Advances in maternal immunization science and implementation in times of COVID-19-
How has the COVID-19 pandemic impacted the future of maternal immunization?

A COVAX Maternal Immunization Working Group Webinar

November 18th 2021

Presenter Reminders

- Please **turn on your video** during your assigned session. As a presenter / panelist, your video will be shown to the audience unless you turn it off.
- As a presenter, **you can mute / unmute yourself to speak**.
- Please **say "next slide"** to advance the slides. Monika will be sharing her screen with everyone's presentations already loaded.
- If you do not see the correct slide on your screen, it may be due to internet connectivity issues. Please **say the name of the slide header** that you'd like to see on the screen. As a backup, please **open your slides separately in PowerPoint** to reference the materials in the event internet issues arise.
- The moderator of your session will chime in if you are over time. Otherwise, it is up to you to stay within your allocated time.
- **Q&A Chat**: Please DO NOT click "answer live" and kindly only type in responses to the questions asked by attendees

Meeting Norms and Recording Disclaimer

Throughout the workshop, please ask any questions in the **“Q&A”** function. If you see that your question is already asked, you can “like” the question in the **“Q&A”** function.

During the discussion sessions, please “**Raise Your Hand**” if you want to say something. If called on by the moderator, **you will be unmuted to intervene**.

For any technical or connectivity issues please contact:

Dane Ichimura Dane.Ichimura@gatesfoundation.org

For any logistical issues please contact:

Amanda Berzins Amanda.Berzins@gatesfoundation.org.

This workshop will be **recorded**. Recording might be shared after the webinar.

Please be mindful of the diverse audience attending the meeting when participating in open discussions.

Workshop Agenda

Time (PDT)	Session	Speaker
7:00 am PT (5 min)	Workshop welcome	Ajoke Sobanjo-ter Meulen Flor Munoz
7:05 am PT (15 min)	Keynote lecture: Research and Development approaches to Maternal Immunization	Melanie Saville
7:20 am PT (50 min)	**Session 1 - Vaccine benefit-risk assessment post approval**	Moderator: Andy Stergachis
7:20 am PT (10 min)	Vaccine effectiveness in pregnant women - Israel	Noa Dagan
7:30 am PT (10 min)	Vaccine reactogenicity in pregnant women - US	Alisa Kachikis
7:40 am PT (10 min)	The power of obstetric surveillance systems – the UK's experience tracking COVID-19 during pregnancy and the impacts of variants and vaccination	Marian Knight
7:50 am PT (10 min)	COVID disease burden and vaccination strategies among pregnant women in Brazil	Cristiana M. Toscano
8:00 am PT (10 min)	Questions & Answers	Andy Stergachis

Workshop Agenda

Time (PDT)	Session	Speaker
8:10 am PT (55 min)	**Session 2 – Panel discussion** **COVID-19 vaccines: De-risking of vaccine development for maternal immunization** Moderator: Ajoke Sobanjo-ter Meulen	
8:10 am PT (5 min)	Introduction	Ajoke Sobanjo-ter Meulen
8:15 am PT (10 min)	COVID-19 Maternal Vaccine Clinical	Alejandra Gurtman
8:25 am PT (40 min)	Panel discussion: Padmini Srikantiah Shabir A. Madhi Janet A. Englund Kathryn M. Edwards	
9:05 am PT (5 min)	BREAK	

Workshop Agenda

Time (PDT)	Session	Speaker
9:10 am PT (45 min)	**Session 3 – Policy and regulatory considerations: The way forward**	Moderator: Flor Munoz
9:10 am PT (10 min)	COMIT and PREVENT, what we've learned about data-driven policy decisions, and what we should anticipate in the future?	Ruth Karron
9:20 am PT (10 min)	Regulatory guidance/role (FDA) – how does COVID pandemic change the path for vaccine approval and access for pregnant women – Regulatory framework for maternal vaccines in the future	Marion F. Gruber
9:30 am PT (10 min)	Obstetric professional societies role in supporting access of vaccines for pregnant women	Linda O. Eckert
9:40 am PT (15 min)	Discussion	Flor Munoz
9:55 am PT (40 min)	**Session 4 – Roundtable Discussion on Pandemic preparedness, Maternal immunization post COVID-19** Moderator: Denise Jamieson // Curators: Ajoke Sobanjo-ter Meulen & Flor Munoz	
9:55 am PT (40 min)	LMIC Post-approval vaccine evaluation	Cristiana M. Toscano
	LMIC Regulatory and policy perspective	Delese Mimi Darko Esperança Sevene
	WHO Perspective	Sami Gottlieb
	Vaccine Policy	Ruth Karron
	Vaccine Hesitancy	Linda O. Eckert
10:35 am PT (5 min)	**Wrap-up**	**Ajoke Sobanjo-ter Meulen** **Flor Munoz**

Ajoke Sobanjo-ter Meulen

MD MSc, Senior Program Officer, Global Health, Pneumonia, Bill & Melinda Gates Foundation, USA

Flor Munoz

MD MSc, Associate Professor, Pediatrics-Infectious Disease, Baylor College of Medicine, USA

Workshop introduction

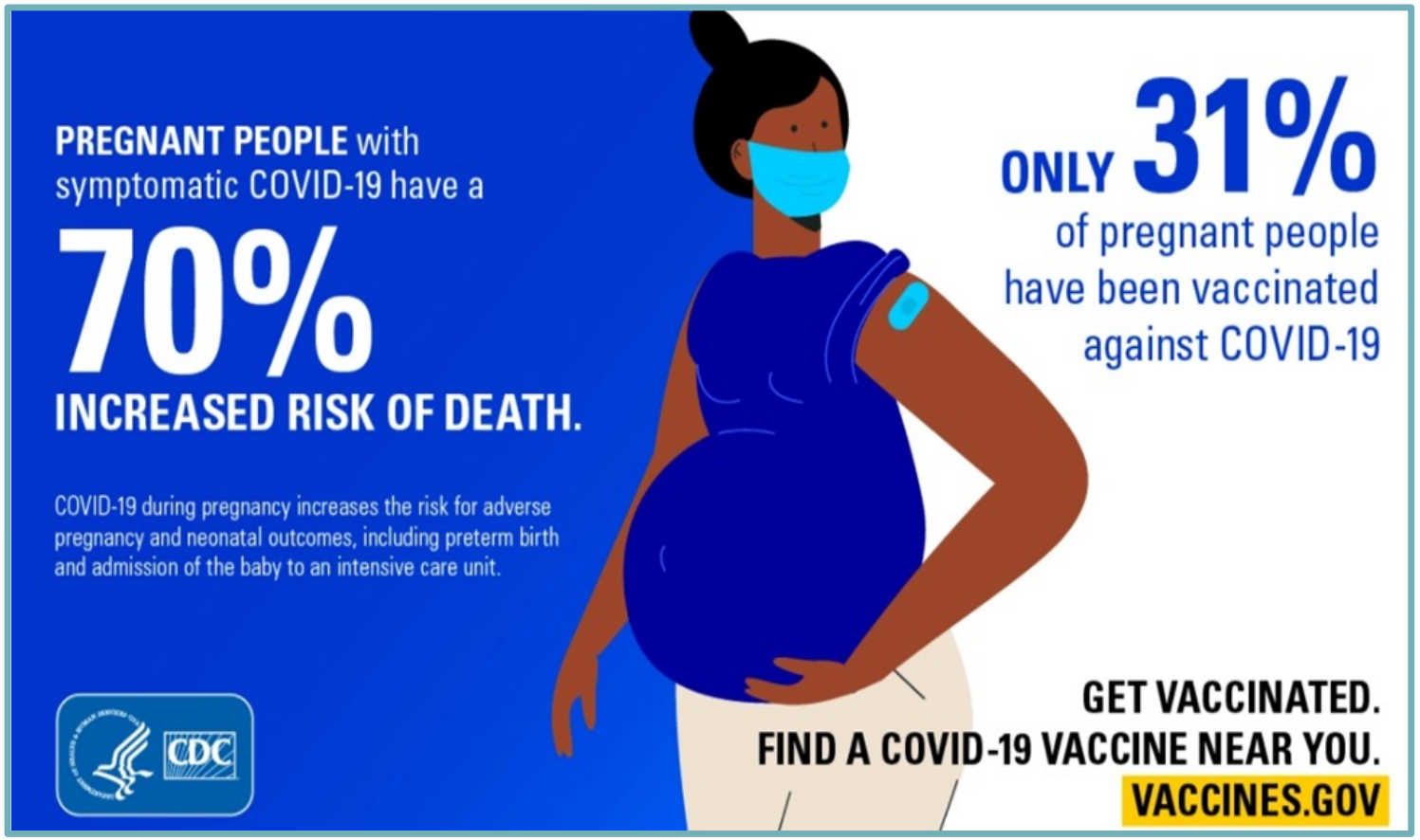
COVID-19 AND PREGNANCY: CLOSING THE PREGNANCY DATA GAP TO ACCELERATE GENDER EQUALITY IN HEALTH INNOVATION

Ajoke Sobanjo-ter Meulen, M.D.

BMGF – Maternal Immunization

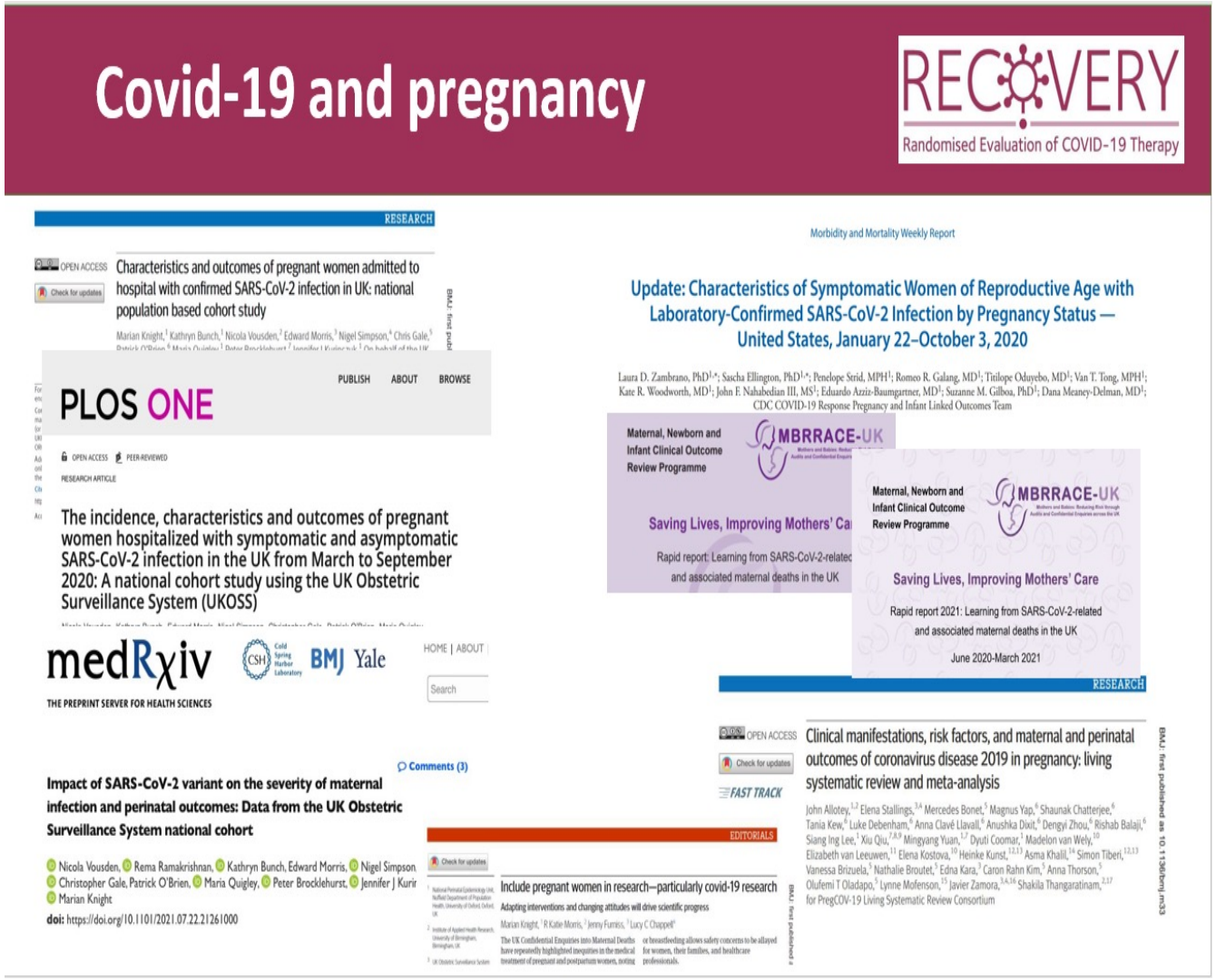
COVID-19 VACCINE AND UNVACCINATED PREGNANT WOMEN

More than 95% of pregnant women who are hospitalized or dying from Covid-19 are UNVACCINATED



Pregnant women were excluded from all COVID-19 vaccine trials and few trials include randomized evaluation of COVID-19 therapy

The RECOVERY trial is linked to UK obstetric surveillance



COVID-19 drives a paradigm shift in clinical research in pregnancy

Global Regulators Envision Paradigm Shift Toward Inclusion of Pregnant and Breastfeeding Women in Clinical Research for Medicines and Vaccines

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FDA News July 21st, 2021

Activity	Year	Region and agency
Content and Format of Labeling for Human Prescription Drug and Biological Products: Requirements for Pregnancy and Lactation Labeling[1]	2014	US, US Food and Drug Administration
Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)[2]	2016	US, US Department of Health and Human Services
Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests[3]	2017	UK, Commission on Human Medicines
PRGLAC Report to Congress[4]	2018	US, Department of Health and Human Services
Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials: Draft Guidance for Industry[5]	2018	US, US Food and Drug Administration
Drug Safety in Pregnancy in a Large, Multisite Database: Mother-Infant Linkage in Sentinel[6]	2018	US, US Food and Drug Administration
ConcePTION – Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now[7]	2019	Europe, Innovative Medicines Initiative
Guideline on Good Pharmacovigilance Practices: Pregnant and Breastfeeding Women[8]	2019	Europe, European Medicines Agency
Postapproval Pregnancy Safety Studies: Guidance for Industry[9]	2019	US, US Food and Drug Administration
Clinical Lactation Studies, Considerations for Study Design: Guidance for Industry[10]	2019	US, US Food and Drug Administration
Programme of Work: Research to Support the Safer Use of Medicine during Pregnancy[11]	2019	UK, Medicines and Healthcare products Regulatory Agency
Strategic Reflection: EMA Regulatory Science to 2025[12]	2020	Europe, European Medicines Agency

Nooney, Clin Pharm and Therapeutics 2021

COVID-19 VACCINE AND PREGNANCY

- ✓ Not associated with any maternal or fetal complications
- ✓ May protect the baby from severe disease

No increased risk of miscarriages in the CDC v-safe vaccine pregnancy registry

Njugan HN, MMWR 2020

Pregnancy data build maternal vaccine confidence

Inclusion of pregnant women in clinical vaccine trials

Pregnancy surveillance data available worldwide

Linked obstetric and vaccine data systems in place before the next pandemic

Rapid access to timely, accessible, and robust data
Saves the lives of mothers and babies

Dr. Melanie Saville

Keynote lecture - Research and Development approaches to Maternal Immunization

COVAX maternal immunization webinar

Melanie Saville

November 18, 2021

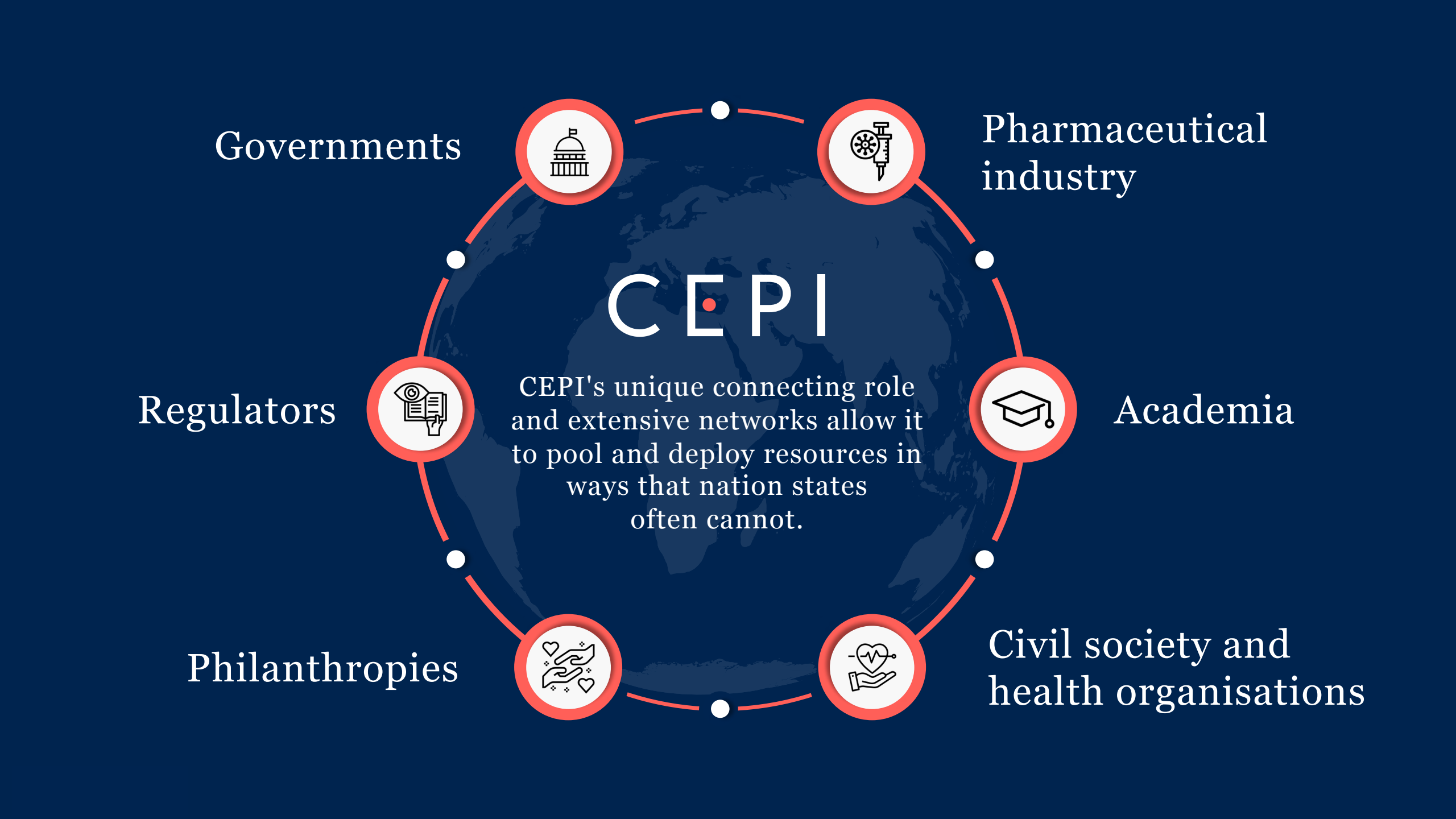
A global partnership

Vision

A world in which epidemics and pandemics are no longer a threat to humanity.

Mission

To accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

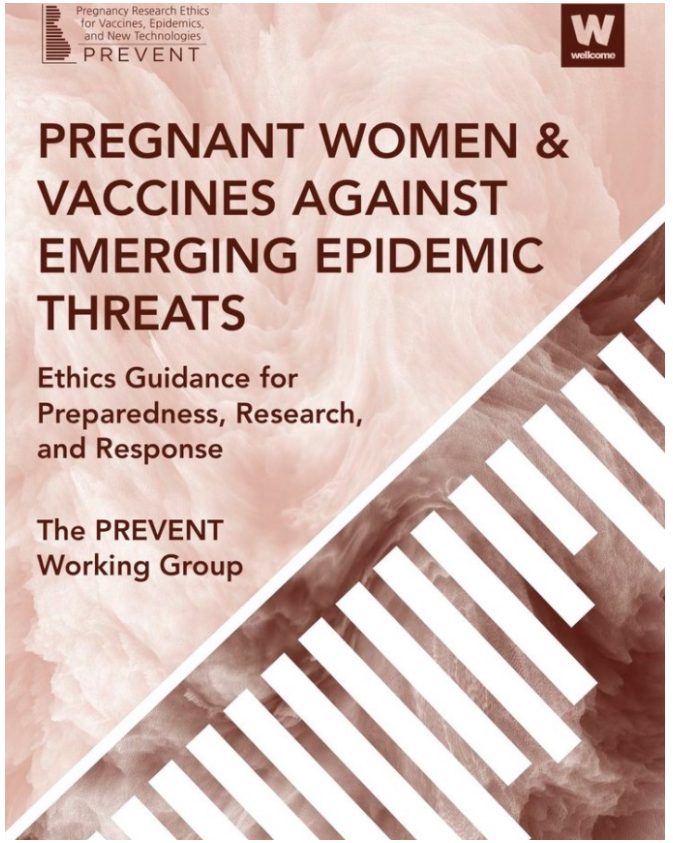

Governments
Pharmaceutical industry
CEPI
CEPI's unique connecting role and extensive networks allow it to pool and deploy resources in ways that nation states often cannot.
Regulators
Academia
Philanthropies
Civil society and health organisations

CEPI's approach to maternal immunization

- Endorse PREVENT guidance

- Facilitate identification of gaps and enablers to promote vaccination against Emerging Infectious Diseases of pregnant and lactating women
  - Stakeholder workshop in 2020 with a focus on Lassa[1]

- Support consensus-building and knowledge-sharing for inclusion of pregnant women in COVID-19 vaccine trials and generation of data to enable maternal immunization of emergency-authorized COVID-19 vaccines
  - COVAX Maternal Immunization working group



CEPI

1: - https://media.tghn.org/articles/MI_WS_short_report_CEPI_-_31_March_updated_May_2020.pdf
- Voss et al., Vaccine, in press

CEPI's contribution to maternal immunization: Vaccine R&D

- Funding for Ebola vaccine trials that **include** pregnant and lactating women
  - Uganda (NCT04028349): N=800, Janssen, MRC/UVRI and LSHTM Uganda Research Unit, Epicentre, 2019-2021
  - DRC (NCT04152486): N=20426, Janssen, LSHTM, Epicentre, MSF, PHE, Ministère de la Santé de la RDC, 2019-2022

- Funding for Ebola vaccine trials that are **specifically designed** to evaluate the safety and immunogenicity in pregnant and lactating women
  - Rwanda (NCT04556526): N=2000, Janssen, Center for Family Health Research (CFHR), Emory University, 2020-2022

CEPI's contribution to maternal immunization: Vaccine Safety

- CEPI has partnered with the Brighton Collaboration for the Safety Platform for Emergency vACcines project in 2019 through the Taskforce for Global Health (https://brightoncollaboration.us/speac)
- Access to vaccine safety expertise, tools and standards
- Benefit-Risk Assessment of VAccines by TechnolOgy (BRAVATO)

SPEAC
a CEPI project
Safety Platform for Emergency vACcines

CEPI

Benefit-Risk Assessment of VAccines by TechnoIOgy (BRAVATO)

- *Standardized vaccine templates* with key benefit/risk assessment considerations, allowing standardized and effective communication of key information
- Originally developed for vector vaccines – VSV-Ebola and Yellow fever-Dengue were initial examples
  - COVID-19 pandemic – proliferation of vaccine candidates of all possible type – templates now for all possible vaccines – nucleic acid (mRNA, DNA), inactivated, etc.
- Template to summarize safety considerations of *Vaccines for Maternal Immunization* in development, with specific sections addressing:
  - Key Questions on the Pathogen, the Disease and Pregnancy
  - General Questions on Specific Vaccine Platforms and Characteristics (Based on the Brighton Collaboration BRAVATO vaccine platform modules)
  - Key Questions on Development and Planning for All Candidate Vaccines (regardless of construct/platform) for Pregnant and Lactating women
  - Key Questions for Post-Licensure Safety Evaluation of Vaccine Use During Pregnancy
  - Summary of Evaluation of Vaccine for Use During Pregnancy and Lactation

SPEAC
a CEPI project
Safety Platform for Emergency vACcines

CEPI

COVAX Maternal Immunization working group

- Important role in promoting maternal immunization with COVID-19 vaccines
- Unique forum for MI experts to
  - Identify and communicate research gaps
  - Facilitate information exchange
- Dissemination through
  - Webinars and reports
  - Website

CEPI

https://epi.tghn.org/covax-overview/clinical-science/maternal-immunization/#ref1

Maternal immunization in the context of WHO priority pathogen vaccine development and disease X

- Leverage learnings from COVID-19
  - Vaccine platform data
  - Knowledge sharing mechanisms (as exemplified by COVAX MIWG)
- Disease-specific approach for priority pathogens
- Inclusion of maternal immunization in pandemic preparedness strategies and concrete disease X development plans

Conclusion

- The COVAX Maternal Immunization Working Group has an important role to play for COVID-19 and beyond
- During the ongoing COVID-19 pandemic, we have witnessed progress in raising awareness, but the inclusion of pregnant women in clinical trials is still lagging behind
- Limited safety surveillance infrastructure in LMICs
- Much has been achieved and much remains to be done – Thank you to all contributors to the MIWG

CEPI

Session 1
Vaccine benefit-risk assessment post approval

Moderator

Andy Stergachis, PhD

Professor of Pharmacy & Global Health

University of Washington, Seattle, WA USA

Noa Dagan

Head of data & AI-driven medicine,

Clalit Research Institute

Vaccine effectiveness in pregnant women - Israel

Vaccine effectiveness (VE) in pregnant women - Israel

Noa Dagan MD, PhD, MPH

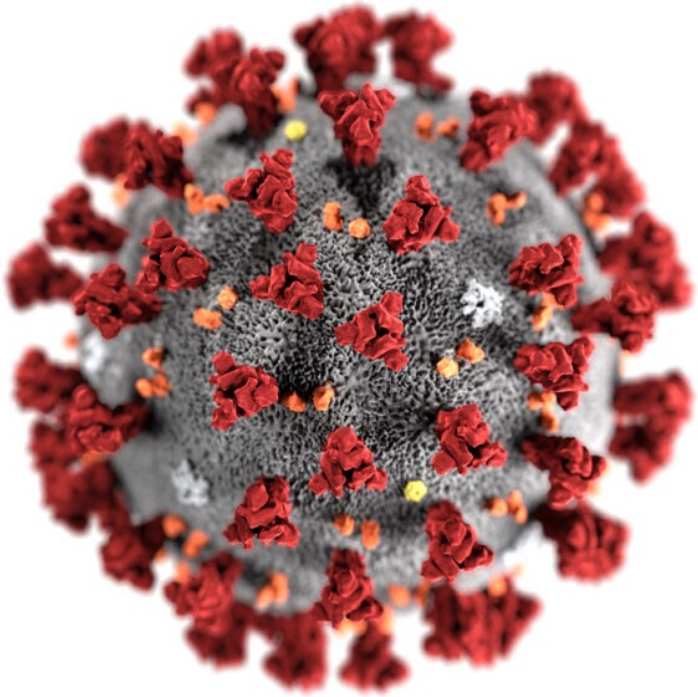
Head of Data & AI Driven Medicine,
Clalit Research Institute, Israel

Lecturer, Software & Information Systems Engineering, Ben Gurion University

November 2021

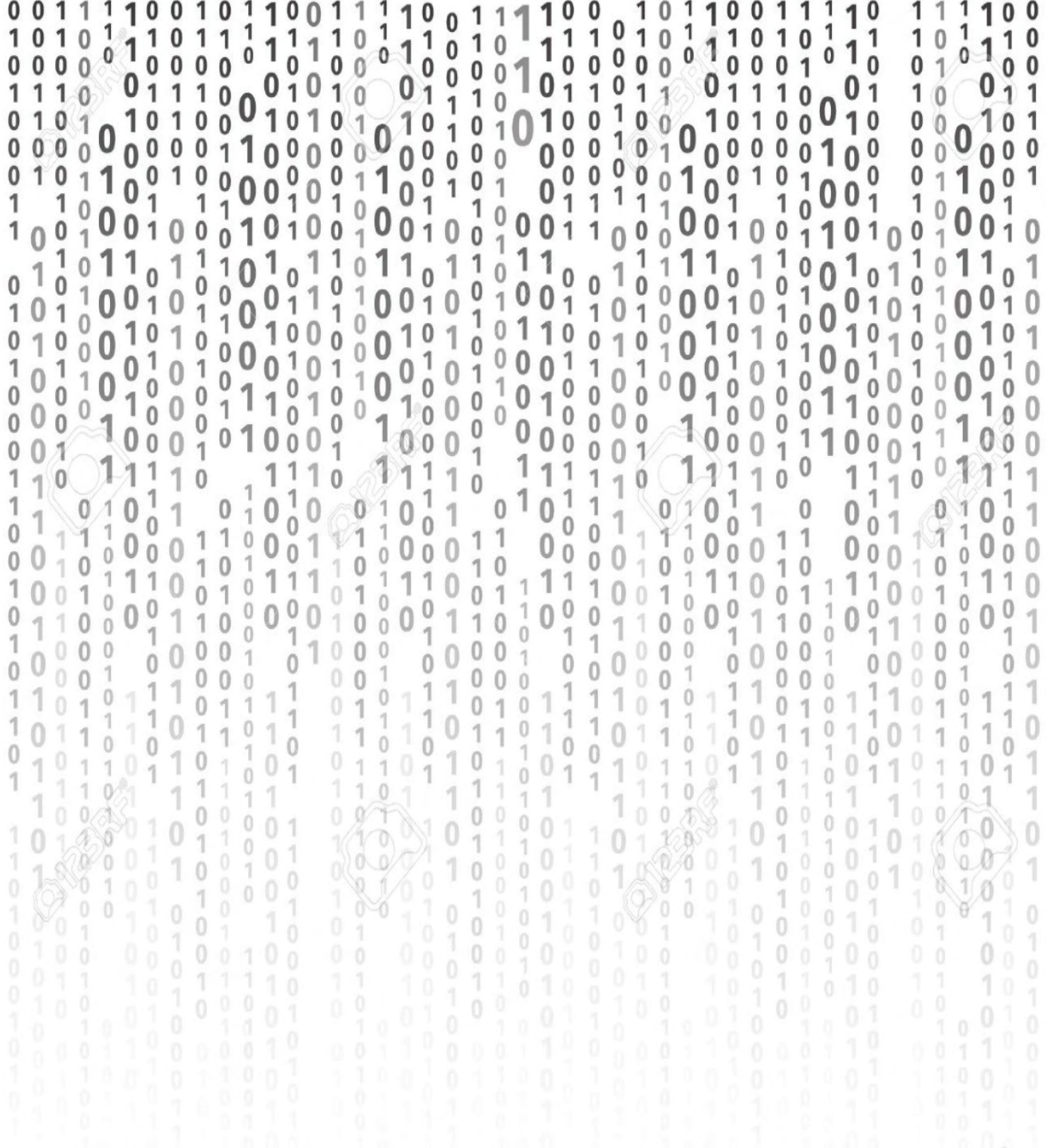
Setting – COVID-19 vaccines in Israel

- Vaccination campaign started on December 20, 2020
- Pfizer vaccines
- Very efficient rollout
- Recommendation for pregnant women shifted from uncertainty to clear recommendation to receive the vaccine
- Percent of pregnant women who got vaccinated increased gradually during the vaccination campaign



Setting – Clalit Health Services

- Largest healthcare organization in Israel (of 4 that provide national health insurance)
- >4.7M members (>50% of population)
- Digitalized >20 years
- Payer & provider
- Clinics & hospitals
- Low attrition rate



The need for observational data to study VE in pregnancy

- Pregnant women were not included in the phase 3 clinical trials of mRNA vaccines
- The immune system is known to undergo alterations during pregnancy => it is plausible that the immune response triggered by mRNA vaccines in pregnant women may be altered
- Confidence in VE among pregnant women was sown to be a strong predictor of COVID-19 vaccine acceptance

Challenge: simulating an RCT using observational data

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein.

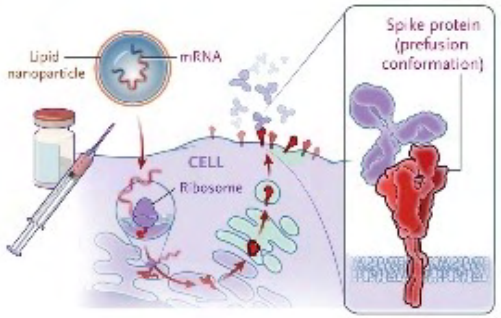
43,548 participants ≥16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

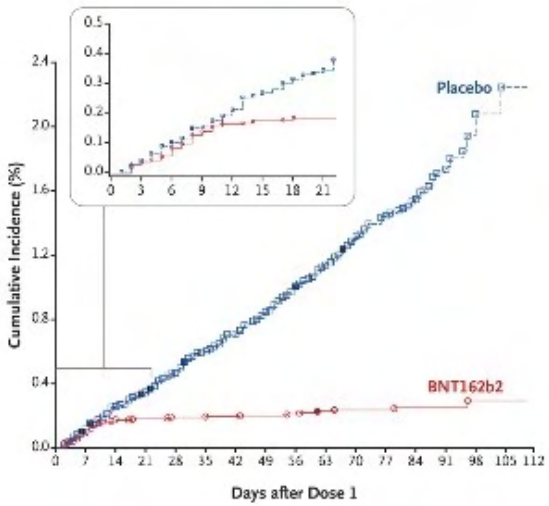
RESULTS

Safety:
Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

Efficacy:
The vaccine showed protection 7 days after the second dose; 95% efficacy was observed.

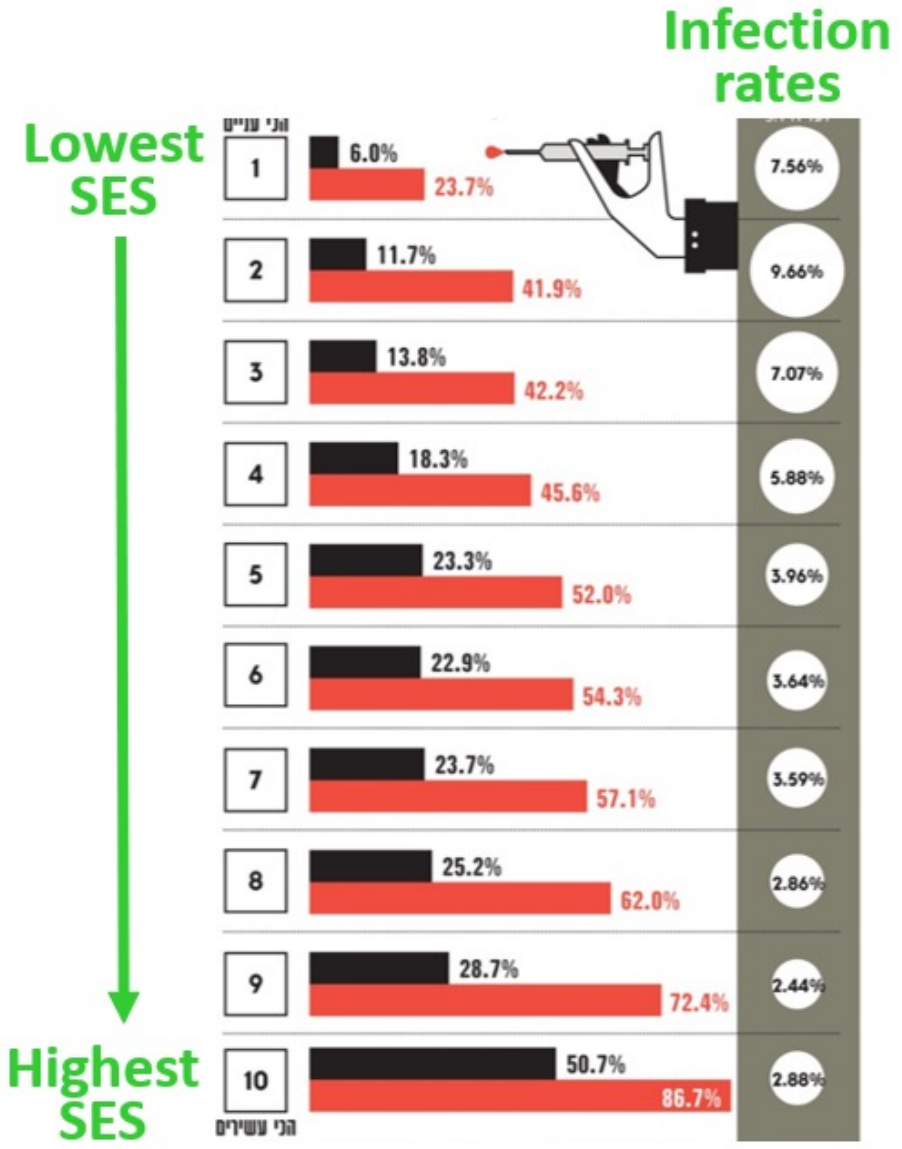
LIMITATIONS AND REMAINING QUESTIONS



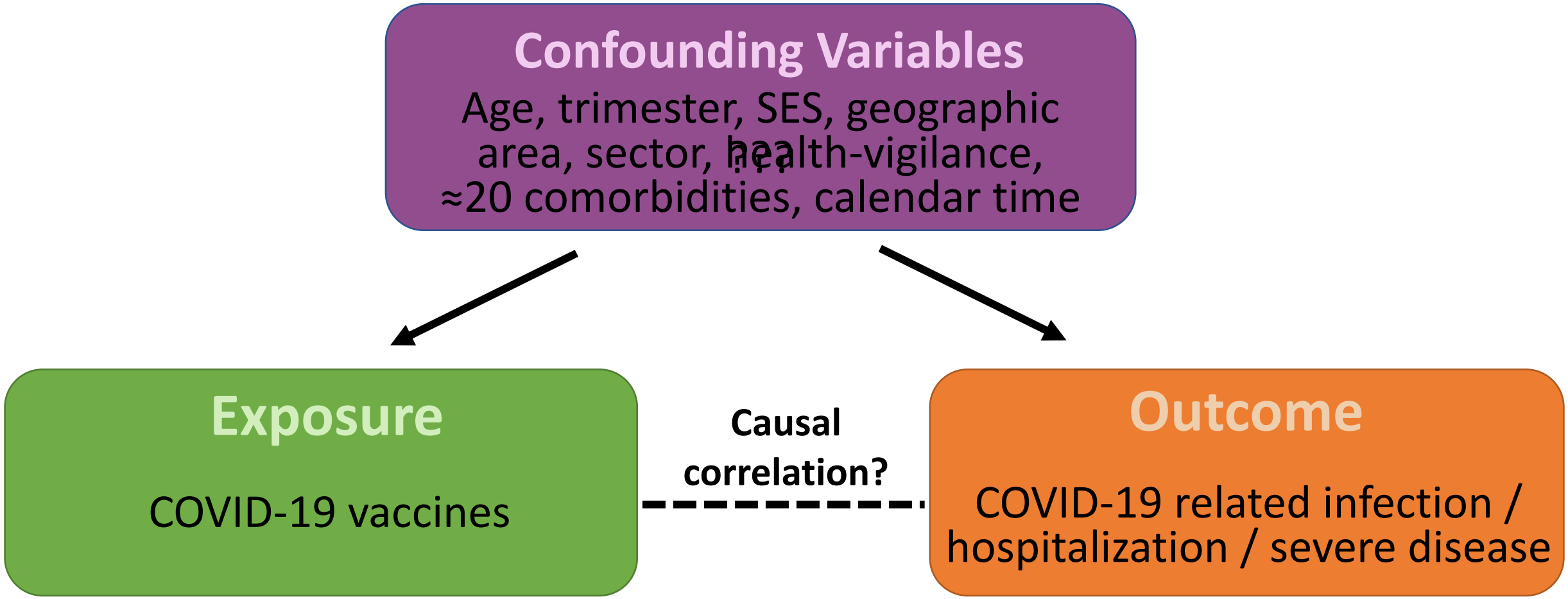


Challenge: simulating an RCT using observational data

- Vaccinated are different than non-vaccinated at baseline:
  - Demographics
  - Geographics
  - Health status
  - Cautiousness
- Hence, the two groups may also be different in their:
  - Likelihood of infection
  - Likelihood of seeking medical care
  - Prognostic factors for severe illness

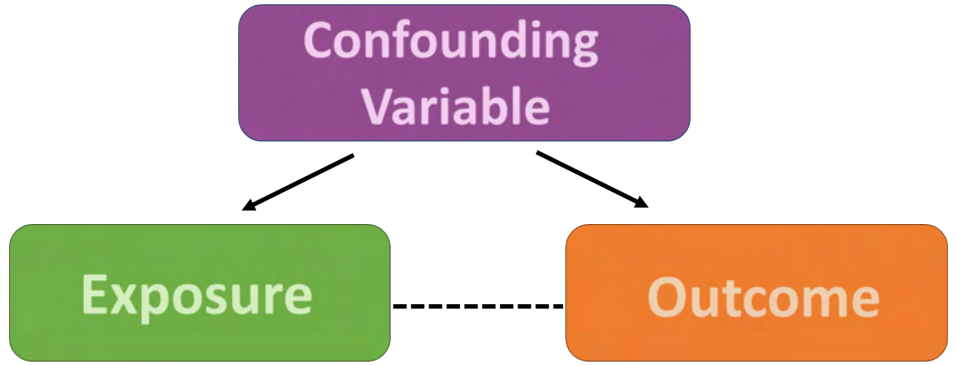


Challenge: simulating an RCT using observational data

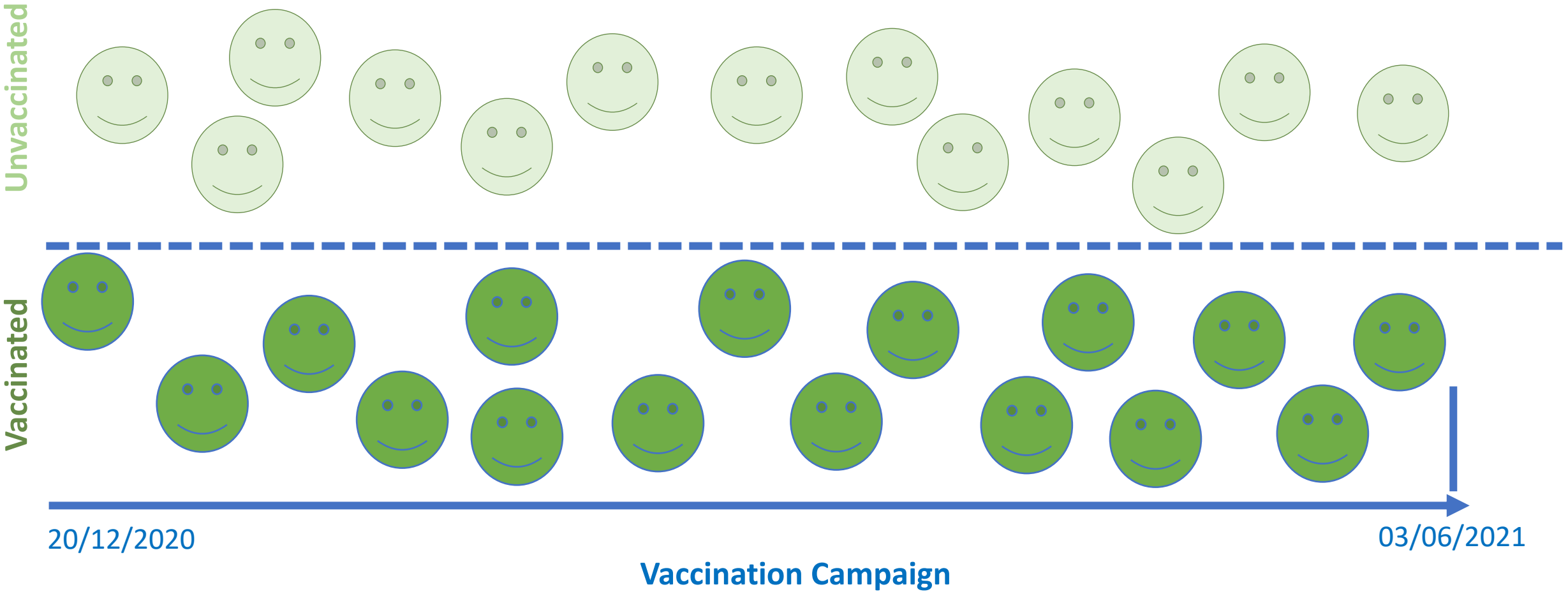


What kind of data is needed for evaluating VE

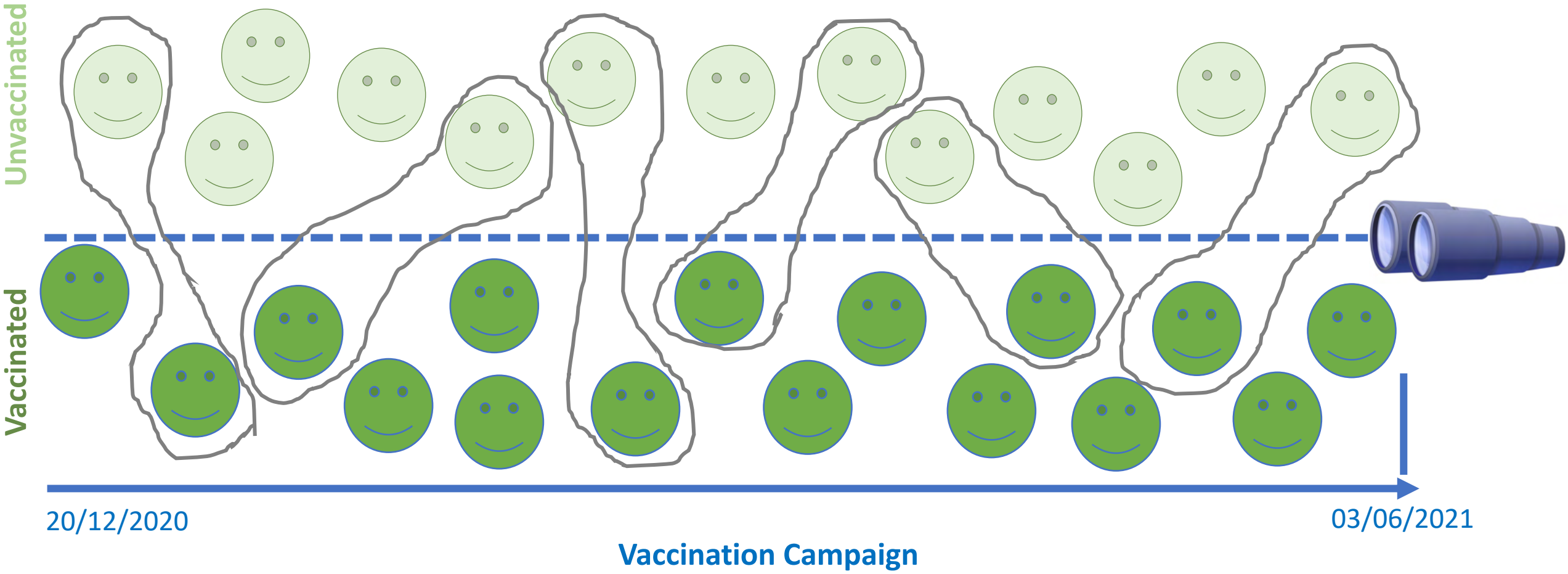
- Anonymized data of a large cohort of individuals that includes:
  - Vaccination status
  - All laboratory COVID-19 PCR tests and results
  - All outcomes for patients that are treated in the community
  - All outcomes for patients that are treated in the hospitals (including hospitalization status, severity and death events)
  - Relevant background sociodemographic information (age, SES, geographic area)
  - Relevant background medical information (pregnancy trimester, all CDC risk factors for severe COVID-19, vaccination history etc.)



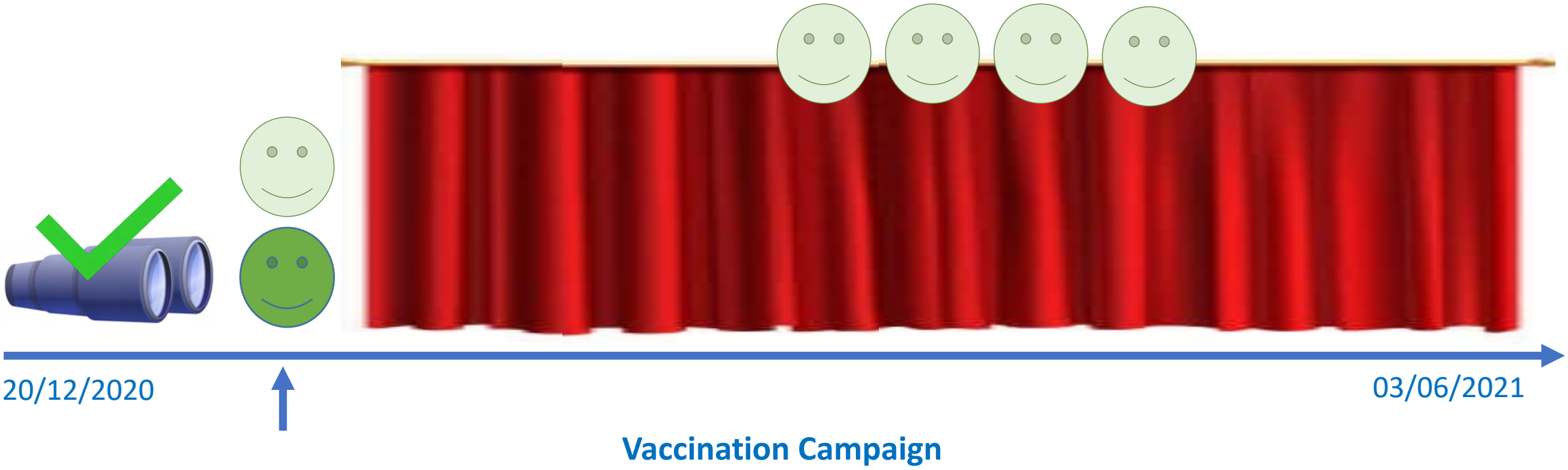
Defining a target trial using observational data



Defining a target trial using observational data



Defining a target trial* using observational data



Vaccinated person

Matched control

* Hernán MA, Robins JM. Using big data to emulate a target trial when a randomized trial is not available. Am J Epidemiol 2016;183:758-64.

nature medicine

BRIEF COMMUNICATION

https://doi.org/10.1038/s41591-021-01490-8

Brief Communication | Published: 07 September 2021

Effectiveness of the BNT162b2 mRNA COVID-19 vaccine in pregnancy

Noa Dagan, Noam Barda, Tal Biron-Shental, Maya Makov-Assif, Calanit Key, Isaac S. Kohane, Miguel A. Hernán, Marc Lipsitch, Sonia Hernandez-Diaz, Ben Y. Reis & Ran D. Balicer

Nature Medicine **27**, 1693–1695 (2021) | Cite this article

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

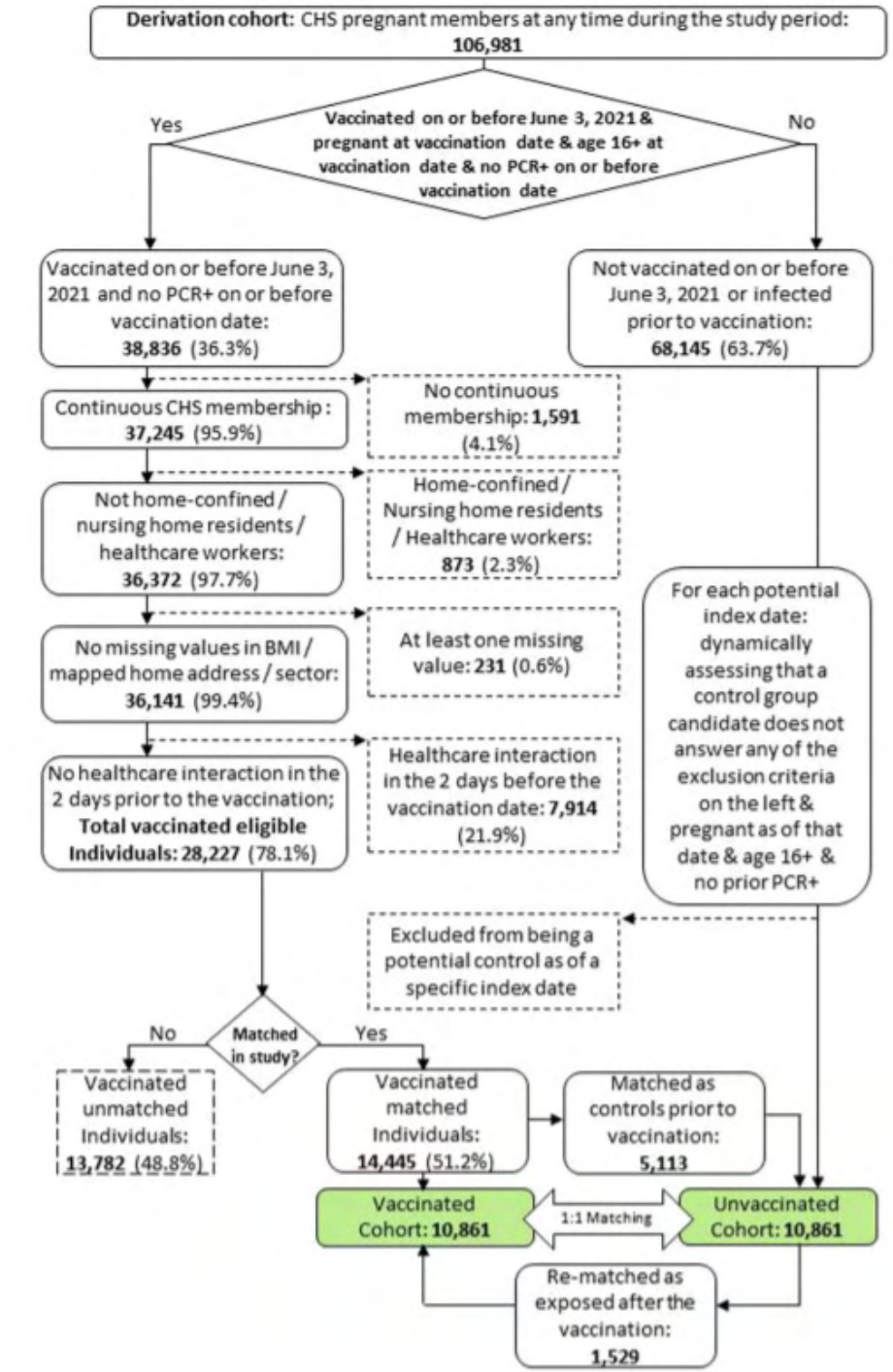
BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting

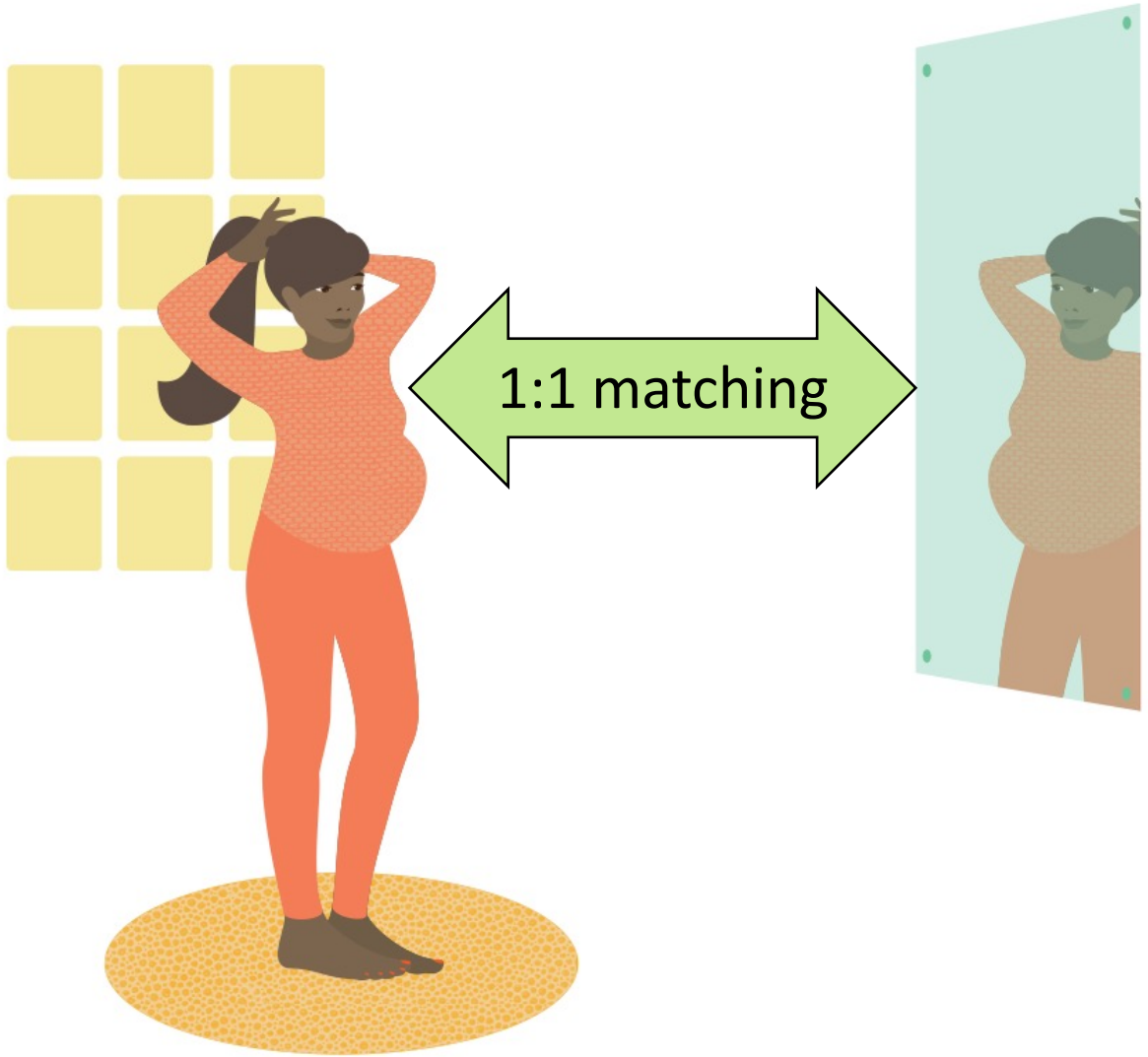
Noa Dagan, M.D., Noam Barda, M.D., Eldad Kepten, Ph.D., Oren Miron, M.A., Shay Perchik, M.A., Mark A. Katz, M.D., Miguel A. Hernán, M.D., Marc Lipsitch, D.Phil., Ben Reis, Ph.D., and Ran D. Balicer, M.D.

Drs. Dagan and Barda contributed equally to this article.

This article was published on February 24, 2021, at NEJM.org.

Based on methodology from our NEJM study of Pfizer VE in the general population from Feb 2021


Derivation cohort: CHS pregnant members at any time during the study period: 106,981
Yes
Vaccinated on or before June 3, 2021 & pregnant at vaccination date & age 16+ at vaccination date & no PCR+ on or before vaccination date
No
Vaccinated on or before June 3, 2021 and no PCR+ on or before vaccination date: 38,836 (36.3%)
Not vaccinated on or before June 3, 2021 or infected prior to vaccination: 68,145 (63.7%)
Continuous CHS membership: 37,245 (95.9%)
No continuous membership: 1,591 (4.1%)
Not home-confined / nursing home residents / healthcare workers: 36,372 (97.7%)
Home-confined / Nursing home residents / Healthcare workers: 873 (2.3%)
No missing values in BMI / mapped home address / sector: 36,141 (99.4%)
At least one missing value: 231 (0.6%)
No healthcare interaction in the 2 days prior to the vaccination; Total vaccinated eligible Individuals: 28,227 (78.1%)
Healthcare interaction in the 2 days before the vaccination date: 7,914 (21.9%)
For each potential index date: dynamically assessing that a control group candidate does not answer any of the exclusion criteria on the left & pregnant as of that date & age 16+ & no prior PCR+
Excluded from being a potential control as of a specific index date
No
Matched in study?
Yes
Vaccinated unmatched Individuals: 13,782 (48.8%)
Vaccinated matched Individuals: 14,445 (51.2%)
Matched as controls prior to vaccination: 5,113
Vaccinated Cohort: 10,861
1:1 Matching
Unvaccinated Cohort: 10,861
Re-matched as exposed after the vaccination: 1,529


1:1 matching


Negative
control
Outcome*

*

Table 1 Vaccine effectiveness measures

From: Effectiveness of the BNT162b2 mRNA COVID-19 vaccine in pregnancy

Period	Documented infection		Symptomatic infection		Hospitalization		Severe disease	
	1 – RR (95% CI)	RD (95% CI)	1 – RR (95% CI)	RD (95% CI)	1 – RR (95% CI)	RD (95% CI)	1 – RR (95% CI)	RD (95% CI)
Days 14–20 after first dose	67% (40–84%)	309.22 (145.43–485.69)	66% (32–86%)	223.59 (82.44–361.63)	3 versus 0[a]		2 versus 0[a]	
Days 21–27 after first dose	71% (33–94%)	157.30 (41.42–285.23)	76% (30–100%)	116.52 (26.92–217.92)	5 versus 0[a]		0 versus 0[a]	
Days 7–56 after second dose	96% (89–100%)	933.40 (685.60–1192.33)	97% (91–100%)	621.70 (433.68–847.26)	89% (43–100%)	132.28 (31.67–241.03)	1 versus 0[a]	

RRs and RDs (per 100,000 persons) of COVID-19 outcomes for vaccination versus no vaccination at several time points after vaccination in pregnant women who are members of the CHS, 20 December 2020 through to 3 June 2021. The study population numbered 10,861 individuals in each arm and 1,529 individuals were first included as unvaccinated and then re-recruited as vaccinated.

[a]Estimates were only calculated for cells with more than five events; otherwise, raw counts are reported.

Main conclusions:

- BNT162b2 mRNA COVID-19 vaccine is highly effective in pregnant women for the variants circulating in Israel at the time of the study
- Vaccine effectiveness was comparable to that estimated in the general population
- => It is plausible that the VE estimated in the general population for future variants may be used to infer the effectiveness in pregnant women for the same variants

Lessons for the next pandemic:

- The importance of good data infrastructures
- The importance of developing research capabilities for producing real-time research insights to inform the population

Clalit
Research
Institute

Alisa Kachikis, MD, MSc

Assistant Professor of Maternal-Fetal Medicine,

Department of Obstetrics & Gynecology

University of Washington

Vaccine reactogenicity in pregnant women - US

Vaccine reactogenicity in pregnant women - US

Alisa Kachikis, MD, MSc

COVAX MATERNAL IMMUNIZATION WORKING GROUP WEBINAR

November 18, 2021

UW Medicine

DISCLOSURES

Consultant on maternal immunization related projects

- GlaxoSmithKline
- Pfizer

Co-Investigator on COVID-19 seroprevalence study funded by Merck.

OVERVIEW

- Available data sources early on:
  - COVID-19 in pregnancy
  - COVID-19 vaccine in pregnancy
- Studies on vaccine reactogenicity in the United States
- What have we learned?

OVERVIEW

- Available data sources early on:
  - COVID-19 in pregnancy
  - COVID-19 vaccine in pregnancy
- Studies on vaccine reactogenicity in the United States
- What have we learned?

Data sources in the US: COVID-19 infection in pregnancy

Start of the pandemic

- Knowledge about increased morbidity and mortality with influenza, also SARS, MERS, in pregnancy.
- Uncertainty about impact of COVID-19 illness in pregnant individuals.

- CDC surveillance
- Establishment of national and regional registries and collaborations
  - PRIORITY registry (UCSF)
  - Washington State COVID-19 in Pregnancy Collaborative
- Site specific data (i.e. New York)

Data sources in the US: COVID-19 vaccine in pregnancy

Presentation of results of clinical trials to:

- Food and Drug Administration (FDA) for consideration of Emergency Use Authorization (EUA)
- CDC's Advisory Committee for Immunization Practices (ACIP)

Data in the pregnant population

- Pregnant persons were EXCLUDED from clinical trials
- DART data: only available for Pfizer
- Limited data on vector virus vaccines (e.g. Ebola vaccine) in pregnancy

Data sources in the US: COVID-19 vaccine in pregnancy

Post approval data sources on vaccine reactogenicity in pregnant individuals

- CDC's VSAFE data and prospective study
- Vaccine Adverse Event Reporting Surveillance (VAERS) system
- Site specific studies:
  - University of Washington's Registry for COVID-19 vaccine in Pregnancy and Lactation with prospective survey-based study

OB/GYN OBSTETRICS & GYNECOLOGY UNIVERSITY OF WASHINGTON

OVERVIEW

- Available data sources early on:
  - COVID-19 in pregnancy
  - COVID-19 vaccine in pregnancy
- Studies on vaccine reactogenicity in the United States
- What have we learned?

The NEW ENGLAND JOURNAL of MEDICINE

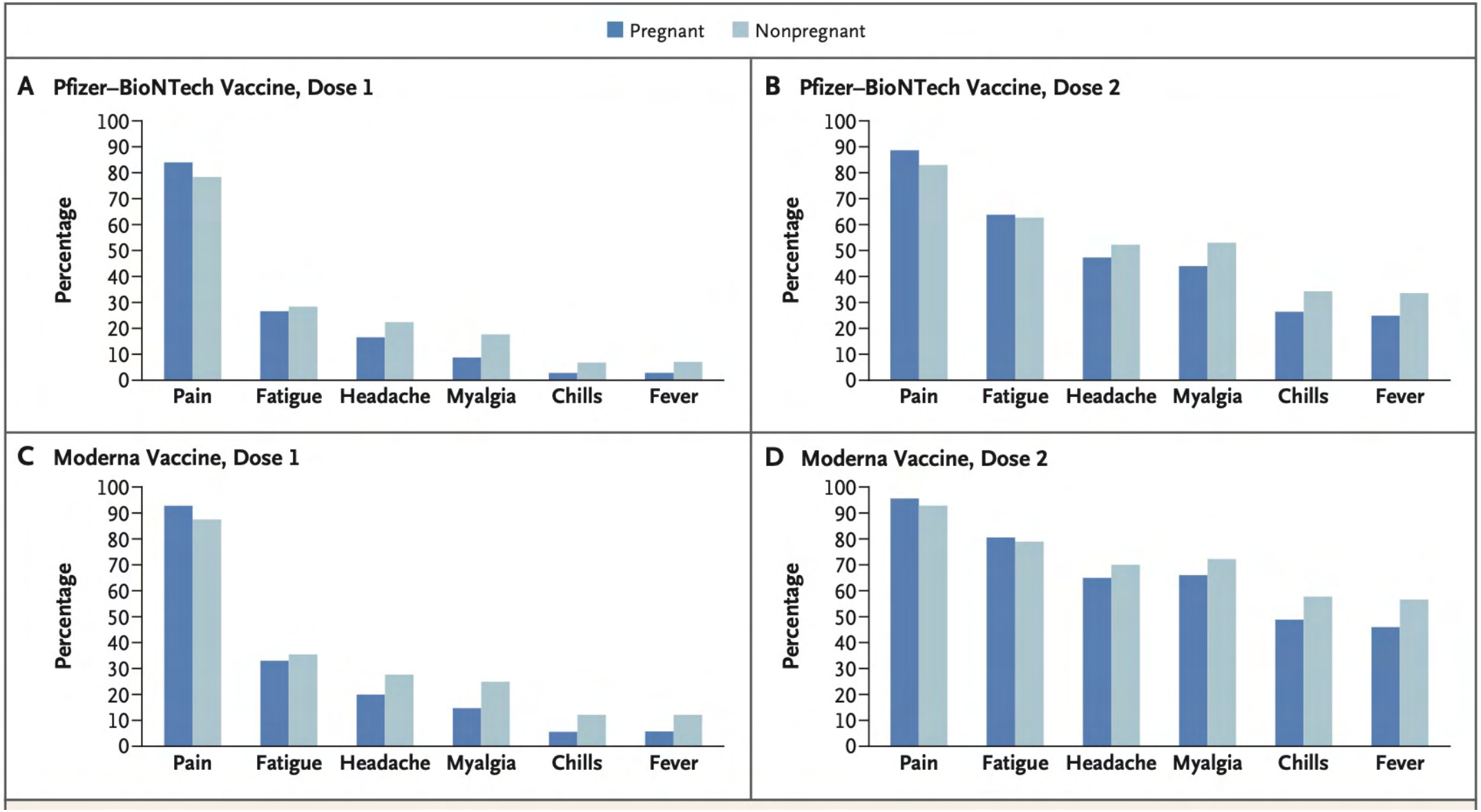
ORIGINAL ARTICLE

Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons

Tom T. Shimabukuro, M.D., Shin Y. Kim, M.P.H., Tanya R. Myers, Ph.D., Pedro L. Moro, M.D., Titilope Oduyebo, M.D., Lakshmi Panagiotakopoulos, M.D., Paige L. Marquez, M.S.P.H., Christine K. Olson, M.D., Ruiling Liu, Ph.D., Karen T. Chang, Ph.D., Sascha R. Ellington, Ph.D., Veronica K. Burkel, M.P.H., Ashley N. Smoots, M.P.H., Caitlin J. Green, M.P.H., Charles Licata, Ph.D., Bicheng C. Zhang, M.S., Meghna Alimchandani, M.D., Adamma Mba-Jonas, M.D., Stacey W. Martin, M.S., Julianne M. Gee, M.P.H., and Dana M. Meaney-Delman, M.D., for the CDC v-safe COVID-19 Pregnancy Registry Team*

CDC

- V-SAFE
- VAERS
- Dec 14– Feb 28, 2021
- 35,691 participants who reported pregnancy



Most Frequent Local & Systemic Reactions Reported via V-safe Surveillance System on the Day after Vaccination

JAMA Network | Open™

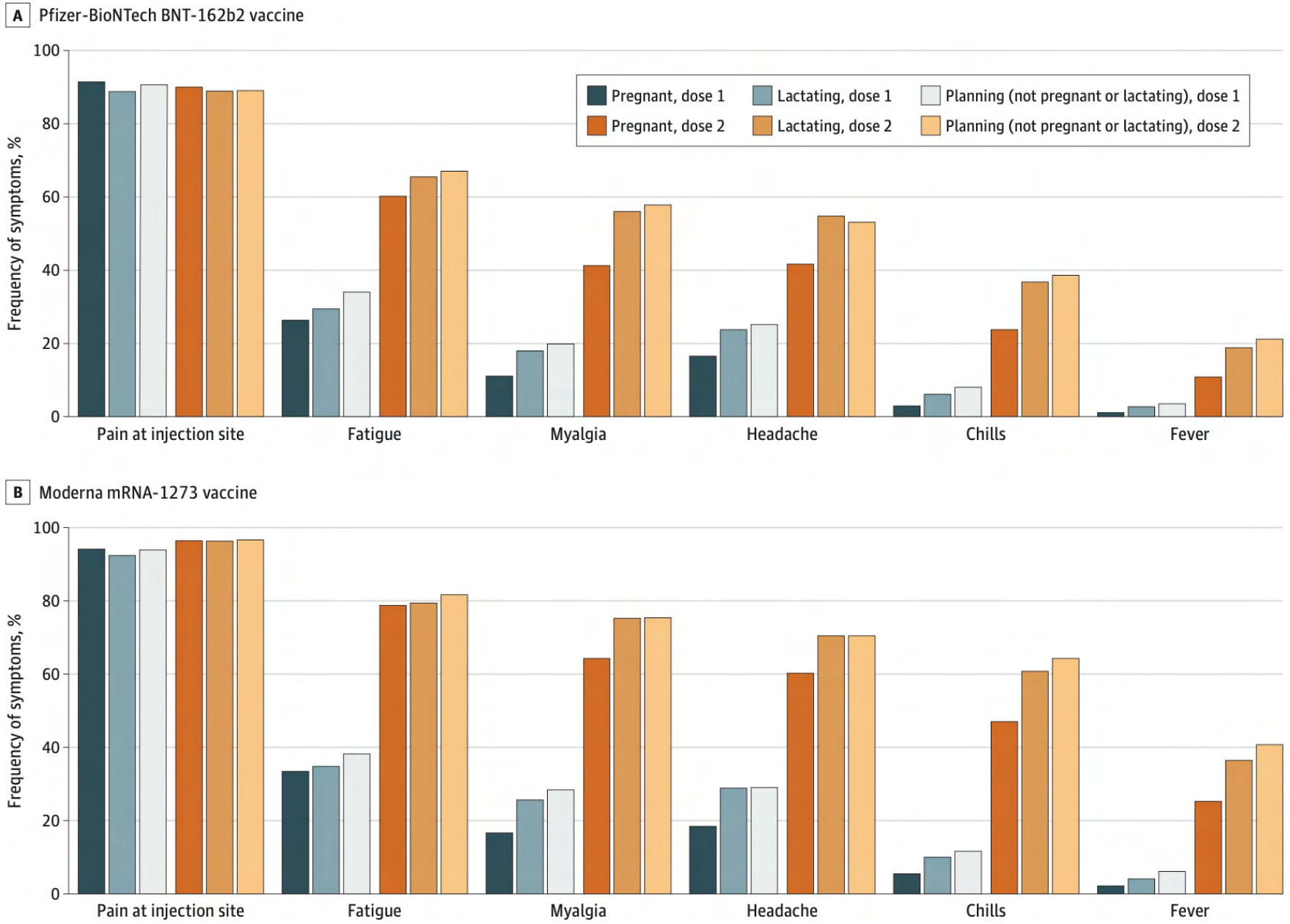
Research Letter | Public Health

Short-term Reactions Among Pregnant and Lactating Individuals in the First Wave of the COVID-19 Vaccine Rollout

Alisa Kachikis, MD, MS; Janet A. Englund, MD; Michael Singleton, PhD; Isabela Covelli, BS; Alison L. Drake, PhD, MPH; Linda O. Eckert, MD

University of Washington prospective survey-based study

- Data: Jan 23 – March 16, 2021
- 17 525 participants with known pregnancy status
  - Pregnant: 7809; Lactating: 6815; Planning pregnancy: 2901



REACTIONS 1 DAY POST-VACCINATION

UW Medicine

RESPONSES RELATED TO LACTATION

- Interrupted breastfeeding:
  - 1st dose: 2.3%
  - 2nd dose: 2.2%
- Decreased milk supply for less than 24 hours
  - 1st dose: 5.0%
  - 2nd dose: 7.2%
- Concerns about the infant after vaccination:
  - 1st dose: 3.0%
  - 2nd dose: 4.4%

Any concerns with infant after feeding with breastmilk (qualitative data), self-limited

- mostly:
  - Feeling unsure about the vaccine in general
  - Worry about breastmilk supply
  - Sleepiness
  - Fussiness
- Less commonly:
  - Rash
  - Diarrhea
  - Congestion

OTHER RESPONSES

	Pregnant participants (n= 7456)	Lactating participants (n= 6466)	Participants planning pregnancy (n= 2669)
Should individuals receive the COVID-19 vaccine …	… if pregnant?	… if lactating?	… if planning pregnancy?
Yes	6153 (82.5)	6080 (94.0)	2520 (94.4)
Depends on the circumstances	1300 (17.4)	382 (5.9)	148 (5.6)
No	3 (0)	4 (0.1)	1 (0)

OVERVIEW

- Available data sources early on:
  - COVID-19 in pregnancy
  - COVID-19 vaccine in pregnancy
- Studies on vaccine reactogenicity in the United States
- What have we learned?

WHAT HAVE WE LEARNED?

- Having data for the pregnant population is extremely important in the midst of a pandemic
- Data collection:
  - Establishing networks of hospitals/care centers for prospective clinical data collection
  - Surveillance systems and surveys can be effective ways to collect data
- Characteristics of pregnant individuals
  - May perceive their own risks with disease or treatment differently
  - Extremely willing to participate in research

QUESTIONS?

Marian Knight

Professor of Maternal and Child Population Health, University of Oxford, UK

The power of obstetric surveillance systems – the UK's experience tracking COVID-19 during pregnancy and the impacts of variants and vaccination

OXFORD POPULATION HEALTH

UNIVERSITY OF OXFORD

NPEU

UKOSS

UK Obstetric Surveillance System

The power of obstetric surveillance systems: the UK's experience tracking COVID-19 during pregnancy and the impacts of variants and vaccination

Professor Marian Knight,

National Perinatal Epidemiology Unit, University of Oxford, UK

UKOSS
UK Obstetric Surveillance System

UK Obstetric Surveillance System

- Established in all obstetric units in the UK since 2005 (n=194 hospitals)
- Effectively covers the whole birth population of the UK
- Monthly case reporting, including negative case reports
- Rapid responsive studies conducted with other emerging infections (Influenza A/H1N1, Zika virus)
- ‘Pandemic portfolio’ study funded and hibernated in 2012

Knight M, Brocklehurst P, O’Brien P, Quigley MA, Kurinczuk JJ. Planning for a cohort study to investigate the impact and management of influenza in pregnancy in a future pandemic. Southampton (UK): NIHR Journals Library; 2015.
Simpson CR, Beever D, Challen K, et al. The UK's pandemic influenza research portfolio: a model for future research on emerging infections. Lancet Infect Dis. 2019;19(8):e295-e300. doi:10.1016/S1473-3099(18)30786-2

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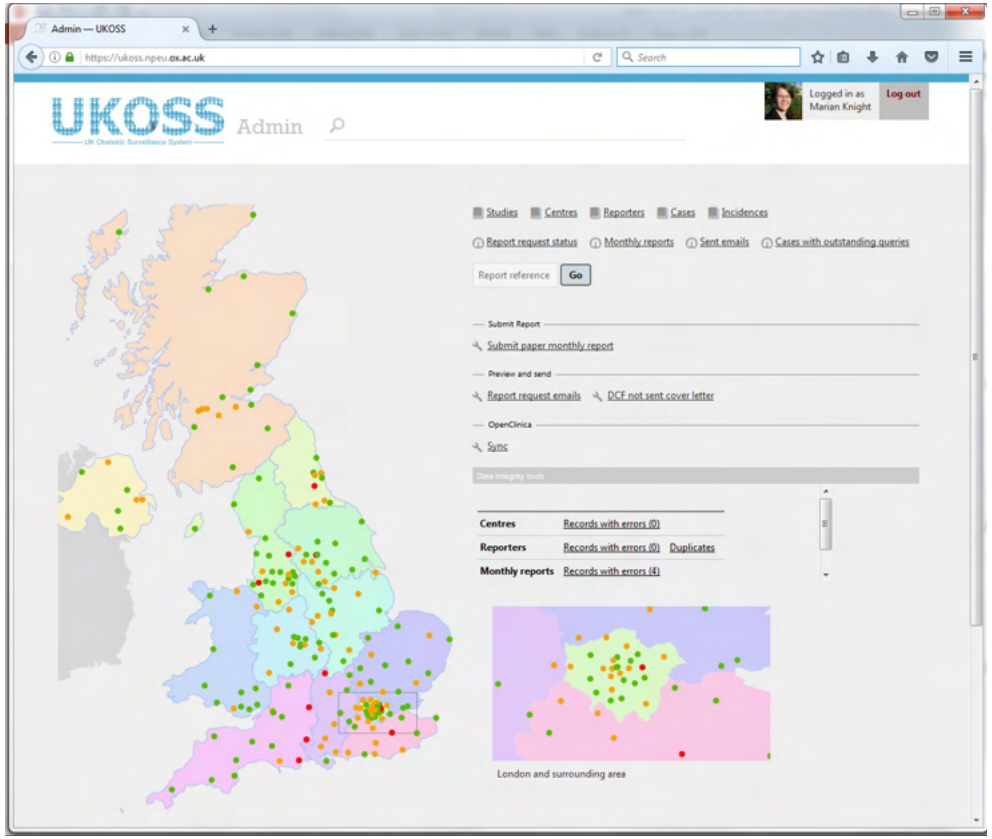
UK Obstetric Surveillance System (UKOSS)



- Monthly prospective case collection from obstetric anaesthetist, obstetrician, midwife and risk midwife (individualised by hospital)
- Anonymous information collected on women's characteristics, treatment and outcomes in order to improve quality of care
- Conditions included change over time
- Central data collection

Completed Studies

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2006
- Eclampsia
- Peripartum Hysterectomy
- Acute Fatty Liver
- Antenatal PE
- TB

2007
- Gastroschisis

2008
- Extreme Obesity
- FMAIT

2009
- Therapies for peripartum haemorrhage
- Multiple repeat caesarean section
- Pregnancy in renal transplant recipients

2010
- H1N1v influenza in pregnancy
- Antenatal Stroke
- Failed Intubation
- Malaria
- Congenital Diaphragmatic Hernia
- Myocardial Infarction
- Uterine Rupture

2011
- Sickle cell disease in pregnancy
- Placenta accreta
- Aortic dissection
- Obstetric cholestasis

2012
- Pregnancy in non-renal transplant recipients
- Pulmonary vascular disease
- Severe maternal sepsis
- HELLP
- Pregnancy in women with a gastric band

2013
- Myeloproliferative disorders
- Pituitary tumours
- Massive transfusion in obstetric haemorrhage

2014
- CKD stage 5
- Cardiac arrest in pregnancy
- ITP in pregnancy
- Pregnancy in women aged 48 or over

2015
- Adrenal tumours in pregnancy
- Pregnancy in women with artificial heart valves
- Anaphylaxis in Pregnancy

2016
- Pregnancy in women with a gastric bypass
- Vasa praevia
- Pulmonary embolism
- Pulmonary aspiration

2017
- Breast cancer in pregnancy
- Cystic Fibrosis
- Epidural haematoma or abscess
- Female Genital Mutilation type 3
- Severe epilepsy in pregnancy
- Single Twin Demise
- Spontaneous haemoperitoneum in pregnancy
- WHO GLOSS Global Maternal Sepsis Study
- Zika virus in pregnancy

2018
- Seasonal influenza
- Low maternal plasma fibrinogen

2019
- Near-miss suicide
- Impacted fetal head
- High Neuraxial Block

2020
- Cirrhosis in pregnancy
- Diabetic ketoacidosis in pregnancy
- Hyponatraemia

2021
- COVID-19 Vaccination in Pregnancy
- Extremely preterm prelabour rupture of membranes (EPPROM)

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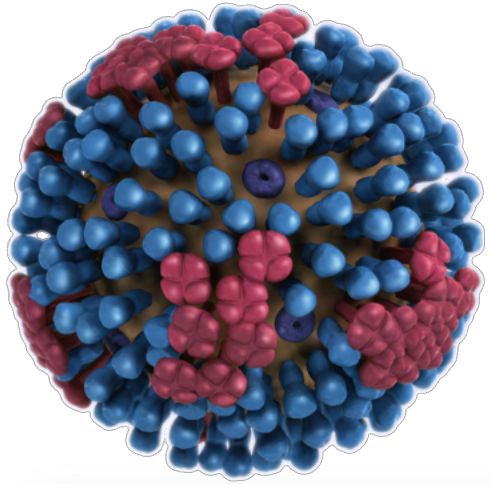
A 9 year gestation

2009 A/H1N1 influenza



2011 – call for 'hibernated studies'

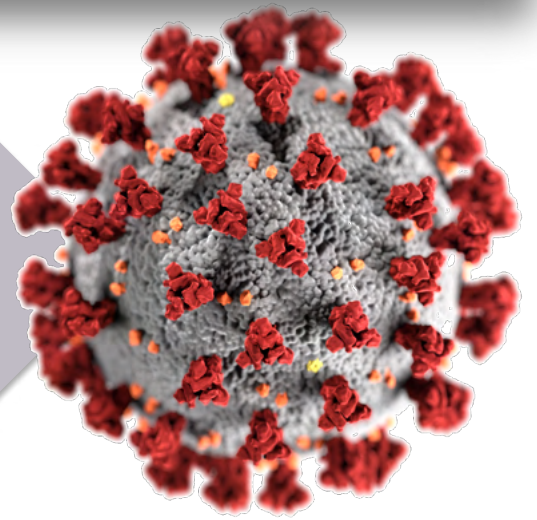
2012 - Funding awarded: study materials and database prepared

2015
Possible modification for other viruses

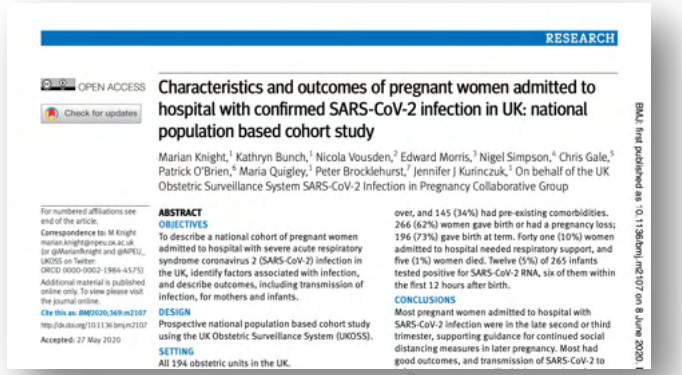
2017
Activated for seasonal influenza

2018
Rapid activation exercise

February 2020
Request to modify for SARS-CoV-2



22/03/2020
SARS-CoV-2



RESEARCH

OPEN ACCESS

Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study

Marian Knight,[1] Kathryn Bunch,[1] Nicola Vousden,[2] Edward Morris,[3] Nigel Simpson,[4] Chris Gale,[5] Patrick O'Brien,[6] Maria Quigley,[1] Peter Brocklehurst,[7] Jennifer J Kurinczuk,[1] On behalf of the UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group

ABSTRACT

OBJECTIVES

To describe a national cohort of pregnant women admitted to hospital with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in the UK, identify factors associated with infection, and describe outcomes, including transmission of infection, for mothers and infants.

DESIGN

Prospective national population based cohort study using the UK Obstetric Surveillance System (UKOSS).

SETTING

All 194 obstetric units in the UK.

over, and 145 (34%) had pre-existing comorbidities. 266 (62%) women gave birth or had a pregnancy loss; 196 (73%) gave birth at term. Forty one (10%) women admitted to hospital needed respiratory support, and five (1%) women died. Twelve (5%) of 265 infants tested positive for SARS-CoV-2 RNA, six of them within the first 12 hours after birth.

CONCLUSIONS

Most pregnant women admitted to hospital with SARS-CoV-2 infection were in the late second or third trimester, supporting guidance for continued social distancing measures in later pregnancy. Most had good outcomes, and transmission of SARS-CoV-2 to

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Research

Perinatal outcomes after maternal 2009/H1N1 infection: national cohort study

BMJ 2011 ; 342 doi: https://doi.org/10.1136/bmj.d3214 (Published 14 June 2011)
Cite this as: BMJ 2011;342:d3214

Article | Related content | Metrics | Responses | Peer review

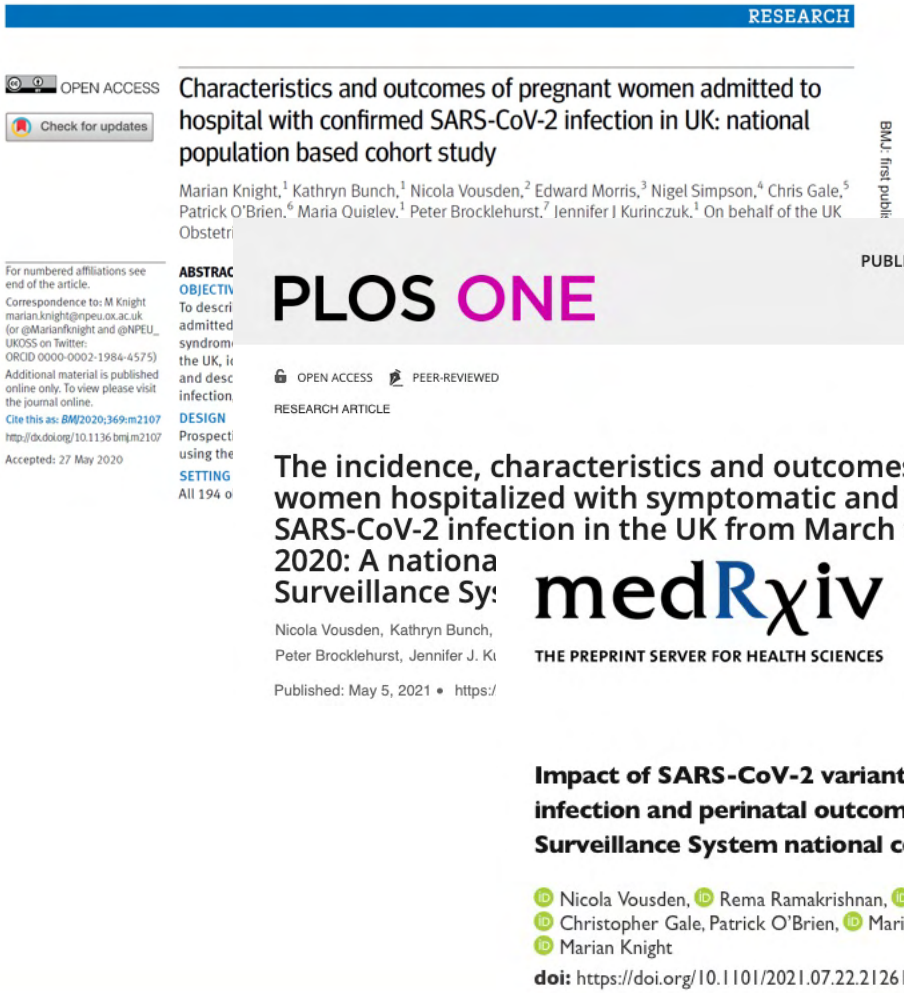
Matthias Pierce, medical statistician [1],
Jennifer J Kurinczuk, reader in perinatal epidemiology and deputy director [1], Patsy Spark, programmer [1],
Peter Brocklehurst, clinical epidemiologist and director [1], Marian Knight, senior clinical research fellow [1]
on behalf of UKOSS

Author affiliations

Correspondence to: M Knight marian.knight@npeu.ox.ac.uk

UKOSS
UK Obstetric Surveillance System

Covid-19 and pregnancy



RESEARCH

OPEN ACCESS

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Marian Knight,[1] Kathryn Bunch,[1] Nicola Vousden,[2] Edward Morris,[3] Nigel Simpson,[4] Chris Gale,[5] Patrick O'Brien,[6] Maria Quigley,[1] Peter Brocklehurst,[7] Jennifer J Kurinczuk,[1] On behalf of the UK Obstetr

For numbered affiliations see end of the article.

Correspondence to: M Knight marian.knight@npeu.ox.ac.uk (or @Marianfknight and @NPEU_UKOSS on Twitter: ORCID 0000-0002-1984-4575)

Additional material is published online only. To view please visit the journal online.

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Accepted: 27 May 2020

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RESEARCH ARTICLE

The incidence, characteristics and outcomes of pregnant women hospitalized with symptomatic and asymptomatic SARS-CoV-2 infection in the UK from March to September 2020: A nationa Surveillance Sy

Nicola Vousden, Kathryn Bunch, Peter Brocklehurst, Jennifer J. Ku

Published: May 5, 2021 • https:/

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Impact of SARS-CoV-2 variant on the severity of maternal infection and perinatal outcomes: Data from the UK Obstetric Surveillance System national cohort

Nicola Vousden, Rema Ramakrishnan, Kathryn Bunch, Edward Morris, Nigel Simpson, Christopher Gale, Patrick O'Brien, Maria Quigley, Peter Brocklehurst, Jennifer J Kurinczuk, Marian Knight

doi: https://doi.org/10.1101/2021.07.22.21261000

EDITORIALS

Check for updates

1 National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, UK

2 Institute of Applied Health Research, University of Birmingham, Birmingham, UK

3 UK Obstetric Surveillance System

Include pregnant women in research—particularly covid-19 research

Adapting interventions and changing attitudes will drive scientific progress

Marian Knight, [1] R Katie Morris, [2] Jenny Furniss, [3] Lucy C Chappell[4]

The UK Confidential Enquiries into Maternal Deaths have repeatedly highlighted inequities in the medical treatment of pregnant and postpartum women, noting or breastfeeding allows safety concerns to be allayed for women, their families, and healthcare professionals.

BMJ: first published a

Maternal, Newborn and Infant Clinical Outcome Review Programme

MBRRACE-UK Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

Saving Lives, Improving Mothers' Care

Rapid report: Learning from SARS-CoV-2-related and associat

Maternal, Newborn and Infant Clinical Outcome Review Programme

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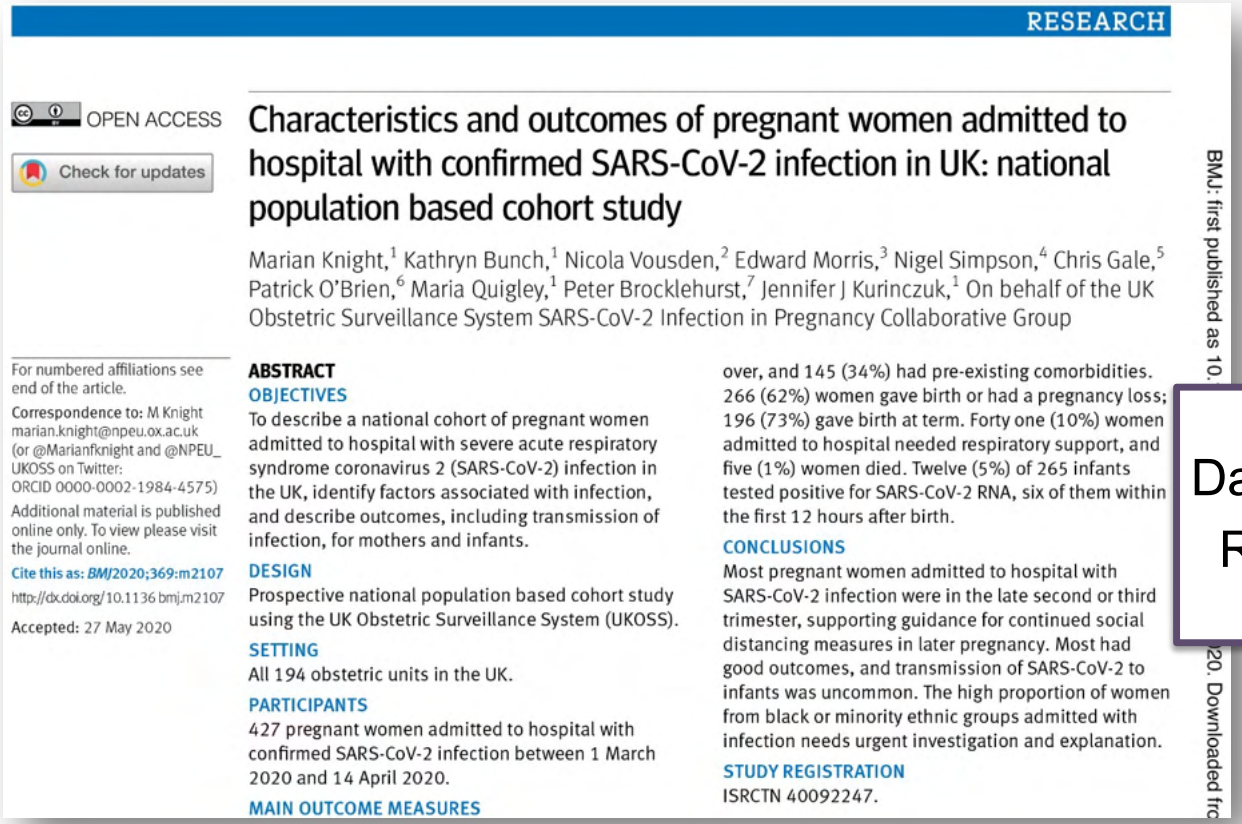
Saving Lives, Improving Mothers' Care

Rapid report 2021: Learning from SARS-CoV-2-related and associated maternal deaths in the UK

June 2020-March 2021

Epidemiology and outcomes



RESEARCH

OPEN ACCESS

Check for updates

Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study

Marian Knight,[1] Kathryn Bunch,[1] Nicola Vousden,[2] Edward Morris,[3] Nigel Simpson,[4] Chris Gale,[5] Patrick O'Brien,[6] Maria Quigley,[1] Peter Brocklehurst,[7] Jennifer J Kurinczuk,[1] On behalf of the UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group

For numbered affiliations see end of the article.

Correspondence to: M Knight marian.knight@npeu.ox.ac.uk (or @Marianfknight and @NPEU_UKOSS on Twitter: ORCID 0000-0002-1984-4575)

Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ*2020;369:m2107

http://dx.doi.org/10.1136/bmj.m2107

Accepted: 27 May 2020

ABSTRACT

OBJECTIVES

To describe a national cohort of pregnant women admitted to hospital with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in the UK, identify factors associated with infection, and describe outcomes, including transmission of infection, for mothers and infants.

DESIGN

Prospective national population based cohort study using the UK Obstetric Surveillance System (UKOSS).

SETTING

All 194 obstetric units in the UK.

PARTICIPANTS

427 pregnant women admitted to hospital with confirmed SARS-CoV-2 infection between 1 March 2020 and 14 April 2020.

MAIN OUTCOME MEASURES

over, and 145 (34%) had pre-existing comorbidities. 266 (62%) women gave birth or had a pregnancy loss; 196 (73%) gave birth at term. Forty one (10%) women admitted to hospital needed respiratory support, and five (1%) women died. Twelve (5%) of 265 infants tested positive for SARS-CoV-2 RNA, six of them within the first 12 hours after birth.

CONCLUSIONS

Most pregnant women admitted to hospital with SARS-CoV-2 infection were in the late second or third trimester, supporting guidance for continued social distancing measures in later pregnancy. Most had good outcomes, and transmission of SARS-CoV-2 to infants was uncommon. The high proportion of women from black or minority ethnic groups admitted with infection needs urgent investigation and explanation.

STUDY REGISTRATION

ISRCTN 40092247.

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630 women notified

Data not received=51
Reporting error=35

Duplicates=15
Not admitted=87
Not infected in pregnancy=15

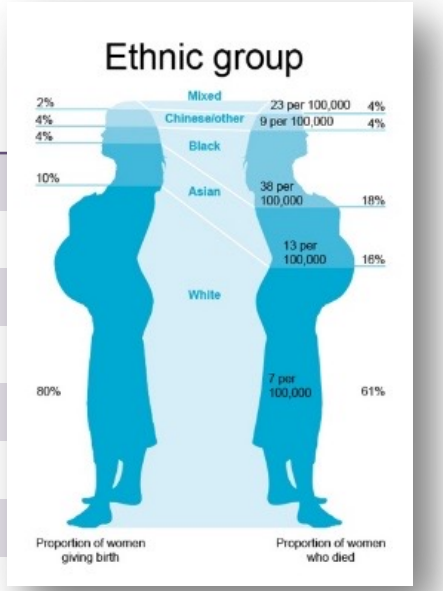
427 pregnant women hospitalised with confirmed SARS-CoV-2

4.9 women hospitalized with SARS-CoV-2 per 1000 giving birth (95%CI 4.5-5.4)
01/03/2020-14/04/2020

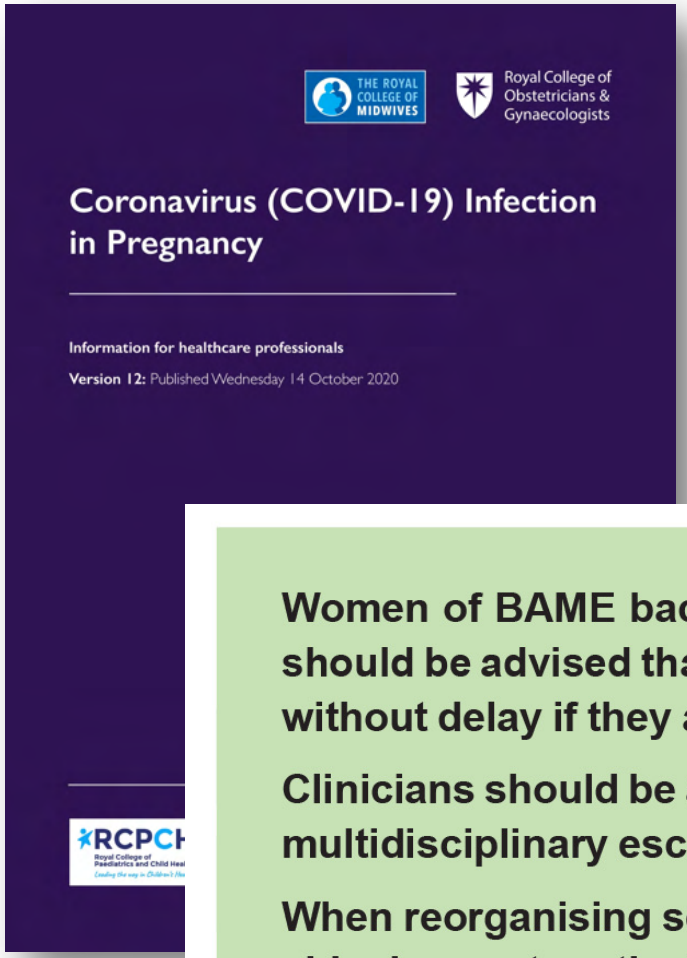
UKOSS
UK Obstetric Surveillance System

Inequalities

Characteristic	Incidence of admission with SARS-CoV-2 in pregnancy per 1000 maternities	Rate ratio (95% CI)
Age (years)		
<20	1.6	0.4 (0.1 to 1.1)
20-34	3.9	1 (ref)
≥35	8.8	2.3 (1.8 to 2.7)
BMI (kg/m^2)		
Normal (<25)	3.5	1 (ref)
Overweight (25 to <30)	6.8	2.0 (1.5 to 2.5)
Obese (≥30)	8.7	2.5 (2.0 to 3.2)
Ethnic group (England Only)		
White	3.5	1 (ref)
Asian	13.9	4.0 (3.1 to 5.1)
Black	28.4	8.1 (6.2 to 10.5)
Chinese/ other	9.5	2.7 (1.7 to 4.0)
Mixed	6.9	2.0 (0.9 to 3.8)



MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK



Royal College of Obstetricians and Gynaecologists/Royal College of Midwives guidance

Women of BAME background, [or with other risk factors such as hypertension, diabetes or raised BMI], should be advised that they may be at higher risk of complications of COVID-19; we advise they seek advice without delay if they are concerned about their health.

Clinicians should be aware of this increased risk, and have a lower threshold to review, admit and consider multidisciplinary escalation of symptoms in women of BAME background.

When reorganising services, maternity units should be particularly cognisant of evidence that BAME individuals are at particular risk of developing severe and life threatening COVID-19 disease.

RCOG Coronavirus (COVID-19) and pregnancy guideline (Royal College of Obstetricians and Gynaecologists and The Royal College of Midwives 2020)

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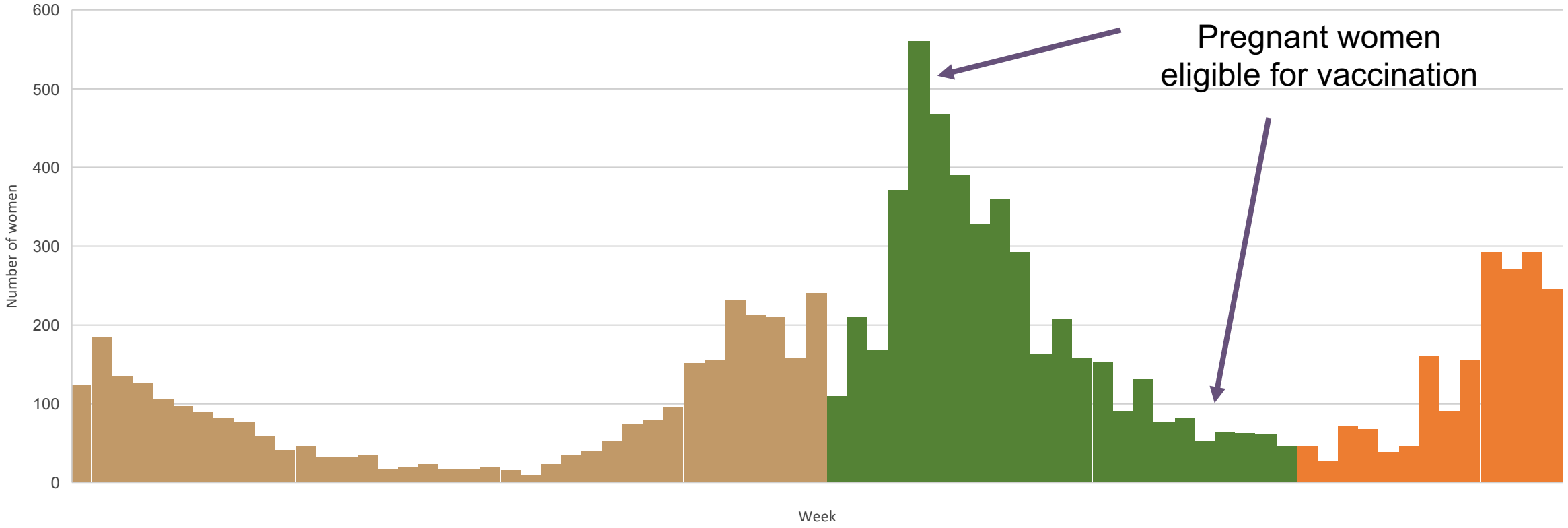
Hospital admissions with COVID-19 over time



Wildtype
(01/03/20 – 30/11/20)

Alpha variant
(01/12/20 – 15/05/21)

Delta variant
(16/05/21 – 15/08/21)

https://www.medrxiv.org/content/10.1101/2021.07.22.21261000v1

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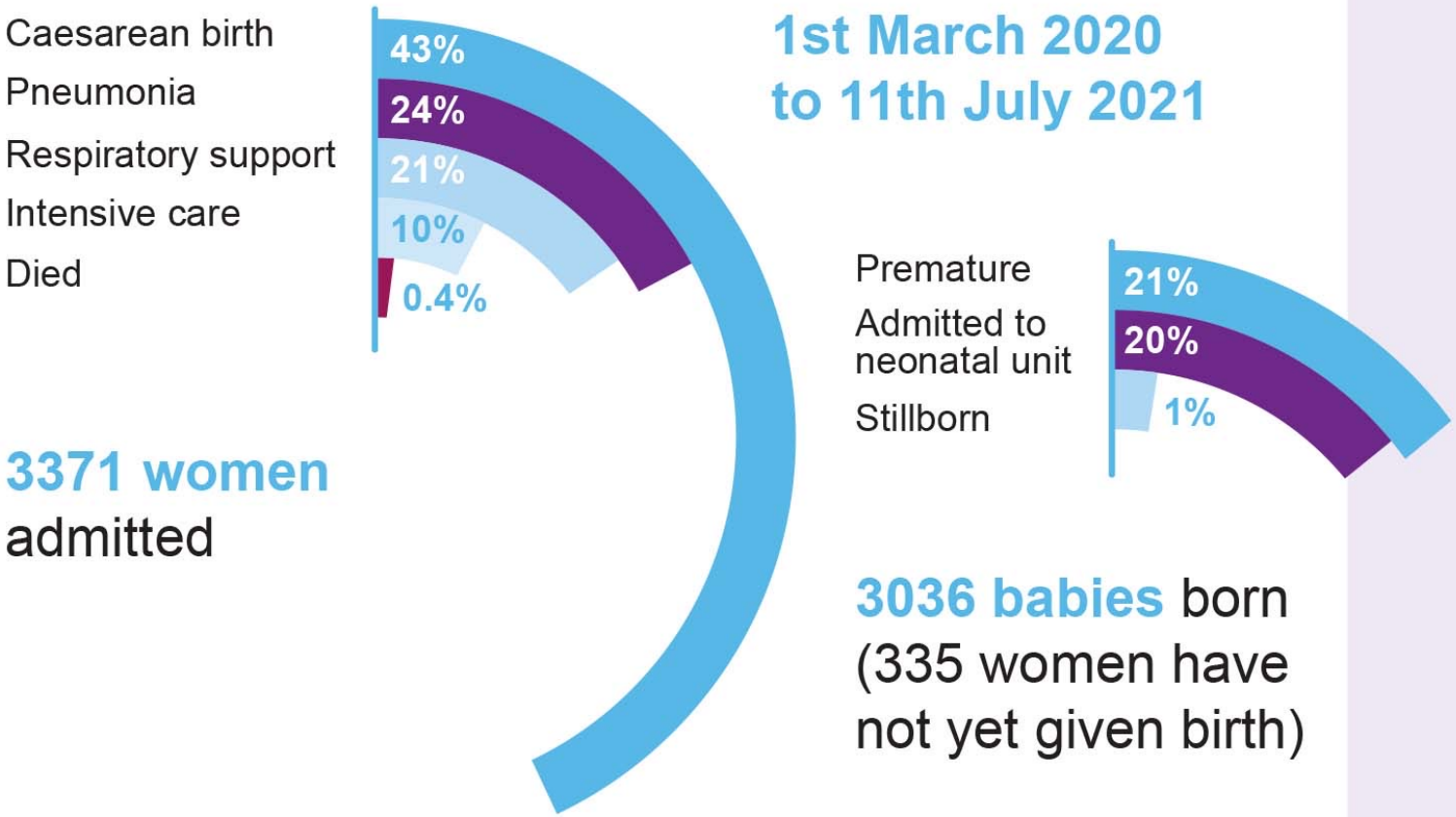
Outcomes of COVID-19 for pregnant women and their babies after admission to hospital with symptoms



1st March 2020 to 11th July 2021

3371 women admitted

3036 babies born (335 women have not yet given birth)

https://www.medrxiv.org/content/10.1101/2021.07.22.21261000v1.full-text

Respiratory support needs during Wildtype, Alpha and Delta variant periods

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	Wildtype N=1435 (%)	Alpha N=1765 (%)	Delta N=171 (%)	OR Alpha vs. Wildtype (95% CI)	aOR Alpha vs. Wildtype (95% CI)	OR Delta vs. Alpha (95% CI)	aOR Delta vs. Alpha (95% CI)
Composite indicator of moderate to severe infection	350 (24.4)	631 (35.8)	77 (45.0)	1.72 (1.48-2.01)	1.75 (1.48-2.06)	1.47 (1.07-2.02)	1.53 (1.07-2.17)
Evidence of pneumonia on imaging	274 (19.1)	486 (27.5)	63 (36.8)	1.61 (1.36-1.90)	1.65 (1.38-1.98)	1.54 (1.12-2.13)	1.64 (1.14-2.35)
Respiratory support required	183 (20.3)	466 (27.2)	52 (33.3)	1.47 (1.21-1.78)	1.39 (1.13-1.71)	1.34 (0.95-1.90)	1.43 (0.97-2.11)
Critical Care received	111 (7.7)	199 (11.3)	26 (15.2)	1.52 (1.19-1.94)	1.61 (1.24-2.10)	1.41 (0.91 -2.20)	1.60 (0.99-2.59)

https://www.medrxiv.org/content/10.1101/2021.07.22.21261000v1

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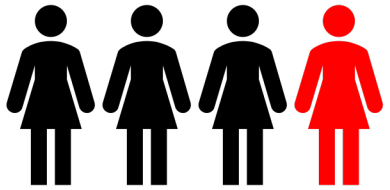
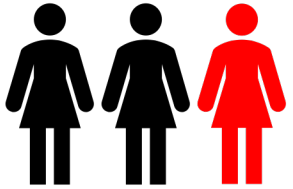
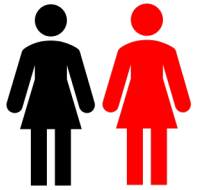
Disease severity

The proportion of hospitalized symptomatic women with moderate to severe COVID-19 has increased

- First wave: 
- Alpha variant: 
- Delta variant: 

Pregnant and postpartum women appear disproportionately severely affected compared to non-pregnant people of reproductive age

https://www.medrxiv.org/content/10.1101/2021.07.22.21261000v1

UKOSS
UK Obstetric Surveillance System

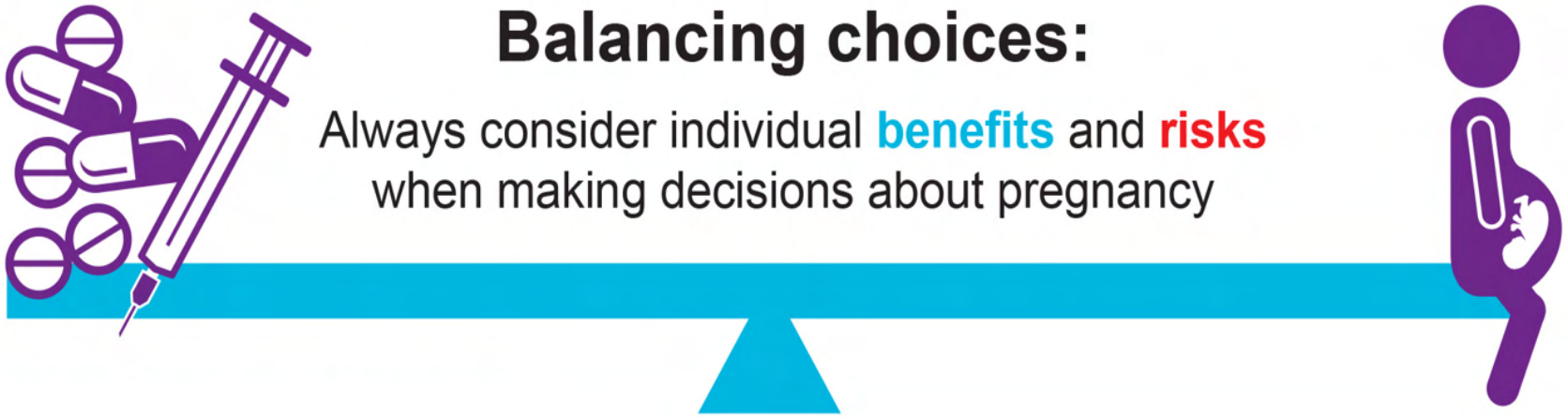
Pharmacological management

	Wildtype N=1435 (%)	Alpha N=1765 (%)	Delta N=171 (%)	OR Alpha vs. Wildtype (95% CI)	aOR Alpha vs. Wildtype (95% CI)	OR Delta vs. Alpha (95% CI)	aOR Delta vs. Alpha (95% CI)
Pharmaco-logical Management Total*	99 (6.9)	253 (14.3)	28 (16.3)	2.26 (1.77-2.88)	2.37 (1.83-3.07)	1.17 (0.76-1.79)	1.35 (0.87-2.12)
Tocilizumab	0 (0)	22 (1.3)	7 (4.1)	NC	NC	NC	NC
Steroids for maternal indication	68 (4.7)	219 (12.4)	25 (14.6)	NC	NC	NC	NC
Regeneron Monoclonal Antibodies	0 (0)	6 (0.3)	0 (0)	NC	NC	NC	NC
Recruited to RECOVERY	21 (1.5)	87 (4.9)	0 (0)	NC	NC	NC	NC

UKOSS
UK Obstetric Surveillance System

Covid-specific medical therapies in pregnant women

- Covid-specific medical therapies are still used infrequently, even for women who are critically ill
- Steroids for maternal indication administered to only around a quarter of pregnant women admitted to intensive care



UKOSS
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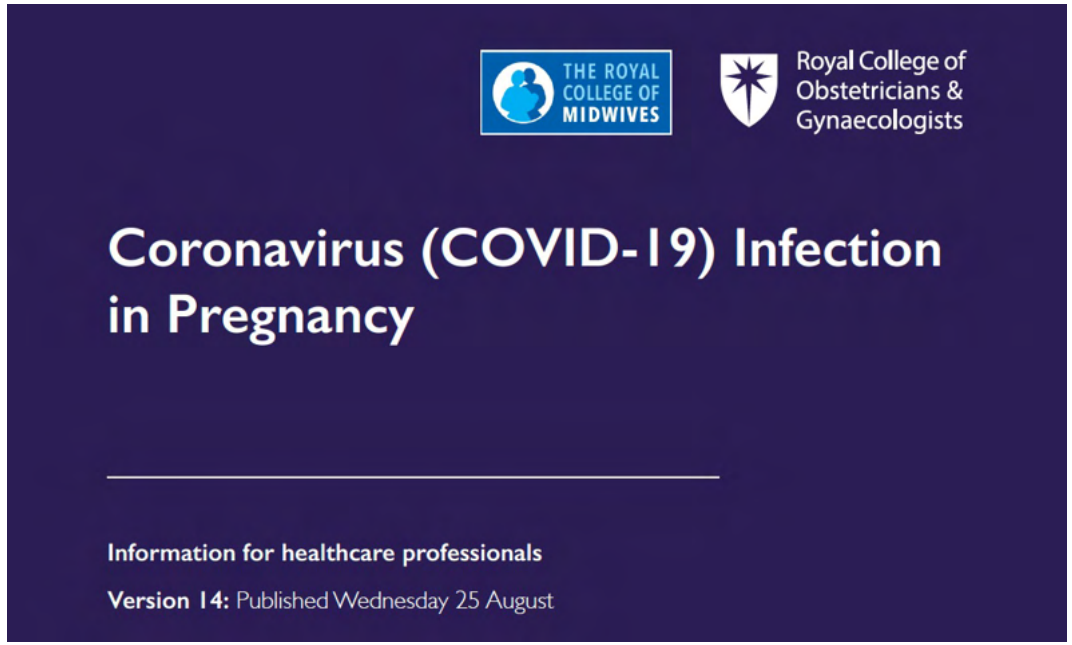
RECOVERY
Randomised Evaluation of COVID-19 Therapy

- Follow-up of pregnant RECOVERY participants
- The same as non-pregnant, + linkage to UKOSS

Covid-19 and pregnancy: RCOG



Quick reference summary of acute COVID-19 management in pregnancy

Quick reference only, see section 6 for further detail.

- Assess – admit, or discharge with clear advice about symptom deterioration and specific contact details.
- Oxygen to maintain saturations above 94%, escalating with e.g. nasal prongs, masks, CPAP, IPPV, ECMO
- No antibiotics unless additional bacterial infection suspected.
- LMWH for VTE prophylaxis
- Steroids if oxygen is needed (e.g. oral prednisolone 40 mg once daily or IV hydrocortisone 80 mg twice daily, with intramuscular dexamethasone 6 mg twice daily for four doses followed by oral prednisolone as below if fetal lung maturity is also required).
- MDT review – is escalation required? Does birth need expediting?
- Strongly consider tocilizumab (400 mg/600 mg/800 mg single IV infusion depending on weight) if C-reactive protein at or above 75 mg/l or in ICU.
- Strongly consider REGEN-COV monoclonal antibodies (8 g single IV infusion) in those with no SARS-CoV-2 antibodies.

Remdesivir should only be considered for those who are not improving or who are deteriorating.

Azithromycin, hydroxychloroquine and lopinavir/ritonavir have been shown to be ineffective and should not be offered.

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Delta variant and perinatal outcomes

Overall:

- 1 in 100 have a stillbirth
- 1 in 3 have a preterm birth
- 1 in 5 babies admitted to neonatal unit

Delta variant:

- 1 in 100 have a stillbirth

- In Alpha variant: 23% increase in NNU admission

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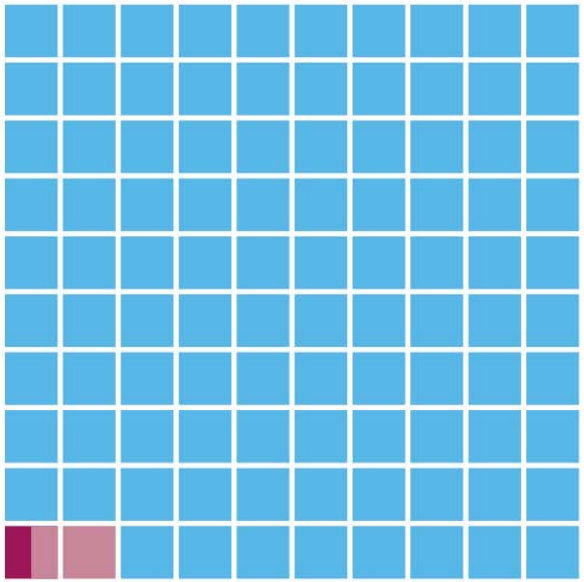
UK Obstetric Surveillance System

Impact of vaccination:

Hospital admissions with symptomatic COVID-19 in pregnancy

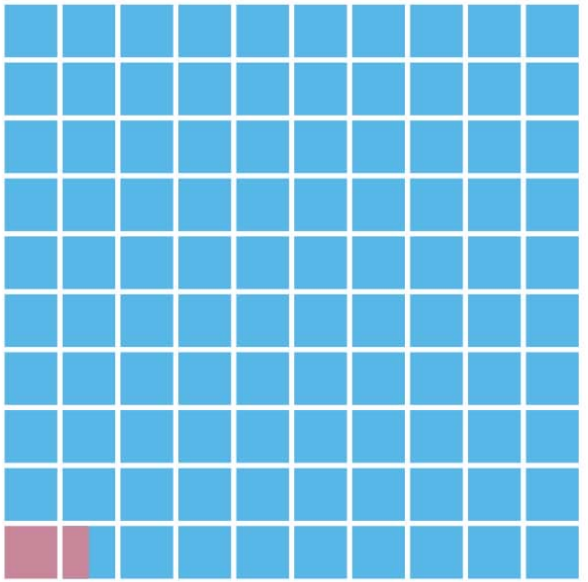
1st February 2021 to 30th September 2021

1714 pregnant women admitted to hospital with symptomatic COVID



98.1% unvaccinated
1.5% one dose
0.4% two doses

235 of whom (14%) were admitted to intensive care



98.7% unvaccinated
1.3% one dose

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Hospital admissions with symptomatic COVID-19 in pregnancy

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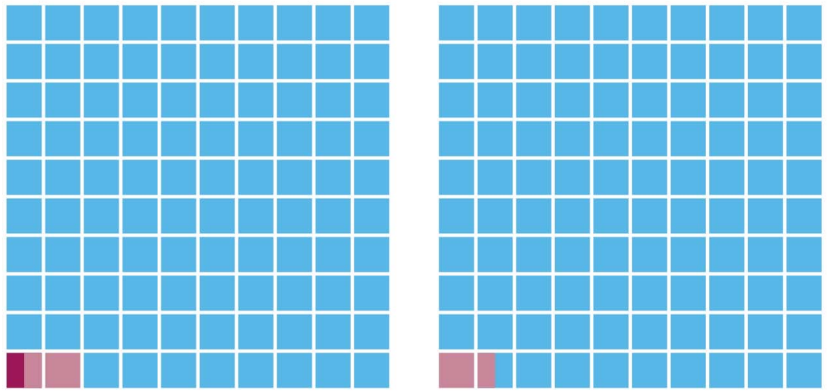
1714 pregnant women admitted to hospital with symptomatic COVID

235 of whom (14%) were admitted to intensive care



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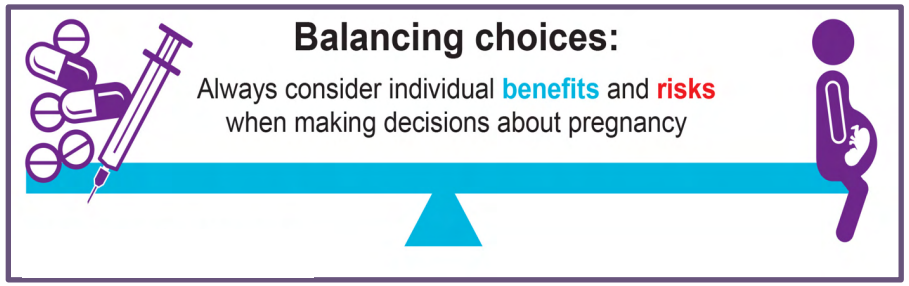
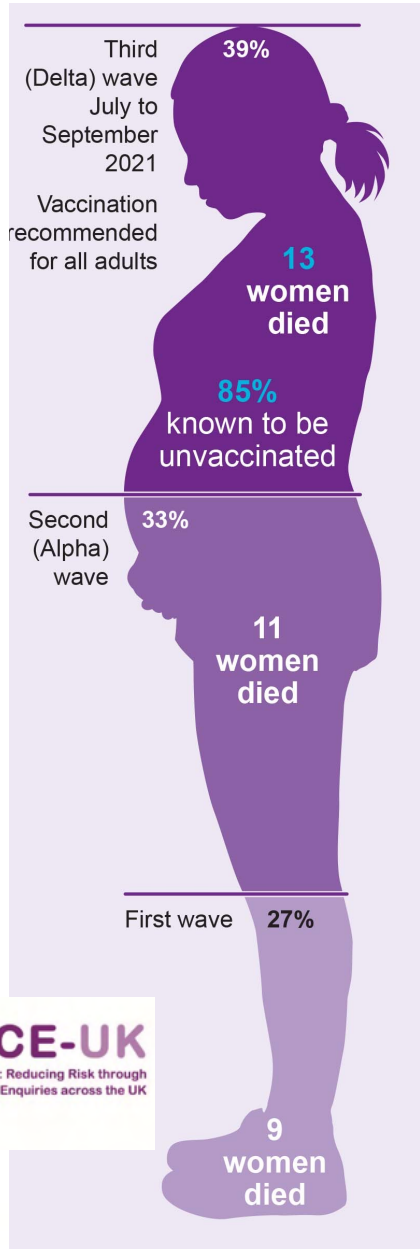


Maternal deaths during pregnancy or up to 42 days after pregnancy with COVID-19



MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

UKOSS
UK Obstetric Surveillance System

Summary

- Obstetric Surveillance Systems allow for rapid activation of covid-19 studies
- Ethnicity, obesity, age and comorbidities increase risk of hospitalization and severity
- Risks to pregnant women have increased with changing variants
  - 1 in 3 have pneumonia and need respiratory support
  - 1 in 8 need intensive care
  - Up to 1 in 3 have a preterm birth
  - 1 in 5 babies need neonatal unit admission
- Evidence of reluctance to use evidence-based medical therapies in pregnancy
- ***Vaccination is strongly protective against severe disease in the real world***

Acknowledgements

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FUNDED BY
NIHR | National Institute for Health Research

Cristiana Toscano, MD, PhD

Professor at the Federal University Goiás in Brazil and Member of the PAHO TAG and WHO SAGE working group on COVID-19 vaccines

COVID disease burden and vaccination strategies among pregnant women in Brazil

DSC DEPARTAMENTO DE SAÚDE COLETIVA
IPTSP INSTITUTO DE PATOLOGIA TROPICAL E SAÚDE PÚBLICA
UFG UNIVERSIDADE FEDERAL DE GOIÁS

COVID disease burden and vaccination strategies among pregnant women in Brazil

Advances in maternal immunization science and implementation in times of COVID-19

November 18th, 2021

Cristiana Toscano, MD, PhD
Professor, Head, Collective Health Department
Federal University of Goiás (UFG), Brazil
Member of the PAHO Technical Advisory Group of Experts on Immunization (TAG)
Member of the COVID-19 working group, Strategic Advisory Group of Experts (SAGE)-WHO

Disclaimer and Acknowledgements

- No conflicts of Interests to declare
- Disclaimer
  - Infectious Disease Epidemiologist, Professor at the University
  - Technical consultation meetings and technical committees
  - Not part of the Brazilian MoH
  - Not representing policies and positions of any of the institutions below

- Slides, Data and Thanks:
  - Literature
  - Ministry of Health, Imunization and Surveillance Bulletins
  - Pan-American Health Organization

Outline

- COVID Burden of Disease in Pregnant Women in Brazil
- Maternal vaccination strategy in Brazil and in the Latin American Region
- Evidence on maternal COVID-19 vaccine effectiveness
- COVID-19 vaccine safety surveillance system in pregnant women

COVID-19 Disease Burden in Pregnant Women

COVID-19 vaccination in pregnancy, Brazil

Jan 17, 2021

Covid-19 vaccination starts

Early May 2021

257.9 cases & 20.3 deaths/100,000 pregnant women

Ntl Rec to vaccinate Pregnant women (and post-partum) [1]

April 26th, 2021

[1]Nota Técnica 467/2021 - CGPNI/DEIDT/SVS/MS
[2]Nota Técnica 627/2021 - CGPNI/DEIDT/SVS/MS

Severe Acute Respiratory Syndrome in Pregnant Women, Brazil, 2021, by mid-May 2021

- **Estimated pregnant women in Brazil: 2,488,052**

	Número	Incidência/100 mil habitantes
Casos SRAG	6.880	276,52
Casos de SRAG por covid-19	4.442	178,53
Óbitos por SRAG	541	21,74
Óbitos de SRAG por covid-19	514	20,75

Fonte: SIVEP-Gripe, atualizado em 17/05/2021, dados sujeito a alterações

Mortality among pregnant and recently pregnant women with SARIs is high among those with COVID-19, particularly in regions where maternal mortality is already high.

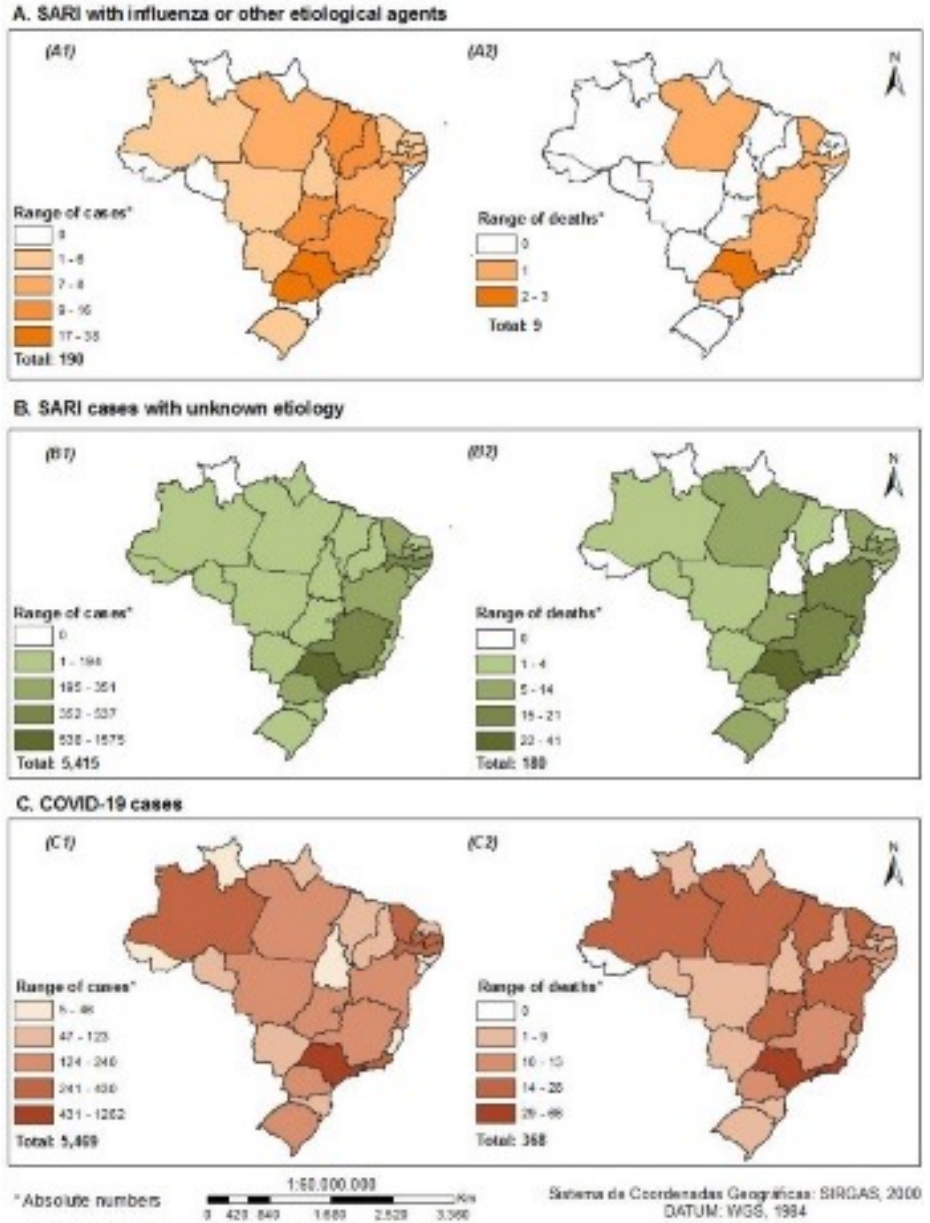
Characteristics and outcomes of pregnant women with COVID-19 and SARI in Brazil, Jan – Nov 2020

- Data from SIVEP-Gripe (national surveillance system) in Brazil
  - n = 945,460 SARI cases
- Characteristics of 11,074 women aged 10–49 who were
  - pregnant (7964) or
  - recently pregnant (3110)
- COVID-19 was confirmed in 50% of the study population
- Mortality among those with COVID-19 was elevated, compared with the other SARI groups
- High mortality among pregnant women with COVID-19 aged 30-39 or who had hypertension/other cardiovascular diseases or diabetes, when compared with their counterparts with other SARIs

[&]Leal, L et al. Braz J Infect Dis, Sept-Oct 2021; 25(5): 101620.
doi: 10.1016/j.bjid.2021.101620.

Fig. 2 Distribution of cases and deaths due to SARIs among pregnant and recently pregnant women, by state, SIVEP-Gripe, Brazil, January-November 2020 (*n* = 11,074)

A. SARI with influenza or other etiological agents
   A1-Number of confirmed cases
   A2-Number of reported deaths
B. SARI cases with unknown etiology
   B1-Number of confirmed cases
   B2-Number of reported deaths
C. COVID-19 cases
   C1-Number of confirmed cases
   C2-Number of reported deaths



&Leal, L et al. Braz J Infect Dis, Sept-Oct 2021; 25(5): 101620. doi: 10.1016/j.bjid.2021.101620.

Published evidence on COVID disease burden in pregnant women in LMIC

- Data from the Brazilian Ministry of Health's Influenza Epidemiological Surveillance Information System (SIVEP-Gripe) by April 2021
  - disproportionately large number of maternal deaths attributed to COVID-19, particularly during the postpartum period
  - Racial disparities
  - High maternal in-hospital fatality rates

Table 1
Outcomes[a] of Black and White pregnant & postpartum women hospitalized with laboratory-confirmed COVID-19 in the U.S. and Brazil[b].

	Total (Black, White, Other, and NR)[c]	Black[d]	White[d]
Postpartum			
Brazil – December 6	*n = 685*	*n = 36*	*n = 195*
Death	106 (15·5%)	10 (27·8%)	28 (14·4%)
ICU Admission	228 (33·3%)	17 (47·2%)	57 (29·2%)
Invasive Ventilation	119 (17·4%)	9 (25·0%)	26 (13·3%)
Pregnant			
Brazil – December 6	*n = 2522*	*n = 146*	*n = 822*
Death	160 (6·3%)	10 (6·9%)	40 (4·9%)
ICU Admission	490 (19·4%)	32 (21·9%)	171 (20·8%)
Invasive Ventilation	178 (7·1%)	11 (7·5%)	54 (6·6%)
U.S. – June 7	*n = 2587*	*n = 461*	*n = 492*
Death	16 (0·6%)	6 (1·3%)	<5 (<1·1%)[e]
ICU Admission	120 (4·6%)	28 (6·1%)	12 (2·4%)
Invasive Ventilation	42 (1·6%)	9 (2·0%)	<5 (<1·1%)[e]
Non-Pregnant/Non-Postpartum			
Brazil – December 6	*n = 34,469*	*n = 1590*	*n = 13,410*
Death	4812 (14·0%)	294 (18·5%)	1554 (11·6%)
ICU Admission	8548 (24·8%)	423 (26·6%)	3440 (25·7%)
Invasive Ventilation	3763 (10·9%)	212 (13·3%)	1406 (10·5%)
U.S. – June 7	*n = 4808*	*n = 1119*	*n = 803*
Death	208 (4·3%)	74 (6·6%)	37 (4·6%)
ICU Admission	757 (15·7%)	194 (17·3%)	158 (19·7%)
Invasive Ventilation	225 (4·7%)	48 (4·3%)	44 (5·5%)

[a] These results should be interpreted with caution, due to the high rate of incomplete reporting in the U.S.

[b] For the U.S., we conservatively included data on all deaths (hospitalized or not) use the report did not differentiate between them. [6] We assume that most

*Gurzenda S and Castro M. Eclinical Medicine 36 (2021) 100917.
https://www.thelancet.com/action/showPdf?pii=S2589-5370%2821%2900197-8

COVID-19 vaccination in pregnancy, Brazil

Jan 17, 2021

Covid-19 vaccination starts

April 26th, 2021

Ntl Rec to vaccinate Pregnant women (and post-partum) [1]

Early May 2021

257.9 cases & 20.3 deaths/100,000 pregnant women

May 7th, 2021

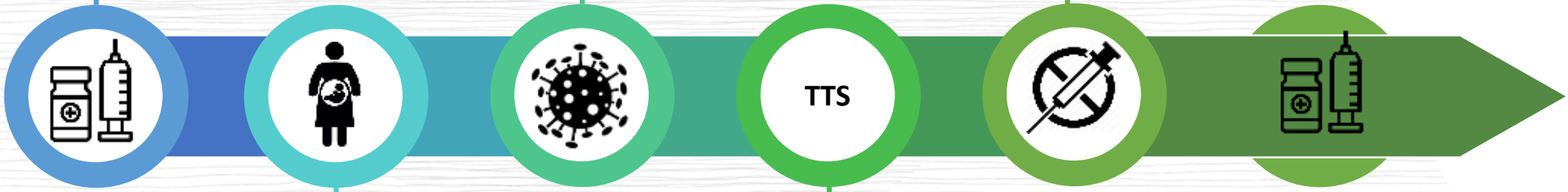
Death of pregnant women post Vx

May 14th, 2021

Suspension of COVID-19 vaccination in pregnant women[2]

July 6th, 2021

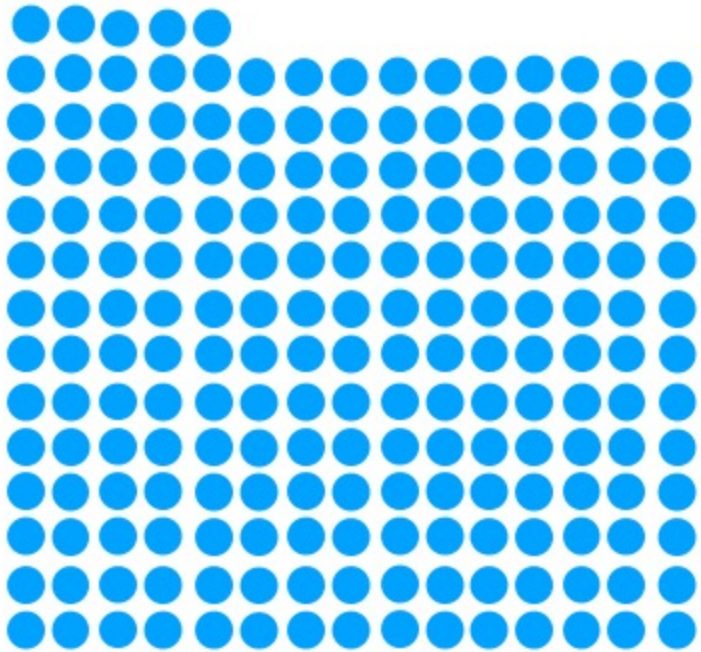
Reinstatement of Maternal Vaccination



[1]Nota Técnica 467/2021 - CGPNI/DEIDT/SVS/MS
[2]Nota Técnica 627/2021 - CGPNI/DEIDT/SVS/MS

Risk Benefit Analysis

Hospitalization due to COVID-19 in pregnant women in Brazil, 2021



~200/100.000

Deaths due to COVID-19 in pregnant women in Brazil, 2021

~20/100.000

TTS post-COVID-19 vaccination with AstraZeneca/Oxford

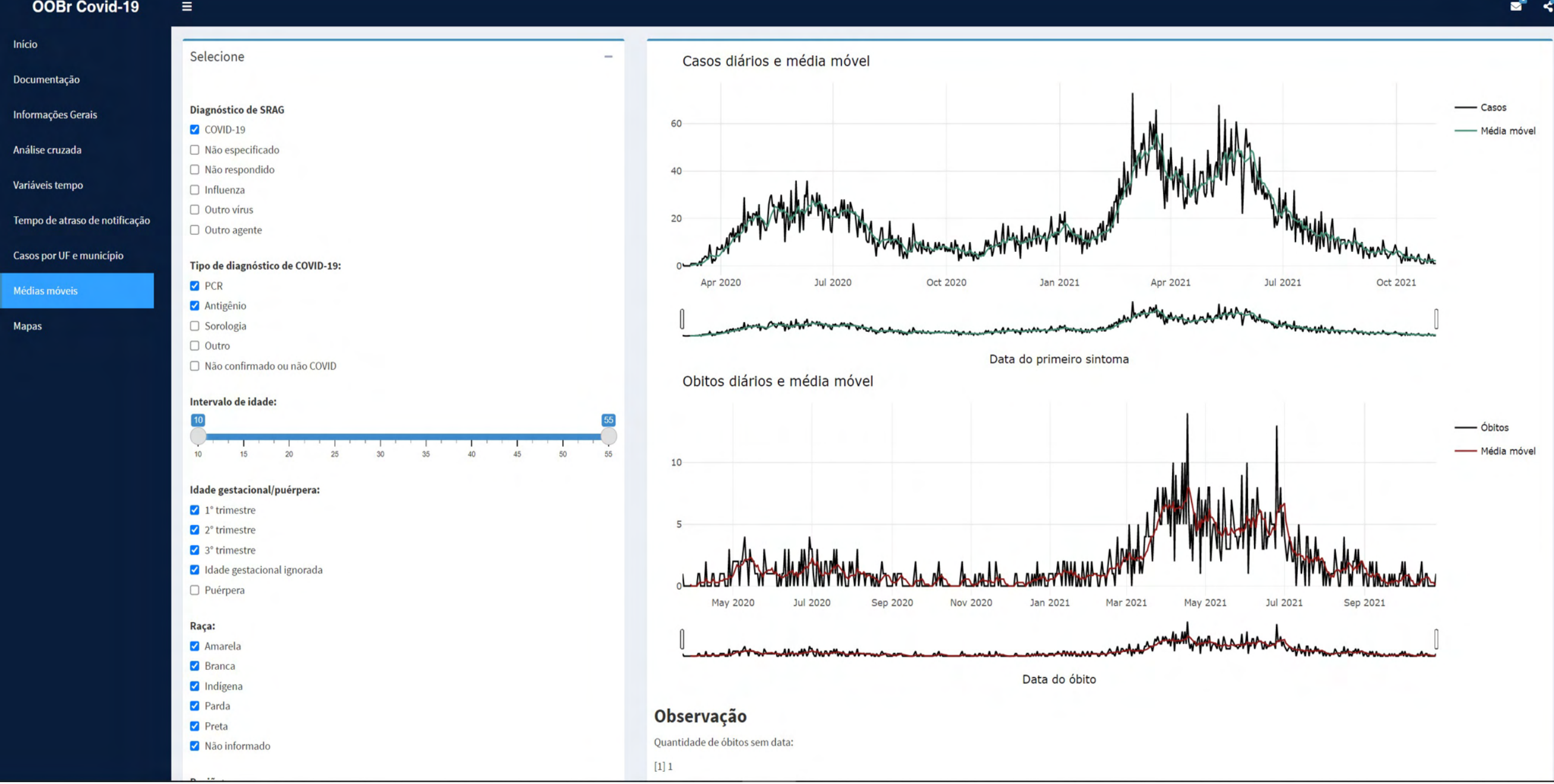
~1/100.000

Brazilian Obstetric Observatory (OOBr) COVID-19

- Created in April 7, 2021
- Part of the Brazilian Obstetric Observatory
- Public dashboard, updated weekly when new data are released by the Ministry of Health.
- Numerous exploratory data analyses available
- Dynamic visualization and filtering, which can be customized by the user.
- Available at (in Brazilian Portuguese):

https://observatorioobstetrico.shinyapps.io/covid_gesta_puerp_br

[&]Leal, L et al. Braz J Infect Dis, Sept-Oct 2021; 25(5): 101620.
doi: 10.1016/j.bjid.2021.101620.



https://observatorioobstetrico.shinyapps.io/covid_gesta_puerp_br

Severe Acute Respiratory Syndrome and COVID vaccination in Pregnant Women, Brazil – Nov 15th, 2021

- Estimated pregnant women in Brazil: 2,488,052
- COVID vaccination
  - 1.15 million pregnant and post-partum women have received 1st dose (46%)
  - 867K women received second dose (35%)
- Disease Burden

	Number	Incidence/100,000 pop
SARS cases (unspecified)	14,024	563.54
SARS cases due to COVID-19	18,601	747.61

https://observatorioobstetrico.shinyapps.io/covid_gesta_puerp_br

Maternal COVID-10 vaccine effectiveness

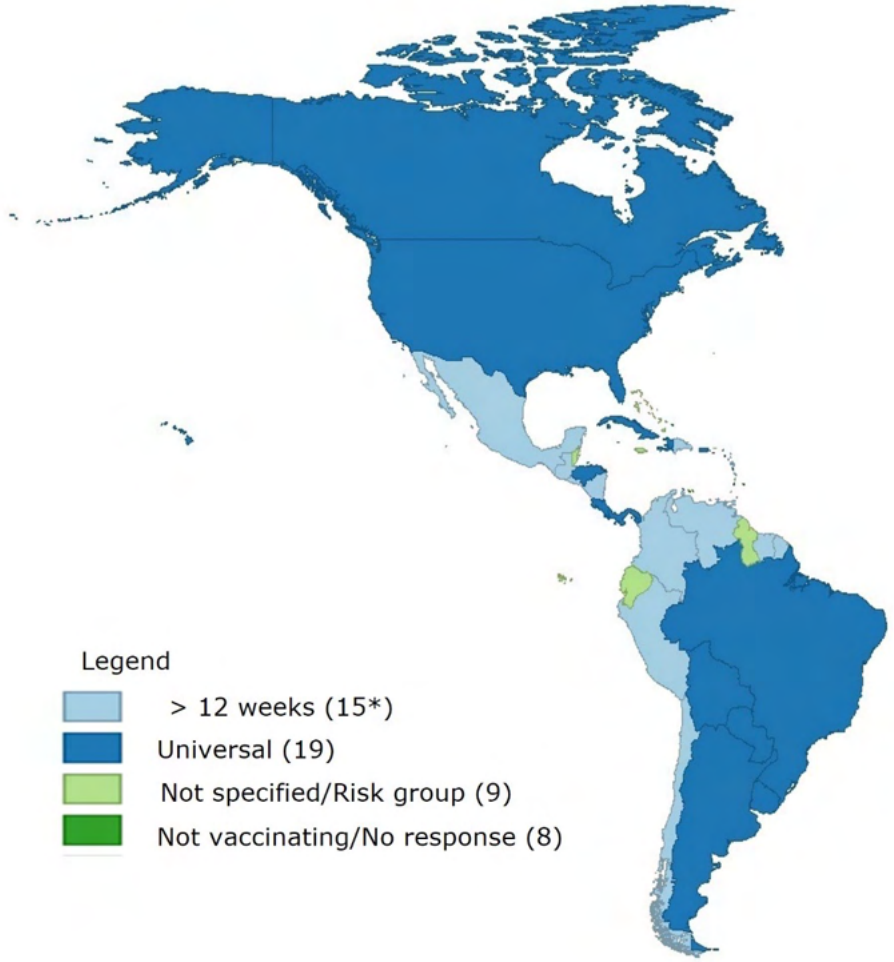
CoronaVac inactivated COVID VE in Pregnant Women in Brazil

- Test negative design, 19,838 pregnant women aged 18 to 49 years with PCR tests conducted in Brazil, from
- Data linkage
  - records of negative and positive SARS-CoV-2 PCR tests to national vaccination records
  - records of test positive cases with notification of severe, hospitalized or fatal Covid19
- CoronaVac VE (2-dose)
  - 41% (95% CI 27.1- 52.2) against symptomatic Covid-19
  - 85% (95% CI 59.5-94.8) against severe Covid-19
  - 75% (95% CI 27.9- 91.2) in preventing progression to severe Covid-19 among those infected

PrePrint, Nov 12th 2021. Paixão, ES et al. Effectiveness of the CoronaVac Vaccine in Prevention of Symptomatic and Progression to Severe COVID-19 in Pregnant Women in Brazil. Available at SSRN: https://ssrn.com/abstract=3962119

Maternal COVID-19 Vaccination in Brazil and LAC Region

Number of countries with recommendations on the use of COVID-19 vaccines in pregnant women, Region of the Americas, 2021



*Mexico and Suriname > 9 weeks; Chile > 16 weeks

Source: Country reports to FPL-IM/PAHO. Data as of 15 November 2021

Countries with COVID-19 Vaccinaton Policies for Pregnant Women in LAC

Policy	# Countries/Territories
Pregnant not specified	7
Pregnant risk group	2
Pregnant >12 weeks	13
Pregnant >9 weeks	2
Pregnant Universal	19
No Vaccinating PW	2
No response	6
Total	51

Source: eJRF country-reports

Adverse events following COVID-10 vaccination in pregnant women

COVID-19 Post-Vaccination Adverse Events in pregnant women Brazil, by Nov 16th 2021

Total eventsl:1,320
(65.5/100 K doses)

By vaccine

- **AstraZeneca: 734**
- **Sinovac: 195**
- **Pizer: 381**
- **Janssen: 10**

Severe events: 206
(10.2/100 K doses)

- **AstraZeneca: 60**
- **Sinovac: 40**
- **Pizer: 105**
- **Janssen: 10**

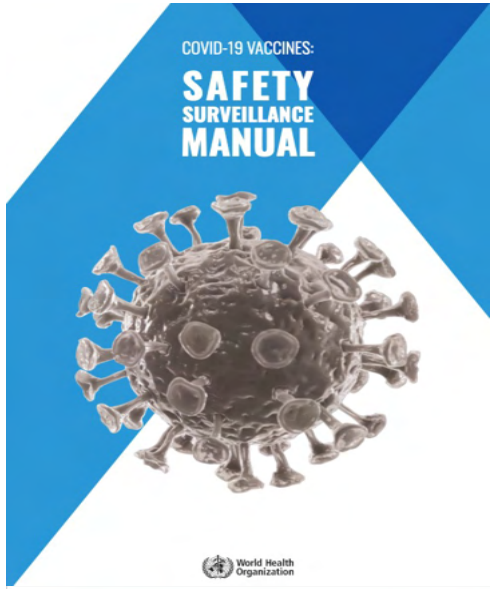
Deaths: 79
(3.9/100 K doses)

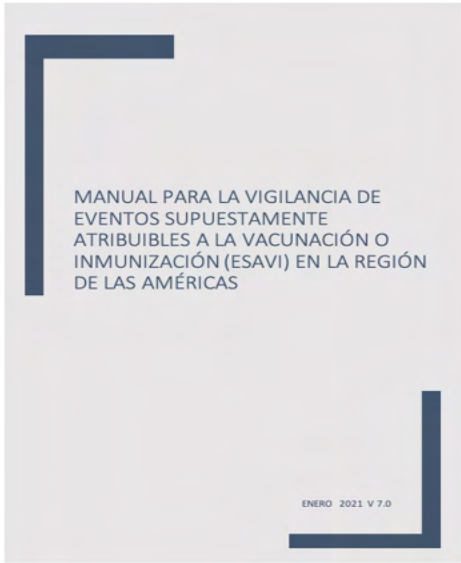
- **AstraZeneca: 15**
- **Sinovac:17**
- **Pizer: 47**
- **Janssen: 0**

*Excluindo São Paulo
Fonte: Planilha compartilhada pela CGPNI/DEIDT/SVS/MS

OPS/OMS

Regional Monitoring System Strategies of ESAVI





OPS

Gaps and data needs

- COVID surveillance and disease burden in pregnant women
- Routine monitoring and information on COVID vaccine coverage in pregnant women
- Ongoing routine monitoring of COVID-19 vaccine safety surveillance system
    - Data analysis and sharing
- Ongoing vaccine effecetiveness and impact studies
- Prospective enhanced safety surveillance studies

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Thank you!!!!!

ctoscano@ufg.br

Q&A

Session 2 – Panel discussion
COVID-19 vaccines: De-risking of vaccine development for maternal immunization

Moderator

Ajoke Sobanjo-ter Meulen

MD MSc, Senior Program Officer, Global Health, Pneumonia, Bill & Melinda Gates Foundation, USA

PANELISTS

Alejandra Gurtman

MD, Vice President, Vaccine Research and Development, Pfizer Inc

Janet Englund

MD, Professor of Pediatrics, University of Washington, Pediatric Infectious Diseases, Seattle Children's Hospital, Seattle, WA USA

Padmini Srikantiah

MD MPH, Deputy Director, Global Health, Pneumonia

Kathryn M. Edwards

MD, Sarah H. Sell and Cornelius Vanderbilt Professor, Department of Pediatrics

Vanderbilt University School of Medicine

Shabir A. Mahdi

MD, PhD, Dean and Professor of Vaccinology, University of the Witwatersrand, South Africa

Alejandra Gurtman

Vice President
Vaccine Research and Development
Pfizer Inc

COVID-19 Maternal Vaccine Clinical

COVID-19 Maternal Vaccine Clinical

Alejandra Gurtman, MD

Pfizer

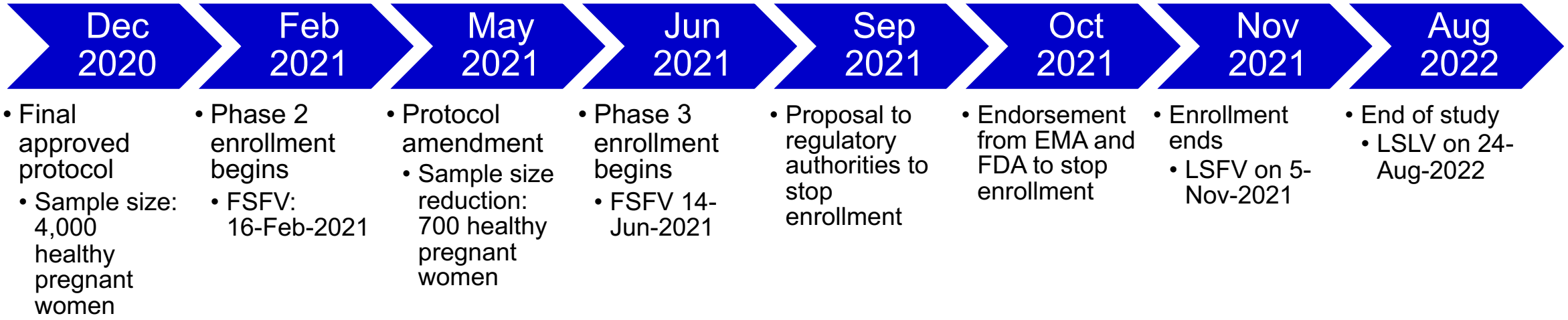
Vaccine Research and Development

Nov 18, 2021

Timeline for COVID Vaccine in Pregnant Women

- April 2020: Interaction initiated with CBER through IND regarding a potential maternal study
- July 2020: DART study initiated
- Dec 18, 2020: CBER accepted DART Study
- Dec 22, 2020: Final maternal immunization protocol submitted to CBER
  - Phase 2/3 design with initial smaller cohort
  - Stopping rules incorporated

C4591015 — Timeline of Key Events



Recommendation for vaccination of pregnant women

Increased global availability of COVID-19 vaccines

Challenges with enrollment

C4591015 Study

- Enrolment stopped early due to recruitment challenges secondary to global availability and universal recommendation of COVID-19 vaccination in pregnant women
- **345 maternal participants enrolled (<10% of initial target)**
  - Brazil, South Africa, Spain, UK, and US
  - Mozambique included originally
    - Regulatory process was longer than other countries
    - Central Ethics Committee concerns about availability of vaccine for pregnant women as vaccine was not included in the country vaccination plan at the time, due to storage conditions and cost
  - Phase 2: 209 participants
  - Phase 3: 136 participants
- **247 infants born to maternal study participants**

Questions

- How important is to obtain an indication for pregnant women?
  - What is the medical value of an indication when the vaccine is recommended?

- Clinical trial initiation – how quickly can we really do it?

- Distinction on access after approval in high and LMICs
  - How critical is to include both in clinical trials?
  - How much do we need to anticipate logistics after approval (COVID vaccine shipment/storge in LIC countries)

- If we move forward with the same platform and include pregnant women in other studies evaluating vaccines against different pathogens
  - Will regulators agree that a DART study from a platform is sufficient or would it be an expectation to repeat (ie COVID DART to be use for other mRNA vaccines)
  - Will a change in antigen delivery (LNPs) require additional DART studies

- For other platforms, should we consider doing Phase 1 in pregnant women or just allowing them to be in phase 3

- How do we anticipate ideal GA for new platforms?
  - How are we going to evaluate safety signals vs disease. (Zika microcephaly)
  - How early can we go

- How important is to assess benefit from direct vaccination and protection to pregnant women and/or infant protection

Discussion Panel Members and Example Questions

Panel Members	Potential Discussion Questions
Padmini Srikantiah	1. How has the use of mRNA COVID-19 vaccine in pregnancy shaped the BMGF RSV Vaccine strategy?
Shabir A. Mahdi	2. Learning from the COVID-19 pandemic: What do vaccine developers need to know to enable equitable access to vaccines for pregnant women in LMIC?
Janet Englund	3. What has COVID-19 vaccine development taught us about maternal vaccine confidence and uptake in pregnant women?
Kathryn M. Edwards	4. What can we do better to generate timely, accessible, and robust vaccine safety data in pregnant women prior to and during pandemics?

Session 3
Policy and regulatory considerations: The way forward

Moderator

Flor Munoz

MD MSc, Associate Professor, Pediatrics

Infectious Disease, Baylor College of Medicine, USA

Ruth Karron

Professor, Department of International Health, Johns Hopkins Bloomberg School of Public Health; Director, Center for Immunization Research

COMIT and PREVENT, what we've learned about data-driven policy decisions, and what we should anticipate in the future?

Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies

PREVENT

COMIT

Covid-19 Maternal Immunization Tracker

What have we learned about data-driven policy decisions?

What should we anticipate in the future?

Ruth Karron

18 November 2021

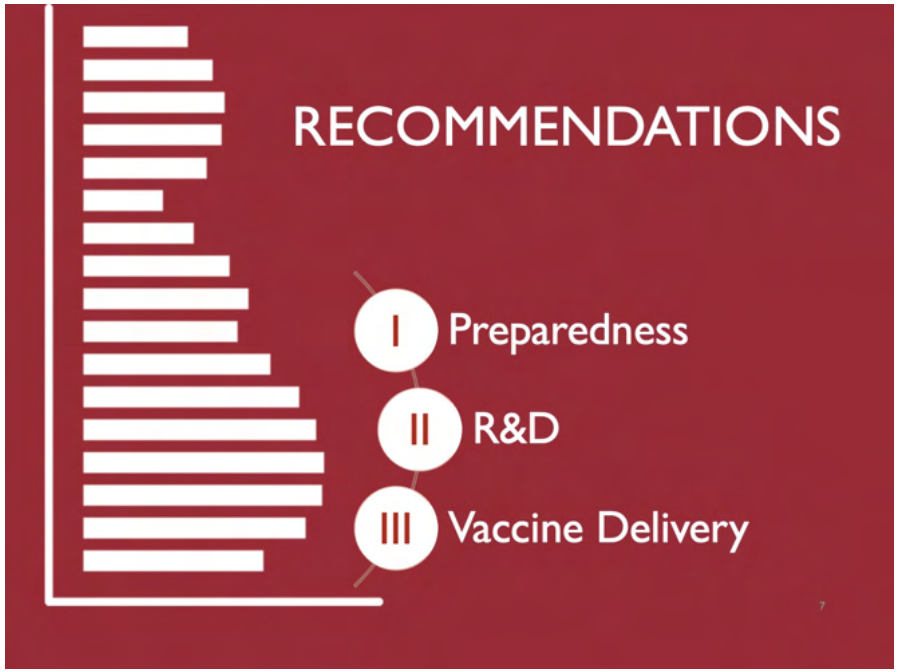
Beginning with the conclusion…

- As a global community, we have already developed frameworks to consider and plan for the needs of pregnant people in the context of epidemic and endemic diseases

- Pregnant people have been and will continue to be disadvantaged unless deliberate and concerted actions are taken by governments, regulators, vaccine developers, and supranational organizations

PREVENT Guidance

- **22 Recommendations** across 3 domains to equitably and responsibly include the interests of pregnant people and their offspring in the development and delivery of epidemic vaccines



Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Review

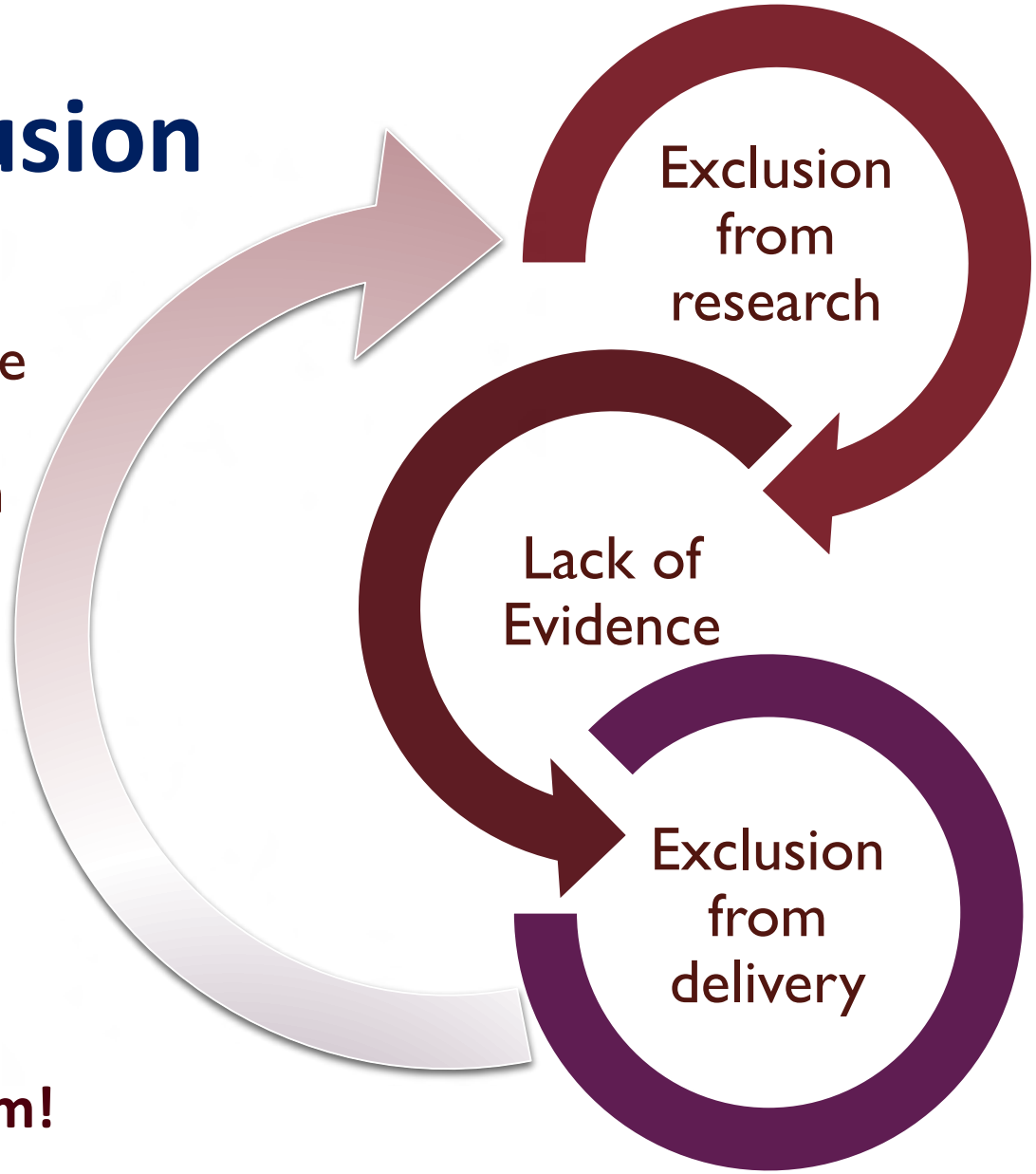
Pregnant women & vaccines against emerging epidemic threats: Ethics guidance for preparedness, research, and response

Carleigh B. Krubiner[a,1,*], Ruth R. Faden[a,b], Ruth A. Karron[b], Margaret O. Little[c], Anne D. Lyerly[d], Jon S. Abramson[e], Richard H. Beigi[f], Alejandro R. Cravioto[g], Anna P. Durbin[b], Bruce G. Gellin[h], Swati B. Gupta[i], David C. Kaslow[j], Sonali Kochhar[k], Florencia Luna[l], Carla Saenz[m], Jeanne S. Sheffield[n], Paulina O. Tindana[o,2], The PREVENT Working Group

Available Open Access in Vaccine: https://doi.org/10.1016/j.vaccine.2019.01.011
English, Spanish and French versions also available at: vax.pregnancyethics.org

The Presumption of Exclusion

perpetuated cycle of exclusion and evidence gaps on products and platforms



Morally unacceptable… need a new paradigm!

The Presumption of Inclusion: a virtuous cycle

Include pregnant women in vaccine R&D and deployment

UNLESS

scientific & ethical justification for exclusion

(*e.g., that risks > benefits*)

- ❑ not ***automatic*** inclusion of pregnant women in every vaccine study or campaign **BUT**
- ❑ changes the default: burden of proof for exclusion, not inclusion

Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies
PREVENT

PREVENT Guidance in the context of the COVID-19 pandemic

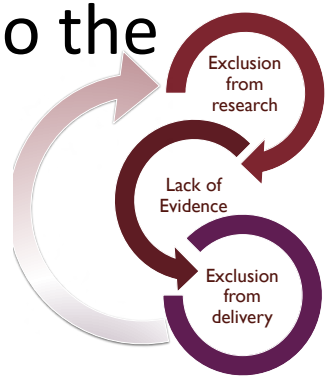
- **Recommendation #7:** Pregnant women should not be left behind as new technologies are developed ✗
- **Recommendation #9:** Non-clinical studies required prior to clinical evaluation during pregnancy (DART studies) should be conducted early in clinical development, as promising and appropriate candidates move to phase 2 ✗
- **Recommendation #11:** Pregnant women should have the opportunity to enroll in studies conducted during outbreaks when prospect of benefit >risk for pregnant women, their offspring, or both ✗
- **Recommendation #17:** Pregnant women should be offered vaccines as part of an outbreak or epidemic response. Pregnant women should only be excluded if a review of available evidence by relevant experts concludes that the risks to pregnant women and their offspring from the vaccine are demonstrably greater than the risks of not being vaccinated. ✗

What have we learned about data-driven policy decisions?

COVID-19 Maternal Immunization Tracker (COMIT) provides:

- a global snapshot of public health policies that influence access to COVID-19 vaccines for pregnant and lactating people.

- maps, tables and country profiles to document the response to the dynamic state of the pandemic and emerging evidence.

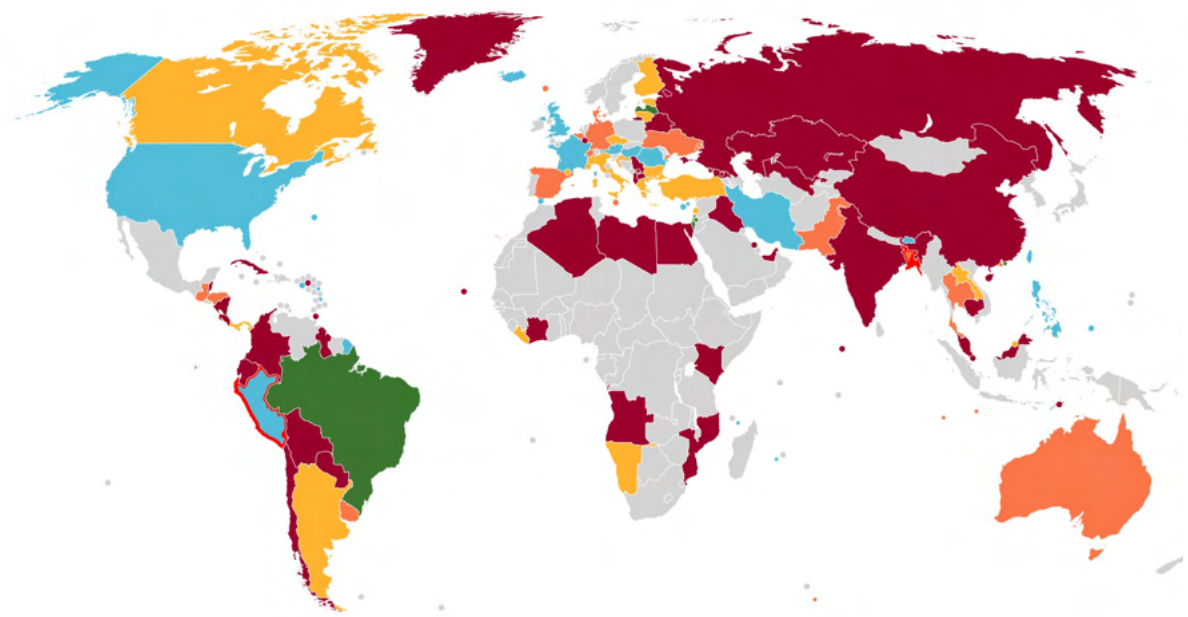


https://www.comitglobal.org/

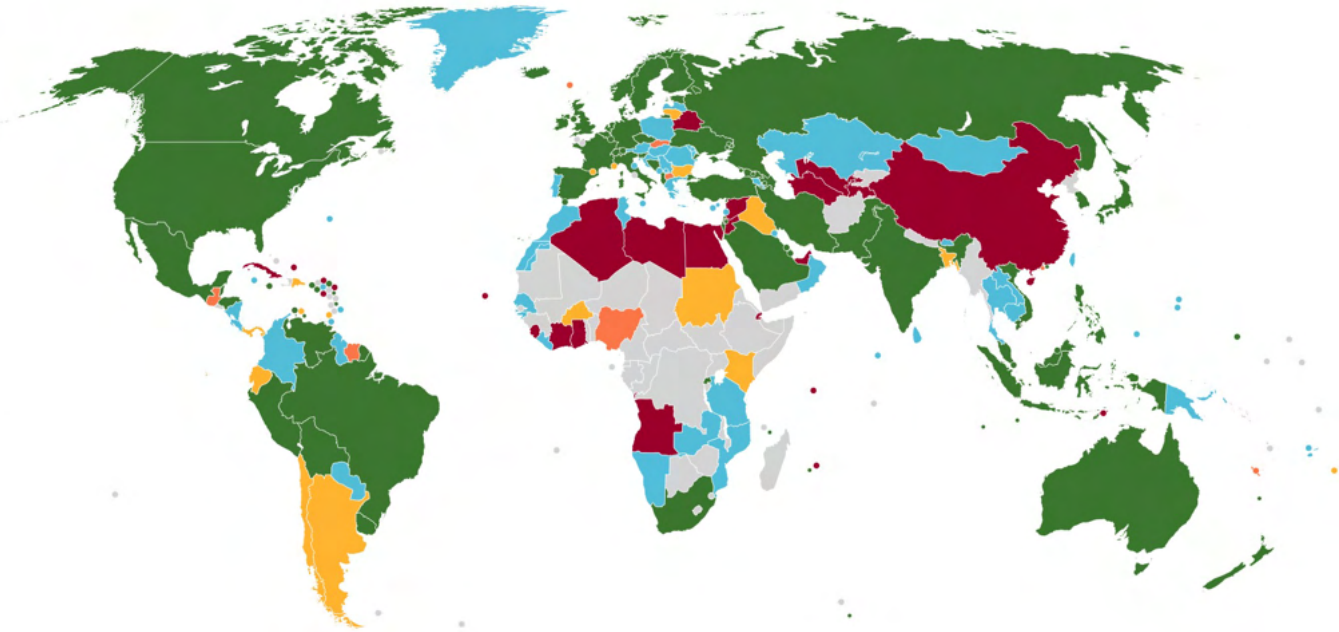
COMIT
Covid-19 Maternal Immunization Tracker

COVID-19 vaccine policies for pregnant and lactating people worldwide.

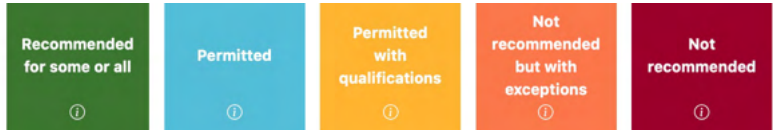
Policies for COVID-19 vaccination during pregnancy have evolved over time



23 April 2021



16 November 2021



www.comitglobal.org

Absence of data delayed permissive recommendations

106 countries/territories (54%) that issued guidance on COVID-19 vaccine and eligibility referenced the absence of safety or efficacy data in pregnant persons

Mozambique (Mar 2021): *"As there are no data on efficacy and safety in specific population groups, children <15 years and pregnant women are excluded from this vaccination process. These groups may be vaccinated later, as soon as scientific evidence of safety and efficacy is produced."*

Countries also cited the absence of DART data as a reason to not permit use of certain vaccines in pregnancy.

France (April 2021): *"As a precautionary measure, while awaiting the final results of studies carried out in animals for the AstraZeneca vaccine and in view of the influenza-like syndromes having been reported with this vaccine, it is recommended to give preference to pregnant women mRNA vaccines (Comirnaty® or Moderna®), or the Covid-19 Janssen® vaccine."*

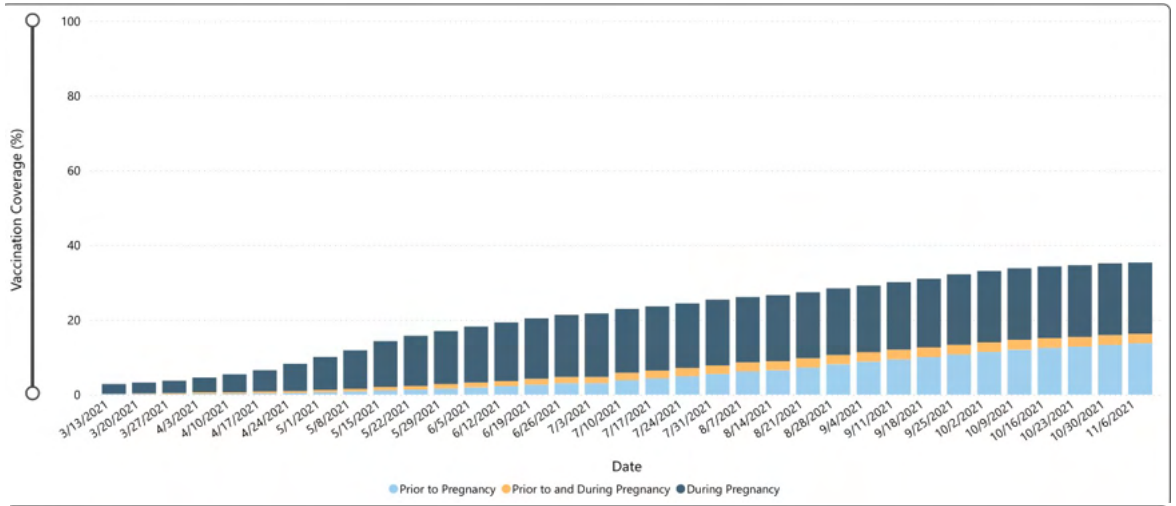
Availability of data facilitated recommendations

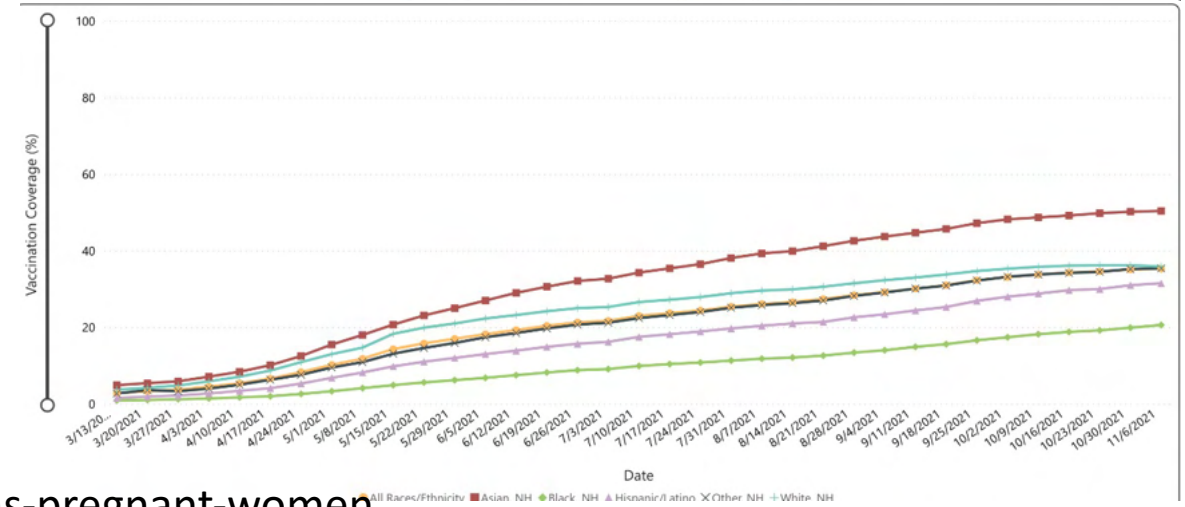
65 countries/territories (33%) cited observational data, and in some cases, these data were cited as the primary reason for a **shift in position**, as in the Netherlands in July:

Netherlands (July 2021): *"Pfizer and Moderna's vaccines against COVID-19 are mRNA vaccines. Based on the research data and efficacy of these vaccines, there is no reason to believe that these vaccines would be harmful when used during pregnancy. We now know that 90,000 pregnant women in the United States have been vaccinated with the mRNA vaccines from Pfizer and Moderna. No serious side effects have been reported. That is why it is recommended that all pregnant women - if they are called upon to do so - be vaccinated."*

Policy ≠ Uptake

% of U.S. Pregnant People Fully Vaccinated with COVID-19 vaccine as of 6 Nov 2021

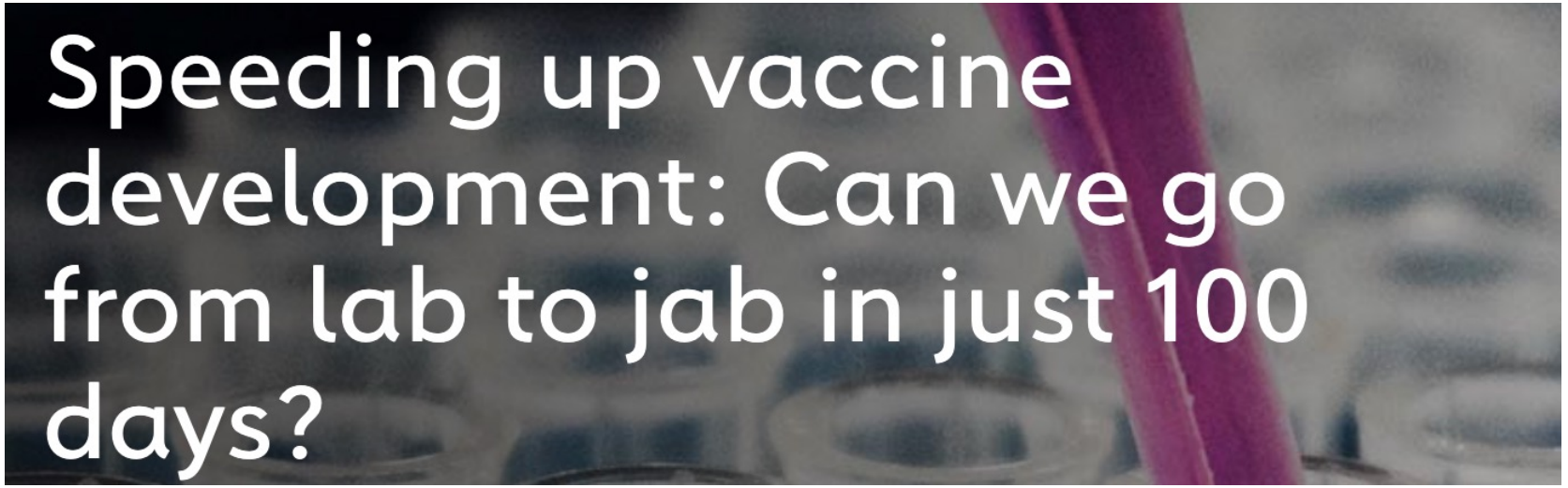




https://covid.cdc.gov/covid-data-tracker/#vaccinations-pregnant-women

What should we anticipate in the future?

Without specific efforts and concerted plans for change, inequities for pregnant people may increase…



www.gavi.org

Acknowledgements

Ruth Faden Principal Investigator Johns Hopkins Berman Institute of Bioethics	Carleigh Krubiner Co-Principal Investigator Johns Hopkins Berman Institute of Bioethics	Ruth Karron Co-Principal Investigator Johns Hopkins Bloomberg School of Public Health
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Jon Abramson Wake Forest University School of Medicine	**Richard Beigi** Magee-Womens Hospital of University of Pittsburgh Medical Center	
Alejandro Cravioto Universidad Nacional Autónoma de México Faculty of Medicine	**Anna Durbin** Johns Hopkins Bloomberg School of Public Health	
Bruce Gellin Sabin Vaccine Institute	**Swati Gupta** International AIDS Vaccine Initiative (IAVI)	
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Florencia Luna FLACSO-Argentina Bioethics Program & CONICET	**Carla Saenz** Pan American Health Organization Regional Program on Bioethics	
Jeanne Sheffield Johns Hopkins University School of Medicine	**Paulina Tindana** Navrongo Health Research Centre	

Ruth Faden
Carleigh Krubiner
Eleonor Zavala
Chizoba Wonodi
Elana Jaffe
Andrew Nicklin
Rachel Gur-Arie

Marion F. Gruber, PhD

Regulatory guidance/role (FDA) – how does COVID pandemic change the path for vaccine approval and access for pregnant women – Regulatory framework for maternal vaccines in the future

COVAX Maternal Immunization Working Group Webinar

Did the COVID-19 Pandemic Change the Path For Vaccine Approval and Access For Pregnant Women?

Regulatory Framework For Maternal Vaccines In The Future

Marion F. Gruber, PhD

November 18, 2021

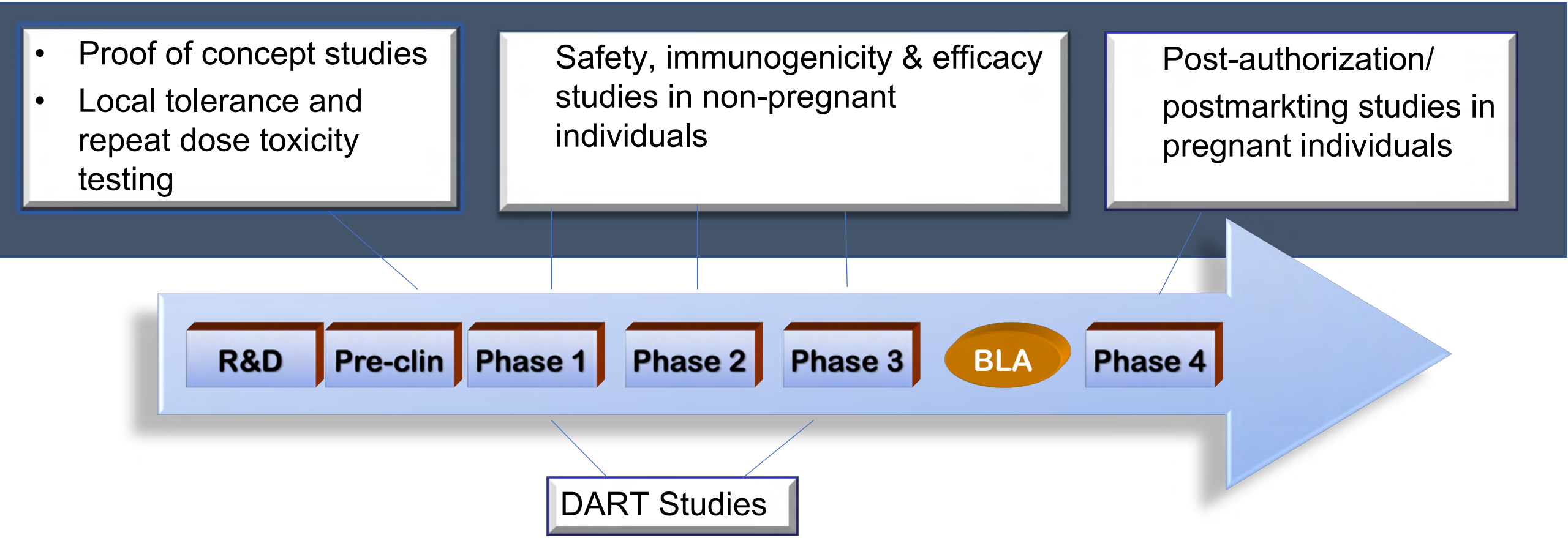
Disclaimer

- The following opinions and statements made represent my personal views.
- The opinions expressed herein do not represent those of FDA.
- The statements made have not been evaluated by FDA.

COVID-19 Pandemic – Situation presenting for pregnant women

- Pregnant women are at increased risk from complications due to COVID-19 leading to adverse pregnancy outcomes.
- FDA encouraged COVID-19 vaccine developers to present a plan for including pregnant women early in COVID-19 vaccine trials.
  - Vaccine manufactures did not propose plans on gathering safety and immunogenicity in pregnant women early in development.
- DART studies were the rate limiting step with respect to inclusion of pregnant women in clinical trials
- Pregnant women were excluded from participation in phase 3 clinical safety and efficacy trials with COVID-19 vaccines.
- Data from women with inadvertent pregnancies in these trials were limited and did not allow conclusions about the safety and effectiveness of candidate COVID vaccines in pregnancy.

Vaccine Development Pathway: Current Approach



FDA Initiatives

- Pregnant and lactating women should not be protected from participation in research, but rather should be protected *through* participation in research
- FDA convened the Vaccines and Related Biological Products Advisory Committee (VRBPAC) in November 2015 to publicly discuss clinical trial considerations for vaccines for use in pregnancy
- VRBPAC acknowledged that development of vaccines for use during pregnancy is possible with consideration of unique scientific, clinical and regulatory considerations
- Manufacturers should seek guidance on clinical development programs for vaccine to be administered during pregnancy

Highlights Of Recent Pregnancy And Lactation Activities in the United States And Europe

Activity	Year	Region and agency
Content and Format of Labeling for Human Prescription Drug and Biological Products: Requirements for Pregnancy and Lactation Labeling[1]	2014	US, US Food and Drug Administration
Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)[2]	2016	US, US Department of Health and Human Services
Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests[3]	2017	UK, Commission on Human Medicines
PRGLAC Report to Congress[4]	2018	US, Department of Health and Human Services
Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials: Draft Guidance for Industry[5]	2018	US, US Food and Drug Administration
Drug Safety in Pregnancy in a Large, Multisite Database: Mother-Infant Linkage in Sentinel[6]	2018	US, US Food and Drug Administration
ConcePTION – Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now[7]	2019	Europe, Innovative Medicines Initiative
Guideline on Good Pharmacovigilance Practices: Pregnant and Breastfeeding Women[8]	2019	Europe, European Medicines Agency
Postapproval Pregnancy Safety Studies: Guidance for Industry[9]	2019	US, US Food and Drug Administration
Clinical Lactation Studies, Considerations for Study Design: Guidance for Industry[10]	2019	US, US Food and Drug Administration
Programme of Work: Research to Support the Safer Use of Medicine during Pregnancy[11]	2019	UK, Medicines and Healthcare products Regulatory Agency
Strategic Reflection: EMA Regulatory Science to 2025[12]	2020	Europe, European Medicines Agency

Nooney J. *et al* 2021 Clin. Pharm.& Therap. Vol 110, No.4)

Global Regulators Call For A Paradigm Shift Toward Inclusion of Pregnant Women in Clinical Trials

Research	COVID-19 pandemic highlighted the need for addressing gaps in clinical trial research in pregnant women
Call to Action	Call to action on approaches to clinical trials in pregnant and lactating women
Global Regulatory Strategy	Experience with providing COVID-19 vaccines and therapeutics to pregnant women should be leveraged to form a global strategy for collecting systematic data for this patient population
Collection of Safety Data	Need for systematic plan to collect safety and immunogenicity data early in clinical development, e.g., “maternal immunization plan”?

FDA, MHRA and EMA: “Assessing Access to Safe Medicines in Pregnancy and breastfeeding (Nooney J. et al 2021 Clin. Pharm.& Therap. Vol 110, No. 4)

FDA National and International Initiatives

Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC)

To advise the Secretary of HHS on research and the development of safe and effective therapies specific to pregnant women and lactating women

Include and integrate pregnant women and lactating women in the clinical research agenda

Proactive protocol planning for inclusion of pregnant women

ICRMA Workshop on Pregnancy & Lactation

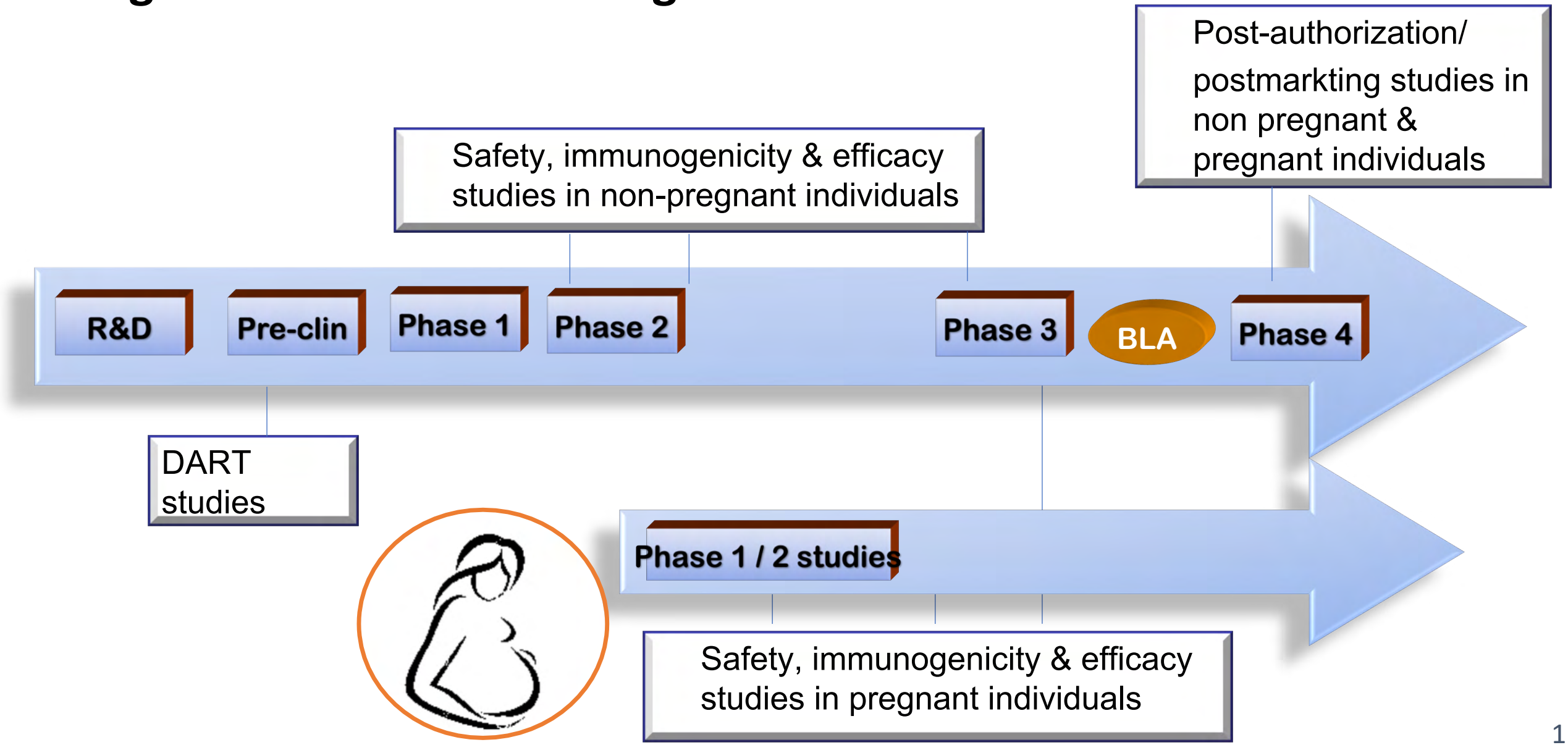
Support for international collaboration and a global strategy for collecting systematic data in pregnant women

Pregnancy and Lactation Cluster

Working Group formed by the FDA Office of Global Policy and Strategy, FDA medical product centers, EMA and MHRA

To foster a consistent global approach across regulatory jurisdictions to assure evidence-based safe and effective use of medicines during pregnancy and lactation

Potential Vaccine Development Pathway: Integration of Studies in Pregnant Women



Concluding Remarks

- The COVID-19 pandemic highlighted:
  - The need for including pregnant women in pre-licensure clinical trials
  - Necessity of “paradigm shift ”towards inclusion of pregnant and lactating women in clinical trials
- Global regulators put forth a united call to action for including pregnant women in medical research and opportunities for change in nonclinical, clinical and post-marketing data collection
  - https://www.fda.gov/news-events/fda-voices/global-regulators-envision-paradigm-shift-toward-inclusion-pregnant-and-breastfeeding-women-clinical

THANK YOU

Linda Eckert

MD
Professor Obstetrics & Gynecology
Adjunct Professor, Global Health
University of Washington

Obstetric professional societies' role in supporting access of vaccines for pregnant women

Obstetric professional societies role in supporting access of vaccines for pregnant individuals

LINDA O ECKERT, MD, FACOG
Professor, Department of Obstetrics & Gynecology
Adjunct Professor, Department of Global Health
University of Washington

November 18, 2021

UW Medicine

FINANCIAL DISCLOSURES

No disclosures

PERTINENT HATS

POLICY MATTERS

- Practicing obstetrician for ~30 years – including Liberia in 1987 when tetanus was huge killer of moms and babies
- WHO in 2009 as the HPV vaccine focal point and 2014 began consultancies with WHO in maternal immunization
- GAIA as the obstetrics coordinator for developing key terms of interest
- ACOG Expert Immunization Advisory Group since its 2011 inception
- GAVI immunization review committee 2012-2018, and 2020 ongoing
- ACOG Liaison to ACIP 2019

AMERICAN COLLEGE OF OBSTETRICS AND GYNECOLOGY (ACOG)

ACOG Immunization, Infectious Disease and Public Health Preparedness Work Group

- Began in 2011
- Group of ~12 Ob/Gyns and Peds – most with ID training
- Advise ACOG on policy and also create educational materials
- ACOG staff members very active
- Flu and Tdap recommendations in Pregnancy

PANDEMICS/EPIDEMICS EXPANDED NEED AND RESPONSES

- H1N1 Pandemic – quite active
- ZIKA – began producing rapid cycle information and advice

ACOG
The American College of Obstetricians and Gynecologists

When Covid hit – ACOG IEWG was poised to act

Expertise

- Third time around in OB ID “urgent/emergent” situation
- Front line providers
- Vaccine researchers/experts- PASSIONATE BELIEVERS in maternal immunization

Cross leadership

- SMFM leaders
- CDC ACIP past and current voting members
- VRPAC
- Peds ID

Formed active writing subgroups – with standing calls

- Covid working group

WHAT HAPPENED: a case study of the COVID-19 vaccine in the US – vaccine clinical trials

Development of the vaccine

- Accelerated process given high public interest and adequate funding
- Pregnant persons were EXCLUDED from clinical trials despite high level advocacy by key professional organizations to include them.

Recommendations were made by ACOG and SMFM, TO INCLUDE the pregnant population in clinical trials

ACOG

Society for Maternal-Fetal Medicine

WHAT HAPPENED: a case study of the COVID-19 vaccine in the US-initial vaccine data

Presentation of results of clinical trials to:

- Food and Drug Administration (FDA) for consideration of Emergency Use Authorization (EUA)
- CDC's Advisory Committee for Immunization Practices (ACIP)
- DART data: only available for Pfizer

NIH CDC FDA

ACOG

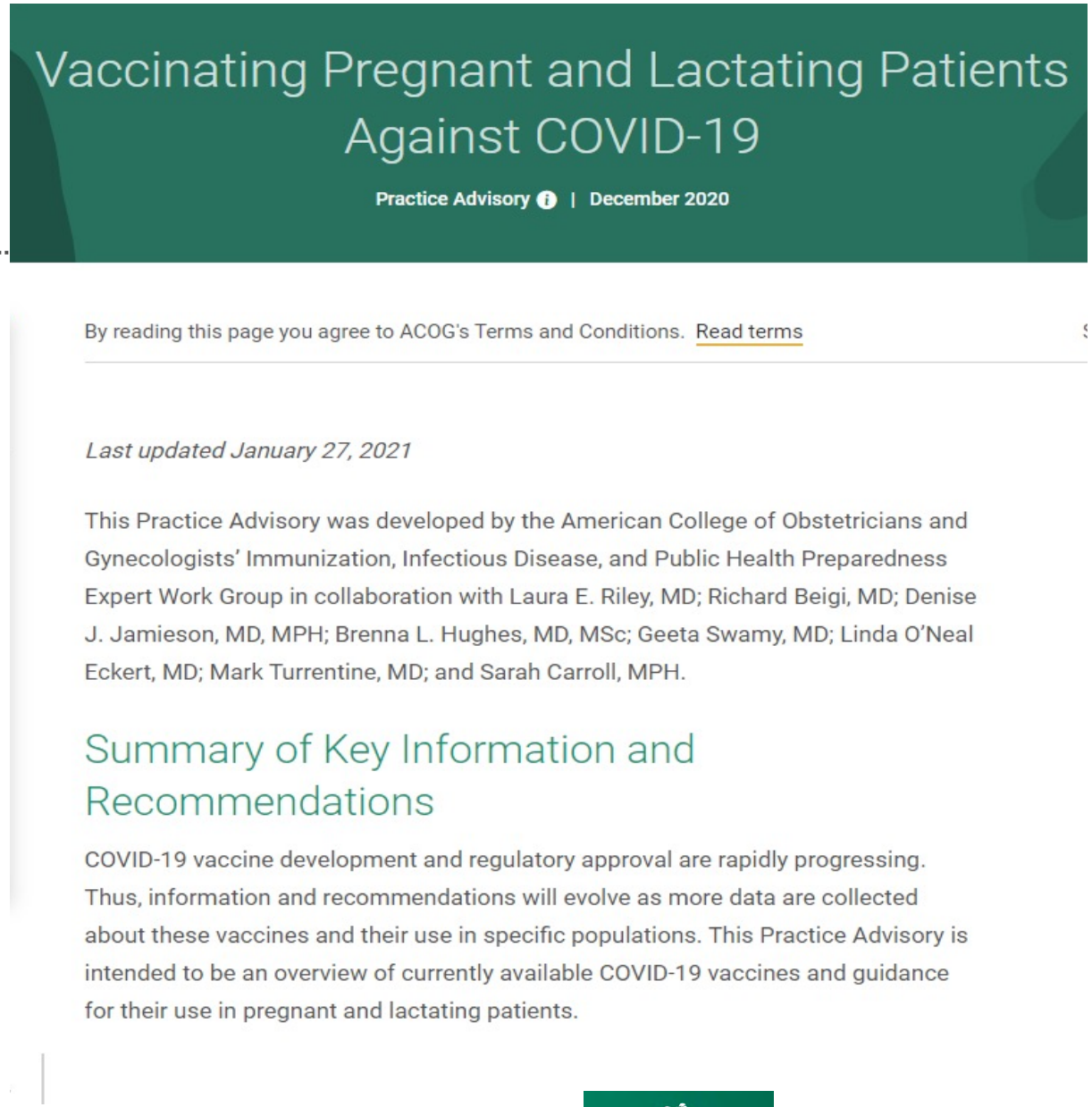
Society for Maternal-Fetal Medicine

ACOG and SMFM in alignment prepare joint statements highlighting the need for vaccines TO BE AVAILABLE to the pregnant population given risks for extreme morbidity and mortality with COVID-19 illness (*published 1 day following ACIP vote*).

ACOG Practice Advisory

Comprehensive clinical guidance for ACOG members regarding COVID-19 Vaccination for Pregnant and Lactating Individuals.

MULTIPLE UPDATES
Latest: Nov 3, 2021



Vaccinating Pregnant and Lactating Patients Against COVID-19

Practice Advisory | December 2020

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Last updated January 27, 2021

This Practice Advisory was developed by the American College of Obstetricians and Gynecologists' Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group in collaboration with Laura E. Riley, MD; Richard Beigi, MD; Denise J. Jamieson, MD, MPH; Brenna L. Hughes, MD, MSc; Geeta Swamy, MD; Linda O'Neal Eckert, MD; Mark Turrentine, MD; and Sarah Carroll, MPH.

Summary of Key Information and Recommendations

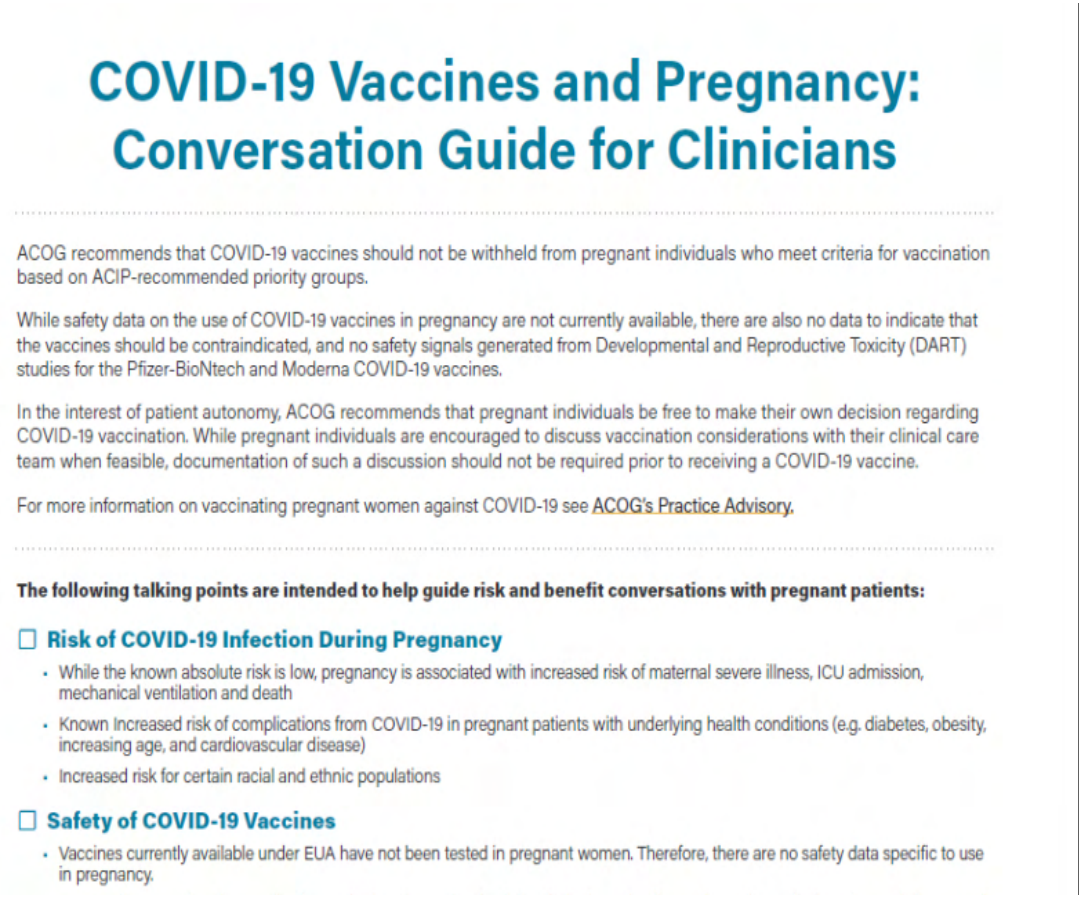
COVID-19 vaccine development and regulatory approval are rapidly progressing. Thus, information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations. This Practice Advisory is intended to be an overview of currently available COVID-19 vaccines and guidance for their use in pregnant and lactating patients.

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care

Conversation Guide for Clinicians

Highlights the main conversation points for clinicians from ACOG's Practice Advisory to help discuss COVID-19 vaccines with pregnant individuals.

- Intended to help guide risk/benefit conversations



COVID-19 Vaccines and Pregnancy: Conversation Guide for Clinicians

ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.

While safety data on the use of COVID-19 vaccines in pregnancy are not currently available, there are also no data to indicate that the vaccines should be contraindicated, and no safety signals generated from Developmental and Reproductive Toxicity (DART) studies for the Pfizer-BioNtech and Moderna COVID-19 vaccines.

In the interest of patient autonomy, ACOG recommends that pregnant individuals be free to make their own decision regarding COVID-19 vaccination. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

For more information on vaccinating pregnant women against COVID-19 see ACOG's Practice Advisory.

The following talking points are intended to help guide risk and benefit conversations with pregnant patients:

☐ **Risk of COVID-19 Infection During Pregnancy**

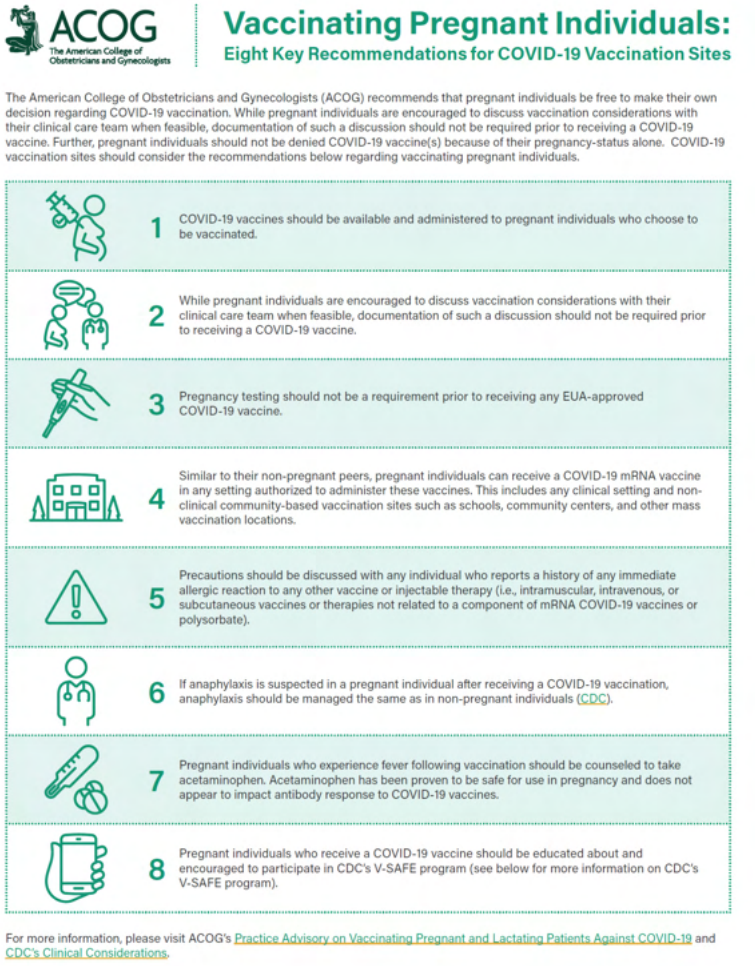
- While the known absolute risk is low, pregnancy is associated with increased risk of maternal severe illness, ICU admission, mechanical ventilation and death
- Known Increased risk of complications from COVID-19 in pregnant patients with underlying health conditions (e.g. diabetes, obesity, increasing age, and cardiovascular disease)
- Increased risk for certain racial and ethnic populations

☐ **Safety of COVID-19 Vaccines**

- Vaccines currently available under EUA have not been tested in pregnant women. Therefore, there are no safety data specific to use in pregnancy.

Vaccinating Pregnant Individuals: Eight Key Recommendations for COVID-19 Vaccination Sites

- Brand new resource from ACOG intended for all variations of COVID-19 vaccination sites
- Provides key recommendations from ACOG regarding COVID-19 vaccines and pregnancy
- Not intended to be a guide for risk/benefit conversations



ACOG
The American College of Obstetricians and Gynecologists

Vaccinating Pregnant Individuals:
Eight Key Recommendations for COVID-19 Vaccination Sites

The American College of Obstetricians and Gynecologists (ACOG) recommends that pregnant individuals be free to make their own decision regarding COVID-19 vaccination. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine. Further, pregnant individuals should not be denied COVID-19 vaccine(s) because of their pregnancy-status alone. COVID-19 vaccination sites should consider the recommendations below regarding vaccinating pregnant individuals.

1. COVID-19 vaccines should be available and administered to pregnant individuals who choose to be vaccinated.
2. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.
3. Pregnancy testing should not be a requirement prior to receiving any EUA-approved COVID-19 vaccine.
4. Similar to their non-pregnant peers, pregnant individuals can receive a COVID-19 mRNA vaccine in any setting authorized to administer these vaccines. This includes any clinical setting and non-clinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations.
5. Precautions should be discussed with any individual who reports a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate).
6. If anaphylaxis is suspected in a pregnant individual after receiving a COVID-19 vaccination, anaphylaxis should be managed the same as in non-pregnant individuals (CDC).
7. Pregnant individuals who experience fever following vaccination should be counseled to take acetaminophen. Acetaminophen has been proven to be safe for use in pregnancy and does not appear to impact antibody response to COVID-19 vaccines.
8. Pregnant individuals who receive a COVID-19 vaccine should be educated about and encouraged to participate in CDC's V-SAFE program (see below for more information on CDC's V-SAFE program).

For more information, please visit ACOG's Practice Advisory on Vaccinating Pregnant and Lactating Patients Against COVID-19 and CDC's Clinical Considerations.

Statement on Access to COVID-19 Vaccines for Pregnant Individuals

In response to reports of pregnant individuals being denied COVID-19 vaccines simply because of their pregnancy status, ACOG leveraged the *Maternal Immunization Task Force* to publish a **joint statement with 17 partner organizations, further advocating for pregnant individuals** to be free to make their own decision regarding their health, in conjunction with their clinical care team when appropriate.

MATERNAL IMMUNIZATION — TASK FORCE —

ACOG · American Academy of Family Physicians · American College of Nurse-Midwives · AWHONN

JOINED BY

AAPA · American Academy of Pediatrics · ACP · AMA · APhA · APHA · AIM · IAC · IDSA · NACDS · NACCHO · National Foundation for Infectious Diseases · National Medical Association · NPWH · Society for Maternal-Fetal Medicine · VACCINATE YOUR FAMILY

Maternal Immunization Task Force and Partners Urge That COVID-19 Vaccine be Available to Pregnant Individuals

All pregnant individuals who choose to receive the COVID-19 vaccine must be allowed to do so in alignment with their state and local vaccination allocation plan. This includes the estimated 330,000 health care workers who are pregnant and should be allowed to receive the vaccine as part of the first phase of vaccine distribution plans. Reports of pregnant individuals being refused vaccination are concerning.

Pregnant individuals who otherwise meet the criteria for COVID-19 vaccines should not be denied the opportunity to be vaccinated, should they choose to do so. Although a conversation with a clinician may be helpful for patients to aid in their decision-making, it should not be required prior to vaccination.

As the COVID-19 vaccine rollout continues, use must reflect the vaccines' federal regulatory authorization as well as information and recommendations from the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, and expert healthcare organizations.

Currently, available data demonstrate that pregnant individuals are at increased risk of more severe illness and death due to COVID-19 than their non-pregnant counterparts[1]. Providing pregnant individuals with the opportunity to be vaccinated can be critical to allowing them to protect themselves, particularly if their occupation puts them at increased risk of contracting the virus or they have underlying and comorbid conditions.

When pregnant individuals are excluded from the opportunity to decide whether to be vaccinated, it not only violates their bodily autonomy, it also puts them at risk of severe outcomes and death related to COVID-19 illness. Excluding this critical population at increased risk of severe illness and death related to COVID-19 is unethical.

In the interest of allowing pregnant individuals who would otherwise be considered a priority population for vaccines to make their own decisions regarding their health, our groups strongly recommend pregnant individuals should be free to make their own decision in conjunction with their clinical care team. All pregnant individuals must be supported in their decision about COVID-19 vaccination, whether they choose to receive the vaccine, or they opt to decline.

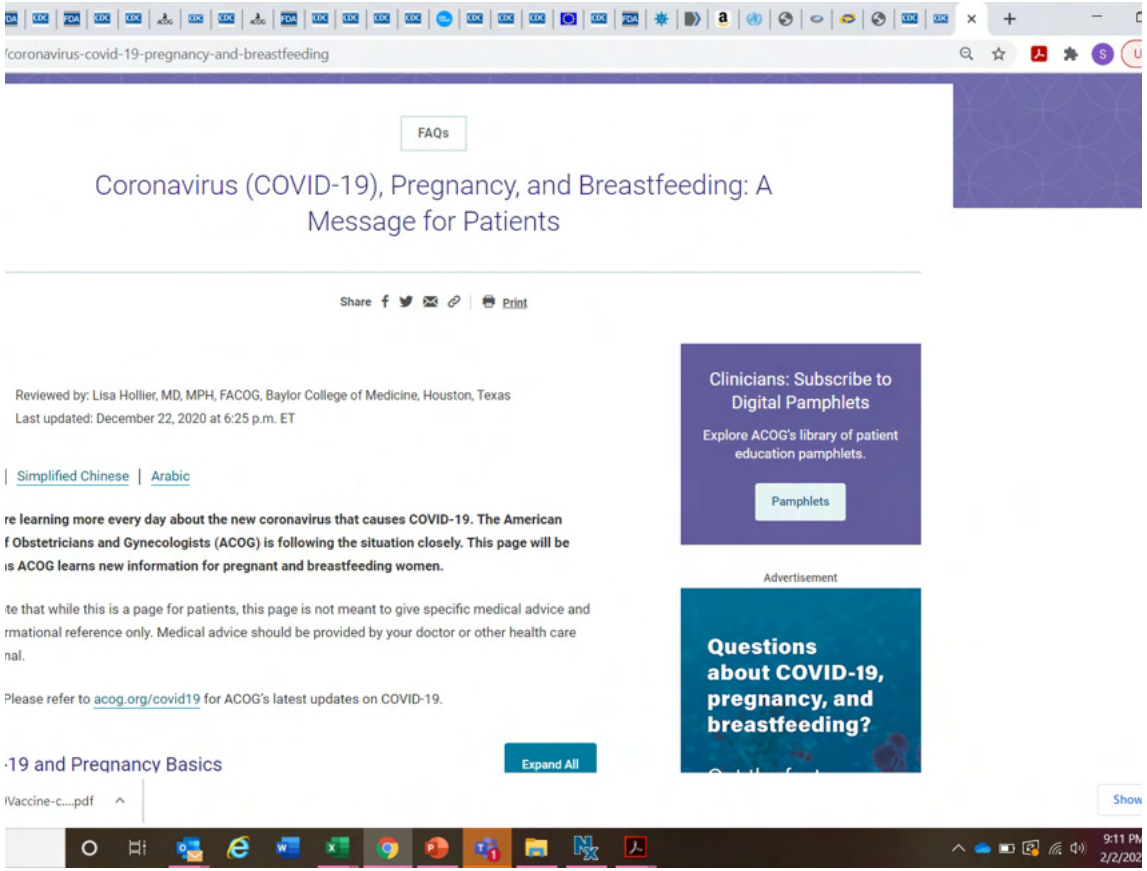
For more information, please visit ACOG's Practice Advisory on Vaccinating Pregnant and Lactating Patients Against COVID-19 and the CDC's Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

[1] Zambrano LD, Ellington S, Strid P, et al. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1641–1647. DOI: http://dx.doi.org/10.15585/mmwr.mm6944e3

Patient Education Resources

COVID-19 resources on ACOG's Patient Education Portal include:

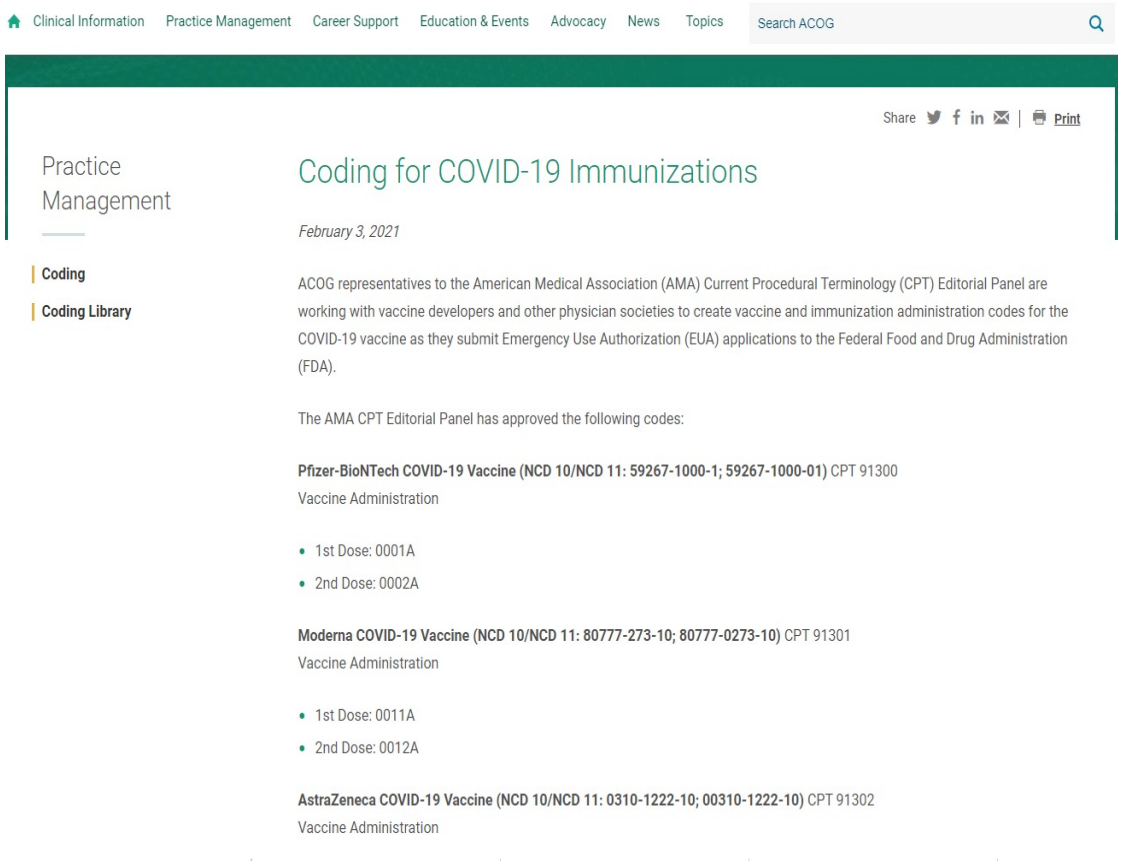
- Expert columns
- Frequently Asked Questions



UW Medicine

Coding for COVID-19 Immunizations

Brand new practice management resource outlining coding specifics for COVID-19 vaccines



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Practice Management

Coding

Coding Library

Coding for COVID-19 Immunizations

February 3, 2021

ACOG representatives to the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel are working with vaccine developers and other physician societies to create vaccine and immunization administration codes for the COVID-19 vaccine as they submit Emergency Use Authorization (EUA) applications to the Federal Food and Drug Administration (FDA).

The AMA CPT Editorial Panel has approved the following codes:

Pfizer-BioNTech COVID-19 Vaccine (NCD 10/NCD 11: 59267-1000-1; 59267-1000-01) CPT 91300
Vaccine Administration

- 1st Dose: 0001A
- 2nd Dose: 0002A

Moderna COVID-19 Vaccine (NCD 10/NCD 11: 80777-273-10; 80777-0273-10) CPT 91301
Vaccine Administration

- 1st Dose: 0011A
- 2nd Dose: 0012A

AstraZeneca COVID-19 Vaccine (NCD 10/NCD 11: 0310-1222-10; 00310-1222-10) CPT 91302
Vaccine Administration

ACOG (and SMFM) quickly responded to World Health Organization Recommendations

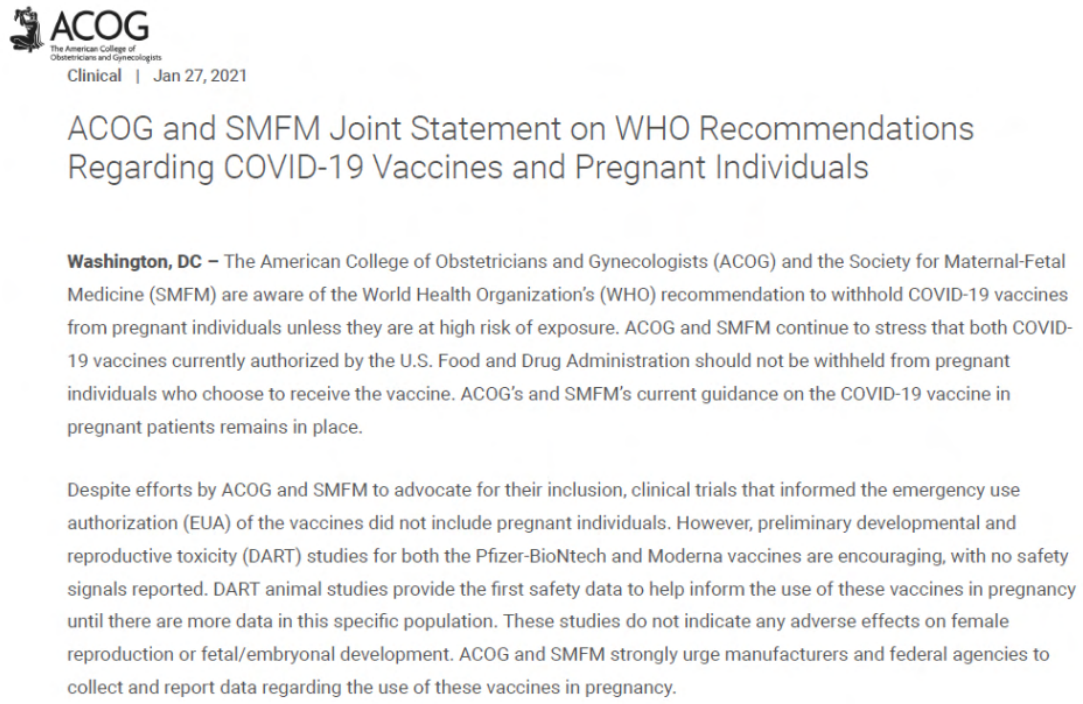
- WHO recommendations for both the Pfizer and Moderna vaccines initially explicitly stated that these vaccines should not be given to pregnant women unless they are high-risk of exposure, such as health care workers.

- These recommendations did not align with CDC nor ACOG and other obstetric medical societies.

ACOG Response to WHO Recommendations

Recognizing that the WHO recommendations would create confusion among clinicians and the public, ACOG and SMFM worked quickly to put out a statement affirming its recommendations that **COVID-19 vaccines should be available to all pregnant individuals who are eligible and choose to be vaccinated**.

- This statement yielded immense engagement in ACOG social media



ACOG
The American College of Obstetricians and Gynecologists

Clinical | Jan 27, 2021

ACOG and SMFM Joint Statement on WHO Recommendations Regarding COVID-19 Vaccines and Pregnant Individuals

Washington, DC – The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) are aware of the World Health Organization's (WHO) recommendation to withhold COVID-19 vaccines from pregnant individuals unless they are at high risk of exposure. ACOG and SMFM continue to stress that both COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration should not be withheld from pregnant individuals who choose to receive the vaccine. ACOG's and SMFM's current guidance on the COVID-19 vaccine in pregnant patients remains in place.

Despite efforts by ACOG and SMFM to advocate for their inclusion, clinical trials that informed the emergency use authorization (EUA) of the vaccines did not include pregnant individuals. However, preliminary developmental and reproductive toxicity (DART) studies for both the Pfizer-BioNtech and Moderna vaccines are encouraging, with no safety signals reported. DART animal studies provide the first safety data to help inform the use of these vaccines in pregnancy until there are more data in this specific population. These studies do not indicate any adverse effects on female reproduction or fetal/embryonal development. ACOG and SMFM strongly urge manufacturers and federal agencies to collect and report data regarding the use of these vaccines in pregnancy.

WHO Revised Recommendations

- Shortly after the ACOG statement and strong engagement and support from members, WHO revised their recommendation to be slightly more permissive:

“those pregnant women at high risk of exposure to SARS-CoV-2 (e.g. health workers) or who have comorbidities which add to their risk of severe disease, may be vaccinated in consultation with their health care provider.”

WHAT HAPPENED: a case study of the COVID-19 vaccine in the US- data in pregnant individuals builds

Start of the pandemic

- Knowledge about increased morbidity and mortality with influenza, also SARS, MERS, in pregnancy.
- Uncertainty about impact of COVID-19 illness in pregnant individuals.

- CDC surveillance
- Establishment of national and regional registries and collaborations
  - PRIORITY registry (UCSF)
  - Washington State COVID-19 in Pregnancy Collaborative
- Site specific data (i.e. New York)

WHAT HAPPENED: a case study of the COVID-19 vaccine in the US – vaccines recommended

Increasing studies showing 1) safety of COVID-19 vaccines in pregnancy and lactation and 2) risk with COVID-19 illness and 3) successful antibody transfer

- Statements ACOG, SMFM and CDC RECOMMENDING COVID-19 vaccines for pregnant people

Messaging by:

- CDC, national groups
- Obstetrical associations
- State departments of health
- Hospital systems provider groups
- Other health groups

Recipients:

- Health providers
- Pregnant people

Kachikis A, Englund JA, Singleton M, Covelli I, Drake AL, Eckert LO. JAMA Netw Open 2021;4:e2121310. doi: 10.1001/jamanetworkopen.2021.2131;
Prabhu M, Murphy EA, Sukhu AC, Yee J, Singh S, Eng D, et al. Obstet Gynecol. DOI: 10.1097/AOG.0000000000004438. Available at: https://journals.lww.com/greenjournal/Fulltext/9900/Antibody_Response_to_Coronavirus_Disease_2019.184.aspx.

WHAT HAPPENED: a case study of the COVID-19 vaccine in the US

ONGOING ADVOCACY BY OBSTETRIC SOCIETIES

- ACOG also used their media department to reach out, and encouraged all members of Expert Immunization Workgroup to take interviews
  - IMPLICATIONS FOR ME as the ACOG Liaison to CDC: Over 20 different conversations with reporters
  - Liaised with media and University of Washington
- ACOG now recruiting vaccine champions to better equip and create a cadre of spokespersons for local educational and adovacy efforts

ACOG is RECRUITING

COVID-19 Vaccine Confidence Champion Network

On September 29, 2021 CDC issued an urgent health advisory to increase COVID-19 vaccination among people who are pregnant, recently pregnant, who are trying to become pregnant, or who might become pregnant in the future to prevent serious illness, deaths, and adverse pregnancy outcomes. The advisory also calls on health departments and clinicians to educate pregnant people on the benefits of vaccination and the safety of recommended vaccines. ACOG is looking for Champions committed to enthusiastically recommending COVID-19 vaccination and facilitating conversations in an effort to increase confidence in the vaccines, the vaccinator, and the health system.

Society of Obstetricians and Gynaecologists of Canada

SOGC Statement on COVID-19 Vaccination in Pregnancy

POLIQUIN, V; CASTILLO, E; BOUCOIRAN, I; WONG, J; WATSON, H; YUDIN, M; MONEY, D; VAN SCHALKWYK, J; ELWOOD, C on behalf of the Infectious Disease Committee of the Society of Obstetricians and Gynaecologists of Canada

Original date: December 18, 2020
Revised and reaffirmed date: May 25th, 2021

https://sogc.org/common/Uploaded%20files/Latest%20News/SOGC_Statement_COVID-19_Vaccination_in_Pregnancy.pdf

Editorial

Editorial

Gynecologists and Obstetricians Working Group to Face the COVID-19 Pandemic in Brazil: Successful Experience to be Followed

Silvana Maria Quintana[1] Geraldo Duarte[1]

[1] Faculdade de Medicina, Universidade de São Paulo, Ribeirão Preto, SP, Brazil

Rev Bras Ginecol Obstet 2021;43(8):585–587.

- Ministry of Health established 17 member speciality working group for Covid-19
- Also developed online surveillance system to track pregnancy morbidity and mortality*

"the partnership with support of the Gynecology and Obstetrics Specialty Societies in the country was essential to broaden the debate and publicize the safety and effectiveness of vaccines during pregnancy and puerperal period"

"the effects of vaccination reflected in the reduction of maternal mortality by ~92% in our country."

*https://observatorioobstrico.shyinyapps.io/covid_gest_puerp.bv/

Up-to-Date page on Society links to COVID-19 information

UpToDate®

Society guideline links: COVID-19 – Obstetric and neonatal health care

Introduction

This topic includes links to society and government-sponsored guidelines from selected countries and regions around the world. We will update these links periodically; newer versions of some guidelines may be available on each society's website. Some societies may require users to log in to access their guidelines.

Includes links to International Societies (FIGO), and multiple continents/regions: UK, India, S America, N America…

Summary: Role of Obstetric Professional Societies

OBSTETRIC PROFESSIONAL SOCIETIES CAN AND DO PLAY AN IMPORTANT ROLE IN SUPPORTING ACCESS OF VACCINES FOR PREGNANT WOMEN

- Established body of experts, experienced with maternal immunization, public health and infectious diseases, and familiar with roll of policy is critical
- Early engagement and cross collaboration across similar societies and pools of expertise
- Point persons for communication and organization critical
- Excellent opportunity for improving international discussion and advocacy

PROACTIVE PLANNING IS CRITICAL

Summary: Role of Obstetric Professional Societies

ACKNOWLEDGEMENTS

- ACOG COVID writing group: Sarah Carroll, ACOG – immense leadership
- Laura Riley, Rich Beigi, Linda O Eckert, Brenna Hughes, Denise Jamieson, Geeta Swamy, Mark Turrentine
- COVID work group at CDC
- Research colleagues: Drs. Alisa Kachikis and Janet Englund at University of Washington
- Media contacts: Jamila Vernon with ACOG, Barbara Clements with UW

QUESTIONS?

Q&A

Session 4
Roundtable Discussion on Pandemic preparedness, Maternal immunization post COVID-19

Moderator

Denise Jamieson, MD MPH

James Robert McCord Professor &

Chair Department of Gynecology & Obstetrics,

Emory University School of Medicine

PANELISTS

Cristiana Toscano MD, PhD,

Professor at the Federal Universtiy Goiás in Brazil and Member of the PAHO TAG and WHO SAGE working group on COVID-19 vaccines

Sami Gottlieb

Medical Officer, World Health Organization, Dept of Sexual and Reproductive Health and Research

Delese Mimi Darko

Chief Executive Officer,
Ghana Food and Drugs Authority

Ruth Karron

Professor, Department of International Health, Johns Hopkins Bloomberg School of Public Health; Director, Center for Immunization Research

Sevene Esperança

Associate Professor of Clinical Pharmacology at Eduardo Mondlane University, President of the National Pharmacovigilance Committee, Member of Technical-Scientific Committee for the Prevention and Response to the Covid-19 Pandemic Maputo, Mozambique

Linda Eckert

Professor Obstetrics & Gynecology
Adjunct Professor, Global Health
University of Washington

Discussion Panel Members and Example Questions

Panel Members

Cristiana Toscano

Delese Mimi Darko

Sevene Esperança

Sami Gottlieb

Ruth Karron

Linda Eckert

Potential Discussion Questions

1. What data are needed for the next pandemic and what types of surveillance systems (pre and post vaccine roll out) should be set up?
2. What data are needed to characterize 1) the susceptibility and severity of disease in pregnancy and pregnancy outcomes, and 2) the safety and efficacy of potential interventions such as vaccines. How should these data be collected and how could the data collection and sharing be made more efficient?
3. What lessons learned from COVID-19 can be applied to future vaccines for pregnant women?
4. How can we improve communication around maternal vaccination to improve maternal acceptance? (eg. when to share information, what type of information, by whom?) Is knowing results from preclinical studies (e.g. DART) reassuring/sufficient for OB providers and vaccinators when deciding about vaccination of pregnant women?
5. What lessons learned from COVID-19 can be applied to future pandemics in terms of protecting pregnant persons; what else should we do now to prepare for the next pandemic?

Ajoke Sobanjo-ter Meulen

MD MSc, Senior Program Officer, Global Health, Pneumonia, Bill & Melinda Gates Foundation, USA

Flor Munoz

MD MSc, Associate Professor, Pediatrics-Infectious Disease, Baylor College of Medicine, USA

Wrap-up

Maternal Immunization Working Group

Clinical Development & Operations SWAT Teams