### **UIM 2023**

**Pandemics** 

Science & Leadership

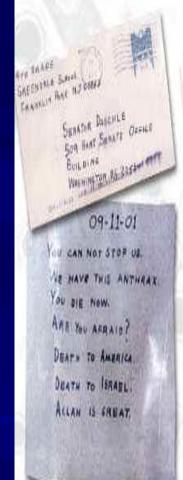
Richard H. Beigi, MD, MSc.

President, UPMC Magee-Womens Hospital
Professor Reproductive Sciences UPSOM

### Disclosures

- Member of ACOG COVID-19 WG
  - Co-PI for NIH/NIAID-MOMI-Vax
    - No Commercial COl's



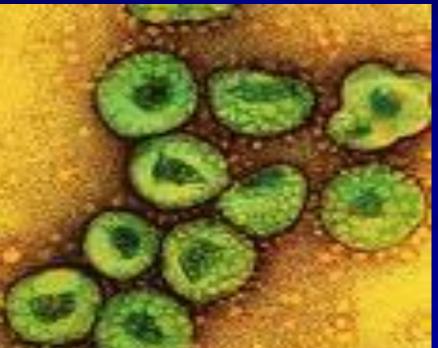




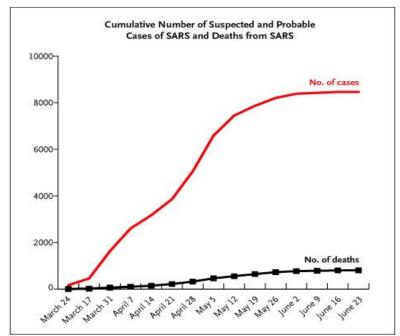












Data are from the World Health Organization (WHO). Cases identified in China between November 1, 2002, and February 28, 2003, were added to the March 31 total.





## Bio-preparedness

- Prepare for biologically-derived disasters
  - Rare, yet potentially significant

### Goal:

- Conceptualize scenarios and
- Preemptively plan to **minimize** disruption, morbidity and mortality:
  - Pregnant women
  - Unborn fetuses
  - Family structure
- Hospital Preparedness
  - Maternity hospital in particular

# Pathogens vs. Humanity



"The Triumph of Death" Pieter Bruegel @1562

## Modern Flu Pandemics

1918-19 "Spanish Flu"	1957-58 "Asian Flu"	1968-69 "Hong-Kong Flu"	1976 "Swine Flu"
U. S. Mortality <u>≥</u> 500K	U.S. Mortality ≥ 68K	U. S. Mortality ≥ 34K	Minimal

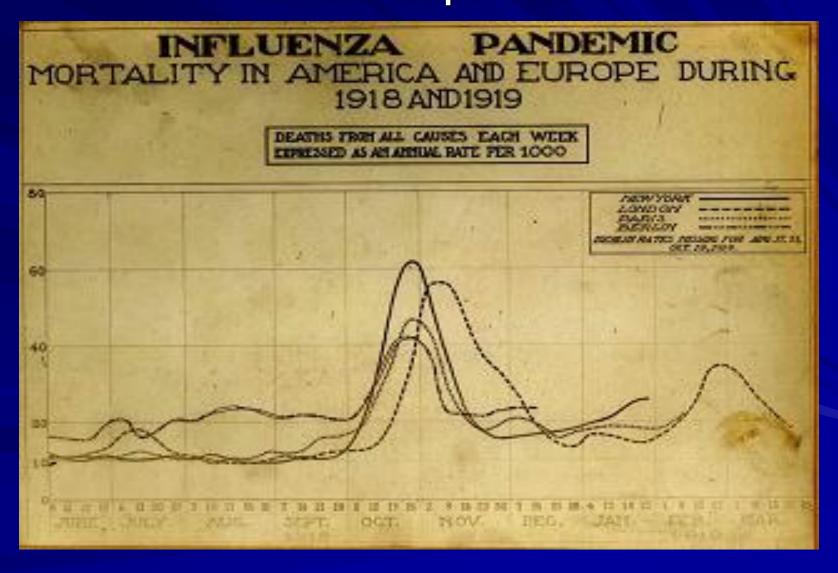
**Not Spain** Asian Asian **Fort Dix** ? Europe, ? Asia

? Avian

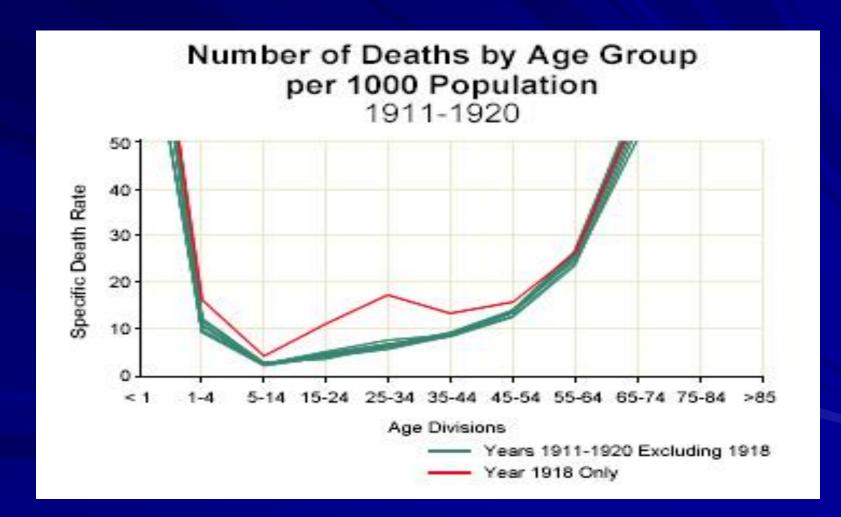
**H1N1** 

Avian Avian Swine H2N2 H3N2 H<sub>1</sub>N<sub>1</sub>

# Influenza Pandemic Line Graph Mortality in America and Europe During 1918 and 1919 Deaths from all causes each week expressed as an annual rate per 1000



## 1918 Pandemic



# Summary of Pandemic Influenza in Pregnancy

- Pandemics disproportionately affect pregnant women
  - Higher morbidity & mortality
  - Pneumonia key
    - High pregnancy wastage
  - 1918 Flu strain slowly became endemic
- Obstetricians and Maternity Hospitals: Central Role

# When Will the Next Pandemic Occur?

- NOT IF.....WHEN
- New strain
- Susceptible population + conditions suitable for quick dissemination
- Highly communicable

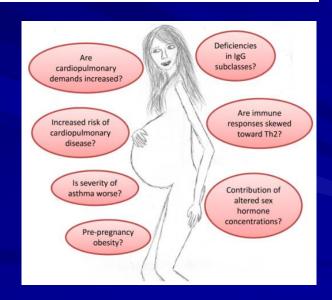


# The NEW ENGLAND JOURNAL of MEDICINE

### Emergence of a Novel Swine-Origin Influenza A (H1N1) Virus in Humans

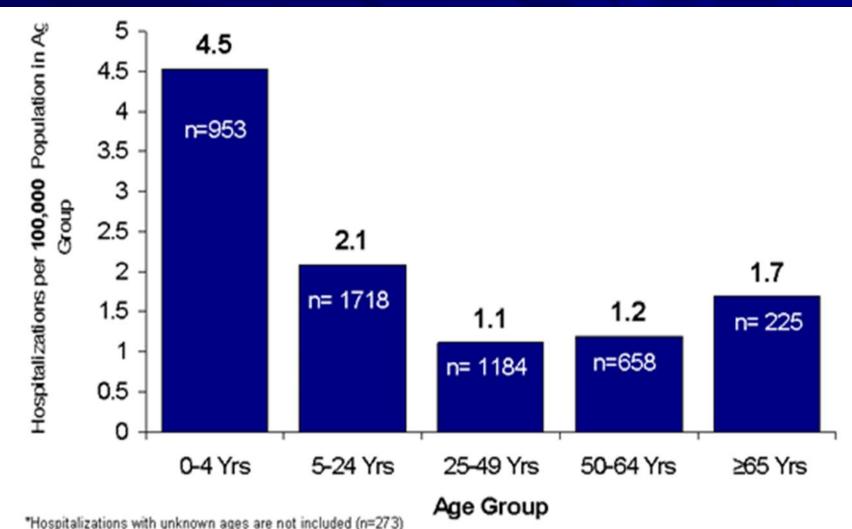
Novel Swine-Origin Influenza A (H1N1) Virus Investigation Team\*







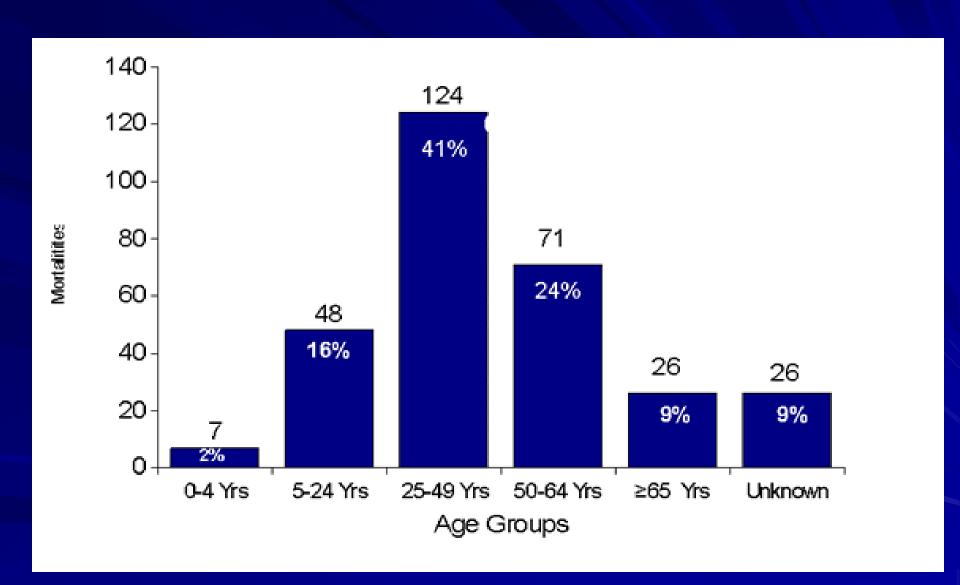
### H1N1 U.S. Hospitalization Rate per 100,000 Pop



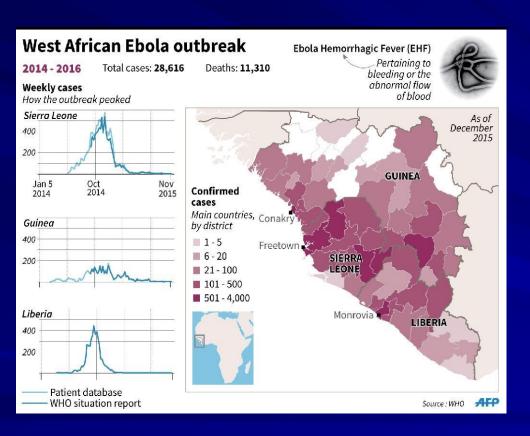
<sup>\*</sup>Hospitalizations with unknown ages are not included (n=273)

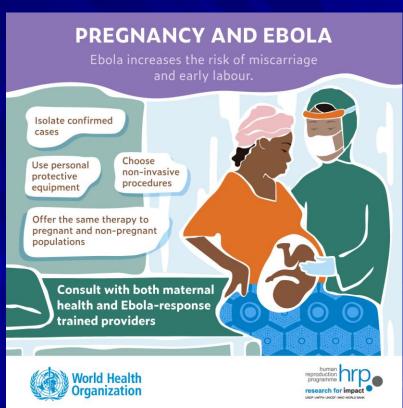
<sup>\*</sup>Rate / 100,000 by Single Year Age Groups: Denominator source: 2008 Census Estimates, U.S. Census Bureau at: http://www.census.gov/popest/national/asrh/files/NC-EST2007-ALLDATA-R-File24.csv

### H1N1 U.S. Deaths



## Ongoing Epidemics (2013-'16)

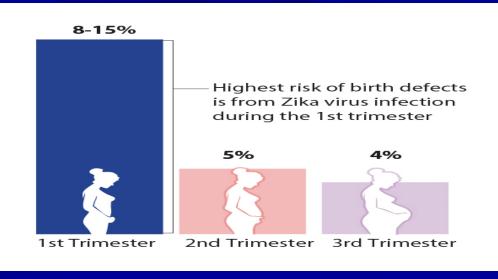




# Ongoing Epidemics (2017)

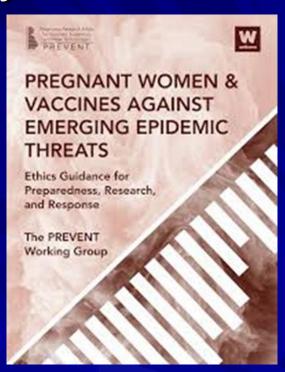






# Emerging Infectious Diseases in Pregnancy

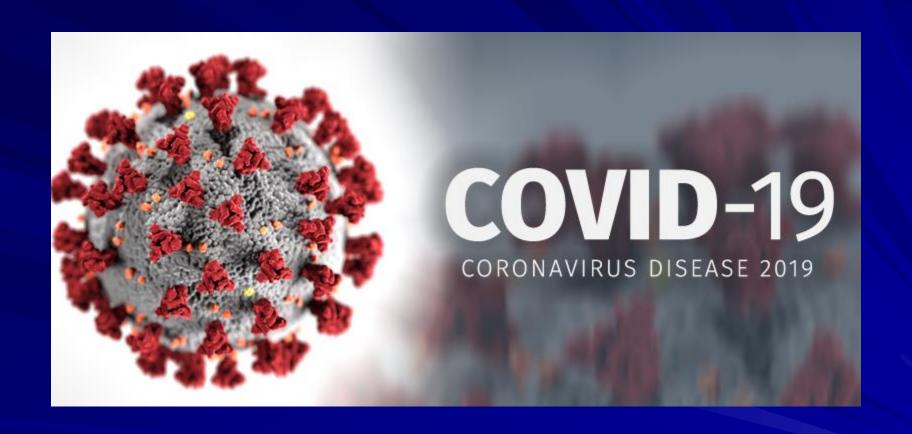
It has been recognized for centuries that pregnant women have unique susceptibilities to many infectious diseases that predispose them to untoward outcomes compared with the general adult population. It is thought a combination of adaptive alterations in immunity to allow for the fetal allograft combined with changes in anatomy and physiology accompanying pregnancy underlie these susceptibilities. Emerging infectious diseases are defined as those whose incidence in humans has increased in the past two decades or threaten to increase in the near future. The past decade alone has witnessed many such outbreaks, each with its own unique implications for pregnant women and their unborn fetuses as well as lessons for the health care community regarding response and mitigation. Examples of such outbreaks include, but are not limited to, severe acute respiratory syndrome, the 2009 H1N1 pandemic influenza, Ebola virus, and, most recently, the Zika virus. Although each emerging pathogen has unique features requiring specific considerations, there are many underlying principles that are shared in the recognition, communication, and mitigation of such infectious outbreaks. Some of these key principles include disease-specific delineation of transmission dynamics, understanding of pathogen-specific effects on both mothers and fetuses, and advance planning and contemporaneous management that prioritize communication among public health experts, clinicians, and patients. The productive and effective working collaboration among the Centers for Disease Control and Prevention, the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine has been a key partnership in the successful communication and management of such outbreaks for women's health care providers and patients alike. Going forward, the knowledge gained over the past decade will undoubtedly continue to inform future responses and will serve to optimize the education and care given to pregnant women in the face of current and future emerging infectious disease outbreaks.



Beigi RH. Emerging infectious diseases in pregnancy. Obstet Gynecol. 2017

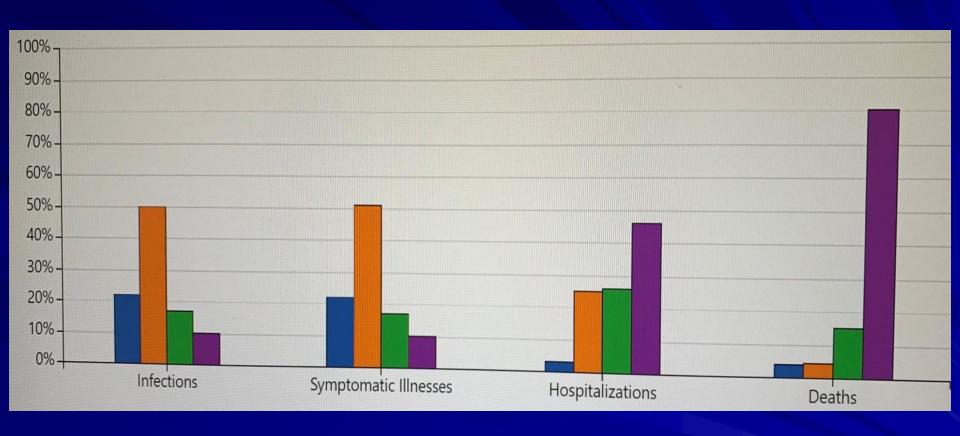
### Key considerations:

- Impact of disease on pregnancy (gestational age specific)
- Impact of pregnancy on disease course
- Countermeasures (? How best to include pregnancy)
  - Ethics → Justice, Primum Non Nocere, etc.
  - NPI, Rx, Vaccines, monoclonals, etc.



1<sup>st</sup> Quarter 2020

### U.S. % COVID-19 Cases, Hospitalizations, Deaths by age categories





# Summary COVID-19 Epidemiology (Generalizations)

- Case rates spread across age groups
- Bulk of overall hospitalizations/M&M:
  - Older age groups + Co-morbidities
  - High-risk categories
- What about pregnancy?

### Early 3-6 months

Pregnant women may be at increased risk for severe illness from COVID-19 compared with non-pregnant women



Pregnant women and their families should take steps to stay healthy and reduce their risk for getting COVID-19

CDC.GOV bit.ly/MMWR62520 MMWR

# COVID-19 Pregnancy & Risk of Severe Disease

Outcome	Pregnant women (n=8,207) No. (%)	Nonpregnant women (n=83,205) No. (%)	Adjusted risk ratio (95% CI)
Hospitalization	2,587	4,840	5.4
	(31.5)	(5.8)	(5.1-5.6)
ICU admission	120	757	1.5
	(1.5)	(0.9)	(1.2-1.8)
Mechanical ventilation	42	225	1.7
	(0.5)	(0.3)	(1.2 – 2.4)

### Key findings from living systematic review

- Pre-existing comorbidities, advanced maternal age, high BMI and non-white ethnicity are risk factors for severe COVID-19 in pregnancy
- Pregnant women vs reproductive aged women with COVID-19
  - Higher ICU admissions, need of mechanical ventilation, ECMO
  - No differences in mortality
- Pregnant women with COVID-19 vs pregnant women without COVID-19
  - Higher rates of **preterm births** (induced or spontaneous)
  - Higher admission to neonatal unit or ICU
  - No differences in rates of Caesarean sections
- COVID-19 may be associated with increased maternal death, but more data needed

Source: Allotey et al, Clinical manifestations, risk factors, and maternal and perinatal outcomes of COVID-19 in pregnancy: living systematic review and meta-analysis <a href="https://www.bmj.com/content/372/bmj.n615">https://www.bmj.com/content/372/bmj.n615</a> (Updated 10 Mar 2021)

Source: https://www.cdc.gov/mmwr/volumes/69/wr/mm6925a1.htm?s\_cid=mm6925a1\_w#T2\_down

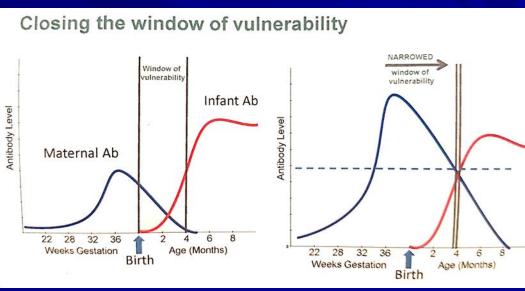
# FETAL & NEONATAL OUTCOMES

- Vertical transmission of SARS-CoV-2 may occur, but appears to be uncommon
- Pregnant people with COVID-19 are at increased risk for preterm birth
- Some data suggest an increased risk for other adverse pregnancy complications and outcomes, such as:
  - Preeclampsia,
  - Coagulopathy, and
  - Stillbirth
- Data now indicate that neonates born to people with COVID-19 are also at increased risk for admission to the neonatal intensive care unit

### Concept of Maternal Immunization

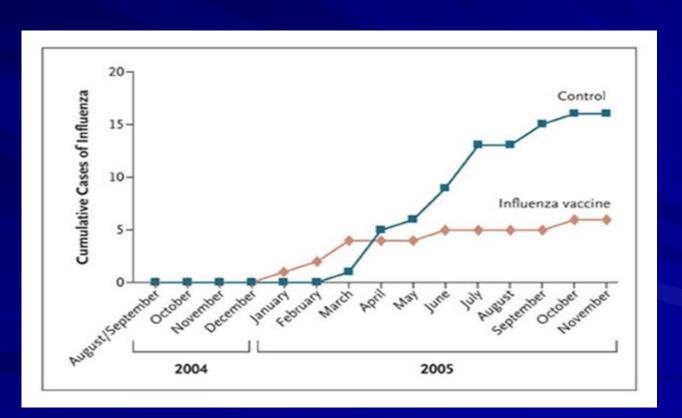
To boost maternal levels of pathogen-specific antibodies and endow the neonate and infant with sufficient concentrations of antibodies to resist infections during a period of increased vulnerability





### **Maternal Immunization**

- Recognized for > 100 yrs
  - Smallpox, pertussis, tetanus, etc.



### **Concerns over Maternal Immunization**

- Most prevalent concern is SAFETY
- Potential risks to mother: Reactions to vaccine, fever, fetal loss, possible induction of labor, effect on other pregnancy outcomes
- Potential risks to infant: Birth defects, infection (?), prematurity, low birth weight, tolerance to vaccine antigens, response to natural infection

Risk from Disease

Risk from Vaccine

# ADDRESSING PATIENT QUESTIONS & CONCERNS

Will COVID-19 vaccines affect my fertility?

Are COVID-19 vaccines safe during pregnancy?

I already had COVID-19, why do I need to get vaccinated?

I'm nervous because COVID-19 vaccines are so new and were developed so quickly

I'm young and healthy, why should I get vaccinated?

# How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

#### PHASE 1



### 20-100 healthy volunteers

- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

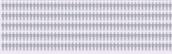
#### PHASE 2



#### several hundred volunteers

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

#### PHASE 3



#### hundreds or thousands of volunteers

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

### FDA licenses the vaccine only if:

- It's safe and effective
- Benefits outweigh risks

Vaccines are made in batches called lots.





Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.

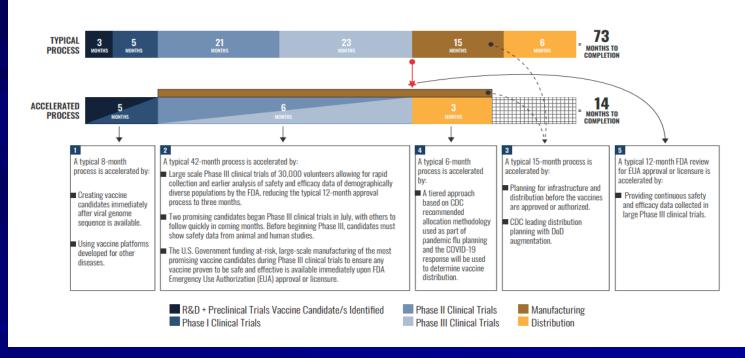
The FDA inspects manufacturing facilities regularly to ensure quality and safety.



FOR MORE INFORMATION, VISIT HTTPS://WWW.FDA.GOV/CBER



MISSION: Deliver 300 million doses of safe and effective vaccine by 1 January 2021.



https://media.defense.gov/2020/Aug/12/2002475961/-1/-1/1/WARP-SPEED-VACCINE-TIMELINE.PDF

## mRNA VACCINES

- Development and use of mRNA vaccines is relatively new
- mRNA vaccines consist of messenger RNA (mRNA) encapsulated by a lipid nanoparticle (LNP) for delivery into the host cells.
- These vaccines utilize the body's own cells to generate the coronavirus spike protein (the relevant antigens), which, similar to all other vaccines, stimulates immune cells to create antibodies against COVID-19.

## **MRNA VACCINES**

- Not a live virus vaccine
- No adjuvant
- Do not enter the nucleus
- Do not alter human DNA in vaccine recipients & cannot cause any genetic changes

#### 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., et al., for the CDC v-safe COVID-19 Pregnancy Registry Team\*

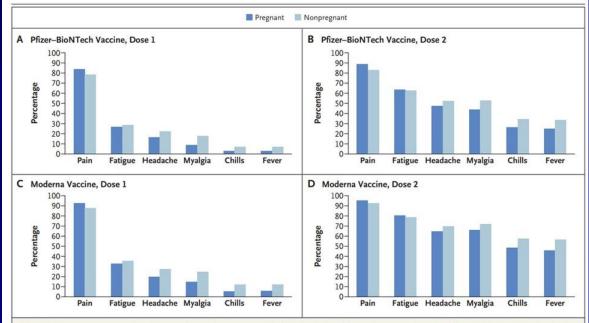


Figure 1. Most Frequent Local and Systemic Reactions Reported in the V-safe Surveillance System on the Day after mRNA Covid-19 Vaccination. Shown are solicited reactions in pregnant persons and nonpregnant women 16 to 54 years of age who received a messenger RNA (mRNA) coronavirus disease 2019 (Covid-19) vaccine — BNT162b2 (Pfizer–BioNTech) or mRNA-1273 (Moderna) — from December 14, 2020, to February 28, 2021. The percentage of respondents was calculated among those who completed a day 1 survey, with the top events shown of injection-site pain (pain), fatigue or tiredness (fatigue), headache, muscle or body aches (myalgia), chills, and fever or felt feverish (fever).

December 14, 2020, to February 28, 2021

A total of 35,691 v-safe participants 16 to 54 years of age identified as pregnant

Among 3958 participants enrolled in the vsafe pregnancy registry, 827 had a completed pregnancy

Preliminary findings did not show obvious safety signals among pregnant persons who received mRNA Covid-19 vaccines.

However, more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes.

## **Emerging Data: V-Safe**

## V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant women as of February 18, 2021\*

Outcomes	Background rates'	V-safe pregnancy registry overall
	16009	region y overan
Pregnancy outcome		and the same of th
Miscarriage (<20 weeks)	26%	15% <sup>†</sup>
Stillbirth (≥ 20 weeks)	0.6%	1%
Pregnancy complications		
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension <sup>5</sup>	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal		
Preterm birth	10.1%	10%
Congenital anomalies <sup>a</sup>	3%	4%
Small for gestational age	3-7%	4%
Neonatal death	0.38%	0%

<sup>\*</sup> Sources listed on slide 33; '93% of these were pregnancy losses <13 weeks of age; 'Pre-eclampsia or gestational hypertension diagnosed during pregnancy and/or during deliveny, 'Congenital anomalies (overall) diagnosed after deliveny only; 'Birthweight below the 10th percentile for gestational age and sex using INTERGROWTH-21st Century growth standards

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., <u>et al.</u>, for the CDC v-safe COVID-19 Pregnancy Registry Team, Re

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry
	%	no./total no. (%)
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk <sup>15-17</sup>	10-26	104/827 (12.6)‡
Stillbirth: ≥ 20 wk <sup>18-20</sup>	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk <sup>21,22</sup>	8-15	60/636 (9.4)¶
Small size for gestational age <sup>23,24</sup>	3.5	23/724 (3.2)
Congenital anomalies 25 **	3	16/724 (2.2)
Neonatal death <sup>26</sup> ††	<1	0/724

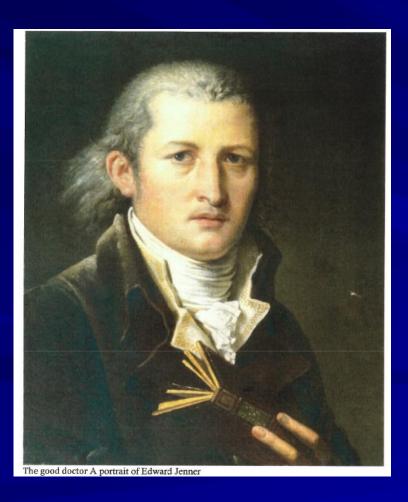
- \* The populations from which these rates are derived are not matched to the current study population for age, race and ethnic group, or other demographic and clinical factors.
- Data on pregnancy loss are based on 827 participants in the v-safe pregnancy registry who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer-BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021, and who reported a completed pregnancy. A total of 700 participants (84.6%) received their first eligible dose in the third trimester. Data on neonatal outcomes are based on 724 live-born infants, including 12 sets of multiples.
- ± A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation.
- The denominator includes live-born infants and stillbirths.
- The denominator includes only participants vaccinated before 37 weeks of gestation.
- Small size for gestational age indicates a birthweight below the 10th percentile for gestational age and infant sex according to INTERGROWTH-21<sup>st</sup> growth standards (http://intergrowth21.ndog.ox.ac.uk). These standards draw from an international sample including both low-income and high-income countries but exclude children with coexisting conditions and malnutrition. They can be used as a standard for healthy children growing under optimal conditions.
- \*\*\* Values include only major congenital anomalies in accordance with the Metropolitan Atlanta Congenital Defects Program 6-Digit Code Defect List (www.cdc.gov/ncbddd/birthdefects/macdp.html); all pregnancies with major congenital anomalies were exposed to Covid-19 vaccines only in the third trimester of pregnancy (i.e., well after the period of organogenesis).
- †† Neonatal death indicates death within the first 28 days after delivery.

### Vaccine Hesitancy





# Jenner & Birth of Vaccination (Variolization, Inoculation, Immunization)



AN

#### INQUIRY

INTO

THE CAUSES AND EFFECTS

OF

THE VARIOLÆ VACCINÆ,

A DISEASE

DISCOVERED IN SOME OF THE WESTERN COUNTIES OF ENGLAND,

PARTICULARLY

GLOUCESTERSHIRE,

AND KNOWN BY THE NAME OF

THE COW POX.

BY EDWARD JENNER, M.D. F.R.S. &c.

QUID NOBIS CERTIUS IPSIS

SENSIBUS ESSE POTEST, QUO VERA AC PALSA NOTEMUS.

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PRINTED, FOR THE AUTHOR,

BY SAMPSON LOW, No. 7, BERWICK STREET, SOHO:

AND SOLD BY LAW, AVE-MARIA LANE; AND MURRAY AND RIGHLEY, FLEET STREET.

1798.

### Immunization & Anti-vaccination



#### Smallpox "Remedies":

- Leeches,
- Silver needles to lance pox
- Purgatives (??)



Have I got moos for you The 'wonderful effects of cowpox' depicted by James Gillray (1802), ridiculing all those who believed that vaccination could turn people into cattle



### VACCINEIQ

#### VACCINE HESITANCY CONTINUUM

#### **VACCINE HESITANCY**

**VACCINE ACCEPTANCE** 

The delay in acceptance or refusal of vaccination despite the availability of vaccination services

The acceptance of a vaccine or series of vaccines

The Range of Vaccination Behavior





### MYTH:

# THE COVID-19 VACCINE CAUSES WOMEN TO BE INFERTILE AND IS HARMFUL DURING PREGNANCY



# COVID-19 VACCINES AND FERTILITY

Morris, R.S. documented in women that seropositivity to the SARS-CoV-2 spike protein, whether from vaccination or infection, does not prevent embryo implantation or early pregnancy development.

Pregnancy rates.				
	Reactive vaccine	Reactive infection	Nonreactive	P value
All patients	n = 35	n = 20	n = 88	
Biochemical (%)	80.0	73.7	73.9	.19
Clinical (%)	65.7	52.6	62.5	.15
Ongoing (%)	65.7	47.4	52.3	.11
Euploid only	n = 17	n = 10	n = 40	
Biochemical (%)	82.4	80	80	.97
Clinical (%)	70.6	70	70	.99
Ongoing (%)	70.6	70	60	.68

Morris, R.S. SARS-CoV-2 spike protein seropositivity from vaccination or infection does not cause sterility, F&S Reports, 42 2021, https://www.sciencedirect.com/science/article/pii/S2666334121000684

# WILL COVID-19 VACCINES AFFECT MY FERTILITY?



There is no evidence that the COVID-19 vaccines affect fertility. ACOG recommends vaccination for anyone who may consider getting pregnant in the future.

### How a vaccine's safety continues to be monitored

BENEFIT

FDA and CDC closely monitor vaccine safety after the public begins using the vaccine.

The purpose of monitoring is to watch for adverse events (possible side effects). Monitoring a vaccine after it is licensed helps ensure that possible risks associated with the vaccine are identified.

#### **Vaccine Adverse Event Reporting System (VAERS)**

VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients and healthcare professionals.

#### Vaccine Safety Datalink (VSD) and Post-Licensure Rapid Immunization Safety Monitoring (PRISM)



Two networks of healthcare organizations across the U.S.

 VSD can analyze healthcare information from over 24 million people.  PRISM can analyze healthcare information from over 190 million people.



Scientists use these systems to actively monitor vaccine safety.

#### Clinical Immunization Safety Assessment Project (CISA)

CISA is a collaboration between CDC and 7 medical research centers.

- Vaccine safety experts assist U.S. healthcare providers with complex vaccine safety questions about their patients.
- CISA conducts clinical research studies to better understand vaccine safety and identify prevention strategies for adverse events following immunization.

Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like if scientists detect a new <u>serious side effect</u>).

FOR MORE INFORMATION, VISIT HTTPS://WWW.CDC.GOV/VACCINESAFETY

SHOULD PREGNANT WOMEN BE VACCINATED FOR COVID-19?

## YES!!



cdc.gov/coronavirus

### TIMELINE OF ACOG COVID-19 VACCINE RECOMMENDATIONS

Dec. 11, 2020



Pregnant people excluded from clinical trials

Only animal model data in pregnancy – no safety signals indicated



Dec. 21, 2020

Moderna COVID-19 vaccine recommended

**ACOG Practice Advisory** revised - to recommend access to both mRNA vaccines

ACOG recommends pregnant people have access to COVID-19 vaccines

ACOG recommends risk-benefit conversation with a clinician

ACOG receives reports of pregnant people being denied access to COVID-19 vaccines

ACOG develops Eight Key Recommendations for COVID-19 Vaccination Sites

Jan. 2021

Dec. 13, 2020



Jan. 2021

CDC begins reporting numbers of people enrolled in v-safe after vaccine health checker who identify as pregnant (15,000 first reported) Feb. 28, 2021

ACIP votes to recommend the use of J&J/Janssen COVID-19 vaccine

ACOG guidance updated to reflect availability of J&J/Janssen

ACOG leads statement: Maternal Immunization Task Force and Partners Urge That COVID-19 Vaccine be Available to Pregnant Individuals First safety data from the vsafe pregnancy registry reported at ACIP

Reactogenicity profile and adverse events **did not** indicate any safety concerns

Feb. 3, 2021

Mar 1. 2021

48



Over 100,000 pregnancies reported in the v-safe registry & 5,000 enrollees in CDC's v-safe pregnancy registry



#### **June 2021**

Delta variant dominates areas of the country; COVID-19 cases surge Increased hospitalization, ICU admission reported among pregnant people

Data from CDC's v-safe pregnancy registry published in NEJM

No safety signals identified

No increased risk of miscarriage

June. 2021

ACOG recommends COVID-19 vaccination for all pregnant people

**July 30, 2021** 

**September 22, 2021** 

Pfizer-BioNTech mRNA vaccine authorized for use as a booster dose for certain populations

October 21, 2021

CDC recommends the use of Moderna and J&J/Janssen boosters

ACOG updates guidance to include recommendations for Pfizer-BioNTech booster vaccination for pregnant individuals who received Pfizer-BioNTech

October 1, 2021

ACOG updates guidance to recommend Moderna and J&J/Janssen boosters during pregnancy

**November 3, 2021** 

December 16, 2021

CDC gives preferential recommendation to mRNA vaccines for primary series and booster COVID-19 vaccine doses

July 13, 2022

CDC recommends the use of Novavax COVID-19 vaccine

ACOG updates guidance to reflect preferential recommendation for mRNA vaccines for primary and booster COVID-19 vaccine doses

**)** January 25, 2022

ACOG updates guidance to recommend Novavax COVID-19 Vaccine

August 5, 2022

#### **September 1, 2022**

CDC recommends the use of bivalent mRNA COVID-19 vaccines for use as a booster dose in all individuals aged 12 years and older, replacing previous recommendations for monovalent COVID-19 vaccines

ACOG updates guidance to reflect new recommendations for the use of bivalent mRNA COVID-19 vaccines for use as boosters; recommending bivalent boosters for pregnant individuals

**September 12, 2022** 

### ACOG PRACTICE ADVISORY

Comprehensive <u>clinical</u> <u>guidance</u> regarding COVID-19 Vaccination

- FDA & ACIP recommendations
- Efficacy & safety information
- ACOG recommendations

#### COVID-19 Vaccination Considerations for Obstetric-Gynecologic Care

Practice Advisory (i) | December 2020

By reading this page you agree to ACOG's Terms and Conditions. Read terms

Last updated November 16, 2022

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 Updates

This Practice Advisory provides an overview of the currently available COVID-19 vaccines and guidance for their use in pregnant, recently pregnant, lactating, and nonpregnant individuals aged 12 years and older. For guidance and recommendations for the use of these vaccines in individuals aged 11 years or younger, please visit the website of the American Academy of Pediatrics. For additional information regarding severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) infection and treatment, see ACOO's Frequently Asked Questions.

### LACTATING INDIVIDUALS

- ACOG strongly recommends that lactating individuals be vaccinated against COVID-19.
- Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine.
- There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine.
- Current data demonstrate that lactating people who have received mRNA COVID-19 vaccines have antibodies in their breast milk, suggesting a potential protective effect against infection in the infant, although the degree of clinical benefit is not yet known.



After you get vaccinated, the antibodies made by your body may be passed through breastmilk and may help protect your baby from the virus. ACOG recommends that breastfeeding women be vaccinated against COVID-19.

# ACOG BOOSTER RECOMMENDATION GRAPHIC

### **COVID-19 VACCINE BOOSTERS**DURING PREGNANCY

All people, including pregnant people should receive a bivalent mRNA COVID-19 vaccine booster dose following the completion of their last COVID-19 primary vaccine dose or monovalent booster.

#### Bivalent mRNA COVID-19 vaccines are now the recommended vaccines for use as a booster for individuals aged 5 years and older.

- Monovalent mRNA COVID-19 vaccines are no longer authorized for use as a booster.
- Bivalent mRNA COVID-19 vaccines are the default for booster vaccination. However, Novavax's monovalent COVID-19 vaccine is allowable for use as a booster (not primary vaccination) when a person has not yet received any booster dose and:
- » is unable to get a bivalent mRNA COVID-19 vaccine, or
- » is unwilling to get a bivalent mRNA COVID-19 vaccine.
- Bivalent mRNA COVID-19 vaccines are only authorized for use as boosters. They are not authorized for use as primary doses at this time. Individuals must complete their primary monovalent COVID-19 vaccine series before receiving a bivalent mRNA COVID-19 booster.
- Booster vaccination may occur in any trimester, and emphasis should be on vaccine receipt as soon as possible to maximize maternal and fetal health.



### Then & Now











### Then & Now





### TWO CITIES PROTEST WEARING FLU MASKS

PASADENA, Jan. 21.—Fifty Pasadenans, many prominent, were under arrest here today charged with appearing in public without "flu" masks. The police started enforcement of the "flu" mask ordinance yesterday.



### Then & Now



#### LODGE HALL COBWEBS

Grip Ban on All Meetings Until Places Are Renovated; 21 Theaters Reopen,

Dr. Robertson Warns Against Relaxing Precaution, Despite FLU CURFEW TO Wane of Epidemic

#### HEALTH ORDER DOOMS POLICE RAID SALOONS IN WAR ON INFLUENZA: KEEP CHIIRCH WINDOWS OPEN

Stringent New Orders Are Issued for Preventing Spread of Epidemic; Police Ambulances Are Drafted: 100,000 Doses of Vaccine on Way.

1.613 NEW CASES SHOW DECREASE IN CITY; DOWNSTATE HIT WORST

#### SOUND FOR CITY SATURDAY NIGHT

Persons Not on Business Expected to Quit the Streets at 9 o'Clock.

The currew will ring or, rather, blow in Chicago temorrow night.

Promptly at 9 o'clock the whistles of

#### 'NONESSENTIAL' **CROWDS BARRED** IN EPIDEMIC WAR

Churches and Saloons Exempt: Conventions, Athletics, Parties Hit.

FREE DOCTOR

#### CHURCH WINDOWS SAYS ROBERTSON

Health Department Gives Out New Rules in Fight on

public to man Brit-Red Cross he neigh-Inspector Striving to Enforce Order

Two men and a woman were shot the head yesterday at Powell and Market



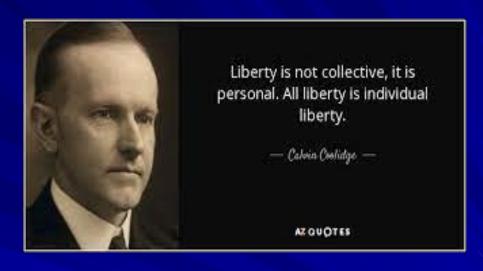
Admission Free.

### Blacksmith Strikes Health

the kend the Red treet when Henry D. Miller, an inchoosing spector in the city Health Department of the Committee Co

### Ongoing Underlying Issue







The proper balance between individual liberty and central authority is a very ancient problem.

Arthur Keith

### Many of us lived this as well

It's amazing how many parents went from, "I don't understand my kid's 6th grade math homework" to, "I'm an infectious disease expert" in just six months.



### Expectations

- COVID era will continue for some time now regular biosphere pathogen
  - Transition of SARS-CoV-2 to endemicity
- We will have future Pandemics
  - Predictably unpredictable in nature & timing
  - Predictable in occurrence
  - Pregnant population (challenges & opportunities they present) will stay prominent