Countries: The Government of Australia has stated that priority groups are identified using public health, medical and epidemiological evidence on who would be most affected if they contracted COVID-19, and those most likely to be exposed. Disability care staff and disability care residents have been included in the first phase of vaccination under phase "1a" and younger adults with disabilities have been included in phase "1b".

Further, in the United Kingdom, while persons with disability were placed low on the priority list, the Government has revised the list after requests from disability groups and has included adults with learning disabilities, Down's syndrome as clinically extremely vulnerable, vaccinating them on a priority basis.

Even the United States Centre for Disease Control and Prevention (CDC) has also recognised the fact that persons with Down's syndrome might be at an increased risk for severe illness from the virus that causes COVID-19 and has accordingly listed Down syndrome in the list of co-morbidities.

22. World Health Organisation Guidelines: The World Health Organisation (WHO) SAGE ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES IN THE CONTEXT OF LIMITED SUPPLY, has also classified Persons with disability as a priority group, behind health

workers etc. Copy of the WHO SAGE ROADMAP is annexed herein as ANNEXURE P/8.

23. Policy Brief -UN Secretary General- Disability Inclusive Response to COVID-19: That according to this Policy note published in May 2020, Persons with disabilities are at greater risk of contracting COVID-19. It notes that,

"they may experience barriers to implement basic protection measures such as hand-washing and maintaining physical distancing for several reasons: lack of accessibility of water, sanitation and hygiene (WASH) facilities; a reliance on physical contact to get support; inaccessibility of public health information; or being placed in institutional settings which are often overcrowded and unsanitary. These barriers are exacerbated for those living in informal settlements and/ or affected by humanitarian emergencies". The policy brief also states that, "Persons with disabilities are at greater risk of developing more severe health conditions and dying from COVID-19. They have greater health requirements and poorer health outcomes. For example, they are more susceptible to secondary conditions and co-morbidities, such as lung problems, diabetes and heart disease, and obesity, which can worsen the outcome of COVID-19 infections. The barriers to accessing healthcare are further exacerbated during the COVID-19 crisis, making timely and appropriate care difficult for persons with disabilities."

Copy of the Policy Brief by UN is annexed herein as ANNEXURE P/9.

DIRECTIONS/OPINIONS OF THE COURTS OF JUDICATURE ON VACCINATION

24. On 30.4.2021, the Hon'ble Supreme Court was pleased to pass an Order in Suo Motu Writ Petition (Civil) No. 3 of 2021 titled "In Re: Distribution of Essential Supplies and Services During Pandemic", wherein it observed as under:

> "34. On 20 April 2021, the Central Government rolled out a revised strategy of COVID-19 vaccination for all persons over 18 years of age, with effect from 1 May 2021. This new age group consists of approximately 59 crore people, which would require 122 crore vaccine doses under the current two-dose vaccine regime of Covishield and Covaxin which have been authorized for emergency use in India....
>
> 36.... For one thing, even this age group would consist of persons who suffer from vulnerabilities.... The available stock of vaccines is not adequate to deal with the requirements of both the categories... The object of vaccinating the 18-44 age group cannot be achieved in the absence of stocks being available."
>
> Copy of the Suo Moto order of the Hon'ble Supreme Court dated 30.04.2021 is annexed herein as ANNEXURE P/10.

25. That it is relevant to mention that the the High Court of Judicature at Madras vide order dated 19.04.2021 in hearing the W.P. No. 2951 of 2021 titled Meenakshi Balasubramanian vs. Union of India and Anr., for including Persons with Disability and their caregivers as a priority group for administering COVID-19 vaccine has emphasised upon, and directed that,

"The State may also consider administering vaccine to persons above the age of 18 but suffering from any form of disability as indicated in the Schedule to the Rights of Persons with Disabilities Act, 2016 instead of confining it to the disabilities indicated in the Union's annexure. Every endeavour should be made by the State to enable vaccination as expeditiously as possible to protect the lives of persons with disabilities. Immediate steps should be taken by the State to ensure that vaccination centres are accessible to persons with disabilities by constructing ramps or other measures in accordance with the said Act of 2016."

Copy of the order dated 19.04.2021 by the High Court at Madras is annexed herein as ANNEXURE P/11.

26. That in addendum ad supra, even the High Court of Judicature at Karnataka vide order dated 27.04.2021 in W.P. No. 8475/2021 in deciding priority vaccination for persons with disabilities, has directed the State government to ensure, "necessary assistance is rendered to the persons who are suffering from benchmark disabilities for the purposes of registering themselves for vaccination...and ensure that priority is given to the persons with benchmark disability in vaccination."

That the Hon'ble Court also passed the following interim directions:

"10. We therefore issue the following interim directions:

a) The State Government shall immediately evolve a scheme/mechanism or giving priority to vaccination of Covid-19 to the persons with benchmark disabilities;

b) The State Government may consider authorising the District Disabled Welfare Officers or any other officers to receive requests for

vaccination by SMS, Whatsapp or Email either from the persons suffering from benchmark disability and/or from respective caregivers;

c) The State Government shall make effective arrangements for providing vaccination to the persons with benchmark disabilities and their caregivers by ensuring that they are not required to wait in the queue at vaccination centres;

d) Needless to add that those persons who suffer from benchmark disabilities and who are unable to move out of their respective residences, necessary arrangements will have to be made for vaccination at the doorstep;

e) We leave to the State Government how to evolve scheme/ mechanism for complying with the aforesaid directions;"

Copy of the order dated 19.04.2021 by the High Court at Karnataka is annexed herein as ANNEXURE P/12.

27. It is submitted that touch and close contact/proximity are two ways that the virus spreads rapidly. The COVID Prevention Protocols demand a six-feet distance, frequent washing of hands and wearing of masks as stringent preventive measures apart from vaccination. Persons with disabilities and their caregivers require vaccination at a priority level as they may be unable to follow social distancing, wearing of masks or avoid contact due their disabilities. A vast majority of persons with disabilities, due to their disabilities, either rely on tactile modes on a daily basis (in the case of the visually impaired), or may not be able to wear masks due to drooling and related problems, or are incapable of maintaining social distancing (in the case of persons with autism and intellectual and developmental disabilities) or require a constant caregiver

(in the cases of certain persons with disabilities with high-support needs) are class of persons who are per se at high risk. The only way to ensure that persons with disabilities are saved from the COVID 19 is to ensure that all persons with disabilities are vaccinated along with their caregivers based on their UDID cards or certificates of disability.

28. Upon being aggrieved and Dissatisfied by the Inaction on behalf of the Respondent Authorities, and owing to the fact that there is no police/ scheme/ plan/ method etc for giving priority of vaccines to Disabled Persons, especially ones with High Support Needs, the Petitioner begs to move this Petition in Public Interest on the following Grounds:

GROUNDS

I. For that persons with disabilities have the right to equality and the right to life under Articles 14 and 21 of the Constitution of India. Article 47 of the Constitution casts a primary duty on the State to improve public health. In Vincent Panikurlangara v. Union of India, (1987) 2 sec 165 the Apex Court held that, "A healthy body is the very foundation for all human activities. That is why the adage "Sariramadyam Khaludharma Sadhanam". In a welfare State, therefore, it is the obligation of the State to ensure the creation and the sustaining of conditions congenial to good health." The Hon'ble Apex Court ruled further "While endorsing what has been said above, we would refer to Article 47 in Part IV of the Constitution. That article provides: "The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in part icu lar, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health."

This article has laid stress on improvement of public health and prohibition of drugs injurious to health as one of the primary duties of the State. Quoting Akhil Bharatiya Soshit Karamchari Sangh v. Union of India [(1981) 1 SCC 246 the Court pointed out that: (SCC pp. 308-09, para 123)

"The fundamental rights are intended to foster the ideal of a political democracy and to prevent the establishment of authoritarian rule but they are of no value unless they can be enforced by resort to courts. So they are made justiciable. But, it is also evident that notwithstanding their great importance, the Directive Principles cannot in the very nature of things be enforced in a court of law.... It does not mean that directive principles are less important than fundamental rights or that they are not binding on the various organs of the State."

II. For that in a series of pronouncements during recent years, this Court has culled out from the provisions of Part IV of the Constitution several obligations of the State and called upon it to effectuate them in order that the resultant picture by the Constitution Fathers may become a reality. As identified, maintenance and improvement of public health have to rank high for being indispensable to the very physical existence of the community; the betterment of which assists in building of a society as envisaged by the Constitution makers. Attending to public health, in the petitioner's opinion, therefore, is of high priority.

III. For That evident is the situation of risk and humanitarian emergency which the COVID 19 pandemic is for a person with disability. Considering the fact that certain persons with disabilities cannot wear masks, cannot avoid tactile sensory inputs or avoid touch, maintain social distancing and have other limitations due to their disabilities, Articles 11 and 25 of the Convention on the Rights of Persons with Disabilities (CRPD) are attracted. Article 11 provides that,

"States Parties shall take, in accordance with their obligations under international law, including international humanitarian law and international human rights law, all necessary measures to ensure the protection and safety of persons with disabilities in situations of risk, including situations of armed conflict, humanitarian emergencies and the occurrence of natural disasters."

Article 25 provides that, "States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability.

States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation. In particular, States Parties shall:

a. Provide persons with disabilities with the same range, quality and standard of free or affordable health care and programmes as provided to other persons, including in the area of sexual and reproductive health and population -based public health programmes;

b. Provide those health services needed by persons with disabilities specifically because of their disabilities, including early identification and intervention as appropriate, and services designed to minimize and prevent further disabilities, including among children and older persons;

c. Provide these health services as close as possible to people's own communities, including in rural areas;

d. Require health professionals to provide care of the same quality to persons with disabilities as to others, including on the basis of free and informed consent by, inter alia, raising awareness of the human rights, dignity, autonomy and needs of persons with disabilities through training and the promulgation of ethical standards for public and private health care;

e. Prohibit discrimination against persons with disabilities in the provision of health insurance, and life insurance where such insurance is permitted by national law, which shall be provided in a fair and reasonable manner;

f. Prevent discriminatory denial of health care or health services or food and fluids on the basis of disability."

IV. For that there is an urgent need to regard and act in accordance with the provisions in the Rights of Persons with Disabilities Act, 2016, being Section 8, Section 25(1), Sections 25(2)(l) - which provide as follows:
8. Protection and safety. -(1) The persons with disabilities shall have equal protection and safety in situations of risk, armed conflict, humanitarian emergencies and natural disasters. (2)The National Disaster Management Authority and the State Disaster Management Authority shall take appropriate measures to ensure inclusion of persons with disabilities in its disaster management activities as defined under clause (e) of section 2 of the Disaster Management Act, 2005 (53 of 2005) for the safety and protection of persons with disabilities.

(3) The District Disaster Management Authority constituted under section 25 of the Disaster Management Act, 2005 (53 of 2005) shall maintain record of details of persons with disabilities in the district and take suitable measures to inform such persons of any situations of risk so as to enhance disaster preparedness.

(4) The authorities engaged in reconstruction activities subsequent to any situation of risk, armed conflict or natural disasters shall undertake such activities, in consultation with the concerned State Commissioner, in accordance with the accessibility requirements of persons with disabilities.

25. Healthcare. - (1) The appropriate Government and the local authorities shall take necessary measures for the persons with disabilities to provide,-

a. free healthcare in the vicinity specially in rural area subject to such family income as may be notified;

b. barrier-free access in all parts of Government and private hospitals and other healthcare institutions and centres;

c. Priority in attendance adn treatment

(2) The appropriate Government and the local authorities shall take measures and make schemes or programmes to promote healthcare and prevent the occurrence of disabilities and for the said purpose shall- (i) healthcare during the time of natural disasters and other situations of risk;

(j) essential medical facilities for life saving emergency treatment and procedures;

V. For that a conjoint reading of the above makes it clear that all persons with disabilities and their caregivers should be vaccinated on a priority basis irrespective of their age and type of disability. It is submitted that not doing so will defeat the statutory, UNCRPD and Constitutional Rights of persons with disabilities in toto.

VI. For that even the WHO-SAGE Guidelines for allotment and prioritisation of vaccines call for prioritising vaccination for persons with disabilities. The basic guiding principles are:

a. Human Well-Being

Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development.

b. Equal Respect

Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration.

c. Global Equity

Ensure equity in vaccine access and benefit globally among people living in all countries, particularly those living in low-and middle-income countries.

d. National Equity

Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic.

e. Reciprocity

Honour obligations of reciprocity to those individuals and groups within countries who bear significant additional risks and burdens of COVID-19 response for the benefit of society.

f. Legitimacy

Make global decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties.

VII. For that the respondent's failure to safely provide vaccines for disabled persons with high support needs and benchmark disabilties, without jeopardizing their health on priority basis is violative of the Rights of Persons with Disabilities Act, 2016.

VIII. For that vaccinating such persons would help to break the chain of the spreading of the Coronavirus.

29. The Petitioner submits that he has not filed a similar petition on the same cause of action either before this Hon'ble High Court or before any other Hon'ble Court seeking similar reliefs.

30. That there is no other alternative efficacious and speedy legal remedy than to move a writ application under Article 226 of the Constitution of India and seek appropriate direction and or directions and/or relief(s). The remedy sought for if granted would be adequate and complete.

31. There are no latches on the part of the Petitioners in moving the instant petition and the balance of convenience and/or inconveniences is in favour of your Petitioner for passing the order, as prayed for herein by the petitioner.

32. That the petitioner has filed this Public Interest Litigation in accordance with Appendix IV of the Appellate Side Rules of the Hon'ble High Court at Calcutta. That your petitioner submits that there are a number of disabled persons across the state, who owing to their disability, poverty, geographical distance, would not be in a position to approach this Hon'ble Court.

33. That the application made is bonafide and for the ends of justice.

In the circumstances, your Petitioner humbly prays that Your Lordships would graciously be pleased to pass the following orders:

A. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the Respondents, their agents, servants, subordinates, employees and/or assignees to make efforts to augment vaccination of all consenting persons with disabilities and the caregivers of persons with disabilities, and individuals with high support needs, above the age of 18 years against COVID19 by administering Covishield or Covaxin and/ or any other competent vaccines that may be available to them irrespective of the nature of their disability on a priority basis in compliance with the request made by the Department of empowerment of Persons with disabilities notification;

B. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the

Respondents, to Organise special camps at every district under the supervision of the jurisdictional District Social Welfare Officer or appoint a Nodal Officer in every District for the same.

C. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the Respondents, to under the supervision of the District Social Welfare Officer, oversee, assist and ensure door to door vaccination on a priority basis for consenting persons with High support needs and benchmark disabilities, during the third and subsequent phases of vaccination throughout the country;

D. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the Respondents, in taking a progressive approach, provide vaccination to persons with disability, for free of costs.

E. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the Respondents- to in light of notification by Ministry of Health and Family welfare- set up special accessible queues for the PwDs in Vaccination Centres and make the Centres disabled friendly.

F. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the Respondents, to Organise vaccination drives for persons with disabilities in institutions for the abandoned and destitute, run and managed by the Government and NGOs;

G. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the Respondents, to organise vaccination drives in mental health institutions both Government and private psychiatric nursing homes and those run by NGOs;

H. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the Respondents, to organize vaccination drives in leprosy colonies for persons affected with leprosy and their family members in the State of West Bengal.

I. A writ of or in the nature of Mandamus and/or any other or appropriate writ(s) or order(s) or direction(s) do issue commanding the Respondents, for evolving a scheme/mechanism for complying with the aforesaid essential prayers.

J. Directing the department of this Hon'ble Court to publish the order of this petition.

K. And pass any further order or direction as this Hon'ble Court may deem fit and proper, in the facts and circumstances of the case, in the interest of justice.

And for this act of kindness, the petitioner as in duty bound shall ever pray.

Jaiman Upadhyay.

Srijata Sarma

AFFIDAVIT

I, Soumen Upadhyay son of Shibdas Upadhyay, aged about 57 68 years, by faith -Hindu, by occupation- Social service, residing at 2/3 Central park Second Street, City Centre Durgapur, Barddhaman pin-713216, do hereby solemnly affirm and say as follows:-

1. That I am the petitioner in the instant case and I am well acquainted with the facts and circumstances of the present case and and I am authorized to affirm the instant petition on behalf of the other petitioner and I am competent to affirm the affidavit.

2. That the statements made in paragraph nos. 1 to 5 are true to my knowledge and the statement made in paragraph nos. 6 to 14 are derived from the records which I belief to be true and rest are my humble submission before this Hon'ble court.

Soumen Upadhyay.

Prepared in my office

Sd.

Advocate

The Deponent is known to me,

Clerk to, Sd.

Advocate

Solemnly affirm before me on,
this the 29 day of May, 2021

I Certify that all annexures are legible

Sd

Advocate

COMMISSIONER

AFFIDAVIT

I, Snigdha Sarkar, Daughter of Sudhindra Chandra Sarkar, aged about- 27 years, by faith Hindu, by occupation – social service, residing at- Flat no. 21 J 374 B.P.Township, Patuli kolkata-700094,do hereby solemnly affirm and say as follows:-

1. That I am the petitioner in the instant case and I am well acquainted with the facts and circumstances of the present case.

2. That the statements made in paragraph nos.1 to 5 are true to my knowledge and the statement made in paragraph nos.6-16 are derived from the records which I belief to be true and rest are my humble submission before this Hon'ble court.

Prepared in my office

Sd

Advocate

Snigdha Sarkar

The Deponent is known to me,

Clerk to, Sd

Advocate

Solemnly affirm before me on,
This the 24th day of May, 2021

I Certify that all annexures are legible.

Sd

Advocate

COMMISSIONER

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P. 7

COVID 19 CRISIS SUPPORT NETWORK FOR Persons with Disabilities

Contacts- Soumen Upadhyay – 9434086363, Snigdha Sarkar – 9433969558, Email - ccsnpwd@gmail.com

TO WHOM IT MAY CONCERN

Dear Sir/ Madam

We are furnishing below the details of COVID 19 Crisis Support Network for PWDs:

COVID 19 Crisis Support Network for PWDs is a network initiated by Disability Activists Forum WB (a Federation of different NGOs and disability activists representing a cross disability network of our state) and PARIVAAR BENGAL (an accredited State Federation of PARIVAAR, National Confederation of Parents Organizations (**NCPO**) for the Persons with Intellectual & Developmental Disability), encompassing subsequently a large number of NGOs across West Bengal and many committed individuals who are working for the Rights and Rehabilitation of People with Disabilities. The prime objective of the network is to support PWDs & their families during the current Covid 19 pandemic crisis and beyond.

The present situation of lockdown in view of the Pandemic Novel Corona virus has disastrously affected persons with disabilities and their families in India. We are especially concerned about the status of persons with different disabilities and their families living in West Bengal during lockdown, fearing that their access to basic amenities and food resources are limited, and the strain that is put on disabled people and their Caregivers, who are forced to be enclosed in their living quarters. While the Central and the State governments are reaching out to the people with rations and other necessary amenities, we feel that there is urgent need to track, to the extent possible, the condition of the families and persons with disabilities in different districts of West Bengal.

This NETWORK started on April 20th, 2020 with an objective to act unitedly in support of the Persons with Disabilities and their families during Covid 19 Pandemic. Within few days many respected personalities and NGOs across the state joined hands and together we could reach out to the PWDs as many as possible at each corner of the state - from Siliguri to South and North 24 Pargana.

The prime aim of the network is to support the PWDs & their families within Kolkata and beyond by supplying essential food rations and medicines to the beneficiaries in crisis.

Our Network has the strength of almost One Hundred (100) members throughout the state of West Bengal, which is overwhelming. There are 41 volunteers to execute the plan on the ground. The Network also have many resource persons to strengthen its cause.

We got volunteers to help the PWDs, who are in need of food, medicines etc. to organize through coordinating with local police, councilor or NGOs/Clubs etc., and /or if required the volunteers would try to organize caregivers to help the PWDs in distress.

Activities during past one year –

1. Letter expressing our concerns and our expectations from the state govt. has been mailed to our **Honorable Chief Minister**. Copies were sent to:

COVID 19 CRISIS SUPPORT NETWORK FOR Persons with Disabilities
Contact:- Soumen Upadhyay – 9434086363, Snigdha Sarkar – 9433969558, Email - ccsnpwd@gmail.com

a. The Chief Secretary,
b. Minister Dept. of WCD & SW,
c. Secretary Dept. of WCD & SW,
d. Commissioner Disabilities, WB
e. Principal Secretary Dept. of Health & FW,
f. Director Dept. of Health & FW Dept.

2. letter to different media houses has been mailed with a request to highlight the plight of people with disabilities and also letting people know about the initiative led by this group.

3. letter has also been sent to the Director General of Police, West Bengal and the Commissioner of Police, Kolkata respectively for spreading the information about the support activities by this network.

4. Appeal has been sent to a Corporate House for supporting activities of the network. We are working to tap another Corporate House for the support.

5. Decision was taken and implemented to support the PWDs & their families with Food packets & medicines in the first phase of long lockdown and therefore, we connected with different NGOs in districts to get list of PWDs in crisis and then reached out to them with possible support.

6. As per the decision, supports were provided to approximately more than 2000 PWDs along with their families at different districts of the state. A List of the same is given below:

List of Beneficiaries supported by CCSNPWD through member NGOs

District	Location	No of food packets	No of Medicine packets
Hooghly	Bansberia, Boropara, Rabindranagar, Hooghly, Naldanga, Chinsurah, Serampore, Chinsurah, Bandel, Bansberia, Tribeni, BTPS Township, Mogra, Debanandapur	118	12
Nadia	Kalyani, Haringhata, Madanpur, Shimurali, Chakdaha, Habibpur, Nabadwip	160	26
Murshidaba	Baharampur, Sargachi, Beldanga	14	
North 24 Paragana	Kanchrapara, Halisahar	140	10
Cooch Behar	Mathabhanga, Coochbehar Town	38	

COVID 19 CRISIS SUPPORT NETWORK FOR Persons with Disabilities

Contacts- Soumen Upadhyay – 9434086363, Snigdha Sarkar – 9433969558, Email - ccsnpwd@gmail.com

ipurduar	Jateswar, Tatipara, Samuktala, APD Town	17	
arjeeling	Mirik Lower Sourinbasti Tea Estate	38	
owrah	Jagatballavpur, Amta, Maju	11	
lorth 24 'argana	Hasnabad	250	
lorth 24 'argana	Hinglegani, Sundarban	70	
looghly	Singur	21	
lorth 24 'argana 30.05.2020]	Hasnabad [Beneficiaries includes very marginalised poor people also]	400	
:oochbehar	Tufanganj	17	
stha utism upport roup	Siliguri	20	
		5	
:hinsurah ense ociety	Mogra & Polba-Dadpur Block, [Beneficiaries includes very marginalised poor people also]	600	
IENTAID	Joka, South 24 Parganas	45	
)ther upports			6
ledicine	Uttarpara		
aby Food Buiscuits	Astha Autism Support Group	10	
ledicine	Chinsura Sense Socity		4
:CSN	Alipurduar, 25.06.2020	28	
			58
OTAL	**No of Beneficiaries**	**2002**	**2060**

Now when the 2nd Wave of Covid is at its peak now, our Network has decided to move for Vaccination of the Persons with Disabilities at a priority basis and we have already appealed to the Director, Health Services, Govt of West Bengal and also to the State Commissioner Disabilities, Govt of West Bengal on 28th and 30th April 2021.

With warm regards
Soumen Upadhyay
JI Convener

Snigdha Sarkar
JI Convener

ভারত সরকার

Unique Identification Authority of India

Government of India

তালিকাভুক্তির আই ডি/Enrollment No.: 1040/19522/02181

27/08/2012

To

স্নিগ্ধা সরকার

Snigdha Sarkar

FLAT NO-21 J-374 B.P. TOWNSHIP

PATULI KOLKATA

Panchasayar Kolkata

West Bengal 700094

MN124998178DF

আপনার আধার সংখ্যা/ Your Aadhaar No. :

3178 9444 6553

আধার - সাধারণ মানুষের অধিকার

ভারত সরকার

GOVERNMENT OF INDIA

স্নিগ্ধা সরকার

Snigdha Sarkar

পিতা : সুধীন্দ্র চন্দ্র সরকার

Father : SUDHINDRA CHANDRA SARKAR

জন্ম সাল / Year of Birth : 1961

মহিলা / Female

33

ভারত সরকার
Unique Identification Authority of India
Government of India

তালিকাভুক্তির আই ডি / Enrollment No : 1058/20045/40659

To
SOUMEN UPADHYAY
সৌমেন উপাধ্যায়
3 3 CENTRAL PARK
SECOND STREET
CITY CENTRE
Durgapur (m Corp.)
City Centre,Barddhaman
West Bengal - 713216
9434358617

08/03/2013

KL813834314FT

81383431

আপনার আধার সংখ্যা / Your Aadhaar No. :

6082 2053 5953

আধার – সাধারণ মানুষের অধিকার

ভারত সরকার
Government of India

সৌমেন উপাধ্যায়
SOUMEN UPADHYAY
পিতা : শিবদাস উপাধ্যায়
Father : Shibdas Upadhyay

জন্মতারিখ/DOB : 15/01/1953
পুরুষ / Male

6082 2053 5953

আধার – সাধারণ মানুষের অধিকার

COVID 19 CRISIS SUPPORT NETWORK FOR Persons with Disabilities

Email – ccsnpwd@gmail.com

Ref No CCSN/01/21-22

Date: April 28, 2021

The Director,
Health Services,
Department of Health & Family Welfare,
Govt. of West Bengal
Swasthya Bhavan,
Salt Lake,
Kolkata

Sub: Covid 19 vaccination for Persons with Disabilities

Dear Sir,

Greetings from CCSN (Covid Crisis Support Network for Persons with Disabilities), a platform of NGOs, Parents Associations, concerned individuals in Disability Sector throughout West Bengal. It was formed in last April 2020, to support the families having disabled members during the Covid period.

We are relieved that the Persons with Disabilities above 18 years would be vaccinated from 1st May 2021 which would be safe because they are more susceptible and vulnerable to the infection.

Many of these youngsters such as those with Autism, Developmental Disability, Multiple Disability, and Psychosocial Disability cannot cope with crowd and are not able to stand in queue for long owing to their disability. Unless we can find an accessible way to vaccinate them, many of these youngsters will remain out of this protection drive and will be at risk. We, therefore, request you the following reasonable accommodations in the vaccination centers in our state.

- Requesting to please designate all disability certificate issuing hospitals across the state to accord priority in vaccination to persons with disabilities.
- To please instruct and sensitize the staffs at the vaccination centers.
- Requesting you to please earmark a waiting room for the Persons with Disabilities and their escorts in the vaccination centers.
- We also request you to display posters / banners in the vaccination centers in this regard and put appropriate signage to guide the Persons with Disabilities and their escorts.
- Persons with Disabilities should have the vaccination facility on the ground floor as many cannot climb steps due to mobility restriction.

Arrangement for home service (as was done during the election for super senior citizens and the Persons with Disabilities) will be extremely helpful for the people with disabilities, if possible.

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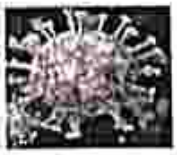

COVID 19 CRISIS SUPPORT NETWORK FOR Persons with Disabilities

Email – ccsnpwd@gmail.com

Since vaccination is also done by many private health centers, may we request you to ask them to give priority in providing vaccination to the people with disabilities considering their needs?

In this regard, we do hereby attach an office Memo, that attaches importance to give priority to the Persons with Disabilities, by the Department of Empowerment of Persons with Disabilities, Government of India.

We trust you will find our request for reasonable accommodation justified and kindly take necessary measures.

Sir, in this regard, may we approach you to please have a meeting with us in person or in a Webinar for just half an hour at your affordable time so that we may interact of the problems the Persons with Disability face without the above facilities.

Thanking you and looking forward to an early positive response from your end.

With sincere regards,

(Soumen Upadhyay)
Jt Convener
9434086363

Snigdha Sarkar
Jt Convener
9433969558

Enclosed: Memo issued by Department of Empowerment of Persons with Disabilities to give Priority and preference for the Treatment and Vaccination to Persons with Disabilities

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COVID 19 CRISIS SUPPORT NETWORK FOR Persons with Disabilities

Email – ccsnpwd@gmail.com

Ref No CCSN/02/21-22

Date: April 30, 2021

The State Commissioner (Disabilities),
Department of Women & Child Development and Social Welfare,
Govt. of West Bengal
Suvanna Sall Lake,
Kolkata 700091

Sub: Covid 19 vaccination for Persons with Disabilities

Dear Sir,

Greetings from CCSN (Covid Crisis Support Network for Persons with Disabilities), a platform of NGOs, Parents Associations, concerned individuals in Disability Sector throughout West Bengal. It was formed in April 2020, to support the families having disabled members during the Covid period

We are relieved that the Persons with Disabilities above 18 years would be vaccinated from 1st May 2021 which would be safe because they are more susceptible and vulnerable to the infection

You are aware that many of these youngsters such as those with Autism, Developmental Disability, Multiple Disability, and Psychosocial Disability cannot cope with crowd and are not able to stand in queue for long owing to their disability. Unless we can find an accessible way to vaccinate them, many of these youngsters will remain out of this protection drive and will be at risk

We have already communicated our concerns to the Director, Health Services and have made requests to accord priority to persons with disabilities in the vaccinations process.

We do hereby attach an office Memo, by the Department of Empowerment of Persons with Disabilities, Government of India

May we make the following requests to you

- Reinforce our appeal with your intervention
- Monitor the vaccination process within Kolkata and at the districts by engaging administration and the LLCs to effectively support persons with disabilities to get priority vaccination, as requested.

Sir, in this regard, may we approach you to please have a meeting with us in person or virtually for half an hour at your convenient time so that we may interact regarding the problems the Persons with Disabilities face without the above facilities

Thanking you and looking forward to an early positive response from your end

With sincere regards,

(Soumen Upadhyay)
JI Convener
9434086363

(Snigdha Sarkar)
JI Convener
9433969558

Enclosed

1. Copy of letter to the Director, Health Services, Govt. of WB
2. Memo issued by Department of Empowerment of Persons with Disabilities to give Priority and preference for the Treatment and Vaccination to Persons with Disabilities
3. Copy to Assistant Commissioner, Disabilities, Govt. of West Bengal

Guidance note for COWIN 2.0

1. Background:

To reduce the burden of the COVID-19 pandemic in the country, India started the COVID-19 vaccination programme on 16th January 2021 targeting 30 crore beneficiaries based on priority groups identified by NEGVAC. A detailed guideline for planning (including training, logistics & vaccine management), implementation, tracking and management of AEFIs, monitoring and evaluation of the COVID vaccination programme at the National, State and District level was released on 28th Dec 2020 (https://www.mohfw.gov.in/pdf/COVID19VaccineGUIDEChapter1New.pdf).

One of the key aspects of the COVID Vaccination programme in India has been the roll out of COWIN portal. COWIN is an end to end solution that has utilities for the entire public health system from national up to the vaccinator level. The COWIN 1.0 system allowed for creation of users (admins, supervisors, vaccinators), registration of beneficiaries (bulk upload and individual registration), facilities/planning unit and session sites followed by planning and scheduling sessions and implementation of vaccination process.

As on 24th February 2021, more than 1.23 crore (~1.09 crore 1st dose and ~14 lakh 2nd dose) doses have already administered through more than 263,000 session at more than 45,000 sites targeting the health care workers and frontline workers.

In accordance with the prioritization as guided by the NEGVAC, the next phase of vaccination is due for citizens of age appropriate categories, including initially the people above 60 years of age and those aged from 45 years to 60 years and have the co-morbidities. To augment and simplify the process of registration vaccination, the MoHFW is coming with COWIN 2.0, based on the feedbacks received during the implementation of Phase I of Covid-19 vaccination drive.

2. Purpose of document:

This guidance note is intended to specify the underlying principles that guide the design of COWIN 2.0, for vaccination of eligible citizens. This document also defines key roles, responsibilities, and SOPs for various modules of COWIN2.0. The document also highlights the key features/modules and relevant of the COWIN 2.0 intended to be used by programme manages at the state/district and facility level. Further guidance will also be issued from time to time whenever necessary.

3. Terms and their meaning:

a. **Eligible Beneficiary** – Following persons are eligible for coverage –

A. All Health Care Workers and Frontline Workers as specified by the MoHFW.

B. All citizens that are aged, or will attain the age of, 60 years or more as on 1st January 2022.

C. All such citizens that are aged, or will attain the age of, 45 years to 59 years as on 1st January 2022, and have any of the specified comorbidities, which have been recommended by National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) and approved by Government of India from time to time, subject to certification to that effect by a Registered Medical Practitioner. The list of specified co-morbidities (20) and the form for comorbidity certificate are annexed at Annexure 1(A) and 1(B) respectively.

b. **COVID Vaccination Centers (CVCs)** – Is a health center where COVID vaccines will be administered. **Types of CVCs are detailed para 4.2.**

c. **Government COVID Vaccination Center (GCVC)** – Is a Government Health Facility being operated as a COVID Vaccination Center.

d. **Private COVID Vaccination Center (PCVC)** – Is a Private Health Facility which complies with the requirements as specified in para 4.2(c).

e. **Vaccinator (Vaccination Officer 1 (VO1))** – A trained health care worker who will provide the vaccination services at the CVC. Vaccinator Officers could be from public health facilities or private health facilities. Their roles and responsibilities are already detailed in the Operational Guidelines.

f. **Verifier (Vaccination Officer 2 (VO2))**– Verifier Officer will be the person responsible for verifying the identity of the beneficiaries at the time of vaccination before a vaccine dose is administered. Verifier will also be responsible for on-site registration and verification and of HCWs, FLWs and citizens, at the CVC.

g. **CVC Manager** – The CVC Manager will be responsible for overall planning, implementation, and grievance redressal at the CVC. He will also be responsible for maintaining stocks and accounts & safekeeping of vaccines supplied to the CVC.

h. **CVC Location** – The geo location of the CVC as identified by any GIS software using latitudes and longitudes.

i. **Vaccination Cycle** – A period of not more than 28 days for which a Target Number of Doses are planned.

j. **Target Number of Doses** – The number of doses planned to be administered decided by respective State/UT Government for a Vaccination Cycle. Total vaccination slots for a vaccination cycle should not exceed the Target Number of Doses. The Targets should further be decided district-wise and within a district Vaccination Center-wise for preparing and entering the Vaccination Time Tables for Vaccination Centers in COWIN.

k. **Vaccination Time Table** – The date-wise schedule to be populated in COWIN for each Vaccination Center with details of various types of Vaccination Slots.

l. **CVC Session Capacity** - The total number of Vaccination Slots for a CVC for a day. This would be decided based on operational capacity for a CVC in day. The CVC Session Capacity is variable and is an input to the system by the District Admin at the time of creation of a session.

m. **Vaccination Slots** – The number of doses to be administered at a CVC in a day including all types of Vaccination Slots. Following types of vaccination slots will be available –

A. **Reserved Slots** – These can be further classified as:

1. **Mobilization slots** - Slots for which respective State/UT Government shall mobilize beneficiaries for on-site registration, appointment, verification and vaccination (all on-site on the same day). There will not be any need for pre-registering beneficiaries through online interface for this. **Proportion of such slots will be decided by respective State/UT Government.**

2. Slots reserved for 2nd dose for beneficiaries who have already received 1st dose, including HCWs, FLWs and citizens, at a CVC. These slots will be filled by the COWIN system based on data available in the system regarding vaccination details of partly vaccinated beneficiaries (such as CVC, Vaccine Type and Vaccination Date).

B. **Open slots** – Open for online appointments by general citizens. The number of Open Slots for a session will be worked out by subtracting the number of Reserved Slots from the CVC Session Capacity.

4. The Framework and underlying Principles:

4.1. Determination of Target Number of Doses for a Vaccination Cycle –

a) The schedule of vaccination of Eligible Beneficiaries, is closely linked with availability of vaccine doses. The States/UTs will decide the target number of doses to be administered in a Vaccination Cycle, based on already available vaccine doses and additional doses like to be available in a Vaccination Cycle.

b) Since, when a beneficiary is being vaccinated with 1st dose, COWIN will automatically confirm the appointment of the beneficiary for the 2nd dose at the same Vaccination Center, the target number of doses should be decided with careful consideration of available stocks and requirement of vaccine stocks for 2nd dose vaccinations for the already partly vaccinated beneficiaries.

c) The Ministry will, from time to time, indicate the state-wise allocation of vaccine doses to the States/UTs.

4.2. **Vaccination Centers**: A CVC must be a health facility and can be one of the following types:

a) Government Health Facilities (GCVC) – These include all Government Medical Colleges, District Hospitals, Sub-District Hospitals, Community Health Centers, Primary Health Centers and Sub-Health Center. Government Health Facilities also include Central Institutions, Health Facilities of other Ministries such as Railways, ESIC, Home etc. and all CGHS Dispensaries.

b) Private Health Facilities (PCVC) – For a Private Health Facility to be operated as a PCVC, it would be necessary for such a facility to be empaneled either under the PMJAY or under the CGHS or under any health insurance scheme of the state/UT government. Hence, the private facilities will include –

1. All Hospitals empaneled under the PMJAY.
2. All Hospitals empaneled under the CGHS.
3. All Hospitals empaneled under the health insurance scheme(s) of any state/UT government.

c) For any Private Health Facility to be operated as a PCVC, the facility must have the following –

1. Sufficient Cold Chain equipment and capacity.
2. Sufficient rooms/space for waiting area, vaccination and observation post vaccination.
3. Sufficient number of trained vaccinators and verifiers
4. Ability to manage the Adverse Events Following Immunization (AEFI), as per the norms and guidelines of the Ministry.

4.3. **Free & Paid services** – Vaccination will be provided free of charge at the Government Health Facilities and will be on payment basis in the Private Health Facilities, at a rate as may be decided by the Government of India from time to time.

4.4. **Determination of the number and list of CVCs to be operated:**

a) States will be required to plan adequate number of sites (COVID Vaccination Centers) along with appropriate geographical spread, for achieving the Target as decided by the State/UT for a period. The State and districts will be required to pre-register these CVCs in COWIN portal before the registration is opened for Citizens (*Annexure 2 (A) - Registration of CVCs*).

b) States must ensure that all PMJAY/CGHS empaneled facilities are registered on COWIN with correct details.

c) Although, the list of CVCs with Open Slots will be available in public domain through COWIN or other COWIN compliant applications, the list of CVCs must also be adequately publicized by the concerned State/UT using all necessary mediums for informing the citizens.

4.5. **Vaccination Time Table for a CVC:**

a) The District Administrator will create a Vaccination Time Table (using COWIN 2.0) for vaccination at each CVC based on the target doses to be administered and the number of days in which the coverage is planned.

b) The number of days or dates may be decided by the respective State/UT Government.

c) Determination of the session capacity for a day: The CVC Capacity for a day will be an input to the system. The minimum capacity for a day will be equal to the number of 2nd doses due at a CVC for that day.

d) **Determination of Open Slots:**

1. Apart from the CVC Capacity, the District Admin will also specify the percentage of remaining capacity (CVC Capacity – 2nd dose reserve) to be opened for online appointments by citizens.

2. The number of open slots for a session will then be calculated by the system by subtracting total reserve slots from the CVC capacity.

Example: If the specified CVC capacity for a session on 5th March is 200, the 2nd doses due on 5th March at that CVC is 50 and the specified %age of open

slots is 40%, then – a) the remaining capacity is 150 (200 – 50 2nd dose slots), b) The number of online open slots is 150*40% = 60 and c) the number of reserved slots for on-site registration = 200 – 50 – 60 = 90.

3. If the specified %age is zero, then the whole session will be for reserved slots. There will not be any open slots and such sessions will not be visible to the citizens for online appointment.

4. If the specified %age is 100%, then there will not be any mobilization slots and all the remaining capacity (after subtracting the 2nd dose capacity from Session Capacity), will be classified as open slots, which will available to the citizens for online appointment.

e) Following **precautions** are suggested –

1. **It is recommended that, to begin with, based on local context and plan, one particular CVC may be either fully reserved or their full capacity is opened for online self-appointment, to avoid the confusion and problems in physical queue management on site at the CVC.**

2. If it is so decided that a CVC will have both the reserved and the open slots, **session timings for open slots may be carefully selected** to avoid overlap of beneficiaries between the ones coming through online appointment and the ones being mobilized for mobilization slots. The timings for on-site registrations in such a case should also be carefully publicized.

3. Session capacities for a CVC and the number of CVCs should be increased incrementally to leave the room for new mobilization slots/ open slots, as in the later period, the number of 2nd doses due will progressively increase.

f) Further details of creation of Vaccination Time Table are given in Annexure 3. (*Annexure 3 – Creation of Vaccination Timetable and Vaccination Slots in COWIN 2.0*)

4.6. Access to Citizens/beneficiaries –

a) Advance Self Registration (Online Registration and Appointment):

1. Registration and appointment will be available to citizens through the COWIN Portal or through other IT Applications such as Arogya Setu etc.
2. Basic demographic details of beneficiaries and details of the photo ID Card to be used by the beneficiary at the time of vaccination will be captured at the time of registration.
3. The list of the CVCs along with date and time of availability of vacant slots will be available to the citizens at time of registration and appointments.

wherein he/she would be able to choose the CVC of his/her choice and book and appointment based on the slots available.

4. The details of the process for Online Registration and Appointment for Citizens is at Annexure 4 (*Annexure 4 – Online Registration for Citizens*).

b) **Facilitated Cohort Registration (Mobilization of Beneficiaries)**: The States/UTs may plan to fully reserve identified CVCs for some sessions at a CVC for on-site registration of beneficiaries. In such cases State/UT/District teams should make all necessary efforts and arrangements to mobilize sufficient number of beneficiaries so as to utilize full planned capacity.

c) 2nd dose appointments will be automatically scheduled by the System.

d) On-site Registration of eligible beneficiaries will also be possible. However, this must be planned carefully so as to avoid overcrowding of willing beneficiaries.

e) All beneficiaries, regardless of the mode of access, i.e. through online registration or mobilization through on-site registration, must be advised to carry the following for verification at the time of vaccination –

1. Aadhar Card; and
2. Electoral Photo Identity Card (EPIC); and
3. The Photo ID card specified at the time of registration in case of online registration.
4. Certificate of comorbidity for citizens in age group of 45 years to 59 years
5. Employment certificate/ Official Identity Card – (either but with photo) for HCWs and FLWs.

4.7. Coverage of HCWs and FLWs: The vaccination of HCWs and FLWs will also happen using the new utility. The detailed SOPs for coverage of HCWs/FLWs are at Annexure 5. (*Annexure 5 – Registration and Vaccination of HCWs and FLWs using COWIN 2.0*)

4.8. Verification, vaccination and certification of beneficiaries at the time of vaccination

a) Multiple Verifiers and Vaccinators can be assigned for a session at the CVC.

b) The full list of beneficiaries, as available in COWIN, will be visible to all verifiers and vaccinators designated for a session, i.e. all verifiers and vaccinators will work on the same full list.

c) Verification will be done by Verifier (Vaccination Officer 2).
Verification will preferably be done using Aadhar.

d) In case Aadhar authentication is not possible at a CVC for any reason, the Verifier will verify the identity and eligibility of the beneficiary from the photo ID Card indicated by the beneficiary at the time of registration.

e) If the identity and eligibility of a beneficiary is established upon verification, the beneficiary will be vaccinated and his/her vaccination status will be updated, else the beneficiary will not be vaccinated.

f) All Vaccination Events must be recorded in real time through the COWIN Vaccinator Module.

g) The process for certification and AEFI reporting remain the same as in the current version of COWIN.

5. The COWIN system will transition to Version 2.0 from 27th February. The system will be run in test mode on 27th and 28th February. Once the transition is done from the backend, which is planned on the night of 26th February, all sessions planned after 26th February will be deleted. The states must finalize their data for sessions held on February 26th by 9:00 pm. It is therefore advised that the sessions for 26th of February may be closed by 9:00 pm and no sessions be scheduled for 27th and 28th of February. This period will be utilized for registration of CVCs, planning and population of sessions, populating the due lists for 2nd doses and preparing the system for providing access to citizens.

Annexure 1(A): List of specified Comorbidities for determination of eligibility of citizens in age group 45 to 59 years

SN	Criterion
1	Heart Failure with hospital admission in past one year
2	Post Cardiac Transplant/Left Ventricular Assist Device (LVAD)
3	Significant Left ventricular systolic dysfunction (LVEF <40%)
4	Moderate or Severe Valvular Heart Disease
5	Congenital heart disease with severe PAH or Idiopathic PAH
6	Coronary Artery Disease with past CABG/PTCA/MI **AND** Hypertension/Diabetes on treatment
7	Angina**AND** Hypertension/Diabetes on treatment
8	CT/MRI documented stroke **AND** Hypertension/Diabetes on treatment
9	Pulmonary artery hypertension **AND** Hypertension/Diabetes on treatment
10	Diabetes (> 10 years**OR**with complications) **AND** Hypertension on treatment
11	Kidney/ Liver/ Hematopoietic stem cell transplant: Recipient/On wait-list
12	End Stage Kidney Disease on haemodialysis/ CAPD
13	Current prolonged use of oral corticosteroids/ immunosuppressant medications
14	Decompensated cirrhosis
15	Severe respiratory disease with hospitalizations in last two years/FEV1 <50%
16	Lymphoma/ Leukaemia/ Myeloma
17	Diagnosis of any solid cancer on or after 1st July 2020 **OR**currently on any cancer therapy
18	Sickle Cell Disease/ Bone marrow failure/ Aplastic Anemia/ Thalassemia Major
19	Primary Immunodeficiency Diseases/ HIV infection
20	Persons with disabilities due to Intellectual disabilities/ Muscular Dystrophy/ Acid attack with involvement of respiratory system/ Persons with disabilities having high support needs/ Multiple disabilities including deaf-blindness

Annexure 1(B): Certificate to identify individuals with co-morbidities that enhance the risk of mortality in COVID-19 disease for priority vaccination
(To be filled by a Registered Medical Practitioner)

Name of beneficiary: _____
Age: _____ Gender: _____
Address: _____
Mobile phone number: _____
Identification document: _____

I, Dr. _____, working as _____ have reviewed the above named individual and certify that he/she has the below mentioned conditions based on the records presented to me. A copy of the records on which this certificate is based is attached.

Presence of ANY ONE of the following criteria will prioritize the individual for vaccination

SN	Criterion	Yes/No
1.	Heart Failure with hospital admission in past one year	
2.	Post Cardiac Transplant/Left Ventricular Assist Device (LVAD)	
3.	Significant Left ventricular systolic dysfunction (LVEF <40%)	
4.	Moderate or Severe Valvular Heart Disease	
5.	Congenital heart disease with severe PAH or Idiopathic PAH	
6.	Coronary Artery Disease with past CABG/PTCA/MI AND Hypertension/Diabetes on treatment	
7.	AnginaAND Hypertension/Diabetes on treatment	
8.	CT/MRI documented stroke AND Hypertension/Diabetes on treatment	
9.	Pulmonary artery hypertension AND Hypertension/Diabetes on treatment	
10.	Diabetes (> 10 yearsORwith complications) AND Hypertension on treatment	
11.	Kidney/ Liver/ Hematopoietic stem cell transplant: Recipient/On wait-list	
12.	End Stage Kidney Disease on haemodialysis/ CAPD	
13.	Current prolonged use of oral corticosteroids/ immunosuppressant medications	
14.	Decompensated cirrhosis	
15.	Severe respiratory disease with hospitalizations in last two years/FEV1 <50%	
16.	Lymphoma/ Leukaemia/ Myeloma	
17.	Diagnosis of any solid cancer on or after 1st July 2020 Orcurrently on any cancer therapy	
18.	Sickle Cell Disease/ Bone marrow failure/ Aplastic Anemia/ Thalassemia Major	
19.	Primary Immunodeficiency Diseases/ HIV infection	
20.	Persons with disabilities due to Intellectual disabilities/ Muscular Dystrophy/ Acid attack with involvement of respiratory system/ Persons with disabilities having high support needs/ Multiple disabilities including deaf-blindness	

I am aware that providing false information is an offence.

Name of RMP: _____
Medical Council registration number of RMP: _____
Date of issuing the certificate: _____ (Signature of RMP)
Place of issue: _____.

Annexure 2 - Registration of Vaccination Centers – COWIN 2.0

1. The State and districts will be required to pre-register the CVCs in COWIN portal before the registration is opened for General Citizens. The list of these CVCs will be available to the citizens at time of registration wherein s/he can choose the CVC of his/her choice and book and appointment based on the slots available.

2. A CVCs **must be a health facility**. Various classifications of CVC Types such as Government/Private, Free/Paid and type of health facility such as MC/DH/SDH/CHC/PHC/SHC/Central or PMJAY/CGHS/Other etc. will be captured on COWIN at the time of CVC Registration.

3. The key principles to be followed for identification of a CVC is as follows:

   3.1. **The State/UT government shall decide the district-wise number of CVCs** and indicate the numbers to the districts.

   3.2. The list of CVCs in a district, will be decided by the respective District Task Force (DTF).

   3.3. All CVCs will be operated under the supervision of District Administration. The District Task Force will ensure that requisite arrangements are made at the CVCs at all stages viz. Planning, Preparation, Logistics and Operations, as prescribed in Operational Guidelines and hereinafter.

   3.4. All Private CVCs must be registered on COWIN by the DIO concerned. These will also be operated under the supervision of District Administration. Registration may be done suo-moto.

   3.5. A CVC will be Registered by the District Admin on COWIN, through a "Manage **Vaccination Centers**" feature provided on COWIN to District Admin. This can be done by editing the details of existing Session Sites or by adding new Vaccination Centers.

   3.6. The option for activating/inactivating a Vaccination Center will also be available.

   3.7. All such CVCs where vaccination slots for online appointments have been kept, shall be declared on COWIN along with such number of slots, well in advance, to provide options to the citizens for Registration and Appointment.

   3.8. **A CVC, when opened as per para 3.5 above,** will be available to any citizen for appointment regardless of his\her location. The states may, however, decide to limit the open appointment slots.

3.9. The number of CVCs in a district would be worked out on the basis of estimated number of beneficiaries to be covered, the period in which coverage is targeted, and number of available vaccine doses and vaccinators/verifiers. The DIO should ensure that sufficient CVCs are registered on COWIN to ensure full coverage within the targeted period.

3.10. All PMJAY and CGHS empaneled health facilities, particularly such private health facilities, must be registered on COWIN as CVCs.

4. Every CVC will be mapped to a Cold Chain Point (CCP). The details of CCPs must be updated by the DIOs for ensuring correct mapping.

5. A CVC shall usually have only one type of vaccine throughout the vaccination drive. This is necessary to avoid mixing of vaccine types in 1st and 2nd dose of a beneficiary.

6. Each CVC will have a designated CVC Manager who will be responsible for overall planning, implementation, and grievance redressal at the CVC. (*Annexure 2(B) – Roles and Responsibilities of CVC Manager*)

7. The DIO will designate the vaccinators and verifiers for each session at a GCVC. If a CVC Manager is created by the DIO, the GCVC Manager will also be able to add vaccinators and verifiers. However, the GCVC Manager should only add the staff of his/her own institution only.

8. For PCVCs, the verifiers and vaccinators will be added by the CVC Manager himself. There will be no dependency for PCVC Managers on the DIOs for doing so.

9. The standard data attributes for a CVC to be Registered on COWIN are given in Table 1. Initially, all the CVC will be registered by the District Admin.

Table 1: Attributes of COVID-19 Vaccination Centers (CVC)

S. No.	Attribute	Data specification	Precautions
CVC Location Attributes			
1	CVC ID – NIN/PMJAY/ CGHS/ Other	Numeric	The correct ID must be entered.
2	CVC Name	Alphanumeric (Max 30 characters)	The Name should be the name by which the institution/ facility, it is commonly known among citizens.
3	CVC Category	Government / Private	This will be the key attribute for registration. In case of private, it should only be a health facility

			empaneled under the PMJAY or CGHS.
4	Address	Existing masters of COWIN shall be used. All selections through drop down boxes	
a)	State		
b)	District		
c)	Block		
d)	Pin Code		
e)	Locality/village		
5	Location	1. Location to be captured through vaccinator module or	Location should be captured through any GPS devise on site or by other means; and the values must be entered correctly
a)	Latitude		
b)	Longitude		
		2. The system will also provide option for user inputs on latitude and longitude	
CVC Logistics Attributes			
6	Cold Chain Point	Selection from Drop down box within district	At any point of time, a CVC must be mapped to any one CCP in the district. Will be editable as per the logistics plan
7	Vaccine Type	COVI-SHIELD/ COVAXINE – Select from drop down box	Correct mapping should be done
CVC – Site Management attributes			
8	CVC Manager details		
a)	Name	Alphanumeric	Should be same as in Official Records
b)	Mobile number	Numeric (10 digits)	Validations to be kept. This will also be the user ID for the CVC Manager.
9	Verifiers	To be updated by DIO/CVC Manager as per need	• The verifiers will be assigned through the "user management" section. • Every CVC should have sufficient number of verifiers designated (at least 1 per 120 slots), for any day. • Mobile numbers of the verifiers must be correct and kept up to date • A verifier may discharge the role of a vaccinator also but not vice versa.

10	Vaccinators	To be assigned by the DIO/CVC Manager	• The vaccinators will be assigned through the "user management" section. • Every CVC should have sufficient number of vaccinators designated (at least 1 per 120 slots). for any day. • Mobile numbers of the vaccinators must be correct and kept up to date.

Annexure 2(B) - Roles and Responsibilities of CVC Manager

Each CVC will have a CVC Manager. The CVC Manager will be registered by the DIO. He/ She will be responsible for all operations at the CVC, as per the Operational Guidelines and this Document. The key roles and responsibilities of the CVC Manager a as follows:

1. S/he will have access to the COWIN and will be able to view and download the list of beneficiaries allotted and vaccinated at her/his site.

2. S/he will also be responsible for deployment of adequate number of trained vaccinators and verifiers for a date, based on the doses to be administered on that date.

3. S/he will ensure adequate logistic arrangements like internet connectivity, enough computers/smart phones/tablets, printers etc.

4. S/he will ensure adequate mechanisms for queuing, verification, vaccination, observation, AEFI reporting etc at the CVC.

5. S/he will also receive and return vaccine stocks and will ensure that all vaccinations are recorded in COWIN in real time and that beneficiaries are verified for eligibility and then vaccinated.

6. S/he will also ensure for display of suitable signages for guiding the movement of the beneficiaries at the CVC.

7. Will ensure that all the protocols as per the Operational Guidelines are followed in terms of AEFI management, waiting room, observation room, etc (https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf).

8. The PCVC manager will also have the rights to create and populate the Vaccination Time Table for his CVC. All slots in the PCVCs will be open slots subject to some slots reserved for 2nd dose of HCWs/FLWs (for existing PCVCs).

9. The PCVC Manager will also be responsible for ensuring that a printed copy of the vaccination certificate is provided to the beneficiaries on-site. There will not be any separate charge for this.

Annexure 3 - Creation of Timetable and Appointment Slots in COWIN 2.0

The District Admin will prepare a Vaccination Time Table for each CVC for the period of Vaccination Cycle. The date-wise schedule for the days/dates on which the vaccination is to be organized a CVC along with necessary inputs in terms of various types of slots, will be prepared and populated on COWIN by the District Admin. The Time Table so prepared will then be declared for the citizens to enable them to choose the CVC and date from among the CVCs where open vaccination slots are still available. The timetable will be worked out by the respective state/district, based on target and number of days identified for vaccination. The key principles and steps to be followed for creation of timetable and appointment slots are as follows:

1. There will be only one session in a day at each CVC. All vaccinators and verifiers will work on the same and full list of beneficiaries for a session.

2. Appointment slots will be of 2 types –

   2.1. **Reserved Slots** – These can be further classified as:

      a) **Mobilization slots** - Slots for which respective State/UT Government shall mobilize beneficiaries for Facilitated Cohort Registration for on-site registration, appointment, verification and vaccination (all on-site on the same day). There will not be any need for pre-registering beneficiaries through online interface for this.

      b) Slots reserved for 2nd dose for beneficiaries who have already received 1st dose, including HCWs, FLWs and citizens, at a CVC. These slots will be filled by the COWIN system based on data available in the system regarding vaccination details of beneficiaries (such as CVC, Vaccine Type and Vaccination Status (Not/Partly/Fully vaccinated) and Vaccination Date).

   2.2. **Open slots** – Open for online appointments by general citizens. The number of Open Slots for a session will be worked out by subtracting the number of Reserved Slots from the CVC Session Capacity.

3. The number of open slots, for a day (session), to be populated in Vaccination Time Table for the Vaccination center, will be worked out by subtracting the total number of reserved slots (mobilization slots + 2nd dose slots) from the total session capacity specified by DIO while preparing the Vaccination Time Table.

4. Sessions will be pre-scheduled by only filling the timetable for a CVC at the COWIN Portal and identifying the number of Total Slots, Reserved Slots and Open Slots.

5. **Timetable** entries for a GCVC would be done by the DIO. For the PCVCs, the Time Table entries can be done by the PCVC Manager himself. This would include:

5.1. Selection of session-date.

5.2. The total number of vaccination slots for the selected date. This will also be the session size (or CVC capacity) for the selected date.

5.3. %age of open slots will be entered by the DIO.

5.4. For a particular date, the system will automatically reserve as many slots for 2nd dose as the number of 1st doses administered on the date that is 28th day before the session-date (the date for which the DIO is planning the session).

5.5. Based on the CVC capacity and the %age specified (para 5.3), the system will calculate the number of Open Slots and Mobilization Slots (See example in para 4.5(d)(2))

5.6. The Mobilization Slots, will be for such beneficiaries who do not have access to internet/ smart phones and thus will be mobilized for onsite registration, and slots for 1st dose vaccination of HCWs and FLWs, wherever so planned, if necessary.

5.7. Balance number of slots will be classified as "**Open Slots**" for online booking and appointment and the vacancies therein will be visible to citizens.

5.8. **For Private Facilities, no slots will be kept reserved for mobilization**. For such CVCs, the number of open slots for a day will be equal to total no. of slots minus the slots reserved for 2nd doses by the COWIN system. However, in case all the open slots are not fully booked by the citizens or if there are vacant slots available towards the end of the day, the CVC may use such slots for on-site registration, scheduling and verification of available eligible beneficiaries, if any.

5.9. For a completely new CVC, since there are no slots to be reserved for 2nd dose, all slots can be classified as Reserved or Open, in the initial period up to 28 days from the date of first session at such a facility.

6. While declaring the schedule, the COWIN system would also declare the number of slots available for appointments to beneficiaries through COWIN platform. Depending on the local context and strategy, for any CVC, the states may decide to -

6.1. Declare full capacity as open (Open Slots) for online appointments; or

6.2. Do not open the CVC for open appointments and keep the full capacity as reserved capacity for Mobilization slots and 2nd dose reserve slots; or

6.3. Declare partial capacity as open for appointments and retain the balance capacity as reserve capacity for Reserve Slots.

7. **It is recommended that, to begin with, one particular CVC may be either fully reserved or their full capacity is opened for online self-appointment, to avoid the confusion and problems in physical queue management on site at the CVC.**

8. If Mobilization slots are kept or some of the CVCs are fully reserved for Mobilization, then the respective state/UT government shall ensure mobilization of sufficient number of beneficiaries for on-site registration and vaccination.

9. The beneficiaries mobilized for the Mobilization slots shall be registered on-site through the Vaccinator module.

10. No lists need to be pre-populated (by the DIO/SIO etc.). The due list will get filled up as citizens/beneficiaries schedule their appointments for 1st dose (and automatic second dose) on open-slots, through on-site registration for reserved slots and through 2nd dose appointments of HCWs/FLWs that are already partially vaccinated.

11. The District Admin and CVC Manager will ensure that Sufficient number of vaccinators and verifiers are designated as per the total number of vaccination slots. (at least 1 vaccinator per 120 and at least 1 verifier per 120).

12. **Efforts should be made by the States/UTs/District administration to register as many eligible beneficiaries as possible by facilitating registration through the Common Service Centers or through Arogya Setu App, so as to reduce the need for reserved slots.**

13. Vaccine type available at a CVC will not be displayed to the citizens at the time of online registration.

14. Appointments will close for a day for a site, at 3:00 pm on day for which the slots were opened. Based on the planned beneficiary load at a CVC including both Reserved and Mobilisation slots, the DIO must ensure adequate availability of vaccine at the CVC, while simultaneously ensuring that vaccine wastage is minimized.

15. Vaccine batch number will have to be assigned by the DIO for each session before the session plan is finalized.

Annexure 4 – Online Registration and Appointments for Citizens

Registration:

1. Citizens will be able to register and book and appointment for vaccination using the COWIN 2.0 portal or through other IT applications such as Arogya Setu etc. The various steps for successful registration and appointment booking are as follows:

1.1. Any person will be able to register at the COWIN portal through their mobile number.

1.2. OTP verification will be done prior to registration to ensure veracity of the mobile number

1.3. After registration, an account will be created on COWIN for the person. The person can access (login) his/her account on COWIN using the mobile phone number used at the time of registration. Features for adding beneficiaries, editing their details and for booking appointment(s) will be available in the citizen's account. The citizen can delete only beneficiaries as have been added by him/her.

1.4. With one mobile number, a person can register as many as **four beneficiaries.** However, all those registered on one mobile number will have nothing in common except the mobile number. The ID Card Number for each such beneficiary **must** be different.

1.5. A mobile number cannot be used for making more than four registrations. If one out of the four beneficiaries registered in an account is vaccinated, only three registrations are left, and so on.

1.6. Till the time of vaccination, all the records of registration and appointment can be edited/deleted by the person making the registration/appointment. Only when a person gets vaccinated, the record is locked and cannot be edited/deleted.

1.7. Beneficiary then selects the ID card type and provides ID Card number. In case Aadhar is being used, consent will be **obtained and recorded.**

1.8. Following basic demographic details will be captured at the time of registration –

a) ID Card Type - one of the cards as prescribed in para 1.9.
b) ID card Number - As recorded in the ID Card selected.
c) Name - As recorded in the ID Card selected.
d) Year of Birth - As recorded in the ID Card selected.
e) Gender - M/F/O

1.9. The user will be advised to enter the details of (c), (d) and (e) of para 1.8, as recorded in the ID Card selected by the user.

1.10. Following Photo Identity Documents can be used by citizens for availing online registration–

a) Aadhar Card/Letter
b) Electoral Photo Identity Card (EPIC)
c) Passport
d) Driving License
e) PAN Card
f) NPR Smart Card
g) Pension Document with photograph

1.11. If age of the beneficiary is from 45 years to 59 years, the beneficiary will be prompted to confirm if he/she has any specified comorbidity. In such cases, the beneficiary will also be advised to bring the comorbidity certificate signed by a Registered Medical Practitioner, as prescribed in annexure I(B).

1.12. Once all the necessary details are recorded by the beneficiary, registration is completed and following actions will be taken –

a) An acknowledgement (Registration Slip/Token) will be sent to beneficiary on his registered mobile number.

b) Facility for downloading and printing etc. will also be available.

Appointments:

1. A COVID-19 Vaccination Time Table (VTT) (for each Vaccination Center) will be published by the States/Districts, on COWIN.

2. Any beneficiary will be able to choose and book a slot for vaccination at the VCs declared in the VTT, anytime and anywhere, based on his/her preference and convenience.

3. There will be only one live appointment for a beneficiary at any point of time for each dose.

4. The COWIN portal will provide the facility for booking an appointment based on the Vaccination Centers declared by the states/UTs, with their location, the dates on which appointment slots are provided and the capacity declared as Open Slots and the vacancies available at the time of booking.

5. Vaccine type will not be disclosed at the time of appointment.

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6. The list of sites and availability of open slots for each site will be displayed. The beneficiary will select the Vaccination Center of his/her choice and the date where vacant slots are available. Subsequent to which, an Appointment Ticket will be generated.

7. Second dose will also be scheduled at the same CVC on 29th day of the date of appointment of the 1st dose, at the time of appointment for 1st dose.

8. The beneficiary will have the option to change the slot for 2nd dose in the period 29th day to 42nd day of the first dose. Such an option, however, will only be available –

   a) Only when the 1st dose has already been administered, and if so –
   b) Only for such CVCs where the vaccine type is the same as the vaccine type of the 1st dose appointment.

9. Special reserved 2nd dose slots will be kept by the system to offer alternatives to such beneficiaries who are not able to avail vaccination for 2nd dose in the period of 29th day to 42nd day of administration of first dose.

10. If a beneficiary cancels a 1st dose appointment, then appointment of both doses will be cancelled.

11. Option for cancellation of second dose appointment will not be available.

12. Appointments for any date for a Vaccination Center will be closed at 3:00 pm on the day for which the slots were opened for the date. (for logistics arrangements)

13. A disclaimer will be included in the Appointment Slip to the effect that –

   a) "This appointment does not create any entitlement to COVID-19 vaccination and that vaccination will be provided subject to verification of the identity of the person for whom the slot has been booked"; and that,
   b) "In the event of cancellation of the session on the booked date due to any reason, beneficiary will have to reschedule an appointment"

14. The beneficiary will be advised that he\she should carry –

   a) The Aadhar Card (if available); and
   b) The Photo ID Card of which the details have been provided by him; and
   c) Mobile phone through which he\she has registered;

Annexure – 5 – SOPs For coverage of HCWs and FLWs through COWIN 2.0

- COWIN 2.0 will have flexible provisions to manage COVID Vaccination of Health Care Workers and Front-Line Workers.
- Scheduling will only be done by the system for 2nd dose of partly vaccinated beneficiaries on the 29th day from the date of administration of the 1st dose.
- Facility for "On site allotment" will be available both for 1st dose and 2nd dose.
- Facility will also be available for onsite registration, verification and vaccination of unregistered beneficiaries in the vaccinator module.

The process flow for various use cases is as follow:

1. **Registered HCW/FLWs –**

1.1. HCWs & FLWs Registered on COWIN but Not Vaccinated:

1. Those HCWs and FLWs who are registered on COWIN but not yet Vaccinated may visit CVC (COVID Vaccination Centre) and Vaccinator can use the existing "Allot Beneficiary" feature to pull the data of beneficiary.
2. This process can be executed by inter-district by selecting "All" District in filter as well as inter-state by selecting "All" States in filter.
3. Beneficiary can be vaccinated after following due verification process.

1.2. HCWs & FLWs Registered on COWIN and Partially Vaccinated

1. DIO will create sessions at all the CVCs where the 2nd dose is due from 1st March onwards. Such non-health facilities which were operated as a CVC for 1st dose vaccination of HCWs/FLWs, will have to also be operated for the 2nd dose at least once on the 29th day from the date of administration of the 1st dose. In such cases, fresh 1st doses may not be administered at these sites.

2. Such HCWs and FLWs who are registered on COWIN and are partially vaccinated and are due on the date (29th day only) will be automatically slotted for 2nd dose at the CVC where these were administered the first dose, based on date of first dose of Vaccination.

3. The number of such beneficiaries for any day will be considered at reserved slots for 2nd dose of HCWs/FLWs and will be subtracted from session capacity to determine open slots for that day at that CVC.

4. On-site Allotment feature will also be available for such HCWs/FLWs.

5. In case of any inter-state or inter-district transfer, Vaccinator can use "Allot Beneficiary" feature to pull the data of beneficiary. This process can be executed by inter-district by selecting "All" District in filter as well as inter-state by selecting "All" States in filter.

6. Allot Beneficiary feature will work only if Type of Vaccine for Dose 1 is same as Type of Vaccine for dose 2.

7. If the beneficiary is partly vaccinated but his vaccination details could not be recorded in the system for any reason (backlog cases), details of first dose vaccinations will be captured and 2nd dose will be administered.
   a) Following details of 1st dose will be captured –

      - Date of First Vaccination
      - Type of First Vaccine (COVISHIELD OR COVAXIN)
      - State and District of First Vaccination

   b) Certificate for first dose will not be generated in such cases.

8. Beneficiary can be vaccinated after following due verification process.

1.3. **HCWs & FLWs Registered on COWIN and Fully Vaccinated** – No action required.

2. Unregistered HCWs & FLWs:

2.1. Since, unregistered beneficiaries will interact with the system for the first time, it would be important to ensure that eligibility of beneficiaries in terms of their actually being HCWs/FLWs will be important. The plan for onsite registration must be prepared in close coordination with the concerned health facility in-charge or the head of the office, as the case may be. Health Facilities or offices may be mapped (not on COWIN) to the Vaccination Centers and a sufficiently senior official, from the concerned health facility (for HCWs) and office (for FLWs), must be deputed at the Vaccination Center to verify the employment credentials of the HCWs/FLWs of their health facility/office.

2.2. It may be noted that in an office not all FLWs may be eligible. For example, not all the revenue staff may have been deputed for COVID containment duties or not all the officials may be deputed on poll duty etc. While planning for such offices, it must be ensured that officials of the concerned department do make sure that 1) ineligible persons are not sent for vaccination and 2) An official may be present at the

Vaccination Center for verification of employment credentials and COVID duties etc., for those who do walk in for on-site registration

2.3 A close watch must be kept on the process and any attempts by ineligible persons for availing this facility may be viewed seriously

2.4 Following processes will be followed –

1. The HCW/FLW can visit identified CVC (COVID Vaccination Centre) for on-spot registration

2. Beneficiary to provide relevant Identity card or Authentication document to confirm that beneficiary is serving as FLW and HCW. Concerned facility office in-charge re confirm the credentials of the HCW/FLW

3. Once eligibility is established, the verifier to ascertain and record is the beneficiary has come for 1st dose or is due for Second dose vaccination

4. If the beneficiary has come for first dose then it's a case of new registration. If second dose is due then it's a case of new registration and backlog data entry of 1st dose.

5. **HCW and FLWs Not Registered on COWIN and not vaccinated – New registration**

   a) Following details will be captured to register the beneficiary –

   - Name
   - Mobile Number
   - Type of Beneficiary (HCW/FLW)
   - Sub Category:
     a. HCW- State, Central, Private
     b. FLW- MHA-CAPF, MHA-State Home Department, MoHUA, Revenue, PRI, RPF, Polling officials, Kumbh Mela.
   - Photo ID type
   - Photo ID Number

   b) After registering the beneficiary and Beneficiary can be vaccinated by following due verification process

6. **HCW and FLWs Not Registered on COWIN – Partially Vaccinated (backlog cases)**

   a) Beneficiary will first be registered with the details as in para 2.4(5)(a) above.

b) Following details of 1st dose will be captured –

- Date of First Vaccination
- Type of First Vaccine (COVISHIELD OR COVAXIN)
- State and District of First Vaccination

c) After registering beneficiary can be vaccinated with 2nd dose by following due verification process.

d) Certificate for first dose will not be generated in such cases.

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Ministry of Health and Family Welfare

nion Health Secretary Reviews COVID Vaccination Drive and Preparations for April 2021 with all States and UTs

No shortage of Vaccines with States; Centre will continually replenish States' Supplies

Need to keep Vaccine Wastage below 1% re-emphasized

Posted On: 31 MAR 2021 2:37PM by PIB Delhi

Shri Rajesh Bhushan, Union Health Secretary and Dr R S Sharma, CEO, National Health Authority (NHA) and Chairperson, Empowered Group on COVID Vaccination chaired a high-level meeting through video conference today with Health Secretaries, State Mission Directors of NHM and State Immunization officers of all States and UTs to review the status, pace and issues regarding COVID vaccination across the country as well as the preparations for April 2021 when vaccination would be extended to all persons above the age of 45. A key theme underlying the meet was the identification of low vaccine coverage pockets particularly in districts showing COVID surge and for taking corrective actions there.

The following was advised to the States and UTs regarding the vaccination coverage of Health Care Workers (HCW)s & Front Line Workers (FLW)s:

1. Ensure that only eligible beneficiaries are registered and vaccinated under category of HCW and FLW.
2. Archive incorrect/duplicate entries on CoWIN platform.
3. Identify pockets of low vaccination coverage – health facility/professional association/blocks, districts etc., for taking corrective action.
4. Saturation of vaccination of these groups on priority.

Regarding the involvement of Private COVID Vaccination Centres (CVC)s, the States/UTs were asked to:

1. Conduct regular reviews of vaccinations at Private CVCs with respect to their capacity utilization.
2. Undertake GIS analysis of CVCs to identify need for additional CVCs within States/UTs.
3. Address apprehensions of Private CVCs regarding vaccine supply, guidelines etc proactively.

On the issue of Vaccine Stocks, the States and UTs were advised to ensure that:

1. There is no sedimentation of vaccine stocks at any level of storage.

istribution based on consumption to avoid overstocking as well as under-stocking at Cold Chain Points and CVCs.

. Regular review of vaccine stocks and consumption is undertaken to identify gap areas and address the same.

he Centre also advised the States and UTs for the following:

1. Maintain vaccine wastage at less than 1% (present National Wastage Percentage being 6%).
2. Regularly review vaccine wastage across all levels to minimize the same.
3. Ensure timely utilization of available stocks to avoid expiry of vaccines without usage.
4. Timely updating of data of vaccine consumption to be ensured on CoWIN & eVIN portals.

Dr. R S Sharma assured that there is no problem in the storage and logistics of vaccines. He re-emphasized the point that there is no value in conserving vaccines for the second dose and that States must promptly supply vaccines to all government and private hospitals where there is a demand.

....

MV

HFW/Secretary VC- States & UTs/31st March2021/2

(Release ID: 1708680)

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Public Health England

Protecting and improving the nation's health

Deaths of people identified as having learning disabilities with COVID-19 in England in the spring of 2020

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Summary

Aim of the review

The Department of Health and Social Care, with the support of the Chief Medical Officer for England, commissioned Public Health England (PHE) to review the available data on the deaths of people with learning disabilities in England during the COVID-19 pandemic.

The review looked at:

- deaths from COVID-19 of people with learning disabilities
- factors impacting the risk of death from COVID-19 of people with learning disabilities
- deaths in care settings of people with learning disabilities

Methods

The review used 3 main sources of data:

1. English Learning Disabilities Mortality Review (LeDeR) Programme (1).
2. NHS England's COVID-19 Patient Notification System (CPNS), which records deaths in hospital settings (2).
3. Care Quality Commission (CQC) statutory notifications of deaths of people receiving social care (3).

Where possible, findings are compared to the general population of England.

The number of people identified as having learning disabilities who died with COVID-19

PHE used data from the LeDeR and CPNS datasets to establish the number of people in England, identified as having learning disabilities, who definitely or possibly died from COVID-19 from the start of the pandemic to 5 June 2020.

LeDeR and CPNS identify deaths of people known to adult services as having learning disabilities. The introductory section sets out the evidence that this is a small proportion of the people identified by schools as having learning disabilities. There is no data source that provides data about deaths

in this wider group of adults whose learning disabilities are not identified by health or social service.

LeDeR and CPNS are incomplete sources. The study estimated that only 65% of eligible deaths are reported to LeDeR and 25% of deaths reported to CPNS have learning disabilities status recorded as 'not known'. This means that calculations of rates of deaths per 100,000 population using either are likely to underestimate the real figures. Where rates are presented, 2 figures are given. The rate using the actual reported number of deaths of people with learning disabilities is given first. Alongside this an estimate of the likely rate is given based on an estimate of the extent of under-reporting for LeDeR data or a proportionate distribution of deaths with learning disabilities status 'not known' for CPNS data.

Main findings

LeDeR received 623 reports of deaths of people with learning disabilities considered definitely or possibly COVID-19 related occurring between the start of February and 5 June. On the basis of the likely level of under-notification, this suggests an estimated national total of 956 deaths.

The number of deaths occurring between the start of February and 5 June reported to LeDeR as possibly or definitely due to COVID-19 represents a crude rate of 240 deaths per 100,000 adults with learning disabilities, 2.3 times the rate in the general population for the same period. The estimated rate, adjusting for the likely level of under-notification, was 369 per 100,000 adults with learning disabilities, 3.6 times the rate in the general population.

CPNS recorded 490 deaths of adults with learning disabilities with COVID-19 up to 5 June. This represents a rate of 192 deaths per 100,000 adults with learning disabilities, 3.1 times the rates for adults without learning disabilities. If people dying with learning disabilities status 'not known' included the same proportion with learning disabilities as those for whom a status was recorded, there would have been 651 deaths of adults with learning disabilities, giving a rate of 254 per 100,000 population, 4 times the rate for adults without learning disabilities.

In 2018 and 2019, 60% of deaths of people with learning disabilities occurred in hospital settings. In 2020, 82% of COVID-19 deaths, and 45% of deaths from other causes occurred in hospitals. In the general population a smaller proportion of COVID-19 deaths (63%) occurred in hospitals (4).

Information on the numbers of deaths of people with learning disabilities in registered care settings was available for the period 10 April to 15 May 2020

The overall number of deaths from all causes was 2.3 times that recorded in the same period the previous year. More information can be found in the 'Deaths in care settings among people with learning disabilities' section.

During the peak 3 weeks, number of deaths from all causes for people with learning disabilities was 3 times the average reported for the corresponding period in the 2 previous years. For the general population in the same weeks, the number was 2 times the average for the 2 previous years.

Out of the deaths recorded in the CPNS system up to 5 June, 1.8% were of people recorded having had learning disabilities. GPs in England recognise only 0.57% of adults registered with them as having learning disabilities. So, adults with learning disabilities were over-represented by at least 3.1 times among those dying. The disparity was much larger in younger age groups.

Sections of the population with learning disabilities at greatest risk

COVID-19 has affected different sections of the population to different degrees. In the general population, death rates have been higher for older people, males, people from Black and minority ethnic groups and people living in areas of greater socioeconomic deprivation (5).

PHE looked at the impact of these factors on the numbers and rates of death for people with learning disabilities between 21 March and 5 June 2020.

Main findings

Age

COVID-19 deaths in people with learning disabilities were spread more widely across the adult age groups than in the general population. The 10 year age band with the largest number of deaths was 55 to 64 years for people with learning disabilities but over 75 for the general population. This reflects the pattern of deaths in previous years, and in 2020 from causes other than COVID-19.

COVID-19 increased the number of deaths for people with learning disabilities by a greater margin than for the general population across the adult age spectrum.

Age specific COVID-19 death rates per 100,000 population were higher for people with learning disabilities in all adult age groups but by a greater margin in younger age groups.

Sex

The age standardised COVID-19 death rate was higher for men than for women with learning disabilities by 1.4 times in LeDeR notifications and 1.6 times in CPNS records of hospital deaths. This was slightly less than the corresponding differentials for the general population and for hospital patients without learning disabilities.

Standardising for age and sex, the rate of COVID-19 deaths notified to LeDeR, from 21 March to 5 June, was 451 per 100,000 for people with learning disabilities, 4.1 times the rate for the general population of England (109 per 100,000). Adjusting this to allow for the likely level of under-notification to LeDeR suggests a rate of 692 per 100,000, 6.3 times the general population rate.

Ethnic group

The proportions of COVID-19 deaths in people with learning disabilities that were of a person from an Asian or Asian British group, or a Black or Black British group were around 3 times the proportions of deaths from all causes seen in these groups in corresponding periods of the 2 previous years, and greater than the proportions in deaths from other causes in 2020.

The number of deaths of people with learning disabilities from all causes in 2020 for White groups was 1.9 times the number in the 2 previous years. For Asian and Asian British groups it was 4.5 times the number and for Black and Black British groups, 4.4 times.

Regions of the country

The number of deaths from all causes in the period studied rose for people with learning disabilities by 3.7 times in London but by only 1.6 times in the South West. Other regions had intermediate levels of increase.

The data available was not adequate to support more detailed analysis of area level social deprivation.

Deaths in care settings

Social care carries potential additional risk of transmission of respiratory viruses because of frequent contact with staff and other care recipients. The study looked at the extent to which people with learning disabilities appear to have been at additional risk from COVID-19 due to the types of social care they receive.

Death rates in care settings were estimated from numbers of notifications to the COC and numbers reported as receiving social care for learning disabilities in annual social care statistics. COC data covered a shorter period from 10 April to 15 May 2020.

Main findings

COVID-19 accounted for 54% of deaths of adults with learning disabilities in residential care in this period, slightly less than for people with learning disabilities generally, but still much more than in the general population.

The crude rate of COVID-19 deaths for adults with learning disabilities in residential care was higher than the rates of COVID-19 deaths of adults with learning disabilities generally as estimated from LeDeR. It was 2.3 times the rate calculated from actual LeDeR notifications and 1.5 times the estimated rate adjusting for likely under-notification. This difference is likely in part to reflect the greater age and disability in people in residential care.

Data from PHE indicates that care homes looking after adults with learning disabilities were less likely than other care homes to have had COVID-19 outbreaks. This is likely to be related to the fact they have fewer bed spaces.

COVID-19 accounted for 53% of deaths of adults with learning disabilities receiving community-based social care. It is hard to comment on the overall scale of deaths in these contexts because the numbers of people receiving care from providers likely to report their deaths is not clear. This level of additional mortality is similar to that seen in residential care.

Introduction

There are clear reasons to be concerned about the impact of the Severe Acute Respiratory Syndrome Coronavirus 2 (COVID-19) pandemic on people with learning disabilities. Their physical health problems have been widely documented in both research and National Health Service (NHS) statistics. Among many other issues they have substantially higher death rates from respiratory infections than the general population and higher rates of some important risk factors for COVID-19 including diabetes and obesity (6,7,8).

Substantial numbers of adults with learning disabilities receive some form of social care on a continuous basis. According to the most recently available figures, GPs have 255,575 adults on learning disabilities registers (9,10). Local authorities report 29,590 (equivalent to 12%) living in residential care and a further 111,190 (equivalent to 44%) receiving some form of community based social care (11). Most types of social care involve mixing with staff, and many involve mixing with other care recipients. This poses a risk of transmission of respiratory viruses.

A substantial number of people identified as having learning disabilities by their GP, as well as a much larger number identified in schools but not subsequently identified by health or social care services, are also likely to have had problems during the COVID-19 pandemic. Many are likely to have had difficulty following government advice about self-isolation, social distancing and infection prevention and control. They may not have grasped the new significance of key symptoms or the advice to get tested if they develop these. Many have difficulty accessing healthcare in ordinary times and are likely to have had more difficulty negotiating the new ways to do this if needed. All these factors suggest people with learning disabilities are likely to have been more vulnerable than others in the various stages of the COVID-19 pandemic (12). This study is only able to report on deaths of people identified as having learning disabilities who are known to adult health or social care services, or who have family or friends likely to report their deaths to LeDeR.

A study for Improvement Cymru identified deaths in 2020 and 4 earlier years in a cohort of just over 15,000 people with earlier hospital diagnoses of learning disabilities (13). It found a standardised COVID-19 death rate between 1 March and 26 May 2020 for this group which was between 3 and 8 times higher than the rate for the general population of Wales.

The Chief Medical Officer for England commissioned PHE to analyse available data on deaths of people with learning disabilities with COVID-19

"to inform policy and practice to reduce the risk and impact going forward of COVID-19 on people with learning disabilities". The terms of reference are set out in Annexe 1.

Other than data relating to deaths, there is limited statistical information currently collected which provides national information about the health and healthcare of people with learning disabilities in the rapid way needed for monitoring epidemic diseases. Data about COVID-19 test results, hospital admissions and intensive care does not record usable information about whether the people involved had learning disabilities.

There are 3 sources of information about deaths, which cover the whole of England and in which learning disabilities status has been systematically recorded during the pandemic. The terms of reference directed the work specifically to these. They are:

- the English Learning Disabilities Mortality Review (LeDeR) Programme (1)
- NHS England's COVID-19 Patient Notification System (CPNS) which records deaths in hospital settings (2)
- Care Quality Commission (CQC) statutory notifications of deaths of people receiving social care (3)

This report sets out what this data shows about the impact of COVID-19 on deaths of people known to have learning disabilities.

Approaches and assumptions

The study aimed to establish how badly the community of people with learning disabilities was hit by the first wave of the COVID-19 pandemic. Ideally, this would have required information about the numbers and details of all the people who had died, and the size and structure of the population from which they were drawn. Unfortunately, none of the available sources presented a complete picture of deaths among people with learning disabilities. The only one with a comprehensive scope (LeDeR) has known limitations in coverage (14). Information about the population with learning disabilities in England was also incomplete (see Annexe 2). This section sets out the approaches used to get as clear a picture of the situation as possible given the uncertainties arising from the limitations of the data.

Two main approaches were used: examination of numbers of deaths and calculation of rates.

Analyses of numbers of deaths

The simpler approach, less demanding in terms of the completeness of the data, was to look at changes in the number of deaths between 2020 and previous years. Changes in numbers of deaths of people with learning disabilities were compared to changes for the general population. For this approach it is not essential that the data source captures all deaths of people with learning disabilities, as long as the proportion captured does not alter substantially. LeDeR is described in more detail in the next section. It started collecting data in July 2016. For this study, data on numbers of deaths reported to it was available from the start of 2018 and to June 2020.

In interpreting trends in numbers of deaths, the stability of reporting of deaths to LeDeR is important. For practical purposes the study assumed that referral channels to LeDeR remained roughly stable over the period from the start of 2018 to the study end point in early June 2020. There are two reasons why this assumption may not completely hold. The first is that as the system was new and becoming embedded over this period. Increasing awareness of it could have increased the number of relevant deaths being notified. This could have made it appear as though numbers of deaths were rising. However, deaths can be, and are, notified to LeDeR months or years after they happen. As people became more aware of the service, they could have reported deaths which occurred at any time after its inception. The other reason for questioning the assumption of stable reporting is that the exceptional circumstances of the pandemic could have increased or decreased the likelihood of deaths being notified in this context.

The approach of comparing numbers of deaths in 2020 with an earlier period was also used with the CQC data which provided counts of death notifications for a comparable period of 2019. This is a statutory notification process, so reporting of eligible deaths is likely to be more dependable. It could not be used for the hospital deaths data in the CPNS as this covers only the pandemic period and only deaths attributed to COVID-19.

Rates and population

A more commonly used and more satisfactory approach to quantifying the extent of deaths in population subgroups is calculation of rates of death per unit of population, per unit of time. In addition to numbers of deaths, this requires data about the size of the population in which the deaths have occurred. If sufficiently detailed data is available about the age and sex structure of the population, rates can be standardised to take account of differences in the composition of population groups compared.

Identifying the numbers in the population with learning disabilities is not simple. Learning disability is distributed on a continuum from mild to profound. Epidemiological studies of the proportion of populations with learning disabilities have given widely differing results (15). In part this reflects a distinction between the 'administrative' prevalence, which is the number known to health, social, educational or other types of service providers, and the 'true' prevalence, which is the number of people who actually have learning disabilities, many of whom may not have been identified as needing services. True prevalence figures can only be established by population-based survey methods. Administrative prevalence estimates vary depending on the purpose served by the data source used. Studies in the United States and Australia have demonstrated that estimates based on data from education services give much higher figures than those from health or social care services (16,17).

This is reflected in current English administrative prevalence data. Schools identify that 4.15% of children have learning difficulties arising from intellectual disabilities (3.50% moderate learning difficulties and a further 0.65% severe or profound learning difficullies) (18), general practices identify 0.50% of patients on their learning disabilities registers (9), and local authority social services departments provide long term social care supports to 0.34% of adults (11). Previous PHE publications have discussed this range of prevalence figures (19). An important issue when interpreting the deaths data available for this study is which of these levels of ascertainment is likely to be reflected in referrals made to the LeDeR programme and recording of learning disabilities in respect of deceased individuals on the CPNS system.

LeDeR developed out of the Confidential Inquiry into Premature Deaths of People with Learning Disabilities (CIPOLD) (20). CIPOLD was one of the initiatives to address the deficiencies identified by the independent inquiry into Access to Healthcare for People with Learning Disabilities (21). CIPOLD and LeDeR have formed part of a decade of work by the NHS and partner agencies to increase awareness of the needs of people with learning disabilities in healthcare settings. In primary care services this has involved learning disabilities registers and annual heallh checks. More widely it has involved the appointment of hospital liaison nurses, primary care liaison nurses, initiatives to improve the accessibility of health services, enhancing communication between different elements of health services and between health and social care services, and monitoring uptake by people with learning disabilities of key interventions such as cancer screening and influenza immunisation. All these initiatives centre round GP learning disabilities registers, and drives to ensure that everyone with learning disabilities is registered to ensure they get the benefits.

LeDeR depends on voluntary notifications of deaths by people familiar with deceased individuals. When deaths of adults with learning disabilities are notified to the programme, it is usually done by health or care staff but some are notified by relatives. Publicity to encourage notification has been focussed through professional networks and third sector campaigning groups. The process of undertaking reviews of deaths notified to LeDeR is organised by staff in NHS region offices. Reviews increase awareness of the process through local health and social services.

This positioning suggests that the population whose deaths are likely to be reported to LeDeR is probably most closely approximated by the population on GP learning disabilities registers. Unfortunately, there is no current direct evidence on this point. The CIPOLD study specifically asked whether deceased individuals had been on learning disabilities registers. It found that in 92% of the deaths referred to them they had been (20). The regular LeDeR dataset does not ask this question. However, LeDeR care reviews do ask whether deceased individuals had a learning disabilities health check with their GP in the year prior to their death. This data is not published as its accuracy is difficult to verify, but the proportion of cases in which records show the deceased did have a health check is consistently higher than the national coverage of the health check programme. This suggests that a large proportion of reports to LeDeR are the deaths of people whose learning disabilities were known to their GP.

By contrast, the CPNS system was set up to monitor all deaths from COVID-19 occurring in English hospitals. The question in this case is what characterises the people who nursing or medical staff identify and record as having had learning disabilities.

During the period covered by this study, the relevant acute facilities of hospitals were under intense pressure from the large number of patients. Patients would probably only have been admitted to hospital in extreme clinical conditions. Staff would have faced great pressure managing patients' physical needs and many patients who would usually have had no cognitive impairment, would have been admitted in febrile states, or nursed under sedation, making assessment of their intellectual faculties difficult or impossible until they moved into a recovery phase. It seems likely that hospital staff would initially have depended on information provided by referring doctors, relatives or care homes for details of whether patients had learning disabilities. For patients who died it seems unlikely they would have explored further. So, the people hospital staff identified as having learning disabilities are likely to have been those with established care networks who

were on their GPs register. The large proportion (25%) of deceased patients whose learning disabilities status was reported as 'not known' seems to reflect the extreme physical state in which many patients were admitted to hospital care.

On this basis the study assumed that GP learning disabilities registers provide a rough working definition of the population whose deaths are reported to LeDeR and who are likely to have been recorded as having had learning disabilities in CPNS. Data about the size and age and sex structure of this population is available from the Learning Disabilities Health and Care (LDHC) dataset. Unfortunately, it does not provide information about ethnicity.

There is no satisfactory official source of data about the ethnic makeup of the adult population with learning disabilities in England (22). Data is available about children with learning disabilities from school special educational needs statistics (18). However, for a study of COVID-19 deaths, adult data is needed. The Office for National Statistics (ONS) has made estimates of the ethnic composition of the whole population of England up to 2018, although there are significant reservations about their reliability (23). They do not have the status of either official statistics or ONS experimental statistics. But there is no basis for estimating the proportion of adults in each ethnic group who have learning disabilities.

Completeness of data

Both the LeDeR and the CPNS datasets have other problems. In the case of LeDeR, the annual report for 2018 raised the issue of how completely deaths within the scope of the programme are reported (14). It estimated that in most NHS regions the number of deaths notified to them was between 70% and 88% of the likely number of deaths of people on learning disabilities registers. In one region there were 22% more notifications than estimated deaths, suggesting that deaths from previous years were being notified late. In the case of CPNS the 25% of deaths where the learning disabilities status of the deceased is not known has already been mentioned.

As one aim of this study was to compare COVID-19 mortality rates in people with and without learning disabilities, some approach was needed to address these gaps. Rates calculated from LeDeR notifications using simply the numbers of cases reported would underestimate the national rates. Rates calculated from CPNS data using only the numbers of deaths where learning disabilities status was known and recorded would also be likely to produce an underestimate.

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In the case of LeDeR data, the scale of the likely under-reporting can be estimated from the LDHC dataset (10). This collects data annually, from general practices, comparing the health and care of people on learning disabilities registers to that of other people registered with the same practices. It is described further below as it is one of the sources from which the population data for this study is drawn. As well as health and population data, the LDHC records annual numbers of deaths of people on learning disabilities registers from practices able to contribute data. Currently it covers just over half of England. This is the source on which earlier estimates of the completeness of notification to LeDeR were based. For this study, the estimate of under-reporting was revised with the most recent LDHC data (April 2018 to March 2019). This is described fully in Annexe 2.

This report presents basic rates from LeDeR data, using just the numbers of deaths reported and the population estimates from LDHC. Alongside these it presents estimates of the probable rates assuming likely levels of under-notification.

In the case of CPNS data, there is no obvious steer as to how the deaths with learning disabilities status recorded as 'not known' should be considered. This study took two approaches. Basic calculations of rates for people with learning disabilities definitely recorded, assumed that where the deceased's learning disabilities status was recorded as 'not known' they did not to have learning disabilities. Alongside these, a second set of estimates was calculated assuming that people whose status was 'not known' had the same likelihood of having learning disabilities as those whose status was known and they were distributed accordingly. This is described further in section 3.

Terms of reference and presentation

The terms of reference requested PHE to look at the peak 6 weeks of the COVID-19 pandemic. The start of the period of high death rates in England is reasonably clear, the end is less distinct. Numbers of deaths of people with learning disabilities are also relatively low for statistical analysis. Therefore, the period for most of the analyses was extended to the 11 weeks from 21 March to 5 June 2020. This end date was arbitrary, arising from the need to finalise datasets. Only the deaths of adults were included in most of the analyses as very few deaths of children were reported in the 3 datasets, and population data for children with learning disabilities is less reliable than for adults.

Several of the areas set out in the terms of reference naturally overlap. So, findings are organised around 3 main questions:

- How many people with learning disabilities have died with COVID-19?
- What characteristics identify which people with learning disabilities are at greater risk than others?
- Is there evidence of specific risks related to social care provision?

The report begins with a brief description of the main datasets used. This is followed by 3 results sections and a short discussion of the findings. Additional details about the data sources and a fuller description of the approaches to calculating the various measures is given in Annexe 2.

Main sources of data

Learning Disabilities Mortality Review (LeDeR)

LeDeR is a continuing national survey of deaths of people in England with learning disabilities. The LeDeR methodology is described in their most recently annual report (1). Data collection started in July 2016 (24). Deaths are notified to a national team based in Bristol. Reviews of deaths are conducted locally to where the deceased lived, so the Bristol team initially collects only the limited data required to provide regional co-ordinators with the information they need to initiate their work. As full reviews usually take several months, initial notification data was used for the study.

During March 2020 the Bristol team identified a number of deaths in which COVID-19 was reported as a cause of death. In early April they added a question to their notification form asking, 'Do you believe the death is related to COVID-19 (coronavirus)?' Notifiers could answer 'No', 'Possibly', 'Yes - confirmed COVID19', or 'Not known'.

Deaths are often notified several weeks after they occur and are also commonly reported to LeDeR by more than one person. A small number of notifications are made more than a year after the death. If notification data is incomplete, multiple notifications are not always clear. If not initially obvious, they are usually identified by regional review co-ordinators and corrected on the main data system. To allow for these eventualities as far as possible, the initial data extract on which most of the work for this study was done was updated with an extract taken on 4 September, 3 months after the period being described.

Hospital deaths dataset

The COVID-19 Patient Notifications System (CPNS) was set up as part of the national management of the pandemic in the English NHS. Hospitals are required to record deaths on this system when either the deceased had a positive COVID-19 test result or COVID-19 was cited as a main or contributory cause on the death certificate (2).

On 24 March the system was modified to include a question asking whether the deceased had learning disabilities and/or autism. When a death is recorded noting that the deceased did have learning disabilities or autism, a

further question asks which (learning disabilities, autism or both). In 92% of cases where a person was recorded as having learning disabilities this field was left blank. In 4 cases it was recorded that the person had autism but not learning disabilities. These were placed in the 'no learning disabilities' group. Because autism was so rarely reported, for brevity, this data item is referred to in this report as the 'learning disabilities status'.

Anonymised statistical data from this source is available to PHE. An initial data extraction was made in July for the analyses in this report. This was updated on 8 September.

A quarter (25%) of records in CPNS had the learning disabilities field either marked as 'not known' or including no entry. For brevity these are both referred to as having this status 'not known'.

Notifications to the CQC of deaths of people receiving social care

Registered social care providers are required to report deaths of people for whom they are providing care to the CQC under Section 16 of the Registration Regulations (25). Notifications are made using a standard form which includes a question on whether the deceased had learning disabilities. The form was modified on 10 April in response to the rapidly developing numbers of deaths related to COVID-19. From that date it included a question asking, 'Was the death as a result of: Confirmed coronavirus? or Suspected coronavirus?' (26).

Forms documenting all deaths notified between 10 April and 15 May were collated by the CQC, along with the forms documenting deaths notified in the corresponding period of 2019 for comparison. Findings from this exercise were published by the CQC in June and extracts from the data was made available to PHE (3).

Population with learning disabilities

The NHS produces 2 annual measures of the number of people with learning disabilities in England. General practitioners are required to keep a register of patients registered with them who have learning disabilities. An annual count of the number of these is reported in the NHS Digital Quality and Outcomes Framework (QOF) statistics (9). This provides only a total number for each general practice. Further details about the age and sex breakdown, some health characteristics and the numbers of deaths in the preceding year are

collected annually, also by NHS Digital, in the LDHC dataset (10). This dataset is unfortunately only collected from just over half of general practices. Annexe 2 describes how these 2 data sources were used to produce full population estimates for this study. Unfortunately, neither of these data sources gives information about the ethnic profile of patients.

General population mortality data

Data about the numbers of deaths with COVID-19 or from other causes was taken from the provisional national mortality tables collated by the ONS and made available to PHE.

Outbreaks of COVID-19 in residential care settings

Data about outbreaks of COVID-19 in residential care homes comes from the software system PHE centres and regions use to record infectious disease outbreaks reported to them. The extract used for this study was taken on 29 July 2020.

How many people identified as having learning disabilities have died with COVID-19?

Main messages

Both LeDeR and CPNS are incomplete sources. The study estimated that only 65% of eligible deaths are reported to LeDeR. Twenty-five percent of deaths reported to CPNS have learning disabilities status recorded as 'not known'. This means that calculations of rates of deaths per 100,000 population using either are likely to underestimate the real figures. Where rates are presented, 2 figures are given. The rate using the actual reported number of deaths of people with learning disabilities is given first. Alongside this, an estimate of the rate is given based on an estimate of the extent of under-reporting for LeDeR data, or a proportionate distribution of deaths with learning disabilities status 'not known' for CPNS data.

LeDeR received 623 reports of deaths of people with learning disabilities considered definitely or possibly COVID-19 related occurring between the start of February and 5 June. On the basis of the likely level of under-notification, this suggests an estimated national total of 956 deaths.

The number of deaths occurring between the start of February and 5 June, reported to LeDeR as possibly or definitely due to COVID-19 represents a crude rate of 240 deaths per 100,000 adults with learning disabilities, 2.3 times the rate in the general population for the same period. The estimated rate, adjusting for the likely level of under-notification, was 369 per 100,000 adults, 3.6 times the rate in the general population.

CPNS recorded 490 deaths of adults with learning disabilities with COVID-19 up to 5 June. This represents a rate of 192 deaths per 100,000 adults with learning disabilities, 3.1 times the rate for adults without learning disabilities. If people dying with learning disabilities status 'not known' included the same proportion with learning disabilities as those for whom a status was recorded, there would have been 651 deaths of adults with learning disabilities, giving a rate of 254 per 100,000 population, 4 times the rate for adults without learning disabilities.

In 2018 and 2019, 60% of deaths of people with learning disabilities occurred in hospital settings. In 2020, 82% of COVID-19 deaths, and 45% of deaths from other causes occurred in hospitals. In the general population a smaller proportion of COVID-19 deaths (63%) occurred in hospitals (4).

The number of deaths of people with learning disabilities notified to the CQC in registered care settings were available for 5 weeks starting during the peak period of the pandemic. The overall number of deaths from all causes was 2.3 times that notified in the same period the previous year.

During the peak 3 weeks of the pandemic, the number of deaths from all causes for people with learning disabilities was 3 times the average reported for the corresponding period in the 2 previous years. For the general population in the same weeks, the number was 2 times the average for the 2 previous years.

Of the deaths recorded in the CPNS system up to 5 June, 1.8% were people recorded as having learning disabilities. GPs in England recognise only 0.57% of adults registered with them as having learning disabilities. Adults with learning disabilities were over-represented by at least 3.1 times. The disparity was much larger in younger age groups.

Introduction

The 3 available data sources cover different parts of the whole picture of deaths of people with learning disabilities in the COVID-19 pandemic. This section aims to establish the overall scale of deaths and to clarify the overlap of the 3 sources.

Data from the LeDeR and CPNS datasets was used to try and establish the number of people in England with learning disabilities known to services who died, definitely or possibly, as a result of COVID-19 up to 5 June 2020. This provides a way to check the extent to which the 2 data sources agree with each other, allowing for differences in scope. Data from the CQC covers a more limited time period and was compared with LeDeR data for the same period.

Learning disabilities mortality review data

LeDeR data identified 623 deaths, occurring up to 5 June, for which COVID-19 was identified as a possible or definite cause. Of these, 614 were adults and 9 were children or young people aged under 18. The 2 earliest occurred in February, a few weeks before the earliest deaths recorded by ONS for which COVID-19 was given as a certified cause. Larger numbers began to appear in the middle of March.

LeDeR consider the completeness of their data by comparing the number of deaths of people with learning disabilities reported to them with national number estimated from general practice data published regularly by NHS Digital in the LDHC dataset (14). This calculation was repeated with the most recent LDHC data (covering April 2018 to March 2019) (10) and is set out in Annexe 2, Table A2. It suggested that the deaths reported to LeDeR in that period represented around 65% of the number of deaths of people with learning disabilities estimated from general practice data. The estimate ranged from 58% to 74% between regions.

No evidence is yet available about whether deaths with COVID-19, or during the pandemic period, would be more or less likely to be under-reported to LeDeR than deaths in recent years. However, it is worth noting that the table in Annexe 2 shows that for adults, the extent of under-reporting is greater at older ages. So, for a condition such as COVID-19, where deaths tend to be at older ages, the extent of under-reporting is potentially greater than for adults overall. However, it is also possible that the unusual circumstances of the pandemic may have led to more complete reporting.

The calculation of the estimate of the number of deaths of people with learning disabilities with COVID-19 in England, up to 5 June, is set out in Table 3.1. Assuming 65% notification, the reported number suggests an estimated total of 956, with 942 of them being adults.

Crude rates are calculated by dividing the number of deaths by the number in the population. This makes no allowance for differences in the age or sex composition of groups being compared. The crude rate of deaths with COVID-19 for the general adult population of England for the period was 104 per 100,000 adults. Table 3.1 shows that the number of deaths reported to LeDeR gives a rate of 240 per 100,000 adults with learning disabilities. This was 2.3 times the general population rate. The estimate of the likely rate, allowing for only 65% notification of deaths was 369 per 100,000, 3.5 times the general population rate.

LeDeR initial notification records ask where the person died. Table 3.1 also shows the number of adults with learning disabilities reported to LeDeR as dying with COVID-19 in hospital settings, and an estimate of the total allowing for 65% reporting, for comparison with the recorded hospital deaths set out in the next table.

In the analyses using LeDeR data that follows in this report, where population-based rates are calculated for comparison with general population data, the same 2 estimates are presented. One used the actual reported numbers and a second estimated the figure based on the estimate that only 65% of relevant deaths were being reported to LeDeR. Where analyses present simply numbers of deaths, usually comparing numbers for 2020 with numbers for 2018 and 2019, adjustment is not necessary and has not been used. Table and figure legends indicate where the data has been adjusted.

Table 3.1. Numbers of deaths with COVID-19 reported to LeDeR up to 5 June 2020, estimate of national total allowing for under-notification, calculation of death rates using actual notifications and estimated total deaths, COVID-19 death rate for adults in the general population in the same period for comparison.

	Total	Adult	Adult, dying in hospital settings
Deaths reported to LeDeR as definitely or possibly COVID-19 related	623	614	495
Estimated total deaths adjusting for 65% reporting (x 1/0.650)	956	942	759
Estimate of adult population with learning disabilities (from Annexe 2, table A1)		255,575	
Crude rate per 100,000			
Death rate using actual number of notifications		240 (222 to 260)	
Estimated death rate adjusting for likely level of under-notification		369 (340 to 399)	
COVID-19 death rate in the general population		104 (103 to 105)	

Sources: LeDeR (1), LDHC 2018 to 2019 (10); QOF 2018 to 2019 (9), ONS provisional death records 2020; ONS mid-year estimates of population 2019 (27). The figure in the text for the ratio of the COVID-19 death rate for adults with learning disabilities using the adjusted figure to that for the general population appears anomalous; this is caused by rounding the figures for death rates.

Table 3.2 COVID-19 deaths reported in CPNS system and mid-year estimate of population; division of deaths by learning disabilities status, assignment of learning disabilities 'not known' deaths and calculation of death rates for adults with and without learning disabilities using only number definitely recorded as having learning disabilities (assumption 1) and proportionate distribution (assumption 2).

All hospital COVID-19 deaths reported in CPNS by 5 June		27613	
2019 mid-year estimate, England population, aged 18 and older		44,263,393	
Learning disabilities status	With learning disabilities	Without learning disabilities	Learning disabilities status 'not known'
All COVID-19 deaths reported	495	20,313	6,805
COVID-19 deaths of adults reported	490	20,306	6,804
Assigning deaths with learning disabilities status 'not known' to group without learning disabilities group (assumption 1)	490	27,110	
Distribution of deaths with learning disabilities status 'not known' in proportion to known (assumption 2 – and see footnote)	+161	+6643	
Estimate of total adult deaths in hospital settings with proportionate distribution (assumption 2)	651	26,949	
Estimated adult population (number with learning disabilities is subtracted from England mid-year estimate)	255,575	44,007,818	
Crude death rates per 100,000 adults assuming 'not known' group did not have learning disabilities – assumption 1 (95% confidence interval)	192 (175 to 209)	62 (61 to 62)	
Crude death rate per 100,000 adults with proportionate distribution of not 'known group'– assumption 2 (95% confidence interval)	254 (235 to 275)	61 (61 to 62)	

Source: CPNS (2), LDHC 2018 to 2019 (10); QOF 2018 to 2019 (9). Note, number redistributed appears anomalous because figure shown is the sum of a calculation is done in age and sex groups.

Records of hospital deaths

At the time the data for this study was taken, the CPNS database had recorded 27,613 COVID-19 deaths in hospital settings occurring on or before 5 June. Table 3.2 sets out the figures. For 495 of the deaths (including 5 aged under 18) the deceased was recorded as having had learning disabilities. For 6,805 (25%, 1 of these aged under 18) the learning disabilities status of the deceased was recorded as 'not known'. The proportion of deaths with learning disabilities status 'not known' ranged from 15% to 32% between NHS regions.

For calculating rates in relation to the population, the number with learning disabilities status 'not known' was too large to ignore. It is possible that some of these may have had learning disabilities. Since the largest estimate of the proportion of the population who have learning disabilities was below 5% (see introduction), it is likely that the great majority did not. Two assumptions could be made.

1. None of these people had learning disabilities.
2. The proportion of the 'not known' group who had learning disabilities in each age and sex group was the same as the proportion of those whose learning disabilities status was recorded.

Assumption 2 added 161 deaths from the 'not known group' to the group with learning disabilities. Here, and in later rate calculations in this report, figures are given for these 2 possible assumptions.

The choice of assumption made little difference to the rate of hospital COVID-19 deaths among people without learning disabilities. The crude rate, up to 5 June, was 62 per 100,000 adults using the assumption 1, and 61 per 100,000, using the assumption 2. The crude COVID-19 death rate for people identified in CPNS as having learning disabilities (assumption 1) was 192 per 100,000 adults, 3 times the rate for people without learning disabilities. Adding a proportionate number of deaths from the 'not known' group (assumption 2) gave an estimated crude rate of 254 per 100,000, 4 times the rate for people without learning disabilities.

It was not possible to match individuals in the LeDeR and CPNS datasets because neither source allowed access to person identifying information. So, the only available approach for analysing how closely these 2 sources align was to compare the overall numbers. LeDeR notifications indicated that 495 of the deaths of adults with definite or possible COVID-19 notified to them occurred in hospital settings. Adjusting for under-notification as described above suggested this reflected an estimated total of 759. This was 17%

higher than the estimated total from the hospital deaths dataset allowing for proportionate distribution of deaths with unknown status (assumption 2). If the estimate of the level of under-reporting to LeDeR is correct, this would suggest that people with learning disabilities were more likely than others to have their status recorded as 'not known' in the CPNS. The 2 unadjusted figures were very similar. However, the factors likely to introduce incompleteness in the two sources are quite different so this should be seen as a coincidence.

Place of death

The LeDeR notification dataset includes a field recording where people died. Table 3.3 shows the breakdown of place of death for people with learning disabilities dying between 21 March and 5 June with COVID-19, from other causes, and, for comparison, in the corresponding weeks of the previous 2 years. The figures for COVID-19 deaths are slightly smaller than those in Table 3.1 because deaths before 21 March have been omitted to give a clearer comparison.

In earlier years, where place was reported, 60% of deaths from all causes occurred in hospital settings and 33% at the person's usual place of residence (this could be a residential care home). Other types of location were too infrequent for separate reporting. In these weeks in 2020, where the location was recorded, the proportion of deaths with COVID-19 that occurred in hospital settings was substantially higher (82.3%) and the proportion of deaths from other causes in hospital settings was substantially lower (45.1%). The proportion of COVID-19 deaths occurring in hospital settings for people with learning disabilities was higher than for the general population. ONS statistics show that in the same period, only 63.4% of COVID-19 deaths of people in the general population occurred in hospital settings (4).

Table 3.3 Numbers and proportions of deaths of adults with learning disabilities by place of death, for deaths from COVID-19 and other causes in 2020, and all causes in 2 previous years (baseline).

	COVID-19	Other causes	Baseline
Hospital	484 (82.3%)	228 (45.1%)	610 (60.0%)
Usual residence	95 (16.2%)	238 (47.1%)	336 (33.0%)
Other	9 (1.5%)	39 (7.7%)	71 (7.0%)
Total known	588	505	1017
Missing	14	37	28
Total	602	542	1045

Source: LeDeR (1) (unadjusted). Deaths occurring between 21 March and 5 June 2020 and corresponding period in previous 2 years.

Deaths in care settings

In June CQC published their own initial analysis of the statutory notifications of deaths data they had received during 5 weeks of the pandemic (3). They made more detailed extracts of the data relating to people with learning disabilities available to PHE for this study. The deaths on which they reported were notified to them between 10 April and 15 May inclusive. This is a shorter period than was available for the other data sources used in this study.

Table 3.4 sets out the data. In this 5 week period, 386 deaths of people with learning disabilities receiving adult social care were reported. This was 2.3 times the number reported in the corresponding weeks of the previous year (165 deaths). Of these deaths, 206 were reported as being a result of suspected or confirmed COVID-19 and 180 were from other causes.

Table 3.4. Comparison of statutory death notifications of deaths of people with learning disabilities to CQC, 10 April to 15 May 2020 and 2019 with notifications to LeDeR in comparable periods; ratio of total deaths 2020/2019; CQC deaths 2020 as proportion of LeDeR notifications and estimate of national numbers of deaths of people with learning disabilities by adjusting LeDeR figure for under-notification.

	CQC	LeDeR
2020		
COVID-19	206	387
Other causes	180	257
Total	386	644
2019		
Total	165	272
2020 total / 2019 total	2.3	2.4
Estimate of national deaths from LeDeR notifications adjusting for 65% notification		988
CQC notifications as % of LeDeR notifications	59.9%	
CQC notifications as % estimate of national deaths from LeDeR adjusting notifications for under-notification	39.1%	

Sources: Care Quality Commission (3), LeDeR.

These figures were compared with the number of LeDeR notifications of deaths occurring in this shorter time interval. Notifications are usually received by the CQC about 4 days after the death occurs. So, for comparative purposes, deaths reported to LeDeR which occurred between 6 April and 11 May were included. The choice of start and finish dates for this

period are important because the numbers of daily deaths were changing fast at this time. A total of 644 deaths of adults were reported to LeDeR that occurred in this period, 387 attributed to COVID-19 and 257 to other causes. In the same period the previous year 272 deaths had been notified, giving a similar increase (2.4 times).

The number of deaths reported to the CQC in 2020 was just under 60% of the number of notifications to LeDeR. If the LeDeR number is adjusted for the likely level of under-notification it suggests an estimated total of 988 deaths of people with learning disabilities in this period from all causes. The CQC figure would represent 39% of this figure.

Many people with learning disabilities do not receive social care. Annual social care statistics for 2018 to 2019 record a total of 140,780 people receiving some type of social care for a primary need of learning disabilities (11). Numerically this is equivalent to 55% of the adults on GP learning disabilities registers, although it does not necessarily mean that they are all on GP registers. Under the provisions of the 2014 Care Act, a number of people who are recorded in the social care statistics would be receiving care managed and purchased by themselves, or by family members, social workers or other personal assistants, using direct payments from local authorities. It is likely that many of these people purchase care from non-registered providers so their deaths would not be reported to the CQC.

Weekly trend in deaths with COVID-19

Figure 3.1 shows the weekly numbers of deaths (unadjusted) reported to LeDeR occurring in the weeks from 22 February to 5 June 2020. Dark grey sections in the bars show the numbers of deaths not considered to be COVID-19 related, black sections show the numbers where the notifier reported that the death was possibly or definitely the result of COVID-19. The light grey bars alongside show the average number of deaths reported for the corresponding weeks in the 2 previous years. Figure 3.1a shows the pattern for people with learning disabilities, figure 3.1b shows the corresponding pattern for the general population.

The question of whether there may be any important trend in the LeDeR data collection arising from increasing familiarity with the system was raised in the introduction. To check this, the number of deaths in 2020 from causes other than COVID-19 was compared with the numbers in the 2 previous years. The total for the 15 week period shown was 816 compared with an average of 803 in the two previous years which is a rise of 2%. This might occur through random fluctuation. There were 4 occasions when the number of deaths from

causes other than COVID-19 lay outside the 95% confidence intervals of the figure for the 2 previous years. On 2 occasions it was below and on 2 occasions it was above. This gave no indication of a trend likely to distort comparisons of 2020 with 2018 and 2019.

The number of deaths of people with learning disabilities from all causes rose sharply in the week to 27 March. Over the next 3 weeks, assuming that the level of completeness of reporting of COVID-19 deaths of people with learning disabilities to LeDeR was similar to the level for deaths in previous years, there were around 3 times the average number of deaths seen in the corresponding weeks of the 2 previous years. The pattern of this peak for people with learning disabilities was similar to that seen for the general population, possibly starting slightly earlier, but the degree of excess was greater. In the same weeks for the general population the total number of deaths was around 2 times the baseline number. By the end of the period for which data was available, there were still substantial numbers of COVID-19 deaths each week for both groups.

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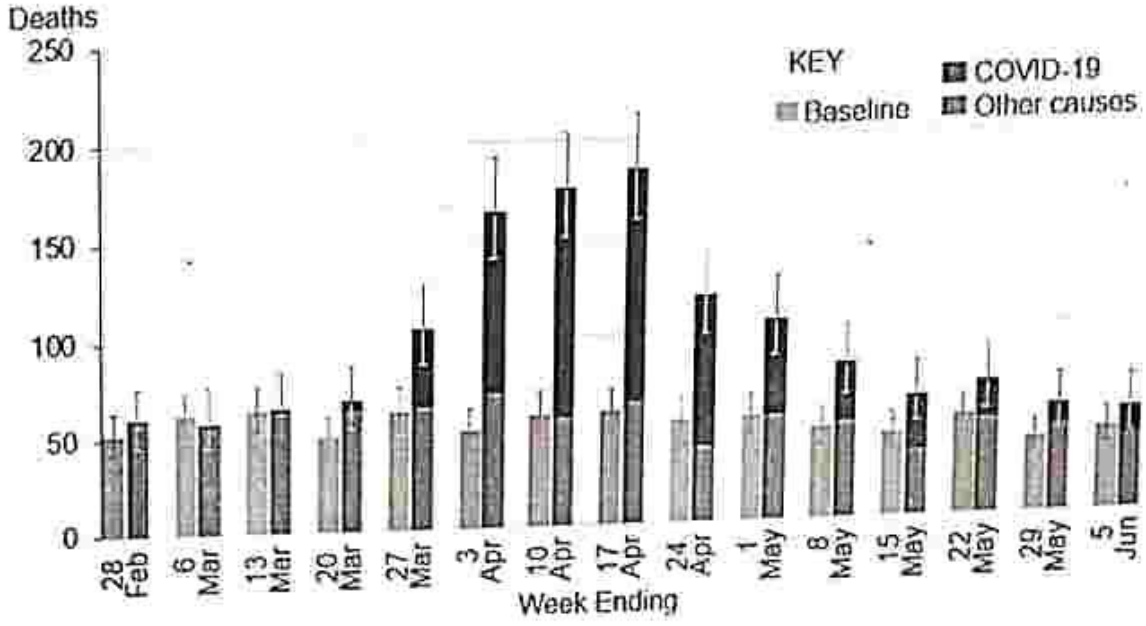
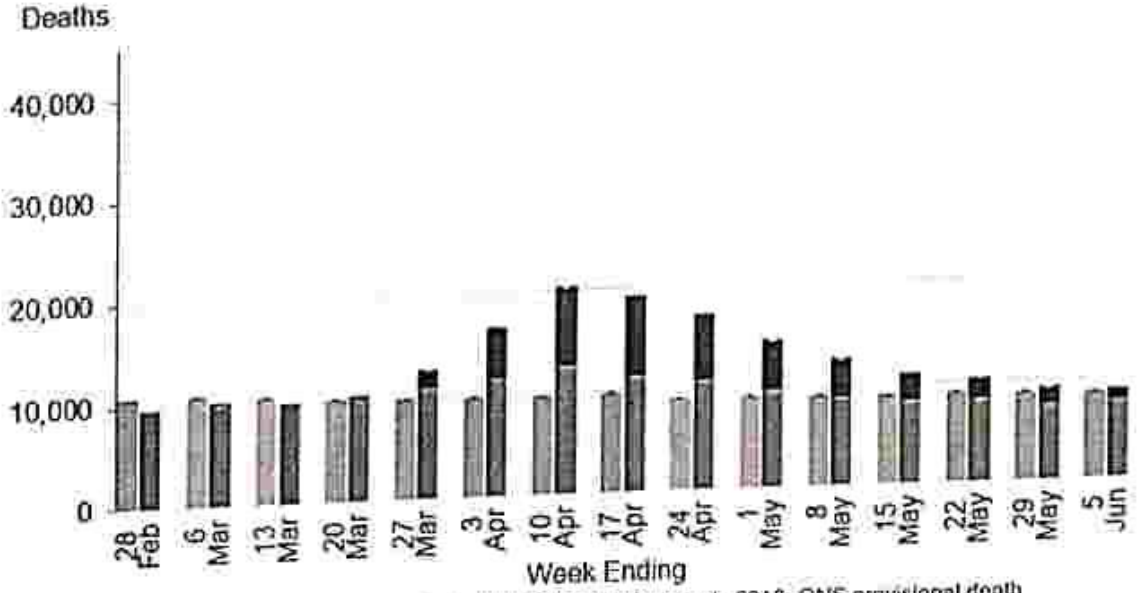
Figure 3.1. Weekly numbers of deaths, with COVID-19 and from other causes, of people with learning disabilities and in the general population, for 2020, and average numbers for 2018 and 2019 (baseline).

3.1a People with learning disabilities



3.1b General population



Sources: LeDeR death notifications (unadjusted) (1), ONS death records 2018, ONS provisional death records 2019 and 2020. Confidence intervals are for total numbers of deaths.

Proportions of deaths where the deceased had learning disabilities

The terms of reference for this report asked PHE to consider the proportion of deaths in which the deceased person had learning disabilities, comparing this with the prevalence of learning disabilities in the population. The CPNS dataset allows this because it treats deaths of people with and without learning disabilities identically. Table 3.5 shows the comparison by age group. The first column shows the proportion of adults registered with GPs on learning disabilities registers. The second gives the total numbers of hospital COVID-19 deaths up to 5 June. The comparison calculation is then done twice, first including only those deaths where the deceased was recorded as having learning disabilities (assumption 1), then including a proportionate number of people with learning disabilities status 'not known' (assumption 2). In each case the number and proportion of deaths is shown, followed by the ratio of the proportion of deaths to the proportion of people on learning disabilities registers.

In both sets of calculations, the table shows that the proportion of people dying in hospital settings with COVID-19 who had learning disabilities was much higher than would be expected from their numbers in the population. The difference was much larger for younger age groups. When a proportionate share of the deaths with learning disabilities status 'not known' was assigned to the learning disabilities group, the differences were larger but the pattern was the same.

The ratios for the oldest age group in this table are likely to be slightly overestimated. This is because the proportion of deaths attributed to COVID-19 which occurred in hospital settings, and so appear in this analysis, was higher for people with learning disabilities than for the general population. Table 3.3 shows it to have been 82.3% for people with learning disabilities while ONS weekly provisional death figures show it to have been 63.5% for the general population in the same period (4). The ONS table shows that the difference was caused by the high proportion of general population COVID-19 deaths that occurred in care homes, a difference only likely to have affected the oldest age group.

Table 3.5 Comparison of proportion of population on GP learning disabilities register with proportion of hospital COVID-19 deaths where deceased was recorded as having learning disabilities. Figures are shown with and without proportionate distribution of deaths with learning disabilities status 'not known'.

			Without distribution			With proportionate distribution		
Age group	% on GP learning disabilities register	Total deaths	Deaths	% of deaths	Ratio	Deaths	% of deaths	Ratio
18-34	0.76	108	24	22.2	29.2	31	28.6	37.6
35-44	0.49	261	31	11.9	24.2	42	15.9	32.5
45-54	0.54	954	58	6.1	11.3	77	8.1	14.9
55-64	0.55	2522	121	4.8	8.7	161	6.4	11.6
65-74	0.36	4979	114	2.3	6.4	152	3.1	8.5
75pl	0.16	18776	142	0.8	4.7	188	1.0	6.3
All adults	0.57	27600	490	1.8	3.1	651	2.4	4.1

Sources: CPNS (2), LDHC 2018 to 2019 (10) and QOF 2018 to 2019 (9). Table shows proportion (%) of people registered with GPs on learning disabilities registers, total hospital COVID-19 deaths, deaths where deceased had learning disabilities as number and proportion (%) of all deaths, and ratio of % of deaths / % on learning disabilities registers by age group. Calculation is done using only deaths with definite record of deceased having learning disabilities (assumption 1), and with proportionate distribution of those with deceased learning disabilities status not known (assumption 2).

Sections of the population with learning disabilities at greatest risk

Main messages

The following comparisons relating to risk factors are findings from the 11 week period from 21 March to 5 June.

Age

COVID-19 deaths in people with learning disabilities were spread more widely across the adult age groups than in the general population. The 10 year age band with the largest number of deaths was 55 to 64 years for people with learning disabilities but over 75 for the general population. This is similar to the pattern of deaths in the two groups in previous years, and in 2020 from causes other than COVID-19.

COVID-19 increased the number of deaths for people with learning disabilities by a greater margin than for the general population in all adult age groups.

Age specific COVID-19 death rates per 100,000 population were higher for people with learning disabilities at all adult age groups but by a greater margin in younger age groups.

Sex

The age standardised COVID-19 death rate for people with learning disabilities was higher for men than for women by 1.4 times in LeDeR notifications and 1.6 times in CPNS records of hospital deaths. This was slightly less than the corresponding differentials for the general population and for hospital patients without learning disabilities.

Standardising for age and sex, the rate of COVID-19 deaths notified to LeDeR, from 21 March to 5 June, was 451 per 100,000 for people with learning disabilities, 4.1 times the rate for the general population of England (109 per 100,000). Adjusting this to allow for the likely level of under-notification to LeDeR suggests a rate of 692 per 100,000, 6.3 times the general population rate.

Ethnic group

The proportions of COVID-19 deaths in people with learning disabilities that were of a person from an Asian or Asian British group, or a Black or Black British group were around 3 times the proportions of deaths from all causes seen from these groups in corresponding periods of previous years, and greater than the proportions of deaths from other causes in 2020.

The number of deaths of people with learning disabilities from all causes in 2020 for White groups was 1.9 times the number in the 2 previous years. For Asian and Asian British groups it was 4.5 times the number and for Black and Black British groups, 4.4 times.

Regions of the country

The number of deaths from all causes in the period studied rose for people with learning disabilities by 3.7 times in London but by only 1.6 times in the South West. Other regions had intermediate levels of increase.

The data available was not adequate to support more detailed analysis of area level social deprivation.

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Introduction

COVID-19 has affected different sections of the population to different degrees. In the general population death rates have been higher for males, people from Black and minority ethnic groups, people living in areas of greater socio-economic deprivation, and, above all, older people (5). This section explores the impact of these factors on numbers and rates of death for people with learning disabilities.

Age

LeDeR data

Figure 4.1 shows overall numbers of deaths by age group. Figure 4.1a shows the number of deaths notified to LeDeR that occurred between 21 March and 5 June. Figure 4.1b shows deaths in the general population of England in the same period. Bars are split into an upper black section representing COVID-19 deaths and a lower dark grey section representing deaths from all other causes. Adjacent light grey bars show average numbers of deaths in the corresponding period in the 2 previous years.

In this 11 week period in 2020, 1,144 deaths of people with learning disabilities were reported to LeDeR, 2.2 times the average figure for the 2 previous years. 53% of the deaths were attributed to COVID-19. In the general population of England, 151,512 deaths were registered, 1.5 times the average for the 2 previous years, with 30% including COVID-19 among the registered causes.

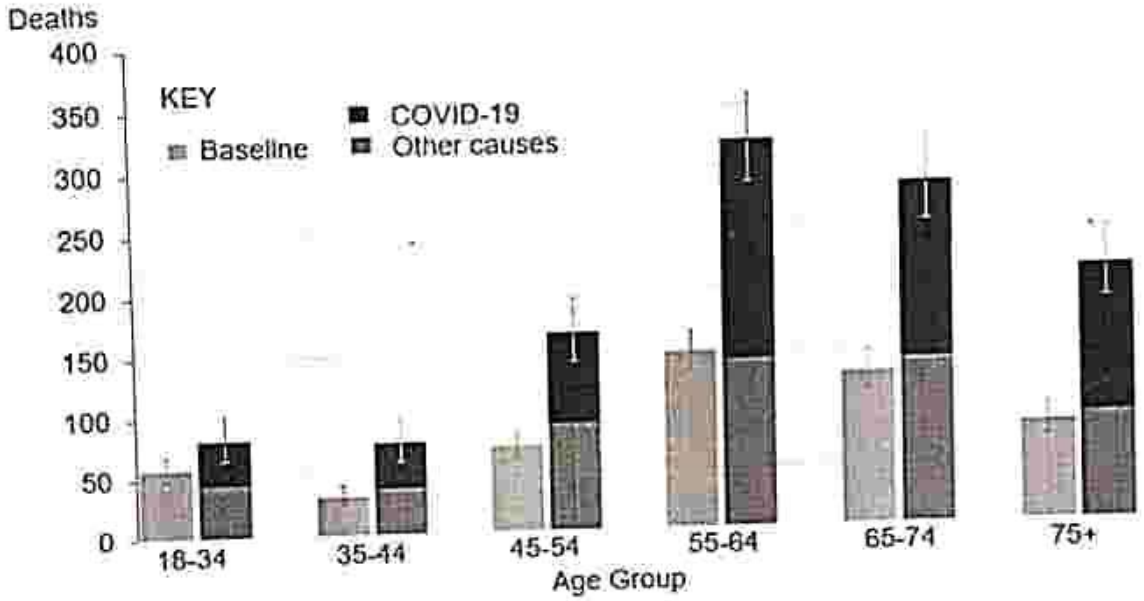
Deaths of people with learning disabilities were more widely spread across the age groups than deaths in the general population. This is usually the case as can be seen from the pattern of deaths in the 2 years prior to 2020. The 10 year age band with the largest number of deaths was 55 to 64. The number and age distribution of deaths from causes other than COVID-19 in 2020 was not significantly different from the average for the 2 previous years. The additional deaths with COVID-19 were spread across the age range but adding greater increments at older ages. At ages 18 to 34 the additional deaths were 0.7 times the average for all causes for the previous 2 years, from age 35 to age 74 they were 1.2 times the previous average, and older ages they were 1.5 times the previous average. Taking all adult age groups together, the number of deaths with COVID-19 was 1.2 times the previous average number from all causes.

For the general population the number of deaths from causes other than COVID-19 at ages below 55 fell to 0.8 times the average for the 2 previous years. At ages 75 and older it rose to 1.1 times the previous average. In the 18 to 34 age group the additional deaths due to COVID-19 were 0.1 times the average number from all causes in the previous 2 years. This rose steadily across the age groups to reach 0.5 times the previous average number of deaths from all causes in the age group 75 and older. Taking all adult age groups together the number of deaths with COVID-19 was 0.45 times the previous average from all causes.

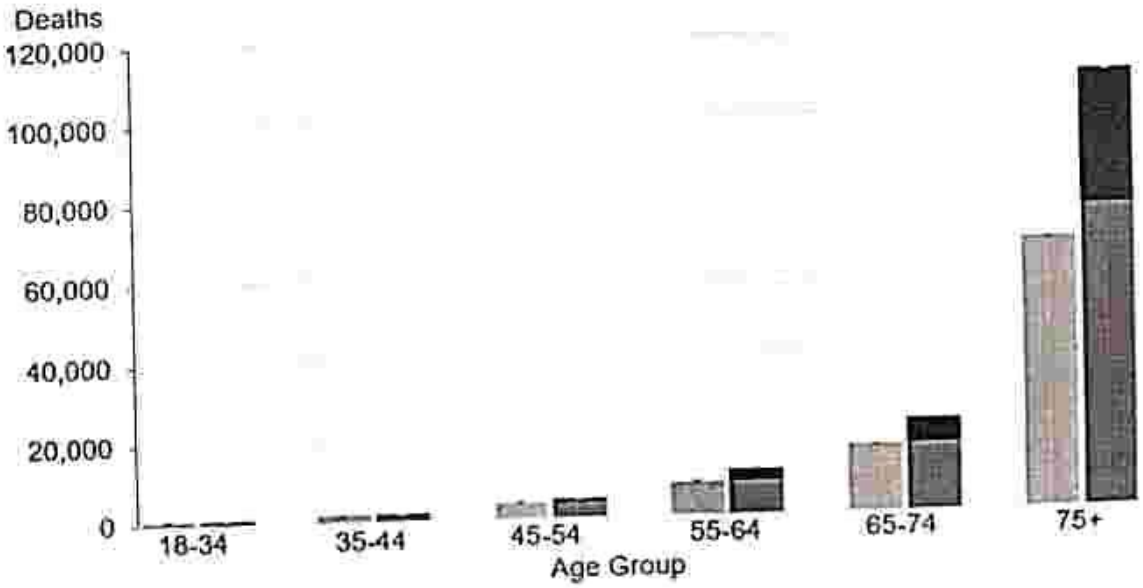
In summary, COVID-19 increased the number of deaths for people with learning disabilities by a greater margin than for the general population, and deaths were more widely spread across the adult age spectrum.

Figure 4.1. Numbers of deaths in weeks 13 to 23 of 2020, with COVID-19 and from other causes, and average for 2 previous years (baseline). 4.1a shows data for people with learning disabilities, 4.2b for the general population.

4.1a People with learning disabilities



4.1b General population

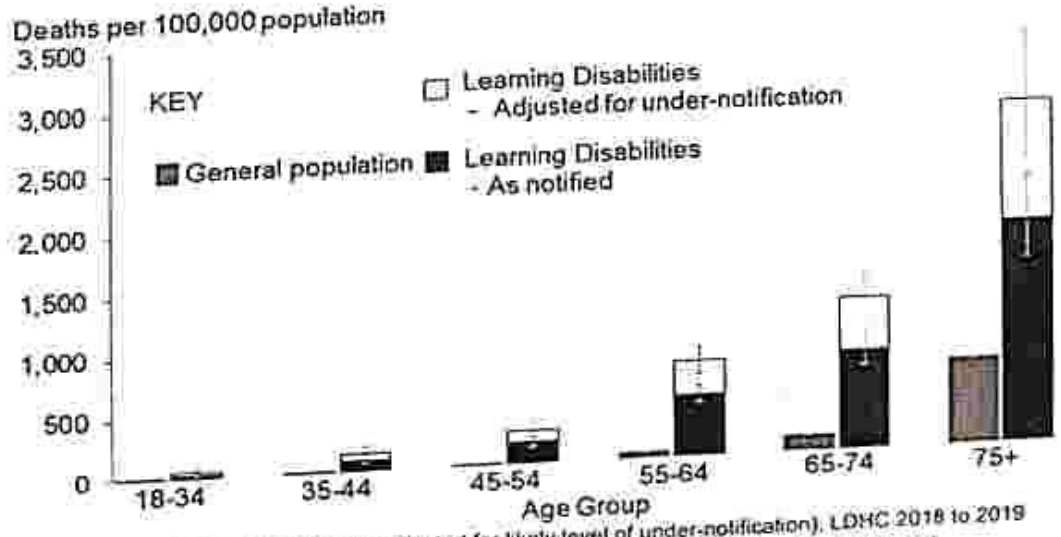


Sources: 4.1a: LeDeR (unadjusted numbers of deaths) (1); 4.1b: ONS death records 2018; ONS provisional death records 2019 and 2020. Confidence intervals are for total deaths.

Figure 4.2 shows age specific death rates for COVID-19, up to 5 June, per 100,000 population for adults with learning disabilities and the general adult population. This makes the comparison clearer because it takes account of the different proportions of the population with learning disabilities in different age groups. Death rates for people with learning disabilities are calculated from numbers of notifications to LeDeR. These are shown as black bars alongside the death rates for the general population in grey. As in the previous chapter, an estimated rate is shown in outline for people with learning disabilities, adjusting the numbers of deaths in people with learning disabilities to allow for the likely level of under-notification to LeDeR. There are 95% confidence intervals bars for both estimates.

As for the general population, older age was associated with higher death rates for people with learning disabilities. However, at every age-group the death rate for people with learning disabilities was substantially higher than for the general population. Using rates calculated only from reports to LeDeR, the rate was 30 times the rate for the general population at ages 18 to 34, 19.2 times at ages 35 to 44, around 10 times between ages 45 and 64, 6.7 times from age 65 and 74, and 2.6 times at older ages.

Figure 4.2 Age-specific rates, per 100,000 adults, to 5 June 2020 for reports of COVID-19 deaths to LeDeR and for COVID-19 deaths in the general population. Grey and black bars show rates using data as notified. Outlined white bars show estimated COVID-19 death rates for people with learning disabilities allowing under-notification.



Sources: LeDeR (1) (unadjusted and adjusted for likely level of under-notification), LDHC 2018 to 2019 (10), QOF 2018 to 2019 (9), ONS provisional death records 2020, ONS Mid-year estimates of population 2019.

Hospital deaths data

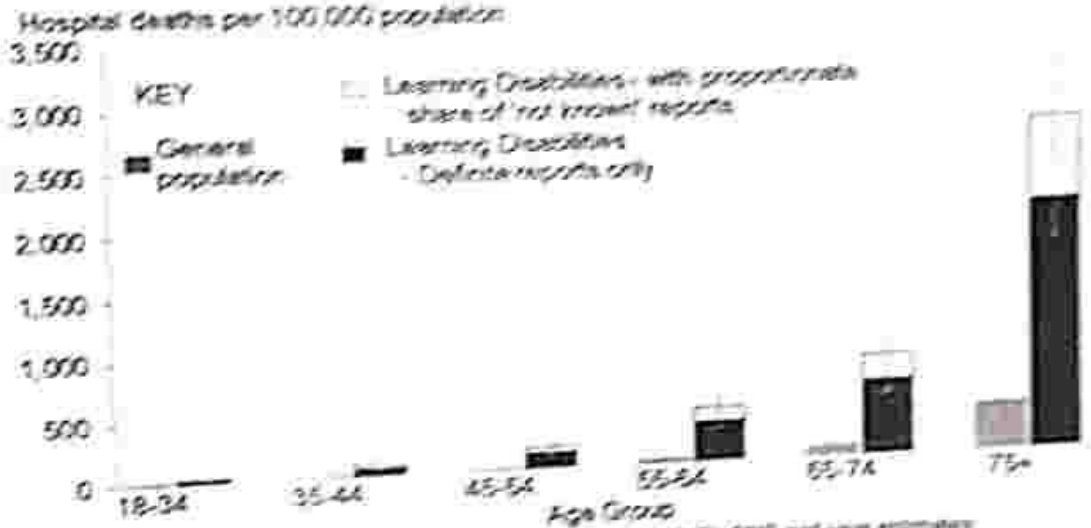
Figure 4.3 shows age-specific rates to 5 June for deaths in hospital settings reported through the CPNS dataset. Rates are shown for people with and without learning disabilities. For people with learning disabilities, 2 estimates are shown using the 2 assumptions set out alongside table 3.2. Solid black bars show the rate calculated using only deaths of people identified in CPNS as having learning disabilities (assumption 1). Outline bars above the black bars show an estimated rate assuming that the proportion of those with unknown status who had learning disabilities in each age and sex group was the same as the proportion in those for whom status was recorded (assumption 2).

Death rates rose sharply with age for both those with and without learning disabilities. Rates for people with learning disabilities were much higher than for those without at all ages. Using rates calculated with assumption 1, assigning all deaths with learning disabilities status 'not known' to the group without learning disabilities, the rate for people with learning disabilities at ages:

- 18 to 34 was 31.7 times the rate for the general population
- 35 to 44 was 23.3 times the rate for the general population
- 45 and 64 was around 10 times the rate for the general population
- 65 to 74 was 7.1 times the rate for the general population
- 75 and older was 5.4 times the rate for the general population

These differentials are similar to those seen in the previous chart. The exception is the oldest age group for which, as explained in relation to table 3.5, the comparison may be affected by a lower proportion of deaths of people without learning disabilities happening outside hospital.

Figure 4.3 Age-specific COVID-19 hospital death rates, to 5 June, per 100,000 adults with and without learning disabilities. Solid black bars show rates with definite record of learning disabilities (assumption 1). Outlines show estimated rates including proportionate share of deaths with learning disabilities status 'not known' (assumption 2). Rates for people without learning disabilities include all 'not known' deaths (assumption 1).



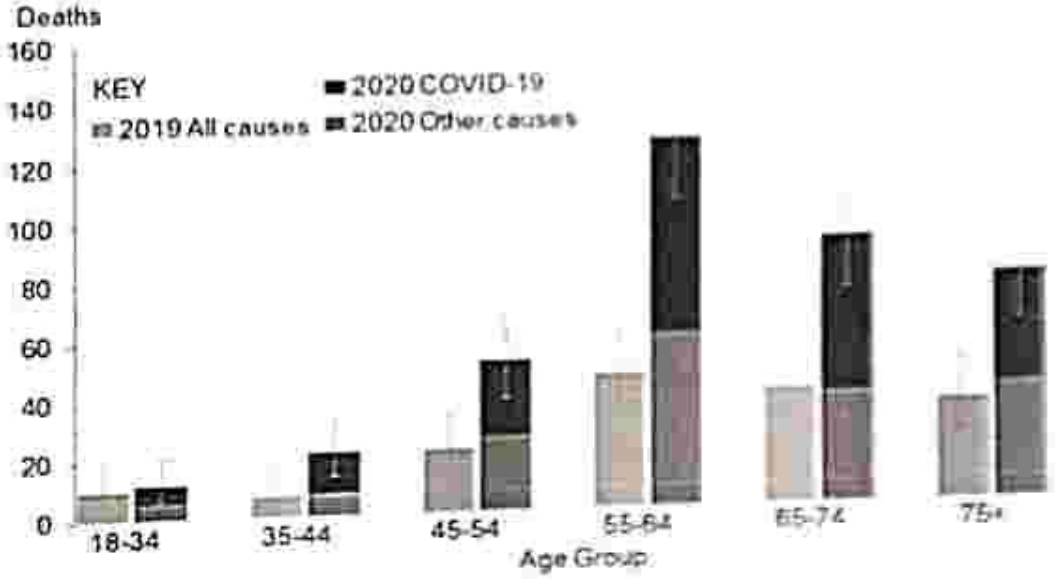
Sources: ONS [2], LDMC 2018 to 2019 [10], OCF 2018 to 2019 [9], ONS mid-year estimates of population 2019 [27]

Deaths of people receiving social care

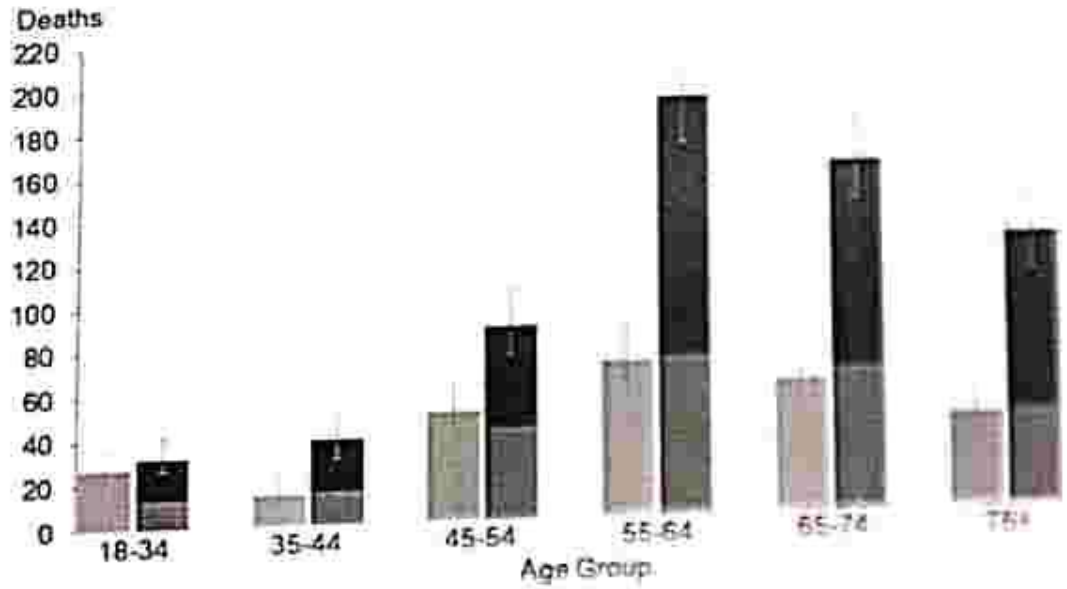
The CQC published a limited amount of data about the age breakdown of the people whose deaths had been reported to them as resulting from COVID-19 (3). It is not possible to calculate age-specific death rates for people with learning disabilities in residential care because there is no detailed data about the ages of people receiving care. Instead, figure 4.4a shows an age profile of the numbers of people with learning disabilities who died, comparing the total deaths in the same period of 2019 with numbers of deaths reported for 2020, separated into suspected or confirmed COVID-19, and other causes of death. For comparison, figure 4.4b shows the LeDeR data covering the shorter period for which the CQC reported and using only a single comparator year, 2019. The overall numbers of deaths reported to LeDeR were consistently higher than those reported to the CQC as noted above. But the change between the 2 years for each was similar.

Figure 4.4a. Deaths of people with learning disabilities reported to CQC 10 April to 15 May, in 2019 and 2020, by age group, and cause of death COVID-19 or other. Figure 4.4b deaths reported to LeDeR occurring in the corresponding period.

4.4a Deaths of people receiving social care notified to the CQC



4.4b All people with learning disabilities notified to LeDeR



Sources: Care Quality Commission (3) LeDeR (unadjusted) (1) 95% confidence intervals are for total deaths

Sex

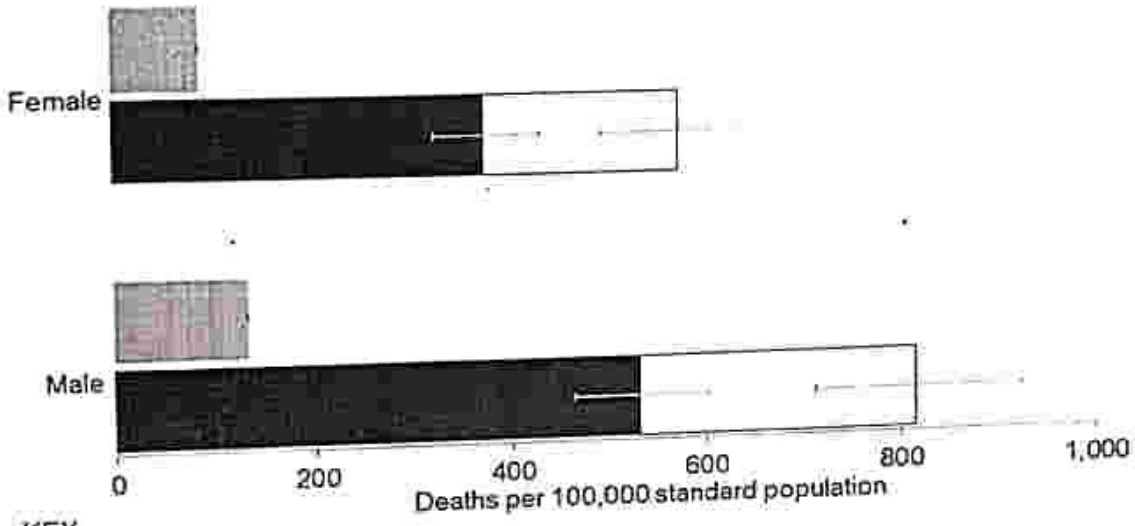
In the general population, there have been higher death rates with COVID-19 in men than women (5). To compare sex-specific death rates for people with learning disabilities to those seen for the general population, the smaller proportion of people with learning disabilities in the older age groups must be considered. Direct standardisation shows what the death rates would be in a population with a standard structure if the age and sex specific death rates seen in relevant groups had applied.

LeDeR data

Figure 4.5 shows directly age standardised COVID-19 death rates for men and women with learning disabilities from LeDeR data set alongside rates for the general population. The solid black bars in the chart show the rates for people with learning disabilities calculated using numbers of deaths reported to LeDeR. Estimates of the rates after adjustment for under-notification are shown in outline. Grey bars show the standardised rates for the general population. Table 4.1 shows the standardised rates, using both unadjusted and adjusted numbers of deaths for male and female adults with learning disabilities and the overall rates for persons, standardised for both age and sex.

The age standardised death rate for men with learning disabilities was 1.4 times that for women with learning disabilities. This is similar to the pattern in the general population for whom the age standardised death rate for men was 1.5 times that for women. However, the rates for people with learning disabilities were substantially higher than those for the general population. Using rates calculated from numbers reported to LeDeR, the age standardised death rate for men with learning disabilities was 4 times the rate for men in the general population, for women 4.3 times and for persons 4.1 times. Using estimates that take account of the likely level of under-notification, the corresponding ratios are 6.1 for men, 6.6 for women and 6.3 for persons.

Figure 4.5 Solid black bars show age-standardised rates, per 100,000 adults, to 5 June 2020, for reports of COVID-19 deaths to LeDeR and for COVID-19 deaths in the general population. Outlines show estimated COVID-19 death rates for people with learning disabilities allowing for likely level of under-notification to LeDeR.



Sources: LeDeR (1), LDHC 2018 to 2019 (9), OOF 2018 to 2019 (10), ONS provisional mortality records 2020, ONS mid-year estimates of population 2019 (16).

Table 4.1 Age standardised COVID-19 death rates to 5 June 2020, per 100,000 adults, for men, women and people, for deaths notified to LeDeR, for the general population, and estimated death rate for people with learning disabilities allowing for likely level of under-notification to LeDeR.

	With learning disabilities		
	Rate calculated from notifications	Estimated rate adjusting for under-notification	General population
Females	371 (320 to 428)	570 (491 to 656)	86 (85 to 87)
Males	531 (465 to 602)	814 (713 to 924)	133 (131 to 134)
Persons	451 (409 to 496)	692 (627 to 761)	109 (108 to 110)

Sources: LeDeR, with and without adjustment for under-notification; LDHC 2018 to 2019 (10), OOF 2018 to 2019 (9), ONS provisional mortality records for 2020, ONS mid-year estimates of population 2019 (27). The figure in the text for the ratio of the unadjusted rate for men with learning disabilities to the rate for men in the general population appears anomalous: this is caused byrounding the figures for death rates.

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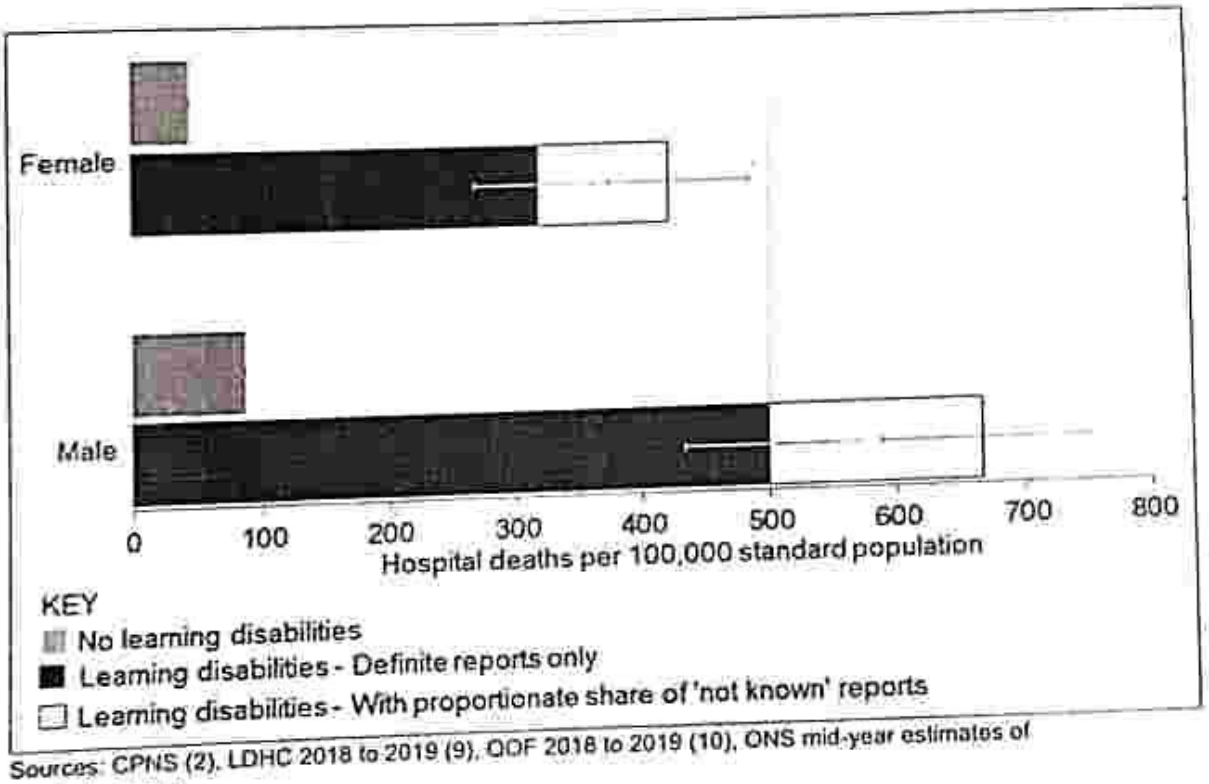
Hospital deaths data

Figure 4.6 shows directly age standardised rates of COVID-19 deaths in hospital settings for men and women, to 5 June. Rates are shown for people with and without learning disabilities. For people with learning disabilities solid black bars show the rate calculated using only deaths of people with learning disabilities identified in CPNS (assumption 1). Outline bars show the estimated rates assigning a proportion of those with learning disabilities status 'not known' to the learning disabilities group (assumption 2). Table 4.2 shows the standardised rates, for male and female adults with learning disabilities, using both assumptions, along with the overall rates for persons, standardised for both age and sex using assumption 1.

Using only deaths where learning disabilities was specified (assumption 1), the age-standardised rate for men with learning disabilities was 1.6 times that for women with learning disabilities. For men without learning disabilities the rate was 1.9 times the rate for women without learning disabilities. Again, using only deaths where learning disabilities was specified, the age standardised rate for men with learning disabilities, was 5.8 times that for men without learning disabilities. The corresponding rate for women was 7.1 times the rate for women without learning disabilities. These ratios, comparing men and women with learning disabilities to their counterparts without is a minimum estimate for the real difference. Using assumption 2, the corresponding ratios were 7.7 times for men and 9.4 times for women.

For people with learning disabilities, the sex differential seen here (figure 4.6) was similar to that for the LeDeR data (figure 4.5). For people without learning disabilities the differential was greater than that in the general population seen in figure 4.5. The greater difference between the sexes in the hospital death rate for the general population could reflect a difference between the sexes in the likelihood of hospitalisation.

Figure 4.6 Age standardised COVID-19 hospital death rates to 5 June per 100,000 adults with and without learning disabilities. Solid black bars show rates with definite record of learning disabilities (assumption 1). Outlines show estimated rates including proportionate number of deaths of people with learning disabilities status 'not known' (assumption 2). Rates for people without learning disabilities include all 'not known' deaths (assumption 1).



Sources: CPNS (2), LDHC 2018 to 2019 (9), OOF 2018 to 2019 (10), ONS mid-year estimates of population 2019.

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Table 4.2 Age standardised COVID-19 hospital death rates to 5 June 2020, per 100,000 adults, for men, women and people with and without learning disabilities. Rates for people with learning disabilities calculated using only deaths with definite record of learning disabilities (assumption 1). Estimates include proportionate share of 'not known' deaths (assumption 2). Rates shown for people without learning disabilities include all 'not known' deaths (assumption 1).

	With learning disabilities		Without learning disabilities (including all 'not known' deaths – assumption.1)
	Rates using only records specifying learning disabilities (assumption 1)	Estimates including proportionate share of 'not known' deaths (assumption.2)	
Females	318 (267 to 374)	420 (362 to 485)	45 (44 to 46)
Males	500 (433 to 573)	666 (588 to 749)	86 (85 to 87)
Persons	409 (367 to 454)	543 (494 to 595)	65 (65 to 66)

Sources: CPNS (2), LDHC 2018 to 2019 (10), QOF 2018 to 2019 (9), ONS mid-year estimates of population 2019 (27). The figure in the text for the ratio of the estimated rate for men with learning disabilities to the rate for men in the general population appears anomalous; this is caused by rounding the figures for death rates.

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Ethnic group

Both the LeDeR and CPNS collect information about the ethnic group of people dying. UK statistics identify 18 ethnic groups. Numbers of deaths of people with learning disabilities were too small for reporting in this level of detail. The 18 groups were therefore condensed into 4 broad groupings. Details are given in Annexe 2.

As noted in the introduction there are no robust estimates of the numbers of people in the population with learning disabilities by ethnic group for the age groups relevant to this study. So, instead of calculating rates of death per 100,000 population, analysis was limited to comparing numbers of deaths in 2020 with the 2 previous years using LeDeR data.

Table 4.3 shows the numbers of deaths reported to LeDeR in 2020 for COVID-19 and other causes broken down by ethnic group. The average number of deaths in the corresponding period of the 2 previous years is shown for comparison, as is the ratio of the total number of deaths in 2020 to the average number in the 2 previous years.

The overall number of deaths for White people with learning disabilities in 2020 was 1.9 times the average number in the 2 previous years. For both Asian or Asian British, and Black or Black British people it was more than 4 times the previous average. The columns showing the split between deaths with COVID-19 and deaths from other causes show that the increase for these 2 groups was largely the result of deaths with COVID-19. There was also an increase in the proportion of deaths where the ethnic group of the deceased was not recorded. These differences were too large to be a chance finding. The observation in respect of Asian or Asian British, and Black or Black British adults with learning disabilities is similar to findings about the impact of COVID-19 on these groups reported by PHE (5).

Table 4.3. Numbers of adult deaths reported to LeDeR, occurring between 20th March and 5th June 2020, and the corresponding weeks of 2018 and 2019, by ethnic group and cause of death (with COVID-19 or other causes); ratio of all causes 2020 to average for 2018 and 2019.

Ethnic group	Average deaths in 2018 and 2019	2020 deaths			All causes 2020 / average of previous years
		COVID19	Other causes	All causes	
White	475.5 (90.9%)	480 (79.7%)	446 (82.3%)	926 (80.9%)	1.9
Asian /Asian British	11 (2.1%)	39 (6.5%)	11 (2.0%)	50 (4.4%)	4.5
Black / Black British	7 (1.3%)	20 (3.3%)	11 (2.0%)	31 (2.7%)	4.4
Other ethnic groups	4.5 (0.9%)	6 (1.0%)	5 (0.9%)	11 (1.0%)	2.4
Missing	25 (4.8%)	57 (9.5%)	69 (12.7%)	126 (11.0%)	5.0

Source: LeDeR (unadjusted numbers) (1). Figures in brackets are percentages by column.

Areas of the country

Regional patterns of deaths in the LeDeR and CPNS datasets were checked for consistency. As noted above, the completeness of the data varied greatly between regions in both. For deaths in hospital settings, there was a gap in the recording of the learning disabilities and autism status in the CPNS dataset. Overall, a quarter of deaths reported had this recorded as 'not known', but the proportion varied substantially between regions. Analyses of differences in rates of death between regions are not reliable when the completeness of recording varies so much. So, for differences by ethnic group, the distribution of numbers of deaths reported to LeDeR in previous years was compared to those reported in 2020.

Figure 4.7 and table 4.4 show a regional breakdown of the numbers of deaths reported to LeDeR occurring between 21 March and 5 June 2020, and the annual average for the 2 previous years. The columns for 2020 distinguish deaths with COVID-19 and those from other causes.

The numbers of deaths of people with learning disabilities reported from causes other than COVID-19 were similar to those reported in previous years. The increase in the additional deaths with COVID-19 varied considerably between regions. In London the number of deaths from all causes was 3.7 times the previous average, in the South West it was 1.6 times. The increase in other regions was between 1.8 and 2.3 times. The pattern of the highest level of excess in London and the lowest in the South West matches that reported by PHE for regional inequalities in the general population COVID-19 death rates (5).

Statistical testing showed that the distribution of deaths from causes other than COVID-19 between regions in this period was not significantly different from the distribution of deaths in previous years. However, as a result of the very different distribution of deaths related to COVID-19, the overall distribution of deaths was different to an extent unlikely to have occurred through random fluctuation.

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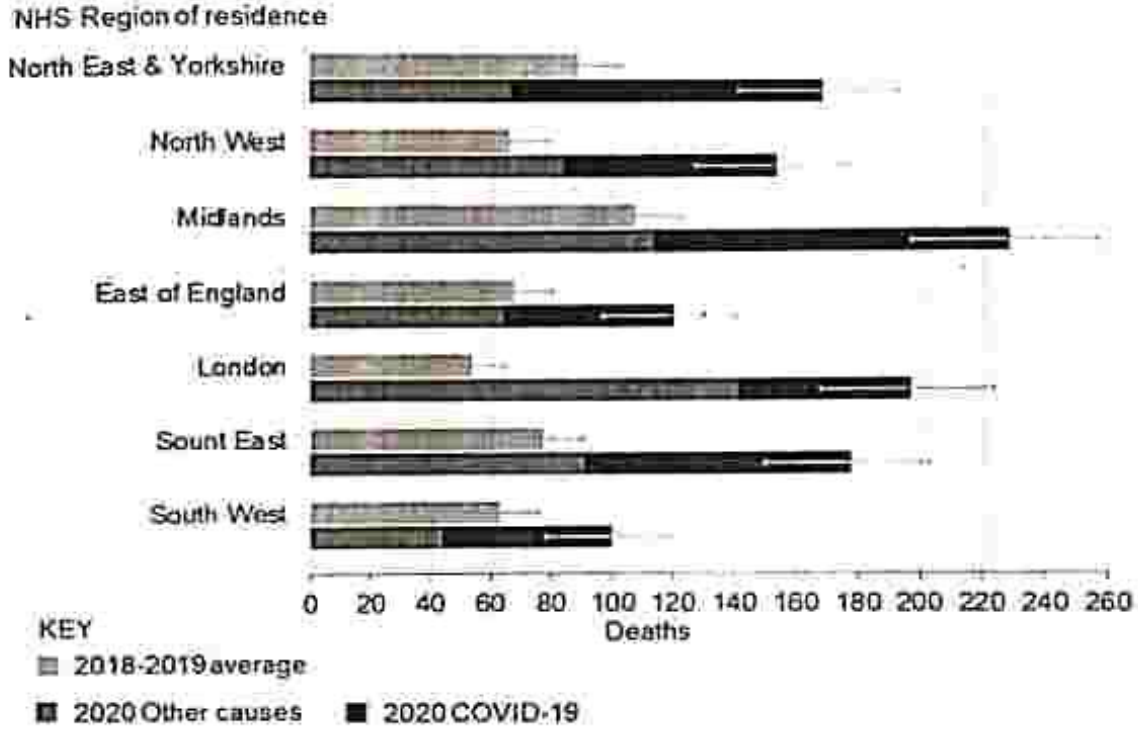
Figure 4.7 Numbers of deaths of adults reported to LeDeR by NHS region of residence, annual average for deaths in 2018 and 2019 and deaths with COVID-19 and from other cause for 2020.



Source: LeDeR (unadjusted numbers) (1). Confidence intervals are for total deaths.

Table 4.4 Numbers of deaths of adults reported to LeDeR, occurring between 21 March and 5 June 2020, by NHS region and cause of death (COVID-19, other causes and all causes), average number for all deaths in 2018 and 2019 and ratio of 2020 all causes to 2018-19 average.

NHS region	Average for 2018 - 2019, all causes	2020 deaths			Ratio, 2020 / average of previous years
		COVID-19	Other causes	All causes	
North East & Yorkshire	89 (16.8%)	68 (11.0%)	102 (18.8%)	169 (14.7%)	1.9
North West	66 (12.6%)	83 (13.8%)	70 (12.9%)	153 (13.4%)	2.3
Midlands	107 (20.5%)	113 (18.8%)	115 (21.2%)	228 (19.9%)	2.1
East of England	68 (12.9%)	64 (10.6%)	56 (10.3%)	120 (10.5%)	1.8
London	54 (10.2%)	141 (23.4%)	56 (10.3%)	197 (17.2%)	3.7
South East	78 (14.8%)	91 (15.1%)	87 (16.1%)	178 (15.6%)	2.3
South West	63 (12.1%)	44 (7.3%)	56 (10.3%)	100 (8.7%)	1.6
England	523	602	542	1144	2.2

Source: LeDeR (unadjusted numbers) [1]

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Social deprivation

PHE's report 'Disparities in the risk and outcomes of COVID-19' review identified strong associations between residence in areas of social deprivation and age standardised COVID-19 mortality rates (5). It was not possible to report on this for people with learning disabilities with either of the main data sources used in this study as neither had available information linking individuals to geographic areas smaller than regions

Deaths in care settings

Main Messages

Death rates in social care settings were estimated from numbers of notifications to the CQC and numbers reported as receiving social care for learning disabilities in annual social care statistics. Findings in this section cover the shorter period, from 10 April to 15 May, for which the CQC collated data from statutory notifications of deaths of people receiving social care from registered providers.

COVID-19 accounted for 54% of deaths of adults with learning disabilities in residential care in the period, slightly less than for people with learning disabilities generally, but still much more than in the general population.

The crude rate of COVID-19 deaths for adults with learning disabilities in residential care was higher than the rate of COVID-19 deaths of adults with learning disabilities generally as estimated from LeDeR. It was 2.3 times the rate calculated from actual LeDeR notifications and 1.5 times the estimated rate adjusting for likely under-notification. This difference is likely in part to reflect the greater age and disability in people in residential care.

Data from PHE indicate that care homes looking after adults with learning disabilities was less likely than other care homes to have had COVID-19 outbreaks. This is likely to be related to the fact they have fewer bed spaces.

COVID-19 accounted for 53% of deaths of adults with learning disabilities receiving community-based social care. It is hard to comment on the overall scale of deaths in these contexts because the number of people receiving care from providers likely to report their deaths is not clear. This level of additional mortality is similar to that seen in residential care.

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Introduction

This section explores the question of whether people with learning disabilities appear to have been at additional risk in relation to the types of social care they receive. Some people with learning disabilities live in residential care homes. A larger number receive various levels of home support which, in normal times, would involve regular contact with care staff.

Residential care homes have a number of characteristics that put residents at additional risk in outbreaks of respiratory viruses. Residents typically have high levels of chronic illness or impairment. They frequently live in close proximity with other residents making quarantining difficult. Hand washing may not be routine for some residents and many residents may have difficulty understanding the need for infection control measures. In normal circumstances care staff come into frequent contact with many residents, adding to the risk of transmission (28). COVID-19 has been associated with high mortality in care home residents in many countries, though a systematic review of reports of outbreaks identified wide variation in the success of their containment (29).

CQC prepared a dataset of the statutory deaths notifications they had received in the 5 week period from 10 April to 15 May and the corresponding period of 2019. They published a report on this data in June 2020 (3). More detailed extracts of the dataset were made available to PHE for this study. As noted in section 3, the time period covered was shorter than that for the other 2 sources discussed in this report. The 5 weeks covered represent roughly two-thirds of the peak in deaths (see figure 3.1), starting during the second of the 3 weeks with the largest numbers of deaths (as recorded in the LeDeR data) and omitting the long tail of deaths.

In publishing the data, CQC distinguished between residential and non-residential social care and community-based adult social care. Making sense of this data would require the numbers of people with learning disabilities receiving each of these the types of care. The data available provides very little detail specifically about people receiving social care with learning disabilities. The short and long term support tables in the Adult Social Care Activity and Finance Report statistics provide only total numbers of people receiving residential care, categorised into residential and nursing care, and 4 categories of non-residential care categorised by the type of funding arrangement (6).

Residential social care

The CQC reported 195 deaths of adults with learning disabilities in the period covered (105 with COVID-19, 90 from other causes).

Table 5.1 shows crude adult death rates calculated using these figures. These rates are not comparable with the rates reported in section 3 and 4 because of the shorter time period they cover and because they are not standardised for age and sex. For comparison, adult COVID-19 death rates for this shorter period for the whole population with learning disabilities from LeDeR (as notified to LeDeR and with adjustment for the estimated level of under-notification) and for the whole general adult population from ONS' statistics are also shown in the table.

During this peak period, the crude rates of deaths with COVID-19 and other causes for adults with learning disabilities in residential care were respectively 2.3 times and 3.0 times the corresponding rates for people with learning disabilities overall notified to LeDeR. They were respectively 1.5 times and 2.0 times the corresponding rates after adjusting for likely levels of under-reporting. It is not surprising that they were higher since people with learning disabilities living in residential care are likely to be older and have multiple or more severe disabilities than those living more independently.

The COVID-19 death rate and the death rate from other causes among people with learning disabilities in residential care were 5.5 times and 2.7 times the corresponding rates in the general population during this peak of the pandemic wave. These comparisons are not standardised for the large age and sex profile differences or the fact that the residential care population are likely to be older and have multiple or more severe disabilities than adults with learning disabilities generally. In this period, COVID-19 was considered to have caused 53.8% of all deaths for adults with learning disabilities in residential care. This was slightly less than in reports to LeDeR, where COVID-19 was given as the possible or definite cause for 60.1% of deaths. It is not surprising that this was much higher than in the general adult population, where COVID-19 was given as a cause for only 36.2% of deaths.

Other figures published by the CQC indicate that the crude death rate for all adults receiving social care in residential settings was much higher than those for people with learning disabilities in residential care (3). This reflects the fact that people in residential care who do not have learning disabilities are a much older and frailer group with inevitably higher death rates. However, it is notable that for this group, only 44% of the total deaths during the period the CQC studied were COVID-19 related. The proportion of deaths

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in residential care that were COVID-19 related for people with learning disabilities was 53.8%.

Table 5.1. Crude death rates (per 100,000) and proportion (%) of deaths attributed to COVID-19, for adults with learning disabilities receiving residential adult social care from notifications to CQC between April 10 to May 15. COVID-19 death rates for the population with learning disabilities (from LeDeR - rates from numbers notified and estimated rates adjusted for under-notification), and for the general population, for a similar period are shown for comparison.

Group		Death rate (per 100,000)	Proportion of deaths due to COVID-19
Adults with learning disabilities in residential care			
	COVID-19	355 (290 to 430)	53.8%
	Other causes	304 (245 to 374)	
	All causes	659 (570 to 758)	
All adults with learning disabilities (LeDeR) CQC period			
	COVID-19	From numbers notified: 151 (137 to 167) Estimate adjusted for under-notification: 232 (195.5 to 241.0)	60.1%
	Other causes	From numbers notified: 101 (89 to 114) Estimate adjusted for under-notification: 154 (136 to 174.	
	All causes	From numbers notified: 252 (233 to 272) Estimate adjusted for under-notification: 387 (357 to 418)	
Adult deaths in the general population in England in the CQC period			
	COVID-19	65 (64 to 66)	36.2%
	Other causes	115 (114 to 116)	
	All causes	180 (178 to 181)	

Sources: CQC COVID-19 deaths dataset with Community Care statistics for numbers in residential care at end March 2019 (3); LeDeR (unadjusted and adjusted for estimated level of notification) (1); LDHC 2018 to 2019 (10); QOF 2018 to 2019 (9); ONS provisional death registrations 2020; ONS mid-year estimates of population 2019 (27). The figure in the text for the ratio of the rate of deaths from causes other than COVID-19 of adults with learning disabilities in residential care to all people with learning disabilities using the adjusted figure appears anomalous; this is caused by rounding the figures for death rates.

Characteristics of homes where deaths occurred

To explore the characteristics of residential homes associated with COVID-19 deaths of people with learning disabilities, the CQC supplied PHE with identifiers of the homes in which deaths had occurred and the dates on which deaths had occurred. These were linked to details of homes from the CQC registration directory (30) and to notifications of COVID-19 outbreaks made to PHE's health protection teams.

Only limited conclusions can be drawn because there is no register of which residential care locations are currently providing social care to people with learning disabilities or in what numbers, and care home registration categories combine learning disabilities and autism in a single category. Care homes frequently obtain registration to provide care for a wider range of clients than they actually go on to look after at any point in time.

At the time to which the data relates, 5,552 social care locations with a primary inspection category of 'residential social care' in England were registered to look after people with learning disabilities or autistic people (omitting 33 locations with no registered number of beds). Table 5.2 summarises the available information about outbreaks and COVID-19 deaths of people with learning disabilities in these facilities.

There were 1,447 homes registered to provide care only for a single 'service user band', namely 'learning disabilities or autistic spectrum disorders'. The remaining 4,105 homes were registered for this and other service user bands. Between them these homes were registered to provide 65,944 beds. Adult social care statistics give the total number of people with learning disabilities receiving all types of residential care at the end of March 2019 as 29,590 (11). This data source has no category for autism. So, not all these beds, and probably not all these locations, were looking after adults with learning disabilities. If all the beds in the learning disabilities and autism only homes were occupied by people with learning disabilities, this would mean that around 19,000 residential care recipients with learning disabilities were receiving care alongside people with other types of need in the remaining 4,105 units. They would form roughly a third of the residents in this group of homes.

Table 5.2 Provision of residential care homes (locations and licensed bed spaces) for people with learning disabilities or autism; total numbers of residents, number and proportion of locations with COVID-19 outbreaks and deaths of people with learning disabilities with COVID-19

	Homes registered only for people with learning disabilities or autistic people	Mixed client homes	Total
Locations registered for people with learning disabilities or autism	1,447	4,106	5,553
Maximum beds	10,873	58,071	68,944
Number of people with learning disabilities in residential care			29,590
Locations with an outbreak (% of all homes in category, note some may not have had current residents with learning disabilities)	114 (7.9%)	625 (15.2%)	739 (13.3%)
Locations with at least one death of a person with learning disabilities (% of all homes in category, note some may not have had current residents with learning disabilities)	18 (1.2%)	65 (1.6%)	83 (1.5%)
COVID-19 deaths - see footnote	22	79	101

Sources: Care Quality Commission CBD April Digital | [1] CQC data on dates of deaths of people with learning disabilities in residential care, notifications of first of outbreaks of COVID-19 in residential care up to 28 July. For locations with an outbreak it is not known whether outbreaks or locations involved people with learning disabilities. For locations with deaths of people with learning disabilities the total count of deaths is a result of the number given in Care Quality Commission CBI as the data source available to PHE for the study (one row) dates of deaths in locations. [] deaths in a location on the same date were registered only a single count.

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Table 5.3. Upper section - distribution of residential care homes by number of licensed beds and licensed service user type. Lower section - numbers of residential care homes and proportions with reported COVID-19 outbreaks by number of licensed beds and licensed service user type.

Size of home	Homes registered only for people with learning disabilities or autistic people	Mixed client homes	Homes not registered for people with learning disabilities or autism	All homes
Proportion of homes				
1 to 9 beds	78.2%	63.1%	5.1%	27.4%
10-19	18.6%	20.7%	12.5%	15.2%
20-39	2.8%	8.5%	38.7%	27.3%
40-59	0.4%	4.0%	24.3%	16.7%
60+	0.0%	3.7%	19.4%	13.4%
Proportion of homes with outbreaks				
1 to 9 beds	5.9%	5.9%	4.4%	5.7%
10-19	13.8%	14.8%	18.0%	16.4%
20-39	17.1%	33.7%	39.7%	39.0%
40-59	50.0%	62.0%	62.3%	62.2%
60+	-	83.0%	75.1%	75.7%
All sizes	7.9%	15.2%	47.5%	35.2%
Total homes	1,447	4,105	9,895	15,447

Sources: Care Quality Commission (30); Notifications to PHE of outbreaks of COVID-19 in residential care up to 29th July 2020 (31)

Out of the units registered only for services users with learning disabilities or autistic service users, 114 had an outbreak of COVID-19 and 18 had at least one death of a resident with learning disabilities with COVID-19. Also, 625 of the mixed user-group units had an outbreak and 65 had at least one death of a person with learning disabilities. The table shows these figures as percentages of all homes in the category. However, it is not possible to say what proportions of homes caring for people with learning disabilities these numbers constitute, as the number of homes with residents with learning disabilities is not known. In the case of the units registered only for service users with learning disabilities or autism this is probably a closer guide than for the mixed user-group units.

One feature of residential care homes for people with learning disabilities or autism likely to have reduced their risk of COVID-19 outbreaks is that they are relatively small. The average size of homes registered only for people with learning disabilities or autistic people was 7.5 beds whereas for mixed purpose units it was 13.4 beds. Residential homes registered for other groups (mainly older people) are substantially larger with an average of 39.5 beds.

Table 5.3 shows the size of residential units in relation to the range of clients for which they are registered, and how this has been associated with COVID-19 outbreaks. Total numbers of homes are at the bottom of the table. The top section shows the distribution of numbers of beds for homes registered for each client group. Homes registered to care for people with learning disabilities or autistic people are much smaller than homes not registered to care for these groups. The bottom section of the table shows the proportions of homes in which COVID-19 outbreaks were recorded by number of beds. There was a strong association.

In summary, people with learning disabilities in residential care had significantly higher death rates than people with learning disabilities generally. COVID-19 accounted for more than half of deaths of those with learning disabilities in residential care during the peak period. The small size of the residential homes in which they live is likely to have been an important factor in avoiding a much worse outcome.

Community based social care

The situation for community based social care is much harder to assess. The CQC were notified of 98 deaths with COVID-19, and 86 from other causes, among people with learning disabilities receiving community-based adult social care from registered providers in the 5 weeks on which they reported (3). This means that 53% of the deaths of people with learning disabilities receiving community-based care in the period were with COVID-19.

There is no record of the numbers of clients for whom registered providers are currently providing care. Social care statistics show total numbers receiving social care classified by the type of funding package, but since the implementation of the 2014 Care Act, people assessed as needing social care have a wider range of options about the types of provider from which this can be obtained. If they wish, they, or their family carers, can make their own arrangements to get care from individuals who do not need to be registered with the CQC. In these cases, their death, if it occurred, would not be reported to the CQC.

The CQC supplied us with the details of providers of non-residential care where a death had been reported. This data was harder to interpret than data relating to residential care. Non-residential care is provided by a wider range of types of provider. Exactly 7,316 care locations were registered to provide potentially relevant services for people with learning disabilities, though, as with residential care, it is not clear how many of these were doing so at the time. Also, 85 (1.2%) of these care organisations reported at least one COVID-19 death of a service user with learning disabilities in the period covered by the CQC data with 73 services reporting a single death and 12 reporting more than one.

Discussion

The key finding of this study was that people with learning disabilities had significantly and substantially higher death rates in the first wave of COVID-19 in England than the general population. Making no allowance for the younger age and different sex ratio of people with learning disabilities, the rate of deaths notified to LeDeR in this group was 2.3 times the death rate in the general population. If this figure is adjusted to allow for the likely level of under-notification to LeDeR it was 3.5 times the general population rate. After standardisation for age and sex the rate calculated just from notifications to LeDeR was 4.1 times the general population rate. Adjusting for the likely level of under-notification it was 6.3 times the general population rate.

The total number of deaths in adults with learning disabilities for the 11 weeks from 21 March to 5 June was 2.2 times the average number for the corresponding period in the 2 previous years. By contrast, the number of deaths in the general population was 1.5 times the average for the 2 previous years.

Deaths with COVID-19 in adults with learning disabilities were spread more widely across the age groups than those in the general population. As in the general population, the COVID-19 death rate in people with learning disabilities was higher for men than for women. The overall increase in deaths was also greater in Asian or Asian-British, and Black or Black-British people.

Residential care homes providing care for people with learning disabilities do not appear to have had the very high rates of outbreaks of COVID-19 seen in homes providing care for other groups, mainly older people. This appears to be related to their smaller number of beds.

Limitations

The study was severely hampered by the limitations and deficiencies of data collected to monitor the health and care of people with learning disabilities in England. The 2 major data sources used, LeDeR and CPNS, both had substantial levels of incompleteness. The patchy nature of the gaps in both these systems made regional analyses unreliable.

The LeDeR system is designed to support qualitative reviews of deaths of people with learning disabilities. It is not primarily intended to report numbers of deaths, or to provide reports within weeks of the occurrence of deaths.

Unlike reviews of child deaths, which are required by law, reviews of the deaths of people with learning disabilities are not mandatory so professionals attending deaths are not required to report them to LeDeR. There is no automatic communication to LeDeR of the deaths of people on GP learning disabilities registers. This makes it likely that notifications of deaths to LeDeR will be incomplete.

A measure of under-notification to LeDeR was available from comparison with the number of deaths of GP patients on learning disabilities registers recorded in the most recent LDHC dataset (covering April 2018 to March 2019). Since LeDeR is a relatively new system, it would have been desirable to check not only the level of completeness of reporting of deaths, but also whether any trend in this was apparent as the system became better known. It was not possible to do this with LDHC as there was only a single overlapping period in the available data. However, the evidence from comparing numbers of deaths from causes other than COVID-19 with numbers of deaths in the 2 previous years set out alongside chart 3.1 does not suggest there is major distortion from this type of influence. The LDHC dataset is also incomplete, offering a sample of data from just over half of England as described in the 'Main sources of data' section (above) and Annexe 2. Its coverage varies considerably between regions, making assessment of LeDeR coverage between regions unreliable.

LeDeR operates under strict information governance rules. These meant it was not possible to identify the local areas where deceased people lived, precluding analysis of any differential impact of COVID-19 on areas of social deprivation. They also precluded making direct links between notifications to LeDeR and records in the CPNS system. This made it impossible to identify the precise extent of overlap and thus estimate the total number of hospital deaths of people with learning disabilities. Questions about the variability of completeness in both LeDeR and CPNS limited the analysis of regional patterns to changes in local numbers.

The difficulties arising from the lack of recording of learning disabilities status for 25% of deaths notified in the CPNS system have been described in the report. The inability to record this in such a large proportion of cases is understandable given the context, as outlined in the introduction.

For calculating rates of death per 100,000 population, the study assumed that the people identified as having learning disabilities in LeDeR and CPNS were broadly people who were on their GPs' learning disabilities registers. The reasons are set out in the introduction. If in reality LeDeR or CPNS capture

deaths in a narrower or broader group of people, rates would be under- or over-estimated as a result.

The most important gap in population data was the lack of data about numbers of people with learning disabilities in Black and minority ethnic groups. Without this, analysis of rate differences between these groups was not possible. As with regional differences, analysis was limited to changes in numbers of deaths between years.

With the problems of under-reporting of deaths to LeDeR, and gaps in recording of learning disabilities status in CPNS, the approach to providing estimates of death rates (per 100,000 population) was, in most cases, to present 2 calculations. One used numbers of deaths recorded as being of people with learning disabilities. These provide a marker of the lowest rates compatible with the data. In the case of LeDeR data they definitely represent under-estimates, and in the case of CPNS they almost certainly do. However, the differences between these rates and those for the general population, or the population assumed not to have learning disabilities, were stark.

The second set of rates represented an estimate of the likely numbers of deaths using all the data available. The accuracy of these will have depended on the validity of the assumptions on which they were based. In all cases the findings suggested even greater differences than the unadjusted figures.

In the case of rates from LeDeR data, the key assumption was about the rate of under-notification. Our estimate of this was based on data from April 2018 to March 2019. It is possible that notification rates may have risen since March 2019, but the data shown in figure 3.1 suggests it is unlikely this would have been by a large margin. In the case of CPNS data the key assumption was that the frequency of learning disabilities in people whose status was recorded as 'not known' would have been the same as in those for whom it was known in each age and sex group. There is no realistic way to test this.

Finally, it is important to reiterate a point made in the introduction. This study was only able to report on mortality in people whose learning disabilities were recognised and recorded by health services or reported to LeDeR by family or friends. There is 0.57% of adults registered with GPs who are on learning disabilities registers. As set out in the introduction, this figure is substantially lower than the numbers currently identified as having the special educational needs of moderate, severe, or profound and multiple learning difficulties in English schools (22). The great majority of people recognised as having

learning disabilities in schools are not recognised as such by health services in adulthood (32).

Those missed are likely to be those with mild or moderate (as opposed to severe or profound) intellectual disabilities without major accompanying physical syndromes. This group are known to have poor physical health, including higher rates of obesity and diabetes, putting them at increased risk of death from COVID-19 (33). They are also likely to have less capacity to understand and follow guidance on social distancing (12).

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Annexe 1. The commission

Terms of reference

Further analysis of data related to the deaths of people with learning disabilities from COVID-19.

This document sets out the formal commission from Department of Health and Social Care, with the support of the Chief Medical Officer, to Public Health England. It establishes the parameters for the requested piece of work, namely further analysis of data related to the deaths of people with learning disabilities (LD) from COVID-19.

Purpose

To conduct analysis, which will inform policy and practice to reduce the risk and impact going forward, of COVID-19 on people with learning disabilities.

Data

The analysis will draw upon all available data regarding the deaths of people with LD from COVID-19. This includes:

1. Deaths in acute settings by long term condition (NHS England) with a diagnosis of COVID-19.
2. Reported deaths to the Learning Disabilities Mortality Review (LeDeR).
3. Death notifications to the Care Quality Commission.

Analysis required

The following metrics have been identified as priority by stakeholders. Analysis should be primarily focused on the peak 6 weeks of the COVID-19 pandemic.

1. Age, ethnicity and gender split of existing data.
2. Comparison to deaths for people with learning disabilities reported in the same period of the previous year.
3. Compare the proportion of COVID-19 deaths among people with learning disabilities to the proportion of people with learning disabilities

in the general population (using appropriate learning disabilities prevalence data).

4. Comparison of mortality rates between people with learning disabilities and the general population making allowance for the differences in the age/sex profile of the 2 groups.
5. Scoping possibility of analysis of LeDeR data to establish where there are high numbers of deaths in single addresses.
6. Breakdown of deaths by setting (those happening in hospital settings and those happening in other types of location).
7. Age and gender standardised mortality rates.

Annexe 2. Data sources and methods

Population data

There is no good source of data about the population of people with learning disabilities in England. In order to calculate rates of death in relation to age, sex or ethnic groups, population data broken down by these characteristics are required. Two sources were used to estimate the size and breakdown by age and sex, both drawn from general practice (GP) information systems and both based on the learning disabilities registers GPs are asked to keep as part of the Quality and Outcomes Framework (QOF).

The first source was the annual QOF data collection (10). This is collected in an automated data extraction from participating general practices. It provides a total figure for number of people on the practice learning disabilities register. Almost all practices participate. Register totals from the 2019 QOF dataset were used to give the total number of people in England identified as having learning disabilities for healthcare provision purposes. However, this source gives no further information about the composition of the population.

The second source was the LDHC dataset (9). This is also collected by direct annual extraction from GP practice information systems. Reports are at clinical commissioning group (CCG) level and include numbers on learning disabilities registers by age group and sex. Data from the most recent (2018 to 2019) extraction provided this population data as at March 2019. It also gave the number of people on learning disabilities registers who died in the year to March 2019. These sources were used to estimate the completeness of the LeDeR data as described below.

However, the LDHC dataset only manages to collect data from practices covering a little over 50% of the population of England each year (9). It is intended to be complete but to date it has not been possible to obtain data from practices using one of the 2 common GP practice information systems. The calculations used to estimate the overall population of England with learning disabilities known to GPs by age group and sex are set out below alongside the estimate of completeness of reporting of deaths of people with learning disabilities to LeDeR.

A further limitation of LDHC data, and inevitably also QOF data, is that the coverage of children and young people is very incomplete. This is because they are counting numbers of people GPs have recorded as on learning

disabilities registers. GPs often do not record this until late in childhood or in adolescence when transition to adult care is being planned.

Ethnic groups

Both LeDeR and the hospital deaths datasets use the full UK national ethnic group coding. For most groups there were insufficient cases for separate analysis, so these were condensed as shown in box 1.

Box 1 Ethnic Groupings used.
White included: White – British, White – Irish, White - Gypsy or Irish Traveller, White - any other White background

Asian / Asian British included: Asian / Asian British – Indian, Asian / Asian British – Pakistani, Asian / Asian British – Bangladeshi, Asian / Asian British – Chinese, Asian / Asian British - any other Asian background

Black / Black British included: Black / Black British – Caribbean, Black / Black British – African, Black / Black British - any other Black background

Other ethnic groups included: Mixed / multiple - White and Asian, Mixed / multiple - White and Black Caribbean, Mixed / multiple - White and Black African, any other Mixed / multiple background, Other ethnic group – Arab, Other ethnic group - any other ethnic group

The possibility of making estimates of the size of the population with learning disabilities in minority ethnic groups was explored. The approach taken was to use ONS estimates of the total population in ethnic minority groups calculated from the 2011 census, combined with estimates of the proportion of children with learning disabilities in minority ethnic groups from school special educational needs statistics (25). This seemed an unreliable approach as it combined the uncertainty of forward projection of minority ethnic populations without correction for international migration with further uncertainty about the relevance of patterns of learning disabilities in people of school age to people in the middle and older age groups where death with COVID-19 is mainly seen. Reported numbers of deaths of people from minority ethnic groups were relatively small, making the statistical confidence intervals of rates relatively wide. The resulting rate calculations were all

statistically inconclusive. For this reason, the analysis presented here is confined to analysis of trends in numbers of deaths.

Learning Disabilities Mortality Review (LeDeR)

LeDeR is a continuing survey of deaths of people with learning disabilities. In its national form it is a relatively recent development, set up in 2015, in response to the Confidential Inquiry into Premature Deaths of People with Learning Disabilities (CIPOLD) (20). It started collecting data in July 2016. Deaths are reported as they occur to the national team in Bristol. Only limited data is collected at this 'notification' stage. This is primarily intended to provide regional teams, responsible for undertaking the reviews, with the information they need to initiate their work. However, as the full review process in most cases takes several months, it would not be sufficiently timely for a study such as this. Instead the initial notification data was used. The LeDeR methodology is described in their most recently published annual report (1).

The LeDeR team provided data for all notifications since the start of January 2018. This provided comparison data for the 2 previous years. Notifications for years before 2017 were more substantially incomplete. The initial data extract, on which the report was developed, was drawn on 19 June 2020, covering deaths on or up to 5 June. This was refreshed with an update extract taken on 4 September. The September refresh identified 147 relevant deaths not in the initial extract and allowed deletion of 24 records which were either duplicates or which had proved to be outside the scope of LeDeR.

Notifications to LeDeR have become quicker over the last 2 years. Comparing deaths occurring up to 5 June in each of the 3 years for which data was available, in 2018, 92% of the deaths currently known about had been notified by 4 September in the same year with a median interval from death to notification of 7 days. In 2019, 94% had been notified by 4th September with a median interval of 6 days. In 2020, the median interval from death to notification for the deaths notified by 4 September was 4 days.

The data provided included LeDeR ID number, date of death, date of notification, sex, age at death, ethnicity, type of place of death, first part of postcode of place of normal residence, and COVID-19 status.

The COVID-19 questions were added to the notification process from 3 April 2020. A pre-existing question asked notifiers to report the cause of death if

they were able. During March 2020 a number of notifiers reported COVID-19 as a suspected or confirmed cause. Local area contacts, responsible for organising reviews have subsequently been asked to advise whether COVID-19 was a suspected or confirmed cause in all deaths occurring in 2020. For this report if the local contact has provided information this has been taken to be more reliable than that provided by notifiers. If not, the information from the notifier was used.

For the epidemic curve (figure 3.1) all deaths were included. For most of the report only deaths of adults are included. This is for consistency. There are no usable population data for calculating death rates for people with learning disabilities aged under 18 and the number of deaths was too small for such calculations to produce usable results.

Many analyses compare deaths in the epidemic period to deaths in the corresponding period in earlier years. For these, the epidemic period was taken to be 21 March to 5 June. The start point is clearer from the epidemic curve than the end point. The end point was a pragmatic choice reflecting the latest point for which reasonably complete data was available at the time the analysis was undertaken.

Completeness of LeDeR data

There is no mandatory requirement for deaths of people with learning disabilities to be reported to LeDeR. It depends on goodwill and wide publicity in a well networked community. Anyone can report deaths either through the LeDeR website or by contacting the LeDeR office at Bristol University. The team scrutinise notifications to identify multiple reports. The numbers of deaths notified stabilised in 2018 and 2019 but the overall number is significantly lower than would be expected based on estimates from the LDHC dataset (1,13).

Estimating the extent to which reporting of deaths to LeDeR is incomplete is critical both for the initial estimate of the total number of deaths with COVID-19 to 5 June and all subsequent calculations of rates of death per 100,000 population. Estimates of the gaps described above in reporting to the LDHC dataset are also critical to estimates of the overall number of deaths. These 2 sets of estimates are linked. Because of their central importance to many findings in this report, this calculation is set out in detail in tables A1 and A2. The calculations here are shown at national level. For the study, most calculations were done at CCG level to allow local populations and estimates of deaths to be calculated for NHS regions. The exceptions, where it was

necessary to undertake a single national calculation, are indicated in the following descriptions.

Table A1 covers estimating the size and structure of the population. Columns A and B show totals for the number of people on learning disabilities registers at the end of March 2019, and the numbers of deaths recorded in the year to March 2019 reported in the LDHC dataset. Deaths are likely to be almost completely recorded in this dataset and the learning disabilities register status of each deceased person is available. The total number of people on learning disabilities registers in practices contributing data to the LDHC dataset was 150,982 (column A total). A total of 1,959 deaths were recorded.

The annual QOF data returns for the same point in time indicate that, nationally, 297,174 people were on their GPs' learning disabilities register. LDHC had thus covered 50.8% of people on learning disabilities registers. Column C of the calculation shows the proportion of people on learning disabilities registers in each age and sex grouping used (calculated nationally). In column D, the missing 146,192 people on registers (297,174 minus 150,982) were shared between the age and sex groups in proportion to the population for whom these details were available. Column E shows the estimated population in each age and sex group, the sum of columns A and D.

The calculations for the number of deaths likely to have occurred is shown in table A2. The total numbers of deaths of people on learning disabilities registers is shown in table A1, column B. Column F of table A2 shows the age and sex-specific death rates per 1000 people with learning disabilities. These were calculated nationally, dividing column B in table A1 by column A in table A1. Using these, an estimate of the likely number of deaths in the missing population was calculated by multiplying the estimates of the number of missing registered people in column D of table A1 by the death rates for the people recorded in the LDHC dataset (column F). This was added to the number of deaths reported in the LDHC dataset to give the estimated total deaths of people on learning disabilities registers in column H. The total for this column suggests that a little under 3,860 people on learning disabilities registers are likely to have died in 2018 to 2019. Column I shows the numbers of deaths reported to LeDeR, for the same age and sex groupings, occurring in the year to the end of March 2019. Column J shows these numbers as a percentage of the expected numbers in column H. This is termed the 'completeness' of reporting.

The estimate of the completeness shows very different patterns for children and adults. For adults, reporting appears to have been most complete in the

younger age groups. It declined noticeably in the 3 oldest age groups (above age 55) for both sexes. The pattern for children was different, with numbers of deaths reported to LeDeR exceeding 5 times the expected number estimated from the LDHC dataset. This probably arises from 2 causes. As noted above, the LDHC dataset is a poor record of children and young adolescents with learning disabilities. This is clear from the fact that the number of people on learning disabilities registers in the 18 year interval from birth to age 17 is smaller than the number in the 7 year interval from 18 to 24 (column A). Deaths of people not on learning disabilities registers will therefore also not be recorded in the LDHC dataset. By contrast, childhood is the time when reporting to LeDeR is most secure. All deaths of children are subject to statutory child death reviews. Cross-reporting from these to LeDeR is an established process which happens almost automatically when a child death review identifies that a deceased child had learning disabilities.

For analytic purposes in this report the issue of incompleteness has been managed in 2 ways. A number of analyses report primarily on changes in numbers of deaths from 2018 and 2019 to 2020. For these analyses no adjustments have been made. In some analyses (table 3.1, figure 4.2, figure 4.5, table 4.1, table 5.1) rates per 100,000 population are calculated. For each of these calculations 2 results are presented. One uses the lowest possible estimate of the number of deaths of people with learning disabilities, the number reported to LeDeR. The other increases this figure by a factor assuming the observed notification rate of 65% applies across all adult age groups.

Table A1 Calculations to estimate the population of England with learning disabilities known to GPs by age and sex, and the completeness of reporting of deaths of people with learning disabilities to LeDeR. See text for explanation.

	A	B	C	D	E
Age / sex group	Population on learning disabilities registers	Deaths of people on learning disabilities registers	Proportion of learning disabilities register population in age /sex group (A /total A)	Missing population shared by age/sex groups (146192 x C)	Estimated total population on learning disabilities registers (A+D)
F00-17	6766	9	4.5%	6551.3	13317.3
F18-24	7878	24	5.2%	7628.1	15506.1
F25-34	12106	41	8.0%	11721.9	23827.9
F35-44	8480	40	5.6%	8211.0	16691.0
F45-54	9347	102	6.2%	9050.5	18397.5
F55-64	7857	208	5.2%	7607.7	15464.7
F65-74	4185	217	2.8%	4052.2	8237.2
F75pl	1790	188	1.2%	1733.2	3523.2
M00-17	14369	11	9.5%	13913.1	28282.1
M18-24	15507	37	10.3%	15015.0	30522.0
M25-34	20467	65	13.6%	19817.7	40284.7
M35-44	12400	49	8.2%	12006.6	24406.6
M45-54	12676	117	8.4%	12273.8	24949.8
M55-64	10425	296	6.9%	10094.3	20519.3
M65-74	5075	315	3.4%	4914.0	9989.0
M75pl	1654	240	1.1%	1601.5	3255.5
England	150982	1959		146192.0	297174.0
England Adults	129847	1939	86.0%	125727.5	255574.5

Table A2 Calculations to estimate the population of England with learning disabilities known to GPs by age and sex and the completeness of reporting of deaths of people with learning disabilities to LeDeR. See text for explanation.

	F	G	H	I	J
Age / sex group	Death rate per 1000 (B/A)	Estimated missing deaths (F x D)	Estimated total deaths (B + G)	Deaths notified to LeDeR in 2018-19	Estimated completeness of reporting (I / H)
F00-17	1.3	8.7	17.7	91	513.7%
F18-24	3.0	23.2	47.2	41	86.8%
F25-34	3.4	39.7	80.7	60	74.4%
F35-44	4.7	38.7	78.7	74	94.0%
F45-54	10.9	98.8	200.8	174	86.7%
F55-64	26.5	201.4	409.4	278	67.9%
F65-74	51.9	210.1	427.1	248	58.1%
F75pl	105.0	182.0	370.0	170	45.9%
M00-17	0.8	10.7	21.7	114	526.5%
M18-24	2.4	35.8	72.8	71	97.5%
M25-34	3.2	62.9	127.9	84	65.7%
M35-44	4.0	47.4	96.4	80	82.9%
M45-54	9.2	113.3	230.3	187	81.2%
M55-64	28.4	286.6	582.6	380	65.2%
M65-74	62.1	305.0	620.0	401	64.7%
M75pl	145.1	232.4	472.4	232	49.1%
England	13.0	1896.8	3855.8	2685	69.6%
England Adults	14.9	1877.5	3816.5	2480	65.0%

NHS England COVID-19 Patient Notification System

Data on COVID-19 deaths in hospital settings is taken from the NHS England COVID-19 Patient Notification System (2). This is one of the data sources set up early in 2020 specifically for managing the COVID-19 emergency. Tables were extracted of numbers of deaths by age group, sex and ethnic group, by age –group, sex and NHS region and by provider trust.

The data source contains records of all patients dying in hospital settings with a laboratory confirmation of the diagnosis of COVID-19 or a mention of this diagnosis among the certified causes of death. Since 24 March there has been a field in the dataset specifying whether or not the deceased patient had learning disabilities. For about a quarter of COVID-19 deaths records up to 5 June 2020 the learning disabilities status was either not entered or recorded as not known.

For most analyses in this report, these deaths with unknown learning disabilities status have been handled in 2 ways. The first approach, giving the lowest possible estimate of the number of deaths of people with learning disabilities is to assume that all deceased individuals with status not known did not have learning disabilities. They are thus all assigned to the not learning disabled group. The alternative approach used, which seems likely to be closer to reality, was to assign deaths with status not known to the learning disabilities and not learning disabled groups in proportion to the numbers with clearly reported status in those groups in each age and sex group.

Calculations of rates

Death rates in this report, are specified either as rates up to 5 June or rates in a specific shorter period. Death rates are normally calculated as deaths per unit population per year. If the observations on which they are based are more or less than a year, it is conventional to scale them up or down to this time period to facilitate comparison. This has not been done here because the set of deaths being reported on represent a distinct period of very high death rates for short duration.

Calculations of standardised rates use the 2013 European Standard Population (35).

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Prepared by: Gyles Glover

Published November 2020
PHE gateway number: GW-1687

PHE supports the UN Sustainable Development Goals

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Office for National Statistics

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Coronavirus (COVID-19) related deaths by disability status, England and Wales: 2 March to 14 July 2020

Comparison of deaths where the coronavirus (COVID-19) was mentioned on the death certificate by broad age group, sex and disability status, using linked census and mortality records on deaths registered up to 21 July 2020.

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Release date:
18 September 2020

Next release:
To be announced

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Main points

This provisional analysis, for the period 2 March to 14 July 2020, compares the risk of death involving the coronavirus (COVID-19) according to a person's disability status as recorded in the 2011 Census; people are counted as disabled if they said their daily activities were limited a little or limited a lot by a health problem or disability lasting or expected to last at least 12 months, in this data source.

- Disabled people (as defined) made up almost 6 in 10 (59%) of all deaths involving COVID-19 in this period; disabled people made up around 16% of the study population followed from the 2011 Census.
- Among all deaths involving COVID-19 of males aged 9 to 64 years in this period, the proportion made up by disabled people (those limited a little or limited a lot in their day-to-day activities) was smallest at 39%; among all deaths involving COVID-19 of females aged 65 years and over in this period, the proportion made up by disabled people was largest, at 67% of these deaths.
- Among both males and females aged 9 years and over, those who were either disabled and limited a lot or disabled and limited a little in 2011 had a statistically significant higher age standardised mortality rate (ASMR) of death involving COVID-19 in this period than those who were non-disabled; male and female disabled people who were limited a lot had a statistically significantly higher ASMR of death involving COVID-19 than disabled people who were limited a little.
- Disabled males whose activities were limited a lot at the 2011 Census had an overall age-standardised rate of death involving COVID-19 of 240.8 deaths per 100,000; for disabled females, the rate was 169.9 deaths per 100,000; the equivalent rates for males and females who were non-disabled in 2011 were 84.2 and 44.4 deaths per 100,000 respectively.
- After adjusting for region, population density, socio-demographic and household characteristics, the relative difference in mortality rates between those disabled and limited a lot and those non-disabled was 2.4 times higher for females and 2.0 times higher for males.
- Our research was based on linking deaths to the 2011 Census, the most timely data available, including people aged 9 years and over; we used a regression model to adjust for specific characteristics for people in private households at the time of the census; we aim to undertake further analysis that takes into account other characteristics such as pre-existing health conditions.

2 . Overview of COVID-19-related deaths by disability status

This article presents provisional analyses of deaths involving the coronavirus (COVID-19) by self-reported disability status, as collected in the 2011 Census in England and Wales. It includes deaths that occurred between 2 March and 14 July 2020, which were registered by 21 July 2020, providing an update to the previous article Coronavirus (COVID-19) related deaths by disability status, England and Wales: 2 March to 15 May 2020.

Disability is one of the protected characteristics under the Equality Act 2010. The population prevalence of disability in 2011 among those resident in private households, as measured by the 2011 Census, was 17%. More recent figures from the Family Resources Survey 2018 to 2019 (using a different measure of disability) (XLSX, 129KB) reported the prevalence of disability as 11.6 million people in England (21% of the population) and 0.8 million people in Wales (25% of the population). Among the study population of usual residents in private households in 2011 who were still alive on 2 March 2020, the population prevalence of disability was 16%.

Further analyses of deaths involving COVID-19 by other protected characteristics such as ethnicity will be published over the coming months.

Throughout this article, up to July 2020 refers to death occurrences between 2 March and 14 July 2020, with up to May 2020 referring to death occurrences between 2 March and 15 May 2020.

formation is available in the Data sources and quality section.

Breakdown of deaths involving COVID-19 by age, sex and disability status

The number of deaths involving the coronavirus (COVID-19) and their percentage distribution across disability categories among the study population to July 2020 is shown in Table 1. Disabled people (those limited a little or limited a lot) made up 6 in 10 (59.5%) of all deaths involving COVID-19 for the period to July 2020 (27,534 of 46,314 deaths). Disabled people made up around 16% of the study population followed from 2 March.

Table 1: Deaths involving COVID-19 by disability status: England and Wales, occurring between 2 March and 14 July 2020

Disability status	Number of COVID-19 deaths	Percentage of COVID-19 deaths	Number of all deaths	Percentage of all deaths
Disabled – limited a lot	14,032	30.3%	59,700	28.0%
Disabled – limited a little	13,502	29.2%	61,021	28.6%
Non-disabled – not limited	18,780	40.5%	92,796	43.5%
Total	46,314	100%	213,517	100%

Source: Office for National Statistics – Coronavirus (COVID-19) related deaths by disability status

Notes

1. Office for National Statistics (ONS) figures based on death registrations up to 21 July 2020 that occurred between 2 March and 14 July 2020 that could be linked to the 2011 Census for the coronavirus (COVID-19) rate of death.
2. Percentage totals do not add up to 100 because of rounding.
3. Deaths were defined using the International Classification of Diseases, 10th Revision (ICD-10). Deaths involving COVID-19 include those with an underlying cause, or any mention, of ICD-10 codes U07.1 (COVID-19, virus identified) or U07.2 (COVID-19, virus not identified). All causes are the total number of deaths registered during the same time period, including those that involved COVID-19.
4. Disability status was defined using the self-reported answers to the 2011 Census question: "Are your day-to-day activities limited because of a health problem or disability which has lasted, or is expected to last, at least 12 months? - Include problems related to old age" (Yes, limited a lot; Yes, limited a little; and No).

Breaking the deaths down further by age and sex, we see that deaths involving COVID-19 for the period up to July 2020 follow the pattern reported in previous Office for National Statistics (ONS) COVID-19 releases, of being more numerous for males at 54.6% (25,291 of 46,314 deaths) and in people aged 65 years and over (90.5% or 41,930 of 46,314 deaths) compared with those aged under 65 years (Table 2).

Amongst deaths of males aged 9 to 64 years, the proportion made up by disabled people (limited a lot or limited a little) was smallest at 38.5% (1,066 of 2,766 deaths). Amongst deaths of females aged 65 years and over, the proportion made up by disabled females was largest, accounting for 67.2% of the total (13,048 of 19,405 deaths).

Deaths involving COVID-19 by age, sex and disability status: England and Wales, occurring between 2 March and 14 July 2020

Disability status	Males		Females	
	Aged 9 to 64 years	Aged 65 years and over	Aged 9 to 64 years	Aged 65 years and over
Disabled – limited a lot	663	6,024	548	6,797
Disabled – limited a little	403	6,588	260	6,251
Non-disabled – not limited	1,700	9,913	810	6,357
Total	2,766	22,525	1,618	19,405

Source: Office for National Statistics – Coronavirus (COVID-19) related deaths by disability status

Notes

1. Office for National Statistics (ONS) figures based on death registrations up to 21 July 2020 that occurred between 2 March and 14 July 2020 that could be linked to the 2011 Census for the coronavirus (COVID-19) rate of death.

2. Deaths were defined using the International Classification of Diseases, 10th Revision (ICD-10). Deaths involving COVID-19 include those with an underlying cause, or any mention, of ICD-10 codes U07.1 (COVID-19, virus identified) or U07.2 (COVID-19, virus not identified). All causes are the total number of deaths registered during the same time period, including those that involved COVID-19.

3. Disability status was defined using the self-reported answers to the 2011 Census question; "Are your day-to-day activities limited because of a health problem or disability which has lasted, or is expected to last, at least 12 months? - Include problems related to old age" (Yes, limited a lot; Yes, limited a little; and No).

4 . Age-standardised mortality rates of death involving COVID-19 by disability status

Age-standardised mortality rates (ASMRs) allow populations with different age structures to be compared fairly. Disability is more common in older populations; therefore, it is necessary to adjust for population age structure in this way.

Age-standardised rates of deaths involving the coronavirus (COVID-19) among males and females aged 9 years and over per 100,000 of the population at risk are presented in Table 3. It shows that amongst both males and females age 9 years and over, those who were either disabled and limited a lot or disabled and limited a little in 2011 had a statistically significant higher rate of death involving COVID-19 than those who were non-disabled in the period to July 2020. Furthermore, male and female disabled people who were limited a lot had a statistically significant higher rate of death involving COVID-19 than disabled people who were limited a little.

Age-standardised mortality rates for deaths involving COVID-19 per 100,000 population with 95% confidence intervals by sex and disability status: England and Wales

Day	Males			Females		
	Rate	Lower 95% confidence limit	Upper 95% confidence limit	Rate	Lower 95% confidence limit	Upper 95% confidence limit
Disabled – limited a lot	240.84*	234.16	247.52	169.89*	164.33	175.45
Disabled – limited a little	150.09*	145.87	154.32	85.70*	83.00	88.40
Non-disabled – not limited	84.24	82.63	85.86	44.42	43.37	45.46

Source: Office for National Statistics – Coronavirus (COVID-19) related deaths by disability status

Notes

1. Office for National Statistics (ONS) figures based on death registrations up to 21 July 2020 that occurred between 2 March and 14 July 2020 that could be linked to the 2011 Census for the coronavirus (COVID-19) rate of death.
2. Percentage totals do not add up to 100 because of rounding.
3. Deaths were defined using the International Classification of Diseases, 10th Revision (ICD-10). Deaths involving COVID-19 include those with an underlying cause, or any mention, of ICD-10 codes U07.1 (COVID-19, virus identified) or U07.2 (COVID-19, virus not identified). All causes are the total number of deaths registered during the same time period, including those that involved COVID-19.
4. * indicates a statistically significantly higher rate compared with the Non-disabled – not limited category for the same sex.
5. Disability status was defined using the self -reported answers to the 2011 Census question: "Are your day-to-day activities limited because of a health problem or disability which has lasted, or is expected to last, at least 12 months? - Include problems related to old age" (Yes, limited a lot, Yes, limited a little; and No).

Figure 1: Males aged 65 years and over who were disabled and limited a lot had the highest age-standardised COVID-19 mortality rate at 860.8 per 100,000

Age-standardised mortality rates for deaths involving COVID-19, by sex, age group and disability status, England and Wales, 2 March to 14 July 2020

Notes:

Office for National Statistics (ONS) figures based on death registrations up to 21 July 2020 that occurred between 2 March and 14 July 2020 that could be linked to the 2011 Census for the coronavirus (COVID-19) rate of death.

2. Deaths were defined using the International Classification of Diseases, 10th Revision (ICD-10). Deaths involving COVID-19 include those with an underlying cause, or any mention, of ICD-10 codes U07.1 (COVID-19, virus identified) or U07.2 (COVID-19, virus not identified).

3. Age-standardised mortality rates (ASMRs) of COVID-19-related death can be interpreted as deaths per 100,000 population during the period of investigation.

4. Non-overlapping error bars denote a statistically significant difference in rates of death.

5. Disability status was defined using the self-reported answers to the 2011 Census question; "Are your day-to-day activities limited because of a health problem or disability which has lasted, or is expected to last, at least 12 months? - Include problems related to old age" (Yes, limited a lot; Yes, limited a little; and No).

Data download

ASMRs for deaths involving COVID-19 in the period to July 2020, amongst males and females aged 9 to 64 years and aged 65 years and over, are presented in Figure 1, to further explore the data and control for differences in population age structure.

The relative gaps in ASMRs between disabled and non-disabled males and females were largest amongst those aged 9 to 64 years. The largest relative gap was between females aged 9 to 64 years who were disabled and limited a lot who had a rate of death involving COVID-19 10.8 times greater than non-disabled females in this age group. Males aged 9 to 64 years who were disabled and limited a lot had a rate of death involving COVID-19 6.5 times greater than non-disabled males.

Relative gaps in ASMRs between non-disabled and disabled groups were smaller in the 65 years and over age group. Males aged 65 years and over, who were disabled and limited a lot, were 2.4 times more likely and females were 3.1 times more likely to die than their counterparts who were non-disabled.

The ASMRs for males and females were statistically significantly higher for those aged 65 years and over, than for those aged 9 to 64 years, for all disability status categories. Even within the disabled and limited a lot category, there was a sizable variation between the younger and older age groups considered. For example, disabled and limited a lot males aged 65 years and over had a mortality rate of 860.8 per 100,000 compared with 70.8 per 100,000 for the younger age group, a rate 12.2 times greater.

Females across all age and disability groups had statistically significant lower ASMRs than males. The lowest rate was amongst females aged 9 to 64 years identifying as non-disabled, at 5.1 deaths per 100,000 up to July 2020.

Non-disabled females had the largest difference in rates between the older and younger age groups, with rates for non-disabled females aged 65 years and over (187.9 per 100,000), 37.2 times higher than those aged 9 to 64 years (5.1 per 100,000). The highest rate amongst females was for those aged 65 years and over who were disabled and limited a lot (589.6 per 100,000). This group were 10.8 times more likely to die than those disabled and limited a lot aged 9 to 64 years (54.8 per 100,000).

The relative differences between groups highlighted in this section are similar to those reported in the period to May 2020. Note that comparing absolute differences in rates for the period considered in this article to July 2020 and the period to May 2020 provided in the previous article should be made with caution given the longer time period at risk now considered.

isability status differences in deaths involving COVID-19, usted for socio-demographic factors

ferences in rates of death involving the coronavirus (COVID-19) may be driven by factors related to the risk of being infected, susceptibility to more severe symptoms, and adverse outcomes, such as the inability to survive once infected by the virus.

Factors affecting the risk of infection are likely to include geographic location and population density, living arrangements, socio-economic profile and working conditions. Differences in these characteristics, and what they may imply for current circumstances, may also be associated with the risk of death once infected. More information on how these factors vary across disability status in the 2011 Census can be found in the technical appendix[1]. It is important to note that this analysis has been undertaken at the population level and will not relate to all people's individual circumstances and backgrounds.

We used Cox proportional hazards regression models to estimate whether the rate of death involving COVID-19 remains greater among the disabled population than the non-disabled population (as classified at Census Day 2011), after taking account of a number of geographic, demographic, socio-economic, living arrangement and exposure measures derived from the 2011 Census. The statistical models are explained in the technical appendix.

It is important to account for these factors to enable us to quantify how much of the excess mortality of disabled people can be explained by differences in these factors and how much remains unexplained. The modelling analyses are based on the population enumerated in private households in the 2011 Census. Those resident in communal establishments in 2011 were excluded because these census enumerations did not contain socio-demographic information used in the modelling.

In Figure 2, we show how the risk of death involving COVID-19 varied by disability status for males and females. We report the hazard ratios for each disability status relative to the non-disabled group, after adjusting for age and for the full range of characteristics described. The hazard ratio is a measure of how much greater or lesser was the rate of death involving COVID-19 in the two disabled groups, those whose day-to-day activity was limited a little and those limited a lot, compared with non-disabled people (no limitation with day-to-day activities) used as the reference group.

A hazard ratio greater than one indicates a greater rate of death involving COVID-19 than the reference group, while a hazard ratio less than one indicates a lower rate of COVID-19 mortality than the reference group. In this analysis, using those non-disabled as the reference group, hazard ratios greater than one denote an increased rate of death among disabled people.

The rate of death generally, and specifically death involving COVID-19, is closely related to age. After adjusting for age, males and females from both disabled groups were at greater risk of death involving COVID-19 up to July 2020 compared with those non-disabled. Disabled males whose day-to-day activities were limited a lot were 2.6 times more likely to die in this period, while those whose daily activities were limited a little were 1.8 times more likely to die, compared with the rate of death involving COVID-19 among those who were non-disabled. The corresponding hazard ratios for females were 3.0 and 1.9, respectively.

Comparing with the shorter time period to May 2020, in the period to July 2020, after adjusting for age, the same (to one decimal place) hazard ratios were noted for males and females whose daily activities were limited a little. The hazard ratio for the period to May 2020 was slightly higher for females whose day-to-day activities were limited a lot, at 3.2 for the shorter time period, and slightly lower for males whose day-to-day activities were limited a lot, at 2.5, although those differences were not statistically significant.

...: The risk of death for females who were disabled and limited a lot was 2.4 times ...than non-disabled females after adjusting for age and other factors

...d ratios of death involving COVID-19 by disability status and sex, England and Wales, 2 March to 14 July

Notes:

1. Cox proportional hazards models adjusting for age and the square of age. Fully adjusted models also include region, population density, area deprivation, household composition, socio-economic position, highest qualification held, household tenure, multigenerational household flags and occupation indicators (including key workers and exposure to others) based on Census 2011.
2. Office for National Statistics (ONS) figures based on death registrations up to 21 July 2020 that occurred between 2 March and 14 July 2020 that could be linked to the 2011 Census for the coronavirus (COVID-19) rate of death.
3. Deaths were defined using the International Classification of Diseases, 10th Revision (ICD-10). Deaths involving COVID-19 include those with an underlying cause, or any mention, of ICD-10 codes U07.1 (COVID-19, virus identified) or U07.2 (COVID-19, virus not identified).
4. Risk of death between 2 March and 14 July 2020.
5. Hazard ratios are compared to the reference category of no disability.
6. Disability status was defined using the self-reported answers to the 2011 Census question, "Are your day-to-day activities limited because of a health problem or disability which has lasted, or is expected to last, at least 12 months? - Include problems related to old age" (Yes, limited a lot; Yes, limited a little; and No).

Data download

The fully adjusted model illustrates the effect on relative differences in rates of death after controlling for region, population density, area deprivation, household composition, socio-economic position, highest qualification held, household tenure, multigenerational household and occupation (including key workers and exposure to others) in 2011. Therefore, the fully adjusted results show relative differences between non-disabled and disabled groups that are not statistically associated with any of the factors listed by which members of the groups might differ.

Adjusting for the factors noted substantially reduces the estimated risk of death involving COVID-19 for disabled people relative to the non-disabled group. More information on how the hazard ratios change when adjusting for different sets of characteristics can be found in the Model diagnostics dataset. After full adjustment, the rate of death involving COVID-19 for the period up to July 2020 was 1.6 and 2.0 times greater for disabled males whose day-to-day activities were limited a little or limited a lot, respectively, compared with those who were non-disabled. The corresponding hazard ratios for females were 1.6 and 2.4 times greater, respectively.

Comparing with the shorter time period up to May 2020, after fully adjusting the model, similar hazard ratios were noted for males whose day-to-day activities were limited a lot and females in either disabled group, as in the period up to July 2020. The hazard ratio for the period up to May 2020 was slightly lower than in the period up to July 2020 for males whose day-to-day activities were limited a lot, at 1.9 for the shorter period. Although this difference is not statistically significant.

This means a sizeable part of the difference in COVID-19 mortality between disabled and non-disabled groups is explained by the different circumstances in which members of those groups are known to live, such as domains of socio-economic disadvantage. However, these factors do not explain the entirety of the difference, suggesting that other unmeasured characteristics associated with disability are involved that require further investigation.

...from the different disability groups may differ in terms of socio-economic characteristics or health ...not included in our model; these differences may relate directly or indirectly to the limitations on activity ...enced by disabled people

...justment for demographic and socio-economic profile has limitations since the characteristics we use were ...rieved from the 2011 Census. Therefore, these may not accurately reflect the study population's current ...umstances in 2020. In particular, the disability status of individuals is likely to change over this period, with ...some people who identified as non-disabled at the time of the 2011 Census moving into disability since then (with the opposite also being possible). The heterogeneity of the "non-disabled group" in 2011 regarding current disability status is likely to underestimate the true difference in risk of dying from COVID-19 between disabled and non-disabled people.

Some disabled people may be more likely to suffer from pre-existing health conditions that are associated with worse outcomes among those infected by COVID-19, which we will aim to take account of in future analyses. The percentage of people in the study population who died prior to March 2020 is also greater for people who identified as disabled in the 2011 Census (21.8% and 39.8% of those whose day-to-day activities are limited a little or limited a lot, respectively) compared with those who identified as non-disabled (2.9%), and it is possible that disabled people who survived until March 2020 have different characteristics to those who died before then.

Notes for: Disability status differences in deaths involving COVID-19, adjusted for socio-demographic factors

1. Please note that the hazard ratios found in the technical appendix relate to the period up to May 2020.

6 . Coronavirus (COVID-19) related deaths by disability status data

Counts of deaths involving COVID-19 and all deaths by disability status, England and Wales
Dataset | Released on 18 September 2020
Counts of coronavirus (COVID-19) related deaths by disability status and age group in England and Wales.

Counts of deaths involving COVID-19 and all deaths by disability status, Wales
Dataset | Released on 18 September 2020
Counts of coronavirus (COVID-19) related deaths by disability status and age group in Wales.

Model estimates of deaths involving COVID-19 by disability status, England and Wales
Dataset | Released on 18 September 2020
Hazard ratios of death involving the coronavirus (COVID-19), by disability status and sex, in England and Wales.

Rates of deaths involving COVID-19 by disability status, England and Wales
Dataset | Released on 18 September 2020
Age-standardised mortality rates (ASMRs) for coronavirus (COVID-19) related deaths, by disability status and other characteristics, in England and Wales.

7 . Glossary

Standardised mortality rates

Age-standardised mortality rates (ASMRs) are used to allow comparisons between populations that may contain different proportions of people of different ages. The 2013 European Standard Population is used to standardise

Cox proportional hazards regression model

The Cox proportional hazards regression model is a multiple regression procedure that measures the association between a time-to-event outcome and a characteristic of interest such as disability, while adjusting for other characteristics expected to also be associated with the outcome.

Hazard ratio

A hazard ratio is a measure of the relative differences in the instantaneous rate of mortality between groups. A hazard ratio greater than one indicates the rate of mortality is higher, and likewise, less than one lower in the population group under study compared with a reference group.

Coronaviruses

The World Health Organization (WHO) defines coronaviruses as "a large family of viruses that are known to cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS)". Between 2001 and 2018, there were 12 deaths in England and Wales due to a coronavirus infection, with a further 13 deaths mentioning the virus as a contributory factor on the death certificate.

Coronavirus (COVID-19)

COVID-19 refers to the "coronavirus disease 2019" and is a disease that can affect the lungs and airways. It is caused by a type of coronavirus. Further information is available from the WHO.

Disability

To define disability in this publication, we refer to the self-reported answers to the 2011 Census question, "Are your day-to-day activities limited because of a health problem or disability which has lasted, or is expected to last, at least 12 months? - Include problems related to old age" (Yes, limited a lot or yes, limited a little or no). This is slightly different to the current Government Statistical Service (GSS) harmonised "core" definition; this identifies as "disabled" a person who self-reports having a physical or mental health condition or illness that has lasted or is expected to last 12 months or more that reduces their ability to carry-out day-to-day activities.

The GSS definition is designed to reflect the definitions that appear in legal terms in the Disability Discrimination Act 1995 and the subsequent Equality Act 2010.

Statistical significance

The statistical significance of differences between the release are determined based on non-overlapping confidence intervals.

Data sources and quality

This article presents provisional analyses of deaths involving the coronavirus (COVID-19) by self-reported disability status, as reported in the 2011 Census in England and Wales. It includes deaths that occurred between 2 March and 14 July 2020, which were registered by 21 July 2020, providing an update to the previous article Coronavirus (COVID-19) related deaths by disability status, England and Wales: 2 March to 15 May 2020.

Throughout this article, up to July 2020 refers to death occurrences between 2 March and 14 July 2020, with up to May 2020 referring to death occurrences between 2 March and 15 May 2020.

As disability status is not recorded on the death certificate, this information was retrieved through record linkage of death registrations to the 2011 Census along with other socio-demographic factors.

The 2011 Census question asked:

"Are your day-to-day activities limited because of a health problem or disability which has lasted, or is expected to last, at least 12 months? Include problems related to old age?"

- Yes, limited a lot
- Yes, limited a little
- No

Those responding that their day-to-day activities were "limited a lot" or "limited a little" were classified as disabled for the purposes of this analysis. Currently, we do not have data sources that will allow us to analyse mortality statistics by learning disabilities or any other specific type of disability.

While data from the 2011 Census are now nine years old, they are still the best currently available for large-scale analyses. Despite this, because of changes in disability status, it is likely that the number of people who are recorded as having an activity-limiting condition is now an underestimate, because those not limited in 2011 may have developed a long-term health condition over the past nine years that limits their activities or any existing health condition may have worsened in severity causing them to become limited. While transitions out of activity limitation are also possible, this is a less likely effect bearing in mind that reported disability tends to increase with age. As such, these contrasts should be treated as conservative estimates of differences.

Analyses have been restricted to those aged 9 years and over because children aged under 9 years would not have been born and therefore included in the 2011 Census. Immigrants entering the country since the 2011 Census are also excluded.

For estimation of relative differences in rates of death in our modelling, we have restricted the analyses to usual residents enumerated in private households at Census 2011. However, for counts and age-standardised mortality rates we have additionally included those resident in communal establishments in 2011. More details on the data used can be found in the technical appendix.

Related links

Coronavirus (COVID-19) latest analysis and data
Webpage | Updated as and when data become available
Latest data and analysis on coronavirus (COVID-19) in the UK and its effect on the economy and society

Deaths registered weekly in England and Wales, provisional
Bulletin | Released weekly
Provisional counts of the number of deaths registered in England and Wales, including deaths involving the coronavirus (COVID-19) pandemic, by age, sex and region, in the latest weeks for which data are available.

Coronavirus and the latest indicators for the UK economy and society
Bulletin | Released weekly
Early experimental data on the impact of the coronavirus (COVID-19) on the UK economy and society. These faster indicators are created using rapid response surveys, novel data sources and experimental methods.

Coronavirus and the social impacts on disabled people in Great Britain: July 2020
Article | Published 20 August 2020
The social impacts of the coronavirus pandemic on disabled people in Great Britain based on indicators from the Opinions and Lifestyle Survey.

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F.2

F.No. 34-03/2021-DD-III

भारतसरकार/ Government of India

दिव्यांगजनसशक्तिकरणविभाग

Department of Empowerment of Persons with Disabilities (Divyangjan)

सामाजिकन्यायऔरअधिकारितामंत्रालय/ Ministry of Social Justice & Empowerment

पाँचवातल, बीविंग, पंडितदीनदयालअंत्योदयभवन , सीजीओकॉम्प्लेक्स, लोधीरोड, नईदिल्ली -110003

5th Floor, B Wing, Pt. DeendayalAntyodayaBhawan, CGO Complex, New Delhi-110003

Dated: 26.04.2021

OFFICE MEMORENDUM

Subject: Priority and preference to Persons with Disabilities in testing, treatment and vaccination of corona virus - reg

The undersigned is directed toforward therewith a copy of representation dated 22.04.2021 received from National Federation of Blind, Delhi alleging that PwDs including persons with visual impairments have to stand in long queue for the purpose of testing, vaccination and treatment for COVID19 induced ailments.

2. In this regard, attention is invited to Section 25 (1)(c) of the RPwD Act, 2016 which mandates priority in attendance and treatment. M/o Health and Family Welfare is therefore requested to issue appropriate instructions to State/UT health authorities and healthcare institutions under its control to ensure that special provisions be made in COVID 19 testing, vaccination and treatment centers for priority in attending to and treatment of PwDs.

(D.K. Panda)
Under Secretary to the Govt. of India
Tel: 24369059

Encl: As Above

M/o Health and Family Welfare
[Shri Lav Agarwal, Joint Secretary]
NirmanBhawan, New Delhi -11
Email: alav@ias.nic.in

CC to:
National Federation of the Blind, Delhi, email: nfbsec.g@gmail.com

WHO SAGE ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES IN THE CONTEXT OF LIMITED SUPPLY

An approach to inform planning and subsequent recommendations based upon epidemiologic setting and vaccine supply scenarios

Version 1.1
13 November 2020

World Health Organization

Contents

Acknowledgements

The WHO SAGE Roadmap for prioritizing the use of COVID-19 vaccines in the context of limited supply was prepared by the SAGE Working Group on COVID-19 vaccines. The drafting of the Roadmap was led by Saad B. Omer, Ruth Faden, Sonali Kochhar, David Kaslow and Sarah Pallas with input from the members of the Public Health Objectives Subgroup (Folake Olayinka, Muhammed Afolabi, Celia Alpuche-Aranda, Hyam Bashour, David Durrheim, Sonali Kochhar, Peter G. Smith, Yin Zundong, Peter Figueroa and Helen Rees) and Annelies Wilder-Smith and Joachim Hombach from the WHO Secretariat, with support of Matthew A. Crane from the Johns Hopkins University School of Medicine. Hanna Nohynek leads the SAGE Working Group on COVID-19 vaccines.

Abbreviations

Allocation Framework	fair allocation mechanism for COVID-19 vaccines through the COVAX Facility
COVAX	COVID-19 Vaccines Global Access
COVID-19	coronavirus disease 2019
NITAG	National Immunization Technical Advisory Group
Prioritization Roadmap	WHO SAGE roadmap for prioritizing uses of covid-19 vaccines in the context of limited supply
SAGE	Strategic Advisory Group of Experts on Immunization
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
RITAG	Regional Immunization Technical Advisory Group
Values Framework	WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination
YLL	years of life lost
WHO	World Health Organization

Introduction

As countries prepare to implement their respective coronavirus disease 2019 (COVID-19) vaccination programmes, the Strategic Advisory Group of Experts (SAGE) on Immunization of the World Health Organization (WHO) is undertaking a three-step process to provide guidance for overall programme strategy as well as vaccine-specific recommendations.

Step 1: A Values Framework. The *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination* (1), issued on 14 September 2020, outlines the general principles, objectives and related (unranked) target groups for prioritization of COVID-19 vaccines.

Step 2: Roadmap for prioritizing uses of Covid-19 vaccines (Prioritization Roadmap) (this document). To support countries in planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability and epidemiologic settings. The Roadmap will be updated, as necessary, to accommodate the dynamic nature of the pandemic and evolving evidence about vaccine impact.

Step 3: Vaccine-specific recommendations: As market-authorized vaccines become available, specific recommendations for the use of these vaccines will be issued. These recommendations may be updated as additional evidence of effectiveness and safety of market-authorized vaccines (as well as other interventions) becomes available, and as epidemiologic and other contextual conditions evolve.

Rationale

Given the urgency and wide-ranging effects of the COVID-19 pandemic, SAGE has developed an approach to help inform deliberation around the range of recommendations that may be appropriate under different epidemiologic and vaccine supply conditions. The SAGE consensus is that currently available evidence is too limited to allow any recommendations for use of any specific vaccine against COVID-19 at this time (7 October 2020). This document should be regarded as a Roadmap for planning purposes only.

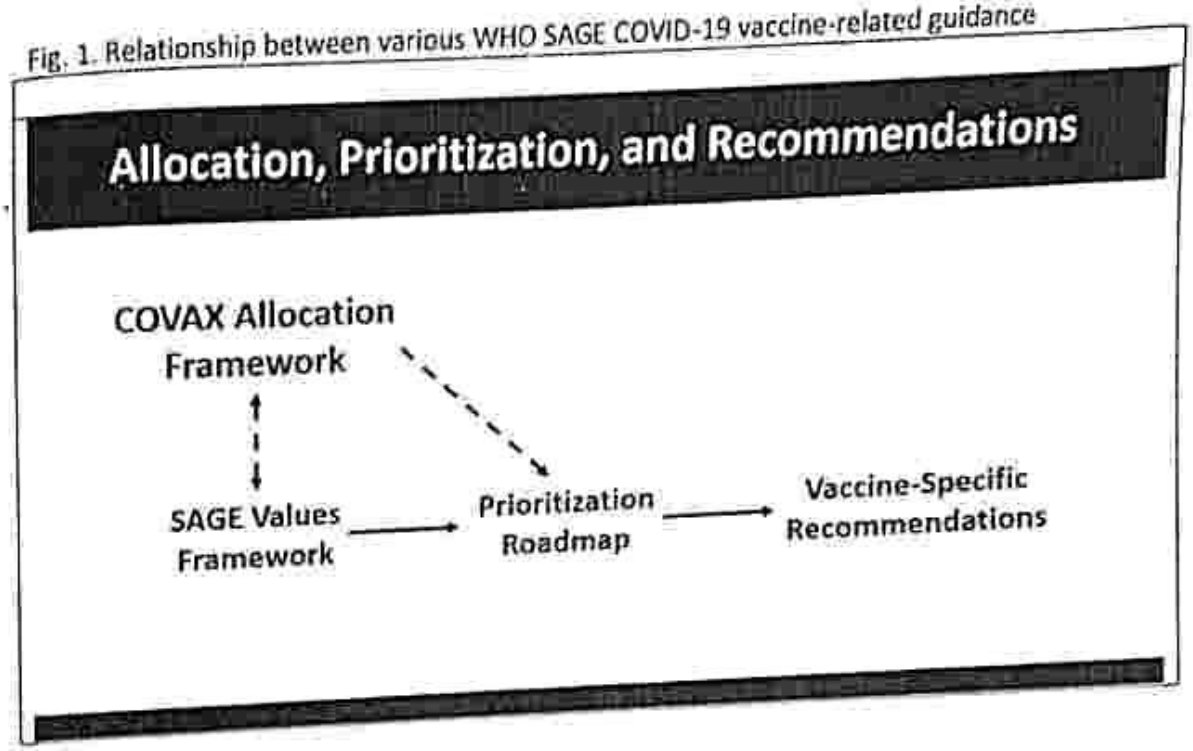
This Roadmap builds on the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*. The Values Framework listed over 20 population subgroups that, if vaccine use needed to be prioritized because of limited supply, would advance one or more of its principles and objectives. The Values Framework did not rank the subgroups in any order. Specific priority group recommendations for each vaccine product as it becomes authorized for use will require the integration of these ethical principles detailed in the Values Framework with evidence and information about: i) the status of the pandemic in the proposed implementation area (that is, the epidemiologic setting in terms of the degree of ongoing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission and COVID-19 burden); ii) the amount and timing of vaccine supply and availability, respectively; iii) specific product characteristics of the available vaccine(s); and iv) the benefit–risk assessment for the different population subgroups at the time vaccination is being considered for deployment; as well as other standard criteria used in developing SAGE recommendations (for example, feasibility, acceptability and resource use). These factors, together with the Values Framework, should guide the appropriate public health strategy for vaccine deployment of specific vaccines.

To assist in developing recommendations for use of vaccines against COVID-19, SAGE proposes a Prioritization Roadmap of COVID-19 vaccines that considers priority groups for vaccination

based on epidemiologic setting and vaccine supply scenarios. These use cases are also set in the context of the overall public health strategy for each epidemiologic setting (Table 1).

This Roadmap is intended to serve as guidance on preparing for vaccine prioritization decisions within countries. Although the Values Framework does include the principle of global equity, this Roadmap does not directly address global allocation decisions. A COVAX Facility allocation mechanism for countries participating in the COVAX Facility has been proposed *(2)*. Fig. 1 shows how it aligns with this Roadmap and the Values Framework.

Fig. 1. Relationship between various WHO SAGE COVID-19 vaccine-related guidance



Process of Roadmap development

The Roadmap builds on the population subgroups identified in the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination* as significant for advancing the Framework's principles and objectives. After prioritization exercises by a subgroup of the SAGE Working Group on COVID-19 Vaccines, a draft of the prioritization table was developed and then critiqued by the full Working Group that includes the chairpersons of all six Regional Immunization Technical Advisory Groups (RITAGS) as well several SAGE members. The draft table was then revised and reviewed multiple times. A similar process was used to develop the narrative sections of the Roadmap. Prioritization took account of emerging modelling information exploring the effectiveness and optimal impact of different vaccination strategies and best available epidemiologic information from academic literature as well as various surveillance organizations. A penultimate round of review by multiple SAGE members resulted in further substantive changes to the Framework, followed by a final review by the full SAGE committee.

Guiding considerations

The following considerations guided the development of this Roadmap.

- This Roadmap must remain fully aligned with the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination* that preceded it.

- To be useful in driving discussions at regional and national levels, the Roadmap needs to be kept as straightforward and concise as possible.
- The Roadmap may be revisited through i) rolling review as new information becomes available; and ii) ongoing dialogue with RITAGs and National Immunization Technical Advisory Groups (NITAGs).

Key assumptions

- The Roadmap assumes any vaccine deployed is fully licensed and has met all the minimal or critical criteria in *WHO Target Product Profiles (TPP) for COVID-19 vaccines (3)*. Less conclusive evidence on benefit–risk, as expected for an emergency-authorized product, might lead to more restricted recommendations.
- The current degree of uncertainty regarding age-independent vaccine efficacy of any specific vaccine was considered (for example, a scenario in which the vaccine is assumed to have the same efficacy at all ages, and another scenario in which the vaccine is assumed to have much lower efficacy in older adults). However, the Roadmap relies on the underpinning assumption, supported by current modelling results, that, given the many-fold higher mortality rate among older individuals *(4, 5)*, even a vaccine with relatively low efficacy in older adults would not significantly change the recommendations for priority use cases in older populations *(6–8)*. If however it were determined that vaccine efficacy in older adults relative to other age groups were so low that individual protection and public health impact became significantly suboptimal, the individuals in older age groups in each scenario would likely be moved to a lower priority use case.
- Similarly, it was assumed that there would not be substantive differences in vaccine efficacy in subgroups (for example, people with comorbidities that increase the risk of severe COVID-19 such as HIV-positive status).
- The Roadmap assumes that non-pharmaceutical interventions are in place to varying degrees as vaccines are introduced and coverage expands. The Roadmap further assumes that vaccine efficacy will not deteriorate if use of non-pharmaceutical interventions is relaxed.
- Although a vaccine's effect on reducing transmission is an important consideration in the recommendations for use, direct evidence of impact on transmission will likely not be available when the first vaccines are authorized for use. The Roadmap assumes that at some point demonstrated evidence of vaccine effectiveness in reducing transmission will be available, sufficient to justify prioritizing vaccination of some groups on the basis of their role in transmission.
- The Roadmap does not account for variation in population seropositivity rates or existing degree of protection within countries or communities which may have already experienced a high degree of community transmission.
- Prioritization exercises undertaken for development of this Roadmap did not directly take account of severe disease, as the risk of this will be closely correlated with the risk of death. Similarly, long-term sequalae from SARS-CoV-2 infection have not been taken into account as evidence on chronic morbidity is still emerging.

Epidemiologic setting scenarios

The epidemiologic setting scenarios used here take into consideration the relative benefits and potential risks of vaccination. Moreover, the public health strategy for use of vaccines

depends upon the burden of disease and on the local epidemiology, particularly the incidence rate of infection in a setting at the time vaccination is being contemplated for deployment. The three proposed broad epidemiologic settings are: (i) Community Transmission, (ii) Sporadic Cases or Clusters of Cases, and (iii) No Cases (Table 1) *(9)*.

Vaccine supply scenarios

As sufficient vaccine supply will not be immediately available to immunize all who could benefit from vaccination, three scenarios of constrained vaccine supply were considered: a Stage I scenario of very limited vaccine availability (ranging from 1–10% of each country's total population) for initial distribution; a Stage II scenario as vaccine supply increases but availability remains limited, (ranging from 11–20% of each country's total population); and a Stage III scenario as vaccine supply reaches moderate availability (ranging from 21–50% of each country's total population). How each of these three vaccine supply scenarios could be considered in recommendations for use in priority groups is illustrated in Table 1.

The Roadmap recognizes that many countries' prioritization decisions will be tied, in part or in whole, to vaccine distribution through the COVAX Facility. Stages I and II in the Roadmap correspond to the Phase 1 supply of up to 20% of each country's population detailed in the latest draft of the WHO *Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility*. The Roadmap's Stage III scenario aligns with the Allocation Framework's Phase 2 supply of more than 20% population coverage (Annex 1).

Overall public health strategies by epidemiologic setting and vaccine supply stage

SAGE recommends overall public health strategies, grounded in the Values Framework, for each of the three epidemiologic scenarios (Table 1). The strategies accommodate the dynamic nature of vaccine supply and epidemiologic conditions in each country.

Community Transmission setting: When vaccine supplies are severely constrained, what is feasible to achieve with limited vaccine availability justifies an initial focus on direct reduction of morbidity and mortality (Annex 2) and maintenance of most critical essential services, while considering reciprocity towards groups that have been placed at disproportionate risks to mitigate consequences of this pandemic (for example, front-line health workers). As vaccine supplies increase, depending on the vaccine characteristics, the strategy expands to reduction in transmission to further reduce disruption of social and economic functions. Special attention is paid to functions that disproportionately impact children (see below) and to the reduction of morbidity and mortality in disadvantaged groups, in keeping with the principles of the SAGE Values Framework.

Sporadic Cases or Clusters of Cases setting: When vaccine supplies are severely constrained, the initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services, and reciprocity, remains. However, in contrast with the Community Transmission epidemiologic setting, this initial focus is concentrated in locations with high transmission or anticipated high transmission. In addition, some vaccine is allocated for emergency reserve use for outbreak response or mitigation (for example, for localized outbreaks). Special attention to reduction of morbidity and mortality of disadvantaged groups in areas of high or anticipated high transmission is maintained. As vaccine supplies increase,

the strategy expands to substantially control transmission and further reduce disruption of social and economic functions.

No Cases setting: This epidemiologic setting applies to countries that have managed to stop transmission through non-pharmaceutical interventions and border controls. When vaccine supplies are severely constrained, the initial focus is on prevention of community transmission from importation of cases, and reciprocity to critical workers, particularly front-line health workers. As vaccine supply increases, older adults, the highest risk group for severe disease and death, are included to minimize harm should epidemic conditions change suddenly. Also, as vaccine supply increases, the strategy expands to preserve control of transmission and, if possible, to reduce reliance on burdensome non-pharmaceutical interventions.

Priority uses of COVID-19 vaccines

The rationale for the inclusion of each prioritized vaccine use case based upon population subgroup is anchored in the Values Framework principles and objectives. For each priority group, the Values Framework objective(s) that would be supported by prioritizing this population for vaccination are indicated by parenthetical abbreviations after the population description (for example, A1); the legend that links these abbreviations to the objectives is provided below Table 1.

While a detailed explanation of the rationale for each of the priority groups is beyond the scope of this document, three examples of rationales are provided in Box 1.

Box 1. Three examples of rationales for priority uses of COVID-19 vaccines

Example 1. Health workers at high to very high risk of becoming infected and transmitting SARS-CoV-2 in the Community Transmission epidemiologic setting

For the Community Transmission epidemiologic setting, health workers at high to very high risk of becoming infected and transmitting SARS-CoV-2 are included in Stage Ia. There are three reasons, linked to the Values Framework, supporting this prioritization. First, protecting these workers protects the availability of a critical essential service in the COVID-19 pandemic response. Also, the indirect health effects of the pandemic beyond COVID-19 are likely to be much worse if such services are compromised or overwhelmed. Second, evidence suggests that health workers are at high risk of acquiring infection and possibly of morbidity and mortality *(10, 11)*. There is also a risk of onward transmission to people who are also at high risk of serious COVID-19 outcomes. Third, prioritization of these workers is also supported by the principle of reciprocity; they play critical roles in the COVID-19 response, working under intense and challenging conditions, putting not only themselves but also potentially their households at higher risk for the sake of others.

There are also pragmatic reasons for prioritizing health workers at high to very high risk of infection. Health workers already interact directly with health systems, which should facilitate effective deployment of a vaccine programme, particularly including if two or more doses need to be administered. Launching a vaccine programme with a relatively accessible target population will allow more time for the development of delivery mechanisms to other priority groups.

In a second step (Stage Ib), older adults defined by age-based risk specific to country or region are included.

Example 2. Sociodemographic groups at significantly higher risk of severe disease or death

For the Community Transmission epidemiologic setting, sociodemographic groups at significantly higher risk of severe disease or death are included in Stage II. The reasons for this prioritization are grounded in the principles of equal respect and equity.

In keeping with the overall public health strategy that places an initial focus on direct reduction of mortality and morbidity, groups with comorbidities or health states that put them at significantly higher risk of severe disease or death are prioritized to Stage II. However, there are other groups in the population who may be at just as high a risk of these severe outcomes but who are not captured in a prioritization solely by comorbidities. These groups disproportionately include those who are systematically disadvantaged with respect to social standing and economic and political power. In many contexts, disadvantaged groups are more likely to experience a higher burden of infection and consequent COVID-19 because of crowded work or living conditions over which they have no effective control *(12–15)*, as well as a higher prevalence of background states of poor health that increase their risk of severe COVID-19 *(16)*. They may also have less access to appropriate health care necessary for the diagnosis of high-risk conditions such as heart failure or chronic kidney disease *(17)*. Some individuals in these groups would likely qualify for prioritization if their comorbidities were known or ascertainable, but because of inequitable access to health care their conditions often will be undiagnosed and untreated.

Which disadvantaged sociodemographic groups are at significantly higher risk of severe disease or death will vary from country to country. In many contexts, the evidence of elevated risk for COVID-19 severe disease and death will be lacking or less clear than for the risk factors like age or comorbidities. Policy-makers may have to decide which disadvantaged groups are likely to be sufficiently burdened by COVID-19 to include in Stage II. While broader efforts must be made to reach out and identify risks among disadvantaged groups, these decisions may have to be based on reasonable assumptions about differential impact inferred from other relevant contexts, including past public health emergencies *(18)*. Table 1 provides examples of groups that, depending on the country context, may fall under this prioritization category.

Example 3. Social/employment groups at elevated risk of acquiring and transmitting infection because they are unable to effectively physically distance

For the Community Transmission epidemiologic setting, social/employment groups at elevated risk of acquiring and transmitting infection because they are unable to effectively physically distance are included in Stage III. There is considerable overlap in the groups that should be considered in this category and the Stage II sociodemographic groups category just discussed. The relevant difference is that for some disadvantaged groups there may not be good reasons to conclude that they are at significantly elevated risk of severe disease and death (and thus that they do not qualify under Stage II). However, these groups may nevertheless still be at increased risk (if not significantly increased risk) of severe COVID-19 due to the reasons related to inequity discussed above. Groups that have no choice but to work without physical distancing or access to personal protective equipment, or no choice but to live in high-density homes in high-density neighbourhoods fall into this category *(19, 20)*. They are disadvantaged relative to other groups in the population who benefit more easily and more significantly from non-pharmaceutical interventions, both in terms of their own risk and in terms of onward transmission to loved ones and co-workers. Incarcerated people also fall into this category, although the rationale is somewhat different. Even if the restriction of their liberty is justified, that does not justify leaving unaddressed the elevated risk associated with being incarcerated.

In an ideal world, policy-makers could clearly distinguish, based on evidence regarding level of risk, which disadvantaged groups fall under Stage II criteria and which under Stage III criteria. In the real world, these decisions may have to be made with only limited relevant data. Adherence to the principles of equal respect and equity will require a careful assessment to ensure that all relevant sociodemographic groups are given equal consideration for both Stages.

How staging of priority groups relates to group size

The staging of priority groups is sequential. If there is insufficient vaccine supply to cover the priority groups in Stage I, the intention is that all these groups are offered vaccine before groups enumerated in Stage II.

With the exception of Stage Ia and Stage Ib, the priority groups within a vaccine supply stage are not ordered for prioritization. The assignment of priority groups was based on assumptions about the size of different priority groups in high-, middle- and low-income country settings. For some priority groups, even estimates of the sizes of different groups were not available. Considerable national variation is expected. In some countries, the amount of vaccine

projected for a vaccine supply stage may be insufficient to cover all the priority groups assigned to that stage and countries will have to prioritize groups within stages.

As an example, consider Stage II in the Community Transmission epidemiologic setting. Receiving vaccine supply up to an additional 10% of population coverage in this stage may be insufficient to address all the groups assigned to that stage, even if Stage I supply is sufficient to cover the groups assigned to Stage I. In deciding which groups in Stage II to prioritize, countries may wish to consult the Values Framework for guidance. For example, determining which ethical principles are most important to the country at a given time may help identify which groups to privilege, if vaccine supply is insufficient to cover all the groups assigned to Stage II.

Gender considerations

While there is evidence that the risk of severe disease and death is higher in males than in females, particularly in older age groups, this difference in risk is diminished when comorbidities and other factors are taken into account *(4, 21)*. In many contexts, women are disproportionately represented in high-risk occupation groups and they often have direct responsibility for caring for elders. Also, in some contexts, women are disadvantaged in terms of access to health care, political and social status, and decision-making authority due to social structural features in some communities. Prioritizing men or women for vaccination could exacerbate underlying gender-based inequities. For these reasons, the Roadmap does not use gender to identify prioritized vaccine use cases. The equal respect principle of the Values Framework underscores the importance of ensuring that immunization delivery systems place equal focus on reaching both men and women in every priority group.

Addressing pregnant women

Pregnant women warrant particular consideration, as this group has been disadvantaged with respect to the development and deployment of vaccines in previous pandemics. Also, specific to COVID-19, evidence is emerging that pregnant women are at elevated risk of serious disease, further increased if they have pre-existing comorbidities, and may be at elevated risk of adverse pregnancy and birth outcomes as well *(22–25)*. However, it seems likely there will be relatively little data about the safety and efficacy of COVID-19 vaccines in these groups when Stage I and perhaps even Stage II vaccine supplies become available, making the prioritization of pregnant women in these early stages problematic. It is imperative that data specific to pregnancy be generated now from, for example, pregnancy-specific safety and bridging studies and from participants who inadvertently become pregnant during Phase III trials. Vaccine developers and funders should prioritize an assessment of vaccine safety and immunogenicity among pregnant women in their clinical development and of safety and effectiveness in post-marketing surveillance plans *(26)*.

Of particular concern is that several groups prioritized in the Roadmap, including health workers and teachers, are in age groups likely to include significant numbers of women who are pregnant (including some who might not be aware of their pregnancy). Guidance on pregnant women in groups prioritized for vaccination before these urgently needed safety data are available will need to await information about the specific characteristics of the vaccines authorized for use, as well as the latest evidence on risks of COVID-19 for pregnant women and their children.

the Roadmap currently prioritizes pregnant women as specific groups in Stage III of two epidemiologic scenarios. By that time, there should be sufficient evidence to assess whether the net benefit of COVID-19 vaccination for pregnant women (with at least some vaccine candidates) outweighs the risks of community-acquired infection and subsequent severe COVID-19. It is possible that as evidence accumulates the risks to pregnant women and to their children will be judged to be great enough to warrant offering vaccine even in the absence of pregnancy-specific evidence about vaccine risk, in which case pregnant women may be added as a priority group to Stage II. Similarly, if the pregnancy-specific risks of vaccines (which may vary with vaccine product) are determined to be higher than the risks from infection and disease, these groups will need to be prioritized for non-vaccine preventive interventions.

Addressing lactating women

Historically, lactating women have also been overlooked in pandemic vaccine development and response. There is, as yet, no evidence that lactating women or their infants are at elevated risk of severe COVID-19. Therefore, they have not been prioritized in the Roadmap. Currently there are no data on any risks to the infant from immunization of their lactating mothers. As data become available, recommendations on lactating women may be provided for vaccine-specific recommendations. At least one manufacturer is enrolling lactating women. As with pregnant women, it is imperative that evidence on the safety of vaccination in lactating women be quickly gathered.

Addressing children

Children also warrant specific consideration for at least two reasons. Children are dependent on adults and the wider society for their well-being, and setbacks in well-being during childhood can have severe negative and sometimes permanent effects that can last a lifetime. Although children are less subject to direct morbidity and mortality impacts of infection from SARS-CoV-2 when compared to other age groups, they have suffered significantly in other ways during the COVID-19 pandemic *(27, 28)*. Physical distancing measures designed to decrease or prevent community transmission of SARS-CoV-2 have included withdrawing children from in-person learning at schools or closing schools altogether. The extent of learning loss and its impact on life prospects is expected to be far greater for children living in poverty or in otherwise disadvantaged groups. Beyond poor learning and constraints of life prospects from disruption in school provision, students have lost social and developmental benefits afforded by in-person learning. Schools often also provide a number of additional functions important for child health and well-being such as social interactions, meal provision and health services including immunizations and shelter from unstable or unsafe home living environments. These additional functions are especially important for children living in disadvantaged circumstances. Taken together, while all children are being harmed by educational disruptions, these effects are hitting the most disadvantaged children hardest, who also have less access to distance learning options, widening further existing inequities in child well-being *(29)*. The health of all children, and especially low-income children, is also being threatened by COVID-19-related disruptions to routine immunization and other child health programmes *(30–32)*.

Although the pandemic has greatly impacted child well-being, children themselves are not directly prioritized as a population group in Table 1 for two reasons. First, trials of COVID-19 vaccine candidates in children have not yet been initiated and thus data on safety and efficacy in this age group are not expected for some time. Second, as already noted, the low risk of severe COVID-19 and death in children does not make them a high priority for direct immunization. However, child well-being is addressed within this Roadmap through the

prioritization of other groups that directly contribute to child well-being. Within the Community Transmission epidemiologic scenario, health workers engaged in immunization delivery are prioritized to ensure that routine childhood immunization delivery will be safely maintained. Teachers and other adult staff employed in school settings are prioritized within this epidemiologic scenario as well to facilitate the full reopening of in-school education.

Considering comorbidities in vaccine prioritization

The evidence on specific comorbidities and the increased risk of severe COVID-19 is increasing. What is already clear is that i) several comorbidities increase this risk; ii) the increase in risk varies between specific comorbidities, and thus equity concerns would arise if all comorbidities were to be given similar weight; iii) in many countries, if everyone with a comorbidity were to be prioritized in early vaccine supply scenarios, those eligible for vaccination would well-exceed supply; and iv) the list of relevant comorbidities will be location dependent *(4, 21, 33)*.

Based on these considerations, countries should use relevant local and regional data to identify the comorbidities associated with different levels of risk from COVID-19 (for example, significant versus moderate risk). One approach is to identify the additional risk associated with each comorbidity. Another approach is to prioritize individuals who have two or more relevant comorbidities *(34)*. As evidence develops, further guidance from SAGE on comorbidities and risk associated with severe COVID-19 will be communicated. Moreover, the SAGE Working Group on COVID-19 Vaccines is currently developing further guidance on comorbidities that put individuals at significantly higher risk.

Community engagement, effective communication and legitimacy

Community engagement and effective communication are essential to the success of COVID-19 vaccine programmes. These elements are grounded in the legitimacy principle of the Values Framework. This principle requires that prioritization decisions be made through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties. Adhering to the legitimacy principle is a way to promote public trust and acceptance of a COVID-19 vaccine.

When applied in practice, countries may embrace the legitimacy principle through practical strategies which improve the public's perception and understanding of vaccine development and prioritization processes. Examples of such strategies include i) culturally and linguistically accessible communications made freely available regarding COVID-19 vaccination; ii) recruitment of community opinion leaders to improve awareness and understanding of such communications; and iii) inclusion of diverse and affected stakeholder opinions in decision-making. Efforts towards community engagement and effective communication are additionally important in subpopulations which may be unfamiliar with or distrustful of health-care systems.

As outlined in the Values Framework, there must be no tolerance for personal, financial or political conflict of interest or corruption in the prioritization of groups to have access to COVID-19 vaccines. In all cases, decision-makers must be able to publicly defend their decisions and actions by appealing to reasons that even those who disagree can view as reasonable, and not arbitrary or self-serving. Countries should ensure that individuals are

not able to use their social, financial or political privilege to bypass country-level prioritization.

Guidance development and decision-making under conditions of considerable uncertainty

The Roadmap was developed with only limited information, under conditions of considerable uncertainty. The novelty of the SARS-CoV-2 pathogen and evolving epidemic, economic and social circumstances present challenges in making decisions about priority groups for vaccine use at this time. Aside from unknown factors of clinical and epidemiologic importance, this document makes a number of plausible assumptions regarding vaccine characteristics. If a candidate vaccine does not meet these assumptions, the selection of priority groups may warrant reconsideration to best fulfil the principles and objectives adopted within the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*.[9] Moreover, nuanced models of various prioritization scenarios are only now starting to emerge, and modelling-based evidence is rapidly evolving. For all these reasons, the Roadmap may be amended in light of evolving evidence.

Another limitation of the Roadmap is that it is unable to address all possible contingencies. Table 2 considers the implications of some changes in circumstances that could affect use of the Roadmap.

Ongoing activities and next steps

To assess both the usefulness and robustness of the Roadmap in a variety of settings worldwide, RITAGs and NITAGs will be engaged in reviewing and critically assessing the Roadmap. It is anticipated that refinements of the Roadmap will be needed after the engagements of and feedback from national and regional stakeholders, including potentially further prioritization within priority groups.

Table 1. Epidemiologic setting and vaccine supply scenarios, and recommendations for priority use cases for vaccines against Covid-19 in the context of limited supply[a,b]

(a) Epidemiologic setting scenario: Community Transmission – defined in Legend 2

Overall public health strategy for this epidemiologic setting: Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions.
(A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1) – labels explained in Legend 1

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	Stage Ia (initial launch): • Health workers at *high to very high risk* of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** Stage Ib: • Older adults defined by age-based risk specific to country/region; specific age cut-off to be decided at the country level. **(A1) (C1)**
Stage II (limited vaccine availability, for 11–20% nat. pop.)	• Older adults not covered in Stage I. **(A1) (C1)** • Groups with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death. Efforts should be made to ensure that disadvantaged groups where there is underdiagnosis of comorbidities are equitably included in this category. **(A1) (C1) (C2)** • Sociodemographic groups at *significantly higher risk* of severe disease or death (depending on country context, examples may include: disadvantaged or persecuted ethnic, racial, gender, and religious groups and sexual minorities; people living with disabilities; people living in extreme poverty, homeless and those living in informal settlements or urban slums; low-income migrant workers; refugees, internally displaced persons, asylum seekers, populations in conflict settings or those affected by humanitarian emergencies, vulnerable migrants in irregular situations; nomadic populations; and hard-to-reach population groups such as those in rural and remote areas). **(A1) (B1) (B2) (C1) (C2)** • Health workers engaged in immunization delivery (routine programme-specific and COVID-19). **(A1) (A2) (B2) (C1) (C2) (D1)** • High-priority teachers and school staff (depending on country context, examples may include: preschool and primary school teachers because of the critical developmental stage of the children they teach, teachers of children where distance learning is very difficult or impossible). **(A2) (A3) (B1) (C1) (C2)**

Stage III (moderate vaccine availability, for 21–50% nat. pop.)	• Remaining teachers and school staff. **(A2) (A3) (B1) (C1) (C2)** • Other essential workers outside health and education sectors (examples: police officers, municipal services, child-care providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories). **(A2) (A3) (D1)** • Pregnant women (see text under *Addressing pregnant women*). **(A1) (B1) (B2) (C1)** • Health workers at *low to moderate risk* of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** • Personnel needed for vaccine production and other high-risk laboratory staff. **(A1) (A2) (A3) (D1)** • Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance (depending on country context, examples may include: people living or working in detention facilities, incarcerated people, dormitories, informal settlements or urban slums; low-income people in dense urban neighbourhoods; homeless people; military personnel living in tight quarters; and people working in certain occupations such as mining and meat processing). **(A1) (B1) (B2) (C1) (C2)**

(b) Epidemiologic setting scenario: Sporadic Cases or Clusters of Cases – defined in Legend 2

Overall public health strategy for this epidemiologic setting: Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to substantially control transmission and minimize disruption of social and economic functions.
(A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1) – labels explained in Legend 1

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	• Health workers at *high to very high risk* of acquiring and transmitting infection as defined in Annex 3, *in areas with high transmission or anticipated high transmission*. (A1) (A3) (D1) • Older adults defined by age-based risk specific to country/region – specific age cut-off to be decided at the country level – *in areas with high transmission or anticipated high transmission.* (A1) (C1) • Emergency reserve of vaccines for utilization for outbreak response or mitigation (for example, severe localized outbreak). (A1) (A2)
Stage II (limited vaccine availability, for 11–20% nat. pop.)	• Health workers at *high to very high risk* of acquiring and transmitting infection as defined in Annex 3, *in the rest of the country.* (A1) (A3) (D1) • Older adults defined by age-based risk specific to country/region – specific age cut-off to be decided at the country level – *in the rest of the country* (A1) (C1) • Groups with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death *in areas with high transmission or anticipated high transmission*. Efforts should be made to ensure that disadvantaged groups where there is underdiagnosis of comorbidities are equitably included in this category. (A1) (C1) (C2) • Sociodemographic groups at *significantly higher risk* of severe disease or death *in areas with high transmission or anticipated high transmission* (depending on country context, examples may include: disadvantaged or persecuted ethnic, racial, gender, and religious groups and sexual minorities; people living with disabilities; people living in extreme poverty, homeless and those living in informal settlements or urban slums; low-income migrant workers; refugees, internally displaced persons, asylum seekers, populations in conflict settings or those affected by humanitarian emergencies, vulnerable migrants in irregular situations; nomadic populations; and hard-to-reach population groups such as those in rural and remote areas). (A1) (B1) (B2) (C1) (C2)
Stage III (moderate vaccine availability,	• Primary and secondary teachers and school staff *in areas with high transmission or anticipated high transmission.* (A2) (A3) (B1) (C1) (C2) • Other essential workers outside health and education sectors (examples: police officers, municipal services, childcare providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories) *in areas with high transmission or*

for 21–50% nat. pop.)	*anticipated high transmission.* **(A2) (A3) (D1)** • Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance *in areas with high transmission or anticipated high transmission* (depending on country context, examples may include: people living or working in detention facilities, incarcerated people, dormitories, informal settlements or urban slums, low income people in dense urban neighbourhoods, homeless people, military personnel living in tight quarters, and people working in certain occupations for example, mining, meat processing). **(A1) (B1) (B2) (C1) (C2)** • Health workers at *low to moderate risk* of acquiring and transmitting infection as defined in Annex 3 *throughout the country.* **(A1) (A3) (D1)** • Age groups at high risk of transmitting infection by age-based risk specific to country/region; specific age cut-off to be decided at the country level. **(A1) (A2)** • Personnel needed for vaccine production and other high-risk laboratory staff. **(A1) (A2) (A3) (D1)** • Pregnant women (see text under *Addressing pregnant women*). **(A1) (B1) (B2) (C1)**

(c) Epidemiologic setting scenario: No Cases – defined in Legend 2

Overall public health strategy for this epidemiologic setting: Initial focus on prevention of community transmission; also, reciprocity. Expand to preserve control of transmission and reduce reliance on most burdensome non-pharmaceutical interventions, as well as to protect highest risk individuals in the event of importation-associated outbreaks.

(A1) (A2) (A3) (B1) (C1) (C2) (D1) – labels explained in Legend 1

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	• Health workers at high to very high risk of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** • Essential travellers at risk for acquiring infection outside the home country and reintroducing infection upon return to home country (for example, students, business travellers, migrant workers, aid workers). Countries should define essential travellers in a way that constrains the ability of economically and politically powerful individuals to exploit this priority group to their advantage. **(A1) (A2) (A3)** • Border protection staff screening for imported cases and workers for outbreak management (for example, isolation and quarantine managers, immunization deployment staff). **(A1) (A2) (D1)** • Emergency reserve utilization for focused outbreak response (for example, importation outbreaks). **(A1) (A2)**
Stage II (limited vaccine availability, for 11–20% nat. pop.)	• Health workers at low to moderate risk of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** • All travellers at risk for acquiring infection outside the home country and reintroducing infection upon return to home country. **(A1) (A2)** • Emergency reserve of vaccines utilization for outbreak mitigation (for example, importation outbreaks). **(A1) (A2)**
Stage III (moderate vaccine availability, for 21–50% nat. pop.)	• Older adults defined by age-based risk specific to country/region; specific age cut-off to be decided at the country level. **(A1) (C1)** • Age groups at high risk of transmitting infection by age-based risk specific to country/region, specific age cut-off to be decided at the country level. **(A1) (A2)** • Primary and secondary school teachers and staff. **(A2) (A3) (B1) (C1) (C2)** • Other essential workers outside health and education sectors (examples: police officers, municipal services, child-care providers, agriculture and food workers)

	transportation workers, government workers essential to critical functioning of the state not covered by other categories). (A2) (A3) (D1)

National equity considerations. Ensure that vaccine prioritization within countries takes into account the disproportionate burdens of the COVID-19 pandemic on social groups that are systematically disadvantaged. (C1) (C2)

[a] For individuals in more than one priority group, the highest applicable priority group determines the order in which they should receive COVID-19 vaccine.

[b] Current modelling suggests that (given the many-fold higher mortality rate among older individuals) age-dependent vaccine efficacy would not significantly change the recommendations for priority use cases in older populations for a strategy based on mortality reduction (5–8, 35). If vaccine efficacy in older adults relative to other age groups were so low that individual protection and public health impact became significantly suboptimal, the individuals in older age groups in each scenario would likely be moved to a lower rank.

Legend 1. Value objectives applied to priority groups

A. Well-being	(A1) Reduce deaths and disease burden from the COVID-19 pandemic.
	(A2) Reduce societal and economic disruption (other than through reducing deaths and disease burden).
	(A3) Protect the continuing functioning of essential services, including health services.
B. Equal respect	(B1) Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being made and implemented.
	(B2) Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.
C. Equity	(C1) Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic.
	(C2) Develop the immunization delivery systems and infrastructure required to ensure priority populations have access to COVID-19 vaccines, and which ensures equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations.
D. Reciprocity	(D1) Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers.

Legend 2. WHO transmission categories corresponding to epidemiologic setting scenarios

Transmission category[a]	Definition

No Cases	Countries/territories/areas with no confirmed cases.
Sporadic Cases	Countries/territories/areas with one or more cases, imported or locally detected.
Clusters of Cases	Countries/territories/areas experiencing cases, clustered in time, geographic location and/or by common exposures
Community Transmission	Countries/area/territories experiencing larger outbreaks of local transmission defined through an assessment of factors including, but not limited to: • large numbers of cases not linkable to transmission chains; • large numbers of cases from sentinel laboratory surveillance or increasing positive tests through sentinel samples (routine systematic testing of respiratory samples from established laboratories); • multiple unrelated clusters in several areas of the country/territory/area.
Scenario transitions: From lower to higher transmission scenario: change to be reported at any time (in the next weekly update). From higher to lower transmission scenario: observe during a 28-day period before confirming downgrading of transmission.	

* Definitions correspond to those used elsewhere in WHO epidemiologic reports, using definitions published in the WHO interim guidance on public health surveillance for COVID-19 published on 7 August 2020, available here.

Table 2. Summary table of the application of the Roadmap under various contingencies

Contingency	Change in the application of the Roadmap
Number and timing of vaccine doses	
Fewer vaccine courses available than expected	The Roadmap is unchanged. Some individuals receive vaccination later than they would otherwise.
Vaccine requires two doses rather than one	The Roadmap is unchanged, but some individuals receive vaccination later.
Vaccine efficacy	
Low vaccine efficacy among older adults or other population subgroup	Current modelling suggests that (given the many-fold higher mortality rate among older individuals) age-dependent vaccine efficacy would not significantly change the recommendations for priority use cases in older populations *(6–8, 35)*. If vaccine efficacy in older adults relative to other age groups were so low that the prioritization of older adults was expected to lead to substantially worse overall outcomes in number of lives saved, individuals in the older age groups in each scenario would likely be moved to a lower rank. Similar considerations apply for individuals with comorbidities.
Low vaccine efficacy in preventing transmission	The importance of high coverage of the most vulnerable groups is increased.
Vaccine safety	
Unanticipated vaccine adverse events	Only prioritize individuals or groups for whom vaccine benefits continue to outweigh the risks.
Vaccine uptake	
Vaccine acceptance and uptake is lower than expected	The Roadmap is unchanged. Community engagement and risk communication are enhanced.
Number of vaccine types	
More than one vaccine type available	The Roadmap is unchanged, but which vaccines are allocated to which population groups must take into account the benefits and risks of the vaccine for each population subgroup. As authorized vaccines become available, SAGE will make vaccine-specific recommendations.
Epidemic conditions and immune status	

Epidemic spread is continuing when the vaccine becomes available	The Roadmap is unchanged. Public health messages must continue to stress the need for personal protective measures (for example, masks, social distancing, hand washing, ventilation).
Risk profile of a previously identified high-risk group changes (for example, due to higher infection rate in earlier infection waves than in later waves)	The general structure of the Roadmap is unchanged. The relevant consideration is risk level: if a group is no longer high-risk it should be lowered in priority. However, due to equity concerns, as many of these groups are likely to be disadvantaged there must be a substantial level of evidence supporting the change, which the immunization programme/government should present to justify the change.
Social, Economic and Legal Contexts	
Some countries do not provide free vaccine access to non-citizens or people without documentation of legal status	The Roadmap is unchanged. This practice violates the principle of equity and the goals of public health. However, in such cases, other sources of financial support (for example, philanthropy, civil society organizations, pharmaceutical companies) should be sought to provide vaccination for those individuals.

Source: Adapted from National Academies of Sciences, Engineering, and Medicine's Framework for Equitable Allocation of COVID-19 Vaccine *(54)*, with permission.

References

In the interests of specificity during the COVID-19 pandemic – during which new data become available by the day – the references below that deal with COVID-19 or SARS-CoV-2 exceptionally include both the day and month of publication (where available). This is meant to assist the reader in quickly determining the exact date of publication.

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Annex 1. Alignment of the COVAX Facility allocation mechanism and Prioritization Roadmap

COVAX Facility allocation mechanism*		Prioritization Roadmap	
Phase	*% country population to be covered by vaccine supply*	*Stage*	*% country population to be covered by vaccine supply*
Phase 1: Proportional allocation, to cover Tier 1 target groups	Indicative initial tranche: 3% Subsequent tranches to reach 20%	Stage I	1–10%
		Stage II	11–20%
Phase 2: Weighted allocation based on risk assessment	> 20%	Stage III	21–50%
*Note: the COVAX Facility allocation mechanism is still in draft form; further details from the current draft approach are available (here)			

Annex 2. Reduction of deaths versus reduction of years of life lost

Years of life lost (YLL) is a measure that is thought by many to integrate a commitment to maximizing health benefit with a commitment to promoting equity, where equity is understood to include an obligation to ensure that younger people have a fair chance to reach later stages of life. There are good ethics arguments for using YLL in many allocation contexts, including in this particular pandemic *(1,2)*. However, the particular epidemiology of the current pandemic supports using reducing deaths as a preferred strategy for within-country prioritization. The risk of COVID-19-related mortality is extremely high in older age groups compared to that in younger age groups. For example, in the United States, the mortality risk has been estimated to be 90 times higher among 65–74-year-olds compared to 18–29-year-olds *(3)*. A similar pattern of significantly higher mortality in older age groups has been observed in multiple other countries. The evidence identified to date from modelling analyses suggests that using YLL instead of deaths would not substantially alter the priority ranking of older people relative to younger people when age is the only dimension considered *(4, 5)*. Supplementary unpublished sensitivity analyses prepared for the WHO SAGE Working Group on COVID-19 Vaccines support this finding. As priority rankings would not change, expressing the policy objective in terms of reduction in the number of deaths rather than YLL has programmatic advantages, even if YLL reaches the same conclusions about relative prioritization. Reduction of number of deaths is more easily understood by and communicated to the general public and is likely to be widely endorsed as an important objective at a time when securing public support for and confidence in vaccine programmes is critically important. A prioritization approach relying on YLL could be viewed as disrespectful to older people by failing to address their disproportionately higher risk of death *(6)*.

YLL also does not address the primary equity challenges in prioritization of COVID-19 vaccines within countries and thus the commitment of the Values Framework to equity does not in this pandemic require use of YLL. In a pandemic with a mortality pattern similar to seasonal influenza where the very young as well as older adults have disproportionately high mortality, or that of the 1918 influenza pandemic where young adults were a high-mortality risk group, equity considerations could well require a focus on YLL. Also, in the current COVID-19 pandemic the equity issues in allocation of vaccine between countries are markedly different from those in within-country prioritization. Standard expected years of life lost, a measure of disease burden often used for cross-national comparative purposes, can help illustrate the commitment of the Values Framework to global equity, as long as global inequities in access to testing and other surveillance technologies do not unfairly skew assessments of this metric.

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Annex 3. Definition of health workers[1]

Health workers are all people engaged in work actions whose primary intent is to improve health. This includes health service providers, such as doctors, nurses, midwives, public health professionals, lab-, health- and medical and non-medical technicians, personal care workers, community health workers, healers and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers and social workers, and other occupational groups in health-related activities. Health workers include not only those who work in acute care facilities but also those employed in long-term care, public health, community based care, social care and home care and other occupations in the health and social work sectors as defined by the International Standard Industrial Classification of All Economic Activities (ISIC), revision 4, section Q: Human health and social work activities.

The following levels may be useful in assessing the risk of occupational exposure to SARS-CoV-2 for jobs or tasks of health workers, prior to introducing mitigation measures:

a) Low risk (caution) - Jobs or work without frequent, close contact with the public or others that do not require contact with people known to be or suspected of being actively infected with the virus responsible for COVID-19. Workers in this group have minimal occupational contact with the public and other co-workers, for example performing administrative duties in non-public areas of healthcare facilities, away from other staff members, telehealth services in individual offices

b) Medium risk - Jobs or tasks with close, frequent contact with the general public or others but that do not require contact with people known to be or suspected of being actively infected with the virus responsible for COVID-19. In areas where COVID-19 cases continue to be reported, this risk level may apply to workers who have frequent and close contact with the people in busy staff work areas within a healthcare facility and work activities where safe physical distance may be difficult to maintain, or tasks that require close and frequent contact between co-workers. In areas without community transmission of COVID-19, this scenario may include frequent contact with people returning from areas with known higher levels of community transmission. Examples include, providing care to the general public who are not known or suspected of having COVID-19, or working at busy staff work areas within a healthcare facility

c) High risk - Jobs or tasks with high potential for close contact with people who are known or suspected of having COVID-19, as well as contact with objects and surfaces possibly contaminated with the virus, e.g. the direct patient care, domestic services or home care for people for people with COVID-19. Jobs and tasks that may fall under this category may include: entering a known or suspected COVID-19 patient's room, providing care for a known or suspected COVID-19 patient not involving aerosol-generating procedures; transportation of people known or

[1] Classifying health workers: Mapping occupations to the international standard classification, based on the International Standard Classification of Occupations (ISCO, 2008) revision)http://www.who.int/hrh/statistics/Health_workers_classification.pdf?ua=1#:~:text=The%20classification%20of%20health%20workers%20is%20based%20on%20the%20International%20Standard%20Classification%20of%20Occupations%20(ISCO,%202008)., accessed Nov 2020

suspected to have COVID-19 without separation between the driver and the passenger.

d) Very high risk - jobs and tasks with risk of exposure to aerosols with SARS-CoV-2, the settings where performing aerosol-generating procedures are performed on patients with COVID-19, such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, sputum induction, bronchoscopy, spirometry, and autopsy procedures and working with COVID19 patients in crowded, enclosed places without adequate ventilation

Policy Brief:

A Disability-Inclusive Response to COVID-19

1. Executive Summary

The global crisis of COVID-19 is deepening pre-existing inequalities, exposing the extent of exclusion and highlighting that work on disability inclusion is imperative. People with disabilities—one billion people—are one of the most excluded groups in our society and are among the hardest hit in this crisis in terms of fatalities.

Even under normal circumstances, persons with disabilities are less likely to access health care, education, employment and to participate in the community. They are more likely to live in poverty, experience higher rates of violence, neglect and abuse, and are among the most marginalized in any crisis-affected community. COVID-19 has further compounded this situation, disproportionately impacting persons with disabilities both directly and indirectly.

An integrated approach is required to ensure that persons with disabilities are not left behind in COVID-19 response and recovery. It calls for placing them at the centre of the response, participating as agents of planning and implementation. All COVID-19 related action must prohibit any form of discrimination based on disability and take into consideration the intersections of gender and age, among other factors. This is necessary effectively and efficiently to address and prevent barriers that may arise during response and recovery.

Disability inclusion will result in a COVID-19 response and recovery that better serves everyone, more fully suppressing the virus, as well as building back better. It will provide for more agile systems capable of responding to complex situations, reaching the furthest behind first.

This Policy Brief highlights the impact of COVID-19 on persons with disabilities and in doing so, outlines key actions and recommendations to make the response and recovery inclusive of persons with disabilities. While the brief contains specific recommendations focusing on key sectors, it identifies four overarching areas of action that are applicable for all.

1. **Ensure mainstreaming of disability in all COVID-19 response and recovery together with targeted actions.** A combination of mainstream and disability-specific measures are necessary to ensure systematic inclusion of persons with disabilities.

2. **Ensure accessibility of information, facilities, services and programmes in the COVID-19 response and recovery.** Accessibility is fundamental to the inclusion of persons with disabilities in the immediate health and socio-economic response to COVID-19. If public health information, the built environment, communications and

technologies, and goods and services are not accessible, people with disabilities cannot take necessary decisions, live independently and isolate or quarantine safely, or access health and public services on an equal basis with others.

3. **Ensure meaningful consultation with and active participation of persons with disabilities and their representative organizations in all stages of the COVID-19 response and recovery.** Persons with disabilities have important contributions to make in tackling the crisis and building the future. Many persons with disabilities have experience of thriving in situations of isolation and alternate working arrangements that can offer models for navigating the current situation. Perspectives and lived experiences of disability contribute to creativity, new approaches and innovative solutions to challenges.

4. **Establish accountability mechanisms to ensure disability inclusion in the COVID-19 response.** Ensure inclusive investments to support disability-inclusive outcomes. Governments, donors, UN agencies and other actors need to establish mechanisms to monitor investments to ensure it is reaching persons with disabilities. Disaggregating data by disability is key to ensure accountability.

Inclusion of persons with disabilities in the COVID-19 response and recovery is a vital part of achieving the pledge to leave no one behind, and a critical test of the global commitments of the Convention of the Rights of Persons with Disabilities (CRPD), the 2030 Agenda for Sustainable Development, the Agenda for Humanity and the United Nations Disability Inclusion Strategy. It is also central to the UN's commitment to achieve transformative and lasting change on disability inclusion.

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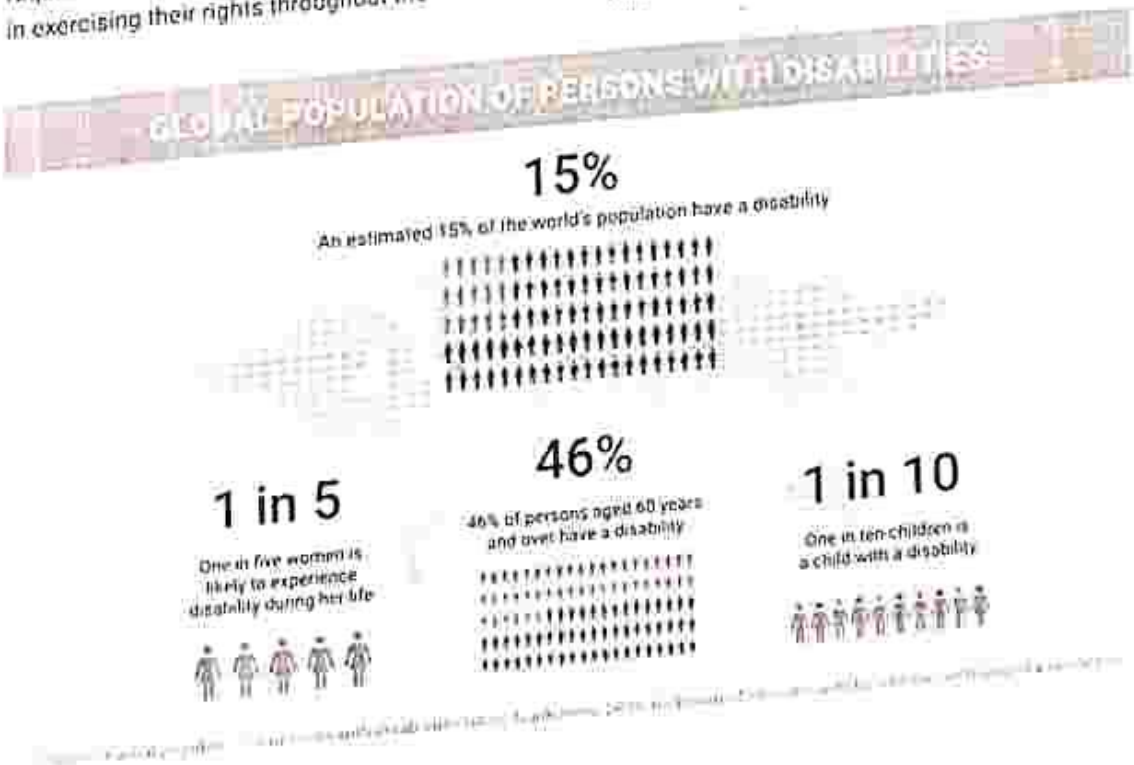
2. How COVID-19 impacts persons with disabilities

Persons with disabilities are disproportionately impacted by the COVID-19 outbreak. An estimated 46% of older people aged 60 years and over are people with disabilities.[1] One in every five women is likely to experience disability in her life, while one in every ten children is a child with a disability.[2] Of the one billion population of persons with disabilities, 80% live in developing countries.[3]

They represent a diverse population of people with different impairments and support requirements, who face significant barriers in exercising their rights throughout the lifecycle. Some groups face even greater marginalization—for example persons with intellectual and psychosocial disabilities, persons who are deafblind—who are more likely to be excluded from services, live or be detained in institutions, and experience higher rates of violence, neglect and abuse.

As the report 'Shared Responsibility, Global Solidarity' on the socio-economic impact of the pandemic reflects, COVID-19 is not simply a health crisis—it is attacking societies at their core.[4] The response is feeding on pre-existing social and economic inequalities associated with disability and threatens to exacerbate them further.



Persons with disabilities are at greater risk of contracting COVID-19. They may experience barriers to implement basic protection measures such as hand-washing and maintaining physical distancing for several reasons: lack of accessibility of water, sanitation and hygiene (WASH) facilities; a reliance on physical contact to get support; inaccessibility of public health information; or being placed in institutional settings which are often overcrowded and unsanitary.[5] These barriers are exacerbated for those living in informal settlements and/or affected by humanitarian emergencies.

Persons with disabilities are at greater risk of developing more severe health conditions and dying from COVID-19. They have greater health requirements and poorer health outcomes. For example, they are more susceptible to secondary conditions and co-morbidities, such as lung problems, diabetes and heart disease, and obesity, which can worsen the outcome of COVID-19 infections.[6] The barriers to accessing healthcare are further exacerbated during the COVID-19 crisis, making timely and appropriate care difficult for persons with disabilities.

Persons with disabilities living in institutions are more likely to contract the virus and have higher rates of mortality. Persons with disabilities, including older people with disabilities, represent the majority of institutionalized people globally.[7] People with disabilities are also overrepresented in the prison population, particularly persons with intellectual and psychosocial disabilities.[8] People in institutional settings, such as nursing homes[9], social care homes and psychiatric facilities, as well as detention facilities and penitentiaries[10], experience significant barriers to implement basic hygiene measures and physical distance, and have limited access to COVID-19-related information, testing and healthcare. Emerging evidence indicates that people in institutional settings are experiencing the highest rates of infection and mortality from COVID-19.[11] The percentage of COVID-19 related deaths in care homes—where older persons with disabilities are overrepresented—ranges from 19% to 72% in countries in which official data is available.[12]

Persons with disabilities are at greater risk of discrimination in accessing healthcare and life-saving procedures during the COVID-19 outbreak. In some countries, health care rationing decisions, including triage protocols

of intensive care beds, ventilators), are not being based on an individual prognosis, but rather on discriminatory criteria, such as age or assumptions about quality or value of life based on disability.[12] Moreover, access to healthcare, rehabilitation and assistive technologies for persons with disabilities, including with respect to accessibility and affordability,[13] can also be curtailed due to the increased pressure on healthcare systems.

Persons with disabilities are particularly disadvantaged by the socio-economic consequences of COVID-19 and measures to control the pandemic. COVID-19 has both short-term and far-reaching implications for people with disabilities in many areas of life, which may be further exacerbated in humanitarian and disaster contexts and fragile settings.

- **Impact on employment and social protection.** Already facing exclusion in employment[14], persons with disabilities are more likely to lose their job and experience greater difficulties returning to work during recovery.[15] In most countries social protection systems offer little support to persons with disabilities and their families with much less access to social insurance. Only 28% of persons with significant disabilities have access to disability benefits globally, and only 1% in low-income countries.[16] The increased demand for unpaid care and domestic work in the context of the pandemic is deepening already existing inequalities[17] which may be exacerbated for women with disabilities.[18]

- **Impact on education.** While reliable figures on students with disabilities are not yet available, it is likely that the current crisis has exacerbated their exclusion from education.[19] As detailed in the policy brief on the impact of COVID-19 on children, students with disabilities are least likely to benefit from distance learning solutions.[20] Lack of support, access to the internet, accessible software and learning materials is likely to deepen the gap for students with disabilities. Disruption to skills and training programmes are likely to have far-reaching effects on youth with disabilities who face a multitude of barriers to entering the workforce.

- **Impact on support services.** For many people with disabilities, access to support services is essential to lead safe, healthy and independent lives. Measures to contain the spread of COVID-19 have resulted in

significant disruptions to services, support systems and informal networks, such as personal assistance, sign language and tactile interpretation, and psychosocial support. The economic impact of COVID-19 may also lead to even greater cuts within existing services in the post-pandemic period.

- **Impact of violence on persons with disabilities**. The policy brief on the impact of COVID-19 on women documents early reports which indicate a substantial increase of domestic violence in the midst of lockdown measures,[22] which has a particular impact on women and girls with disabilities.[23] Given that both children and adults with disabilities are at much higher risk of violence than their peers without disabilities,[24] it can be assumed that they are disproportionately impacted. Increased stigma and discrimination against persons with disabilities within communities has also been reported.[25]

3. Foundations for a disability-inclusive COVID-19 response and recovery

A human rights-based approach to disability is required to ensure persons with disabilities are not left behind.[24] Both the CRPD and the 2030 Agenda call for placing persons with disabilities at the centre of all our efforts, as agents of planning and implementation.

A combination of mainstreaming and targeted measures is necessary in all interventions. Persons with disabilities share the same primary needs as everyone else: health protection and treatment, basic services, shelter and income. The best way to address their inclusion is through mainstreaming disability in all plans and efforts. Targeted measures need to complement disability mainstreaming by addressing specific requirements that cannot be met by making general responses inclusive.

NON-DISCRIMINATION

Non-discrimination is a core human rights principle. COVID-19 response and recovery must prohibit discrimination on the basis of disability, as well as any criteria which could have a disproportionate impact on persons with disabilities. It is necessary to recognize and take measures against disadvantage experienced by persons with disabilities by taking proactive steps, including through reasonable accommodation, to ensure they equally benefit from COVID-19 response measures.[25]

INTERSECTIONALITY

Persons with disabilities experiencing intersectional and multiple discrimination as a result of their gender identity, age, ethnicity, race, sexual orientation, origin, location and legal status, among other factors, will carry a heavier burden of the immediate and long-term economic and social consequences of the pandemic.[26] COVID-19 response and recovery needs to reflect and respond to the multiple and intersecting forms of discrimination faced by persons with disabilities to ensure that the most marginalized groups among them are not left behind.

ACCESSIBILITY

Ensuring accessibility of facilities, services and information is fundamental to a disability inclusive COVID-19 response and recovery. If public health information, buildings, transport, communications, technologies, goods and services are not accessible, persons with disabilities cannot take necessary decisions, live independently and isolate or quarantine safely, or access health and public services on an equal basis with others. Such measures do not need to add greatly to overall cost especially if the needs of the maximum number of users are considered in the initial design.[7] Research shows that if they are considered from the design stage, ensuring accessibility can cost as little as 1% more.[8]

PARTICIPATION

Persons with disabilities have the right to participate fully and effectively in decisions that affect their lives.[9] They are a diverse, non-homogenous population who possess unique knowledge and lived experience of disability that others do not.

Close consultation and active involvement of people with disabilities and their representative organizations at all stages–from planning and design to implementation and monitoring–is key to ensuring inclusive response. Partnerships and collaboration will improve effectiveness and accountability, assist in directly achieving inclusion and ensuring that all action related to COVID-19 benefits persons with disabilities, and contributes to longer-term development and recovery.

ACCOUNTABILITY

Accountability is essential for ensuring that the COVID-19 response and recovery is inclusive and respectful of the rights of persons with disabilities. Governments, UN entities and other actors are accountable to affected populations, including persons with disabilities, and mechanisms need to be established to engage with communities to inform programming and adjust it according to feedback.

DATA DISAGGREGATION

To understand the different ways in which people with disabilities experience the impact of COVID-19, and to monitor their inclusion in all phases of the response and recovery, ensuring the collection and availability of disaggregated data by disability is essential. To that end, data should be collected using internationally recognized methods, such as the Washington Group tools.[10] More in-depth qualitative data can be collected through needs assessments and surveys, such as the WHO Model Disability Survey. For planning purposes, where primary data collection is not undertaken or secondary data sources on disability is not available, the World Bank/WHO 15 per cent estimate of persons with disabilities in the population may be used.[11]

4. Sectoral actions and recommendations for a disability-inclusive COVID-19 response and recovery

The following section outlines key actions to protect persons with disabilities from contracting COVID-19 and the impact of lockdowns, physical distancing and isolation measures, and to achieve a disability-inclusive response and recovery.

HEALTH

People with disabilities are more susceptible to contracting COVID-19, and barriers to accessing health services, including testing, are exacerbated during the crisis. Lockdowns can lead to restricted access to essential goods and medicines, as well as limit access to supports. The disruption of wider health services puts persons with disabilities at a disadvantage as they may require more frequent access due to underlying health conditions.[21]

Ensure accessible public health information. An appropriate response requires measures to ensure that information is accessible, up to date, and keeps pace with the rapidly changing knowledge evidenced during the pandemic.[22]

For example, Inclusion Europe has produced information and [illegible] on COVID-19 in Easy to Read format in multiple languages. Through the Joint UN Partnership on the Rights of Persons with Disabilities (UN PRPD) programme[23] in Nepal, information on COVID-19 includes accessibility features, [illegible] sign language

Implement protective measures against COVID-19. Access to appropriate WASH facilities that make frequent hand-washing possible is essential, as is the targeted provision of protective measures for those providing support to persons with disabilities either at home or in institutions. The distribution of personal protective equipment to persons with disabilities needs to be tailored to their impairment. For example, given that masks make it impossible to read lips or see facial expressions, deaf and hard of hearing persons will benefit better from face shields

Ensure accessibility to services. Measures need to be put in place to facilitate the timely access to health services for persons with disabilities, such as transportation to healthcare facilities, access to sign language

interpretation in hospitals, as well as the procurement of goods, medicines and services. Essential health services, including sexual and reproductive health, must be accessible—for example, ensuring telehealth programmes are accessible for persons with disabilities who require different modes of communication. By way of example, the United Arab Emirates has launched a national programme to test persons with disabilities in their homes, and as of mid-April, had conducted 650,000 COVID-19 tests of persons with disabilities.

Ensure non-discrimination in the allocation of scarce medical resources. It is important to mitigate the risk of discriminatory decisions in resource allocation that put people with disabilities at a high level of disadvantage[9] by applying ethical principles that prioritize treatment for persons in situations of particular vulnerability.[10]

Make mental health interventions inclusive of persons with disabilities. Anxiety, lockdowns, isolation, and information consumption, loss of livelihoods and support systems due to the pandemic impact on mental health of all people, including persons with disabilities. As documented in the policy brief on the impact of COVID-19 on older persons, physical distancing measures that restrict visitors and group activities in institutions can also negatively affect physical, as well as mental health and well-being.[11] Mental health and psychosocial support needs to be accessible and not discriminate against persons with disabilities.

WHO has produced guidelines on Disability considerations during the COVID-19 outbreak.

PROTECTING PEOPLE IN INSTITUTIONAL SETTINGS

institutional settings have become COVID-19 hotspots, highlighting systemic challenges in these settings. People with disabilities in institutional settings face heightened risk of contracting and dying from COVID-19. Their situation is compounded by greater risks, such as abuse, restraint, isolation and violence.

Prepare institutions to prevent and respond to potential infections. This includes promoting testing and preventive measures within institutions to reduce infection risks, addressing overcrowding, isolation and physical distancing measures among residents, modifying visiting hours, ensuring use of protective equipment is mandatory, and improving hygiene conditions. It is important to guarantee that those who contract the virus receive adequate treatment and health care and, when needed, are transferred to hospitals and/or emergency care units. In Canada, for example, [illegible] have been issued with specific measures for institutional settings.

Reduce the number of people within institutions. It is important to take immediate action to discharge and release persons with disabilities from institutions, whenever possible. Deinstitutionalization strategies need to be accelerated and reinforced with clear timelines and concrete benchmarks.

Reduce the number of persons with disabilities in prisons, whenever possible. It will be important to explore early release and probation or shorten or commute sentences. Other possible measures would include reducing the use of pre-trial detention and promptly ensuring support in the community through family and/or informal networks.[39] In a number of countries around the world, prisoners with disabilities have been released.

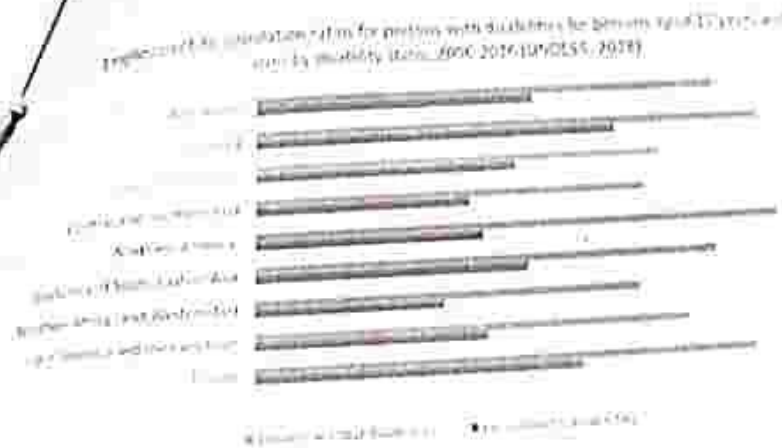
SUPPORT SERVICES

Many persons with disabilities rely on support services for daily living and to participate in their communities. These include personal assistance and language and cultural interpretation, in-home services and peer support, amongst others.

Ensure the continuity of support services. It is important to develop and implement service continuity plans, particularly for people with disabilities with high support needs, as well as measures to reduce potential exposure to COVID-19 during the provision of services.[40] This includes practical guidance and accurate advice to informal carers on how to support persons with disabilities in a manner safe for everyone.

Expand community support for persons with disabilities. The growth in demand for support services in the community without a corresponding supply of services can increase pressure on families to provide unpaid informal care, with negative consequences on both persons with disabilities and family members, particularly women.[41]

In Argentina, Peru, Spain and other countries, for instance, persons who provide support to people with disabilities are exempted from restrictions of movement and physical distancing.[42] Community support networks



have also developed in Colombia and other countries which recruit volunteers that support persons with disabilities and older persons with their groceries and other purchases.[44]

SOCIAL PROTECTION AND EMPLOYMENT

Social protection has already proven a key element in the immediate relief to be provided to persons affected by the socio-economic impact of the crisis.[45] It is particularly relevant for persons with disabilities out of work, who have lost their job or their income resulting from the informal economy, all of which are at risk of poverty and extreme poverty.

Expand mainstream and disability-targeted social protection and adapt delivery mechanisms to provide adequate relief and support to persons with disabilities and their families. This can be done by: advancing and/or increasing payments of disability benefits; extending coverage to persons with disabilities already registered but who were not previously eligible; and through (online) registration of persons with disabilities; providing disability top-ups to beneficiaries of mainstream social assistance schemes, including to family members who have to stop work to support persons with disabilities; and establishing electronic payment and home delivery for cash and essential food and non-food items.

Employment and working conditions need to be responsive to accessibility and inclusion. Persons with disabilities who continue working, whether essential workers or others, may need specific protection or adjustments to stay safe during the pandemic. At all times it is important that employers and workplaces provide accessible environments and reasonable workplace adjustments based on individual needs. Persons with disabilities who own businesses or work in the informal economy may need particular support to be able to maintain their livelihoods.

Alternate working arrangements and conditions made accessible and inclusive. Platforms and new ways of meeting must be accessible to all, and adequate adjustments put in place to allow persons with disabilities to work from home.

Ensure disability-inclusive Occupational Health and Safety (OSH) measures. New OSH measures may apply particularly to persons with disabilities. In such cases, different arrangements may be required, such as priority to work from home or placed in paid leave.

Approaches to coming out of lockdown need to be sensitive to the particular situation of persons with disabilities. Persons with disabilities and their family members or support services have different levels of vulnerability to COVID-19. Some persons with disabilities, including older persons with disabilities, may need to isolate for longer than other groups. Social protection and working arrangements need to be adaptive to support their ability to do this.

The International Labour Organization (ILO) has developed a guidance note on socio-economic actions for persons with disabilities. Information is also available on: Disability inclusion in COVID-19 and the world of work and Social protection measures for persons with disabilities in the COVID-19 crisis.

EDUCATION

Students with disabilities are likely to face greater barriers in accessing distance learning or rejoining classes once they are available, and face increased risk of dropping out of education during disruptions to learning.

Ensure distance learning is accessible to, and inclusive of, students with disabilities. Education actors need to take measures to ensure continuity of learning for students with disabilities and return to school programmes. This may include providing specialized equipment to support their learning, including assistive technology and devices, and support to caregivers/parents of children with disabilities. UNICEF has produced a guidance note for staff and partners on supporting the learning of children in areas of school closures, which includes guidance on making learning accessible to children with disabilities.[40]

Address impacts that go beyond learning. For many children with disabilities, peer relations, social perception and social competence are significant aspects of their Individual Education Plans, all of which are challenged in the context of school closures. School closings can also mean that many children with disabilities will not access complementary services,[41] such as food and medical check-ups, or referral mechanisms for abuse and neglect.

Ensure that return to school programmes are inclusive. Education actors need to ensure that return to school programmes are inclusive of children and young persons with disabilities, in recognition of the increase in the learning/achievement gap. This may include development of plans for accelerated education, remedial, and catch-up programmes.

PREVENTION OF AND RESPONSE TO VIOLENCE

Persons with disabilities often face incidents of violence in situations of isolation, with women and girls with disabilities at even higher risk.[48] Reporting and access to domestic violence services and assistance are particularly challenging, as these are commonly not inclusive of, nor accessible to persons with disabilities.

Ensure inclusive and accessible victim assistance services. It is important to ensure that reporting mechanisms and access to victim assistance services are accessible to persons with disabilities.[49] Being proactive and innovative in outreach to those who are isolated, including through voluntary networks, has proven to be a key measure, as well as ensuring that online counseling and other technology-based solutions are accessible and respond to the diversity of people with disabilities.

Strengthen awareness raising and knowledge. Building capacity of services and communities to prevent disability-related violence is key, as is promoting awareness-raising about violence against persons with disabilities, particularly women and girls. For example, UN Women Papua New Guinea is working with partners to integrate COVID-19 aspects to improve quality and standards for counselling and case management services that will particularly target women with disabilities. Women with disabilities are being supported to run campaigns on ending violence against women in a pandemic.

HUMANITARIAN CONTEXTS

Persons with disabilities in humanitarian and disaster contexts face specific and heightened challenges in the COVID-19 outbreak: barriers to implementing basic hygiene measures; physical distancing limitations in high-density sites; barriers to accessing health care on the basis of both disability and legal status, which may determine and restrict their access to health care and other services.[50] The Inter-Agency Standing Committee (IASC) Guidelines on Inclusion of Persons with Disabilities in Humanitarian Action provide detailed sectoral information for stakeholders working in humanitarian contexts.[51]

Ensure disability-inclusive humanitarian assistance and disaster response. National and local coordination mechanisms, as well as Preparedness and Response Plans need to be disability-inclusive. In particular, it is important to ensure that Humanitarian Response Plans factor in responses targeted towards persons with disabilities, including in WASH, health, and food and nutrition, with adequate resourcing, monitoring and adjustment, as required. Concrete adaptions in humanitarian assistance could include, for example, improving accessibility of WASH facilities; distribution of additional or disability-specific hygiene items and supplies, targeted shelter assistance for at-risk individuals to allow for physical distancing; in-kind provision of goods, cash and voucher assistance, and direct service provision, and providing alternative arrangements for food and non-food items distribution to households of persons with disabilities.

5. Delivering on the SDGs – Building Back Better

Everything we do during and after the COVID-19 crisis must have a strong focus on building more equal, inclusive and sustainable economies and societies that are more resilient in the face of pandemics and the many other global challenges we face.

Countries' immediate efforts towards social and economic recovery will be crucial for progress towards the Sustainable Development Goals (SDGs), including addressing inequalities and ensuring that no one is left behind[52].

While building back better[53], it is critical that persons with disabilities are part and parcel of the response which countries, often with the support of the UN, are preparing. These responses, if well designed, can address the exclusion and discrimination faced by persons with disabilities, thus creating more resilient communities and systems.

To build equal, inclusive and resilient communities it is important to:

1. **Meaningfully engage persons with disabilities at all stages of the response:** When supporting local initiatives, governments, UN entities, international donors and civil society organizations need to promote, fund and monitor the inclusion of persons with disabilities in all stages of design and implementation of the relevant measures.

2. **Prioritize persons with disabilities in the socio-economic response:** National and sub-national economic models and assumptions need to be critically reviewed to identify gaps that disproportionately impact persons with disabilities and take into account the cost of under-investment in disability-inclusion.

3. **Track inclusion and empowerment of persons with disabilities in national response and recovery plans:** A long-term inclusive response needs to be closely tied to inclusive national development planning and financing processes. Disability inclusion should be a requirement in all COVID-19 actions and systems to allow tracking and accountability (e.g. OECD DAC disability marker).[54]

4. **Improve health outcomes for persons with disabilities:** This entails building accessible health systems, rights-based training of health personnel and ensuring universal health coverage for persons with disabilities as a cornerstone for achieving the health-related SDG targets. Further, improving the determinants of health for persons with disabilities is critical.

5. **Build sustainable and disability-inclusive social protection systems:** Universal disability allowances across the life cycle addressing disability-related

extra costs should be designed so that these are compatible with employment and other social assistance schemes aiming at basic income security.

6. **Address the specific situation of workers with disabilities in all sectors:** Stimulus packages, including those that will promote training and jobs in the transition to a green economy should explicitly include persons with disabilities in general, as well as women and youth with disabilities in particular.

7. **Invest in community-based solutions now:** Particular attention needs to be given to persons with disabilities living in residential institutions and funds should be used to initiate, accelerate and complete deinstitutionalization strategies and transition to community-based solutions. This includes investing and developing support services and implementing inclusive services at local level, such as education and primary health care, including rehabilitation, as cornerstones for achieving the SDG targets for persons with disabilities.

8. **Initiate multi-stakeholder dialogue and collaboration:** Inter-sectoral linkage is required to address the multi-dimensional nature of disability and the inter-sectoral response that is necessary. Bringing together all stakeholders—government, UN entities, private sector, organizations of persons with disabilities and broader civil society—in the design, implementation and monitoring of the long-term rebuilding plan will be critical.

6. Conclusion

COVID-19 has created a human crisis of unprecedented scale, which is disproportionately impacting one billion people with disabilities. This requires an unprecedented response—an extraordinary scale-up of support and political commitment—to ensure that people with disabilities have access to essential services, including to immediate health and social protection services, to tide over the crisis.

A disability inclusive COVID-19 response and recovery will better serve everyone. It will provide for more inclusive, accessible and agile systems capable of responding to complex situations, reaching the furthest behind first. It will pave the way for a better future for all.

21

P-10

Reportable

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION

Suo Motu Writ Petition (Civil) No.3 of 2021

IN RE: DISTRIBUTION OF ESSENTIAL SUPPLIES AND SERVICES DURING PANDEMIC.

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ORDER

This order has been divided into the following sections to facilitate analysis:

A Introduction

B Outline of the Disaster Management Act

C Medical Infrastructure

C.1 Submissions in UOI's Affidavits

C.2 National Policy for Admission in Hospitals

D Oxygen allocation and availability

E Vaccines

E.1 Vaccine capacity and disbursal

E.2 Vaccine pricing

F Potentiality of Compulsory Licensing for vaccines and essential drugs

G Supply of Essential Drugs

G.1 Submissions in the Central Government's Affidavits

G.2 Recommendations

G.3 Black Marketing

H Recommendations for augmenting healthcare workforce

I Epilogue

J Conclusion

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A

Introduction

1 The genesis of this *suo motu* writ petition is in an order dated 22 April 2021. This Court took note of the unprecedented humanitarian crisis in the country, following the outbreak of the COVID-19 pandemic. Notices were issued to the Union of India[1], the Governments of the States and Union Territories[2], and to several petitioners who were before the High Courts. The Court observed:

> "the Union Government, the State Governments/Union Territories and the parties, who appeared to have approached the High Courts to show cause why uniform orders be not passed by this Court in relation to
> a) Supply of oxygen;
> b) Supply of essential drugs;
> c) Method and manner of vaccination; and
> d) Declaration of lockdown"

The Court directed the Central Government to :

> "1. Report on the existence or otherwise and requirement of setting up of a coordinating body that would consider allocation of the above resources in a consultative manner (with the involvement of concerned States and Union Territories).
> 2. Consider declaration of essential medicines and medical equipment including the above articles as essential commodities in relation to COVID.
> 3. In respect of coordination of logistical support for inter-State and intra-State transportation and distribution of the above resources."

2 The Court also had appointed an *Amicus Curiae* to assist it. However, the *Amicus Curiae* was, on his request, relieved of his position on 23 April 2021. Hearings in the matter were then conducted on 27 April 2021, where the Court appointed two new *Amici*: Mr Jaideep Gupta and Ms Meenakshi Arora, learned Senior Counsel. They will be assisted by Mr Kunal Chatterjee and Mr Mohit Ram.

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[1] "UOI" referred interchangeably as "Central Government"
[2] Collectively referred as "State Government"

learned counsel and Advocate-on-Record. The Court began the hearing by noting that the jurisdiction it assumed under Article 32 did not automatically lead to the erosion of a High Court's jurisdiction under Article 226. Rather, the Court stressed on the importance of the jurisdiction under Article 226, and how High Courts may be better equipped to deal with issues within their own States. However, this Court assumed jurisdiction over issues in relation to COVID-19 which traverse beyond state boundaries and affect the nation in its entirety.

3 The Court noted that it was in receipt of an affidavit dated 23 April 2021 filed by the UOI. However, the Court directed the UOI to file an additional affidavit and the respective governments of the States/Union Territories to file fresh affidavits on four issues. The relevant extract of the order reads thus:

> "(i) Supply of oxygen – The Court should be apprised by the Union of India on
> (a) The projected demand for oxygen in the country at the present point of time and in the foreseeable future;
> (b) The steps taken and proposed to augment the availability of oxygen, meeting both the current and projected requirements;
> (c) The monitoring mechanism for ensuring the supply of oxygen, particularly to critically affected States and Union Territories as well as the other areas;
> (d) The basis on which allocation of oxygen is being made from the central pool; and
> (e) The methodology adopted for ensuring that the requirements of the States are communicated to the Central Government on a daily basis so as to ensure that the availability of oxygen is commensurate with the need of each State or, as the case may be, Union Territory.
>
> (ii) Enhancement of critical medical infrastructure, including the availability of beds, Covid treatment centres with duly equipped medical personnel on the basis of the projected requirement of healthcare professionals and anticipated requirements. The Union government will consider framing a policy specifying the standards and norms to be observed for admitting patients to hospitals and covid centres and the modalities for admission;

(iii) The steps taken to ensure due availability of essential drugs, including Remdesivir and Favipiravir among other prescribed drugs and the modalities which have been set up for controlling prices of essential drugs, for preventing hoarding and for ensuring proper communication of the requirements at the level of each District by the District health authorities or Collectors to the Health Departments of the States and thereafter by the states to the Union Ministry of Health and Family Welfare so that the projected requirements are duly met and effectively monitored on a daily basis.

(iv) Vaccination
(a) Presently two vaccinations have been made available in the country, namely, Covishield and Covaxin;
(b) As of date, the vaccination programme has extended to all citizens of the age of 45 years and above;
(c) From 1 May 2021, the vaccination programme is to be opened up also to persons between the age groups of 18 to 45, in addition to the existing age group categories. The Union of India shall clarify (i) the projected requirement of vaccines as a result of the enhancement of coverage, (ii) the modalities proposed for ensuring that the deficit in the availability of vaccines is met; (iii) steps proposed for enhancement of vaccine availability by sourcing stocks from within and outside the country; (iv) modalities for administering the vaccines to meet the requirements of those in the older age group (forty five and above) who have already received the first dose; (v) modalities fixed for administering the vaccine to meet the additional demand of the 18-45 population; (vi) how the supplies of vaccines will be allocated between various states if each state is to negotiate with vaccine producers; and (vii) steps taken and proposed for ensuring the procurement of other vaccines apart from Covishield and Covaxin and the time frame for implementation; and
(d) The basis and rationale which has been adopted by the Union government in regard to the pricing of vaccines. The government shall explain the rationale for differential pricing in regard to vaccines sourced by the Union government on one hand and the states on the other hand when both sources lead to the distribution of vaccines to citizens."

4 This Court then received an additional affidavit dated 29 April 2021 from the UOI, and fresh affidavits by the various States/UTs addressing the four issues mentioned in its order dated 27 April 2021. In the hearing conducted on 30 April 2021, this Court heard submissions by Mr Tushar Mehta, learned Solicitor

General of India, who was appearing on behalf of the Central Government. Several other counsels have made brief interjections, including Mr Vikas Singh, Senior Counsel and President of the Supreme Court Bar Association. This Court also heard a presentation on oxygen supply in India by Ms Sumita Dawra, Additional Secretary, Department of Promotion of Industry and International Trade, Ministry of Commerce and Industry. As such, unless specified otherwise, the directions and observations in the present order are limited to the UOI.

5 During the course of the hearing, this Court directed that the individual States/UTs shall be given an opportunity to discuss their affidavits at a later hearing. Further, the Court also directed the learned *Amici* to prepare a tabular compilation in relation to all the Interlocutory Applications which have been filed in this petition. On the basis of the issues raised, they shall also be considered in a later hearing. Before delving into a substantive discussion, we would like to clarify that the jurisdiction exercised in this matter is merely to facilitate a dialogue of relevant stakeholders, the UOI, the States and this Court, in light of the pressing humanitarian crisis, and not with a view to usurp the role of the executive and the legislature. This bounded-deliberative approach[3] is exercised so that the UOI and States can justify the rationale behind their policy approach which must be bound by the human rights framework which presently implicates the right to life under Article 21 and right to equality under Article 14 of the Constitution.

[3] Sandra Fredman, "Adjudication as Accountability: A Deliberative Approach" in Nicholas Bamforth and Peter Leyland (eds), *Accountability in the Contemporary Constitution* (Oxford University Press, 2013)

B Outline of the Disaster Management Act

6 The Disaster Management Act, 2005[4] came into effect on 26 December 2005. The DMA provides for the effective management of disasters and matters connected or incidental to such disasters. COVID-19 falls under the definition of a disaster under Section 2(d)[5] of the DMA and the provisions of the DMA were invoked for the first time to deal with the present pandemic. Under Section 6(2)(i) of the DMA, the National Disaster Management Authority[6] issued an order dated 24 March 2020 directing the Ministries, UOI, State/UTs and their authorities to take effective measures to prevent the spread of COVID-19 in the country. Thereafter, the Home Secretary, Ministry of Home Affairs as the Chairperson of the National Executive Committee, which assists the NDMA in its functions, in an order dated 24 March 2020 issued guidelines for the initial 21 days' lockdown on account of COVID-19.

7 Section 2(e) defines disaster management as a continuous and integrated process of planning, organizing, coordinating and implementing measures in relation to the disaster. Section 2(e) provides:

> "2...
> (e)"disaster management" means a continuous and integrated process of planning, organizing, coordinating and implementing measures' which are necessary or expedient for–
> (i) prevention of danger or threat of any disaster;
> (ii) mitigation or reduction of risk of any disaster or its' severity or consequences;
> (iii) capacity-building;

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[4] "DMA"
[5] "2...(d) "disaster" means a catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or man-made causes, or by accident or negligence which results in substantial loss of life or human suffering or damage to, and destruction of, property, or damage to, or degradation of, environment, and is of such a nature or magnitude as to be beyond the coping capacity of the community of the affected area;"
[6] "NDMA"

(iv) preparedness to deal with any disaster;
(v) prompt response to any threatening disaster situation or disaster;
(vi) assessing the severity or magnitude of effects of any disaster;
(vii) evacuation, rescue and relief;
(viii) rehabilitation and reconstruction;.."

Section 2(n) of DMA defines a "National Plan" as the plan for disaster management for the whole country prepared under Section 11 of DMA. Section 3 of the DMA constitutes the NDMA with the Prime Minister as the Chairperson, *ex officio*. Section 6 lists down the powers and functions of the NDMA. Under Section 6(2)(b), NDMA has the power to approve the National Plan. Section 11 of the DMA provides the procedure for drawing up and implementation of the National Plan in the following terms:

"11. National Plan
(1) There shall be drawn up a plan for disaster management for the whole of the country to be called the National Plan.
(2) The National Plan shall be prepared by the National Executive Committee having regard to the National Policy and in consultation with the State Governments and expert bodies or organisations in the field of disaster management to be approved by the National Authority.
(3) The National Plan shall include--
(a) measures to be taken for the prevention of disasters, or the mitigation of their effects;
(b) measures to be taken for the integration of mitigation measures in the development plans;
(c) measures to be taken for preparedness and capacity building to effectively respond to any threatening disaster situations or disaster;
(d) roles and responsibilities of different Ministries or Departments of the Government of India in respect of measures specified in clauses (a), (b) and (c).
(4) The National Plan shall be reviewed and updated annually.
(5) Appropriate provisions shall be made by the Central Government for financing the measures to be carried out under the National Plan.
(6) Copies of the National Plan referred to in sub-sections (2) and (4) shall be made available to the Ministries or Departments of the Government of India and such Ministries

or Departments shall draw up their own plans in accordance with the National Plan."

8 A National Plan includes, *inter alia*, measures for disaster prevention, mitigation, preparedness and roles and responsibilities of different Ministries in terms of Section 11(3) of DMA. A National Plan for the entire country was prepared in the year 2016 and was revised and notified in November, 2019. The National Plan, 2019 provides a framework to the Government agencies to deal with different aspects of disaster management. Section 11(4) of the DMA provides that the National Plan is to be revised and updated annually making it a 'dynamic document'. The executive summary of the National Plan succinctly captures its purpose and contours in the below extract:

> "...The National Disaster Management Plan (NDMP) provides a framework and direction to the government agencies for all phases of disaster management cycle. The NDMP is a "dynamic document" in the sense that it will be periodically improved keeping up with the emerging global best practices and knowledge base in disaster management. It is in accordance with the provisions of the DM Act, 2005, the guidance given in the National Policy on Disaster Management (NPDM) 2009, and the established national practices..."

9 Section 12 of the DMA empowers the NDMA to recommend guidelines for the minimum standard of relief to be provided to persons affected by disaster. NDMA can create guidelines stipulating minimum standards of relief for providing ex gratia assistance on account of loss of life and restoration of means of livelihood in terms of Section 12(iii) of DMA. In light of the human suffering and loss of livelihood that has accompanied this pandemic, NDMA may consider laying down minimum standards of relief in this regard. We clarify that this is not

a direction of this Court, however a suggestion that can be looked into by the NDMA. Under Section 12(iv) of the DMA, the NDMA has been given wide powers to provide guidelines for any such relief that may be necessary.

10 In addition to the above provisions, Section 35 of the DMA empowers the Central Government to take measures which it deems to be necessary or expedient for the purpose of disaster management. Section 35(2)(a) provides for coordination of actions between the Central Government and State Governments and their respective authorities in relation to disaster management. Section 35(2)(e) obliges the Central Government to assist and cooperate with the State Governments as requested by them or otherwise deemed appropriate by it.

11 Section 36 of DMA provides for the responsibilities that have to be undertaken by the Ministries or Departments of the Central Government. While Section 36(h) empowers the Central Government to take any actions that it may consider necessary for disaster management, Section 36(d) specifically enables it to review its policies with a view to incorporate provisions necessary for prevention of disaster, mitigation or preparedness. Under Section 36(f), it is the responsibility of every Ministry or Department of Central Government to provide assistance to the State Governments for (i) drawing up mitigation, preparedness and response plans, capacity-building, data collection and identification and training of personnel in relation to disaster management; (iii) carrying out rescue and relief operations in the affected area; (iii) assessing the damage from any disaster; and (iv) carrying out rehabilitation and reconstruction. Section 35(g) provides that the Central Government is responsible for making available its resources to the National Executive Committee or a State Executive Committee

for the purposes of, *inter alia*, transporting personnel and relief goods to and from the affected area.

12 The provisions of Sections 35 and 36 of the DMA that have been discussed above have been enacted in the spirit of cooperative federalism in order to ensure that Central Government can assist and enable the State Governments to effectively tackle the disaster in question.

13 The learned Solicitor General has submitted that the Central Government is operating under the broad framework of the National Plan and the plan is already in force. The plan specifically deals with "Biological and Public Health Emergencies". Further, different States have their own Disaster Management Plans in place. It has been submitted that the National Plan does not and cannot contain step by step instructions or specific directions for the day to day management of the pandemic by the Government agencies. Such aspects are kept open for executive decision, in view of the dynamic nature of the disaster in question. Further, since COVID-19 is a novel virus, the knowledge in relation to such a virus is contemporaneous in nature and is subject to constant development. A three Judge bench of this Court in its judgement in **Centre for Public Interest Litigation vs Union of India**[7] had noted that there was no need to develop a fresh National Plan under Section 11 for COVID-19 since a National Plan was already in place, which was being supplemented by various orders and measures taken by competent authorities under DMA. Justice Ashok Bhushan, speaking for this Court, observed that:

[7] 2020 SCC OnLine SC 652

> "40. The Disaster Management Act, 2005 contain ample powers and measures, which could be taken by the National Disaster Management Authority, National Executive Committee and Central Government to prepare further plans, guidelines and Standard Operating Procedure (SOPs), which in respect to COVID-19 had been done from time to time. Containment Plan for Novel Coronavirus, 2019 had been issued by Ministry of Health and Family Welfare, Government of India. There were no lack of guidelines, SOPs and Plan to contain COVID-19, by Nodal Ministry had been brought on record issued by Ministry of Health and Family Welfare, Government of India, i.e., Updated Containment Plan for Large Outbreaks Novel Coronavirus Disease, 2019 (COVID-19)."

14 Therefore, the National Plan, 2019 can be supplemented by the issuance of additional guidelines to tackle any aspect of disaster management including the issue of admission to hospitals and access to essential drugs and vaccines in respect of COVID-19.

C Medical Infrastructure

C.1 Submissions in UOI's Affidavits

15 In relation to the broad issue of medical infrastructure, the Central Government begins its affidavit dated 23 April 2021 and additional affidavit dated 29 April 2021 by describing its 'three-tier setup' of Covid Care Centers[8], Dedicated COVID Health Centers[9] and Dedicated COVID Hospitals[10] which was recommended to the States for tackling the COVID-19 pandemic, for which the UOI also provided funds under an emergency response package from the National Health Mission and State Disaster Response Fund.

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[8] 'CCC'
[9] 'DCHC'
[10] 'DCH'

The present status of these is: (i) 2,084 DCH (of which 89 are under the Central Government and the rest 1,995 with State Governments), (ii) 4,043 DCHC; and (iii) 12,673 CCC. Cumulatively, they have 18,52,265 beds in total, out of which 4,68,974 beds are in DCH. It was also noted that Central Government hospitals have also been converted into DCH.

17 Further, tertiary care hospitals under ESIC, Defence, Railways, paramilitary forces, Steel Ministry, *et al*, are also being leveraged for case management. Even as many as 3816 railways coaches spread over 16 railway zones have been converted into CCC. Finally, the DRDO has also set up large field hospitals with capacities ranging from 1,000 to 10,000 isolation beds.

18 It was noted that through coordination between Central Government and State Governments, isolation beds (with/without oxygen) were increased to around 15.7 lakhs, as compared to 10,180 before the first lockdown; similarly, ICU beds were increased to more than 85,000, as compared to 2,168 before the first lockdown. Similar upgrades were provided to necessary equipment such as Ventilators, N95 masks and PPEs.

19 The affidavit provides the following details of the efforts taken by UOI to create projections for each State, and how it was communicated to them:

(i) It has developed an IT module for projections of expected cases based on ongoing caseload, so as to alert States and districts to be prepared in advance. The projections by the Central Government were regularly shared in writing with the States, along with reports containing emergency

plans. This tool was also made available to States, to map their own projections at the State level;

(ii) Details of the meetings conducted by the Prime Minister, the Minister of Health and Family Welfare, the Cabinet Secretary, the Secretary (H) and the DGHS were provided; and

(iii) Details of letters (which seem to have been sent on a monthly basis) sent by the Central Government to the State Governments indicate that they informed the State Governments of the projected cases for the coming month, along with the number of Oxygen Supported Beds, ICU Beds and of Ventilators that will be required to manage the projected cases. Thereby, the State Governments which were found lacking in their numbers were directed to ramp up their facilities.

20 In relation to the preparedness for the second wave of the COVID-19 pandemic, the affidavits state that:

(i) After the first wave, the Central Government has been consistently writing to the State Governments from 4 December 2020 with numbers of projected cases, along with the directions requiring them to arrange the necessary infrastructure which will be needed;

(ii) State Governments were requested by the UOI to formulate a comprehensive plan in relation to:

(a) Bed capacities, ICU beds, further identification of additional hospitals, preparation of field hospital facilities, ensuring sufficient oxygen supported beds and oxygen supplies;

(b) Deployment of requisite HR training and mentoring of doctors and nurses for management of patients, strengthen ambulance services and centralized call center-based services for allocation of beds;

(c) Suitable initiatives for (among other things) achieving and maintaining adequate level of testing, surveillance and risk communication for promoting wearing of masks, physical distancing, hand hygiene;

(d) Sufficient referral linkages for districts with deficit infrastructure through deployment of additional ambulances, wherever necessary; and

(iii) On 20 April 2021, the Ministry of Health and Family Welfare[11] wrote to the State Governments with their projections and reminded them also of the funding avenues being made available to all States under NHM funding, State Disaster Response Fund, and other initiatives.

21 The affidavits also note that the Central Government had developed a live portal with all the States and districts where they were asked to feed in their data of cases and details such as people under home isolation, on isolation beds (with or without oxygen) and on ICU beds. Further, the State Governments were also directed to feed in details of the COVID dedicated health care infrastructure created by them, besides the details of containment zones so specified by them. However, the Central Government has alleged that States and districts did not upload their data regularly enough. Additionally, there was also a 'Facility App' which could be used by Covid Health facilities to monitor their patients as well as the availability of logistics with their health facility. However, the Central

[11] "MoHFW"

Government alleges that States, districts and facilities did not use this Facility App.

C.2 National Policy for Admission in Hospitals

22 It has been submitted by the Central Government that health being a state subject, the medical infrastructure is largely created and maintained by the respective State Governments. Since we are yet to hear from the State Governments, we shall not be issuing any directions or making comprehensive observations in relation to this issue.

23 However, based on the affidavits submitted by the Central Government and the hearings which followed, we have come to understand that there is no national policy on how admissions must take place in the various tiers of hospitals (CCC, DCHC and DCH). Gaining admission into a hospital with a bed is one of the biggest challenges being faced by most individuals during this second wave of the COVID-19 pandemic. Left to their own devices, citizens have had to suffer immeasurable hardship. Different states and local authorities follow their own protocols. Differing standards for admission in different hospitals across the nation leads to chaos and uncertainty. The situation cannot brook any delay. Accordingly, we direct the Central Government to frame a policy in this regard, in exercise of its statutory powers under the DMA, which will be followed nationally. The presence of such a policy shall ensure that no one in need is turned away from a hospital, due to no fault of their own. Such a policy should, *inter alia*, address the following issues in relation to admission:

Requirement of a positive test for COVID-19 virus, which may become difficult for many individuals since testing facilities are overwhelmed, test results are taking inordinately long time and the new strain of the COVID-19 virus is sometimes not even picked up by a regular RT-PCR test;

(ii) Some patients are being refused service based on arbitrary factors. For example, the hospitals in Ahmedabad were initially refusing to take in patients who did not arrive in the government-run '108' ambulances. While this rule has now been removed, after objections were noted by the Gujarat High Court during hearings in a *suo motu* public interest litigation[17], we note that such rules cannot be allowed to crop up in other places;

(iii) Some reports have also been brought to our attention that hospitals are refusing to admit individuals who cannot produce a valid ID card which shows that they belong to the city where the hospital is located. Given how overstretched our hospitals are during the second wave of the COVID-19 pandemic, it is entirely plausible that individuals may travel to other cities in desperation, since beds may not be available in their city. The rural health infrastructure is seriously deficient. Hence, no hospital should be allowed to deny them entry solely based on this reason or any other issues with identity proofs;

(iv) A related issue is when individuals often get their family member admitted in a hospital in one city, but have to travel to another city to look for oxygen or essential drugs and are denied their use because they are to be bought

[17] **Suo Motu vs State of Gujarat**, RWrit Petition (PIL) No 53 Of 2021

for an individual admitted in a different city. As was true for the above such rule, this is also unacceptable and should not be allowed;

(v) Admissions to hospital must be based on need. The Central Government, in consultation with the respective State Governments, must formulate guidelines on the stage at which hospitalization is required so as to ensure that scarce hospital beds are not occupied by persons who do not need hospitalization. This aspect should be based on the advice of medical experts and can be suitably altered given the needs of each State (or regions within the State) and in the course of the experiences gained during the pandemic; and

(vi) Directions are hereby issued to all States, Union Territories, and all public agencies, to ensure that the above orders are implemented forthwith. The Central, State and Union Territory governments shall issue necessary orders and circulars, incorporating the above directions, within three days, which shall be in force till replaced by an appropriate uniform policy, devised by the central government, statutorily.

Oxygen allocation and availability

24 The Central Government has argued the following:

(i) By its order dated 11 September 2020, the Ministry of Home Affairs[13], in exercise of its powers under Section 10(2)(h) of the DMA had constituted an Empowered Group-II as an inter-ministerial body to ensure availability of essential medical equipment and oxygen management;

(ii) Medical oxygen is critical to treatment of COVID affected patients. The entire available capacity of oxygen is used for supply for industrial and medical use, which is in the form of Liquid Medical Oxygen[14]. The major suppliers for both industrial and medical oxygen are steel plants in the public and private sectors, and private entities;

(iii) Oxygen is not produced evenly in India. While some States may be oxygen producing States such as Maharashtra, Rajasthan and Jharkhand; other States/UTs such as Delhi, Goa and Madhya Pradesh, do not have production capacity and rely on supply of oxygen from oxygen producing States;

(iv) For an estimation of the required oxygen supply, an Empowered Group I was constituted which categorized patients into three categories:

- Class I comprising of 80% of the cases which are mild and do not require oxygen;

[13] "MHA"
[14] "LMO"

- Class II comprising of 17% cases which are moderate and can be managed on non-ICU beds and 50% of these may require oxygen @10L/min; and
- Class III comprising of 3% of cases which are severe ICU cases requiring approximately 24L/min oxygen.

(v) On the basis of the categorization provided by Empowered Group I, oxygen requirement of different States on the basis of active cases is being calculated which is around 8462 MT. Based on the trend of active cases, the "doubling rate of cases" is calculated for each State, which implies, the number of days in which COVID cases are likely to double. The number of active cases are projected on the basis of the doubling rate and oxygen requirement is calculated. These projections get changed daily on the basis of real time change;

(vi) In order to ensure supply of oxygen to all States, a mapping exercise of the sources of supplies with the demand of medical oxygen to the critically affected States was undertaken jointly by the Department of Promotion of Industry and Internal Trade, MoHFW, Ministry of Steel, Petroleum and Explosives Safety Organisation, oxygen manufacturers etc. During the course of the mapping exercise, States were requested to indicate their projections for requirement of medical oxygen based on expected active case load. These projections were to be given as on 20 April, 25 April, and 30 April 2021. The following was the forecast provided by the major States:

S. No.	State	Forecast for requirement for medical oxygen (MT) as on		
		Apr-20	Apr-25	Apr-30
1	Maharashtra	1500	1750	2000
2	Uttar Pradesh	400	650	800
3	Chhattisgarh	215	295	382
4	Karnataka	300	155	111
5	Kerala	89	99	104
6	Delhi	300	349	445
7	Tamil Nadu	200	320	465
8	Madhya Pradesh	445	565	700
9	Rajasthan	125	124	124
10	Gujarat	1000	1050	1200
11	Haryana	180	180	180
12	Punjab	126	82	82
	TOTAL	4880	5619	6593

(vii) Based on these projections, an indicative mapping framework was drawn up and approved by an order dated 15 April 2021, which provided the name of the supply point, the State to which supply was allocated and the quantity to be supplied. Subsequently, due to continuous changes in the number of cases and the need for medical oxygen, a revised projection was issued by States for 20 April 2021, which provided:

S. No.	State	Forecast for requirement for medical oxygen (MT) for 20th April		
		Initial	Revised	Remarks
1	Maharashtra	1500	1500	-
2	Uttar Pradesh	400	800	100% increase
3	Chhattisgarh	215	215	-
4	Karnataka	300	300	-

S. No.	State	Forecast for requirement for medical oxygen (MT) for 20th April		
		Initial	Revised	Remarks
5	Kerala	89	89	-
6	Delhi	300	700	133% increase
7	Tamil Nadu	200	200	-
8	Madhya Pradesh	445	445	-
9	Rajasthan	125	147	18% increase
10	Gujarat	1000	1000	-
11	Haryana	180	180	-
12	Punjab	126	126	-
13	Telangana	-	350	-
14	Andhra Pradesh	-	400	-
15	Uttarakhand	-	75	-
	TOTAL	4880	5619	

(viii) Following this, a revised supply plan for medical oxygen to 15 States for meeting their demand was issued by an order dated 18 April 2021. Certain States, such as Delhi, Rajasthan, Punjab, Uttar Pradesh, Uttarakhand and Madhya Pradesh, faced challenges despite this allocation. Issues such as logistical bottlenecks in transportation, incidents of local authorities in disrupting supplies to other states were reported. Due to this, allocation orders were further amended by orders dated 21 April 2021, 22 April 2021, 24 April 2021, 25 April 2021 and 26 April 2021. The MHA also issued orders dated 22 April 2021 and 25 April 2021 under the DMA to direct States/UTs to ensure uninterrupted movement of medical oxygen;

(ix) The major principles on the basis of which the amendments were made were to: (a) ensure that projected requirement of LMO is allocated as far as possible; (b) allocate sources located within the State or closest to the State while balancing requirements from States which have no/low internal

manufacturing capacity; (c) ensure feasible transportation; (d) ensure minimum disruptions in existing supply chains;

(x) As an instance, the allocation summary for 28 April 2021 has been placed on record:

Sl No	State	Production Capacity on 28/04/2021 (MT)	Need of State (MT)	Existing Allocation (MT)	Oxygen taken by the respective States as 24/04/2021 (MT)
1	Maharashtra	1209.18	1784	1784	1389.19
2	Goa	No Bulk Manufacturing Plant	11	11	
3	Gujarat	847.00	1000	975	904.20
4	Dadra & Nagar Haveli	No Bulk Manufacturing Plant	20	20	
5	Karnataka	625.00	770	802	441.19
6	Madhya Pradesh	No Bulk Manufacturing Plant	649	649	613.82
7	Delhi	No Bulk Manufacturing Plant	470	490	361.99
8	Haryana	246.86	180	232	228.64
9	Uttar Pradesh	244.00	857	857	640.68
10	Punjab	No Bulk Manufacturing Plant	137	177	180.38
11	Chandigarh		20	40	
12	Tamil Nadu	366.00	280	220	396.68

(xi) After the Central Government procures and allocates the quantity of medical oxygen to each State, it is the State Government's responsibility to arrange transportation to pick up their allotted quantity from the supply point;

(xii) Given the fact that the mapping exercise has to be continuously updated according to the need of the situation across States, the Central Government also put in an interactive mechanism called the "Virtual Central Control Room" consisting of senior officers of Additional/Joint Secretary rank to monitor and find solutions to any problems that may arise on a real time basis. We have been apprised that the daily allocation of the

supply of oxygen is sanctioned and uploaded on this virtual room, in which the Chief Secretaries of all States/UTs are members;

(xiii) In addition to the management of supply and demand of medical oxygen, the Central Government has also taken the following steps to ensure augmentation of supply in the country:

(a) **Licenses to industrial gas manufacturers:** By an order dated 7 April 2020, the Drug Controller General of India[15] allowed licenses to be issued to industrial gas manufacturers for manufacturing medical oxygen within 24 hours of receipt of the application by DCGI;

(b) **Enhanced production of LMO in steel plants and by private manufacturers:** Steps have been taken to reduce production of other liquid products which are required for manufacturing steel (such as argon and nitrogen) and enhance the capacity of liquid oxygen. This has resulted in immediate enhancement of 293 MT. Additionally, the steel sector has made available the liquid oxygen in its storage tanks (approx. 16,000 MT as on 21 April 2021). Supplies have increased from 1000 MT in the first week of April 2021 to 2600 MT on 21 April 2021. Moreover, private manufacturers have also enhanced production of medical oxygen;

(c) **Restrictions on use of industrial oxygen:** By an order dated 18 April 2021, the MoHFW restricted industrial use of oxygen. Supply of oxygen for all industrial use was completely prohibited on 21 April 2021, except for certain industries such as ampoules and vials; pharmaceuticals;

[15] "DCGI"

petroleum refineries; nuclear energy facilities; and oxygen cylinder manufacturers. These have added 1000 MT of additional oxygen;

(d) **Augmentation in availability of tankers:** India has 1224 oxygen tankers (16732 MT capacity) and efforts are being made to increase this capacity to 2000 tankers through conversion of nitrogen and argon tankers and import of 138 cryogenic tankers;

(e) **Commissioning of PSA plants:** Pressure Swing Absorption[16] is a technology to generate oxygen at a local level. PSA plants established in hospitals enable self-sufficiency in generation of oxygen. MoHFW is in the process of commissioning 162 PSA Plants (154 MT capacity). The following statistics have been furnished :

Number of plants installed:	38
Number of plants to be installed by 30 April 2021	21
Number of plants to be installed by 31 May 2021	105
Number of plants to be installed by 30 June 2021[17]	51
Number of PSA Plants for district headquarters (under planning)	500

(f) **Import of medical oxygen:** A global tender was floated to import 50,000 MT of medical oxygen to be supplied in 90 days and quotations have been received. As an interim measure, quotations from bidders were called within 24 hours as to the quantities they could offer, prices etc. Orders have been placed with 2 foreign suppliers, i.e., SSB Cryogenic Equipment Ltd. for 200 MT and Gulf Industrial Gases Abu

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[16] "PSA"

[17] As per the affidavit dated 23 April 2021, the UOI has stated that "a further 105 plants will be installed by 31.05.2021 and thereafter increasing to 156 plants by 30.06.2021."

Dhabi for 1800 MT. Another order is also being placed with M/s Ultra-Pure Gases India for import of 500-1500 MT;

(g) **Augmentation of availability of cylinders:** 1,02,400 oxygen cylinders were procured in April and May 2020 and distributed to States. Orders for additional 1,27,000 cylinders were placed on 21 April 2021. The Central Government proposes to address the additional demand through regulated portable oxygen system technology;

(h) **Setting up of jumbo container based COVID hospitals using gaseous oxygen:** Apart from LMO, the gaseous oxygen production capacity in the steel sector is 43,000 MT per day against which 26,000 MT per day is being produced. Two private entities, AMNS and JSW are setting up "Jumbo" COVID centres with 1000 bed oxygen facilities in Hazira, Vijayanagar and Dolvi using gaseous oxygen; and

(i) **Transportation by Air & Rail:** Railways are being used for long distance transport of tankers through 'roll on roll off' service and an "Oxygen Express" - a double engine train which gets a green corridor - is being run from supply point to destination. As an instance, the first rake with 7 empty tankers reached Mumbai from Vizag to transport 105 MT from RINL Vizag to Kalamboli. In addition to this, defence aircraft for carrying empty tankers to supply point are being deployed. However, it is technically not possible to bring in oxygen filed tankers in an aircraft.

25 During the course of the hearing, the Solicitor General has also sought to lay down the facts and figures pertaining to production and supply of oxygen, daily supply to States and challenges faced in supply chain logistics before the

Court by means of a power point presentation. We note the submission of the Solicitor General that the figures given in the power point presentation are revised on a daily basis and that the presentation is not to be treated as a submission made on oath by the Solicitor General, which may give rise to a cause of action for litigation in future either before this Court or the High Courts. Ms Sumita Dawra, Additional Secretary, Department of Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, who is one of the senior administrative officers in charge of oxygen procurement and supply coordination, has given an overview of these issues and made a presentation before us. We would like to record our appreciation for the contribution made by Ms Dawra and her team, who despite being infected by the COVID-19 virus, has continued to work and manage the supply of medical oxygen that the country so desperately needs today. It is through the earnest contribution of officers such as Ms Dawra, who are working round the clock, that the country is able to deal with the storm created by one of the worst humanitarian crises we have seen.

26 Based on the above facts and figures, the Solicitor General has stated that there is no dearth of oxygen supply in the country as on date and steps are being taken continuously to augment the supply of oxygen. Having said that, the Solicitor General has also admitted that there has been a shortage of supply to certain States and has attributed this shortage to various factors including the failure of State Governments to lift the allocated quantity of oxygen from the supply point; transportation bottlenecks caused by inter-State movement of tankers; and technical failure of certain plants leading to reassessment of allocation on a real time basis.

27 Submissions have also been made on the issue of supply of oxygen by Mr Rahul Mehra, learned Senior Counsel appearing for the Government of National Capital Territory of Delhi[18]. Mr Rahul Mehra submits that the GNCTD is facing an acute shortage of the supply of oxygen as it had been allocated a substantially lower quantity of oxygen as against its projected demand. Mr Mehra pointed out that initially as on 15 April 2021, the projected demand of GNCTD for 20 April 2021 was 300 MT/day, for 25 April 2021 it was 349 MT/day, and for 30 April 2021 it was 445 MT/day. However, due to a surge in cases, the projected demand was revised by GNCTD on 18 April 2021 to 700MT/day and this was immediately communicated to the Central Government. Despite the increase in projected demand, the supply of oxygen to GNCTD has continued in terms of the allocation order dated 25 April 2021, in which 490 MT/day were allocated. As against this as well, the manufacturers have only been able to supply 445 MT/day. Mr Mehra has clarified that as on the date of the hearing their demand was 700MT/day, however their projected demand for the coming days is stated to be 976 MT/day as the GNCTD has planned an increase in medical infrastructure, including beds with oxygen cylinders and beds for patients in intensive care unit.

28 Opposing his submission, the Solicitor General and Ms Dawra stated that no revised projections have been received from GNCTD till date. The Solicitor General has also sought to highlight that the government of GNCTD has failed to offtake the allocated quantity of oxygen from the supply point.

29 Having heard the submissions of both counsels on the issues pertaining to supply of oxygen to GNCTD, we note that the Central Government (on page 63)

[18] 'GNCTD'

its affidavit dated 23 April 2021 has admitted that the projected demand for GNCTD as of 20 April 2021 had increased by 133% from 300 MT/day to 700 MT/day. According to the figures of allocation given in the affidavit dated 23 April 2021 and the presentation given by Ms Dawra, the existing allocation of GNCTD remains at 490 MT/day. This situation must be remedied forthwith. The situation on the ground in Delhi is heart rending. Recriminations between the Central Government (which contends that GNCTD has not lifted its allocated quantity) and GNCTD (which contends that despite its projected demand the quantity allocated has not been enhanced) can furnish no solace to citizens whose lives depend on a thin thread of oxygen being available. On the intervention of the Court during the hearing, the Solicitor General states that he has instructions to the effect that GNCTD's demand of medical oxygen will be met and that the national capital will not suffer due to lack of oxygen. We issue a peremptory direction in those terms. In the battle of shifting responsibility of supplying/off-taking of oxygen, lives of citizens cannot be put in jeopardy. The protection of the lives of citizens is paramount in times of a national crisis and the responsibility falls on both the Central Government and the GNCTD to cooperate with each other to ensure that all possible measures are taken to resolve the situation. Learned Senior Counsel for GNCTD has assured the court after taking instructions at the 'highest' level that the issue will be resolved completely in a spirit of co-operation. During the course of the hearing, the Solicitor General has assured that henceforth he will ensure that the deficit of oxygen is rectified and supply is made to the GNCTD according to their projected demand (which may be revised in the future) on a day by day basis. We accept his submission and

direct compliance within 2 days from the date of the hearing, that is, on or before midnight of 3 May 2021.

30 With regard to the issue of the supply and availability of medical oxygen for the entire country, we have noted that efforts are being made to augment the availability of oxygen. While the Central and State Governments are in the process of managing the supply of oxygen, at the same time, it is critical that a buffer emergency stock of oxygen is created so that in the event that the supply chain is disrupted to any one or more hospitals in an area for any reason, the buffer or emergency stocks can be used to avoid loss of human lives. These emergency stocks must be so distributed so as to be easily accessible without delay in every local area. We have also seen the situation that has developed in the last 24 hours in Delhi where patients, including among them medical professionals, died because of the disruption of supplies and the time lag in the arrival of tankers. This deficit shall be rectified immediately by the Central Government by creating buffer stocks and collaborating with the States through the virtual control room on a 24 by 7 basis. In view of the deaths which are being caused daily by the disruption of supplies, this direction is more crucial than ever. We therefore, direct the Central Government in collaboration with the States to prepare a buffer stock of oxygen to be used for emergency purposes to ensure supply lines continue to function even in unforeseen circumstances. The location of the emergency stocks shall be decentralised so as to be immediately available if the normal supply chain is disrupted to any hospital for any reason. The emergency stocks shall be created within the next four days. The replenishment of the emergency stocks will also be monitored on a real time basis through the

virtual control room in active consultation with each state/UT. This is in addition to the day to day allocations.

31 In addition to the above, we direct the Central Government to consider the following suggestions, which may assist in increasing the availability of oxygen and ensure transparency of demand-supply management, and provide a clarification to this Court:

(i) We understand that the Virtual Central Control Room of the Central Government displays the allocation of supply of oxygen by the Central Government to each State/UT. By extension of this, a mechanism for displaying real time updates of supply of oxygen from each State to hospitals in each district, along with the remaining stock of oxygen with the hospitals may be maintained and shared with the citizens to ensure transparency. This will also ensure that citizens can easily identify the hospitals where medical aid can be availed;

(ii) The government shall clarify the steps being taken on planning on the use of oxygen concentrators to reduce the demand of LMO, such that LMO is needed only for critical patients. A comprehensive plan on augmenting the production/import of these oxygen concentrators may be considered;

(iii) The expected supply of oxygen/containers to be received from outside India should be suitably augmented to cater to anticipated increases in the demand and shortfall of domestic availability. Pending the early finalization of the global tender a decision may be taken on the need to continue imports to bridge the gap in availability; and

(iv) A review shall be made of any restrictions on inter-State travel of trucks or tankers carrying oxygen/other medical aid equipment (such as GST related issues, documentation) which might cause a hindrance in their movement.

The Central Government may consider implementing a system to track and map the supply tankers which would allow better management of resources and allow diversion of resources from one State to the other in case of emergencies.

Vaccines

32 The previous order of this Court dated 27 April 2021 directed the Central Government to clarify, *inter alia*: (i) the projected availability of vaccines and proposed steps to boost supply and distribution; and (ii) the vaccine pricing and distribution *among* states. Upon perusing the affidavits filed by the Central Government and after having the benefit of oral arguments of the Solicitor General, we have arrived at the following understanding on the two broad issues outlined above. We would once again re-iterate that we do not attempt to delve into the role of the executive in designing policy choices. We are merely seeking to enter into a dialogue with the relevant stakeholders in order to ensure probity and transparency of the measures underway. We are cognizant that it is ultimately up to the executive to frame and implement policies that it deems appropriate, with the topmost regard to public interest.

E.1 Vaccine capacity and disbursal

33 The Central Government has apprised us of its constitution of a National Expert Group on Vaccine Administration for COVID-19[19] on 7 August 2020 and operationalization of the immunization programme from December 2020. It was further stated that as of 26 April 2021, over 13.5 crore vaccine doses (approx. 9% of the Indian population) have been administered to Frontline Workers, Healthcare Workers and persons who are 45 years of age and higher in the 3 Phases of immunization. It was submitted that these vaccines have been

[19] "NEGVAC"

centrally procured and administered free of cost to the abovementioned groups who were identified based on specific vulnerabilities and a higher mortality rate on account of the COVID-19 infection.

34 On 20 April 2021, the Central Government rolled out a revised strategy of COVID-19 vaccination for all persons over 18 years of age, with effect from 1 May 2021. This new age group consists of approximately 59 crore people, which would require 122 crore vaccine doses under the current two-dose vaccine regime of Covishield and Covaxin which have been authorized for emergency use in India. This revised strategy enables vaccine procurement by State Governments and private hospitals, purportedly for accelerating the immunization programme which is critical to curb the pandemic. In response to the query of this Court on the necessity of the revised strategy, the Central Government furnished the following justification:

> "During the ongoing consultation with the states, demands/concerns were raised by the various State Governments to expand the scope of vaccination drive to include the beneficiaries beyond the priority groups identified by NEGVAC as approved by Central Government. As a matter of co-operative federalism, it was felt necessary to allow play in the joints and to de-centralize vaccine procurement and to enable the States to expand vaccination drives to other groups between the age of 18-44 years. However, since the priority group as identified by Union of India (which had more vulnerability) was not fully vaccinated, it was considered imperative to carry out two drives separately i.e. in a decentralized manner to achieve higher efficiency and reach. Thus the States were given a participatory role to undertake the procurement of vaccine and for vaccination of any other 'groups identified drive' for the 18-44 age group. This would also keep the existing drive of critical groups unobstructed as the 50 percent of the vaccines procured through the GoI channel would continue to support and provide free of cost vaccine to the most vulnerable age groups of 45 years plus in the country health care workers and frontline worker

identified by the Union of India who were entitled to get vaccinated under Phase II."

(emphasis supplied)

35 In response to the queries of the Court on how the supplies of vaccines will be allocated between various states if each State Government is to negotiate with vaccine producers, the Central Government has furnished the following justification in order to iron out the inequities between States:

"For the remaining 50% non-government of India channel, the states and the private hospitals are free to procure vaccine for 18-44 years population, however, to have an equitable distribution of vaccine across the country, states have been allocated the available vaccine quantity in proportion to the population between 18-44 years of age of the respective state so as to ensure equitable distribution of vaccine as there is a possibility of some states having better bargaining power due to geographical advantage etc."

(emphasis supplied)

36 During the course of the hearing, this Court has expressed its reservations *prima facie* on the validity of the revised policy under which the states and private hospitals are to procure 50% of the vaccines in order to immunize persons in the 18-44 years age group. For one thing, even this age group would consist of persons who suffer from vulnerabilities. Once the vaccination programme has been opened up for persons other than the 45 plus age group, it would not be logical to impose the obligation to source vaccinations for the 18-44 age group on the State Governments. This will, *inter alia*, leave each State Government to negotiate supply schedules, delivery points and other logistical arrangements with the manufacturers. At present, there are only two manufacturers for the authorized vaccines (with one other vaccine - Sputnik V, in the process of

manufacture). The available stock of vaccines is not adequate to deal with the requirements of both the categories. The Central Government must take the responsibility of providing guidance to every State on the quantities to be supplied to each State, the vaccine(s) being allocated, the period of delivery, and the number of persons who can be covered for vaccination, among other details. Leaving the State Governments to negotiate directly with manufacturers will produce chaos and uncertainty. The object of vaccinating the 18-44 age group cannot be achieved in the absence of stocks being available.

37 Besides the above issues, the Central Government is directed to clarify the following issues in order to ensure the protection of the fundamental rights to equality and to life and personal liberty for all persons who will be eligible to take the vaccine from 1 May 2021:

(i) Whether the Central and State Governments have introduced any initiatives for ensuring the immunization of persons who do not have access to digital resources as otherwise the mandatory requirement of registration over the Co-WIN digital portal for persons in the age group of 18-44 years will deprive a large class of citizens of vaccination;

(ii) Since the Central Government commits to vaccinating persons over 45 years, free of cost, in view of their vulnerability, whether walk-in facilities for vaccination will continue for these persons after 1 May 2021;

(iii) Whether the Central or State Governments propose to undertake targeted vaccination drives for persons who are providing on-ground assistance during the second wave of the pandemic - such as crematorium workers,

who were not considered as Frontline or Healthcare workers for Phase 1 of the vaccination drive;

(iv) Whether, and if so what, steps being undertaken by INYAS, the nation-wide mass awareness campaign for COVID-19 vaccination, for ensuring outreach in rural areas and socio-economically underprivileged sections of society including the possibility of using mobile vans, vehicles and railways to vaccinate such people as well as those living in remote areas, near their doorsteps so as to minimize their travel and potential infection with COVID-2019. Efforts must also be made that a lack of an identity proof does not create a hindrance in the process of immunization of all individuals, specifically, the underprivileged;

(v) Whether the Central government will revisit its policy by procuring 100% of the doses which can then be equitably disbursed to the State Governments; and

(vi) Since the vaccine administration is now to be a shared responsibility of the Union and the States, the Central Government and the State Governments shall provide- (a) a breakup of the current and projected availability of vaccine stocks for the next 6 months; and (b) a timeline for achieving immunization of the newly eligible 59 crore persons who are aged between 18-44 years.

These issues are of vital importance, since vaccination appears to be one of the most important strategies to combat further spread of the pandemic, and would also provide a measure of security and assure the people about their health and well-being.

Vaccine pricing

38 Since the advent of the revised rollout strategy with effect from 1 May 2021, only persons aged 45 years and above are guaranteed a free vaccine. The reason of higher efficiency and speed has been furnished as a justification for enabling State Governments and private hospitals to directly procure vaccines. We have come to understand that a few State Governments have committed to free immunization under the revised strategy. On specific enquiry on the rationale in regard to the differential pricing for procurement by the Central Government and the State Governments, the Central Government has furnished the following justification:

> "It is submitted that liberty to decide prices on arm's length basis by and between the State Government and hospitals is based on the concept of creating an incentivized demand for the private vaccine manufacturers in order to instill a competitive market resulting in increased production of vaccines and market driven affordable prices for the same. Simultaneously, the free vaccination by the Central Government for above referred priority age groups would continue and it is always open for each State Government either to offer free vaccination or subsidise it for the additional identified earmarked priority group identified by the State Governments [age 18-44 years].
>
> 63. The new strategy was devised after multiple Inter-Ministerial teams were deputed by Govt. of India to various manufacturing sites to understand their requirement and to provide pro-active and customized support to significantly augment vaccine production capacities [which is the prime priority of the Central Government at this juncture], in the form of advance payments, facilitating more sites for production etc. This approach, on the one hand, incentivizes vaccine manufacturers to rapidly scale up their production and on the other hand, it would also attract new vaccine manufacturers. It would make pricing, procurement and administration of vaccines more flexible and competitive and would further ensure augmented vaccine production as well as wider availability of vaccines in the country."
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> (emphasis supplied)

39 *Prima facie*, there are several aspects of the vaccine pricing policy adopted by the Central government which require that policy be revisited. All vaccines, whether in the quantity of 50% purchased by the Central Government or the remaining 50%, are to be used for vaccinating citizens. The end use is the same. The Central Government proposes to purchase half of the total quantity falling within its fifty per cent quota while for the rest, the manufacturers would declare in advance the price to be fixed, allowing the State Governments to negotiate their terms. As of date, the manufacturers have suggested two different prices, a lower price which is applicable to the Central Government and a higher price which is applicable to the quantities purchased by the State Governments. It is likely that compelling the State Governments to negotiate with manufacturers on the ground of promoting competition and making it attractive for new vaccine manufactures will result in a serious detriment to those in the age group of 18 to 44 years, who will be vaccinated by the State Governments. The social strata of this age group also comprises persons who are *Bahujans* or belong to other under privileged and marginalized groups, like many in the other population age groups. They may not have the ability to pay. Whether or not essential vaccines will be made available to them will depend upon the decision of each State Government, based on its own finances, on whether or not the vaccine should be made available free or should be subsidized and if so, to what extent. This will create disparity across the nation. The vaccinations being provided to citizens constitute a valuable public good. Discrimination cannot be made between different classes of citizens who are similarly circumstanced on the ground that while the Central government will carry the burden of providing free vaccines for the 45 years and

above population, the State Governments will discharge the responsibility of the 18 to 44 age group on such commercial terms as they may negotiate. *Prima facie*, the rational method of proceeding in a manner consistent with the right to life (which includes the right to health) under Article 21 would be for the Central Government to procure all vaccines and to negotiate the price with vaccine manufacturers. Once quantities are allocated by it to each State Government, the latter would lift the allocated quantities and carry out the distribution. In other words, while procurement would be centralized, distribution of the vaccines across India within the States/UTs would be decentralized. While we are not passing a conclusive determination on the constitutionality of the current policy, the manner in which the current policy has been framed would *prima facie* result in a detriment to the right to public health which is an integral element of Article 21 of the Constitution. Therefore, we believe that the Central Government should consider revisiting its current vaccine policy to ensure that it withstands the scrutiny of Articles 14 and Article 21 of the Constitution.

40 In light of the justification offered for non-interference in the prices that are set by the manufacturers, irrespective of their variance from the prices for procurement of the Central Government, we would like to seek the following clarifications:

(i) Whether any other alternatives were considered by the Central Government for ramping up the immunization drive in India, particularly in light of its initial strategy of a centralized free immunization drive;

(ii) The methodology which the Central Government was envisaging to procure adequate vaccine doses for the population prior to the revised strategy which was announced amidst the second wave of COVID-19; and

(iii) Whether any studies and figures were relied upon in order to arrive at the conclusion that decentralized procurement would spur competitive markets to incentivize production and eventually drive down the prices of the vaccines. Whether these studies are of relevance in a pandemic when vaccines are a scarce and essential commodity which is being produced by a limited number of manufacturers for a limited number of vaccines.

41 The Central Government has submitted that the Finance Ministry has sanctioned a credit of Rs 3000 crores for Covishield manufacturer - Serum Institute of India[20] and Rs 1500 crores to Covaxin manufacturer - Bharat Biotech. Additionally, another Rs 65 crores is stated to have been provided to Bharat Biotech's production center at Bangalore. In bolstering its argument for augmentation of vaccine production, the Central Government has provided the Court with further information on advance funding (of unspecified amounts) that is being provided to R&D and manufacturing facilities. In light of this investment, the Central Government should consider revisiting its policy bearing in mind what has been stated above, the following issues and other relevant information:

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[20] "SII"

Whether, and if so, the Finance Ministry or any other funding organization of the Government of India have made any grants/sanctions to Bharat Biotech and the SII in the past, like the current infusion of Rs 1500 crores and Rs 3000 crores, respectively. If so, breakup and corelation with the total cost of development and production of the two vaccines;

(ii) Whether the current procurement prices for the Central Government account for infusion of funds for production, infrastructure and other aid provided by it. If so, the basis on which the same benefit is denied to procurement by State Governments which equally service the needs of citizens; and

(iii) The full extent of direct and indirect grant/aid provided for research, development and manufacture of all existing vaccines and future vaccines that it proposes to authorize. For instance, the Central Government has submitted in its affidavit that the Department of Biotechnology has facilitated the trials for Sputnik V.

F Potentiality of Compulsory Licensing for vaccines and essential drugs

42 Several drugs that are at the core of the COVID treatment protocol are under patents in India including Remdesivir, Tociluzumab and Favipiravir. On 2 October 2020, a communication was issued by the UOI, along with South Africa, to the Council for Trade-Related Aspects of Intellectual Property which stated that there were several reports about intellectual property rights hindering timely

provisioning of affordable medical products to patients[21]. The communication also reported that some members of the World Trade Organization had carried out urgent amendments to their national patent laws to expedite the process of issuing compulsory/government use licenses.

43 In India, the patent regime is governed by the Patents Act, 1970[22]. Section 92 of which envisages the grant of a compulsory license, *inter alia*, in circumstances of national emergency and extreme urgency. Once a declaration of national emergency is made, and the relevant patents notified, any person interested in manufacturing the drug can make an application to the Controller General of Patents who can then issue a compulsory license. The patentee would be paid a reasonable royalty as fixed by the Controller General of Patents. Further, under Section 100 of the Patents Act, the Central Government can authorize certain companies to use any patents for the "purpose of the government". Indian companies can begin manufacturing the drugs while negotiating the royalties with the patentees. If the Central Government or its authorized company is not able to reach an agreement with the patentee, the High Court has to fix the reasonable royalty that is to be paid to the patentee. Another alternative is for the Central Government to acquire the patents under Section 102 from the patentees. If the Central Government and the patentee is not able to reach a consensus on the price of the patents, it is up to the High Court to fix the royalty. Additionally, under Section 66 of the Patents Act, the Central Government is also entitled to revoke a patent in the public interest.

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[21] Council for Trade-Related Aspects of Intellectual Property Rights, Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of Covid-19, Communication From India And South Africa, IP/C/W/669, 2nd October, 2020, available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q/IP/C/W669.pdf&Open=True

[22] "Patents Act"

The utilization of these flexibilities has also been detailed in the Trade Related Aspects of Intellectual Property Rights Agreement[23]. Even as TRIPS obliges countries to ensure a minimum level of patent protection, it creates a permissive regime for the carving out of exceptions and limitations that further public health objectives[24]. This is evident from a conjoint reading of Articles 7, 8, 30 and 31 of TRIPS. Article 7 outlines the objectives of the TRIPS as being to ensure the effective enforcement of intellectual property in a way that, *inter alia*, is 'conducive to social and economic welfare'. Article 8 gives member countries the freedom to take measures that protect public health and nutrition. Article 8(2) allows for the taking of TRIPS-compatible measures aimed at preventing the abuse of intellectual property rights. Articles 30 and 31 deal with exceptions to the rights of patent owners, by allowing grant of compulsory licenses. It leaves countries with significant breathing space to determine how the compulsory licensing or government-use levers can be triggered. While such determinations must be made on the individual merits of each case[25], the aforesaid caveat does not apply when the compulsory license grant is for national emergency, extreme urgency or public non-commercial use[26].

45 According to the 2001 Doha Declaration, TRIPS should be interpreted in a manner supportive of the right of members to protect public health and to promote access to medicines[27]. It recognizes the right of WTO members to use the full extent of the TRIPS flexibilities to secure this objective. Para 5(b) of the Doha

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[23] 'TRIPS'
[24] Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines Promoting Innovation and Access to Health Technologies, (United Nations Secretary-General, 2016), p. 16.
[25] TRIPS Agreement, Article 31(a)
[26] TRIPS Agreement, Article 31(b)
[27] World Trade Organization, 'Ministerial Declaration of 14 November 2001' (November 2001) WT/MIN(01)/DEC/1, 41 ILM 746, para 4

Declaration provides the freedom to each member to grant compulsory licenses and to determine the grounds on which the licenses are granted. Para 5(c) leaves it up to each nation to determine what constitutes a national emergency or extreme urgency. In the context of the COVID-19 pandemic, we note that several countries such as Canada and Germany have relaxed the legal regimes governing the grant of compulsory licenses[28].

46 Whether and if so, the extent to which these provisions should be utilized is a policy decision for the Central Government. We have flagged the issue for its consideration. We have only outlined the legal framework within which the Central Government can possibly consider compulsory licensing and government acquisition of patents. The Central Government is free to choose any other course of action that it deems fit to tackle the issue of vaccine requirements in an equitable and expedient manner, which may involve negotiations with domestic and foreign producers of vaccines. We clarify that it is up to the Central

[28] 'COVID-19 IP Policy Tracker' (WIPO, 16 July 2020), *available at* https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access

Government to choose the best possible measures it can undertake during the current crisis keeping in mind that public interest is of paramount importance.

G Supply of Essential Drugs

G.1 Submissions in the Central Government's Affidavits

47 In relation to the broad issue of "Supply of Essentials", in its affidavit dated 23 April 2021 and additional affidavit 29 April 2021, with respect to Remdesivir, the UOI urged that:

(i) Remdesivir is a patented drug which is being manufactured in India under licensing agreements between the patent holder, M/s Gilead, a US based company and seven Indian companies. Under such agreements, these Indian companies are allowed to manufacture Remdesivir for distribution;

(ii) In its affidavit dated 23 April 2021, it was submitted on behalf of the Central Government that the current production is about 74 lakhs vials per month and once the additional manufacturing sites of the seven manufacturers become operational by May 2021, the production capacity will increase to 90 lakhs vials per month. In its additional affidavit dated 29 April 2021, the Central Government has submitted that as on 23 April 2021, the production capacity has increased to 1.03 crore vials per month;

(iii) The Central Government allocated 11 lakhs vials of Remdesivir to nineteen States with a high case load between 21 to 30 April through a letter issued on 21 April 2021. This allocation was revised and expanded to all States and UTs through a letter issued on 24 April 2021;

(iv) The Central Government has directed the States to appoint nodal officers to ensure unrestricted and timely movement of Remdesivir. A control room has been set up in this regard by the National Pharmaceutical Pricing Authority[29] which is monitoring supplies as allocated. A helpline has been set up by NPPA and manufacturers have been directed to address the hindrances in the movement of the drug. A WhatsApp group with nodal officers has also been created to enable coordination and officials of MHA, NPPA and CDSCO are also part of the group;

(v) Remdesivir, its Active Pharma Ingredients[30] and formulations have been placed under export ban since 11 April 2021;

(vi) The Ministry of Finance has issued a notification on 20 April 2021 exempting customs duty on the Remdesivir injection, and API of Remdesivir and Betacyclodexterin, which are used in the manufacture of the injection. All the SEZ/EOU manufacturing units of M/s Mylan and M/s Honous Lab, who are manufacturing Remdesivir on behalf of some of the seven manufacturers have also been directed to start manufacturing Remdesivir for domestic supply;

(vii) CDSCO has directed all State Drug Controllers on 10 April 2021 to conduct a special investigation drive to prevent hoarding and black-marketing of Remdesivir in the country. DCGI and State Drug Controllers have been taking stringent action against such activities and enforcement action has been taken in thirty-four cases across the country;

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[29] "NPPA"
[30] "API"

(viii) MHA has issued an advisory on 22 April 2021 to States and Union Territories to facilitate smooth movement of supplies. A "Covid Drug Management Cell" consisting of the Department's Senior Officers and others has been constituted on 26 April 2021 to oversee and identify common concerns raised by States in relation to Remdesivir;

(ix) NPPA has revised the maximum retail price of a 100 mg/vial of Remdesivir to Rs 3500; and

(x) The Central Government is also looking at the possibility of importing Remdesivir.

48 The UOI made the following submissions on the availability of Tociluzumab injections:

(i) Tociluzumab is manufactured by a Swiss Company, M/s Roche, which does not have any manufacturing facility in India or any agreements with domestic pharma companies to manufacture the drug. It is imported in the country by Cipla. India is completely dependent on imports;

(ii) It is listed as an investigational therapy drug (off-label) under the National Clinical Management Protocol for COVID-19 for severe cases. There are domestically produced alternatives which are equivalent to or better than Tociluzumab such as itulizumab, dexamethasone and methyl prednisolone. However, an incorrect public perception has been created that only Tociluzumab can treat the inflammatory burst condition in COVID-19 patients since it is an imported drug. This has led to the acute shortage in the availability of the drug and has created public panic; and

(iii) The supply of Tociluzumab is being monitored by NPPA and CDSCO.

The UOI has made the following submissions on the availability of other drugs:

(i) The National Clinical Management Protocol for COVID-19 does not include Favipiravir (popularly known as Fabiflu) due to insufficient peer reviewed evidence to substantiate its use in mild to moderate cases of COVID-19. However, it is being prescribed by certain doctors. The clinical management protocol is a dynamic document which is reviewed periodically and is subject to further evaluation based on medical research and evidence that comes up in future; and

(ii) On 24 April 2021, Department of Pharmaceuticals[31], NPPA and DCGI had reviewed the production and supply of other drugs such as Favipiravir, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine. A meeting was conducted on 25 April 2021 by NPPA and DCGI with manufacturers to review stock position, availability and production plans.

G.2 Recommendations

50 In respect of the essential drugs, this Court has been informed that the Central Government is taking steps to augment the production of Remdesivir. It has been brought to our notice that seven Indian companies are manufacturing this drug under a licensing agreement with a US based company, M/s Gilead. The current production capacity as on 23 April 2021 is noted to be at 1.03 crores vials per month. The Central Government should provide us with the details of the actual rate of production and a breakup of demand for the drug from different

[31] 'DoP'

States. Further, while it has been submitted on behalf of the Central Government that it is allocating the stocks based on a rational criterion of equitable distribution keeping in mind the existing constraints on the availability of the drug, this Court should be provided with details of the methodology used for such allocation.

51 We have been informed by the Central Government in its affidavit that NPPA has revised the maximum retail price of Remdesivir to Rs 3500. However, it has come to our notice that several other drugs which are being prescribed by doctors for treating COVID-19 patients like Favipiravir, Tociluzumab, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine are being priced at exorbitant rates creating issues of access and affordability. While this is not a direction of this Court, the Central Government can consider invoking its statutory powers under paragraphs 19 and 20 of the Drugs Price Control Order, 2013. Under paragraph 19[32] of the Drugs Price Control Order, 2013 the Government in extraordinary circumstances, if it considers necessary in public interest, can fix a ceiling price or retail price of the drug for a certain period. COVID-19 is a crisis of an unprecedented nature and qualifies as an extraordinary circumstance. It will be in public interest to ensure that the price of essential drugs is fixed in such a manner that it is available even to the most marginalized sections of the society. The Government can even monitor the prices of the drugs under paragraph 20[33] of the Drugs Price Control Order, 2013

[32] "19. Fixation of the Ceiling Price Under Certain Circumstances. Notwithstanding anything contained in this order, the Government may, in case of extraordinary circumstances, if it considers necessary to do so in public interest, fix the ceiling price or retail price of any drug, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index of that year."

[33] "20. Monitoring the Prices of Non-Scheduled Formulations. (1) the Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to

and ensure that no manufacturer increases the prices of the drugs by more than 10% of the maximum retail price during the preceding 12 months and where the increase is beyond 10% of the maximum retail price, it can oblige the manufacturer to reduce it to the level of 10% for the next 12 months.

52 The Central Government has submitted that it plans to import Remdesivir. It can also consider importing other essential drugs to meet the immediate demand of the drug while the production is ramped up. We hasten to clarify that this does not constitute a direction of this Court and ultimately this decision falls under the domain of the executive.

53 We note that there are certain medicines which are being prescribed by doctors which are not mentioned in the National Clinical Management Protocol for COVID-19 like Favipiravir. However, since these medicines are being prescribed by doctors, people are facing significant inconvenience in obtaining them due to their shortage in certain parts of the country. The Central Government should consider whether the production of such medicines should be augmented to meet the demand or instructions should be given to the doctors to not recommend such medicines unless they have been included in the national protocol.

54 It has been submitted on behalf of the Central Government that on 24 April 2021, DoP, NPPA and DGCI reviewed the production and supply of drugs such as Favipiravir, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine. The supply of Remdesivir and Tociluzumab is already under the consideration of the Central Government. A meeting was also held on

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the level of ten percent of maximum retail price for next twelve months. (2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of the increase in price in addition to the penalty."

25 April 2021 by DoP, NPPA and DGCI with the manufacturers to review stock position, availability and production plans. The Central Government should provide details of estimated demand of essential drugs mentioned above, production capacity, existing stocks, details of allocation and supply of such drugs.

55 As discussed in **Section F**, the Central Government can also consider using its powers under Sections 92, 100 or 102 of the Patents Act to increase production of essential drugs to ensure that it is commensurate to the demand. The Central Government's affidavit testifies to existence of capacity of public sector organizations and institutes, which can assist in augmenting production of various drugs and formulations. The utilization of these capabilities to augment production, once licensing is resorted to, will be in the interests of the general public. This Court is further of the opinion that *prima facie* the present circumstance warrant the government's examination of its the extraordinary powers, meant to be used in extreme situations, such as the current pandemic, for fixing drug prices, be it vaccines, or patented formulations, having regard to the provisions of the Drugs and Cosmetics Act, 1940 and other provisions[34]. We are cognizant that invocation of the above provisions, if any, is ultimately a policy decision of the Central Government and may encompass negotiations with the concerned stakeholders. We hope that the Central Government will adopt a route that best serves the public interest.

[34] Paragraph 3 and 19 of the Drugs Price Control Order, 2013.

G.3 Black Marketing

56 This Court would like to take judicial notice of the fact that several critical drugs, used to treat COVID-19, such as Remdesivir and Tocilizumab, are being sold at significantly inflated prices or in fake form. This is a condemnable attempt to exploit people's misery and profit from their helplessness.

57 In order to clamp down on this practice, the Central Government can consider constituting a special team to identify and prosecute those who: (a) sell medical grade oxygen/COVID-19 medicines at exorbitant prices; and (b) sell fake substances and recover the concerned substances. A protocol for ambulances must also be evolved to avoid citizens being exploited by extracting unconscionable charges. The Central Government can consider creating a platform for easy reporting and redressal of such cases.

H Recommendations for augmenting healthcare workforce

58 It is common knowledge that a large number of medical, nursing and pharmacy students, who graduated in 2020 and would be in the process of graduating in 2021, would be available to augment the workforce in the health sector. The Central Government should, we feel, look into this aspect, and ensure the optimal manner of utilization of their services, regard being had, of course, to their safety and well-being.

59 The Central Government should also consider using health care workforce available with the armed forces and para military forces for the purpose of vaccination.

Epilogue

60 The World Health Organisation[35], while discussing the rapid spread of COVID-19 has not only labelled it an epidemic but also an "infodemic", due to the overabundance of information on the internet, which was riddled with misinformation and disinformation[36]. This highlights the key role internet and technology currently has in all our lives, as the COVID-19 pandemic rages on. Indeed, the WHO recently also conducted a study to understand how individuals between the ages of 18-40 years dealt with the ongoing pandemic using social media[37].

61 It is only appropriate then that when many cities in India are suffering through the second wave of the COVID-19 pandemic, many have turned to the internet, using applications/websites to find critical support. On these platforms, online communities led by members of the civil society and other individuals, have assisted the needy in multiple ways – often by helping them procure oxygen, essential drugs or find a hospital bed through their own networks or by amplifying original requests, and even by offering moral and emotional support. However, it is with deep distress that we note that individuals seeking help on such platforms have been targeted, by alleging that the information posted by them is false and has only been posted in social media to create panic, defame the administration or damage the "national image". We do not hesitate in saying that such targeting

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[35] "WHO"

[36] "Managing the COVID-19 infodemic: Promoting healthy behaviours and mitigating the harm from misinformation and disinformation - Joint statement by WHO, UN, UNICEF, UNDP, UNESCO, UNAIDS, ITU, UN Global Pulse, and IFRC" (*WHO*, 23 September 2020) available at <https://www.who.int/news/item/23-09-2020-managing-the-covid-19-infodemic-promoting-healthy-behaviours-and-mitigating-the-harm-from-misinformation-and-disinformation>

[37] "Social media & COVID-19 A global study of digital crisis interaction among Gen Z and Millennials" (*WHO*, 23 September 2020) available at <https://www.who.int/news-room/feature-stories/detail/social-media-covid-19-a-global-study-of-digital-crisis-interaction-among-gen-z-and-millennials>

shall not be condoned, and the Central Government and State Governments should ensure that they immediately cease any direct or indirect threats of prosecution and arrest to citizens who air grievances or those that are attempting to help fellow citizens receive medical aid. If this does keep happening even after the current order, this Court shall be constrained to use the powers available to it under it contempt jurisdiction. We also direct that all Directors General of Police shall ensure compliance down the ranks of the police forces within their jurisdictions.

62 In these trying times, those desperately seeking help for their loved ones on these platforms should not have their misery compounded through the actions of the State and its instrumentalities. Further, there are two more crucial reasons why such a clampdown on information sharing must be absolutely stopped immediately.

63 The first reason is because sharing information widely is in itself an important tool in combating public tragedies, like the current COVID-19 pandemic. In **K.S. Puttaswamy (Privacy-9J.)** vs **Union of India**[38], one of us (DY Chandrachud, J) speaking for four Judges of a nine-Judge bench of this Court noted academic literature documenting the widespread availability of information and the resultant acknowledgement of the problem is what prevented the drought in Maharashtra in 1973 from becoming as bad as the Bengal Famine of 1943, where the British tried to deny the problem even existed. It was noted thus:

> "267. Civil and political rights and socio-economic rights do not exist in a state of antagonism. The conditions necessary for realising or fulfilling socio-economic rights do not postulate

[38] (2017) 10 SCC 1

the subversion of political freedom. The reason for this is simple. Socio-economic entitlements must yield true benefits to those for whom they are intended. This can be achieved by eliminating rent-seeking behaviour and by preventing the capture of social welfare benefits by persons who are not entitled to them. Capture of social welfare benefits can be obviated only when political systems are transparent and when there is a free flow of information. Opacity enures to the benefit of those who monopolise scarce economic resources. **On the other hand, conditions where civil and political freedoms flourish ensure that governmental policies are subjected to critique and assessment. It is this scrutiny which subserves the purpose of ensuring that socio-economic benefits actually permeate to the underprivileged for whom they are meant. Conditions of freedom and a vibrant assertion of civil and political rights promote a constant review of the justness of socio-economic programmes and of their effectiveness in addressing deprivation and want. Scrutiny of public affairs is founded upon the existence of freedom. Hence civil and political rights and socio-economic rights are complementary and not mutually exclusive.**

268. Some of these themes have been addressed in the writings of the Nobel laureate, Amartya Sen. Sen compares the response of many non-democratic regimes in critical situations such as famine with the responses of democratic societies in similar situations. [Amartya Sen, Development as Freedom (Oxford University Press, 2000) at pp. 178-79.]...

269. In the Indian context, Sen points out that the Bengal famine of 1943 "was made viable not only by the lack of democracy in colonial India but also by severe restrictions on reporting and criticism imposed on the Indian press, and the voluntary practice of "silence" on the famine that the British-owned media chose to follow" [Amartya Sen, The Idea of Justice (Penguin Books, 2009) at p. 339.] . Political liberties and democratic rights are hence regarded as "constituent components" of development. [Id, at p. 347] In contrast during the drought which took place in Maharashtra in 1973, food production failed drastically and the per capita food output was half of that in sub-Saharan Africa. Yet there was no famine in Maharashtra where five million people were employed in rapidly organised public projects while there were substantial famines in sub-Saharan Africa. This establishes what he terms as "the protective role of democracy". Sen has analysed the issue succinctly:

"The causal connection between democracy and the non-occurrence of famines is not hard to seek. Famines kill millions of people in different countries in the world, but they

> don't kill the rulers. The kings and the presidents, the bureaucrats and the bosses, the military leaders and the commanders never are famine victims. And if there are no elections, no opposition parties, no scope for uncensored public criticism, then those in authority don't have to suffer the political consequences of their failure to prevent famines. Democracy, on the other hand, would spread the penalty of famines to the ruling groups and political leaders as well. This gives them the political incentive to try to prevent any threatening famine, and since famines are in fact easy to prevent (the economic argument clicks into the political one at this stage), the approaching famines are firmly prevented." [Amartya Sen, Development as Freedom (Oxford University Press, 2000) at p. 180.]..."

(emphasis supplied)

As such, preventing clampdowns on sharing of information on online platforms is not just in the interest of individuals sharing the information, but the larger democratic structures of our nation. Without the ready availability of such information, it is entirely possible that the COVID-19 pandemic may turn into a tragedy worse than what it already is.

64 The second reason is because sharing information widely will help in the creation of a "collective public memory" of this pandemic. The presence of collective public memory, which refers "*to an extant and taken-for-granted group memory*"[39], is important for the creation of knowledge of the problems plaguing us today, so they may be passed on across time[40]. This is important since we do not have to travel back too much in our past to realise that the pandemic caused by the "Spanish" flu of 1918, which is said to have infected every third person in the world and killed between 50-100 million individuals (compared to the 17 million

[39] Theodore O. Prosise, "The collective memory of the atomic bombings misrecognized as objective history: The case of the public opposition to the national air and space museum's atom bomb exhibit", (1998) 62 Western Journal of Communication 3 316-347, pg 318.

[40] Bryan Hubbard and Marouf A. Hasian, "Atomic Memories of the 'Enola Gay': Strategies of Remembrance at the National Air and Space Museum" (1998) 1 Rhetoric and Public Affairs 3 363-385, pg 364.

who died in World War I), has been almost entirely erased from our collective public memory[41]. Therefore, the widespread sharing of information by individuals living through the COVID-19 pandemic becomes crucial. Furthermore, the role of Courts in creating and preserving this collective public memory cannot be understated. Professors Austin Sarat and Thomas R. Kearns, in their book *History, Memory, and the Law*, describe the function that is played by Courts in the following terms[42]:

> "Law in the modern era is, we believe, one of the most important of our society's technologies for preserving memory. Just as the use of precedent to legitimate legal decisions fixes law in a particular relation to the past, memory may be attached, or attach itself, to law and be preserved in and through law. Where this is the case, it serves as one way of orienting ourselves to the future. **As Drucilla Cornell puts it: "Legal interpretation demands that we remember the future." In that phrase, Cornell reminds us that there are, in fact, two audiences for every legal act, the audience of the present and the audience of the future. Law materializes memory in documents, transcripts, written opinions; it re-enacts the past, both intentionally and unconsciously, and it is one place where the present speaks to the future through acts of commemoration.**
>
> **Because the litigated case creates a record, courts can become archives in which that record serves as the materialization of memory. Due process guarantees an opportunity to be heard by, and an opportunity to speak to, the future. It is the guarantee that legal institutions can be turned into museums of unnecessary, unjust, undeserved pain and death. The legal hearing provides lawyers and litigants an opportunity to write and record history by creating narratives of present injustices, and to insist on memory in the face of denial. By recording such history and constructing such narratives lawyers and litigants call on an imagined future to choose Justice over the "jurispathic" tendencies of the moment."**
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> **(emphasis supplied)**

[41] Jonathan Freedland, 'History suggests we may forget the pandemic sooner than we think' (*The Guardian*, 29 January 2021) available at <https://www.theguardian.com/commentisfree/2021/jan/29/history-forget-pandemic-spanish-flu-covid>

[42] Austin Sarat and Thomas R. Kearns, *History, Memory, and the Law* (University of Michigan Press, 2009) pgs 12-13

Hence, in the present proceedings, we hope to not only initiate a dialogue so as to better tackle the current COVID-19 pandemic but also to preserve its memory in our public records, so that future generations may evaluate our efforts and learn from them.

65 We speak not only as members of this Court, but also as grateful citizens of the country, and commend the outstanding work of our all healthcare professionals (doctors, nurses, healthcare workers, laboratory technicians, ward staff, ambulance drivers, crematorium workers etc.) during this crisis. They have truly gone beyond their call of duty and toiled day in and day out, relentlessly without rest amidst great challenges. It is absolutely necessary to take urgent steps for their well-being to ensure that our appreciation for their tremendous efforts is not reduced to rhetoric. This is especially important since another factor which affects how collective public memory of any event is created is by the rhetoric surrounding it[43]. As such, our public memory of this public event has to transcend its conception as a "war" against the virus of COVID-19 itself, but rather to remember that it is "*the complex epidemiological circumstances that promote these outbreaks and the under-resourced health systems that are tasked with disease containment*"[44]. While the healthcare professionals have been at the forefront of tackling this crisis, we have to recognize their contribution as medical healthcare professionals who have undertaken "*to protect public health using*

[43] Nicole Maurantonio, "The Politics of Memory" in Kate Kenski and Kathleen Hall Jamieson (eds) *The Oxford Handbook of Political Communication* (Oxford University Press, 2014)
[44] Luke Shors, "Waging Another Public Health "War?" (*Think Global Health*, 26 February 2020) available at <https://www.thinkglobalhealth.org/article/waging-another-public-health-war>

proven scientific evidence and best practices and to serve to community at large"[45], and not just as "CORONA WARRIORS".

66 We also do not hesitate to note that the treatment meted out to these public healthcare professional during this COVID-19 pandemic has sometimes been less than ideal. The following are some of the issues we wish to highlight:

(i) Recently, there were reports that the Pradhan Mantri Garib Kalyan Package Insurance Scheme, an insurance scheme of Rs 50 lakhs which had been extended to about 22 lakh healthcare professionals, was set to expire on 24 March 2021 and would not be renewed. While we are happy to note that UOI's affidavit of 23 April 2021 states that this Scheme has been extended for one year starting April 2021, we have also been informed that till date only 287 claims have been settled under it, which includes claims from the families of 168 doctors who died after contracting COVID-19 while treating patients. We direct the Central Government to inform this Court as to how many claims are pending under the Scheme, and the timeline within which the Central Government expects to settle them;

(ii) Healthcare personnel are at an obvious heightened risk of contracting the COVID-19 virus. However, we are aware of reports that indicate that infected healthcare personnel are left to fend for themselves without adequate availability of beds, oxygen or essential drugs. Further, some of them have also often been asked to report back to duty within 10 days of first testing positive for COVID-19 (provided they are asymptomatic), even

[45] Elena N. Naumova, "The traps of calling the public health response to COVID-19 "*an unexpected war against an invisible enemy*"" (2020) Journal of Public Health Policy (2020) 41 233-237, pg 233

though a longer recuperation period is often recommended. While we are dealing with a terrible second wave of the COVID-19 pandemic, there must be an effective policy to ensure that the nation truly acknowledges their effort and creates incentives for them. We hope it will be remedied soon by the Central and State Governments through the introduction of appropriate guidelines and measures;

(iii) It is unclear what measures are currently being taken to ensure that healthcare personnel can continue to serve others while not risking the health of their family members. We hope that the respective State Governments, with necessary assistance from the Central Government, can ensure this takes place; and

(iv) The Central Government should, we feel examine and ensure that in addition to the schemes it has framed, other facilities such as availability of food, resting facilities during intervals between work, transportation facilities, non-deduction of salary or leave account, if afflicted by COVID 2019 or related infection, overtime allowance, in both public and private hospitals, and a separate helpline for doctors, and healthcare professionals, in cases of COVID 2019 related emergencies, is provided. All these, we feel, would show these professionals that we do not show our appreciation in mere words, but also care for them.

67 The issues mentioned above are only symptomatic of the other broader issues that are being faced by healthcare professionals, who are instrumental in combating the pandemic. Hence, we hope their welfare is considered seriously by the Central and State Governments. Further, we would wish to use this order to

place on record our sincerest appreciation for all the public healthcare professionals - not just limited to the doctors, but also nurses, hospital staff, ambulance drivers, sanitation workers and crematorium workers. It is through their dedicated efforts that the effect of COVID-19 pandemic is being currently tackled in India.

68 In light of the continuing surge of infections in the second wave of the pandemic, we direct the Central Government and State Governments to put on record the efforts taken to curb the spread of the virus and the measures that they plan on taking in the near future. At the same time, we would seriously urge the Central and State Governments to consider imposing a ban on mass gatherings and super spreader events. They may also consider imposing a lockdown to curb the virus in the second wave in the interest of public welfare. Having said that, we are cognizant of the socio-economic impact of a lockdown, specifically, on the marginalized communities. Thus, in case the measure of a lockdown is imposed, arrangements must be made beforehand to cater to the needs of these communities.

J Conclusion

69 The present order has primarily considered the submissions (written and oral) of the UOI. These submissions have been reproduced here as a matter of public record and to contextualize the clarifications that are being sought by our Court in order to serve its dialogic role. We reiterate, for abundant caution, that the data and submissions reproduced above are not its endorsement or acceptance. In terms of the above discussion, we hereby pass the following directions:

(i) The UOI shall ensure, in terms of the assurance of the Solicitor General, that the deficit in the supply of oxygen to the GNCTD is rectified within 2 days from the date of the hearing, that is, on or before the midnight of 3 May 2021;

(ii) The Central Government shall, in collaboration with the States, prepare a buffer stock of oxygen for emergency purposes and decentralize the location of the emergency stocks. The emergency stocks shall be created within the next four days and is to be replenished on a day to day basis, in addition to the existing allocation of oxygen supply to the States;

(iii) The Central Government and State Governments shall notify all Chief Secretaries/Directors General of Police/Commissioners of Police that any clampdown on information on social media or harassment caused to individuals seeking/delivering help on any platform will attract a coercive exercise of jurisdiction by this Court. The Registrar (Judicial) is also directed to place a copy of this order before all District Magistrates in the country;

(iv) The Central Government shall, within two weeks, formulate a national policy on admissions to hospitals which shall be followed by all State Governments. Till the formulation of such a policy by the Central Government, no patient shall be denied hospitalization or essential drugs in any State/UT for lack of local residential proof of that State/UT or even in the absence of identity proof;

(v) The Central Government shall revisit its initiatives and protocols, including on the availability of oxygen, availability and pricing of vaccines, availability

of essential drugs at affordable prices and respond on all the other issues highlighted in this order before the next date of the hearing, that is, 10 May 2021. Copies of all affidavits to be served upon the *Amici* in advance; and

(vi) Several other suggestions have been made before this Court in IAs and writ petitions filed by diverse parties. In order to streamline the further course of hearing, we have requested the *Amici* to collate and compile these suggestions which would be taken up later. The present order has focused on certain critical issues in view of the urgency of the situation.

.....J.
[Dr Dhananjaya Y Chandrachud]

.....J.
[L Nageswara Rao]

.....J.
[S Ravindra Bhat]

New Delhi;
April 30, 2021

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 19.04.2021

CORAM :

The Hon'ble Mr.SANJIB BANERJEE, THE CHIEF JUSTICE

AND

The Hon'ble Mr.JUSTICE SENTHILKUMAR RAMAMOORTHY

W.P.No.2951 of 2021

Meenakshi Balasubramanian .. Petitioner

-vs-

1.The Union of India,
Rep. by its Secretary,
Ministry of Health and Family Welfare
Room No.348; 'A' Wing, Nirman Bhavan,
New Delhi 110 011.

2.The State of Tamilnadu,
Rep. by its Secretary,
Health and Family Welfare Department,
Fort St. George, Chennai 600 009. .. Respondents

Petition filed under Article 226 of the Constitution of India praying for issue of Writ of Mandaus to direct the 1st respondent to include Persons with Disability and their caregivers as a priory group for administering COVID-19 vaccine.

For Petitioner : Mr.A.Yogeshwaran

For Respondents : Mr.D.Simon
Central Govt. Stdg. Counsel
for R-1

: Mr.V.Jayaprakash Narayanan
State Government Pleader
for R -2

ORDER

(Made by The Hon'ble Chief Justice)

The matter pertains to disabled persons being given priority in the process of vaccination. Unfortunately, the complete lack of action on the part of the Union has delayed the matter and only today certain documents have been filed on behalf of the Union.

2. Pursuant to an observation made by this Court when the matter was last taken up and the Union was not represented, the State is agreeable to provide a separate counter at all vaccination centres run by the Government all over the State to vaccinate only persons with disabilities.

3. The petitioner seeks to make out that persons with disabilities are more vulnerable and claims that they are at least six times more at risk than others. The petitioner suggests that the age restriction that is otherwise in vogue, should not be applied to persons with disabilities.

4. As of now, the guidelines issued by the Union provide for vaccination to all persons who have crossed the age of 45, irrespective of whether they suffer from any co-morbidity. In addition, frontline workers even below the age of 45 and those who are at risk have been or are being administered the vaccine. However, as far as this Court is informed, vaccination is available only to adults.

5. The Court must be careful in issuing an order so that the good that is sought to be achieved thereby is not undone by an uninformed decision which may have an adverse effect. Accordingly, the statement of the State is recorded that all Government vaccination centres will have a separate counter throughout the day when vaccination is undertaken at such centres exclusively for persons with disabilities. At

any rate, persons with disabilities should be given priority in being vaccinated even if the numbers do not warrant an exclusive counter being set up at every Government vaccination centre. The Union has relied on a document appended at page 21 of the typed set filed on behalf of the Union on March 19, 2021. The last entry is in the form of a certificate to identify individuals with co-morbidities that enhance the risk of mortality. Item 20 in the list of criteria deals with persons with disabilities due to intellectual disabilities/muscular dystrophy/acid attack with involvement of respiratory system/person with disabilities having high support needs/ multiple disabilities including deaf-blindness.

6. Though the document apparently otherwise restricts the eligibility age of vaccination to 45 years and above, in the current context of all persons 45 years and above being eligible for vaccination, there would be no meaning to provide for an additional certificate if the form is also interpreted to apply only to those who have attained the age of 45. Accordingly, the State is directed to give priority to such persons suffering from disability as indicated in the relevant Annexure, irrespective of whether such person has attained

the age of 45 but subject to a previous reasoned basis being arrived at as to what would be the minimum appropriate age for a person to be vaccinated. Such decision should be taken by the State within the next three days and in consultation with the Union, if necessary. The primary consideration in determining the minimum age would be whether the various vaccines have an adverse impact on infants, children or persons who have not attained adulthood. The manufacturers may also be consulted in such regard as to the adverse effect of the relevant vaccination on persons upto or below a particular age.

7. It needs to be emphasized that every care should be taken to obtain information and arrive at a reasoned decision as to the appropriate age before the vaccination is opened up to persons suffering with disabilities or the kind of disabilities indicated in the relevant document relied upon by the Union. The State may also consider administering vaccine to persons above the age of 18 but suffering from any form of disability as indicated in the Schedule to the Rights of Persons with Disabilities Act, 2016 instead of confining it to the disabilities indicated in the Union's annexure. Every endeavour

should be made by the State to enable vaccination as expeditiously as possible to protect the lives of persons with disabilities. Immediate steps should be taken by the State to ensure that vaccination centres are accessible to persons with disabilities by constructing ramps or other measures in accordance with the said Act of 2016.

8. W.P.No.2951 of 2021 is disposed of. There will be no order as to costs.

(S.B., CJ.) (S.K.P., J.)
19.04.2021

Index : Yes/No

sra

To

1.The Secretary to Govt. of India,
Ministry of Health and Family Welfare
Room No.348; 'A' Wing, Nirman Bhavan,
New Delhi 110 011.

2.The Secretary to State of Tamilnadu,
Health and Family Welfare Department,
Fort St. George, Chennai 600 009.

The Hon'ble Chief Justice
and
Senthilkumar Ramamoorthy, J.

(sra)

W.P.No.2951 of 2021

19.04.2021

Daily Orders for Case WP 8475/2021

No	Judge(s) Name	Date of Order	Daily Order
1	CHIEF JUSTICE AND SURAJ GOVINDARAJ	23/04/2021	Issue notice to the respondents. The learned Additional Government Advocate takes notice for the first and second respondents. As this petition requires urgent consideration, list it before this Court on 26th April, 2021, as special sitting is supposed to be held on the said date. The learned counsel for the petitioner is at liberty to serve the Central Government Standing Counsel appearing for the third respondent about the date fixed in the matter.
2	CHIEF JUSTICE AND SURAJ GOVINDARAJ	27/04/2021	1. Heard the learned counsel appearing for the petitioner and the learned Advocate General and the learned Additional Government Advocate appearing for the respondents. 2. The issue raised in this petition concerns the vaccination of Covid-19 to persons with benchmark disability as defined in Clause (r) of Section 2 of the Rights of Persons with Disabilities Act, 2016 (for short, 'the Disability Act'). 3. Several difficulties in the way of persons with benchmark disabilities getting vaccination have been set out in the petition. There are written submissions filed by the learned counsel for the petitioner. He is placing reliance on the order dated 19th April 2021 passed by the High Court of Judicature at Madras in W.P.No.2951/2021. 4. In this petition, we are concerned with Section 25 of the Disability Act. It deals with healthcare. Clause (c) of Sub-Section (1) of Section 25 enjoins the appropriate government and local authorities to take necessary measures for the persons with disabilities to provide priority in attendance and treatment. The appropriate government is defined in Clause (b) of Section 2 of the Disability Act. 5. Thus, in view of Clause (c) of Sub-Section (1) of Section 25, the persons with benchmark disabilities must get priority in treatment. The treatment in the present day context will include covid-19 vaccination. 6. Our attention is invited to the Karnataka State Rights of Persons with Disabilities Rules 2019 (for short, 'the said Rules'). In each District, under Rule 28 of the said Rules, a District Level Committee on Disability is required to be constituted by the State Government of which District Disabled Welfare Officer is a Member Secretary. The functions of the District Level Committee have been set out in Rule 29 of the said Rules. Sub-Rule 6 of Rule 29 of the said Rules authorizes the State Government to assign any other functions to the District Level Committee. 7. The learned Advocate General assures the Court that necessary steps will be taken by the State Government in the light of the rights of the persons with benchmark disability as contemplated by Section 25 of the said Act of 2016. 8. The State Government will have to ensure that necessary assistance is rendered to the persons who are suffering from benchmark disabilities for the purposes of registering themselves for vaccination. The State Government may consider of issuing directions to the District Level Committee and District Disabled Welfare Officer to receive the applications either in the form of SMS, Whatsapp messages or email from the persons with disabilities and ensure that priority is given to the persons with benchmark disability in vaccination. 9. Needless to add that the object of providing the Covid-19 vaccination to persons with benchmark disabilities will be effective only if caregivers of the persons with benchmark disabilities are also provided vaccination on priority basis. 10. We therefore issue the following interim directions: a) The State Government shall immediately evolve a scheme/ mechanism for giving priority to vaccination of Covid-19 to the persons with benchmark disabilities; b) The State Government may consider authorising the District Disabled Welfare Officers or any other officers to receive requests for vaccination by SMS, Whatsapp or Email either from the persons suffering from benchmark disability and/or from respective caregivers; c) The State Government shall make effective arrangements for providing vaccination to the persons with benchmark disabilities and their caregivers by ensuring that they are not required to wait in the queue at vaccination centres; d) Needless to add that those persons who suffer from benchmark disabilities and who are unable to move out of their respective residences, necessary arrangements will have to be made for vaccination at the doorstep; e) We leave to the State Government how to evolve scheme/ mechanism for complying with the aforesaid directions; f) Steps taken by the State Government shall be placed on record by a memo on 12th May 2021 when this petition will be listed at 11.00 a.m.

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No	Judge(s) Name	Date of Order	Daily Order
3	CHIEF JUSTICE AND SURAJ GOVINDARAJ	12/05/2021	This petition be listed along with W.P.No.6435/2020 and connected matters on 13th May 2021.
4	CHIEF JUSTICE AND ARAVIND KUMAR	13/05/2021	adjourned

DISTRICT: KOLKATA

IN THE HIGH COURT AT CALCUTTA
CONSTITUTIONAL WRIT
JURISDICTION
(APPELLATE SIDE)

W.P.A(R) No. 159 of 2021

In the matter of:
An application under Article 226 of the Constitution of India.

And

In the matter of:
Covid Crisis Support Network & Ors
...Petitioners

-Versus-

The Union of India & Ors
...Respondents

APPLICATION

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