IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL WRIT JURISDICTION)

Writ Petition (Civil) No. ..... of 2021

IN THE MATTER OF:

Delhi Commission for Protection of Child Rights ...Petitioner

Versus

Union of India & Anr … Respondents

WITH

I.A. No. of 2021: An Application for Exemption from filing welfare stamp and Notarized Affidavit.

PAPER BOOK

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ADVOCATE FOR THE PETITIONER: PRATEEK K. CHADHA

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SYNOPSIS

The petitioner in the instant case is Delhi Commission For Protection of Child Rights, Government of NCT of Delhi. The petitioner is a statutory body created under the Commissions for Protection of Child Rights Act, 2005, to protect and monitor the implementation of the rights of the children as well as promote their cause. The petitioner has in pursuance of its mandate undertaken many activities for the welfare of the pregnant women and lactating mothers including but not limited to commissioning studies to evaluate Pradhan Mantri Matru Vandana Yojana (PMMVY), and Integrated Child Development Scheme (ICDS). The petitioner has also undertaken five rounds of rapid surveys to monitor and improve the distribution of Take Home Ration (THR) for the beneficiaries such as pregnant women and lactating mothers. It is noteworthy that the health of pregnant women and lactating mothers is inextricably connected with and directly impacts on the mortality and health of children.

To protect the population from the Covid19 pandemic, the Government had rolled out its vaccination drive on January 16th, 2021. India has adopted a phased manner for vaccinating the population, where vaccinations rolled out from 16th January 2021 were prioritised for frontline and healthcare workers, followed by all persons aged above 60 years and those with certain comorbidities. From 01st April 2021, vaccination was extended to all citizens above the age of 45 years. Finally from 1st May 2021, vaccination for the age group 18 years and above was made available.

Pertinently, pregnant and lactating women through an Advisory issued by the Ministry of Health and Family Welfare (vide letter No. T-22020/14/2020-IMM dated 14th January 2021), have been excluded from the category of persons eligible to take the vaccine, and no subsequent change has been made to the said Advisory, despite later evidence, medical research and studies all demonstrating the need to vaccinate pregnant and lactating women, to protect them from Covid19.

The Federation of Obstetric and Gynaecological Societies of India (hereinafter referred to as 'FOGSI') is a medical professional organization representing practitioners of obstetrics and gynecology in India since 1950. With 258 member societies and over 37,000 individual members spread over the length and breadth of the country, FOGSI is amongst the largest membership based organizations of specialized medical professionals in India. In April 2021, in its position statement on covid vaccination for pregnant and breastfeeding women, FOGSI has recommended that ,

> "*As matters stand in our country, every individual needs protection from the surging COVID-19 infections. We are in the midst of the second wave. There is a need to prevent further waves and the vaccine is the best and long term solution to this. This protection should extend to pregnant and lactating women. The very real benefits of vaccinating pregnant and lactating women seem to far outweigh any theoretical and remote risks of vaccination. Lactating women should also be considered as COVID vaccine*

candidates as there are no known adverse effects on the neonate who is breastfeeding. In fact, there is a passage of protective antibodies to the child, which may be a beneficial effect. The method of administering and monitoring the vaccine and the schedule of vaccination should be the same for pregnant and lactating women as for the general population"

FOGSI has further stated that obstetricians and gynaecologists and women's health care providers should be allowed to administer the Covid vaccines in pregnant & breastfeeding women with preparations to manage adverse events. They have pointed out that the method of administering and monitoring the vaccine and the schedule of vaccination should be the same for pregnant and lactating women as for the general population and concluded that "*there is no obvious basis for excluding pregnant or lactating women from vaccination.*"

FOGSI's report has also reviewed and cited the studies conducted by the Centre for Disease Control and Prevention (hereinafter referred to as 'CDC) the national public health agency in U.S.A.. Countries such as the U.S A. and the U.K. have started the vaccination drive to include this group of women. Pregnant women are classified as high risk by the CDC, the national regulatory authority in the United States as compared to non-pregnant women. It is pertinent that in India pregnant women are not categorized as a high risk group with regard tom Covid19

The CDC, USA has recommended that pregnant women can receive a COVID-19 vaccine as during pregnancy it can

protect them from severe illness from COVID-19. In the USA, around 90,000 pregnant women have been vaccinated and no safety concerns have been identified. The study is based on a registry of 100,000 pregnant and lactating women who have received the MRNA vaccination. CDC data also provides evidence that immunisation of pregnant and lactating mothers has led to transfer of antibodies to the infant and hence extending protection of the vaccination to the infant. World over, especially in Brazil, maternal death due to Covid-19 has been acknowledged as being on the rise and requiring special attention, including through vaccination.

World Health Organization (WHO) in March 2021, has recommended vaccination of pregnant women after establishing the design of a mechanism to monitor the effects of vaccination on pregnant women. Thus, what is necessary is a scientific and medical analysis of the effects of vaccination, in order to proceed with vaccination of pregnant women.

In this context the Petitioner consulted leading medical experts including Dr. Gagandeep Kang (Professor, Christian Medical College, Vellore & Member COVID Working Group, Government of India) and relied on scientific evidences from medical literature such as reports authored by CDC, U.S.A the reports of the Joint Committee on Vaccination and Immunisation (hereinafter referred to as 'JCVI') in United Kingdom, the advisories and reports put out by the World Health Organisations, and the statements issued by FOGSI in India amongst others, only to conclude that pregnant and lactating women should receive Covid-19

vaccine to protect them and the neonates from Covid19. As per Dr. Kang, the vaccines available in India are or are equivalent to inactivated vaccines which are considered safe in pregnancy and with the FOGSI recommendation, there is no need for further discussion. Dr. Kang emphasised the fact that pregnant and lactating women should get the vaccine at any stage in pregnancy or whenever available when breastfeeding.

As per media reports the National Technical Advisory Group (NTAGI) constituted by the Government of India has also advised the Respondent No. 1 to vaccinate pregnant women and lactating mothers. However, the Government of India is yet to accept the recommendation and operationalise it.

This Hon'ble court in the case of *Vincent Panikurlangara vs. Union of India &Ors [(1987) 2 SCC 165]*, held that in a welfare State, it is the obligation of the State to ensure the creation and maintaining of conditions congenial to good health. Similarly, in the case of *CESC Ltd. vs. Subash Chandra Bose [(1992) 1 SCC 441]*, this Hon'ble court relied on international instruments and concluded that right to health is a fundamental right.

In the case of *Consumer Education and Research Centre vs. Union of India[(2010) 15 SCC 699]*, This Hon'ble court for the first time explicitly held that 'the right to health is an integral fact of a meaningful right to life.' In the case of *Paschim Banga Khet Mazdoor Samity &Ors vs State of West Bengal &Anr [(1996) 4 SCC 37]*, it was held by the Supreme Court that Article 21 of the Constitution casts an obligation

on the State to take every measure to preserve life. The Court found that it is the primary duty of a welfare State to ensure that medical facilities are adequate and available to provide treatment.

Thus, on the basis of above held legal principles, right to health is recognised as a part of right to life under Article 21 of the Constitution. The State has a constitutional obligation towards protecting the health of women and children, and particularly pregnant women and lactating mothers, as this directly impinges on the health and well being of the new born child. Vaccination will advance this objective of promoting health as it will boost the immunity and provide resistance against this pandemic and therefore no class of persons should be excluded on arbitrary grounds.

Section 13(1) of the Commissions for Protection of Child Rights Act 2005 mandates the petitioner to examine all factors that inhibit the enjoyment of rights of children especially during a crisis like disaster and recommend remedial measures. Thus, the petitioner has a significant stake and hence locus standi on the issue of health of pregnant and lactating women and new-born care in the light of above submissions. The petitioner has a legal obligation to monitor and review the schemes related to pregnancy care, new born care, lactating mothers, inquire into specific complaints or take suo-motu cognizance and advise the authorities concerned. Not doing so would be an abdication of statutory responsibilities. In furtherance of its mandate under the Commissions For Protection of Child Rights Act, 2005 and

based on the consultations with experts, and review of medical literature, the petitioner had formally advised the Respondents vide its letter dated 12.05.2021 to:

a. Categorise Pregnant and Lactating mothers as belonging to the high-risk category.
b. Include pregnant women and lactating mothers within the vaccination drive and setting up a task force to work on operationalising a standard procedure and can help materialise a mechanism to track and monitor Pregnant Women & Lactating Mothers post vaccination.
c. develop education material and Standard Operating Protocols to educate women on the side effects of vaccination, effects of vaccination on pregnant and lactating mothers and ensure that informed consent is taken before taking the vaccine.
d. Create a registry to register pregnant women and lactating mothers being vaccinated so that a continuous monitoring mechanism can exist to see if the vaccine has an adverse effect on pregnant women. Continuous monitoring of all pregnant and lactating women receiving vaccination is necessary. Hence a separate registry such as the V-safe registry in the United States should be created to collect such data.

The Recommendations given by the petitioner are essential and need to be adopted, as the vaccination of pregnant women and lactating mothers will promote their health, which in turn will directly affect the life of the infant and if they have

antibodies due to the vaccine, the infant will also benefit from the same. The aforementioned formal advisory dated 12.05.2021 from the Petitioner to the Respondent recommending vaccination of pregnant women and lactating mothers was not acted upon, considered or even acknowledged by the Respondents.

The Covid-19 pandemic poses a dynamic threat, and medical experts have altered and evolved their opinion as new evidence has emerged from research and studies. In light of the overwhelming medical and expert advice calling for vaccination of pregnant and lactating women, as documented by FOGSI and revealed in consultations, the Respondent's advisory dated 14 January 2021 is no longer medically valid or constitutionally sustainable. The exclusion of pregnant and lactating women from vaccination now falls foul of Article 14, 15 and 21 of the Constitution, as it constitutes unreasonable classification and is thus an arbitrary and discriminatory advisory which by denying vaccination to a class of women violates their right to life. This further threatens the life of new born children and reproductive health of women, whose health is likely to be compromised due to the Respondent's impugned advisory.

Hence, the present Writ petition.

LIST OF DATES & EVENTS

14.01.2021	Pregnant and lactating women through an advisory issued by the Respondent No. 1(vide letter No. T-22020/14/2020-IMM dated 14th January 2021), have not been recommended to take the vaccine.
16.01.2021	The Central government rolled out its Covid-19 vaccination drive. The government has adopted a phased manner for vaccinating the population, where vaccinations rolled out from 16th January 2021 prioritised frontline/healthcare workers, and elderly persons above 60 years of age, or those with certain comorbidities.
March, 2021	WHO Strategic Advisory Group of Experts on Immunization recommended that pregnant women may receive the vaccine if the benefits of vaccination outweigh the potential risks.
01.04.2021	The vaccination drive was extended to all citizens above the age of 45 years.
01.05.2021	Vaccination for the age group 18 years and above was made available.

12.05.2021	The Petitioner formally advised the Government to India for the vaccination of Pregnant Women and Lactating Mothers however, no response has been received.
18.05.2021	Hence, the present Writ Petition.

IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL WRIT JURISDICTION)

Writ Petition (Civil) No. ..... of 2021

IN THE MATTER OF:

Delhi Commission for Protection of Child Rights
Through its Secretary,
5th Floor, ISBT Building, Kashmere Gate
New Delhi, Delhi 110006 ...Petitioner

Versus

1. Union of India through Secretary,
   Department of Health & Family Welfare,
   Nirman Bhawan, Maulana Azad Road,
   New Delhi 110011. …Respondent No. 1

2. Indian Council of Medical Research
   through its Director General,
   V. Ramalingaswami Bhawan, P.O. Box No. 4911,
   Ansari Nagar, New Delhi-110029 …Respondent No. 2

(All are contesting Respondents)

WRIT PETITION OF MANDAMUS UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA

To,
THE HON'BLE CHIEF JUSTICE OF INDIA
AND HIS COMPANION JUSTICES
OF THE HON'BLE SUPREME COURT OF INDIA

The humble petition on behalf
of the Petitioner above named

MOST RESPECTFULLY SHOWETH:

1. That the instant petition is filed by Delhi Commission for Protection of Child Rights (DCPCR), Government of NCT of Delhi. The petitioner is a statutory body created under the Commissions for Protection of Child Rights Act, 2005 to protect and monitor the implementation of the rights of the children as well as promote their cause.

2. That the petitioner has undertaken dozens of activities for the welfare of the pregnant women and lactating mothers including but not limited to commissioning studies to evaluate Pradhan Mantri Matru Vandana Yojana (PMMVY), and Integrated Child Development Scheme (ICDS). The petitioner has also undertaken five rounds of rapid surveys to monitor and improve the distribution of Take Home Ration (THR) for the beneficiaries such as pregnant women and lactating mothers. It is pertinent to mention that the health of pregnant mothers has a direct impact on the health of the child.

3. That the Petitioner has no personal interest in the present case and that the petition is not guided by self-gain of any person/institution/body and that there is no motive other than public interest in filing this writ petition.

4. That section 13(1) of the Commissions for Protection of Child Rights Act 2005 empowers the petitioner to examine all factors that inhibit the enjoyment of rights of children especially during a crisis like disaster and recommend remedial measures. The statute empowers the petitioner to

suo-moto initiate inquiries into deprivation of child rights as well as policy issues related to them. The petitioner has a legal obligation to monitor and review the schemes related to pregnancy care, newborn care, lactating mothers, inquire into specific complaints or take suo-motu cognizance and advise the authorities concerned.

5. That the Petitioner diligently studied the medical literature on the subject of excluding pregnant women and lactating women from vaccines with the help of organisation Indus Action and consulted experts such as Dr. Gagandeep Kang, Dr Rajani Bhat, and Dr. Aparna Hegde amongst others and recommended guidelines to the Government of India.

6. That Respondent No. 1 rolled out its Covid-19 vaccination drive on 16.01.2021. It adopted a phased manner for vaccinating her population, where vaccinations rolled out from 16.01.2021 with prioritized for frontline/healthcare workers, followed by all persons aged above 60 years and those with comorbidities. From 01st April 2021, vaccination was extended to all citizens above the age of 45 years. Finally, from 1st May 2021, vaccination for the age group 18 years and above was made available.

7. That pertinently, pregnant and lactating women through an Advisory issued by Respondent No.1, The Ministry of Health and Family (vide letter No. T-22020/14/2020-IMM dated 14th January 2021), have been excluded from the category of persons eligible to take the vaccine, and no

subsequent change has been made to the said Advisory despite later medical evidence, scientific research and studies suggesting the need to vaccinate pregnant and lactating women. A true copy of the letter dated 14.01.2021 issued by the Ministry of Health and Family Welfare, Government of India is annexed and marked hereto as **Annexure P-1 (Pg. Nos. 21to 24).**

8. That each year, 2.6 crore (Vital Statistics of India based on the Civil Registration system 2018) women deliver a child, and in addition to that there are another 2.6 crore lactating mother and so close to 5.2 crore women excluded from the current vaccination program. Clearly, this is a critical population both in numbers and their vulnerability to Covid-19.

9. That the Federation of Obstetric and Gynaecological Societies of India (hereinafter referred to as 'FOGSI') is a professional organization representing practitioners of obstetrics and gynecology in India since 1950. With 258 member societies and over 37,000 individual members spread over the length and breadth of the country, FOGSI is amongst the largest membership based organizations of specialized professionals in India. In its position statement on covid vaccination for pregnant & breastfeeding women published in April 2021, FOGSI has recommended that obstetricians and gynaecologists and women's health care providers should be allowed to administer the Covid vaccines in pregnant & breastfeeding women with

preparations to manage adverse events. They have pointed out that the method of administering and monitoring the vaccine and the schedule of vaccination should be the same for pregnant and lactating women as for the general population and concluded that "*there is no obvious basis for excluding pregnant or lactating women from vaccination.*" A true copy of the statement dated NIL of Federation of Obstetric and Gynaecological Societies of India is annexed and marked hereto as **Annexure-P-2 (Pg. Nos. 25 to 40).**

10. That it is pertinent to note that FOGSI has recommended that pregnant women receive vaccination and has also cited the studies conducted by the Centre for Disease Control and Prevention in the U.S., Countries such as the USA and the U.K. have started the vaccination drive to include this group of women as *Pregnant mothers are classified as high risk* by the Centre for Disease Control, the regulatory authority in the United States as compared to non-pregnant women.

11. That it is reiterated that the Respondents have not categorized pregnant and lactating women as high risk category. The Centre for Disease Control and Prevention, US classifies pregnant women as being "*At increased risk for severe illness from COVID-19 when compared to non-pregnant people*". Increased risk of severe illness which includes illness that requires hospitalization, intensive care, or a ventilator, or may even result in death and they are also at risk of adverse pregnancies such as preterm birth. Pregnant women with Covid-19 might also be at increased

risk of adverse pregnancy outcomes, such as preterm birth. Poor maternal outcomes are associated with poor perinatal outcomes.

12. That the Centre for Disease Control and Prevention, US has recommended that pregnant women can receive a COVID-19 vaccine. This is because getting a COVID-19 vaccine during pregnancy can protect them from severe illness from COVID-19. In the USA, around 90,000 pregnant women have been vaccinated and no safety concerns have been identified. The study is based on a registry of 100,000 pregnant and lactating women who have received the MRNA vaccination as of now provides corroborating evidence.

13. That the Centre for Disease Control data also provides evidence that immunisation of pregnant and lactating mothers has led to transfer of antibodies to the infant and hence extending protection of the vaccination to the infant. World over, especially in Brazil, maternal death due to Covid-19 has been acknowledged as being on the rise and requires urgent attention and intervention. A true copy of the recommendation dated NIL issued by the Centre for Disease Control, USA is annexed and marked hereto as **Annexure-P-3 (Pg. Nos. 41 to 52).**

14. That in the United Kingdom, the Joint Committee on Vaccination and Immunization has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group. A true copy of

the recommendation dated NIL issued by the Joint Committee on Vaccination and Immunisation, United Kingdom is annexed and marked hereto as **Annexure-P-4 (Pg. nos. 53to 54).**

15. That the World Health Organization (hereinafter referred to as 'WHO') has recommended vaccination of pregnant women post designing & establishing the design of a surveillance mechanism to monitor the effects of vaccination. A true copy of the recommendation dated NIL issued by the WHO is annexed and marked hereto as **Annexure-P-5 (Pg. Nos. 55 to83).**

16. That pregnant and lactating women not only belong to the high risk category but there are potential other negative impacts on the health and well-being of pregnant and lactating women due to Covid19. A UNICEF Report of March 2021, titled, '*Direct and Indirect Effects of COVID-19 Pandemic and Response in South Asia published by the UN*', studied the impact of Covid-19 on mortality, hospitalisations, and ICU admissions due to the disease and the impact of nation-wide lockdown on maternal and child mortality, educational attainment of children, and the region's economy. According to this study, at the country-level, the largest increase in the number of stillbirths is expected in India (60,179, 10% increase). Similarly, the number of maternal deaths is also expected to increase in 2020 as a result of the COVID-19 pandemic response, with the highest number of deaths anticipated in India (7,750, 18% increase). Child mortality is estimated to increase in

India by 15.4% and neonatal mortality by 14.5%. A true copy of the Report dated NIL, March, 2021 published by United Nations Children's Fund (UNICEF) is annexed and marked hereto as **Anenxure-P-6 (Pg. Nos. 84to 140).**

17. That the current datasets exist only for mRNA vaccines, Gynaecologists associations such as FOGSI are of the opinion that the theoretical benefits of India's vaccines would outweigh the risk of the disease. Covaxin is a killed (inactivated) virus vaccine while Covishield is a Adenovirus vector-based vaccine. Both are non-replicating. While inactivated virus vaccines are considered safe during pregnancy, adenovirus vector-based Zika virus vaccine used in pregnant mice showed no safety concerns.

18. That the petitioner consulted many experts including Dr. Gagandeep Kang (Professor, Christian Medical College, Vellore& Member COVID Working Group, Government of India). As per Dr. Kang, the vaccines available in India are or are equivalent to inactivated vaccines which are considered safe in pregnancy and with the FOGSI recommendation, there is no need for further discussion. Dr. Kang emphasised on the fact that pregnant and lactating women should get the vaccine at any stage in pregnancy or whenever available when breastfeeding. A true copy of the email correspondence with experts including Dr. Gagandeep Kang is annexed and marked hereto as **Anenxure-P-7 (Pg. Nos. 141 to 146).**

19. That after scrutinising the medical literature on the subject and the views expressed by experts in the field both domestically and internationally, as well as based of the consultations with experts the Petitioner [Delhi Commission for Protection of Child Rights (DCPCR)] sent a communication and formally advised the Government of India on 12.05.2021 to:

    a) Categorise Pregnant and Lactating mothers as belonging to the high-risk category.
    b) Include pregnant women and lactating mothers within the vaccination drive and setting up a task force to work on operationalising a standard procedure and can help materialise a mechanism to track and monitor Pregnant Women & Lactating Mothers post vaccination.
    c) Develop education material and Standard Operating Protocols to educate women on the side effects of vaccination, effects of vaccination on pregnant and lactating mothers and ensure that informed consent is taken before taking the vaccine.
    d) Create a registry to register pregnant women and lactating mothers being vaccinated so that a continuous monitoring mechanism can exist to see if the vaccine has an adverse effect on pregnant women. Continuous monitoring of all pregnant and lactating women receiving vaccination is necessary. Hence a separate registry such as the V-safe registry in the United States should be created to collect such data.

A true copy of letter 12.05.2021 issued by the Delhi Commission for Protection of Child Rights is annexed and marked hereto as **Annexure-P-8 (Pg. Nos. 147to 150).**

20. That, till date the Government of India has neither responded to the aforesaid letter nor has taken any action on the issue.

21. As per the media reports the National Technical Advisory Group (NTAGI) constituted by the Government of India has also advised the Government to vaccinate pregnant and lactating mothers. However, the Government of India is yet to accept the recommendation and operationalize it. A true copy of the News Report published by the Hindustan Times on the NTAGI's advisory seeking vaccination of pregnant and lactating women is annexed and marked hereto as **Annexure-P-9 (Pg. Nos. 151 to 155).**

22. Further, the issue of vaccinating pregnant women remains in suspension since January 2021, posing a grave threat to the right to life of women and children.

GROUNDS

A. Because the impugned advisory dated 14 January 2021 is no longer consistent with the medical and expert opinion on the issue of vaccination for pregnant and lactating women, and amounts to an unreasonable classification which denies such women their right to reproductive health and medical

care by excluding them from the vaccination against Covid-19.

B. Because the latest medical opinion, both domestically and internationally, is of the overwhelming view that pregnant and lactating women need to be treated as a 'high-risk' category of persons who ought to be vaccinated on priority. FOGSI's recommendations, published in the last week of April 2021, state:

"*There is a need to prevent further waves and the vaccine is the best and long term solution for this. This protection should extend to pregnant and lactating women.* ***The very real benefits of vaccinating pregnant and lactating women seem to far outweigh any theoretical and remote risks of vaccination. Lactating women should also be considered as Covidvaccine candidates as there are no known adverse effects on the neonate who is breastfeeding. In fact, there is a passage of protective antibodies to the child, which may be a beneficial effect.*** *The method of administering and monitoring the vaccine and the schedule of vaccination should be the same for pregnant and lactating women as for the general population.*" (Emphasis supplied)

C. Because it is a matter of record that the impugned advisory is a document limited to the factual position at the time of its publication, viz. 14 January 2021, and is subject to change as new evidence emerges. In page 2 of the said document under the heading 'Contraindication', it is stated that pregnant and lactating women should not be vaccinated

"at this time" as they have not been subjected to vaccine trials so far. However, in the four months since the publication of the impugned advisory, there is ample evidence to suggest that pregnant and lactating women ought to be vaccinated. In view of the latest medical opinion, if the impugned advisory is not revoked, it would amount to an arbitrary denial of vaccination to pregnant and lactating women, and would be hit by the doctrine of arbitrariness under Art. 14, thereby calling for it to be struck down upon judicial review.

D. Because the denial of vaccination to pregnant and lactating women amounts to a denial of access to maternal health, which in turn acts as a threat to the life, health and well being of the neonate child. This Hon'ble Court has on numerous occasions held that access to maternal, reproductive and sexual health is a right of a woman which flows from the right to life under Article 21. As such, there is a constitutional obligation on the State to provide necessary health care including vaccination against Covid-19 to all women without any discrimination, unless such exclusion is protected as a reasonable classification in view of the conspectus of medical and expert opinion and evidence available as on date. It is submitted that the exclusion of pregnant and lactating women is not based on sound medical evidence or opinion as is presently available, and is based on mere theoretical apprehension which is unfounded and stands refuted by medical experts. Thus, it amounts to a discriminatory bar on the right to health by

denial of vaccination to pregnant and lactating women, which is constitutionally impermissible.

E. Because in the case of *Maneka Gandhi v. Union of India AIR 1978 SC 597*, it was stated by this Hon'ble court that: "Right to life enshrined in Article 21 means something more than animal instinct and includes the right to live with human dignity, it would include all these aspects which would make life meaningful, complete and living."

F. Because this Hon'ble Court in the case of *Vincent Panikurlangara vs. Union of India & Ors [(1987) 2 Scc 165]*, held that in a welfare State, it is the obligation of the State to ensure the creation and maintaining of conditions congenial to good health.

G. Because in the case of *CESC Ltd. vs. Subash Chandra Bose [(1992) 1 SCC 441]*, this Hon'ble Court relied on international instruments and concluded that right to health is a fundamental right.

H. Because in the case of *Consumer Education and Research Centre vs. Union of India t[(2010) 15 SCC 699]*, this Hon'ble Court for the first time explicitly held that 'the right to health is an integral fact of a meaningful right to life.'

I. Because in the case of *Paschim Banga Khet Mazdoor Samity & Ors vs State of West Bengal & Ans [(1996) 4 SCC 37]*, it was held by this Hon'ble Court that Article 21 of the Constitution casts an obligation on the State to take every

measure to preserve life. The Court found that it is the primary duty of a welfare State to ensure that medical facilities are adequate and available to provide treatment.

J. Because on the basis of above held legal principles, right to health is a part of right to life under Article 21 of the Constitution and it is of utmost importance. Vaccination will only be helpful in maintaining this health as it will boost the immunity and provide resistance to survive this pandemic and therefore it should not be excluded for any individual.

K. Because on the basis of above held legal principles, right to health is recognised as an integral part of right to life under Article 21 of the Constitution. Vaccination Of pregnant women and lactating mothers will promote the advancement of this right to health as it will boost the immunity and provide resistance to survive this against the pandemic. The unreasonable and untenable exclusion of this class of women therefore constitutes a grave breach of the right to life of women and children.

L. Because the section 2 (b) of Commissions for Protection of Child Rights Act, 2005 that lays down the definition of "child rights" as follows:

""Child rights" includes the children's rights adopted in the United Nations convention on the Rights of the Child on the 20th November, 1989 and ratified by the Government of India on the 11th December, 1992;"

M. Because the Government of India ratified the United Nations Convention on the Rights of the Child (UNCRC) as was except on a particular clause related to minimum age of employment. The Article 24 of the United Nations Convention on the Rights of the Child and the same is being reproduced herein for the convenience:

"2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:

(a) To diminish infant and child mortality;

…….

(*d) To ensure appropriate prenatal and postnatal health care for mothers;*

(e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;

(f) To develop preventive health care, guidance for parents and family planning education and services."

N. Because the Respondent State has an obligation under international law to protect the right to health of all women without discrimination. The vaccination, or refusal for vaccination, of pregnant and lactating women directly affects reproductive health of said women. General Recommendation No. 24 of the CEDAW Committee states that under Article 12 of CEDAW,

"*It is discriminatory for a State party to refuse to provide legally for the performance of certain reproductive health services for women.*"

O. Because the petitioner has a significant stake in the issue of health of pregnant women and new-born care in the light of above submissions. The petitioner has a legal obligation to monitor and review the schemes related to pregnancy care, newborn care, lactating mothers, inquire into specific complaints or take suo-motu cognizance and advise the authorities concerned. It is reiterated that not doing so would be an abdication of statutory responsibilities.

23. That the petitioner graves leave to add, to alter or delete from the grounds mentioned above.

24. That the petitioner has not filed any other Petition before this Hon'ble Court or any other Court seeking the same reliefs.

PRAYER

Therefore, in the light of facts and circumstances mentioned herein above, it is humbly requested to this Hon'ble Court to grant the following reliefs:

i. Issue of a direction, order or writ, including writ in the nature of mandamus commanding the concerned respondent authorities under the Government of India to categorise Pregnant Women and Lactating mothers as belonging to the high-risk category and be given priority in vaccination; and

ii. Issue a direction, order or writ, including writ in the nature of mandamus directing the concerned respondent authority under the Government of India to include pregnant women and lactating mothers within the vaccination drive on priority basis and set up a task force to work on operationalising a standard procedure and in materialising a mechanism to track and monitor Pregnant Women & Lactating Mothers post vaccination; and

iii. Issue a direction, order or writ, including writ in the nature of mandamus directing the concerned respondent authority to develop education material and Standard Operating Protocols to educate women on the side effects of vaccination, effects of vaccination on pregnant and lactating mothers and ensure that informed consent is taken before taking the vaccine; and

iv. Issue a direction, order or writ, including writ in the nature of mandamus directing the concerned respondent authority to create a registry to register pregnant women and lactating mothers being vaccinated so that a continuous monitoring mechanism can exist to see if the vaccine has an adverse effect on pregnant women; and

v. Issue a direction, order or writ, including writ in the nature of mandamus directing the concerned respondent authority of the Government of India to set up separate vaccination centres for pregnant women and lactating mothers to protect them from infection as they are a high risk category; and;

vi. Issue a direction, order or writ, including writ in the nature of mandamus directing the concerned respondent authority to engage Anganwadi Centres and Asha Workers for vaccination drive to reach out to pregnant women and lactating mothers from low socio-economic backgrounds; and

vii. Issue a direction, order or writ, including writ in the nature of mandamus directing the concerned respondent authorities to make an option on CoWin Portal so that the pregnant women and lactating mothers, can classify / identify themselves as PW /LM and be prioritized while providing slots for vaccination; and

viii. Pass any other order or direction which this Hon'ble Court deems fit and proper in the interest of Justice, Equity and Good Conscience.

DRAWN BY: Vrinda Grover, Kumar Shanu
& Soutik Banerjee
Date: 18.05.2021
Place: New Delhi

FILED BY:

PRATEEK K. CHADHA
ADVOCATE FOR THE PETITIONER

IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL WRIT JURISDICTION)

Writ Petition (Civil) No. ..... of 2021

IN THE MATTER OF:

Delhi Commission for Protection of Child Rights ...Petitioner

Versus

Union of India &Anr. …Respondents

AFFIDAVIT

I, Rakesh Bhatnagar son of the late Shri. C.P. Bhatnagar aged about 60-year-old having office at fifth floor, ISBT, Kashmere Gate, Delhi- 110006 do hereby solemnly affirm and state on oath. That I am working as Secretary of the Delhi Commission for Protection of Child Rights and as such aware of the facts and circumstances of the case and competent to swear the instant affidavit.

1. I am working as Secretary in the Delhi Commission for Protection of Child Rights in the present Writ Petition and am fully aware of the facts and circumstances surrounding the present case. Thus, I am authorized and competent to swear and depose the present affidavit on behalf of the Petitioner.

2. That I am conversant with the facts and circumstances of the case and am competent to swear this affidavit.

3. That I have read the contents of the accompanying Synopsis and list of dates (page B_to K), writ petition (page1___to__20_) and IAs (page no. 156___ to 158_) and

state that the same are true to the best of my knowledge, information and belief.

4. That the instant petition is based on information available in public domain. That the Annexures are true to their respective originals.

5. That I have done whatever inquiry/investigation that was in my power to do and collected all data/material which was available and which was relevant for this court to entertain the instant petition. I further confirm that I have not concealed in the present petition anydata/material/information which may have enabled this Hon'ble Court to form an opinion whether to entertain the instant petition or not and/or whether to grant any relief.

6. That there is no personal interest/ gain, private motive or oblique reason in filing the present Petition.

DEPONENT

VERIFICATION

I, the above named Deponent, do hereby verify, that the contents of the above affidavit are true and correct to the best of my knowledge and no part of it is false and that nothing material has been concealed thereform.

Verified at New Delhi on this 18th day of May, 2021

DEPONENT

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

डॉ. मनोहर अगनानी, भा.प्र.से.
अपर सचिव

DR. MANOHAR AGNANI , IAS
Additional Secretary

DO No. T-22020/14/2020-Imm
Date: 14th January 2021

Dear All,

As you are aware that COVID-19 vaccine is scheduled for roll-out in the country on 16th Jaunaury 2021 and the States/UTs have already received vaccines for the same.

In this regard, a comparative factsheet for both the vaccines that will be used during the introduction have been prepared which contains information on vaccine platform, physical specifications, dosage, cold chain storage requirements, contraindications and minor AEFIs. A detailend note on contrainidcations and special precautions has also been prepared and is enclosed.

You are requested to kindly disseminate the above mentioned documents to Programme Managers across all levels and through them to cold chain handlers and vaccinators for ready reference.

With kind regards,

Yours sincerely,

14/01/2021

(Dr. Manohar Agnani)

Enclosure: As above

To,
Additional Chief Secretary/Principal Secretary/Secretary, Health & Family Welfare
All States/UTs

Copy to:
1. Mission Director, NHM, All States/UTs
2. State Immunization Officers, All States/UTs

Precautions and Contraindications for COVID-19 Vaccination

1. **Authorized Age Group:** Under the EUA, COVID-19 vaccination is indicated only for 18 years and above.
2. **Co-administration of vaccines:** If required, COVID-19 vaccine and other vaccines should be separated by an interval of at least 14 days
3. **Interchangeability of COVID-19 Vaccines** is not permitted: Second dose should also be of the same COVID-19 vaccine which was administered as the first dose.

Contraindication

1. Persons with history of:
   - Anaphylactic or allergic reaction to a previous dose of COVID-19 vaccine
   - Immediate or delayed-onset anaphylaxis or allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc.
2. Pregnancy & Lactation:
   - Pregnant & Lactating women have not been part of any COVID-19 vaccine clinical trial so far. Therefore, women who are pregnant or not sure of their pregnancy; and lactating women should not receive COVID-19 vaccine at this time

Provisional / temporary contraindications: In these conditions, COVID vaccination is to be deferred for 4-8 weeks after recovery

1. Persons having active symptoms of SARS-CoV-2 infection.
2. SARS-COV-2 patients who have been given anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma
3. Acutely unwell and hospitalized (with or without intensive care) patients due to any illness

Special precautions:

Vaccine should be administered with caution in persons with history of any bleeding or coagulation disorder (e.g., clotting factor deficiency, coagulopathy or platelet disorder).

Following conditions are not contraindicated for COVID vaccines

- Persons with a past history of SARS-CoV-2 infection (sero-positivity) and or RT-PCR positive illness
- History of chronic diseases and morbidities (cardiac, neurological, pulmonary, metabolic, renal, malignancies)
- Immuno-deficiency, HIV, patients on immune-suppression due to any condition (the response to the COVID 19 vaccines may be less in these individuals)

Other Important Issues to consider

- Vaccine specific contraindications may apply as the new information becomes available

Comparative Sheet for different Covid-19 vaccines, under Indian Government supply

Indicator	COVISHIELD	COVAXIN
Type of Vaccine	Recombinant COVID-19 vaccine based on Viral Vector Technology	Whole-Virion Inactivated Corona Virus Vaccine
No. of doses in each vial	10	20
Shelf life	6 months	6 months
Expiry date available on vial	Yes	Yes
Vaccine Vial Monitor (VVM)	Not Available	Not Available
Route	Intramuscular (IM) Injectable	Intramuscular (IM) Injectable
Physical Appearance of Vaccine	Clear to slightly opaque, colourless to slightly brown	Whitish translucent
Dose	0.5 ml each dose	0.5 ml each dose
Course	2-doses	2-doses
Schedule	4-weeks apart	4-weeks apart
Vaccination during Pregnancy	Not recommended	Not recommended
Vaccination < 18 years of age	Not recommended	Not recommended
Vaccination to Lactating mother	Not recommended	Not recommended
Storage and transportation	$+2^0$C to $+8^0$C at all levels	$+2^0$C to $+8^0$C at all levels
Cold chain storage space in secondary packaging	2.109 cm^3	1.7187 cm^3
Shake test	Not applicable	Not applicable
Open Vial Policy	Not applicable (Discard after 4 hours of opening)	Not applicable (Discard after 4 hours of opening)
Freeze Sensitive	Yes	Yes
Discard the vaccine vial, if found	'frozen' or 'frozen and thawed'	'frozen' or 'frozen and thawed'
Discard the vial, if	Solution is discoloured or visible particles are observed	Presence of particulate matter or other coloration
AEFI	Some mild AEFI may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills and arthralgia, nausea	Some mild AEFIs may occur like injection site pain, headache, fatigue, fever, body ache, abdominal pain, nausea and vomiting, dizziness-giddiness, tremor, sweating, cold, cough and injection site swelling
AEFI	Paracetamol may be used to provide symptomatic relief from post-vaccination adverse reactions	
Other	Very rare events of demyelinating disorders have been reported following vaccination with this Vaccine without the causal relationship establishment	
	As with other intramuscular injections, COVISHIELD should be given with caution to individuals with thrombocytopenia	
Any other instruction		Shake well, before use Use of Chloroquine and Corticosteroids may impair antibody response.

Packaging details –

Packaging details	Doses		Dimension		Total Volume	
	COVISHIELD	COVAXIN	COVISHIELD	COVAXIN	COVISHIELD	COVAXIN
Primary	10	20			21.09 cm^3	34.37 cm^3
Secondary	500	320	L-18.5 cm, W-9.5 cm, H- 6 cm	L- 10 cm, W-10 cm, H-5.5 cm	1053 cm^3	550 cm^3
Tertiary	3,000	7680	L-31 cm, W-19 cm, H-13.3 cm	L- 41 cm, W-20 cm, H- 18 cm	7833 cm^3	14760 cm^3
Quaternary (A)*	12,000	Not Applicable	L-57.9 cm, W-46.4 cm, H-37cm	Not Applicable	99402 cm^3	Not Applicable
Quaternary (B)	12,000	Not Applicable	L-60 cm, W-48 cm, H-41cm	Not Applicable	1,18,080 cm^3	Not Applicable

//True Copy//

Annexure-P-2

FOGSI

POSITION STATEMENT

COVID VACCINATION FOR PREGNANT & BREASTFEEDING WOMEN

Dr Alpesh Gandhi
President

Dr Nandita Palshetkar
Immediate Past President

Dr S Shanthakumari
President Elect

Dr Anita Singh
Vice President

Dr Atul Ganatra
Vice President

Dr T Raminidevi
Vice President

Dr Archana Baser
Vice President

Dr Ragini Agrawal
Vice President

Dr Jaydeep Tank
Secretary General

Dr Madhuri Patel
Deputy Secretary

Dr Sunil Shah
Joint Secretary

Dr Suvarna Khadilkar
Treasurer

Dr Parikshit Tank
Joint Treasurer

Contributors

Dr Alpesh Gandhi, Dr Ashish Gokhale, Dr Ashwin Vachchani

Dr Atul Ganatra, Dr Bharati Maheshwari, Dr Kasturi Donimath

Dr Neerja Bhatla, Dr Parikshit Tank, Dr Parul Shah, Dr Rajesh Mhatre

Dr Reena Wani, Dr S Ajith, Dr Saroj Singh, Dr Srinivas Gadappa

Dr Vanadana Kanumury

Disclaimer : The recommendations in this document are based on the evidence as on the date of publication. As new evidence accumulates, some of the recommendations may change. This would be guided by growing global and Indian experience, published literature, guidelines from international and national professional bodies, and government guidelines. Users should use these guidelines in accordance with the latest government regulations and advisories.

COVID-19 was declared as a global public health emergency by the World Health Organization on 30 January 2020. Incidentally, the first case of COVID-19 was diagnosed and declared in India on the same day. Later, on 11 March 2020, WHO declared it as a pandemic. Globally, 145 million cases have occurred and resulted in over 3 million deaths. In India, 16 million individuals have been infected and this has resulted in 189000 deaths as of 25th April 2021. (1) In India, the pandemic, especially in its second wave, is putting enormous burden on the health infrastructure.

There is no precise data for COVID-19 infections in pregnancy and puerperium at a global or national level. FOGSI has initiated the National Registry on COVID -19 Infection in Pregnancy for this purpose. (2) Other countries have their national surveillance systems such as the UKOSS. Pregnant women are not at increased risk of getting infected as compared to the general population. Just as for the general population, COVID-19 has an asymptomatic or mild course for most pregnant women. However, compared to non-pregnant women and pregnant women who are not infected with COVID-19, pregnant women who are infected with COVID are more likely to need hospitalization, critical care and mortality. (3)

In addition to the general preventive measures (use of mask, hand washing, social distancing, general hygiene and care), the COVID vaccine is thought to be the definitive tool to slow down or halt the pandemic.

The global scientific community is in a race to develop vaccines against the coronavirus. There are literally hundreds of candidate vaccines which are being evaluated in the world. The principle of vaccination is that humoral (antibody production) and/or cellular immunity is generated to counter future infection. The technology used to develop COVID vaccines is presented in a snapshot in the table.(4)

Technology or type of vaccine	Examples	Mechanism	Advantages	Challenges
Whole virus vaccine – killed	Covaxin (Bharat Biotech), Sinovac (Sinopharma, China)	The COVID-19 virus is passed through cell lines & replicated. The genetic material is inactivated. This inacti vated or killed virus is injected into the host to induce immunity. Other vaccine examples – Hepatitis A	Well established technology. Can be mass produced. Manufacturing process is relatively simple.	Needs booster.
Whole virus vaccine – live attenuated	A50-18 NOT MARKETED	A mutant strain of COVID-19 virus which has lost its virulence is isolated. It is passed through cell lines and replicated. The live attenuated virus is injected into the host. Other vaccine examples – measles, yellow fever	Well established technology. Potentially more robust immune response than killed virus. May not need a booster dose.	Not suitable for immunocomp romised individuals as the virus has the potential to cause disease. The virus may be transmitted to the fetus if a pregnant woman is immunized. The implications of such transmission are not known.

Protein subunit vaccine	Novavax	A subunit of the COVID-19 virus particle which has the potential to generate immunity is isolated. An example is the spike protein of the COVID-19 virus. It is manufactured in large quantities in the laboratory. This protein is injected and induces antibodies which can destroy pathogenic viral particles. Other examples - Hepatitis B	No risk of disease transmission as only a protein is used. No virus (killed, attenuated or vector) is used.	Identifying the particular protein is a long process. Mainly induces B cell immunity and overall immune response may be lower. It may be further modulated by other immune mechanisms. Booster shots are necessary.
Viral vector vaccine	Covishield (Astra Zeneca, Oxford, UK) Sputnik V (Gamaleya, Russia) Jansen (Johnson and Johnson) CanSino Biologics (Chinese military)	A harmless adenovirus is used to deliver the genetic material from the COVID-19 virus to the host and induce immunity. Other examples: Ebola vaccine.		Complex to manufacture. Mass production may take time. Previous exposure to the vector may blunt the immune response. Requires booster. Adenovirus transmission to the fetus in a pregnant woman can occur. This poses a purely theoretical risk as pathogenicity is negligible.

Nucleic acid vaccine	Pfizer BioNTech Moderna	The COVID-19 virus mRNA is isolated and replicated. It is injected into the host. This induces immunity by generation of antibodies.	Cannot trigger disease process. Maximum data in pregnancy is related to these vaccines.	Completely new approach to vaccine development. No other vaccines of this type have been used in humans routinely. Requires ultracold chain for transport, which may be a challenge in the developing world.

For pregnant women, live attenuated vaccines are contraindicated. It should be noted that none of the COVID vaccines available in the market globally are live attenuated. Other vaccines which may have some theoretical considerations regarding transmission are the viral vector vaccines. We emphasize that these considerations are theoretical. One can conclude that based on the mechanism of the available COVID vaccines; there is no obvious basis for excluding pregnant or lactating women from vaccination.

In terms of storage, most of the vaccines can be stored and transported at 2 to 8 degrees Celsius. This is the standard cold chain that is used. However, mRNA vaccines (Pfizer BioNTech, Moderna) are to be stored at minus (-)70 degrees Celsius. This requires special storage and transport freezers and poses another logistic challenge.

All vaccines at present recommend 2 doses. They are to be administered intramuscular preferably on deltoid muscle. Vaccinated person is to be observed for 30 minutes for any immediate adverse effects. The interval between two doses is generally 4 to 8 weeks. The only exception is the Janssen vaccine from Johnson and Johnson which is meant to be a single dose.

At present, two vaccines are being used in India. They are:

- COVISHIELD – being produced by Serum Institute of India (SII) in collaboration with Astra-Zeneca. This is an adenovirus based viral vector vaccine.

- COVAXIN – being produced by Bharat Biotech Ltd. This is an indigenous vaccine and is an inactivated (killed) whole virus vaccine.

The vaccines are approved for emergency use for individuals over 18 years of age by the Central Drugs Standard Control Organization (CDSCO) of India. At present, the individual is not given the choice of vaccine and it is subject to availability at a particular centre.

The vaccination process in India is centrally controlled. Vaccine administration began on 16 January 2021. The registration process and data collection began about a month before that in various geographies. Presently, the registration process is through the COWIN app which allows registration, allots appointments by date and site and provides a vaccination certificate.
The vaccination process was started as “trial mode” in the country. The vaccination drive in India is the largest in the world and has been undertaken in a phased manner. This is based on the risk-benefit ratio of eligibility and vaccine availability. From 1st May 2021, every Indian who is above 18 years of age will be allowed to be vaccinated.

As of date, India has administered 140 million vaccine doses and 22 million individuals have been fully vaccinated. (5) This is a huge achievement in terms of numbers. Only the USA and China have vaccinated more numbers than India. However, in terms of percentage of the population covered, we have a long way to go as this represents 1.5% of Indians who are fully vaccinated and more than 10% who have received one dose.

Sputnik V has also been approved in India but is not yet available. It is expected to become available in India in the near future. The Novavax and Pfizer BioNTech vaccines are also expected to get approval in India shortly.

The rationales of vaccine in COVID-19 are outlined below:(6)

- To reduce the risk of infection as it is a public health problem
- To reduce the risk of severe acute morbidity and mortality from the infection
- To prevent long term effects of infection
- To prevent transmission to other individuals

Besides these direct medical benefits, immunization will ease the enormous burden that healthcare infrastructure is facing. It will allow healthcare to be utilized for non-COVID-19 medical issues as routine. There are also other non-medical benefits of vaccination including the safe resumption of economic activity, social events and life in general as we knew it before COVID-19 arrived.

Studies have shown that various vaccines have a 70 to 90% protection rate. There is nothing to separate the various vaccines in terms of efficacy at present. Individuals should take the COVID vaccine that is available to them at the earliest opportunity.

Countries where a large proportion of individuals have been immunized, have seen a huge reduction in COVID-19 caseloads and mortality.(1) Israel, which has vaccinated 55% of its population, has seen enormous benefits. In the last week, there have been less than 100 daily cases and 2 deaths per day from COVID-19 in Israel. Studies on healthcare workers have also shown protection from moderate or severe disease, hospitalization and death. These are the populations which face the maximum risk and viral load. Vaccination is effective in these high risk situations as well.(7) These data sets are from countries where the mRNA vaccine has been used.

In the UK, the mRNA vaccine and Covishield are being administered. Two large population based surveys have found that vaccination reduced the risk of infection by 65 to 70% after one or two doses are administered. Additionally, no differences were found in the protection offered by either vaccine.(8)

In India, the ICMR has released a press statement on vaccine efficacy a few days ago. The risk of infection after one or two doses of Covaxin or Covishield is 0.02% to 0.04%. This represents an approximately 80% protection rate from infection.(9)

The first study conducted on vaccination in pregnant and lactating women was published last month from USA. The study showed that COVID vaccination generates a robust immune response in pregnant and lactating women which is equivalent to the general population. Additionally, protective antibodies were also isolated in umbilical cord blood and breast milk, implying protection to the fetus and newborn.(10) This data pertains to 131 women who were vaccinated with the mRNA vaccine. At present, there is no data on immunization of pregnant and lactating women with Covishield or Covaxin.

Almost all vaccines have some unwanted effects. They are usually minor, temporary and non-lethal. These effects are looked upon as evidence that an immune response is being generated to the vaccine, which is ultimately the goal.

Commonly seen minor side-effects may be immediate in the form of pain, sweating, and nausea. In the first seven days, the vaccine may cause fever, fatigue, myalgia, arthralgia, lymphadenopathy, local pain, swelling, redness, rash and diarrhea. These effects are seen in significant proportion of the population who receive the vaccine. (11) FOGSI has conducted a survey amongst its members to assess the incidence of side effects. (1 2) 25 to 47% of the 2083 vaccinated members reported some effects such as fever, malaise or local pain. These effects are not serious and do not require any specific medical attention except symptomatic relief.

- Anaphylactic and severe allergic reactions
- Thromboembolic phenomena resulting in cardiopulmonary or cerebrovascular events
- Severe gastrointestinal disturbances
- Facial palsy
- Local infections – cellulitis
- Hospitalization

It is important to emphasize that these are very rare events. In western countries, the events have been reported at a rate of 5 to 10 per million vaccinations. (1 1) In India, till March 2021, 100 million doses had been administered and 617 serious adverse events had been reported. (1 3)

In pregnancy, there could be concerns regarding transmission of infection to the fetus if a woman is vaccinated in pregnancy with a live attenuated vaccine. There are no live attenuated vaccines in the market in India or globally. Therefore, there is no mechanism of such an event.

The other concerns are regarding the occurrence of adverse pregnancy outcomes such as miscarriage, low birth weight, preterm births, stillbirths and congenital anomalies. The data from the American V-Safe registry is reassuring in this regard. There is no increase in maternal side effects with vaccine administration in pregnancy as compared to non-pregnant women. Women who have delivered after receiving the vaccine in pregnancy do not show any increased risk of the above-mentioned events. (1 4) This data pertains to the use of the mRNA vaccine in over 35000 pregnant women. At present, there is no data on immunization of pregnant and lactating women with Covishield or Covaxin.

All COVID vaccines have a risk of thromboembolic phenomena. This is of consideration in pregnancy and puerperium because these states are also thrombogenic. It remains unknown whether the risk of thromboembolism increases due to vaccination in pregnancy or in the puerperium. Based on reported risks from the general population, this additional risk is likely to be rare. As such, there are no such reports that have emerged.

International Recommendations on COVID Vaccine in Pregnancy

International professional bodies have taken a uniformly positive stand on the COVID vaccine in pregnancy and lactation. These statements are based on the ratio of potential benefits and risks of the vaccine versus the disease in a given geographic area. At present, it is believed that the risk of getting COVID-19 in pregnancy and its resulting morbidity is much more than the theoretical risks from the vaccine.

Though some countries have a risk based approach to immunization, FIGO believes that such an approach might actually be of disadvantage to the pregnant woman. (15) The RCOG taking the advisory from the Joint Committee on Vaccination and Immunization (JCVI) has stated that pregnant women should be offered the vaccine with the same criteria as the general population. (16) The ACOG states that pregnancy testing should not be mandated before vaccine administration and neither should it be deferred for women who are in the preconceptional period. (17)

These bodies have emphasized the lack of data of vaccine use in pregnancy. They empower women to make an informed choice in this matter. They do not distinguish between the types of vaccine in pregnancy but advise that the vaccination be completed with the same type of vaccine taken first.

International bodies such as the FIGO, ACOG, RCOG and SOGC mention the need for follow up of women who are vaccinated during pregnancy and lactation and to publish and disseminate such information.

Current Recommendations on COVID Vaccine in maternity care in India

Recommendations on the COVID vaccine in maternity care are important. The guidance on this matter will affect about 50 million lives in India every year (based on 25 million births annually and an equal number in the preconception and post delivery periods.

At present, the recommendations from the Ministry of Health and Family Welfare, Government of India state that pregnancy and lactation are contraindications to vaccinations. (18) This is based on the sound principle that there is no data available to ensure safety in pregnancy. Both the manufacturers in India also state the same in their product literature. This is also relevant from the point of view that vaccination in India was started on a “trial mode”.

With new data from across the world, this may be due for a revision to broaden the vaccine drive and include pregnant and lactating women based on the emerging global data. *At the present time, it is emphasized that individual practitioners cannot advise vaccination to pregnant and lactating women in India until there is a change in recommendations from the MOHFW, GOI.*

FOGSI acknowledges that there is limited data available on the use of COVID vaccines in pregnancy, especially of the vaccines that are available in India. Data from basic science and animal studies have not shown any teratogenic or adverse fetal or neonatal effects of the vaccine.(17,19,20)

As matters stand in our country, every individual needs protection from the surging COVID-19 infections. We are in the midst of the second wave. There is a need to prevent further waves and the vaccine is the best and long term solution to this. **This protection should extend to pregnant and lactating women. The very real benefits of vaccinating pregnant and lactating women seem to far outweigh any theoretical and remote risks of vaccination.** Lactating women should also be considered as COVID vaccine candidates as there are no known adverse effects on the neonate who is breastfeeding. In fact, there is a passage of protective antibodies to the child, which may be a beneficial effect. The method of administering and monitoring the vaccine and the schedule of vaccination should be the same for pregnant and lactating women as for the general population.

The statement is based with an assessment of the following factors:

- Density of population and current infection rates in the country
- A substantial increase in the incidence and severity of COVID-19 infection in pregnant women in recent times(2)
- Risk of infection in pregnancy complicating routine pregnancy care and delivery
- Risk of serious morbidity with infection in pregnancy (even though most pregnant women will have a mild course)
- Demonstrated efficacy of the vaccines available in India and efficient roll out in the country
- Experience of decades of vaccine administration in pregnancy with vaccines for other diseases

Women should be counseled and empowered to make their own decision supported by caregivers. There should not be any discrimination between women who accept or refuse the vaccine as and when it is possible to administer it in our country to pregnant and lactating women.

It is recommended that obstetricians and gynaecologists and women's health care providers should be allowed to administer the COVID vaccines in pregnant & breastfeeding women with preparations to manage adverse events.

In terms of precautions and care, pregnant and lactating women should be cared for in the same manner as the general population after vaccination. In case they have adverse effects, they should contact the health care provider for guidance. It should be noted that as for the general population, pregnant or lactating women who receive the vaccine can be infected even after taking two doses of the vaccine. They should follow the standard preventive safety measures like wearing a mask, hand wash and social distancing.

Common clinical situations and solutions

Vaccine administration and day of period

There is no physiological, endocrine or immunological basis for such a consideration. Women should receive the vaccine on any day of the menstrual cycle, even during menstruation.(17)

Vaccine administration in the preconception period or for women undergoing fertility treatment including assisted reproduction

Women should take the vaccine at any point of time before a pregnancy is confirmed as and when they have an opportunity to do so. There is no basis for deferring pregnancy or treatments for taking the vaccine. There is no evidence that vaccine administration affects fertility or miscarriage rates. (3 , 1 6 , 1 7)

Pregnancy testing before administering the vaccine

This is not necessary and creates a hurdle to vaccine acceptance. It is not recommended to test for pregnancy before vaccination.(17)

Vaccine administered inadvertently to a pregnant woman in early pregnancy

The vaccine does not have any known teratogenic effects as per available evidences. Women who are vaccinated in this manner should not be advised to terminate the pregnancy. They should be counseled that the risk of congenital anomalies does not rise above the baseline risk. However, at the present time, it would be prudent to defer vaccination in the first trimester as there is no substantial available data to establish absence of teratogenicity.(16,17)

Vaccines for a pregnant woman already infected in the past

A pregnant woman faces greater risks in pregnancy if she is infected with COVID-19 as compared to a pregnant woman who is not infected or a non-pregnant woman who is infected. Therefore, vaccination is advisable even if there has been a past infection. As for the general population, vaccination should be deferred for 12 weeks from the infection or 4 to 8 weeks from recovery.

Vaccine for a pregnant woman with co-morbidities (pre-existing or developed in pregnancy)

These co-morbidities do not represent contraindications to the COVID vaccine and in fact, these women will be served maximally from the protective effect. Women with such conditions should consult with their obstetrician or care provider and seek their advice on this.

Vaccine for a breastfeeding woman

There is no evidence of harm from any harm if a vaccine is administered to a breastfeeding woman. In fact, there is possible benefit from the passage of antibodies to the neonate. Breastfeeding women should be vaccinated as per the usual method and schedule of the general population.

Contraindications to vaccination

As for the general population, pregnant and lactating women should avoid vaccination in the following conditions:

- Anaphylactic or allergic reaction to a previous dose of COVID-19 vaccine
- Immediate or delayed-onset anaphylaxis or allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc.
- Temporarily in the following conditions:
  - Diagnosed COVID-19 infection – defer for 12 weeks from infection or 4 to 8 weeks from recovery
  - Active symptoms of COVID-19 infection.
  - COVID-19 infection treated with anti-COVID-19 monoclonal antibodies or convalescent plasma
  - Acutely unwell and hospitalized (with or without intensive care) patients due to any illness.

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IF YOU ARE FULLY VACCINATED

Find new guidance for fully vaccinated people. If you are not vaccinated, find a vaccine.

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Pregnant People

At increased risk for severe illness from COVID-19.

Updated May 13, 2021

Languages

Vaccine Information for People who Are Pregnant or Breastfeeding.

Although the overall risk of severe illness is low, pregnant and recently pregnant people are at an increased risk for severe illness from COVID-19 when compared to non-pregnant people.

On This Page

What You Need to Know

- **Although the overall risk of severe illness is low, pregnant people and recently pregnant people are at an increased risk for severe illness from COVID-19 when compared to non-pregnant people.**[1]
- Having certain underlying medical conditions, and other factors, including age, can further increase a pregnant or recently pregnant person's risk for developing severe illness.
- Pregnant people with COVID-19 are also at increased risk for preterm birth (delivering the baby earlier than 37 weeks) and might be at increased risk for other poor pregnancy outcomes.
- Pregnant and recently pregnant people and people who live with or visit them need to take steps to protect themselves from getting sick with COVID-19.

Increased Risk of Severe Illness

Pregnant and recently pregnant people (for at least 42 days following end of pregnancy) are more likely to get severely ill from COVID-19 compared with non-pregnant people.[1-3] Changes that occur in the body during pregnancy that increase risk for severe illness from respiratory viral infections like COVID-19 can continue after pregnancy. For example, increased risk for developing blood clots during pregnancy can continue after pregnancy and increase the risk for severe illness as seen in cases of H1N1 influenza in recently pregnant people.

Severe illness means that a person with COVID-19 may require:

- Hospitalization
- Intensive care

- A ventilator or special equipment to help them breathe

People with COVID-19 who become severely ill might even die.

See why pregnancy is included in the list of underlying medical conditions that increase a person's risk of severe illness from COVID-19.

Certain Factors Can Increase Risk

Other factors can further increase a pregnant or recently pregnant person's risk for experiencing severe illness from COVID-19, such as having certain underlying medical conditions or being older than a certain age.[3] People with an underlying medical condition should continue to follow the treatment plan prescribed by their healthcare provider.

Conditions in the places where pregnant and recently pregnant people live, learn, work, play, and worship also affect health risks and outcomes, such as getting sick with COVID-19 or developing severe illness. For example, people who are pregnant and work in places where they cannot keep their distance from people who might be sick, like healthcare providers, are at increased risk for getting sick and developing severe illness from COVID-19. Long-standing systemic health and social inequities have put pregnant people from some racial and ethnic minority groups at increased risk of getting sick from COVID-19.

Understanding additional factors that can put pregnant and recently pregnant people at an increased risk can help them make decisions about what kind of precautions to take to protect themselves from infection.

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Effect on Pregnancy Outcomes

Pregnant people with COVID-19 are at increased risk for preterm birth[2,4] (delivering the baby earlier than 37 weeks) and might be at increased risk for other poor outcomes related to pregnancy compared to pregnant people without COVID-19. Other poor pregnancy outcomes, such as pregnancy loss,[2] have been reported.

See the latest data on birth and infant outcomes among pregnant women with COVID-19

Reducing Your Risk of Getting COVID-19

It is especially important for pregnant and recently pregnant people, and those who live or visit with them, to take steps to protect themselves from getting COVID-19.

When going out or interacting with others outside your immediate household, wear a mask.

There is no way to have zero risk of infection, so it is important to know how to be as safe as possible. Consider your own personal situation and the risk for you, your family, and your community when deciding whether or not to go out or interact with people who do not live with you. Ensure you and the people who live with you are taking steps to protect themselves.

The best ways to protect yourself and to help reduce the spread of COVID-19 are to:

- Consider getting a COVID-19 vaccine. Talk with your healthcare provider if you have questions about getting vaccinated.
- Limit in-person interactions with people who might have been exposed to or who might be infected with COVID-19, including people within your household, as much as possible.
- Take steps to prevent getting COVID-19 when you do interact with others.
    - Wear a mask. Avoid others who are not wearing masks or ask others around you to wear a mask that fully covers the nose and mouth and fits well to the face.
    - Keep space between yourself and others (stay at least 6 feet away, which is about 2 arm lengths).
    - Avoid crowds.

- Avoid poorly ventilated spaces.
- Wash your hands often. If soap and water are not available, use a hand sanitizer with at least 60% alcohol.
- Avoid touching your eyes, nose, and mouth with unwashed hands.
- Cover coughs and sneezes with a tissue or the inside of your elbow. Then wash your hands.
- Clean surfaces and things you touch often with soap or detergent.
- Keep at least a 30-day supply of prescription and nonprescription medicines. Talk to your healthcare provider, insurer, or pharmacist about getting an extra supply (for example, more than 30 days) of prescription medicines, if possible, to reduce your trips to the pharmacy.

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COVID-19 Vaccine and Pregnancy

If you are pregnant or were recently pregnant you can receive a COVID-19 vaccine. If you have questions about getting vaccinated, talking with your healthcare provider might help, but is not required.

If you are pregnant and have questions about COVID-19 vaccine

If you would like to speak to someone about COVID-19 vaccination during pregnancy, please contact MotherToBaby. MotherToBaby experts are available to answer questions in English or Spanish by phone or chat. The free and confidential service is available Monday–Friday 8am–5pm (local time). To reach MotherToBaby:

- Call 1-866-626-6847
- Chat live or send an email MotherToBabyexternal icon

If you decide to get vaccinated, you may be able to start doing some things that you had stopped doing because of the pandemic after you are fully vaccinated. Learn more about what you can do when you have been fully vaccinated.

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Staying Healthy During and After Your Pregnancy

- **Keep all of your healthcare appointments during and after pregnancy.** Visit your healthcare provider for all recommended appointments. If you're concerned about going to your appointments because of COVID-19, ask your healthcare provider what steps they are taking to separate healthy patients from those who might be sick or ask about telemedicine options. If you need help finding a healthcare provider, contact your nearest hospital clinic, community health centerexternal icon or health department.
    - Talk to your healthcare provider about how to stay healthy and take care of yourself and your baby.
    - Ask questions you have about the best place to deliver your baby. Delivering your baby is always safest under the care of trained healthcare professionals.
    - You should also talk to your healthcare provider if you think you are experiencing depression during or after pregnancy.

- **Get recommended vaccines during pregnancy.** These vaccines can help protect you and your baby.
    - Get a flu vaccine every year. Others living in your household should also get vaccinated to protect themselves and you.
    - Get the whooping cough (Tdap) vaccine during pregnancy to protect your baby against whooping cough, which can have similar symptoms to COVID-19. CDC recommends all women receive a Tdap vaccine during each pregnancy.
- **Call your healthcare provider if you have any concerns about your pregnancy or if you get sick or think that you may have COVID-19.**
- **Do not delay getting emergency care because of COVID-19.** Emergency departments have steps in place to protect you from getting COVID-19 if you need care. If you need emergency help, call 911 right away.
    - Tell them that you are pregnant or were recently pregnant and are having an emergency. If someone else is driving to the emergency department, call while you are on the way. If you must drive yourself, call before you start driving.

Seek medical care immediately if you experience any urgent maternal warning signs and symptoms (for example, headache that won't go away, dizziness, fever, severe swelling of hand, face, arm or leg, trouble breathing, chest pain or fast-beating heart, severe nausea and throwing up, or vaginal bleeding or discharge during or after pregnancy)**.** These symptoms could indicate a potentially life-threatening complication.

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If You Are Sick or Think You Were Exposed to COVID-19

- If you have symptoms of COVID-19, contact your healthcare provider within 24 hours, and follow steps for when you feel sick.
- If you or someone you know has COVID-19 emergency warning signs (for example, trouble breathing, persistent pain or pressure in the chest, new confusion, inability to wake or stay awake, pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone), **call 911 or call ahead to your local emergency facility.**

    - Notify the operator that you are seeking care for someone who has or may have COVID-19.
- If you think you might have been exposed to someone with COVID-19, contact your healthcare provider. If you don't have a healthcare provider, contact your nearest community health centerexternal icon or health department.

If you are diagnosed with COVID-19, learn about caring for newborns when the mother has COVID-19.

Read information about breastfeeding and caring for newborns.

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More Information

- COVID-19 Toolkit for Pregnant People and New Parents

- Information about COVID-19 Vaccines for People who Are Pregnant or Breastfeeding
- Breastfeeding and Caring for Newborns
- Urgent Maternal Warning Signs
- Things to Know about the COVID-19 Pandemic
- How to Protect Yourself & Others
- What to Do If You Are Sick
- Coping with Stress
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Public Health England

Annexure-P-4

NHS

A guide to COVID-19 vaccination

All women of childbearing age, those currently pregnant or breastfeeding

You must read this before you go for vaccination

Find out more at nhs.uk/CovidVaccine

The COVID-19 vaccines available in the UK have been shown to be effective and to have a good safety profile.

These vaccines do not contain live coronavirus and cannot infect a pregnant woman or her unborn baby in the womb.

COVID-19 vaccination in pregnancy

The Joint Committee on Vaccination and Immunisation (JCVI) has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group. In the USA, around 90,000 pregnant women have been vaccinated mainly with Pfizer and Moderna vaccines and no safety concerns have been identified.

Evidence on COVID-19 vaccines is being continuously reviewed by the World Health Organization and the regulatory bodies in the UK, USA, Canada and Europe.

Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age who are coming for their first dose.

Anyone who has already started vaccination and is offered a second dose whilst pregnant, should have a second dose with the same vaccine unless they had a serious side effect after the first dose.

Is COVID-19 disease serious in pregnancy?

Although the overall risk from COVID-19 disease in pregnant women and their new babies is low, in later pregnancy some women may become seriously unwell and need hospital treatment.

Pregnant women with COVID-19 have a higher risk of intensive care admission than women of the same age who are not pregnant. Women with COVID-19 disease are also 2-3 times more likely to have their babies early than women without COVID-19.

Pregnant women with underlying clinical conditions are at even higher risk of suffering serious complications from COVID-19.

Risk factors for pregnant women

If you have underlying medical conditions such as:

- immune problems
- diabetes
- high blood pressure
- heart disease
- asthma

Or if you are

- overweight
- over the age 35
- in your third trimester of pregnancy (over 28 weeks)
- of black and asian minority ethnic background

You are at more risk from COVID-19 than women of the same age who are not pregnant.

What does this mean for me?

Getting pregnant

There is no need to avoid getting pregnant after COVID-19 vaccination.

There is no evidence that COVID-19 vaccines have any effect on fertility or your chances of becoming pregnant.

If you are pregnant

COVID-19 vaccines offer pregnant women the best protection against COVID-19 disease which can be serious in later pregnancy for some women.

The first dose of COVID-19 vaccine will give you good protection. You need the second dose to get longer lasting protection. You do not need to delay this second dose.

If you have already had a first dose of COVID-19 vaccine without suffering any serious side effects, you can have your second dose with the same vaccine when this is offered.

If your first dose was the AstraZeneca vaccine you should also consider the information in this leaflet www.gov.uk/government/publications/covid-19-vaccination-and-blood-clotting.

No vaccines are 100% effective so it is important to continue to follow current national guidance.

To protect yourself and your family, friends and colleagues, you MUST still:

- practise social distancing
- wear a face mask
- wash your hands carefully and frequently
- open windows to let fresh air in
- follow the current guidance

Breastfeeding

The benefits of breast-feeding are well known.

The JCVI has recommended that the vaccines can be received whilst breastfeeding. This is in line with recommendations from the USA and the World Health Organization.

Like all medicines, vaccines can cause common side effects. It may be helpful to make sure you know what to expect after you have the vaccine, especially if you have had your baby or have other children to look after.

Please read the leaflet 'what to expect after your COVID vaccination' www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination.

The Royal College of Obstetricians and Gynaecologists (RCOG) and Royal College of Midwives (RCM) have a decision guide and other information you may find helpful COVID-19 vaccines and pregnancy (rcog.org.uk – www.rcm.org.uk/guidance-for-pregnant-women).

If you would like to discuss COVID-19 vaccination please contact your midwife, doctor, or nurse.

Vaccination, helping to protect those most vulnerable.

This free leaflet is also available in braille, as a video in BSL, large print, as an audio file and in 19 languages, please visit www.healthpublications.gov.uk to download or order copies now.

COVID-19 Vaccines: Safety Surveillance Manual

Module: Safety surveillance of COVID-19 vaccines in pregnant and breastfeeding women

10 Abbreviations and acronyms

ACT	Access to COVID-19 tools
AACVS	African Advisory Committee on Vaccine Safety
ACE	Angiotensin-converting enzyme
ACT	Access to COVID-19 tools
ADEM	Acute disseminated encephalomyelitis
ADRs	Adverse drug reactions
AEFI	Adverse event following immunization
AESI	Adverse event of special interest
ARDS	Acute respiratory distress syndrome
AVSS	Active vaccine safety surveillance
BMI	Body-mass index
CEM	Cohort event monitoring
CEPI	Coalition for Epidemic Preparedness Innovations
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	Coronavirus disease 2019
DCVMN	Developing Countries Vaccine Manufactures Network
DL	Data linkage
DNA	Deoxyribonucleic acid
EH	e-Health
EPI	Expanded programme on immunization
FIND	Foundation for Innovative New Diagnostics
GACVS	Global Advisory Committee on Vaccine Safety
GBS	Guillain-Barré syndrome
GMP	Good manufacturing practices
GVAP	Global vaccine action plan
HCW	Health care worker
HELLP	Haemolysis, elevated liver enzymes, low platelet count
ICD	International classification of diseases
ICSR	Individual case safety report
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
iS PSUR	Interim simplified periodic safety update report
ISoP	International Society of Pharmacovigilance
ISRR	Immunization stress-related response
LMIC	Low- and middle-income country
LMP	Last menstrual period
MedDRA	Medical dictionary for regulatory activities
MAH	Marketing authorization holder
MH	m-Health
MoH	Ministry of Health
mRNA	Messenger RNA
NIP	National Immunization Programme
NITAG	National Immunization Technical Advisory Group
NRA	National regulatory authority
PASS	Post-authorization safety studies
PBRER	Periodic benefit-risk evaluation report
PER	Pregnancy exposure register
PHEIC	Public health emergency of international concern
PIDM	Programme for International Drug Monitoring
PSUR	Periodic safety update report
PV	Pharmacovigilance

QPPV	Qualified person responsible for pharmacovigilance
RITAG	Regional Immunization Technical Advisory Groups
RMP	Risk management plan
RNA	Ribonucleic acid
SAGE	Strategic Advisory Group of Experts (for immunization)
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SKG	Significant knowledge gap
SIA	Supplementary immunization activities
SS	Sentinel surveillance
STI	Sexually transmitted infection
TGA	Therapeutic Goods Administration (Australian Government Department of Health)
UMC	Uppsala Monitoring Centre (WHO Collaborating Centre for International Drug Monitoring)
US	Ultrasound
VAED	Vaccine-associated enhanced disease
VLP	Virus-like particles
VPD	Vaccine preventable disease
WHO	World Health Organization

11 Glossary

Active safety surveillance	Active (or proactive) safety surveillance is an active system for the detection of adverse events. This is achieved by active follow-up after vaccination. Events can be detected by asking patients directly or by screening patient records. It is best done prospectively.
Adjuvant	A pharmacological or immunological agent added to a vaccine to improve its immune response.
Adverse event following immunization (AEFI): general definition	Any untoward medical event that follows immunization and that does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.
• AEFI by cause: coincidental events	• An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.
• AEFI by cause: immunization anxiety-related reaction	• An AEFI arising from anxiety about the immunization (see immunization stress related responses).
• AEFI by cause: immunization error-related reaction	• An AEFI that is caused by inappropriate vaccine handling, prescribing or administration, that, therefore, is preventable.
• AEFI by cause: vaccine product-related reaction	• An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product, whether the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer).
• AEFI by cause: vaccine-quality defect-related reaction	• An AEFI that is caused or precipitated by a vaccine due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.
Adverse event of special interest (AESI)	A preidentified and predefined medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further specific studies.
Causal association	A cause-and-effect relationship between a causative (risk) factor and an outcome. Causally-associated events are also temporally associated (i.e. they occur after vaccine administration), but events that are temporally associated may not necessarily be causally associated.
Causality assessment	In the context of vaccine AEFI surveillance, a systematic review of data about the AEFI case(s) to determine the likelihood of a causal association between the event and the vaccine(s) received.
Cluster	Two or more cases of the same or similar events related in time, geography (place), and/or vaccine administered. AEFI clusters are usually associated with a particular supplier/provider, health facility, and/or a vial of vaccine or a batch of vaccines.
Contraindication	A situation where a particular treatment or procedure, such as vaccination with a particular vaccine, must not be administered for safety reasons. Contraindications can be permanent (absolute), such as known severe allergies to a vaccine component, or temporary (relative), such as an acute/severe febrile illness.
Immunity	The ability of the human body to tolerate the presence of material 'indigenous' to the human 'body' (self) and to eliminate 'foreign' (non-self) material. This discriminatory ability provides protection from infectious diseases since most microbes are identified as foreign material by the immune system.
Immunization	Immunization is the process whereby a person is made immune or resistant to an infection, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection

Immunization safety	The process of ensuring the safety of all aspects of immunization, including vaccine quality, adverse event surveillance, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste.
Immunization safety surveillance	A system for ensuring immunization safety through early detection, reporting, investigating, and quickly responding to AEFIs.
Immunization stress related responses (ISRR)	Stress response to immunization that may manifest just prior to, during, or after immunization.
Injection safety	The public health practices and policies dealing with various aspects of the use of injections (including adequate supply, administration and waste disposal) so that the provider and recipient are not exposed to avoidable risks of adverse events (e.g. transmission of infective pathogens) and creation of dangerous waste is prevented. All injections, irrespective of their purpose, are covered by this term (see definition of safe injection practices).
Mass vaccination campaign	Mass vaccination campaigns involve administration of vaccine doses to a large population over a short period of time.
Non-serious AEFI	An event that is not 'serious' and does not pose a potential risk to the health of the recipient. Non-serious AEFIs should also be carefully monitored because they may signal a potentially larger problem with the vaccine or vaccination or have an impact on the vaccination acceptability; in general.
Risk management plan (RMP)	The risk management plan is a document established by the vaccine manufacturer that contains the following elements: (a) identification or characterization of the safety profile of the medicinal product(s) concerned; (b) indication of how to characterize the safety profile of the medicinal product(s) concerned further; (c) documentation of measures to prevent or minimize the risks associated with the medicinal product, including an assessment of the effectiveness of those interventions; (d) documentation of post-authorization obligations that have been imposed as a condition of the marketing authorization.
Safe injection practice	Practices that ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected.
Serious AEFI	An event that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.
Severe vaccine reaction	Based on its intensity vaccine reactions can be mild, moderate or severe. The event itself, however, may be of relatively minor medical significance. Severe events do not have regulatory implications unless they are also serious.
Signal (safety signal)	Information that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.
Surveillance	The continual, systematic collection of data that are analysed and disseminated to enable decision-making and action to protect the health of populations.
Trigger event	A medical incident following immunization that stimulates a response, usually a case investigation.
SAGE Values Framework	Values Framework, developed by WHO's SAGE, offers guidance globally on the allocation of COVID-19 vaccines between countries, and guidance nationally on the prioritization of groups for vaccination within countries while COVID-19 vaccine supply is limited

Vaccine	A biological preparation that elicits immunity to a particular disease. In addition to the antigen, it can contain multiple components, such as adjuvants, preservatives, stabilizers, each of which may have specific safety implications.
Vaccine-associated enhanced disease (VAED)	Vaccine-associated enhanced diseases are modified and severe presentations of clinical infections affecting individuals exposed to a wild-type pathogen after having received a prior vaccine against the same pathogen.
Vaccine pharmacovigilance	The science and activities relating to the detection, assessment, understanding and communication of AEFI and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or vaccination.
Vaccination failure	Vaccination failure can be defined based on clinical endpoints or immunological criteria, where correlates or surrogate markers for disease protection exist. Primary failure (e.g. lack of sero-conversion or sero-protection) needs to be distinguished from secondary failure (waning immunity). Vaccination failure can be due to (i) failure to vaccinate, i.e. an indicated vaccine was not administered appropriately for any reason or (ii) because the vaccine did not produce its intended effect
Vaccine reaction	An event caused or precipitated by the active component or one of the other components of the vaccine. It may also relate to a vaccine quality defect.
Vaccine safety	The process that maintains the highest efficacy of, and lowest adverse reaction to, a vaccine by addressing its production, storage and handling. Vaccine safety is a part of immunization safety.
VigiBase	WHO global database of individual case safety reports (ICSRs) including ADRs and AEFIs, maintained by Uppsala Monitoring Centre.
VigiFlow	A web-based individual case safety report (ICSR) management system (E2B compatible) for medicines and vaccines, developed and maintained by Uppsala Monitoring Centre.

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Contents

Key points

- Pregnant women may experience more severe disease and have a higher risk of mortality associated with COVID-19 infection compared with nonpregnant women.
- COVID-19 infection may increase the risk of preterm delivery. Studies are underway globally to assess the risk-benefit profile of COVID-19 vaccines in pregnant and breast-feeding women.
- Immunization programmes need to incorporate surveillance of women who have been vaccinated either intentionally or inadvertently during pregnancy, and their children.
- Passive surveillance approaches need to take into consideration three potential scenarios:
    - maternal AEFIs not directly related to the pregnancy;
    - obstetric adverse events believed to be linked to COVID-19 vaccination during pregnancy; and
    - adverse events in the fetus (in the case of pregnancy loss), neonate or infant suspected to be associated with COVID-19 vaccination during pregnancy.
- Prompt investigations and causality assessment involving health care workers knowledgeable in maternal and neonatal health are needed to mitigate any adverse consequences for the mother-infant pair, as well as the vaccination programme itself.
- Currently, there is a lack of adequate data on the performance of COVID-19 vaccines in pregnant women. Therefore, both active and passive surveillance approaches are recommended.
- National AEFI monitoring programmes designed for routine childhood immunizations will need to be adapted to include COVID-19 vaccinations in adults, including pregnant women. For this the AEFI reporting forms, case investigation procedures, as well as causality assessment procedures will need to be adapted to take into account the specific characteristics of AEFIs following maternal immunization.
- There are challenges in assessing causality in individual cases of adverse birth outcomes due to the specific characteristics of pregnancy exposure to vaccine.
- Active surveillance approaches such as pregnancy exposure registries, cohort event monitoring studies, nested case-control and linkage studies may be used to assess the potential risks of adverse birth outcomes in vaccinated compared with unvaccinated women.
- Embedding AEFI surveillance for COVID-19 vaccines in existing surveillance programmes, such as pregnancy exposure registries for other medicines, may be an efficient way of harnessing existing resources for this purpose.
- Communication strategies for the AEFI programme need to be adapted to take into consideration the different stakeholders that need to be engaged when pregnant and breast-feeding women are vaccinated with COVID-19 vaccines.

1. Introduction

1.1. COVID-19 disease and vaccination in pregnant and breastfeeding women

While there is no indication that pregnant women have an increased susceptibility to infection with SARS-CoV-2, there is evidence that pregnancy may increase the risk of severe illness and mortality from COVID-19 disease in comparison with non-pregnant women of reproductive age.[1] As seen with non-pregnant women, a high proportion of pregnant women have asymptomatic SARS-CoV-2 infection and severe disease is associated with recognized medical (e.g., high body-mass index (BMI), diabetes, pre-existing pulmonary or cardiac conditions[1,2,3,4]) and social (e.g., social deprivation, ethnicity) risk factors. Pregnant women with symptomatic COVID-19 appear to have an increased risk of intensive care unit admission, mechanical ventilation and death in comparison with non-pregnant women of reproductive age, although the absolute risks remain low.[1] COVID-19 may increase the risk of preterm birth, compared with pregnant women without COVID-19, although the evidence is inconclusive.[5]

SARS-CoV-2 has been observed in placenta and some case reports suggest that vertical transmission of the virus to infants born to infected women may occur (as opposed to postpartum infection).[3] However, congenital COVID-19 infections have not been reported so far during the pandemic.[4] The acute effects of the disease on neonates and infants have been secondary to complications arising from severe maternal illness and medically-indicated preterm delivery or caesarean delivery due to clinician concerns.

There is no evidence that SARS-CoV-2 can be transmitted via human breast milk. Consequently, WHO recommends that mothers continue to breastfeed their infants.[4,5,6,7]

Women of reproductive age represent an very large group of the categories of workers who have been prioritized to receive COVID-19 vaccination globally, i.e., health care workers, carers, educators and other front-line essential workers.[8] Several COVID-19 vaccines are under development using various technological platforms and some are already authorized for use under emergency use approval in response to the pandemic. For more information on each platform, and links to relevant, updated information on the status of development refer to the module, COVID-19 vaccines: description and general safety considerations for implementation in this manual.

[1] Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, Kew T, et al. for PregCOV-19 Living Systematic Review Consortium. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. BMJ. 2020;370:m3320. doi: 10.1136/bmj.m3320.

[2] Khalil A, Kalafat E, Benlioglu C, O'Brien P, Morris E, Draycott T, et al. SARS-CoV-2 infection in pregnancy: A systematic review and meta-analysis of clinical features and pregnancy outcomes. EClinicalMedicine. 2020;25:100446. doi: 10.1016/j.eclinm.2020.100446.

[3] Fenizia C, Biasin M, Cetin I, Vergani P, Mileto D, Spinillo A, et al. Analysis of SARS-CoV-2 vertical transmission during pregnancy. Nat Commun. 2020;11:5128. doi: 10.1038/s41467-020-18933-4.

[4] Gale C, Quigley MA, Placzek A, Knight M, Ladhani S, Draper ES, et al. Characteristics and outcomes of neonatal SARS-CoV-2 infection in the UK: a prospective national cohort study using active surveillance. Lancet Child Adolesc Health. 2021; 5:113-21. doi: 10.1016/S2352-4642(20)30342-4.

[5] Centeno-Tablante E, Medina-Rivera M, Finkelstein JL, Rayco-Solon P, Garcia-Casal MN, Rogers L, et al. Transmission of SARS-CoV-2 through breast milk and breastfeeding: a living systematic review. Ann N Y Acad Sci. 2021 Jan;1484:32-54. doi: 10.1111/nyas.14477.

[6] World Health Organization. COVID-19 clinical management: living guidance, 25 January 2021. Available from: https://apps.who.int/iris/handle/10665/338882, accessed 26 March 2021.

[7] Rollins N, Minckas N, Jehan F, Lodha R, Raiten D, Thorne C, et al. A public health approach for deciding policy on infant feeding and mother–infant contact in the context of COVID-19. Lancet Glob Health. 2021;9:e552-7. doi.org/10.1016/S2214-109X(20)30538-6.

[8] World Health Organization. WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination, 14 September 2020. Available from: https://apps.who.int/iris/handle/10665/334299, accessed 26 March 2021.

To date, pregnant women have not been included in Phase II and III clinical trials of COVID-19 vaccines.[9] Hence data on COVID-19 vaccines in pregnant women are insufficient to assess vaccine efficacy or vaccine-associated risks in pregnancy, although studies are underway.[10] Section 1.2 summarizes WHO's current recommendations for COVID-19 vaccination in pregnant and lactating women.

Pregnant women may be exposed to COVID-19 vaccines in two ways:

1. inadvertent vaccination before the woman knows she is pregnant, i.e., at an early gestational stage; or
2. vaccination offered to a woman with confirmed pregnancy who is at high risk of COVID-19 exposure and infection or at risk of severe disease should they become infected, and who choose to be vaccinated.

The risks and benefits of COVID-19 vaccine exposure apply to both the pregnant woman and her fetus, and the timing of exposure during pregnancy may have an impact on the outcomes. It is important that vaccine safety monitoring programmes proactively include pregnant women that have been either inadvertently or knowingly exposed to COVID-19 vaccines, to collect information on associated obstetric and neonatal outcomes.

1.2. WHO recommendations for COVID-19 vaccination in pregnant and breastfeeding women

At present (March 2021), the WHO Strategic Advisory Group of Experts on Immunization (SAGE) currently recommends that pregnant women may receive the vaccine if the benefits of vaccination outweigh the potential risks, such as occupational activities with unavoidable high risk of exposure, and pregnant women with co-morbidities which place them in a high-risk group for severe COVID-19 disease.[8] In other words, vaccination for pregnant women should be considered on an individual basis after consultation between the woman and her health care provider. As more data become available these guidelines will be updated. Routine testing for pregnancy before COVID-19 vaccination is not recommended.

Few vaccines are contra-indicated in breastfeeding women.[11] However, as of March 2021, there are no data available about the safety of COVID-19 vaccines in breastfeeding women and breastfed children. The lack of clinical data on the use of COVID-19 vaccines for breastfeeding women should be weighed against the potential benefits of breastfeeding including the passive transfer of antibodies from breast milk.[8] WHO does not recommend discontinuing breastfeeding after vaccination.[8]

In addition to WHO recommendations, other obstetric and gynaecologist networks recommend that women planning to become pregnant should complete their vaccination course before conception so that they are protected during pregnancy. There is no evidence that the COVID-19 vaccines affect fertility.

1.3. Pregnancy-and vaccine safety surveillance

Pregnant women require special considerations and this influences the design of surveillance systems.

[9] Taylor MM, Kobeissi L, Kim C, Amin A, Thorson AE, Bellare NB, et al. Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action. *Lancet Glob Health.* 2021; 9: e366-7. doi: 10.1016/S2214-109X(20)30484-8.
[10] For example, Clinicaltrials.gov, NCT04754594: Study to evaluate the safety, tolerability, and immunogenicity of SARS CoV-2 RNA vaccine candidate (BNT162b2) against COVID-19 in healthy pregnant women 18 years of age and older.
[11] Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices. General best practice guidelines: special situations. Available from: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/special-situations.html, accessed 26 March 26, 2021.

Maternal and fetal/newborn/infant health needs to be monitored. Exposure to a vaccine can potentially affect both maternal and fetal health. The fetus can be affected:

- indirectly, if an event experienced by the mother, e.g., anaphylaxis, seizures with high fever, has an impact on her health and safety during pregnancy; or
- directly, e.g., theoretical risks of live-attenuated vaccines to the fetus.

Therefore, vaccinated pregnant women, systematic **reporting of both maternal and neonatal/infant adverse events following immunization (AEFIs)** must be incorporated into surveillance systems.

The timing of vaccination, other exposures and birth outcomes in relation to gestational age is critical: The **timing of exposure during the pregnancy** can affect the possible outcomes. Medicines and other teratogenic exposures can cause harm at any time during pregnancy. However, the period of organ and tissue development in the fetus, which typically occurs in the first eight weeks of gestation is critical.[12] For instance, a fetus exposed to an agent known to cause neural tube defects is at highest risk if exposed when the neural tube closes, which occurs at 3 to 6 weeks of gestation, whereas exposure occurring beyond the first trimester is unlikely to cause neural tube malformations.

Obtaining information about the **nature and timing of multiple potentially-confounding exposures,** including prescription, over-the-counter and traditional medicines, vitamins and supplements, and other vaccines, as well as substances such as alcohol, tobacco and illicit drugs, is therefore critical.

Gestational age at the time of vaccination is also important when characterizing birth outcomes such as preterm delivery, small for gestational age and certain congenital anomalies. Thus, relevant clinical data, such as last menstrual period, gestational dating using ultrasound or symphysis fundal height, and assessment of the neonate at birth are important. Standardized case definitions for gestational age assessment and adverse birth outcomes will ensure that data, including risk assessments, can be compared and harmonized across settings.

***Adverse effects may only be apparent sometime after exposure*:** The adverse effects of a potentially teratogenic exposure during pregnancy may only be apparent at the time of delivery, e.g., via surface examination of the neonate, particularly in settings where access to ultrasound services is limited, or later after birth, e.g., in the case of some congenital anomalies or neurodevelopmental delay.[13] Therefore, there can be a significant delay between the vaccine exposure and the identification and assessment of the outcome. Consequently, women who are exposed to COVID-19 vaccine during pregnancy should be followed up to establish the pregnancy outcome and assess the health of the neonate. In most countries, a facility-held or patient-held medical record which documents clinical data during the antenatal and perinatal period can be a useful source of information when investigating AEFIs. This may only be feasible through active surveillance approaches (see section 3.2 for active surveillance approaches).

Many potential contributing factors may coexist: Many suspected obstetric AEFIs have multiple potential causes and mediators including:

- comorbid infectious and non-infectious conditions, such as HIV, malaria, syphilis, diabetes, hypertension, anaemia, nutritional deficiencies;

[12] Vargesson N, Fraga L. Teratogenesis. 2017. In eLS, John Wiley & Sons, Ltd (Ed.). https://doi.org/10.1002/9780470015902.a0026056.

[13] Ajibola G, Zash R, Shapiro RL, Batlang O, Botebele K, Bennet K, et al. Detecting congenital malformations - lessons learned from the Mpepu study, Botswana. PLoS One 2017;12:e0173800. doi: 10.1371/journal.pone.0173800.

- environmental exposure, including radiation, medications, pollutants, alcohol, tobacco and recreational drugs; or
- genetic predisposition, as encountered with hereditary disorders and genetic mutations.

AEFI surveillance and investigations into the role of immunization in adverse obstetric outcomes should consider the possibility of alternative causes. In the case of active surveillance, particularly in pregnancy registries, assessment of these potential confounders requires systematic collection of data on common risk factors for adverse birth outcomes in both exposed and unexposed cohorts of pregnant women.

As a result of these unique conditions, attributing cause to an immunization in pregnancy *for individual cases* is extremely challenging, and often not possible. The investigation and causality assessment of non-obstetric AEFIs in pregnant women themselves, i.e., not the fetus, are similar to the assessment done in any other adults. However, the role of active surveillance systems, such as pregnancy registries, for the evaluation of adverse obstetric outcomes in assessing the safety of vaccines in pregnant women, are important. Ideally, active surveillance should aim to compare the risks of adverse birth outcomes, e.g., stillbirth, neonatal death, low-birth weight, preterm delivery, and birth defects, in COVID-19 vaccine exposed pregnancies with the risks in an appropriate comparison group. This can be, for example, a cohort of unvaccinated pregnant women; or pregnant women who received another vaccine, such as a tetanus or influenza vaccine, or reliably estimated background risks of these outcomes.

1.4. Vaccine safety surveillance methods for COVID-19 vaccination in pregnant women

The aim of vaccine safety surveillance is to enable early detection and initial investigation of AEFIs to determine whether there is a signal that warrants further epidemiological study. Signal investigation allows a rapid response to mitigate any safety issues that could have a negative impact on both the individuals involved and the ongoing vaccine rollout, for instance, if the investigation suggests strong evidence against a causal association, as well as informing further investigation of the AEFI and management of the immunization programme. The specific objectives of vaccine safety surveillance are described in the *WHO Global Manual on Surveillance of Adverse Events following Immunization*.[14] Maternal AEFIs, notified to the health system that are not directly related to the pregnancy should be reported and processed through the routine AEFI reporting system, as recommended. The guidance in this current module on pregnancy is for potential AEFIs relating to obstetric and neonatal/infant outcomes following COVID-19 vaccination.

A combination of both passive and active surveillance methods is recommended for COVID-19 vaccines, which will be used on a large scale. After COVID-19 vaccines are licensed, routine surveillance systems (spontaneous reporting) will be helpful for detecting rare and delayed AEFIs throughout the product cycle.

Once a serious AEFI or an adverse event of special interest (AESI), suspected to be related to an obstetric or neonatal/infant outcome, is detected, additional information on the timing of the vaccine exposure during the pregnancy, presence of other potential causes for the AEFI or AESI and details of birth outcomes or adverse events will need to be collected for further investigation (Section 2.2). Some countries may choose to adopt active surveillance methods, in addition to routine, passive surveillance. Section 3.2 provides an overview of different active surveillance methods that can be

[14] World Health Organization. Global manual on surveillance of adverse events following immunization. Available at: https://www.who.int/vaccine_safety/publications/aefi_surveillance/en/, accessed 26 March 2021.

used to investigate AEFIs for obstetric, neonatal and infant outcomes. Surveillance strategies adopted by individual countries will depend on local resources, infrastructure and diagnostic capacity.

The rollout of COVID-19 immunization programmes will require close collaboration between the maternal and child health services, immunization services, and national pharmacovigilance programmes. Antenatal care providers, including obstetricians and midwives, may not be familiar with systems to detect and report AEFIs and may need training on AEFI surveillance before COVID-19 vaccines are introduced.

In many low- and middle-income countries (LMICs), information on background rates of adverse obstetric or neonatal/infant outcomes are not systematically or routinely collected and the rates are, therefore, not known. In these countries, the risk of erroneously attributing adverse obstetric or neonatal/infant outcomes to immunization is a concern, particularly in the context of high-profile, rapidly developed vaccines, such as the COVID-19 vaccines. Maternal and child health programme research groups, therefore, need to determine appropriate estimates of background rates for key adverse obstetric and neonatal/infant outcomes of interest. Although national statistics of key outcomes, such as stillbirth, neonatal death, maternal death, low birth weight and preterm births, may be available in most countries, rates of birth defects and other outcomes of interest may not. Furthermore, the accuracy and completeness of available data on background rates of pregnancy-related outcomes needs to be evaluated, particularly when the documentation may not be accurate and case ascertainment may be done in a different, non-standard manner.

Regulatory authorities need to be aware that **evidence on the safety profile of COVID-19 vaccines in pregnant women and fetuses/neonates/infants will be constantly evolving** as data are collected through research and the COVID-19 vaccination programme implementation processes. Therefore, regulators need to ensure that vaccine manufacturers and their representatives provide periodic updates on the international and regional safety profile of these vaccines in pregnancy, breastfeeding and infancy. Regulatory decisions relating to safety, made by regulatory authorities in other countries/regions may need to be reviewed for local relevance before being included in the local product information. Any changes made to the product information should be communicated to the immunization programme immediately as these may have programmatic and communications implications.

2. Routine (passive) AEFI surveillance following COVID-19 vaccination in pregnant women

Routine AEFI surveillance is the foundation of any vaccine safety surveillance system through the product cycle. The Adverse events following immunization (AEFI) module[15] in the COVID-19 vaccine safety surveillance manual outlines approaches for investigating AEFIs following COVID-19 vaccines in the general population. Chapter 6 of the *Global manual on surveillance of AEFI*[14] provides details on why AEFIs should be investigated, which AEFIs should be investigated, who should investigate, when and how to investigate AEFIs, specimens and laboratory testing, investigating AEFI clusters and the investigation of deaths following immunization under normal circumstances. The routine AEFI surveillance system should be adapted to accommodate surveillance in pregnant women, particularly if COVID-19 vaccination is offered routinely as standard care. Once an AEFI is suspected following exposure to a particular vaccine, a standard AEFI reporting form should be completed (Appendix 5.1). This will be reviewed by the national pharmacovigilance centre and, if found to be serious (death, hospitalization, disability, prolongation of hospitalization) or is of special interest, a detailed investigation by an investigation team will be conducted. Additional considerations that should be made at the reporting and investigation stages in the context of COVID-19 vaccine exposure in pregnant women are described below.

2.1. Considerations for reporting of AEFIs after administration of a COVID-19 vaccine to pregnant women

1) adjustment of the standard AEFI reporting form to indicate pregnancy (Appendix 5.1)
2) reporting an inadvertent exposure to a vaccine that is causing concern (e.g., anxiety) to the mother/primary caregiver or health care worker,
3) in the instance of an inadvertent pregnancy that is causing concern, the pregnancy should be followed up until delivery and the outcome documented.

All AEFIs are routinely reported through an established procedure using a standard AEFI reporting form (Appendix 5.1). This form has been modified to collect information on whether the vaccinee is pregnant or breast-feeding, the estimated trimester of gestational exposure and to indicate if the AEFI is related to an obstetric/neonatal/infant outcome (Appendix 5.1).

In the case of inadvertent exposure to a COVID-19 vaccine that is causing concern (e.g., anxiety in the mother/primary caregiver or health care worker), exposure in pregnancy should be registered or reported as an adverse event using the standard AEFI report, regardless of whether the pregnant woman experiences other AEFIs. The pregnant woman must be followed-up by health authorities to determine the outcome of the pregnancy (Figure 1). Proactive approaches, such as telephone follow-up by or mobile health SMS alert systems are useful to obtain information about the outcome of pregnancies after vaccine exposure.

A pregnant woman may also voluntarily opt for vaccination, if her risk-benefit assessment by her health care provider favours vaccination.

[15] World Health Organization. COVID-19 vaccines: safety surveillance manual. Available from: https://www.who.int/publications/i/item/10665338400, accessed 27 March 2021.

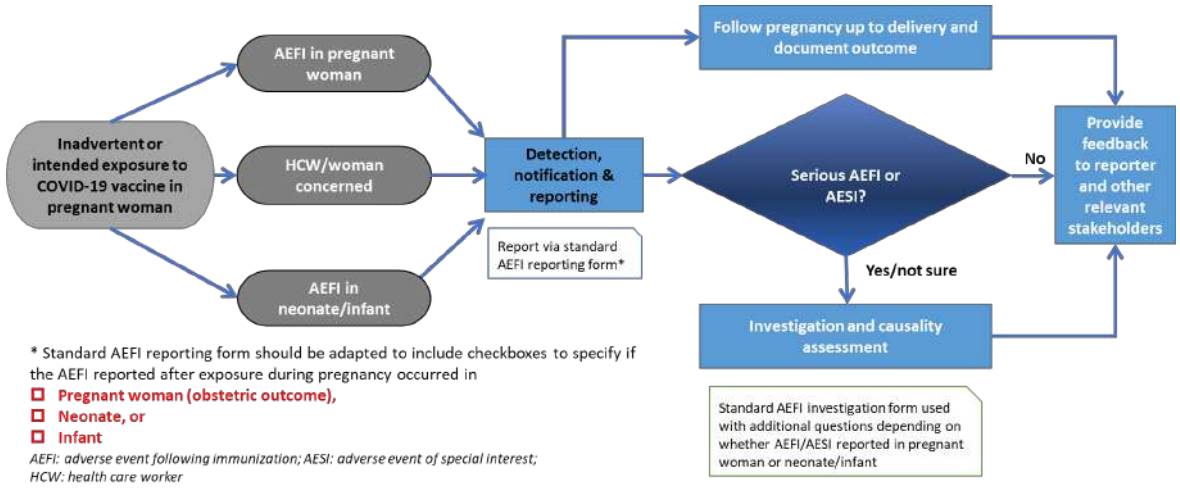

Figure 1: Routine surveillance with additional considerations for COVID-19 vaccine exposure during pregnancy

A healthy birth outcome will be reassuring and nothing more needs to be done. An adverse birth outcome should be investigated in detail promptly and assessed for causality. An AEFI should be reported if:

- the pregnancy outcome is other than a normal delivery;
- a non-pregnancy-related event occurs that the mother/primary caregiver or the health care worker attributes to COVID-19 vaccination;
- any event of concern is observed in the neonate or the mother postpartum;
- the mother/primary caregiver or the health care worker attributes any event to COVID-19 vaccination in the mother (postpartum) or the neonate/infant.

The standard AEFI reporting form should be completed and reviewed by the pharmacovigilance centre for any AEFI. A detailed investigation should be initiated for serious AEFIs and AESIs (information on investigation can be found in the Adverse events following immunization (AEFI) module[15]).

The immunization programme should collaborate with the maternal and child health services to ensure that relevant staff are familiar with reporting procedures for AEFIs, including when reporting is required. Services include primary, secondary and tertiary antenatal, perinatal and post-natal services and expanded programme on immunization (EPI) services. Once an adverse event is suspected by the mother/primary caregiver, or health care worker, the health services should be notified immediately.

2.2. Investigation of serious AEFIs and AESIs

Given that many adverse obstetric and neonatal/infant outcomes, e.g., maternal morbidity, miscarriage, stillbirth, low birth weight, are common and can have multiple aetiologies, routine investigation of all such events is not feasible. Hence, the notification and reporting of serious AEFIs events or AESIs should trigger a detailed investigation to obtain all relevant information about the patient, the vaccine and the vaccination to assess causality. On receipt of the initial AEFI report, the decision-making authority must determine whether the event:

- is a **maternal AEFI** not directly related to the pregnancy (e.g., severe injection-site reaction, anaphylaxis, Guillain-Barré syndrome);
- is an **obstetric adverse event** believed to be linked to the COVID-19 vaccination during pregnancy (see Table 1);

- Affects the **fetus (in the case of pregnancy loss), neonate or infant** suspected to be associated with vaccination during pregnancy.

In all cases the standard AEFI investigation form should be used (see Appendix 5.3 in module on AEFIs). For maternal and neonatal/infant related AEFIs additional information to collect during the investigation are listed in Appendix 5.2 and Appendix 5.3. The investigation form is also available as a software application and aide memoire which can be used to guide the investigation process. Data collected are used for causality assessment (see module on AEFIs).

Table 1: Suggested adverse events of special interest following exposure to COVID-19 vaccines in pregnancy. For standard case definition see the Brighton Collaboration website[16][17,18]

• Maternal death
• Maternal hospitalization
• Maternal thrombotic events
• Hypertensive disorders of pregnancy
• Miscarriage/spontaneous abortion
• Stillbirth
• Preterm birth
• Neonatal death
• Microcephaly
• Major congenital anomalies
• Infant death

In some countries all maternal, fetal and perinatal/neonatal deaths are investigated and reviewed through a confidential enquiry process. The immunization programme should ensure that their investigating procedures complement and support existing clinical surveillance systems. The immunization team may need to collaborate with the confidential enquiry team.

2.3. Profile of the AEFI investigation team

The profile of investigators who conduct the AEFI field investigations will be determined by the operational structure and the expertise available to the surveillance system in the country. In addition to the regular members, the investigation team should have access to obstetric, paediatric and neonatal expertise as required. It is important to include health care workers such as nurses/midwives or others with obstetric and neonatal/infant experience. If expert or additional assistance is required for investigation at the district, province or national level, such assistance should be solicited.

[16] Brighton Collaboration. COVID-19 relevant Brighton Collaboration resources and tools. Available from: https://brightoncollaboration.us/covid-19/, accessed 28 March 2021.

[17] Bonhoeffer J, Kochhar S, Hirschfeld S, Heath PT, Jones CE, Bauwens J, et al. Global alignment of immunization safety assessment in pregnancy – The GAIA project. Vaccine. 2016;34:5993-7. doi: 10.1016/j.vaccine.2016.07.006.

[18] Munoz FM, Eckert LO, Katz MA, Lambach P; Ortiz JR, Bauwens J, et al. Key terms for the assessment of safety of vaccines in pregnancy: Results of a global consultative process to initiate harmonization of adverse event definitions. Vaccine. 2015; 33: 6441-52. doi: 10.1016/j.vaccine.2015.07.112.

3. Active AESI surveillance following COVID-19 immunization in pregnant women

Active vaccine safety surveillance is recommended in addition to the routine, passive surveillance systems discussed above because there is currently a lack of data available on COVID-19 vaccine safety in pregnant women and because of the difficulty of assessing causality of adverse events at the individual level.

Active surveillance aims to detect adverse events on an ongoing basis within a defined group; e.g., pregnant women and their offspring. The events detected can be used to determine the rate of specific adverse events within the group, e.g., pregnant women exposed to vaccine, and to identify any trends or changes via a continuous pre-organized process. In some approaches, e.g., pregnancy exposure registries, the rates of these events can be compared with those in a concurrent or historical cohort of unexposed pregnant women, facilitating the assessment of risk associated with the vaccination.

Active surveillance involves the systematic collection, analysis, and interpretation of data and is especially useful in enhancing passive safety surveillance following the introduction of new vaccines. The specific objectives of immunization safety surveillance are described in the *WHO global manual on Surveillance of adverse events following immunization*[14] and the monitoring and responding to adverse events of special interest (AESI) module in this guide.

Pregnancy exposure registries and prospective cohorts of pregnant women that include women receiving antimalarial, antiretroviral, or antiepileptic treatment, that are already in place could be adapted or expanded to collect information on COVID-19 vaccine exposure. Where conditions and resources allow, a dedicated COVID-19 vaccine pregnancy exposure registry could be implemented. Multinational surveillance consortia involved in COVID-19 infection surveillance in pregnancy could be expanded to include COVID-19 vaccine safety surveillance.[19] In addition, data sharing and data pooling across multiple countries can create larger cohorts that are needed to assess the risk of rare events. If data are going to be pooled there should be a common data exchange standard with standardized definitions for key outcomes (see section 3.1) and the analyses must take into consideration the heterogenicity of data from different settings.

3.1. Standardized case definitions.

It is important that comparable data are collected in the different programmes to enable data harmonization and comparisons. This is necessary at every level of assessment. When a case definition is not available, a standardized definition should be developed and used. This is particularly relevant for rare events (e.g., major congenital anomalies) where combined cohort data may be necessary to ensure analyses are sufficiently powered. Standardized case definitions for obstetric and neonatal events for safety monitoring of vaccines in pregnant women have been developed by the Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) project, managed by Brighton Collaboration (www.brightoncollaboration.org).[17] Definitions are available for some identified AESI for COVID-19 vaccines.[20].The guidance below relates to the surveillance of obstetric and neonatal events.

[19] COVI-PREG: International COVID-19 and pregnancy registry. Available from: https://www.chuv.ch/fr/dfme/dfme-home/recherche/femme-mere/materno-fetal-and-obstetrics-research-unit-prof-baud/covi-preg, accessed 28 March 2021.
[20] Safety Platform for Emergency Vaccines. D2.3.1 Tier 1 AESI: ICD-9/10-CM and MedDRA Codes. Available from https://brightoncollaboration.us/wp-content/uploads/2020/11/SO2-D2.3.1_Tier-1-AESI-ICD-9-10-CM-and-MedDRA-Codes-.pdf, accessed 28 March 2021.

The surveillance for general AESI are described in the monitoring and responding to adverse events of special interest (AESI) module in this guide.

At present (March 2021) there is insufficient evidence from animal studies and clinical trials to guide the definition of AESI specific to pregnant women vaccinated with a COVID-19 vaccine. A suggested list based on expert opinion is given in Table 1. It may not be feasible to monitor all of them. In any active surveillance system, it will be necessary to prioritize surveillance based on relevant elements that are routinely documented and collected during clinical care, many of which are already recorded in delivery or labour ward registers, or as programme indicators. Case detection must be compatible with the diagnostic capacity of the setting, while remaining sensitive and specific. As data accumulate with the increased use of COVID-19 vaccines, AESIs relating to maternal exposure may be identified and this guidance will be updated accordingly.

3.2. Methods for active safety surveillance

Active surveillance is more complex and costly to implement than spontaneous reporting systems. It requires leadership, clearly identified responsibilities for stakeholders, and resource commitment for regular active assessment of outcomes. There are several methods that can be used for active surveillance of COVID-19 vaccine exposure in pregnant women, and the choice will depend on the local availability of resources and existing infrastructure. Resources made available for the COVID-19 vaccination programmes may present opportunities for strengthening systems, training and capacity building (particularly infrastructure/systems for standardized quality data collection) and for encouraging collaboration between programmes. Ideally, active surveillance systems for COVID-19 vaccine safety monitoring should be integrated into existing public health and pharmacovigilance platforms.

3.2.1. General principles

The use of **sentinel sites** for focussed data collection may address some logistical and resource challenges. Sentinel sites are treatment/health care facilities identified for data collection, selected for their geographical location and ability to diagnose accurately and report high-quality data. These sentinel sites should be located in a range of regions, and cover different target populations as well as different COVID-19 vaccine platforms.

It will be important to collect **data prospectively** to minimize recall and reporting bias, and to enable the calculation of event rates.

Knowledge of **background rates** of adverse events is desirable. This information is often lacking or incompletely collected, and the available knowledge will vary across settings. The Safety in Pregnancy: the *Global Vaccine Safety Multi-Country Collaboration* project completed data collection for the assessment of the applicability of GAIA case definitions for selected neonatal outcomes (congenital microcephaly, low birth weight, neonatal death, neonatal infection, preterm birth, small for gestational age and stillbirth) in August 2020 and the results will be available soon.[21] These results may help to determine background rates and provide tested methodology to determine these rates (including definition of denominators). Active surveillance strategies at sentinel sites can be designed to include data collection for unvaccinated pregnant women to enable rates in vaccine-exposed and -unexposed groups to be calculated and compared.

Outcome events must have **standardized definitions** and **ascertainment should be optimized,** although it is possible that the vaccination and the outcome will be recorded in different health care

[21] World Health Organization. 2021. Safety in Pregnancy: the Global Vaccine Safety Multi-country Collaboration Project. Available from: https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/pregnancy-and-lactation/mcc, accessed 28 March 2021.

services, e.g., vaccination in primary care or as part of a mass vaccination campaign and outcome events presenting to obstetric or other health care services.

The exposed group will be all pregnant women with a date of conception before or within 30 days of vaccination.

3.2.2. Prospective cohort studies

3.2.2.1. Pregnancy exposure registries

Pregnancy exposure registries (PERs) are prospective surveillance systems in which women are enrolled at their first antenatal care visit, and then followed through to pregnancy outcome and beyond. Information on vaccination during pregnancy, and outcomes, is actively collected in a standardized and systematic manner. If possible, *all* women presenting for antenatal care at the sentinel site should be considered for inclusion to determine event rates in both vaccinated and unvaccinated women. Individual consent for the use of the data for the purposes of research and surveillance is encouraged, although in certain situations, the need for informed consent can be waived. Such situations include when the research poses minimal risk to the participants; where the rights and welfare of the participants are not compromised; where the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the participants will be provided with additional pertinent information after participation. The conditions for such a waiver would need to be discussed with the relevant ethics committee(s) with a clear explanation to justify the request for a waiver.

Primary care sentinel sites representing a population from a defined geographical area, with a clear referral pathway are preferred. The cohort should be as diverse as possible and not limited by maternal age, maternal health status, or gestational age at presentation.

Depending on resources and the quality of existing record keeping, various data elements can be considered for collection in a pregnancy exposure registry, or data collection can be limited to a few selected clinical variables. Training to improve clinical record-keeping and outcome ascertainment using standardized case definitions should be conducted. All live and stillborn neonates should be examined and weighed, and any external major congenital anomalies noted by surface examination, and, if possible, photographed or referred for expert review (with consent). Common adverse birth outcomes such as low-birth weight, preterm birth and small for gestational age should be recorded and their rates compared between exposure groups to identify any differences in risk.

PERs can be used to assess data quality, describe the epidemiology of exposure and outcomes in the cohort, and to determine and compare event rates, if the numbers are appropriate for this. It could be possible to incorporate COVID-19 vaccine safety surveillance in existing PERs for other health interventions, such as antiretrovirals, antimalarials and other vaccines.

3.2.2.2. Cohort event monitoring exposure during pregnancy

Cohort event monitoring involves enrolling pregnant women who have received a COVID-19 vaccine into a prospective cohort, and systematically recording data on all adverse events that occur over a given period. Importantly, there is no direct control or comparator group. The length of the period, or risk window, will depend on the characteristics of the defined endpoints. For example, if obstetric outcomes are of interest, they will be followed until the end of their pregnancy; and if delayed maternal events and infant events, including their growth and development, are of interest, they will be followed up to 12 months postpartum. Prevalence and rates will have to be compared to historical data or background rates seen in other studies in similar populations. The event rates can be calculated because the numerator, i.e., number of cases, and the denominator, i.e., number vaccinated; will be available.

3.2.2.3. Nested case-control studies

Within an existing enumerated cohort, e.g., Vaccine Safety Datalink or a PER, women with an outcome of interest can be identified, together with a specified number of matched controls who did not present the event of interest. The vaccination status of the cases and controls will then be determined. This study design is useful when the outcomes are rare or when the exposure of interest is difficult to ascertain. Measures of association between exposure and outcome can then be determined, but the risk or event rates cannot.

3.2.3. Record linkage studies – retrospective cohorts

Electronic record linkage studies, for example using a unique patient identifier, offer many advantages. First, encounters and events per individual can be linked across sites, time periods, and services. This addresses the challenge that patients may present to a health care site for the outcome event that is different from the health care site where they were exposed (vaccinated). Second, if it is possible to link the records for mothers and their infants, exposure data in the mother (vaccination) can be linked to outcome data for their infant (hospital admission, death, developmental delay). Established health information systems can facilitate the definition of large cohorts with data for multiple outcome events. Even where individual-level data are unavailable, aggregate data can be used to compare outcome event rates in exposed or unexposed groups. Systems with the capacity to link records are, therefore, needed to successfully implement sustainable vaccine safety monitoring systems.

The use of novel technologies, such as 'mHealth' and mobile devices, can be explored to facilitate data collection in countries with limited health information systems.

Further information on data sharing, repositories and timelines are discussed in the data management module in this manual.

4. Communication

Ongoing communication between various programmes, including the immunization programme, the maternal and child health programme, the national regulatory authority, and the different levels of government is vital to ensure that there is a coordinated approach to maintaining confidence in the immunization programme. A communication strategy for addressing safety concerns around COVID-19 vaccination will require input from relevant communication experts and should be informed by research into public knowledge, attitudes, beliefs and practices.[22]

Before offering vaccines to pregnant women and women of child-bearing age who may be or may become pregnant, they should be routinely informed about the benefits and anticipated potential risks of the vaccine, the risks of the disease the vaccine is trying to prevent. In addition, they should be asked about their pregnancy status, trimester of pregnancy, as well as other information about the presence of any contra-indications.

The importance of employing the key principles of clarity, empathy, openness and transparency, when communicating about COVID-19 vaccine safety to women who are intentionally or inadvertently vaccinated during pregnancy cannot be over-emphasised. The safety communication module in this manual provides useful recommendations and resources for supporting good communication practices.[15] Pregnant women need to take into consideration the risks of COVID-19 disease, as well as the risk of vaccination, not just for themselves, but also for their unborn child. The communication strategy for pregnant women should also solicit the support of antenatal care providers, women's rights and gender equity advocates, midwifery and nursing associations, as well as other relevant civil society organizations.

Both immunization and maternal and child health staff need to be trained on how to counsel women who are inadvertently exposed to COVID-19 vaccines while pregnant. This should be based on the most up-to-date information available on the safety profile of the particular COVID-19 vaccine received. Information resources for pregnant women and clinicians, such as medicine and teratology information centres, poison control centres and COVID-19 hotlines, need to be prepared to provide accurate and up-to-date information on the safety of available vaccines.

As with all vaccinees, counselling women at the time of vaccination on the expected common minor (usually self-limiting) reactions they may experience after vaccination, will provide them with the information they need to prepare for such events should they occur. It will also help them to recognise events that are unexpected or that may require further clinical care. Communication materials that address frequently asked questions around the potential benefits and risks of the vaccines, specifically targeting pregnant women, could be made available on social media platforms as well as at facilities where pregnant women, and women of child-bearing age who are planning a pregnancy, are likely to receive a COVID-19 vaccine.

[22] World Health Organization. (2016). How to implement influenza vaccination of pregnant women: An introduction manual for national immunization programme managers and policy makers. Available from: https://apps.who.int/iris/handle/10665/250084, accessed 29 March 2021.

5. Appendices

5.1. Appendix 5.1

Standard reporting form for adverse events following immunization (AEFI)

AEFI reporting ID number: **Dec 2020**

STANDARD REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFIs)

***Patient name or initials*:** ***Patient's full Address*:** Telephone: Sex: ☐ M ☐ F Pregnant – Yes / No If pregnant – Trimester: I ☐ II ☐ III; ☐ Breast-feeding: Yes No ☐) ***Date of birth (DD/MM/YYYY)*: _ _/_ _/_ _ _ _** *OR Age at onset:* ☐☐*Years* ☐☐ *Months* ☐☐ ☐ *Days* *OR age Group:* ☐ 0 <1 year ☐ 1-5 years ☐ >5-18 years ☐ >18–60 years ☐ >60 years	***Reporter's Name*:** Institution: Designation & Department: Address: Telephone: E-mail: Date patient notified event to health care system (DD/MM/YYYY): _ _/_ _/_ _ _ _ Today's date (DD/MM/YYYY): _ _/_ _/_ _ _ _

Health care facility (or vaccination centre) name:									
Vaccine							***Diluent***		
Name of vaccine (Generic)	**Brand name incl. name of manufacturer*	**Date of vaccination*	**Time of vaccination*	Dose (1st, 2nd, etc.)	**Batch/ lot number*	Expiry date	**Batch/ lot number*	Expiry date	Time of reconsti-tution

Adverse event(s):	Describe AEFI (signs and symptoms):
☐ Severe local reaction ☐ *>3 days* ☐ *beyond nearest joint* ☐ Seizures ☐ *febrile* ☐ *afebrile* ☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Fever≥38°C ☐ Other (specify)..... ☐ Obstetric/ neonatal/infant adverse outcome (specify)_____ Date & time AEFI started (DD/MM/YYYY): __ __/__ __/__ __ __ __ __ ☐☐ h ☐☐min	
Serious: Yes / No: If Yes ☐ death ☐ life-threatening ☐ disability ☐ hospitalization ☐ congenital anomaly ☐ Other important medical event (Specify_____) ***Outcome:*** ☐ recovering ☐ recovered ☐ recovered with sequelae ☐ not recovered ☐ unknown ☐ Died: if checked, date of death (DD/MM/YYYY): __ __/__ __/__ __ __ __ Autopsy done: ☐ yes ☐ no ☐ unknown	
Past medical history (including history of similar reaction or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction), other relevant information (e.g. other cases)***.*** *Use additional sheet(s) if needed:*	

501

502 *First Decision making level to complete:*

Investigation needed: ☐ yes ☐ no	If yes, date investigation planned (DD/MM/YYYY): __ __/__ __/ __ __ __ __

503 *National level to complete:*

Date report received at national level (DD/MM/YYYY): __ __/__ __/__ __ __ __	AEFI worldwide unique ID**:**
Comments:	

504 **Compulsory field*

505

5.2. Appendix 5.2

Recommended additional information to collect for investigations of an obstetric-related AEFI following vaccination of a pregnant woman

Oct 2020

Additional information to collect for investigations of an obstetric-related AEFI following vaccination of a pregnant woman

Aim of the investigation: To determine if there is an association between the reported obstetric AEFI and the vaccine administered during pregnancy.

Additional relevant information from the mother prior to immunization:

Confirmation of the pregnancy by test ☐ Yes/ ☐ No

Gestational age at the time of immunization: _____ weeks or trimester ☐ 1st / ☐ 2nd / ☐ 3rd

Gestational age assessed by:

☐ history (LMP) / ☐ early US (before 24 weeks) / ☐ late US (after 24 weeks) / ☐ fundal height

Past obstetric history:

Parity / obstetric score, Y/N and number:

gravidity _____ parity _____live_____ miscarriage_____termination of pregnancy _____ stillbirth_____ preterm _____

Maternal medical complications in prior pregnancies: ☐ hypertensive disorders [e.g. eclampsia/HELLP syndrome], ☐ gestational diabetes, ☐ premature delivery, ☐ LBW or SGA infants, ☐ neonatal death ☐ other, specify _____

Current pregnancy

Conditions that increase the risk for obstetric complications during this pregnancy: ☐ incompetent cervix, ☐ placenta previa, ☐ oligo-polyhydramnios ☐ Other, specify _____

Maternal nutritional status: ☐ well-nourished ☐ undernourished ☐ overweighed/obese

Maternal health status at the time of vaccination: ☐ normal, ☐ morbidity present (specify)- _____ ; document maternal vital signs and presence/absence of signs and symptoms of acute or active disease in the box below:

Maternal vital signs and presence/absence of signs and symptoms:

Fetal health status at the time of vaccination: normal, ☐ morbidity present (specify)- _____ ; document live fetus, and presence/absence of fetal anomalies (based on obstetric examination, prenatal testing and obstetric ultrasound when available) in the box below:

Live fetus, and presence/absence of fetal anomalies:

Past history of prior adverse reactions to vaccines before pregnancy ☐ yes/ ☐ no

Details of adverse reactions to past vaccination:

Administration of other vaccines during pregnancy ☐ yes/ ☐ no. If yes, specify _____

Administration of concomitant medications, including immunomodulatory agents during pregnancy ☐ yes/ ☐ no.

If Yes, indication/ drug names/ dates:

Existing medical conditions (prior to pregnancy) _____

Active/recent maternal infection with HIV, Hep B, Hep C, TB, malaria, STI, maternal group B Streptococcus, other chronic infections (results of prenatal testing for these) ☐ yes/ ☐ no. If yes, specify _____

Maternal use/abuse of alcohol, drugs, use of nutritional or other supplements ☐ yes/ ☐ no. If yes, specify _____

Receipt of blood products one month before or after vaccination ☐ yes/ ☐ no. If yes, specify _____

Rh isoimmunization ☐ yes/ ☐ no/ ☐ unknown

Other nonmedical events that could have led to the adverse event, e.g., trauma, occupational or environmental factors. ☐ yes/ ☐ no. If yes, specify _____

Additional findings to be verified on clinical examination of the woman (Add additional sheet(s), if necessary):

Vital signs:

- Complete physical examination

Examination of injection site for oedema, induration, fluctuance, necrosis, and regional lymphadenopathy

Obstetric examination:

- Doppler or ultrasound fetal heart beat
- Fundal height

Clinical signs and symptoms consistent with active/new medical condition including infectious and non-infectious conditions: ☐ yes/ ☐ no. If yes, specify _____

Additional laboratory tests to be done to assist with diagnosis and identify possible cause of the AEFI during pregnancy or postpartum **(Add additional sheet(s), if necessary)**:

- Basic haematology, peripheral smear, chemistries (hepatic and renal function), urine
- Serologies for specific pathogens
- Other immunologic tests (antibody response to vaccine, cellular immunity, cytokines, inflammatory markers, etc)
- Viral and bacterial pathogen identification from pertinent sources by appropriate stains, cultures, molecular techniques or serologies as available
- Histopathology of relevant tissues, including the placenta

If autopsy is conducted – special forensic tests recommended (Add additional sheet(s), if necessary):

For the mother:

- Gross anatomy
- Histopathology
- Pathogen identification through appropriate stains, cultures, or molecular methods

For the fetus/neonate/infant:

- Gross anatomy
- Histopathology
- Pathogen identification through appropriate stains, cultures, or molecular methods

510 HELLP: haemolysis, elevated liver enzymes, low platelet count; LBW: low birth weight; LMP: last
511 menstrual period; SGA: small for gestational age; STI: sexually transmitted disease; US: ultrasound

512

5.3. Appendix 5.3:

Recommended additional investigations for AEFI in a neonate/ infant following vaccination of the mother during pregnancy or breastfeeding

Recommended additional investigations for AEFI in a neonate/infant following vaccination of the mother during pregnancy or breastfeeding
Aim of the investigation: To determine if there is an association between the adverse event reported in the neonate/infant when vaccine administered to mother during pregnancy or lactation.
Additional relevant information on the neonate/infant Date of delivery: Type of delivery: Place of delivery (home/institutional): Delivery conducted by: Complications during labour/ delivery: Birth weight (grams): Birth length (cm): Head circumference (cm): Gestational age at birth (weeks): Method of assessing gestational age at birth: ☐LMP; ☐ early ultrasound <24 weeks; ☐ late ultrasound >24 weeks; ☐ Ballard / Dubowitz / other gestational as per dating scan APGAR Score: 1 min ☐ 5 min☐

Additional findings to be verified on clinical examination of the infant (Add additional sheet(s), if necessary):

- Vital signs
- Physical examination of the neonate/infant (standard full system check noting any major or minor anomalies)
- Complete physical examination

Special test(s) done:

e.g. full blood count for thrombocytopenia if petechial rash, bilirubin if jaundiced.

Clinical signs and symptoms consistent with active/new medical condition including infectious and non-infectious conditions

Additional laboratory tests to be done to assist with diagnosis and identify possible cause of the adverse event during pregnancy or postpartum (Add additional sheet(s) if necessary):

- Basic haematology, peripheral smear, chemistries (hepatic and renal function), urine
- Serologies for specific pathogens
- Humoral and cellular responses to vaccine (antibodies, cytokines, inflammatory markers, etc)
- Viral and bacterial pathogen identification from pertinent sources by appropriate stains, cultures, molecular techniques or serologies, as available
- Histopathology of relevant tissues, including the placenta

If autopsy is conducted – special forensic tests recommended (Add additional sheet(s) if necessary):

For the neonate/infant

- Gross anatomy
- Histopathology
- Pathogen identification through appropriate stains, cultures, or molecular methods

516

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SickKids | Centre for Global Child Health

Annexure-P-6

Direct and indirect **effects of the COVID-19 pandemic** and response in South Asia

Commissioned by

unicef

for every child

Publication Date: March 2021

Address: UNICEF Regional Office for South Asia (ROSA)
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This report was commissioned by UNICEF and was implemented by SickKids, Center for Global Child Health, to evaluate the direct and indirect effects the COVID-19 pandemic in South Asia.

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We acknowledge colleagues in UNICEF HQ, UNICEF Country Offices in South Asia, IFPRI-New Delhi, WHO regional Office for South East Asia and UNFPA regional Office for Asia-Pacific for their contributions in reviewing drafts as well as getting the data from National Health Information Systems in respective countries.

Design and layout: Marta Rodríguez, Consultant

Cover Photo: © UNICEF/India/UN0380513/Das/2020

Direct and indirect effects of the COVID-19 pandemic and response in South Asia

Content

Foreword

Over recent decades, South Asia has made remarkable progress in improving the health of mothers and children. Access to life-saving interventions has been expanded, and so millions of needless deaths have been prevented.
The year 2020 brought a great shock to South Asia, as it did to the whole world. The COVID-19 pandemic has had major and multiple impacts – both direct and indirect.

One of the critical indirect impacts has been severe disruptions to the delivery and use of routine services, including essential health and nutrition services. Health systems, which were already stretched in many parts of the region, were not ready to adjust swiftly to the shock. Women and children suddenly faced limitations in accessing facilities. The region saw significant drops in the use of both preventive and curative services. As detailed in this report, Direct and indirect effects of the COVID-19 pandemic in South Asia, the pandemic has undoubtedly resulted in more deaths and more illness – particularly for the most vulnerable women and children. The pandemic is also reversing the development gains made over recent years and risks a negative impact on the overall wellbeing of the population for years to come. It reduces the likelihood of achieving the Sustainable Development Goals.

In South Asia, millions have fallen sick from COVID-19, costing thousands of lives and costing countries billions of dollars. The basic public health tools are key – starting with physical distancing, hand washing, and mask wearing. This report computes the potential to save lives and minimize health care costs by further strengthening the implementation of these across the region.

COVID-19 is likely to remain a significant public health problem for some time. Governments need to achieve a difficult balancing act. They need to continue combatting the pandemic, whilst also minimizing the disruption of the economy and of critical health and other services. This is crucial for the health and well-being of the most vulnerable people. Evidence to help guide this balancing act is urgently required to help guide decisions on how to calibrate COVID-19 mitigation measures.

UNICEF has a mandate to be a voice for every woman and child. In line with this, and to address the critical need for actionable information, we commissioned this study to assess and report on the direct and indirect effects of the COVID-19 pandemic and response. The study focuses on the six most populous countries in South Asia: Afghanistan, Bangladesh, India, Nepal, Pakistan and Sri Lanka. This report will be of value for policy makers, program managers and other stakeholders in prudently fighting the pandemic while increasing the reach to women and children with quality services.

This report is also a call for action. It is a call to governments and to partners. We must urgently come together to address the imperative for focused investment and effort – to strike the difficult balance in the months and years ahead, for the sake of the region's most vulnerable women and children.

Sun Ah Kim
Deputy Regional Director
UNICEF Regional Office for South Asia

Chapter 1: **Background**

The SARS-CoV-2 pandemic and the global response to limit its spread and mortality from COVID-19 has been unprecedented, both in terms of a global health crisis, as well as measures that have been undertaken by countries around the world to combat its spread, including those in South Asia. Response has ranged from physical distancing measures and school closures to travel restrictions and nationwide lockdowns, which has resulted in reduced access to essential healthcare services and wide-ranging disruption of economic activities. As of February 2021, South Asia, which includes Afghanistan, Bangladesh, Bhutan, Maldives, Nepal, India, Pakistan and Sri Lanka, has reported more than 12 million cases of COVID-19, with the vast majority being in India, which has reported more than 10.9 million cases (Figure 1) .

In addition to the direct impact of SARS-CoV-2 in terms of morbidity and mortality, there is growing concern in the global public health community about the extent and scope of the indirect effects COVID-19 pandemic and response on the health, nutrition and social well-being of vulnerable populations in resource-limited settings, especially women and children.

Evidence from past crises, such as the 1997 East Asian financial crisis, the 2008 global financial, and food price increase crises, and the 2013 – 16 Ebola outbreak in West Africa, underscore the vulnerability of these populations and the need for definitive and swift action aimed at alleviating the indirect impacts of the COVID-19 pandemic (2-5).

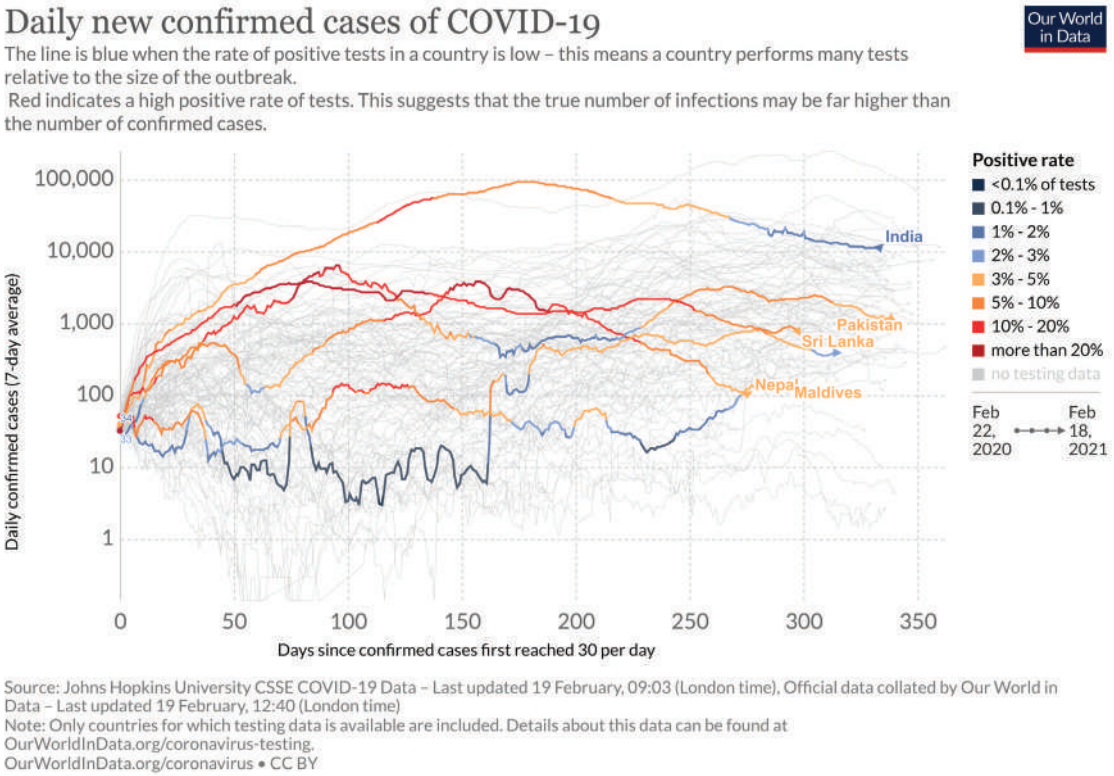

Figure 1: Cumulative confirmed COVID-19 cases and test positivity rate using the log scale, in South Asia

South Asia is home to more than 1.8 billion people, with 1 in 10 living below the international poverty line of US$1.90 and accounting for a third of the global income poor (6). The region also struggles with poor population health and nutrition, educational attainment, and social well-being. South Asia experienced 1.5 million under-5 deaths in 2018, a number that was second only to Sub-Saharan Africa (7). One in three children under five years of age in the region are stunted, and 15% are wasted (7). Furthermore, less than half of pregnant women 15-49 years receive ≥ 4 antenatal care visits (7). However, these aggregate figures obscure the inequities that exists within the region. Country-specific estimates for selected sexual and reproductive, maternal, neonatal, and child health (SRMNCH) indicators are presented in Table 1.

Table 1: Country-specific estimate for selected SRMNCH indicators in South Asia

Selected SRMNCH indicators	AFG	BGD	BTN	IND	MDV	NPL	PAK	SLK
Children received 3 dose of pentavalent vaccine (DPTHepB-Hib)	66	98	97	89	99	91	75	99
Women who received ≥ 4 antenatal care visits	21	47	85	51	82	69	51	93
Women who delivered in health facilities	48	37	74	79	95	57	66	100
Caesarean sections performed in the facilities	7	33	12	17	40	9	22	32
Newborns who received postnatal health check	19	52	30	27	82	58	64	-
Demand for family planning satisfied with modern methods	42	73	85	67	43	56	49	74
CMAM program* (8)	1.5	0	0	0	NA	14.7¥	2.8£	0

All figures are percentages
AFG: Afghanistan; BGD: Bangladesh; BTN: Bhutan; IND: India, MDV: Maldives; NPL: Nepal; PAK: Pakistan; SLK: Sri Lanka
Source: UNICEF Global Databases
*Data for illustrative purposes only. ¥11 of 75 districts have CMAM programs running; £Coverage only available for Khyber Pakhtunkhwa

Similar to other countries in the world, those in South Asia instituted swift and stringent mitigation responses including sweeping lock-down and stay-at-home orders, in March and April 2020. Since then, most countries in South Asia have eased the most severe restrictions, but some, such as school closures, are still in place.

Figure 2 illustrates the composite stringency index for several countries in South Asia from the outset and the current situation. The index, rescaled from 0 – 100, measures the severity of government response across nine indicators, including closure of businesses and schools, and travel restrictions (9).

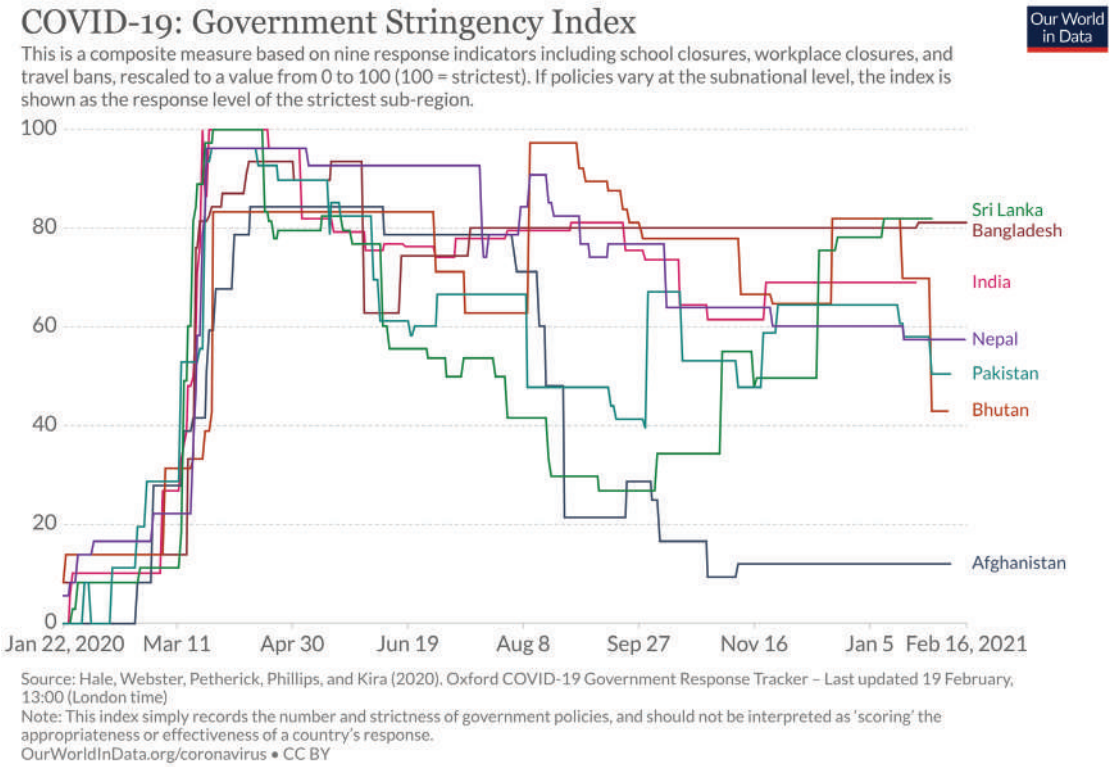

Figure 2: Severity of COVID-19 mitigation response in South Asia

Interruption of essential services is an expected consequence of movement restrictions and closure of services, and were recognized at an early stage of the crisis and COVID-19 mitigation measures. It was anticipated that reduced access to family planning services in low- and middle-income countries (LMICs) could lead to millions of unintended pregnancies in the near future (10). A modelling study used the Lives Saved Tool (LiST) to highlight the potential indirect effects of the pandemic and the response to it on maternal and child mortality (11). According the authors' estimates, the disruption to health services provision and access and the rising food insecurity could lead to additional 253,500 – 1,157,000 child deaths and 12,200 – 56,700 maternal deaths, globally. As a result of these disruptions in South Asia, child mortality could potentially increase by 18 – 40% and maternal mortality by 14 – 52%, over the next year (11).

Given the challenges faced by South Asian countries prior to the current pandemic, the potential impact of COVID-19 pandemic response on the health and well-being of 1.8 billion people was a serious cause for concern. Governments in these countries would need to balance the need for controlling the pandemic within their borders, along with the impact cessation and/or disruption of critical primary health and other services could have on the health and well-being of the most vulnerable of their populations. Notwithstanding the aforementioned health effects, it was recognized that indirect effects of mitigation measures could be much greater than those related to disruption of health services alone. The pathways through which COVID-19 pandemic and response could indirectly impact maternal, child and adolescent health and well-being are presented in Figure 3.

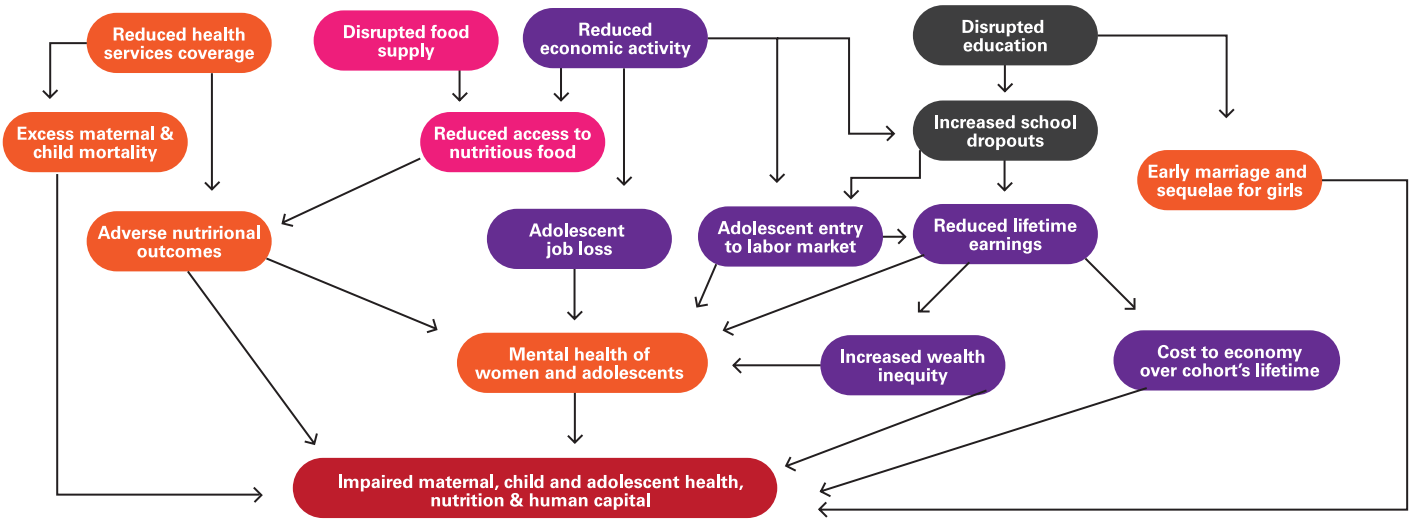

Figure 3: A conceptual framework for the indirect impact of COVID-19 pandemic and response on maternal, child and adolescent health and well-being

At this unprecedented time, governments need information that will help guide their decisions on when to ease/lift COVID-19 mitigation measures. To address this urgent issue, we conducted a series of modelling exercises to assess the expected mortality, hospitalizations and intensive care unit (ICU) admissions due to COVID-19 itself, as well as the impact of nationwide stay-at-home orders implemented to curb the spread of COVID-19 on maternal and child mortality, educational attainment of children, and general economy. We also estimated the potential benefits of mitigation strategies to address these anticipated multi-sectoral challenges focused on the six most populous countries in South Asia: Afghanistan, Bangladesh, Nepal, India, Pakistan and Sri Lanka.

Chapter 2: **Methods**

COVID-19 associated morbidity and mortality and forecasting

Model Structure

To evaluate the effects of public health interventions on COVID-19 and forecast its spread in South Asia, we conducted a simulation study using a computational stochastic individual contact model (ICM) based on an extension of the Susceptible-Infectious-Recovered (SIR) compartment model (12), which was used to provide initial projections for the burden of COVID-19 in Pakistan (13). This model comprises of seven compartments as illustrated in Figure 4 (see Supplementary Table 1 for further details). Three components are similar to SIR compartment model: The S compartment denotes susceptible individuals; the I compartment denotes symptomatic individuals who are both infected with COVID-19 and infectious to others; and the R compartment denotes individuals who have recovered from COVID-19 and are no longer infectious.

The SIR model was expanded with the addition of four compartments (E, Q, H, and F) to model both anticipated mitigating effects of public health intervention strategies as well as measurable impact on public health, and extended to September 2021. Unlike the E compartment in traditional SEIR models, the E compartment in our model denotes asymptomatic COVID-19-positive individuals who are infectious, in order to enable simulation of transmission during the COVID-19 incubation period, as reported by several investigators (14); the Q compartment represents symptomatic (or test-positive) infectious individuals who are self-isolating or in supervised isolation; the H compartment represents individuals who require hospitalization (if the number of required hospitalizations is below the hospital capacity, then it is assumed in the model that these individuals would be hospitalized, but if hospital capacity is exceeded then the excess portion of those requiring hospitalization remain not hospitalized, with consequently higher mortality for that fraction of cases); and the F compartment denotes case fatalities due to COVID-19.

Model parameters

Model parameters were populated using a combination of model calibration for a small subset consisting of four key parameters and choice of plausible values for the remaining ones (Supplementary Table 2). The four parameters chosen for calibration include the daily average number of exposure events involving symptomatic individuals, the probability of transmission by symptomatic cases, the daily hospitalization rate of symptomatic cases and the daily case fatality rate. Weekly totals of case fatalities, as recorded on the Covid-19 page of the Our World in Data (OWID) website (15) were the basis for the calibration, using the mean squared error

$$\mathrm{MSE}(\boldsymbol{\theta}) = \sum_{i=1}^{K} \left[F_i^{\mathrm{model}}(\boldsymbol{\theta}) - F_i^{\mathrm{obs}}\right]^2,$$

where $F_i^{\mathrm{model}}(\boldsymbol{\theta})$ is the total number of deaths simulated for the i^{th} week using the quadruple of parameters $\boldsymbol{\theta}$ for simulation, $i=1,\ldots,K$, $K=14$ is the number of weekly totals between June 1st and August 31st, 2020 (the time period used for calibration) and F_i^{obs} is the corresponding observed number of deaths recorded. Calibrated values for the four key parameters are then chosen to minimize the MSE,

$$\hat{\boldsymbol{\theta}} = \mathbf{argmin}_{\boldsymbol{\theta}}\mathrm{MSE}(\boldsymbol{\theta}),$$

namely where minimization was carried out using sequential Bayesian optimization based on the Expected Improvement criterion proposed by Jones et al (16).

National projections under the various interventions were then carried out running the simulation for one year out starting from September 1st, 2020, using the calibrated parameter values as well as the estimated number of symptomatic, asymptomatic and quarantined and recovered cases obtained at the end of the calibration period. The set of interventions included:

1. Smart lockdowns,
2. Use of face masks, and
3. Hand hygiene

All interventions were assumed to have been applied at present at the 25% adherence level, and the simulation study compared a baseline scenario – in which no further intervention was applied – to scenarios where one intervention at a time was raised to the 50% adherence level, as well as a combination off all different intervention applied at once.

The relative reductions in key inputs, as appearing in Supplementary Table 2, are presented in Table 3 below.

Table 3: Effect estimates for selected interventions aimed at reducing the relative risk of exposure and transmission of COVID-19 and other reparatory viruses

Intervention	Relative risk reduction in		Reference
	Exposure	Transmission	
Smart lockdowns vs. none	0.38 (0.01 - 0.56)		Adapted from Aleta et al (17)
Use of face masks		0.34 (0.26 - 0.45)	From Chu et al (18)
Hand hygiene		0.50 (0.38 - 0.66)	From Talaat M et al (19)
Physical distancing (≥ 1m vs. < 1m)		0.30 (0.20 - 0.44)	From Chu et al (18)
All numbers are relative reduction in risk with 95% CI			

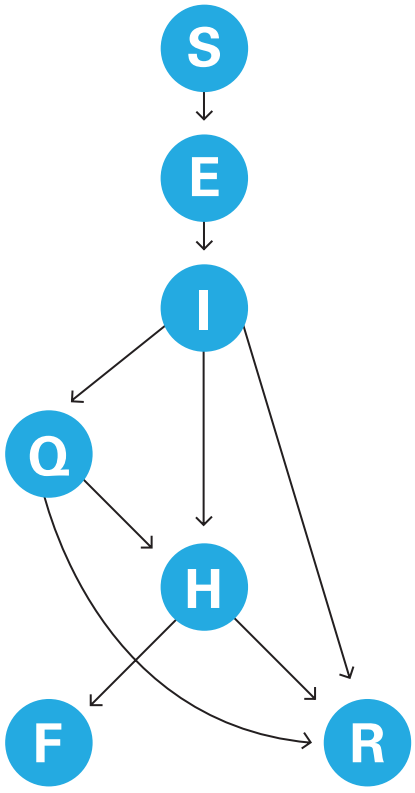

Figure 4: Transition diagram of the extended SIR compartment model. This figure illustrates the transitions between compartments denoted in each box: S - susceptible individuals; E - asymptomatic infectious patients; I - symptomatic infectious patients; Q – self-isolated infectious patients; H – patients requiring hospitalization; R – COVID-19 recovered patients; and F – case fatalities due to COVID-19.

Maternal and child mortality and nutrition

We used the Lives Saved Tool (LiST) and the Family Planning (FamPlan) modules of Spectrum to estimate the increase in maternal and under-5 child mortality, as well as pregnancies, rates of maternal anemia, childhood stunting and wasting, and SGA and LBW, resulting from reduced access and provision of essential SRMNCH services.

We used the most recent Demographic and Health Survey (DHS) and/or MICS from each country to determine baseline (2019) coverage of SRMNCH services. Level of disruption due to COVID-19 pandemic and response was estimated using actual country-specific data available from DHIS/HMIS dashboards. Where health systems data were not available, coverage disruption data were estimated using either a related country-level indicator, or average estimates from the other countries as proxy (Supplementary Table 3). Service disruption was estimated by quarter as follows:

- Compare DHIS/HMIS coverage data between Jan – Mar 2019 and Jan – Mar 2020 (Q1 levels)
- Compare DHIS/HMIS coverage data between Apr – Jun 2019 and Apr – Jun 2020 (Q2 levels)
- 2020 Q3 estimates: 50% recovery from Q2 levels
- 2020 Q4 estimates: 80% recovery from Q2 levels
- 2021 Q1 estimates: 10% increase from 2020 Q4 levels
- 2021 Q2 estimates: 20% increase from 2020 Q4 levels

The interventions included in the LiST and FamPlan modules, along with the estimated disruption to services by each quarter are summarized in Appendix A.

School-age child and adolescent mortality

Mortality estimates for children aged 5-9, 10-14, and 15-19, stratified by sex, were extracted from the IHME GBD Results Tool (20). The causes of death for which data were extracted, and for which the impact of COVID-19 mitigation strategies are estimated, include:

- Road traffic accidents
- Maternal causes for females aged 15-19
- HIV/AIDS, TB, typhoid, and malaria

We assumed that the number of deaths would be distributed equally throughout the year. Therefore, the total number of deaths in each country, and for each age/sex category by cause of death were divided by 12 to estimate the expected number of deaths expected to occur each month.

A literature search was undertaken to identify either a) estimates of the impact of COVID-19 on these causes of death, or b) studies quantifying the impact on cause-specific mortality of certain interventions, from which we calculated an assumed impact on mortality that could be expected if these interventions were removed/unavailable. From this literature search, we identified six papers quantifying the effect of COVID-19 on vehicular injuries among adolescents (21-26). Of these, one study based in Turkey, gave estimates for the impact on adolescent mortality (26). From this, we assumed a distributional impact of COVID-19 on adolescent mortality whereby the first few months of 2020 saw no decrease as compared to previous years, March saw a 20% decrease as lockdown measures were slowly introduced, April and May saw the largest reduction of 60% as lockdowns were in full effect, with the impact gradually increasing back to expected levels by the end of the year.

To estimate the impact of COVID-19 on maternal mortality amongst 15-19 year-old females, we used the expected increase in maternal deaths from our country-specific LiST and FamPlan models. To quantify the impact of reduced treatment coverage on adolescent mortality due to communicable diseases, we use the effect estimated for same during the 2014 – 2015 Ebola outbreak in West Africa (27). Parpia and colleagues (27) calculated that a 50% reduction in treatment coverage in West Africa during the 2014-15 Ebola crisis would lead to a 48% increase in malaria deaths among adolescents in Guinea, a 53.6% increase in Liberia, and a 50% increase in Sierra Leone. Similarly, TB deaths would increase by 51.1%, 59%, and 61.4% in these three countries, respectively, while HIV/AIDS deaths would increase by 16.2%, 13.0%, and 9.1%, respectively. For deaths due to typhoid, we assumed a 30% mortality rate in the absence of any treatment (28). We scaled these estimated percentage increase in deaths by the reduction in facility-based deliveries calculated as part of our LiST analysis mentioned previously. For example, if a 50% decrease in treatment coverage resulted in a 48% increase in malaria deaths, then a 25% decrease in treatment coverage was assumed to result in a 24% increase in mortality. These estimates were used to calculate the expected number of deaths in adolescents by scaling the observed monthly deaths by each of the effect sizes mentioned above.

Educational attainment

The COVID-19 pandemic has forced school closures across the globe. In South Asia, this mitigation strategy has left 420 million children out of school. We assessed the potential impact of the COVID-19 pandemic on educational attainment of school-aged children in six South Asian countries, and its sequelae on individual earnings and national Gross Domestic Product (GDP). Loss in educational attainment can occur in multiple ways, such as loss of learning time or loss of already acquired learning due to school closures (29). However, we focus on the loss of educational attainment that will occur due to the increase in number of students who permanently drop out of school because of prolonged school closures.

We conceptualized the current cohort of children enrolled in primary and secondary schools using population estimates available from UNESCO (30), and net attendance ratios available from the most recent DHS, for each country (31-36). We used age- and quintile-specific school dropout rates (Table 4), adapted from those observed during the 1997 East Asian financial crisis in Indonesia (37).

Table 4: School dropout rates by child age, gender, and wealth quintile

Child characteristic	Primary school (7 - 12 years)	Secondary school (13 - 19 years)
Wealth quintile		
1st	6.2	11.3
2nd	0	4.5
3rd	2.4	2.3
4th	1	2.2
5th	1	2.2
Gender		
Male	2.4	5.6
Female	2.6	3.9
Adapted from Frankenburg et al (37)		

We assumed that those who drop out in primary school would complete 2.5 years, and those who drop out in secondary school would complete 8.5 years of education. The corresponding years of education lost were calculated based on the highest median years of education attained, irrespective of age and gender, for each country (Table 5). We estimated income loss associated with reduced educational attainment by assuming that one less year of primary and secondary education reduces an individual's income by 4.04% and 2.44%, respectively (38). The 2019 GDP per capita, in current US$, for each country was assumed as baseline. A discount rate of 3% was applied to calculate the present value of loss in lifetime earnings.

Table 5: Median years of education completed by age and gender in six South Asian countries

Country	Age category	Gender	Median years of schooling*	Years of schooling lost	
				Primary	Secondary
Pakistan	20 – 24 years	Male	7.7	5.2	0
Bangladesh	15 – 19 years	Female	8.3	5.8	0
India	20 – 24 years	Male	10	7.5	1.5
Nepal	20 – 24 years	Male	9.1	6.6	0.6
Afghanistan	20 – 24 years	Male	7.3	4.8	0
Sri Lanka	20 – 24 years	Female	11.4	8.9	2.9

Source: Most recent country DHS (31-33, 35, 36, 39)
*Assumed for both boys and girls currently enrolled in school

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To address uncertainty around school dropout rates, we also conducted sensitivity analyses using school dropout rates observed during the Ebola crisis in Guinea (40) and Sierra Leone (41). We also conducted sensitivity analysis to address the uncertainty around the economic impact of reduced educational attainment, using an 8% return per year for education, as used by Psacharopoulos et al (42).

Early marriage and adolescent pregnancies

We also estimated the expected number of girls who will drop out of school as a result of the pandemic, using gender-specific school dropout rates observed during the 1997 East Asian financial crisis in Indonesia (37). Dropping out of school is associated with early marriage, especially for girls (43). There is also evidence that number of adolescent pregnancies have increased during the past few months of school closures (44). We used the baseline prevalence of adolescent pregnancies reported in the most recent DHS for each country (31-33, 35, 36, 39), and assumed that adolescent pregnancy rates will increase by 28% as a result of school closures due to COVID-19 pandemic response (44). We assumed that although risk of maternal mortality in adolescent pregnancies will be the same as those observed for women > 19 years (45), risk of neonatal mortality and low birthweight births will increase by 9% and 42%, respectively (46). We also assumed that 20% of children born with low birthweight will be stunted by age 2 years (47), and will lose 10% of their lifetime earnings as a result of their short stature (48).

Economic Impact of COVID-19 control measures

Measures to control the spread of COVID-19 have resulted in wide-ranging disruption of economic activities across the globe. We estimated the economic impact of these strategies on the following outcomes:

1. Change in GDP
2. Job losses
3. Change in poverty rate
4. Change in proportion of population who is food insecure

Given the dynamic nature of the epidemic and the lag in production of many economic inputs, we assumed that the model will be static in nature (i.e. output, employment and poverty will not be an exponential function of ongoing changes per time period, but a function of change from the period prior to the beginning of the epidemic) and as a result may be less sensitive than a fully dynamic model.

The severity of control measures was classified as follows:

- Stage 0 – Baseline: No changes
- Stage 1 – Limited: Warnings/advisories, public gatherings ban, social distancing, schools closures
- Stage 2 – Mild: Closure of shopping areas, imports/exports reduced
- Stage 3 – Moderate: Closure of restaurants, public transport reduced, imports/exports reduced to essential
- Stage 4 – Severe: Closure of parks, public transport closed, all trading restricted

To estimate the impact of the different stages of control measures on output (GDP) we deconstructed output into labor and non-labor related outputs (interest on loans, debt repayment, bonds, etc.).
Our model estimated changes in labor-related output only, as this is the area most likely to be affected by the COVID-19 control measures, leading to reduced capacity of workplaces, factories etc.

The starting point for this part of the model was to estimate the proportion of output (GDP) that is derived from labor-based productivity. Most sets of national accounts highlight this by producing output by sector. Given that we wanted to link output, workforce, capacity, and relative risk of unemployment and proportion of households vulnerable to poverty (relative likelihood of falling into poverty if the primary provider loses income for more than a month), we settled on the following sectors:

1. Agriculture and fisheries,
2. Mining and quarrying,
3. Manufacturing and textiles,
4. Energy generation,
5. Construction,
6. Wholesale and retail trade,
7. Transport and communications,
8. Finance and insurance services,
9. Other private sector and government services

Workforce was estimated by working age population, labor force participation rate, and formal and informal sector worker estimates from the International Labour Organization (ILO). Job losses leading to increase in poverty rates were estimated using the methodology described by Iqbal et al (49). The proportion of labor force laid off at each stage of COVID-19 control measures, is summarized in the table below.

The output model was based on marginal rate of productivity per worker (MPW) as a function of output and workforce data from Jan – Dec 2019.

It was estimated under the following caveats or assumptions:

- No change in stock of capital, or the marginal rate of return on capital (or land)
- No technological advancement/change leading to a rise in relative rate of productivity per worker hour
- Exclude any effects of economies of scale or specialization on changes in MPW, earnings or GDP
- Within the same industry, marginal productivity in worker A will not be affected by the marginal productivity of worker B
- Across industries, marginal productivity of any workers in industry A will not be affected by changes in the marginal productivity of a worker in industry B
- A perfectly competitive market where marginal productivity = marginal cost
- Mitigation strategies will be in place for 12 months, with the impact on outcomes estimated for the same period

Given limited data from other countries and to determine the pandemic's impact on food insecurity, we assessed the relationship between change in household income and food consumption in the previous week as observed in Nepal in April 2020 (51), using a simple linear regression. We then applied the results of this regression to the estimated change in GDP resulting from each stage of mitigation strategies, and assessed the rise in the proportion of population who could become food insecure due to the COVID-19 mitigation response.

Table 6: Labor force laid off by at each mitigation stage, by industry

Industry	Limited Restrictions	Mild Restrictions	Moderate Restrictions	Severe Restrictions
Agriculture	0%	10%	15%	20%
Manufacturing	10%	35%	53%	70%
Electricity & gas	0%	5%	8%	10%
Construction	0%	45%	68%	90%
Wholesale & retail trade	10%	35%	53%	70%
Transport, storage & communications	10%	45%	68%	90%
Finance & insurance	0%	25%	38%	50%
Other private	11%	36%	54%	73%
Government services	17%	20%	30%	40%
Adapted from: Faraz and Khalid, 2020 (50)				


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Chapter 3: **Results**

COVID-19 predicted morbidity and mortality

Based on the results of our extended SIER model, and a potential status quo in infection control and prevention measures, an additional half a million deaths due to COVID-19 are possible in South Asia, between October 2020 and September 2021, (Table 7). This is the number of individuals expected to die of COVID-19, and who likely would not have died in the absence of the pandemic i.e. additional deaths. The highest number of deaths are expected occur in India, with more than 490,000 deaths projected to occur in the country during this period.

Not surprisingly, the expected number of hospitalizations and ICU admission are also expected to be highest in India, with the numbers expected to rise to their highest level in February 2021 (Table 7).

Results for individual mitigations strategies are presented in Appendix B.

Since the observed number of COVID-19 cases and deaths are rising most rapidly in India, compared to other South Asian countries, the impact of modelling the increased coverage and effectiveness of mitigation strategies is also highest in the country (Table 7). Instituting all mitigation strategies could reduce the numbers of deaths due to COVID-19 by 83% (491,117 deaths under the no-additional mitigation scenario vs. 85,821 deaths if all strategies were instituted; Table 7). Similar effects are also noted for hospitalizations and ICU admissions, both of which are expected to decrease by 75% in February 2021, if all mitigation strategies are instituted (Table 7). Results for individual mitigation strategies are presented in Appendix B.

Table 7: Estimated number of COVID-19 deaths, hospitalizations and ICU admissions, by mitigation response and country

Intervention		No additional mitigation			All strategies		
Country	Month	Cumulative Deaths	Hospitalizations*	ICUs*	Cumulative Deaths	Hospitalizations*	ICUs*
India	Sep-20¥	65,228	NA	NA	65,228	NA	NA
	Oct-20	103,994	67,613	11,932	64,676	12,821	2,262
	Nov-20	139,937	76,074	13,425	71,214	9,104	1,607
	Dec-20	178,008	82,772	14,607	75,781	6,354	1,121
	Jan-21	222,202	87,896	15,511	78,916	4,283	756
	Feb-21	267,186	88,209	15,566	81,267	3,079	543
	Mar-21	307,089	84,831	14,970	82,653	2,141	378
	Apr-21	348,060	77,316	13,644	83,721	1,580	279
	May-21	383,795	70,447	12,432	84,526	1,048	185
	Jun-21	418,121	61,320	10,821	85,050	721	127
	Jul-21	445,995	52,311	9,231	85,412	538	95
	Aug-21	470,231	43,937	7,754	85,658	383	68
	Sep-21	491,117	36,442	6,431	85,821	215	38

Intervention		No additional mitigation			All strategies		
Country	Month	Cumulative Deaths	Hospitalizations*	ICUs*	Cumulative Deaths	Hospitalizations*	ICUs*
Pakistan	Sep-20¥	6,298	NA	NA	6,298	NA	NA
	Oct-20	7,374	398	70	7,332	391	69
	Nov-20	7,400	351	62	7,354	295	52
	Dec-20	7,409	404	71	7,361	227	40
	Jan-21	7,423	465	82	7,366	174	31
	Feb-21	7,434	503	89	7,369	147	26
	Mar-21	7,446	552	97	7,372	149	26
	Apr-21	7,464	522	92	7,377	140	25
	May-21	7,473	487	86	7,385	120	21
	Jun-21	7,481	450	79	7,388	114	20
	Jul-21	7,487	380	67	7,388	129	23
	Aug-21	7,499	332	59	7,388	118	21
	Sep-21	7,507	294	52	7,390	140	25
Bangladesh	Sep-20¥	4,281	NA	NA	4,281	NA	NA
	Oct-20	5,086	444	78	4,973	466	82
	Nov-20	5,905	427	75	5,839	432	76
	Dec-20	6,656	316	56	6,623	370	65
	Jan-21	7,266	341	60	7,335	323	57
	Feb-21	7,892	298	53	7,940	271	48
	Mar-21	8,378	268	47	8,345	250	44
	Apr-21	8,840	191	34	8,838	229	40
	May-21	9,209	193	34	9,253	187	33
	Jun-21	9,564	176	31	9,614	165	29
	Jul-21	9,863	171	30	9,916	162	29
	Aug-21	10,159	139	25	10,217	124	22
	Sep-21	10,412	110	19	10,462	96	17
Nepal	Sep-20¥	228	NA	NA	228	NA	NA
	Oct-20	424	65	12	422	57	10
	Nov-20	499	50	9	487	46	8
	Dec-20	555	38	7	536	33	6
	Jan-21	596	30	5	573	28	5
	Feb-21	629	23	4	602	21	4
	Mar-21	654	19	3	625	16	3
	Apr-21	675	15	3	644	13	2
	May-21	690	12	2	659	9	2
	Jun-21	703	8	1	670	8	1
	Jul-21	711	7	1	678	6	1

Intervention		No additional mitigation			All strategies		
Country	Month	Cumulative Deaths	Hospitalizations*	ICUs*	Cumulative Deaths	Hospitalizations*	ICUs*
Nepal	Aug-21	717	5	1	686	5	1
	Sep-21	723	5	1	691	4	1
Afghanistan	Sep-20¥	1,406	NA	NA	1,406	NA	NA
	Oct-20	2,306	442	78	2,157	326	58
	Nov-20	2,850	426	75	2,607	305	54
	Dec-20	3,354	406	72	3,015	288	51
	Jan-21	3,885	378	67	3,455	273	48
	Feb-21	4,375	359	63	3,849	251	44
	Mar-21	4,807	349	62	4,204	248	44
	Apr-21	5,230	323	57	4,565	241	42
	May-21	5,638	311	55	4,910	236	42
	Jun-21	6,075	291	51	5,259	218	38
	Jul-21	6,453	266	47	5,552	201	35
	Aug-21	6,802	241	42	5,825	185	33
	Sep-21	7,106	237	42	6,094	177	31

¥Number of deaths observed as of September 1, 2020. Source: Our World in Data (15)
*Numbers are "snapshots" taken on the 1st of every month, indicating healthcare utilization over time

The direct costs associated with COVID-19 hospitalizations and ICU admissions are commensurate with their observed and expected numbers for each country. We estimated the direct costs as follows:

- Costs of diagnostic tests, assumed to be US$ 20 (52)
- Healthcare utilization costs associated with COVID-19 mortality, assuming a 16 days' stay in the hospital, including ICU admission, and cost of care assumed to be US$ 4,708 (53-55)

To date, the disease is estimated to have cost the region more than US$ 2.4 billion, including cost of testing (US$ 1.9 billion) and healthcare utilization for COVID-19 deaths (US$ 581 million). If the current status quo in terms of testing, and infection control and prevention, is maintained, the region is expected to spend an additional US$ 8.1 billion on COVID-19 diagnostic tests, and between US$ 520 million and US$ 2.4 billion on healthcare utilization by September 2021, depending on the level of mitigation response instituted. India is expected to bear the largest share of these costs with the country having to spend more than US$ 7.8 billion on testing, and US$ 1.7 billion on healthcare utilizations due to COVID-19 infections leading to death by September 2021. Table 8 summarizes the estimated costs associated with COVID-19 diagnostic tests and healthcare utilization until September 2021.

Although there will be costs associated with implementing COVID-19 mitigation strategies, such as households having to spend money out-of-pocket purchasing masks and hand sanitizers, these cannot be measured with any specificity. However, any costs associated with increased use of masks and hand sanitizers will likely be much lower than what countries will spend on COVID-19 healthcare utilization.

Table 8: Estimated costs (US$) of COVID-19 testing, and healthcare utilization, by mitigation response and country

Country	Testing*	No additional mitigation	Hand Hygiene	Smart Lockdowns	Masks	All strategies
India	7,895,416,016	2,312,178,836	659,011,716	1,188,388,652	845,015,380	404,045,268
Pakistan	87,407,669	35,342,956	34,396,648	33,464,464	34,095,336	34,792,120
Bangladesh	78,182,660	49,019,696	49,010,280	48,544,188	48,878,456	49,255,096
Nepal	26,757,389	3,403,884	3,323,848	3,342,680	3,370,928	3,253,228
Afghanistan	NA	33,455,048	29,975,836	32,249,800	31,468,272	28,690,552
Total	**8,087,763,734**	**2,433,400,420**	**775,718,328**	**1,305,989,784**	**962,828,372**	**520,036,264**

All figures are in US$
No testing data available for Afghanistan
*Testing is assumed to continue at the current level

Maternal and child mortality and nutrition

Even before the World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020, coverage of essential SRMNCH services were being affected in several countries of South Asia. The SRMNCH services for which actual DHIS/HMIS data were available for all countries are summarized in Panel 1.
Based on actual data available from country-specific health data systems, coverage of family planning services decreased by 3 – 31% in five of the six South Asian countries included in our analysis (Figure 5) in the first quarter of 2020, compared to that observed during the same period in 2019. Afghanistan is the only country which reported an increase in coverage family planning services over this period, which could be questioned as erroneous (^12%, Figure 5).

In the second quarter of 2020, which corresponds with the most stringent COVID-19 control strategies being instituted in the region, coverage of all essential SRMNCH services declined substantially, with coverage of most services reducing by >50% across South Asia (Figure 5), compared to levels observed during the same period in 2019.

Panel 1: SRMNCH services included and modelled in the LiST analysis

Family planning
Antenatal care (4+ visits)
Tetanus Toxoid (2 or more doses)
Facility births
Postnatal visit within 2 days after birth
Vaccine: DPT3/Penta3
Full immunization
Zinc for treatment of diarrhea – Zinc Supplementation
Antibiotics for pneumonia
SAM- treatment for severe acute malnutrition

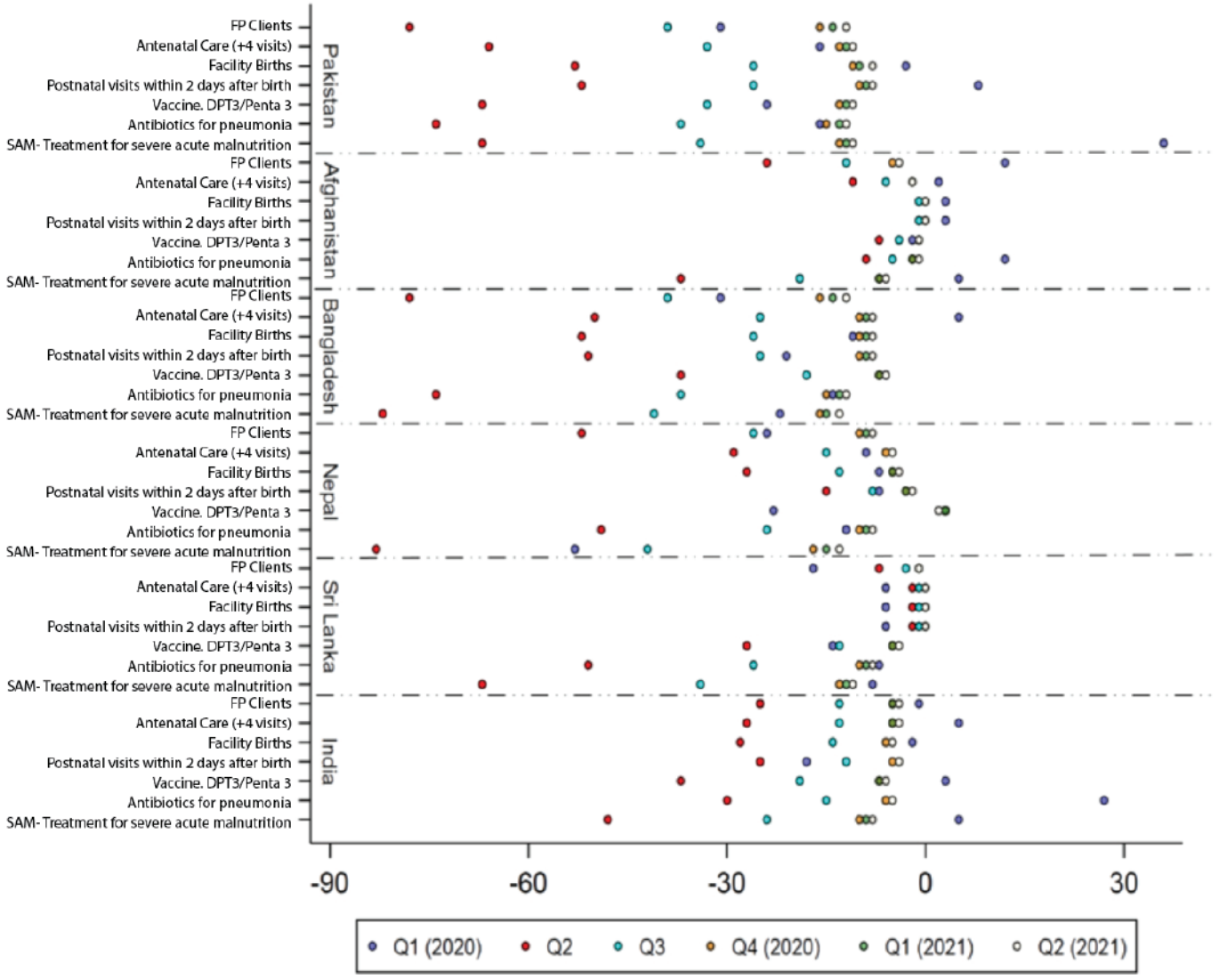

Figure 5: Observed (Quarter 1 and 2) and estimated (Quarter 3 and 4 of 2020, and Quarter 1 and 2 of 2021) coverage disruption of selected SRMNCH services in 2020 and 2021, due to the COVID-19 pandemic response in South Asia

The observed and estimated disruption in SRMNCH services is expected to have had a substantial impact on maternal and child mortality. The number of deaths among children < 5 years are estimated to increase by a total of 228,641 across the six South Asian countries in 2020 compared to the previous year, with 134,789 of these deaths expected to occur in the neonatal period. The greatest increases are anticipated in India (154,020, 15% increase) and Pakistan (59,251, 14% increase) respectively.

The number of stillbirths are also predicted to increase in the region. Across South Asia as a whole, an estimated 89,434 additional stillbirths are anticipated as a result of reduced coverage of essential SRMNCH services. At the country-level, the largest increase in the number of stillbirths is expected in India (60,179, 10% increase), followed by Pakistan (39,752, 11% increase) and Bangladesh (5,502, 3% increase). Similarly, the number of maternal deaths is also expected to increase in 2020 as a result of the COVID-19 pandemic response, compared to those observed in 2019, with the highest number of deaths anticipated in India (7,750, 18% increase) and Pakistan (2,069, 21% increase). Due to the observed and expected reduction in coverage of modern contraceptive methods, more than 3.5 million additional unintended pregnancies are expected in South Asia, with the highest number likely in India (~3 million).

The number of unsafe abortions are also expected to increase in the region, by more than 50%. Overall in South Asia, child and maternal mortality is expected to increase by 14% and 16%, respectively. Table 9 summarizes the estimated increase in maternal and under-5 child mortality, and pregnancies, for each country by each quarter of 2020.

Table 9: Estimated increase in deaths, pregnancies and abortions by country and quarter of 2020

	2020*	Afghanistan	Bangladesh	India	Nepal	Pakistan	Sri Lanka	Overall
Child mortality	Q1	-0.6%	5.0%	0.0%	6.2%	3.2%	16.9%	16.9%
	Q2	2.8%	29.3%	39.3%	12.8%	33.2%	5.1%	5.1%
	Q3	2.0%	13.0%	16.8%	7.1%	16.6%	1.9%	1.9%
	Q4	1.5%	4.7%	5.7%	1.0%	5.0%	0.5%	0.5%
	Overall	**1.4%**	**13.0%**	**15.4%**	**6.8%**	**14.5%**	**6.1%**	**6.1%**
Neonatal mortality	Q1	0.2%	4.4%	2.2%	2.6%	1.2%	24.3%	24.3%
	Q2	2.3%	22.3%	36.5%	16.6%	39.1%	2.5%	2.5%
	Q3	1.7%	9.6%	14.8%	9.8%	20.2%	0.8%	0.8%
	Q4	1.4%	3.4%	4.5%	1.5%	5.4%	-0.1%	-0.1%
	Overall	**1.3%**	**9.9%**	**14.5%**	**7.6%**	**16.5%**	**6.9%**	**6.9%**
Stillbirths	Q1	0.5%	1.2%	1.1%	1.1%	0.8%	51.7%	51.7%
	Q2	1.8%	8.8%	26.7%	14.1%	23.6%	3.0%	3.0%
	Q3	1.5%	2.7%	10.6%	11.1%	16.4%	1.1%	1.1%
	Q4	1.3%	0.7%	2.9%	0.4%	2.3%	0.0%	0.0%
	Overall	**1.3%**	**3.4%**	**10.3%**	**6.7%**	**10.8%**	**14.0%**	14.0%
Maternal deaths	Q1	0.0%	1.6%	-1.6%	6.1%	2.3%	77.2%	77.2%
	Q2	3.3%	24.7%	47.1%	34.4%	47.5%	5.4%	5.4%
	Q3	2.2%	8.3%	18.7%	23.4%	30.1%	2.2%	2.2%
	Q4	1.5%	2.9%	6.0%	3.0%	5.2%	1.1%	1.1%
	Overall	**1.7%**	**9.4%**	**17.6%**	**16.7%**	**21.3%**	**21.5%**	**21.5%**

	2020*	Afghanistan	Bangladesh	India	Nepal	Pakistan	Sri Lanka	Overall
Additional unintended pregnancies	Q1	-2,747	28,873	18,780	2451	14722	2,708	2,708
	Q2	2,567	96,536	2,237,563	11,434	176,453	2,806	2,806
	Q3	518	40,409	622,372	2,901	41,299	1,405	1,405
	Q4	-555	13,956	201,488	-254	2,504	630	630
	Overall	**-217**	**179,774**	**3,080,202**	**16,531**	**234,978**	**7,548**	**7,548**
Additional unsafe abortion	Q1	-7.8%	20.6%	15.3%	26.0%	3.0%	14.1%	14.1%
	Q2	14.5%	58.0%	200.1%	61.8%	52.8%	8.2%	8.2%
	Q3	6.8%	26.6%	74.7%	28.5%	19.6%	4.1%	4.1%
	Q4	2.3%	10.2%	27.4%	10.6%	6.3%	1.8%	1.8%
	Overall	**3.9%**	**28.9%**	**79.4%**	**31.7%**	**20.4%**	**7.1%**	**7.1%**

*Compared to 2019

Compared to 2019 levels, we did not observe a significant impact on child nutrition as measured by changes in rates of childhood wasting and stunting, and SGA and LBW, in 2020 (Supplementary Table 4). This is likely due to low rates of current coverage of many key interventions related to community management of moderate and severe malnutrition and food supplementation. However, based on LiST estimates, rates of maternal anemia increased in Q2 of 2020, corresponding to the largest disruption in coverage of essential health services.

Table 10: Increase in rates of maternal anemia in Q2 2020, compared to 2019, by country

	Afghanistan	Bangladesh	India	Nepal	Pakistan	Sri Lanka
Pregnant women with IDA	2.1%	11.2%	2.3%	20.7%	4.8%	2.0%
Pregnant women with anemia	4.4%	22.8%	5.0%	40.8%	11.0%	3.2%

IDA: Iron deficiency anemia

We also assessed the impact of essential SRMNCH services coverage recovery in Q1 and Q2 of 2021. Given the current state of the pandemic in India (the major population driver) and continued gradual upsurges in other countries of the region, we have used conservative estimates for recovery in anticipation of the persisting COVID-19 challenge in 2021, potentially until an effective vaccine is deployed and widely available. We assumed 10-20% pragmatic increase in service coverage across the continuum of SRMNCH interventions in the first half of 2021, the end-date of the current modelling exercise.

If service coverage improved by 10% in Q1 2021, and 20% in Q2 2021, compared to their Q4 2020 levels, an additional 537 child deaths (0.1% increase), but 97 fewer maternal deaths (0.3% decrease) are expected in the region. Nepal and Sri Lanka are expected to see a decrease in child deaths in both Q1 and Q2 of 2021, whereas Bangladesh, India and Sri Lanka are expected to have fewer maternal deaths in Q1 and Q2 of 2021, compared to those observed in 2019. However, number of unintended pregnancies are still expected to be higher in 2021, compared to those observed during the same period in 2019. This is plausible given the lag period between restitution of family planning services and reduction in unwanted pregnancies.

Table 11 summarizes the estimated impact on maternal and child mortality, and pregnancies, for each country for first two quarters of 2021.

Table 11: Estimated increase in deaths, pregnancies and abortions by country and quarter of 2021

	2021*	Afghanistan	Bangladesh	India	Nepal	Pakistan	Sri Lanka	Overall
Child mortality	Q1	2.7%	0.1%	0.1%	-0.3%	0.5%	-1.2%	0.3%
	Q2	2.7%	-0.4%	-0.4%	-0.3%	-0.1%	-1.3%	-0.2%
	Overall	**2.7%**	**-0.2%**	**-0.2%**	**-0.3%**	**0.2%**	**-1.2%**	**0.1%**
Neonatal mortality	Q1	3.6%	-0.4%	-0.4%	0.1%	0.4%	-1.0%	0.0%
	Q2	3.6%	-0.8%	-0.8%	0.1%	-0.2%	-1.0%	-0.4%
	Overall	**3.6%**	**-0.6%**	**-0.6%**	**0.1%**	**0.1%**	**-1.0%**	**-0.2%**
Stillbirths	Q1	3.6%	-0.2%	-0.2%	0.3%	0.7%	-1.0%	0.2%
	Q2	3.6%	-0.3%	-0.5%	0.3%	0.5%	-1.1%	-0.1%
	Overall	**3.6%**	**-0.2%**	**-0.3%**	**0.3%**	**0.6%**	**-1.0%**	**0.0%**
Maternal deaths	Q1	3.6%	-0.2%	-0.5%	-1.3%	0.6%	-1.1%	0.0%
	Q2	3.6%	-1.4%	-1.0%	0.1%	0.1%	-1.1%	-0.5%
	Overall	**3.6%**	**-0.8%**	**-0.7%**	**-0.6%**	**0.3%**	**-1.1%**	**-0.3%**
Additional unintended pregnancies	Q1	6,536	6592	41151	2533	17399	61	74271
	Q2	6,472	4373	21079	2533	15007	-20	49442
	Overall	**13,008**	**10,964**	**62,230**	**5,065**	**32,406**	**41**	**123,713**
Additional unsafe abortion	Q1	3.6%	-0.2%	-0.5%	-1.3%	0.6%	-1.1%	0.0%
	Q2	3.6%	-1.4%	-1.0%	0.1%	0.1%	-1.1%	-0.5%
	Overall	**3.6%**	**-0.8%**	**-0.7%**	**-0.6%**	**0.3%**	**-1.1%**	**-0.3%**

*Compared to 2019

School-age child and adolescent mortality

The number of deaths due to maternal causes among 15-19 year-old females is estimated to increase by a total of 1,191 across South Asia in 2020, compared to the previous year, with the greatest increases anticipated in India (643) and Pakistan (476), respectively.

A rise in communicable disease-related adolescent mortality is also likely. Across South Asia as a whole, an estimated 5,943 additional deaths from malaria, TB, HIV/AIDS, and typhoid are anticipated as a result of reduced treatment coverage, with the largest increases expected in typhoid (2,243) and malaria (1,965). At the country-level, India is expected to be hit hardest with an additional 3,412 adolescent deaths followed by Pakistan (1,629) and Bangladesh (836).

However, the increases in both adolescent maternal and communicable disease mortality are more than offset by the expected reduction in adolescent deaths as a result of fewer road accident related deaths. An estimated 8,079 fewer adolescents are expected to die in 2020 as a result of traffic accidents across South Asia as compared to the previous year, with the greatest reduction in India (4,145) followed by Pakistan (2,697). Bangladesh is the only country where an increase in the number of adolescent deaths is expected, mainly due to an increase in deaths due to malaria and typhoid (Table 12).

Overall, adolescent deaths caused by road traffic accidents, maternal causes, or communicable diseases are expected to decrease by 945 in South Asia, with the largest reduction expected in Pakistan (533) and Afghanistan (495) (Table 12).

Table 12: Expected change in number of deaths due to road traffic accidents, maternal causes, and communicable diseases among adolescents in 2020 and compared to 2019

Country	2020	RTAs*	Maternal causes	Communicable diseases				Overall
				HIV/AIDS	TB	Typhoid	Malaria	
Pakistan	Q1	-176	13	0	0	0	0	-163
	Q2	-1,407	263	3	459	187	288	-208
	Q3	-879	171	1	225	100	144	-238
	Q4	-176	29	1	112	50	60	76
	Overall	**-2,637**	**476**	**5**	**796**	**336**	**491**	**-533**
India	Q1	-276	-14	0	0	0	0	-291
	Q2	-2211	431	25	491	736	710	183
	Q3	-1382	171	11	227	393	355	-225
	Q4	-276	55	6	113	196	148	242
	Overall	**-4,145**	**643**	**41**	**831**	**1,325**	**1,214**	**-91**
Nepal	Q1	-13	2	0	2	3	3	-3
	Q2	-102	8	1	6	13	12	61
	Q3	-64	6	1	3	7	6	-41
	Q4	-13	1	0	1	4	3	-4
	Overall	**-192**	**16**	**2**	**12**	**27**	**24**	**-110**
Bangladesh	Q1	-38	2	0	5	60	27	57
	Q2	-302	32	0	23	274	123	150
	Q3	-189	11	0	11	146	61	41
	Q4	-38	4	0	6	73	26	70
	Overall	**-566**	**48**	**1**	**46**	**553**	**236**	**318**
Sri Lanka	Q1	-2	1	0	0	1	0	0
	Q2	-19	0	0	0	0	0	-19
	Q3	-12	0	0	0	0	0	-12
	Q4	-2	0	0	0	0	0	-2
	Overall	**-36**	**1**	**0**	**0**	**1**	**0**	**-34**
Afghanistan	Q1	-33	0	0	0	0	0	-34
	Q2	-268	3	0	0	0	0	-264
	Q3	-167	2	0	0	0	0	-165
	Q4	-33	2	0	0	0	0	-32
	Overall	**-502**	**7**	**0**	**0**	**0**	**0**	**-495**
South Asia	Q1	-539	3	0	7	64	30	-434
	Q2	-4309	737	29	980	1210	1133	-219
	Q3	-2693	361	13	466	646	566	-641
	Q4	-539	90	7	233	323	236	349
	Overall	**-8,079**	**1,191**	**50**	**1,685**	**2,243**	**1,965**	**-945**

*Road traffic accidents resulting in death of either pedestrian or passenger
Maternal causes include all pregnancy-related deaths in girls 15 – 19 years

Educational attainment

South Asia is home to approximately 420 million school-aged children who have been out of school since March 2020. At best, only 2 out of every 3 are being reached by remote learning, with children living in rural areas and poorer households less likely to be able to access remote learning (56). The impact on the youngest children, who are within the most sensitive windows for learning, are also likely to be substantial. As a result of prolonged school closures in response to the COVID-19 pandemic almost 9 million (8,788,476) primary and secondary school-aged children (2,724,686, and 6,063,789, respectively) are expected to permanently dropout of schools, with the highest number expected in India (7,017,721) (Table 13).

The disruption in education is also expected to have considerable economic costs over the long term. Across South Asia, lower educational attainment by this cohort will result in a 15 – 23% decrease in their future lifetime earnings, costing the region US$ 63.5 billion over 45 years. The highest cost will be borne by India (US$ 52.8 billion) and Bangladesh (US$ 7.4 billion), followed by Sri Lanka (US$ 1.9 billion). Table 13 summarizes the estimated number of children expected to permanently dropout of school, and the impact this will have on each country's GDP over the course of these children's lifetime.


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Table 13: Number of estimated additional dropouts and present value of per student average income loss in annual, lifetime and national gross GDP terms in six South Asian countries

	Dropouts	Present value of income loss			
	N	%	Per year	Lifetime (45 yrs.)	Gross GDP
		Per student			National
Pakistan					
Primary dropouts	261,305	15.6%	$201	$3,816	
Secondary dropouts	403,695	0%	-	-	
Total	664,999		$ 201	$ 3,816	$997,072,322
Bangladesh					
Primary dropouts	268,631	6.9%	$313	$27,484	
Secondary dropouts	359,972	0%	-	-	
Total	628,602		$313	$27,484	$7,383,005,896
India					
Primary dropouts	2,031,509	20.3%	$427	$18,029	
Secondary dropouts	4,986,212	3.6%	$77	$3,236	
Total	7,017,721		$ 504	$21,265	$52,762,813,476
Nepal					
Primary dropouts	48,703	18.5%	$198	$4,985	
Secondary dropouts	128,893	1.5%	$16	$397	
Total	177,595		$504	$21,265	$293,982,934

	Dropouts	Present value of income loss			
	N	%	Per year	Lifetime (45 yrs.)	Gross GDP
		Per student			National
Afghanistan					
Primary dropouts	79,221	14.8%	$74	$1,820	
Secondary dropouts	83,630	0.0%	-	-	
Total	162,851		$74	$1,820	$144,193,226
Sri Lanka					
Primary dropouts	35,319	23.0%	$886	$29,149	
Secondary dropouts	101,388	6.9%	$267	$8,771	
Total	136,706		$1,153	$ 37,921	$1,918,810,96
Compared to 2019					

To address uncertainty around school dropout rates and the economic impact of reduced educational attainment, we also conducted a series of sensitivity analyses. The results are summarized in Table 14. The models are defined as follows:

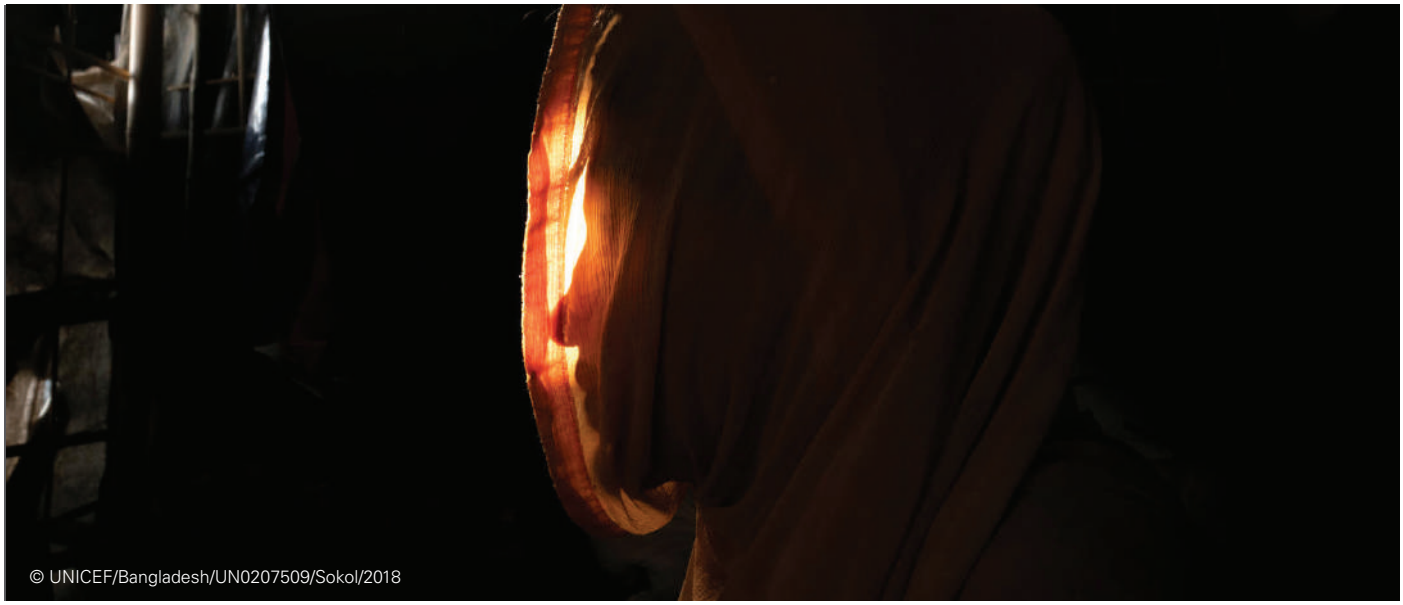
- Model A: Rates of school dropouts assumed as those observed during the 1997 Asian financial crisis in Indonesia and an 8% per year return on education
- Model B: Rates of school dropouts assumed as those observed during the Ebola crisis in Guinea and Sierra Leone and 4.04% per year return on primary education and 2.44% per year return on secondary education
- Model C: Rates of school dropouts assumed as those observed during the Ebola crisis in Guinea and Sierra Leone and an 8% per year return on education

The results of sensitivity analyses demonstrate that the impact of COVID-19 pandemic response on educational attainment and subsequent losses in income could be even worse that what our original model predicts.

The estimated number of school dropouts and the consequent economic impact increase substantially, from 8.8 million children dropping out of school in our original model to more than 45.5 million dropping out under Model C. Similarly, the estimated economic impact on the region increases from US$ 63.5 billion in our original model to almost US$ 1 trillion in Model C.

Table 14: Results of sensitivity analyses to address uncertainty around school dropout rates and economic impact of reduced educational attainment in six South Asian countries.

	Number of dropouts			Economic impact
Country	**Primary-school aged**	**Secondary-school aged**	**Total**	**US$ (Billions)**
Model A				
Pakistan	261,305	403,695	664,999	$2.2
Bangladesh	268,631	359,972	628,602	$16.8
India	2,031,509	4,986,212	7,017,721	$136.0
Nepal	48,703	128,893	177,595	$0.7
Afghanistan	79,221	83,630	162,851	$0.3
Sri Lanka	35,319	101,388	136,706	$5.1
Total	**2,724,686**	**6,063,789**	**8,788,476**	**$161.2**
Model B				
Pakistan	2,248,519	1,895,581	4,144,100	$8.6
Bangladesh	1,921,179	1,386,222	3,307,401	$52.8
India	14,485,269	18,327,017	32,812,287	$320.5
Nepal	336,413	435,455	771,867	$1.9
Afghanistan	578,933	317,645	896,577	$1.1
Sri Lanka	250,759	340,469	591,228	$10.3
Total	**19,821,072**	**22,702,388**	**42,523,460**	**$395.0**
Model C				
Pakistan	2,248,519	1,895,581	4,144,100	$19.3
Bangladesh	1,921,179	1,386,222	3,307,401	$120.0
India	14,485,269	18,327,017	32,812,287	$789.9
Nepal	336,413	435,455	771,867	$4.4
Afghanistan	578,933	317,645	896,577	$2.4
Sri Lanka	250,759	340,469	591,228	$25.9
Total	**19,821,072**	**22,702,388**	**42,523,460**	**$961.9**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Early marriage and adolescent pregnancies

Rates of adolescent pregnancies are quite high in South Asia, with the proportion of girls 15 – 19 years who have given birth ranging from 5.2% in India (32) to 24.6% in Bangladesh (31). Of the 8.8 million children expected to permanently drop out of school, 4.5 million of them are expected to be girls (Table 15). Given the cultural and social context of South Asia, as well as the economic hardship many families in the region are facing as a result of the COVID-19 pandemic and response, many of these girls are likely to be married off early, resulting in an increase in the number of adolescent pregnancies.

Recent data from Kenya shows that the rate of adolescent pregnancies between April and June 2020 has indeed increased by 28%, compared to the same period in 2019 (44).

As a result of the increase in the number of girls dropping out of school early due to the COVID-19 pandemic, the number of adolescent pregnancies are expected to increase by 405,640 in the region, and could lead to an additional 655 maternal and 9,986 neonatal deaths, 154,985 low birthweight births, and 29,000 children who are likely to be stunted by the age of 2 years.

Table 15 summaries the estimated number of girls expected to permanently dropout of school and the sequelae resulting from their early marriages and consequent adolescent pregnancies.

Table 15: Estimated number of additional adolescent pregnancies, maternal and neonatal deaths, low birthweight births and stunted children resulting from girls dropping out of school due to the COVID-19 pandemic in six South Asian countries

Country	School dropouts	Adolescent pregnancies	Maternal deaths	Neonatal deaths	LBW births	Stunted
Pakistan	397,453	28,998	41	1,328	11,118	1,958
Bangladesh	352,250	110,916	192	2,055	44,100	8,409
India	3,531,683	235,069	341	5,893	90,125	16,846
Nepal	84,587	18,406	34	401	5,750	1,070
Afghanistan	69,288	7,095	45	286	2,720	487
Sri Lanka	66,024	5,155	2	22	1,171	230
Total	**4,501,285**	**405,640**	**655**	**9,986**	**154,985**	**29,000**

Compared to 2019

Economic impact of COVID-19 control measures

In the absence of an effective vaccine or clinical treatment, the main strategy used to control the spread of disease has been non-pharmaceutical interventions, such as physical distancing measures, school closures, travel restrictions and nationwide lockdowns. All of these have resulted in wide-ranging disruption of economic activities.

To assess the economic impact of the COVID-19 pandemic response by different stages of severity of mitigation measures, we estimated the impact on GDP, poverty and food insecurity, resulting from wage loss due to the proportion of industry-specific labor force laid off at each stage (Table 16).

It is not surprising that the economic impact of COVID-19 mitigation strategies worsens with the severity of these strategies, with the most severe stage (Stage 4) resulting in a 20 – 28% year-on-year decrease in GDP, with consequent implications for rates of national poverty and food insecurity. Even at the least severe stage (Stage 1), the increase in the share of the population who is food insecure could range from 17.4% in Afghanistan to 18.9% in Sri Lanka. The estimated impact of the COVID-19 pandemic and response, across the range of economic indicators, is summarized in Table 16.

Table 16: Estimated economic impact of the COVID-19 pandemic and response in South Asia, by stages of mitigation strategies

	Stage 1	Stage 2	Stage 3	Stage 4
Pakistan				
Job losses (millions)	1.7	7.1	10.7	14.3
Change in GDP*	– 4%	– 12%	– 18%	– 24%
Rise in poverty rate	1.3%	5.7%	8.5%	11.4%
Rise in food insecurity	18.3%	24.0%	28.1%	32.2%
Bangladesh				
Job losses (millions)	1.8	8.1	12.2	16.2
Change in GDP*	-3%	-13%	-20%	-27%
Rise in poverty rate	1.0%	4.6%	6.8%	9.1%
Rise in food insecurity	18.1%	24.8%	29.3%	33.8%
India				
Job losses (millions)	9.0	53.0	79.5	106.0
Change in GDP*	-4%	-14%	-21%	-28%
Rise in poverty rate	0.6%	3.5%	5.2%	6.9%
Rise in food insecurity	18.5%	25.3%	30.0%	34.7%
Nepal				
Job losses (millions)	0.4	1.7	2.5	3.4
Change in GDP*	-3%	-10%	-15%	-20%
Rise in poverty rate	1.9%	7.9%	11.8%	15.8%
Rise in food insecurity	17.6%	22.4%	25.7%	29.0%
Afghanistan				
Job losses (millions)	0.2	1.0	1.5	2.1
Change in GDP*	-2%	-12%	-17%	-23%
Rise in poverty rate	0.8%	3.6%	5.5%	7.3%
Rise in food insecurity	17.4%	23.6%	27.5%	31.4%
Sri Lanka				
Job losses (millions)	0.4	1.4	2.1	2.8
Change in GDP*	-5%	-15%	-23%	-30%
Rise in poverty rate	3.7%	15.3%	22.9%	30.5%
Rise in food insecurity	18.9%	26.1%	31.2%	36.3%

*Assuming restrictions are in place for 12 months

Chapter 4: **Implications and Way Forward for South Asia**

We systematically quantified the direct and indirect effects of COVID-19 pandemic and response, and the associated economic costs for South Asia. To our knowledge, this is the first study to do so at a regional level and across a large population (> 1.5 Billion). Our analysis provides a comprehensive view of the adverse impact of COVID-19 pandemic and response across a multitude of population health indicators, and the economic consequences of the disease, as well as the mitigation strategies instituted to control it. The results can be used to inform economic and public health policies in South Asia aimed at mitigating the direct and indirect effects of COVID-19 pandemic and response, over the medium and long term.

The current repertoire of interventions for COVID-19 pandemic response has been defined by lead global health agencies focused on "flattening the curve" and curbing the pandemic, without much regard for the resulting economic and public health fall-out. Almost a year into the pandemic, we now know that a one-size-fits-all mitigation response may not have been the right course of action, and in some cases such as India, perhaps applied too early, given the continuing spike in cases, and for too long in light of the impact on the economy (57). Apart from the enormous impact on lives and livelihoods of millions of people living in poverty or forced below the poverty line, the stringent measures also uprooted millions from urban slums to move to rural areas, often on foot and at huge human costs (58). It remains to be seen if this was also a factor in the widespread transmission of COVID-19 beyond major population centers in South Asia, especially India. There are also additional consequences for interrupting the education of children and girls dropping out of school that are life long and difficult to quantify in their entirety. There are also intriguing elements of country-specific responses which suggest that the pandemic could have been brought under control reasonably well and with a more limited impact on economies (59, 60). Recent serological survey data from South Asia underline the need for a regional and/or country-specific response. Given the high prevalence of COVID-19 antibodies observed in Afghanistan, India and Pakistan (ZAB's personal communication and unpublished data), a blanket "stay-at-home" order is not the best way forward for South Asia. Our models help identify evidence-informed mitigation and remedial strategies that will be suitable for low-income countries in general, and for South Asia in particular.

Re-establishing essential maternal and child health services

In addition to dealing with the direct effects of COVID-19, there is a critical need to address the much larger and longer-term fallout from the indirect effects of the pandemic. According to our estimates, additional ~230,000 child, and ~11,000 maternal deaths will occur in South Asia in 2020 alone, as a result of coverage disruption of essential SRMNCH services due to the COVID-19 pandemic and response. This number (> 240,000 maternal and child deaths) is far higher than the COVID-19 deaths observed and expected (< 200,000 by Dec 1, 2020) if no additional mitigation strategies are instituted in the region this year. Furthermore, even if coverage of essential services improves to pre-COVID-19 levels or better, some deficits such as fewer facility births or treatment for diarrhea and pneumonia are opportunities lost for good.

WHO has recommended strategies to minimize the disruption to essential SRMNCH services, including use of telemedicine to minimize patient-provider contact in the midst of the pandemic, strengthening infection prevention and control capacities, and ensuring essential supplies (61). Encouragingly, many countries have indicated the need for technical assistance and support in implementing these strategies to ensure that the impact of COVID-19 on essential SRMNCH services is minimized (61).

In addition, rates of undernutrition, including anemia, stunting and wasting are also likely to increase as disruptions in food supply systems and economic activity lead to increase in poverty and food insecurity. Prospective data from Bangladesh underscores this concern, where households experiencing food insecurity increased by more than 50% during stay-at-home orders implemented in March – May 2020 (62). Similarly, our economic impact model shows, that even the least severe stage of mitigation strategies, which include warnings/advisories, public gatherings ban, social distancing, and schools closures, could increase the share of the population who is food insecure by almost 20%.

As countries, including those in South Asia, continue to ease COVID-19 restrictions, coverage of maternal and child health and nutrition services need to be prioritized. These services include, but are not limited to: 1) prioritization of services to maximize health impact and protect services for the most vulnerable such as pregnant women and young infants or patients with pre-existing conditions 2) ensuring supply chain of essential medicines and commodities with change in protocols as needed to ensure adequate therapy such as provision of longer term supply 3) protection of supply-chain and delivery mechanisms for continued and increasing coverage of childhood immunizations, antenatal care and family planning services, with the aim to avoid stock-outs amid a potential surge in demand for emergency contraception and abortion services; 4) Safe re-opening of ambulatory care systems for antenatal, delivery and child health and nutrition with adequate provision of PPE and a secure, safe environment for patients; 5) improving coverage of community-based nutrition services and immunizations for all antigens included under each country's Expanded Programme on Immunizations, using outreach services such supplementary immunization activities; 6) expanding the capacity of existing fixed and outreach health services such as community health workers , with an increased focus on MNCH, nutrition, and detection and triage of serious illnesses for rapid referral to facilities; and 7) instituting and improving nutrition support services for the most vulnerable, such as community-based management of moderate and acute malnutrition (CMAM) programs, the need for which is likely to increase across the region in the wake of the COVID-19 pandemic.

Strategies for control, prevention and management of COVID-19

Given the current global trajectory of the pandemic, we might be living with COVID-19 for the foreseeable future (for the best part of 2021 and potentially into 2022). In the absence of an effective vaccine or clinical treatments, COVID-19 prevention and management methods will continue to rely on non-pharmaceutical interventions, such as targeted "smart" lockdowns and use of masks, as well as health systems strengthening to successfully resolve severe cases. Even after a vaccine or an effective treatment has been found, it will take time for it be produced and made available globally and at scale (63). Until then, non-pharmaceutical interventions are the world's best defense against COVID-19.


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Measures for personal protection

Many countries, including those in South Asia have invested heavily in procuring and securing supply-chains for personal protective equipment (PPE) for health workers and ventilators for treatment of severe cases of COVID-19. In Pakistan, for example, total number of beds allocated for COVID-19 patients has increased from less than 8,000 in March 2020 to 30,000 in July 2020, including more than 50,000 healthcare staff virtually trained in providing critical care (ZAB personal communication).

Many countries, including India and Pakistan have also issued directives mandating face masks in public spaces (64, 65). However, with limited enforcement, it is unclear what proportion of the population is consistently complying with these mandates. These are however, highly effective and we would strongly endorse the continued focus on the established principles for self and community protection against the spread of COVID-19 including

- Universal usage of appropriate face masks in public places and group settings
- Physical distancing and restrictions on indoor gatherings as well as large scale gatherings outdoors
- Hand sanitization and frequent washing
- Special precautions in public transport, train and air travel

Safe schools

As countries come out of the initial lockdowns imposed to curb the spread of COVID-19, safe reopening of schools is a top priority. School closures in Bangladesh and Nepal have been extended, while those in Sri Lanka were forced to close again after reopening in July and experiencing a spike in cases (66). In India, schools are open on a voluntary basis for older students, but five states and the capital Delhi are continuing with school closures (66). Pakistan has issued a set of Standard Operating Procedures (SOPs) for safe reopening of schools, including a limit of 25 students per class, alternating school days, ban on assemblies and other group events, temperature checks for all entrants into a school, and encouraging use of face masks (67). Reopening of school needs to be done while minimizing risk of COVID-19 exposure and transmission, and policies need to be coordinated between the federal and subsequent administrative levels within a country.

School re-openings also need to be targeted, based on localized rates of disease transmission and public health capabilities around testing and contract tracing. There must also be appropriate support for safe transportation of children to schools with adequate space in buses and vans and utilization of private resources for transportation by families (where and as possible).

Smart lockdowns

As countries emerge from the initial sweeping lockdowns and stay-at-home orders instituted early in the pandemic, smart lockdowns that target potential hot-spots of COVID-19 infection have gained increasing global popularity, and are an extension of the "test, trace and quarantine" policy. Across the globe, these smart lockdowns are being more and more frequently used by governments to stem the spread of the virus, while ensuring continuation and resumption of economic activities (60). The strategy has also been hailed as pivotal for stemming the spread of COVID-19 in Pakistan (59). The impact on India's economy resulting from the sweeping stay-at-home orders instituted on March 24, 2020 (57), also highlights the need for targeted, "smart" lockdowns. In the absence of the understandable lack of political appetite for another wave of blanket, nationwide stay-at-home orders, these smart lockdowns seem to be an effective tool in the world's public health arsenal against COVID-19.

Securing and re-establishing food supply chain

The COVID-19 pandemic has highlighted the vulnerability of existing food systems, with the effects of disruptions being disproportionately felt by the most vulnerable (68). Vulnerable food systems can lead to increase in food insecurity and consumption of poor quality diets, which in turn affects the health and nutrition of populations, especially women and children (69). This pandemic highlights the immediate need to create and facilitate sustainable food systems which ensure an affordable and nutritionally adequate diet to all peoples of the world.

Failure to build and foster resilient food systems which yield improved diet quality, will have immeasurable consequences for the health of most of the world's population. While the state bears a clear responsibility for restituting food security through food supply chain and food systems as well as price-regulation, there is also the need for ensuring adequate financial support and purchasing power for families through cash transfers. There are notable examples of this initiative in South Asia with cash transfer programs such as the Ehsaas program under the auspices of the Benazir Income Support program in Pakistan (70) .

Education

Education has been another indirect casualty of the COVID-19 pandemic, with over 90% of the world's students forced to stay home during temporary school-closures earlier this year. Even prior to the pandemic, disparities in educational attainment existed, both within and across countries. However, the pandemic is expected exacerbate existing inequities, especially along socioeconomic and gendered lines, with serious consequences for school-aged children and adolescent health, nutrition, educational attainment and economic productivity and earnings during adulthood.

Many countries have implemented remote learning polices in the wake of temporary school closures, but 31% of the world's students cannot be reached by remote learning programs, with more than 70% of children from rural and/or poor households unable to access these programs (71). There is also limited focus on early childhood education, with almost 70% of children who were attending preschool prior to the pandemic unable to access remote learning programs (71).

The COVID-19 pandemic is an opportunity to design and enact innovative education programs and policies that will reduce and overcome pre-existing inequities in education access, such as introduction of school shift systems and open air classrooms, and incentivizing continued and increased attendance for girls using conditional cash transfers to families. We need to ensure that all children of the world are able to access quality education, irrespective of their gender or socioeconomic status. Schools in Pakistan are reopening in a phased manner as we speak and early experience indicates that despite much apprehension, it has been possible to get the bulk of secondary school children back to school.

Strict imposition of standard operating procedures and compliance with protocols are needed with sentinel surveillance to ensure that there are no major outbreaks. Given the many primary schools are still closed at the time of writing this report, it is imperative that safe protocols be adopted to get these children back into an education and learning environment soonest before they lose a vital and sensitive year of learning.

Poverty alleviation and safety nets

Designing and implementing these policies will take time, which most of the vulnerable populations, including women, children, people with disabilities and daily wage earners, simply do not have in the wake of the pandemic. This is where poverty alleviation and social support programs can help bridge the gap. Since the start of the pandemic, many countries, including LMICs, have instituted social safety net programs, such as income or food support, to alleviate the hardships brought on by the sweeping lockdowns put in place for several weeks earlier this year.

A recent report from United Nations Development Programme (UNDP) highlights the efficacy of unconditional emergency cash transfers, or temporary basic income (TBI) in ameliorating the worst effects of COVID-19, especially on poor or near-poor households (72). The authors stipulate that at a cost of 0.27 – 0.63% of each country's GDP, TBI is within reach for all 132 countries included in their analysis (72).

One example of a TBI program implemented to mitigate the worst of the immediate effects of the COVID-19 pandemic is Ehsaas Emergency Cash program in Pakistan, which provided a lump sum of PKR 12000 (~US$75) to poor households, and is reported to have reached more than 14.6 million beneficiaries since its inception earlier this year (73, 74). The program is also focusing on gender equality in Pakistan by ensuring that at least 50% of all beneficiaries are women (75).

The World Bank reports that since March 2020, a total of $589 billion has been spent (reported from 114 countries) on social protection programs with per capita spending ranging from $121 in high-income countries to $1 in low-income settings (76). The impact of these on utilization and access to health and nutrition services is still unknown and needs to be estimated.

Data systems and rapid information

The COVID-19 pandemic has highlighted the importance of national health data systems. Not only are these systems necessary for monitoring progress towards public health targets, such as Sustainable Development Goals, they are also critical in detecting infectious disease outbreaks, such as the current COVID-19 pandemic, containing them and minimizing the economic fall-out (77). National health data systems are specially lacking in LMICs, including those in South Asia. Even with support from UNICEF country offices, we had difficulty in obtaining data on COVID-19 cases and deaths, and had to obtain these data from University of Oxford's Our World in Data (OWID) website (15), for our direct effects model.

Investing in health data systems that are updated in real time and publicly available for research collaborations, needs to be a priority at the regional and global level.

Limitations

Our models have several limitations, most if not all, resulting from constraints around data availability, especially at sub-national level. Although we were able to use country-level DHIS/HMIS data for many indicators included in our LiST analysis, for some we either had to use a related country-level indicator or average estimates from the other countries, as proxies (Supplementary Table 3). We also faced limitations with data availability for our models assessing the impact on educational attainment, economy and food insecurity. Even though there is considerable historical evidence on how crises can impact children's schooling and incomes of households, it is limited with reference to the unique effects of the COVID-19 pandemic in both scale and rapidity of spread.

We were constrained to apply the assumptions on rates of school dropouts from Indonesia during the 1997 Asian financial crisis, and households experiencing food insecurity in Nepal in April 2020, across all six countries.

These could well be under-estimates and as one very recent report from Bangladesh indicates that the proportion of households earning less than US$ 1.90 per day increased from <1% to almost 50%, and those experiencing food insecurity increased by more than 50% (62). For our economic impact model, we used labor force attrition by industry estimated for Pakistan across the other five South Asian countries, as country-specific data were not available. Our economic impact model also does not include gender related impacts, since data on capacity and MPW by industry were not disaggregated by gender. This is a limitation since the type of industry, hierarchical position, level of payment, and share within informal sector are all affected by gender.

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Conclusions

Both modelled and prospective data reveal serious consequences of the COVID-19 pandemic with implications for maternal and child health and nutrition (11, 62). Therefore, it is imperative that we now turn our focus towards mitigating the indirect effects of the COVID-19 pandemic and response.

These should include strengthening food systems to ensure a resilient supply of nutritious and affordable foods, creating economic opportunities and income generating activities using a gendered lens, ameliorating inequities in educational attainment, and a renewed focus on improving coverage of basic health and nutrition interventions during pregnancy, infancy and childhood, and adolescence, especially for girls.

Our modelling study also has implications for specific public policy measures that should be undertaken by the region's governments. These include, but are not limited to:

- Increase the coverage of COVID-19 mitigation measures, such as use of masks and hand hygiene, which can lead to ~400,000 fewer deaths over the next year
- Ensure uninterrupted and improved coverage of essential maternal and child health and nutrition services, such as family planning services, antenatal care, skilled birth attendance and postnatal care, and community-based health and nutrition support services
- Ensure safe reopening of schools, with increased focus on continued and increased enrollment of vulnerable children, especially girls.
- Continue social safety net programs to support vulnerable population, with increased focus on women-led households, people with disabilities, and daily wage earners

All countries, including those in South Asia need to continue, and even increase investment in health systems, poverty alleviation, education and creation of human capital, and gender equity, if the world wants to maintain and improve on the gains in maternal, child and adolescent health and nutrition achieved over the past few decades.

We need to do more than just catch up the loss in health and human capital experienced over the past several months. We need to build back better, overcoming gaps in equity and disadvantages faced by populations, simply because of the geographic region they live in. This pandemic may have been unprecedented, but those in the future will not be, and the world needs to be prepared.

Glossary

DHIS	District Health Information System
DHS	Demographic and Health Survey
DPT	Diphtheria, pertussis and tetanus
GDP	Gross Domestic Product
GBD	Global Burden of Disease
HMIS	Health Management Information System
ICU	Intensive care unit
IHME	Institute for Health Metrics and Evaluation
ILO	International Labour Organization
LBW	Low birthweight
LiST	Lives Saved Tool
LMIC	Low and middle income countries
MICS	Multiple Indicator Cluster Survey
MPW	Marginal rate of productivity per worker
Penta	Pentavalent
SAM	Severe acute malnutrition
SGA	Small for gestational age
SRMNCH	Sexual, reproductive, maternal, newborn, and child health
TBI	Temporary basic income
UNDP	United Nations Development Programme
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organization

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Supplementary tables

Table 1:
Compartments and functional definitions of the model

Compartment	Functional definition
S	Susceptible individuals
E	Exposed and infected, not yet symptomatic but potentially infectious
I	Infected, symptomatic, and infectious
Q	Infectious, but (self-)isolated
H	Requiring hospitalization (would normally be hospitalised if capacity available)
R	Recovered, immune from further infection
F	Case fatality (death due to COVID-19, not other causes)

Table 2:
Model parameters for base case scenarios

Variable name	Description	No intervention	Hand hygiene	Face masks	Smart lockdowns	Comments
s.num	Initial number of susceptible (not yet infected) individuals in the simulated population.	Population size divided by the cumulative number of known active cases at the beginning of the calibration period				These values were chosen to scale the simulation size to q.num = 1.
e.num	Initial number of exposed (infected, asymptomatic, and potentially infectious) individuals in the simulated population.	1 at start of calibration. Simulation starts with the value obtained at the end of the calibration period.				Assumptions made for the model; discussed in the manuscript
i.num	Initial number of infected (symptomatic and infectious) individuals in the simulated population.	1 at start of calibration. Simulation starts with the value obtained at the end of the calibration period.				Assumptions made for the model; discussed in the manuscript
q.num	Initial number of infectious but quarantined.	1 at start of calibration. Simulation starts with the value obtained at the end of the calibration period.				The simulation size was scaled according to this choice.
h.num	Initial number of individuals requiring hospitalization.	0 at start of calibration. Simulation starts with the value obtained at the end of the calibration period.				Assumed zero at the beginning of calibration.
r.num	Initial number of recovered (and immune) individuals.	0 at start of calibration. Simulation starts with the value obtained at the end of the calibration period.				Assumed zero at the beginning of calibration.

Table 2:
Model parameters for base case scenarios

Variable name	Description	No intervention	Hand hygiene	Face masks	Smart lockdowns	Comments
f.num	Initial number of fatalities.	0 at start of calibration. Simulation starts with the value obtained at the end of the calibration period.				Assumed zero at the beginning of calibration. Recorded fatalities before start of simulation run are added to the eventual total after rescaling.
act.rate.i	The daily number of exposure events (encounters) between susceptible and infectious (symptomatic).	Calibrated to match fatalities data – discussed in manuscript.	No change from the calibrated value.	No change from the calibrated value.	4% reduction off the calibrated value.	
inf.prob.i	Probability of passing on infection at each exposure event between infectious (symptomatic) people and susceptible.	Calibrated to match fatalities data – discussed in manuscript.	10% reduction off the calibrated value.	7% reduction off the calibrated value.	No change from the calibrated value.	
act.rate.e	The number of exposure events (encounters) between susceptible and exposed (asymptomatic) per day.	Same as act.rate.i.				
inf.prob.e	Probability of passing on infection at each exposure event between exposed (asymptomatic) people and susceptible.	2/3 of inf.prob.i.				
act.rate.q	The daily number of exposure events (encounters) between susceptible and quarantined (symptomatic)	25% of act.rate.e.				
inf.prob.q	Probability of passing on infection at each exposure event between quarantined (symptomatic) people and susceptible.	Same as inf.prob.i.				
quar.rate	Rate per day at which symptomatic (or tested positive), infected people enter self-isolation	0.033333				Value chosen to reflect a 50% probability of self-isolation within 21 days since onset of symptoms.
hosp.rate	Rate per day at which symptomatic (or tested positive), infected people require hospital care	Calibrated to match fatalities data – discussed in manuscript.				
disch.rate	Rate per day at which people requiring hospital care recover	0.066667				Daily recovery rate of 2%
prog.rate	Rate per day at which infected and asymptomatic people become symptomatic.	0.048305				50% of exposed individuals develop symptoms within 2 weeks
rec.rate	Rate per day at which infected and symptomatic people recover.	0.05				Expected recovery duration of 20 days from onset of symptoms (Default value used by Tim Churches)
fat.rate.base	Baseline daily mortality rate for people needing hospitalisation.	Calibrated to match fatalities data – discussed in manuscript.				

Variable name	Description	No intervention	Hand hygiene	Face masks	Smart lockdowns	Comments
hosp.cap	Number of available hospital beds for the modelled population	Extracted from the table downloaded from *https://github.com/owid/covid-19-data/tree/master/public/data. Scaled by the same factor as s.num.*				
fat.rate.overcap	Daily mortality rate for people needing hospitalisation but cannot get into hospital due to the hospitals being full	fat.rate.base times 2.				
fat.tcoeff	Time coefficient for increasing mortality rate for people requiring hospitalization who cannot get a hospital bad	0.5	0.5	0.5	0.5	This assumes that the fatality rate doubles once the number of hospitalizations required exceeds the hospitalization capacity

Table 3:
Summary of indicators used as proxy in LiST analysis, by country

Country	LiST indicator	Proxy indicator from DHIS/HMIS
Afghanistan	Family planning services	Couple year of protection from Afghanistan HMIS data
Afghanistan	Tetanus Toxoid (2 or more doses)	Antenatal care seeking from Afghanistan HMIS data
Afghanistan	Postnatal visit within 2 days after birth	Facility births from Afghanistan HMIS data
Bangladesh	Family planning services	Family planning services from Pakistan DHIS data
Bangladesh	Tetanus Toxoid (2 or more doses)	Antenatal care seeking from Bangladesh HMIS data
Bangladesh	Measles vaccine	DPT3/PENTA3 from Bangladesh HMIS data
Nepal	FP clients, injectable, condom, male and female sterilization	Average of available family planning services from Nepal HMIS data
Nepal	Tetanus Toxoid (2 or more doses)	Antenatal care seeking from Nepal HMIS data
Nepal	Measles vaccine	DPT3/PENTA3 from Nepal HMIS data
Sri Lanka	Tetanus Toxoid (2 or more doses)	Antenatal care seeking from Sri Lanka data
Sri Lanka	Vaccination (DPT3/PENTA3/measles)	Averages of rest of the countries
	Care seeking for diarrhea/pneumonia	
	Malnutrition	
India	FP clients	Average of short term family planning services from India HMIS data

Table 4:
Estimated impact on maternal anemia, childhood stunting and wasting, and small for gestational age (SGA) and low birthweight (LBW), using LiST, by country and quarter of 2020 and 2021

Country	Indicators	2019	2020				2021	
			Q1	Q2	Q3	Q4	Q1	Q2
Afghanistan	Pregnant women with anemia	38.2	38.1	39.0	38.6	38.4	38.4	38.4
	Pregnant women with iron-deficiency anemia	18.6	18.4	19.4	19.0	18.7	18.7	18.7
	Women of reproductive age with anemia	41.9	41.9	42.0	41.9	41.9	41.9	41.9
	Women of reproductive age with iron-deficiency anemia	19.1	19.0	19.2	19.1	19.1	19.1	19.1
	Moderate wasting	7.8	8.0	7.9	7.9	7.9	8.0	8.0
	Severe wasting	3.1	2.9	2.9	2.9	2.9	2.9	2.9
	Moderate stunting	22.0	22.0	22.0	22.0	22.0	21.9	21.9
	Severe stunting	16.0	16.0	16.0	16.0	16.0	16.0	16.0
	Pre-term: Small for gestational age (SGA)	2.6	2.6	2.6	2.6	2.6	2.6	2.6
	Pre-term: Appropriate for gestational age (AGA)	9.0	9.0	9.0	9.0	9.0	9.0	9.0
	Term: Small for gestational age (SGA)	37.4	37.4	37.4	37.4	37.4	37.4	37.4
	Term: Appropriate for gestational age (AGA)	51.1	51.1	51.1	51.1	51.1	51.1	51.1
	Percent low birth weight (LBW)	23.7	23.6	23.6	23.6	23.6	23.6	23.6
Bangladesh	Pregnant women with anemia	45.7	45.2	50.8	48.3	46.7	46.7	44.9
	Pregnant women with iron-deficiency anemia	22.4	21.9	27.5	24.9	23.4	23.4	21.6
	Women of reproductive age with anemia	40.0	40.0	40.3	40.1	40.0	40.0	39.9
	Women of reproductive age with iron-deficiency anemia	20.5	20.5	20.8	20.7	20.6	20.6	20.5
	Moderate wasting	11.3	11.3	11.3	11.3	11.3	11.3	11.3
	Severe wasting	3.1	3.1	3.1	3.1	3.1	3.1	3.1
	Moderate stunting	24.3	24.3	24.2	24.3	24.3	24.3	24.3

Country	Indicators	2019	2020				2021	
			Q1	Q2	Q3	Q4	Q1	Q2
Bangladesh	Severe stunting	11.5	11.5	11.5	11.5	11.5	11.5	11.5
	Pre-term: Small for gestational age (SGA)	3.1	3.1	3.1	3.1	3.1	3.1	3.1
	Pre-term: Appropriate for gestational age (AGA)	10.9	10.9	10.9	10.9	10.9	10.9	10.9
	Term: Small for gestational age (SGA)	36.5	36.5	36.5	36.5	36.5	36.5	36.5
	Term: Appropriate for gestational age (AGA)	49.5	49.5	49.5	49.5	49.5	49.5	49.5
	Percent low birth weight (LBW)	24.4	24.4	24.4	24.4	24.4	24.4	24.4
India	Pregnant women with anemia	50.1	50.1	51.2	51.2	50.3	50.3	50.3
	Pregnant women with iron-deficiency anemia	22.7	22.8	23.9	23.9	23.0	22.9	22.9
	Women of reproductive age with anemia	51.4	51.4	51.5	51.5	51.4	51.4	51.4
	Women of reproductive age with iron-deficiency anemia	21.9	21.9	21.9	21.9	21.9	21.9	21.9
	Moderate wasting	13.7	13.7	13.8	13.7	13.7	13.7	13.7
	Severe wasting	7.7	7.7	7.8	7.7	7.7	7.7	7.7
	Moderate stunting	21.8	21.8	21.6	21.8	21.8	21.8	21.8
	Severe stunting	16.1	16.1	16.0	16.1	16.1	16.1	16.1
	Pre-term: Small for gestational age (SGA)	2.9	2.9	2.9	2.9	2.9	2.9	2.9
	Pre-term: Appropriate for gestational age (AGA)	10.1	10.1	10.1	10.1	10.1	10.1	10.1
	Term: Small for gestational age (SGA)	44.0	44.0	44.0	44.0	44.0	44.0	44.0
	Term: Appropriate for gestational age (AGA)	43.0	43.0	43.0	43.0	43.0	43.0	43.0
	Percent low birth weight (LBW)	27.5	27.5	27.5	27.5	27.5	27.5	27.5
Nepal	Pregnant women with anemia	40.0	44.3	48.3	44.1	41.7	38.6	41.7
	Pregnant women with iron-deficiency anemia	20.3	24.6	28.6	24.4	22.0	18.9	22.0
	Women of reproductive age with anemia	35.2	35.5	35.8	35.5	35.3	35.1	35.3
	Women of reproductive age with iron-deficiency anemia	18.0	18.3	18.6	18.3	18.2	18.0	18.2

Country	Indicators	2019	2020				2021	
			Q1	Q2	Q3	Q4	Q1	Q2
Nepal	Moderate wasting	7.9	7.9	7.9	7.9	7.9	7.9	7.9
	Severe wasting	1.9	1.9	1.9	1.9	1.9	1.9	1.9
	Moderate stunting	23.6	23.8	23.6	23.6	23.7	23.6	23.6
	Severe stunting	11.5	11.6	11.5	11.5	11.6	11.6	11.6
	Pre-term: Small for gestational age (SGA)	3.1	3.1	3.1	3.1	3.1	3.1	3.1
	Pre-term: Appropriate for gestational age (AGA)	10.9	10.9	10.9	10.9	10.9	10.9	10.9
	Term: Small for gestational age (SGA)	36.2	36.2	36.2	36.2	36.2	36.2	36.2
	Term: Appropriate for gestational age (AGA)	49.8	49.8	49.8	49.8	49.8	49.8	49.8
	Percent low birth weight (LBW)	24.3	24.3	24.3	24.3	24.3	24.3	24.3
Pakistan	Pregnant women with anemia	51.3	51.9	53.8	52.5	51.8	51.8	51.8
	Pregnant women with iron-deficiency anemia	22.4	23.0	24.9	23.6	22.9	22.9	22.9
	Women of reproductive age with anemia	52.1	52.2	52.4	52.2	52.2	52.2	52.2
	Women of reproductive age with iron-deficiency anemia	20.2	20.3	20.5	20.3	20.3	20.3	20.3
	Moderate wasting	7.8	7.9	7.9	7.9	7.9	7.9	7.9
	Severe wasting	3.4	3.3	3.4	3.3	3.3	3.3	3.3
	Moderate stunting	20.9	20.9	20.9	20.9	20.9	20.9	20.9
	Severe stunting	23.4	23.4	23.3	23.4	23.4	23.4	23.4
	Pre-term: Small for gestational age (SGA)	3.5	3.5	3.5	3.5	3.5	3.5	3.5
	Pre-term: Appropriate for gestational age (AGA)	12.3	12.3	12.3	12.3	12.3	12.3	12.3
	Term: Small for gestational age (SGA)	43.5	43.5	43.5	43.5	43.5	43.5	43.5
	Term: Appropriate for gestational age (AGA)	40.7	40.8	40.7	40.8	40.8	40.8	40.8
	Percent low birth weight (LBW)	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Sri Lanka	Pregnant women with anemia	35.4	37.5	36.1	35.8	35.6	35.6	35.6

Country	Indicators	2019	2020				2021	
			Q1	Q2	Q3	Q4	Q1	Q2
Sri Lanka	Pregnant women with iron-deficiency anemia	22.3	24.3	23.0	22.7	22.4	22.4	22.4
	Women of reproductive age with anemia	32.7	32.8	32.7	32.7	32.7	32.7	32.7
	Women of reproductive age with iron-deficiency anemia	17.7	17.8	17.7	17.7	17.7	17.7	17.7
	Moderate wasting	7.7	7.8	7.8	7.8	7.8	7.8	7.8
	Severe wasting	3.0	3.0	3.0	3.0	3.0	3.0	3.0
	Moderate stunting	22.2	22.2	22.2	22.2	22.2	22.2	22.2
	Severe stunting	16.2	16.2	16.2	16.2	16.2	16.2	16.2
	Pre-term: Small for gestational age (SGA)	2.4	2.4	2.4	2.4	2.4	2.4	2.4
	Pre-term: Appropriate for gestational age (AGA)	8.3	8.3	8.3	8.3	8.3	8.3	8.3
	Term: Small for gestational age (SGA)	21.9	21.9	21.9	21.9	21.9	21.9	21.9
	Term: Appropriate for gestational age (AGA)	67.4	67.4	67.4	67.4	67.4	67.4	67.4
	Percent low birth weight (LBW)	16.0	16.0	16.0	16.0	16.0	16.0	16.0

Coverage disruption

Afghanistan						
Interventions	Change in 2020				Change in 2021	
	Q1	Q2	Q3	Q4	Q1	Q2
FP clients	12%	-24%	-12%	-5%	-4%	-4%
Injectables	12%	-24%	-12%	-5%	-4%	-4%
Condom	12%	-24%	-12%	-5%	-4%	-4%
IUD	12%	-24%	-12%	-5%	-4%	-4%
Female sterilisation	12%	-24%	-12%	-5%	-4%	-4%
Male sterilisation	12%	-24%	-12%	-5%	-4%	-4%
Implant	12%	-24%	-12%	-5%	-4%	-4%
Safe abortion servicess	--	--	--	--	--	--
Post abortion case management	--	--	--	--	--	--
Ectopic pregnancy case management	--	--	--	--	--	--
Antenatal care (4+ visits)	2%	-11%	-6%	-2%	-2%	-2%
Tetanus Toxoid (2 or more doses)	2%	-11%	-6%	-2%	-2%	-2%
Syphilis detection and treatment	--	--	--	--	--	--
Calcium supplementation	--	--	--	--	--	--
Iron supplementation in pregnancy	--	--	--	--	--	--
Hypertensive disorder case management	--	--	--	--	--	--
Diabetes case management	--	--	--	--	--	--
Malaria case management	--	--	--	--	--	--
MgSO4 management of pre-eclampsia	--	--	--	--	--	--
Fetal growth restriction detection and management	--	--	--	--	--	--
Total home deliveries by clinic staff	-45%	-32%	-16%	-6%	-6%	-5%
Facility births	3%	-1%	-1%	0%	0%	0%
Postnatal visit within 2 days after birth	3%	-1%	-1%	0%	0%	0%
Vitamin A supplementation	--	--	--	--	--	--
Zinc Supplementation	--	--	--	--	--	--
Vaccine:BCG	--	--	--	--	--	--
Vaccine:OPV3	--	--	--	--	--	--
Vaccine:DPT3/Penta3	-2%	-7%	-4%	-1%	-1%	-1%
Vaccine:HepB3	--	--	--	--	--	--
Vaccine: PCV3	--	--	--	--	--	--
Vaccine:RV2	--	--	--	--	--	--
Vaccine: Measles	-6%	-7%	-4%	-1%	-1%	-1%
Fully immunization	--	--	--	--	--	--
Maternal sepsis case management	--	--	--	--	--	--
ORS - oral rehydration solution	--	--	--	--	--	--
Antibiotics for treatment of dysentery	--	--	--	--	--	--
Zinc for treatment of diarrhea – Zinc Supplementation	0%	-21%	-11%	-4%	-4%	-3%
Antibiotics for pneumonia	12%	-9%	-5%	-2%	-2%	-1%
Vitamin A for treatment of measles	--	--	--	--	--	--
ACTs - Artemisinin compounds for treatment of malaria	--	--	--	--	--	--
SAM - treatment for severe acute malnutrition	5%	-37%	-19%	-7%	-7%	-6%

*Based on actual health systems data *Approximated using related indicators for same country

Bangladesh						
Interventions	Change in 2020				Change in 2021	
	Q1	Q2	Q3	Q4	Q1	Q2
FP clients	-31%	-78%	-39%	-16%	-14%	-12%
Injectables	-24%	-68%	-34%	-14%	-12%	-11%
Condom	-15%	-87%	-44%	-17%	-16%	-14%
IUD	-13%	-81%	-41%	-16%	-15%	-13%
Female sterilisation	-27%	-88%	-44%	-18%	-16%	-14%
Male sterilisation	-29%	-96%	-48%	-19%	-17%	-15%
Implant	-65%	-79%	-40%	-16%	-14%	-13%
Safe abortion servicess	--	--	--	--	--	--
Post abortion case management	--	--	--	--	--	--
Ectopic pregnancy case management	--	--	--	--	--	--
Antenatal care (4+ visits)	5%	-50%	-25%	-10%	-9%	-8%
Tetanus Toxoid (2 or more doses)	5%	-50%	-25%	-10%	-9%	-8%
Syphilis detection and treatment	--	--	--	--	--	--
Calcium supplementation	--	--	--	--	--	--
Iron supplementation in pregnancy	--	--	--	--	--	--
Hypertensive disorder case management	--	--	--	--	--	--
Diabetes case management	--	--	--	--	--	--
Malaria case management	--	--	--	--	--	--
MgSO4 management of pre-eclampsia	--	--	--	--	--	--
Fetal growth restriction detection and management	--	--	--	--	--	--
Total home deliveries by clinic staff	--	--	--	--	--	--
Facility births	-11%	-52%	-26%	-10%	-9%	-8%
Postnatal visit within 2 days after birth	-21%	-51%	-25%	-10%	-9%	-8%
Vitamin A supplementation	--	--	--	--	--	--
Zinc Supplementation	--	--	--	--	--	--
Vaccine:BCG	--	--	--	--	--	--
Vaccine:OPV3	--	--	--	--	--	--
Vaccine:DPT3/Penta3	-6%	-37%	-18%	-7%	-7%	-6%
Vaccine:HepB3	--	--	--	--	--	--
Vaccine: PCV3	--	--	--	--	--	--
Vaccine:RV2	--	--	--	--	--	--
Vaccine: Measles	-6%	-37%	-18%	-7%	-7%	-6%
Fully immunization	--	--	--	--	--	--
Maternal sepsis case management	--	--	--	--	--	--
ORS - oral rehydration solution	--	--	--	--	--	--
Antibiotics for treatment of dysentery	--	--	--	--	--	--
Zinc for treatment of diarrhea – Zinc Supplementation	-5%	-66%	-33%	-13%	-12%	-11%
Antibiotics for pneumonia	-14%	-74%	-37%	-15%	-13%	-12%
Vitamin A for treatment of measles	--	--	--	--	--	--
ACTs - Artemisinin compounds for treatment of malaria	--	--	--	--	--	--
SAM - treatment for severe acute malnutrition	-22%	-82%	-41%	-16%	-15%	-13%

*Based on actual health systems data *Approximated using related indicators for same country

India						
Interventions	Change in 2020				Change in 2021	
	Q1	Q2	Q3	Q4	Q1	Q2
FP clients	-1%	-25%	-13%	-5%	-5%	-4%
Injectables	-10%	-64%	-32%	-13%	-12%	-10%
Condom	-2%	-25%	-13%	-5%	-5%	-4%
IUD	1%	-49%	-25%	-10%	-9%	-8%
Female sterilisation	-1%	-86%	-43%	-17%	-16%	-14%
Male sterilisation	-5%	-86%	-43%	-17%	-16%	-14%
Implant	--	--	--	--	--	--
Safe abortion servicess	-6%	-43%	-22%	-9%	-8%	-7%
Post abortion case management	120%	-6%	-3%	-1%	-1%	-1%
Ectopic pregnancy case management	8%	-28%	-14%	-6%	-5%	-4%
Antenatal care (4+ visits)	5%	-27%	-13%	-5%	-5%	-4%
Tetanus Toxoid (2 or more doses)	-2%	-25%	-13%	-5%	-5%	-4%
Syphilis detection and treatment	3%	17%	8%	3%	3%	3%
Calcium supplementation	18%	-9%	-5%	-2%	-2%	-2%
Iron supplementation in pregnancy	0%	-20%	-10%	-4%	-4%	-3%
Hypertensive disorder case management	22%	-29%	-15%	-6%	-5%	-5%
Diabetes case management	10%	-29%	-15%	-6%	-5%	-5%
Malaria case management	5%	-27%	-13%	-5%	-5%	-4%
MgSO4 management of pre-eclampsia	8%	-28%	-14%	-6%	-5%	-4%
Fetal growth restriction detection and management	6%	-27%	-13%	-5%	-5%	-4%
Total home deliveries by clinic staff	-19%	-28%	-14%	-6%	-5%	-5%
Facility births	-2%	-28%	-14%	-6%	-5%	-5%
Postnatal visit within 2 days after birth	-18%	-25%	-12%	-5%	-4%	-4%
Vitamin A supplementation	-1%	-78%	-39%	-16%	-14%	-13%
Zinc Supplementation	-19%	-87%	-44%	-17%	-16%	-14%
Vaccine:BCG	-4%	-28%	-14%	-6%	-5%	-4%
Vaccine:OPV3	2%	-37%	-18%	-7%	-7%	-6%
Vaccine:DPT3/Penta3	3%	-37%	-19%	-7%	-7%	-6%
Vaccine:HepB3	-11%	39%	19%	8%	7%	6%
Vaccine: PCV3	-4%	-28%	-14%	-6%	-5%	-4%
Vaccine:RV2	95%	29%	14%	6%	5%	5%
Vaccine: Measles	-68%	-55%	-27%	-11%	-10%	-9%
Fully immunization	--	--	--	--	--	--
Maternal sepsis case management	8%	-28%	-14%	-6%	-5%	-4%
ORS- oral rehydration solution	-22%	-79%	-39%	-16%	-14%	-13%
Antibiotics for treatment of dysentery	-9%	-75%	-37%	-15%	-13%	-12%
Zinc for treatment of diarrhea – Zinc Supplementation	-19%	-87%	-44%	-17%	-16%	-14%
Antibiotics for pneumonia	27%	-30%	-15%	-6%	-5%	-5%
Vitamin A for treatment of measles	64%	-40%	-20%	-8%	-7%	-6%
ACTs- Artemisinin compounds for treatment of malaria	1%	-88%	-44%	-18%	-16%	-14%
SAM- treatment for severe acute malnutrition	5%	-48%	-24%	-10%	-9%	-8%

*Based on actual health systems data *Approximated using related indicators for same country

Nepal						
Interventions	Change in 2020				Change in 2021	
	Q1	Q2	Q3	Q4	Q1	Q2
FP clients	-24%	-52%	-26%	-10%	-9%	-8%
Injectables	-24%	-52%	-26%	-10%	-9%	-8%
Condom	-24%	-52%	-26%	-10%	-9%	-8%
IUD	-35%	-61%	-30%	-12%	-11%	-10%
Female sterilisation	-24%	-52%	-26%	-10%	-9%	-8%
Male sterilisation	-24%	-52%	-26%	-10%	-9%	-8%
Implant	-13%	-43%	-22%	-9%	-8%	-7%
Safe abortion servicess	--	--	--	--	--	--
Post abortion case management	--	--	--	--	--	--
Ectopic pregnancy case management	--	--	--	--	--	--
Antenatal care (4+ visits)	-9%	-29%	-15%	-6%	-5%	-5%
Tetanus Toxoid (2 or more doses)	-9%	-29%	-15%	-6%	-5%	-5%
Syphilis detection and treatment	--	--	--	--	--	--
Calcium supplementation	--	--	--	--	--	--
Iron supplementation in pregnancy	-14%	-26%	-13%	-5%	-5%	-4%
Hypertensive disorder case management	--	--	--	--	--	--
Diabetes case management	--	--	--	--	--	--
Malaria case management	--	--	--	--	--	--
MgSO4 management of pre-eclampsia	--	--	--	--	--	--
Fetal growth restriction detection and management	--	--	--	--	--	--
Total home deliveries by clinic staff	--	--	--	--	--	--
Facility births	-7%	-27%	-13%	-5%	-5%	-4%
Postnatal visit within 2 days after birth	-7%	-15%	-8%	-3%	-3%	-2%
Vitamin A supplementation	-91%	-3%	-1%	-1%	0%	0%
Zinc Supplementation	--	--	--	--	--	--
Vaccine:BCG	--	--	--	--	--	--
Vaccine:OPV3	--	--	--	--	--	--
Vaccine:DPT3/Penta3	-23%	3%	3%	3%	3%	2%
Vaccine:HepB3	--	--	--	--	--	--
Vaccine: PCV3	--	--	--	--	--	--
Vaccine:RV2	--	--	--	--	--	--
Vaccine: Measles	-23%	3%	3%	3%	3%	2%
Fully immunization	--	--	--	--	--	--
Maternal sepsis case management	--	--	--	--	--	--
ORS - oral rehydration solution	--	--	--	--	--	--
Antibiotics for treatment of dysentery	--	--	--	--	--	--
Zinc for treatment of diarrhea – Zinc Supplementation	-12%	-35%	-18%	-7%	-6%	-6%
Antibiotics for pneumonia	-12%	-49%	-24%	-10%	-9%	-8%
Vitamin A for treatment of measles	--	--	--	--	--	--
ACTs - Artemisinin compounds for treatment of malaria	--	--	--	--	--	--
SAM - treatment for severe acute malnutrition	-53%	-83%	-42%	-17%	-15%	-13%

*Based on actual health systems data *Approximated using related indicators for same country

Pakistan						
Interventions	Change in 2020				Change in 2021	
	Q1	Q2	Q3	Q4	Q1	Q2
FP clients	-31%	-78%	-39%	-16%	-14%	-12%
Injectables	-24%	-68%	-34%	-14%	-12%	-11%
Condom	-15%	-87%	-44%	-17%	-16%	-14%
IUD	-13%	-81%	-41%	-16%	-15%	-13%
Female sterilisation	-27%	-88%	-44%	-18%	-16%	-14%
Male sterilisation	-29%	-96%	-48%	-19%	-17%	-15%
Implant	-65%	-79%	-40%	-16%	-14%	-13%
Safe abortion servicess	--	--	--	--	--	--
Post abortion case management	-3%	-55%	-27%	-11%	-10%	-9%
Ectopic pregnancy case management	--	--	--	--	--	--
Antenatal care (4+ visits)	-16%	-66%	-33%	-13%	-12%	-11%
Tetanus Toxoid (2 or more doses)	-12%	-52%	-26%	-10%	-9%	-8%
Syphilis detection and treatment	--	--	--	--	--	--
Calcium supplementation	--	--	--	--	--	--
Iron supplementation in pregnancy	--	--	--	--	--	--
Hypertensive disorder case management	--	--	--	--	--	--
Diabetes case management	--	--	--	--	--	--
Malaria case management	--	--	--	--	--	--
MgSO4 management of pre-eclampsia	--	--	--	--	--	--
Fetal growth restriction detection and management	--	--	--	--	--	--
Total home deliveries by clinic staff	--	--	--	--	--	--
Facility births	-3%	-53%	-26%	-11%	-10%	-8%
Postnatal visit within 2 days after birth	8%	-52%	-26%	-10%	-9%	-8%
Vitamin A supplementation	--	--	--	--	--	--
Zinc Supplementation	--	--	--	--	--	--
Vaccine:BCG	--	--	--	--	--	--
Vaccine:OPV3	--	--	--	--	--	--
Vaccine:DPT3/Penta3	-24%	-67%	-33%	-13%	-12%	-11%
Vaccine:HepB3	--	--	--	--	--	--
Vaccine: PCV3	--	--	--	--	--	--
Vaccine:RV2	--	--	--	--	--	--
Vaccine: Measles	-15%	-53%	-26%	-11%	-9%	-8%
Fully immunization	0%	-51%	-26%	-10%	-9%	-8%
Maternal sepsis case management	--	--	--	--	--	--
ORS - oral rehydration solution	--	--	--	--	--	--
Antibiotics for treatment of dysentery	--	--	--	--	--	--
Zinc for treatment of diarrhea – Zinc Supplementation	-12%	-69%	-34%	-14%	-12%	-11%
Antibiotics for pneumonia	-16%	-74%	-37%	-15%	-13%	-12%
Vitamin A for treatment of measles	--	--	--	--	--	--
ACTs - Artemisinin compounds for treatment of malaria	--	--	--	--	--	--
SAM - treatment for severe acute malnutrition	36%	-67%	-34%	-13%	-12%	-11%

*Based on actual health systems data *Approximated using related indicators for same country

Sri Lanka						
Interventions	Change in 2020				Change in 2021	
	Q1	Q2	Q3	Q4	Q1	Q2
FP clients	-17%	-7%	-3%	-1%	-1%	-1%
Injectables	-22%	-12%	-6%	-2%	-2%	-2%
Condom	-11%	3%	2%	1%	1%	1%
IUD	-30%	-34%	-17%	-7%	-6%	-5%
Female sterilisation	-1%	-8%	-4%	-2%	-1%	-1%
Male sterilisation	-21%	-55%	-27%	-11%	-10%	-9%
Implant	-19%	-9%	-4%	-2%	-2%	-1%
Safe abortion servicess	--	--	--	--	--	--
Post abortion case management	--	--	--	--	--	--
Ectopic pregnancy case management	--	--	--	--	--	--
Antenatal care (4+ visits)	-6%	-2%	-1%	0%	0%	0%
Tetanus Toxoid (2 or more doses)	-6%	-2%	-1%	0%	0%	0%
Syphilis detection and treatment	--	--	--	--	--	--
Calcium supplementation	--	--	--	--	--	--
Iron supplementation in pregnancy	--	--	--	--	--	--
Hypertensive disorder case management	--	--	--	--	--	--
Diabetes case management	--	--	--	--	--	--
Malaria case management	--	--	--	--	--	--
MgSO4 management of pre-eclampsia	--	--	--	--	--	--
Fetal growth restriction detection and management	--	--	--	--	--	--
Total home deliveries by clinic staff	--	--	--	--	--	--
Facility births	-6%	-2%	-1%	0%	0%	0%
Postnatal visit within 2 days after birth	-6%	-2%	-1%	0%	0%	0%
Vitamin A supplementation	-19%	3%	1%	1%	1%	0%
Zinc Supplementation	--	--	--	--	--	--
Vaccine:BCG	--	--	--	--	--	--
Vaccine:OPV3	--	--	--	--	--	--
Vaccine:DPT3/Penta3	-14%	-27%	-13%	-5%	-5%	-4%
Vaccine:HepB3	--	--	--	--	--	--
Vaccine: PCV3	--	--	--	--	--	--
Vaccine:RV2	--	--	--	--	--	--
Vaccine: Measles	-12%	-23%	-12%	-5%	-4%	-4%
Fully immunization	--	--	--	--	--	--
Maternal sepsis case management	--	--	--	--	--	--
ORS - oral rehydration solution	--	--	--	--	--	--
Antibiotics for treatment of dysentery	--	--	--	--	--	--
Zinc for treatment of diarrhea – Zinc Supplementation	-7%	-48%	-24%	-10%	-9%	-8%
Antibiotics for pneumonia	-7%	-51%	-26%	-10%	-9%	-8%
Vitamin A for treatment of measles	--	--	--	--	--	--
ACTs - Artemisinin compounds for treatment of malaria	--	--	--	--	--	--
SAM - treatment for severe acute malnutrition	-8%	-67%	-34%	-13%	-12%	-11%

*Based on actual health systems data *Approximated using related indicators for same country

Deaths and hospitalizations

Intervention		No additional mitigation			Hand Hygiene			Smart Lockdowns			Masks			All strategies		
Country	Month	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs
India	1/Sep/20	65,228	NA	NA	65,228	NA	NA	65,228	NA	NA	65,228	NA	NA	65,228	NA	NA
	1/Oct/20	103,994	67,613	11,932	77,784	25,700	4,535	91,294	44,743	7,896	83,783	33,395	5,893	64,676	12,821	2,262
	1/Nov/20	139,937	76,074	13,425	90,662	21,920	3,868	114,432	43,770	7,724	100,998	30,865	5,447	71,214	9,104	1,607
	1/Dec/20	178,008	82,772	14,607	100,901	18,487	3,262	135,828	42,001	7,412	115,771	26,972	4,760	75,781	6,354	1,121
	1/Jan/21	222,202	87,896	15,511	109,545	14,824	2,616	156,109	39,629	6,993	128,184	23,101	4,077	78,916	4,283	756
	1/Feb/21	267,186	88,209	15,566	116,676	12,170	2,148	174,339	36,225	6,393	139,125	20,131	3,552	81,267	3,079	543
	1/Mar/21	307,089	84,831	14,970	122,100	10,026	1,769	189,569	32,850	5,797	147,704	16,959	2,993	82,653	2,141	378
	1/Apr/21	348,060	77,316	13,644	126,942	7,797	1,376	204,667	28,577	5,043	155,553	14,509	2,560	83,721	1,580	279
	1/May/21	383,795	70,447	12,432	130,592	6,555	1,157	217,388	24,415	4,309	162,042	12,363	2,182	84,526	1,048	185
	1/Jun/21	418,121	61,320	10,821	133,519	5,214	920	228,789	20,701	3,653	168,005	10,357	1,828	85,050	721	127
	1/Jul/21	445,995	52,311	9,231	135,935	4,275	754	238,071	17,314	3,055	172,840	8,383	1,479	85,412	538	95
	1/Aug/21	470,231	43,937	7,754	138,185	3,649	644	245,890	13,955	2,463	176,663	6,727	1,187	85,658	383	68
	1/Sep/21	491,117	36,442	6,431	139,977	3,014	532	252,419	11,724	2,069	179,485	5,200	918	85,821	215	38

Intervention		No additional mitigation			Hand Hygiene			Smart Lockdowns			Masks			All strategies		
Country	Month	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs
Pakistan	1/Sep/20	6,298	NA	NA	6,298	NA	NA	6,298	NA	NA	6,298	NA	NA	6,298	NA	NA
	1/Oct/20	7,374	398	70	7,220	388	68	7,004	340	60	7,154	387	68	7,332	391	69
	1/Nov/20	7,400	351	62	7,245	304	54	7,015	315	56	7,175	350	62	7,354	295	52
	1/Dec/20	7,409	404	71	7,256	292	51	7,030	340	60	7,183	306	54	7,361	227	40
	1/Jan/21	7,423	465	82	7,267	261	46	7,042	374	66	7,193	306	54	7,366	174	31
	1/Feb/21	7,434	503	89	7,273	242	43	7,049	373	66	7,205	307	54	7,369	147	26
	1/Mar/21	7,446	552	97	7,280	220	39	7,055	388	68	7,215	278	49	7,372	149	26
	1/Apr/21	7,464	522	92	7,285	219	39	7,074	369	65	7,222	260	46	7,377	140	25
	1/May/21	7,473	487	86	7,288	205	36	7,090	346	61	7,228	253	45	7,385	120	21
	1/Jun/21	7,481	450	79	7,292	202	36	7,094	333	59	7,230	255	45	7,388	114	20
	1/Jul/21	7,487	380	67	7,296	184	33	7,099	289	51	7,236	219	39	7,388	129	23
	1/Aug/21	7,499	332	59	7,301	170	30	7,103	258	46	7,240	201	36	7,388	118	21
	1/Sep/21	7,507	294	52	7,306	157	28	7,108	238	42	7,242	185	33	7,390	140	25

Intervention		No additional mitigation			Hand Hygiene			Smart Lockdowns			Masks			All strategies		
Country	Month	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs
Bangladesh	1/Sep/20	4,281	NA	NA	4,281	NA	NA	4,281	NA	NA	4,281	NA	NA	4,281	NA	NA
	1/Oct/20	5,086	444	78	5,032	468	83	4,972	448	79	5,164	462	81	4,973	466	82
	1/Nov/20	5,905	427	75	5,921	431	76	5,812	395	70	5,999	412	73	5,839	432	76
	1/Dec/20	6,656	316	56	6,631	362	64	6,525	366	65	6,675	364	64	6,623	370	65
	1/Jan/21	7,266	341	60	7,253	304	54	7,230	352	62	7,345	305	54	7,335	323	57
	1/Feb/21	7,892	298	53	7,853	263	46	7,830	280	49	7,895	267	47	7,940	271	48
	1/Mar/21	8,378	268	47	8,312	242	43	8,295	243	43	8,320	239	42	8,345	250	44
	1/Apr/21	8,840	191	34	8,797	234	41	8,753	233	41	8,767	221	39	8,838	229	40
	1/May/21	9,209	193	34	9,186	191	34	9,166	201	36	9,154	204	36	9,253	187	33
	1/Jun/21	9,564	176	31	9,506	153	27	9,486	168	30	9,559	177	31	9,614	165	29
	1/Jul/21	9,863	171	30	9,811	166	29	9,770	136	24	9,868	127	22	9,916	162	29
	1/Aug/21	10,159	139	25	10,136	143	25	10,043	141	25	10,135	146	26	10,217	124	22
	1/Sep/21	10,412	110	19	10,410	123	22	10,311	122	22	10,382	105	18	10,462	96	17

Intervention		No additional mitigation			Hand Hygiene			Smart Lockdowns			Masks			All strategies		
Country	Month	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs
Nepal	1/Sep/20	228	NA	NA	228	NA	NA	228	NA	NA	228	NA	NA	228	NA	NA
	1/Oct/20	424	65	12	417	60	11	427	61	11	427	61	11	422	57	10
	1/Nov/20	499	50	9	486	47	8	496	47	8	494	48	8	487	46	8
	1/Dec/20	555	38	7	538	39	7	548	36	6	546	36	6	536	33	6
	1/Jan/21	596	30	5	580	28	5	587	28	5	587	29	5	573	28	5
	1/Feb/21	629	23	4	611	22	4	618	22	4	622	23	4	602	21	4
	1/Mar/21	654	19	3	635	19	3	641	18	3	643	18	3	625	16	3
	1/Apr/21	675	15	3	658	16	3	662	14	2	664	15	3	644	13	2
	1/May/21	690	12	2	675	10	2	676	11	2	681	11	2	659	9	2
	1/Jun/21	703	8	1	685	8	1	688	9	2	692	11	2	670	8	1
	1/Jul/21	711	7	1	694	7	1	696	6	1	703	7	1	678	6	1
	1/Aug/21	717	5	1	700	6	1	704	5	1	711	5	1	686	5	1
	1/Sep/21	723	5	1	706	5	1	710	4	1	716	4	1	691	4	1

Intervention		No additional mitigation			Hand Hygiene			Smart Lockdowns			Masks			All strategies		
Country	Month	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs	Cumulative Deaths	Hospitalizations	ICUs
Afghanistan	1/Sep/20	1,406	NA	NA	1,406	NA	NA	1,406	NA	NA	1,406	NA	NA	1,406	NA	NA
	1/Oct/20	2,306	442	78	2,185	350	62	2,310	405	71	2,268	382	67	2,157	326	58
	1/Nov/20	2,850	426	75	2,669	339	60	2,866	388	69	2,775	348	61	2,607	305	54
	1/Dec/20	3,354	406	72	3,130	324	57	3,383	343	61	3,230	330	58	3,015	288	51
	1/Jan/21	3,885	378	67	3,600	308	54	3,833	320	56	3,736	333	59	3,455	273	48
	1/Feb/21	4,375	359	63	4,011	290	51	4,274	330	58	4,195	301	53	3,849	251	44
	1/Mar/21	4,807	349	62	4,375	290	51	4,669	308	54	4,571	293	52	4,204	248	44
	1/Apr/21	5,230	323	57	4,783	269	48	5,094	287	51	4,985	271	48	4,565	241	42
	1/May/21	5,638	311	55	5,109	240	42	5,458	262	46	5,362	264	47	4,910	236	42
	1/Jun/21	6,075	291	51	5,452	242	43	5,811	262	46	5,747	241	43	5,259	218	38
	1/Jul/21	6,453	266	47	5,760	223	39	6,168	263	46	6,062	233	41	5,552	201	35
	1/Aug/21	6,802	241	42	6,074	217	38	6,528	233	41	6,376	238	42	5,825	185	33
	1/Sep/21	7,106	237	42	6,367	199	35	6,850	220	39	6,684	223	39	6,094	177	31

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Direct and indirect effects of the COVID-19 pandemic in South Asia

For Further Information:
UNICEF Regional Office for South Asia (ROSA)
P.O. Box 5815, Lekhnath Marg, Kathmandu, Nepal
Tel: +977-1-4417082 Email: rosa@unicef.org
Website: www.unicef.org/rosa/

//True Copy//

Gmail

Varuna Singh <varuna3130@gmail.com>

Fwd: Govt of Delhi: Expert Opinion Requested

Anurag Kundu <anurag.kundu@gov.in> Mon, May 17, 2021 at 8:11 PM
To: krshanuk <krshanuk@gmail.com>, varuna3130 <varuna3130@gmail.com>

From: aparnahegde@armman.org
To: "Anurag Kundu" <anurag.kundu@gov.in>
Sent: Monday, May 10, 2021 11:18:09 AM
Subject: Re: Govt of Delhi: Expert Opinion Requested

Dear Mr. Kundu,
Please find attached my edits to the note you have created. While most corrections I have made are minor (some typos etc), there are a few lines I have added in the draft. I am attaching them here for your perusal:

Covaxin is a killed (inactivated) virus vaccine while Covishield is a Adenovirus vector-based vaccine. Both are non-replicating. While inactivated virus vaccines are considered safe during pregnancy, adenovirus vector-based Zika virus vaccine used in pregnant mice showed no safety concerns.

Please find attached the document with my comments.

On Sat, May 8, 2021 at 5:35 PM Aparna Hegde <aparnahegde@armman.org> wrote:
> Hello Mr. Kundu,
> Thank you for the email. I will get back by tomorrow morning.
>
> Warm regards,
> Aparna
>
> On Sat, May 8, 2021, 3:08 PM Anurag Kundu <anurag.kundu@gov.in> wrote:
> > Dear Dr. Hegde,
> >
> > Please find attached a DO letter from Chairperson, Delhi Commission For Protection of Child Rights (DCPCR), Govt of Delhi requesting your expert opinion on the issue of Covid-19 vaccination of pregnant women and lactating mothers.
> >
> > Regards,
> >
> > Office of Anurag Kundu
> > Chairperson, Delhi Commission For Protection of Child Rights
> > Government of NCT of Delhi
> > Email: Anurag.kundu@gov.in /Anurag13kundu@gmail.com
> > Phone Number: 011-23862685
> > Official Address:
> > Room No: 6, 5th Floor,
> > Delhi Commission For Protection of Child Rights (DCPCR)
> > ISBT Building, Kashmere Gate, Delhi-110006
> >
> > *"When people go hungry, it is not food but justice that is in short supply"*

--
Dr. Aparna Hegde
Founder, Chairperson, Managing Trustee, ARMMAN, Mumbai
Assoc Prof (Hon), Urogynecology, Cama Hospital, Grant Medical College, Mumbai

MD, DNB, FCPS, DGO, MS (Stanford University), IUGA International Fellowship, Urogynecology and Pelvic Reconstructive Surgery, Cleveland Clinic Florida,
Consultant Urogynecologist, Global Hospital, Surya Hospital and Womens Hospital,
Founder and Director, C.U.P (Center for Urogynecology and Pelvic Health), New Delhi
Member, IUGA Publications Committee;
Member, International Urogynecology Committee on Prolapse
Member, Editorial Board, International Urogynecology Journal
Member, 7th International Consultation on Continence

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Center for Urogynecology and Pelvic Health
3rd Floor, Sama Hospital, 7 Siri Fort Road, New Delhi 110049, India
Tel. No.: +91 8800130949 |Email: aparnahegde@cupindia.org | www.cupindia.org

https://www.youtube.com/watch?v=GLW8GRoGVro&t=38s

https://www.youtube.com/watch?v=bKUTuRdnqMs&t=4s

Official note for DCPCR-Dr. Hegde edits.docx
21K

Gmail Varuna Singh <varuna3130@gmail.com>

Fwd: Govt of Delhi: Expert Opinion Requested

Anurag Kundu <anurag.kundu@gov.in> Mon, May 17, 2021 at 8:10 PM
To: krshanuk <krshanuk@gmail.com>, varuna3130 <varuna3130@gmail.com>

From: gkang@cmcvellore.ac.in
To: "Anurag Kundu" <anurag.kundu@gov.in>
Sent: Wednesday, May 12, 2021 1:39:21 PM
Subject: Re: Govt of Delhi: Expert Opinion Requested

Dear Mr. Kundu,

Thank you for attending to this very important matter. I have pushing for this recommendation for the past three months with the government of India. It appears that finally there may be a willingness to listen.

The vaccines available in India are or are equivalent to inactivated vaccines which are considered safe in pregnancy. With the FOGSI recommendation, I think there is no need for further discussion. Pregnant and lactating women should get the vaccine at any stage in pregnancy or whenever available when breastfeeding.

Sincerely,

Gagandeep Kang
Professor
The Wellcome Trust Research Laboratory
Division of Gastrointestinal Sciences
Christian Medical College, Vellore
TN 632004 India

From: Anurag Kundu <anurag.kundu@gov.in>
Sent: Wednesday, May 12, 2021 11:52 AM
To: Gagandeep Kang <gkang@cmcvellore.ac.in>
Subject: Govt of Delhi: Expert Opinion Requested

Dear Dr. Kang,

Please find attached a DO letter from Chairperson, Delhi Commission For Protection of Child Rights (DCPCR), Govt of Delhi requesting your expert opinion on the issue of Covid-19 vaccination of pregnant women and lactating mothers. We look forward to your early response.

Regards,

Office of Anurag Kundu
Chairperson, Delhi Commission For Protection of Child Rights
Government of NCT of Delhi
Email: Anurag.kundu@gov.in /Anurag13kundu@gmail.com
Phone Number: 011-23862685
Official Address:
Room No: 6, 5th Floor,
Delhi Commission For Protection of Child Rights (DCPCR)
ISBT Building, Kashmere Gate, Delhi-110006

"When people go hungry, it is not food but justice that is in short supply"

Gmail

Varuna Singh <varuna3130@gmail.com>

Fwd: Govt of Delhi: Expert Opinion Requested

Anurag Kundu <anurag.kundu@gov.in> Mon, May 17, 2021 at 8:09 PM
To: krshanuk@gmail.com, varuna3130 <varuna3130@gmail.com>

From: "rajani bhat" <rajani.bhat@gmail.com>
To: "Anurag Kundu" <anurag.kundu@gov.in>
Sent: Thursday, May 13, 2021 8:46:16 AM
Subject: Re: Govt of Delhi: Expert Opinion Requested

My wholehearted support to you and my sincere apologies for the delay
Sincerely,
Rajani

On Sat, May 8, 2021 at 11:19 PM Anurag Kundu <anurag.kundu@gov.in> wrote:

> Dear Dr. Rajani Bhat,
>
> Please find attached a DO letter from Chairperson, Delhi Commission For Protection of Child Rights (DCPCR), Govt of Delhi requesting your expert opinion on the issue of Covid-19 vaccination of pregnant women and lactating mothers.
>
> Regards,
>
> Office of Anurag Kundu
> Chairperson, Delhi Commission For Protection of Child Rights
> Government of NCT of Delhi
> Email: Anurag.kundu@gov.in /Anurag13kundu@gmail.com
> Phone Number: 011-23862685
> Official Address:
> Room No: 6, 5th Floor,
> Delhi Commission For Protection of Child Rights (DCPCR)
> ISBT Building, Kashmere Gate, Delhi-110006
>
> *"When people go hungry, it is not food but justice that is in short supply"*

DCPCR PW LM Vaccination.docx
13K

13th May 2021

Dear Mr Kundu,

I thank you for your initiative in bringing the vulnerability and needs of a very important group of people who are susceptible to greater harm from Covid-19.

Around the world professional bodies and national health programs are recognising the need to address vaccination in pregnant women and lactating mother(PW and LM)s. This is based on observations of the rising risk to their health with exposure to Covid-19 without the protection offered by vaccination. We are seeing more severe disease in pregnant women in the current surge that India is experiencing.

Our past experience with vaccines that do not contain 'live' virus and the data available so far on the use of mRNA and the Oxford-Astra Zeneca vaccine in PW & LM indicates no greater risk to this group.The Royal College of Obstetrics and Gynecology statement clarifies that there are no reported concerns so far with the Astra Zeneca vaccine in pregnant women .This is based on data from healthcare workers who opted to receive vaccination and from women who received the vaccine without knowing that they were pregnant at the time of vaccination.

Even though vaccine trials did not include pregnant women and lactating mothers , real world data gathered from across the world indicates potential benefit and no increased harm to PW & LM.

Keeping the dire health crisis in mind and the points above , I support your proposal to include PW & LM as a priority in India's Covid-19 vaccination program .

Sincerely,

Dr Rajani Surendar Bhat

Consultant Pulmonologist and Physician

www.boardofdoctors.com

//True Copy//

Annexure-P-8

सत्यमेव जयते

ANURAG KUNDU
CHAIRPERSON

दिल्ली बाल अधिकार संरक्षण आयोग
दिल्ली सरकार
दिल्ली - 110006
DELHI COMMISSION FOR PROTECTION OF CHILD RIGHTS
GOVT. OF NCT OF DELHI
DELHI - 110006

D.O.No.F6(1)/DCPCR/21-22/CPPB/1689-94
Dated:12th May 2021

Dear Sir

I write this letter to bring to your kind attention the issue of Covid-19 vaccination of pregnant women and lactating mothers, which the current vaccination drive rolled out in India for people aged 18 years and above excludes.

India had rolled out it's Covid-19 vaccination drive on January 16th, 2021. India has adopted a phased manner for vaccinating her population, where vaccinations rolled out from 16th January 2021 with priorities for frontline/healthcare workers, and elderlies. From 1st May 2021 vaccination for the age group 18 years and above had been made available.

Currently, Pregnant and lactating women through an advisory issued by the Ministry of Health and Family (vide letter No. T-22020/14/2020-IMM dated 14th January 2021), have not been recommended to take the vaccine. This is an understandable position due to lack of clinical trials data on the effect of the Covid-19 vaccine on pregnant and lactating mothers.

Each year, 2.6 crore (Vital Statistics of India based on the Civil Registration system 2018) women deliver a child, add to that another 2.6 crore lactating mother and we have close to 5.2 crore women who are left out of the current vaccination program. Clearly, this is a critical population both in numbers and their vulnerability priority.

Kindly allow me to draw your kind attention to the recommendation of the Federation of Obstetric and Gynaecological Societies of India (FOGSI position statement on covid vaccination for pregnant & breastfeeding women) has recommended that obstetricians and gynaecologists and women's health care providers should be allowed to administer the Covid vaccines in pregnant & breastfeeding women with preparations to manage adverse events. They have pointed out that the method of administering and monitoring the vaccine and the schedule of vaccination should be the same for pregnant and lactating women as for the general population and concluded that "*there is no obvious basis for excluding pregnant or lactating women from vaccination.*"

However, it must be noted that FOGSI has recommended that pregnant women receive vaccination based on the studies conducted by the Centre for Disease

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Control and Prevention in the U.S. Countries such as the USA and the U.K. have started the vaccination drive to include this group of women as *Pregnant mothers are classified as high risk* by the Centre for Disease Control, the regulatory authority in the United States as compared to non-pregnant women.

India, on the other hand, has not categorised them as high risk. The CDC classifies pregnant women as being *"At increased risk for severe illness from COVID-19 when compared to non-pregnant people"*· Increased risk of severe illness which includes illness that requires hospitalization, intensive care, or a ventilator, or may even result in death and they are also at risk of adverse pregnancies such as preterm birth. Pregnant women with Covid-19 might also be at increased risk of adverse pregnancy outcomes, such as preterm birth. Poor maternal outcomes are associated with poor perinatal outcomes.

Hence, the CDC has recommended that pregnant women can receive a COVID-19 vaccine. This is because getting a COVID-19 vaccine during pregnancy can protect them from severe illness from COVID-19. In the USA, around 90,000 pregnant women have been vaccinated mainly with Pfizer and Moderna vaccines and no safety concerns have been identified. The study is based on a registry of 100,000 pregnant and lactating women who have received the MRNA vaccination as of now provides corroborating evidence.

CDC data also provides evidence that immunisation of pregnant and lactating mothers has led to transfer of antibodies to the infant and hence extending protection of the vaccination to the infant. World over, especially in Brazil, maternal death due to Covid-19 has been acknowledged as being on the rise and requiring special attention.

In the United Kingdom, the Joint Committee on Vaccination and Immunisation (JCVI) has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group.

I now draw your attention to the WHO guidelines for immunization of pregnant women which state the following:

"At present (March 2021), the WHO Strategic Advisory Group of Experts on Immunization currently recommends that pregnant women may receive the vaccine if the benefits of vaccination outweigh the potential risks, such as occupational activities with unavoidable high risk of exposure, and pregnant women with co-morbidities which place them in a high-risk group for severe COVID-19 disease."

WHO has recommended vaccination of pregnant women post designing & establishing the design of a surveillance mechanism to monitor the effects of vaccination

They not only belong to the high risk category but there are potential other negative impacts on pregnant and lactating women due to covid. For instance, at the country-level, the largest increase in the number of stillbirths is expected in India

(60,179, 10% increase). Similarly, the number of maternal deaths is also expected to increase in 2020 as a result of the COVID-19 pandemic response, with the highest number of deaths anticipated in India (7,750, 18% increase). Child mortality is estimated to increase in India by 15.4%. Neonatal mortality by 14.5%. This is based on the report *'Direct and Indirect Effects of COVID-19 Pandemic and Response in South Asia published by the UN'*. It studied the impact of Covid-19 on mortality, hospitalisations, and ICU admissions due to the disease and the impact of nation-wide lockdown on maternal and child mortality, educational attainment of children, and the region's economy.

Evidence on COVID-19 vaccines is being continuously reviewed by the World Health Organization and the regulatory bodies in the UK, USA, Canada and Europe.

I acknowledge that India administers a different set of vaccines other than the MRNA vaccines based for which the CDC data exists. Impact of the vaccines administered in India on pregnant women is still not known due to lack of clinical trials data for the same. Clinical trials for vaccinations happen in three phases and the third phase involves administration to the general public to see the efficacy of the vaccination. The third phase did not include pregnant and lactating women.

Although the current datasets exist only for MRNA vaccines, Gynaecologists associations such as FOGSI are of the opinion that the theoretical benefits of India's vaccines would outweigh the risk of the disease. Covaxin is a killed (inactivated) virus vaccine while Covishield is a Adenovirus vector-based vaccine. Both are non-replicating. While inactivated virus vaccines are considered safe during pregnancy, adenovirus vector-based Zika virus vaccine used in pregnant mice showed no safety concerns.

The Commission diligently studied the medical literature on the subject with the help of organisation Indus Action and consulted experts such as Dr. Gagandeep Kang, Dr Rajani Bhat, and Dr. Aparna Hegde amongst others.

Hence, in exercise of powers vested in the Commission under section 15 of the Commission For Protection of Child Rights Act, 2005 and based of the consultations with experts, and review of medical literature, Delhi Commission For Protection of Child Rights (DCPCR) formally advises the Government of India to :

1. Categorise Pregnant and Lactating mothers as belonging to the **high-risk category**.

2. **Setting up a task force for the following purpose:** A working committee should be set up to look into the matters at the earliest and this category should be included in the vaccination drive. The task force should include experts from not only the health sector but also other institutions that work in operationalising a standard procedure and can help materialise a mechanism to track and monitor Pregnant Women & Lactating Mothers post vaccination.

3. Based on recommendations from other countries and FOSGI, India should not only include Pregnant Women & Lactating Mothers in the vaccination program but also **categorize them as belonging to the high risk category such as in other countries.**

4. **Communication :** Education and Standard Operating Protocols must be developed to educate women on the side effects of vaccination, effects of vaccination on pregnant and lactating mothers and ensure that informed consent is taken before taking the vaccine. Anganwadi Centres with Anganwadi workers and ASHA workers could drive the communication and messaging.

5. **Post Vaccination**: Creating a registry to register pregnant women and lactating mothers being vaccinated so that a continuous monitoring mechanism can exist to see if the vaccine has an adverse effect on pregnant women. Continuous monitoring of all pregnant and lactating women receiving vaccination is necessary. Hence a separate registry such as the V-safe registry in the United States should be created to collect such data.

6. As pointed out there is no existing data in India on the impact of Covid-19 vaccination on pregnant women. The aim of the vaccination drive should not only be to vaccinate this category of the population but also to monitor the impact of the vaccination and gather data on it's safety. Excluding them from the drive entirely is not the answer given the evidence on the effect of Covid-19 on pregnant and lactating mothers.

I hope you give our recommendations a fair consideration. Wishing our country the earliest possible relief from Covid-19 pandemic.

Regards

Sincerely

(Anurag Kundu)
Chairperson, DCPCR

Shri Rajesh Bhushan
Union Secretary (Health)
Government of India
Room No.156-A, C-Wing,
Nirman Bhawan, New Delhi-110001
Email: secyhfw@nic.in

Copy for kind information to:

1. Pr. Secretary to Hon'ble Lt. Governor, Delhi
2. Additional Secretary to Hon'ble Chief Minister, Delhi
3. Secretary to Hon'ble Deputy Chief Minister, Delhi
4. Secretary to Hon'ble Minister (Health), GNCTD
5. Secretary to Hon'ble Minister (Women & Child Development), GNCTD

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HEALTH

Pregnant women may be given choice to take any Covid-19 vaccine: Govt panel

It suggested that pregnant women may be offered the choice to take any Covid-19 vaccine and that lactating women can be inoculated any time after delivery and also suggests increasing gap between two doses of Covishield.

By hindustantimes.com, New Delhi

UPDATED ON MAY 13, 2021 12:11 PM IST

Representational Image(Unsplash)

The National Technical Advisory Group on Immunisation (NTAGI) has recommended increasing the gap between two doses of Covishield vaccine to 12-16 weeks, sources said on Thursday

It has also suggested that pregnant women may be offered the choice to take any COVID-19 vaccine and that lactating women can be inoculated any time after delivery.

The NTAGI has also stated that those having laboratory test proven SARS-CoV-2 illness should defer COVID-19 vaccination for six months after recovery, the sources said.

Currently, the interval between two doses of Covishield is four to eight weeks.

No change in dosage interval for Covaxin has been suggested by the panel.

The recommendations of the NTAGI will be sent to the National Expert Group on Vaccine Adminstration for COVID-19.

India's coronavirus death toll crossed 250,000 on Wednesday in the deadliest 24 hours since the pandemic began, as the disease rampaged through the countryside, leaving families to weep over

the dead in rural hospitals or camp in wards to tend the sick.

MORE FROM THIS SECTION

OPEN APP

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Know all about whether your child should get the Covid-19 vaccine or not

Nora Fa exercise twerkin

The second wave erupted in February, inundating hospitals and medical staff, as well as crematoriums and mortuaries.

Experts still cannot say for sure when numbers will peak and concern is growing about the transmissibility of the variant that is driving infections in India and spreading worldwide.

Indian state leaders clamoured for vaccines to stop the second wave and the devastation it has wrought, urging Prime Minister Narendra Modi to stop exporting doses, ramp up production and help them procure urgent supplies from overseas.

"People will die in the same way in the third and fourth waves as they have this time" without more vaccines, Delhi's Deputy Chief Minister Manish Sisodia told reporters.

Deaths grew by a record 4,205 while infections rose by 348,421 in the 24 hours to Wednesday, taking the tally past 23 million, health ministry data showed. Experts believe the actual numbers could be five to 10 times higher.

(With agency inputs)

This story has been published from a wire agency feed without modifications to the text. Only the headline has been changed.

TRENDING NEWS

Hindustan Times

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Hindustan Times

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Hindustan Times

Are you a pet parent? You'll find this video of

Hi

Sania M 'coache

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IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL WRIT JURISDICTION)

I.A. NO. OF 2021

IN

Writ Petition (Civil) No. ..... of 2021

IN THE MATTER OF:

Delhi Commission for Protection of Child Rights ...Petitioner

Versus

Union of India & Anr … Respondents

APPLICATION FOR EXEMPTION FROM FILING WELFARE STAMP AND NOTARISED AFFIDAVIT.

To

The Hon'ble Chief Justice of India,

and His Companion Judges of the

Supreme Court of India

The humble application of the Applicant/ Petitioner above-named.

MOST RESPECTFULLY SHOWETH:

1. That the Applicant herein is the Petitioner in the present case.

2. The facts and circumstances leading to the present case are fully set out in the accompanying Synopsis, List of Dates and the Writ Petition. The contents of the Writ Petition are

not repeated herein for the sake of brevity and may be read as part of this application as well.

3. That the Applicant herein is filing Vakalatnama without affixing the welfare stamp due to the recent resurge of Covid-19 Pandemic and the accompanying affidavits and vakalatnama could not be attested and notarized for the same reason.

4. That the Applicant undertakes to file welfare stamp and attested affidavits and notarized vakalatnama as soon as regular functioning commences.

5. It is therefore in the interest of justice that this Hon'ble Court be pleased to exempt the Petitioners herein from filing welfare stamp and attested affidavits and along with the present Writ Petition.

6. That the present application is filed *bona fide* and in the interest of justice. No material facts have been concealed in the application.

PRAYER

It is therefore most respectfully prayed that this Hon'ble Court may be pleased to

(i) Exempt the Petitioners herein from filing welfare stamp and attested affidavits and along with the present Writ Petition; and

(ii) Pass such other order or orders as this Hon'ble Court may deem fit and proper in the facts and circumstances of the present case.

AND FOR THIS ACT OF KINDNESS THE APPLICANT AS IN DUTY BOUND SHALL EVER PRAY

FILED BY

DRAWN ON : 18.05.2021

FILED ON : 18.05.2021

PLACE : NEW DELHI

PRATEEK K. CHADHA

ADVOCATE FOR THE PETITIONER/ APPLICANT

SECTION PIL-W

IN THE SUPREME COURT OF INDIA

(CIVIL ORIGINAL WRIT JURISDICTION)

Writ Petition (Civil) No. ..... of 2021

IN THE MATTER OF:

Delhi Commission for Protection of Child Rights ...Petitioner

Versus

Union of India & Anr … Respondents

I N D E X

S.No.	Particulars	Copy	Court Fee
1.	Writ Petition along with Affidavit		

Certified that the copies are correct

Filed on: 18.05.2021

Clerk: - I.D. Applied for
Name Yogesh

(PRATEEK K. CHADHA)
ADVOCATE FOR THE PETITIONER
AOR CODE: 2651
D-416, LGF, Defence Colony
New Delhi-110024
Phone-09871588144

VAKALATNAMA

IN THE SUPREME COURT OF INDIA
WRIT PETITION (CIVIL) NO. OF 2021

Delhi Commission for Protection of Child Rights — Petitioner(s)

Versus

Union of India and Another — Respondent(s)

I, Delhi Commission for Protection of Child Rights through its Secretary in the above do hereby appoint and retain **Prateek K. Chadha**, Advocate-on-Record to act and appear for me/us in the above Suit Appeal/Petition/Reference and on my/our behalf to conduct and prosecute (or defend) the same and all proceedings that may be taken in respect of any application connected with the same of any against decree or order passed therein, including proceedings in taxation and application for Review, to file and obtain return of documents, and to deposit and receive money on my/our behalf in the said suit Appeal/Petition/Reference and in application of Review and to represent me/us and to take all necessary steps on my/our behalf in the above matter.
I/we agree to ratify all acts done by the aforesaid Advocate in pursuance of this authority.

Dated this the 18th day of May, 2021

ACCEPTED AND IDENTIFIED & CERTIFIED

(PRATEEK K. CHADHA)

(Rakesh Bhatnagar, Secretary, DCPCR)
PETITIONER(S)/RESPONDENT(S)/ APPELLANT(S)
Delhi Commission for Protection of Child Rights
Govt. of N.C.T. of Delhi
5th Floor, ISBT Building, Kashmere Gate, Delhi-110006

MEMO OF APPEARANCE

The Registrar,
The Supreme Court of India
New Delhi

Please enter my appearance on behalf of the Petitioner(s)/Respondent/ Appellant(s)_____ in the above matter.

Dated 18.05. **2021**

(PRATEEK K. CHADHA)
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