# C19 AND “VACCINES”

An OBGYN’s Experience

# Pregnancy Drug Categories

| Category | Interpretation | Details |
|---|---|---|
| A | Human studies show no risk | Adequate, well-controlled studies in pregnant women have not shown an increased risk of fetal abnormalities to the fetus in any trimester of pregnancy |
| B | No evidence of risk in studies | Animal studies have revealed no evidence of harm to the fetus, however, there are no adequate and well-controlled studies in pregnant women. OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester. |
| C | Risk cannot be ruled out | Animal studies have shown an adverse effect and there are no adequate and well-controlled studies in pregnant women. OR No animal studies have been conducted and there are no adequate and well-controlled studies in pregnant women. |
| D | Positive evidence of risk | Adequate well-controlled or observational studies in pregnant women have demonstrated a risk to the fetus. However, the benefits of therapy may outweigh the potential risk. For example, the drug may be acceptable if needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective. |
| X | Contraindicated in pregnancy | Adequate well-controlled or observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities or risks. The use of the product is contraindicated in women who are or may become pregnant. |

| | | |
|---|---|---|
| X | Contraindicated in pregnancy | Adequate well-controlled or observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities or risks. The use of the product is contraindicated in women who are or may become pregnant. |

## Category X Drugs

- Valproate
- Methotrexate
- Ribavirin
- Triazolam
- Bosentan
- Aliskiren
- Emergency contraception: Levonorgestrel, Ulipristal
- Griseofulvin
- Methylene blue
- Oxytocin
- Riociguat
- Isotretinoin

https://wikem.org/wiki/Drug_pregnancy_categories

# Are mRNA Injections Category X?

# Obstetric Blunders:

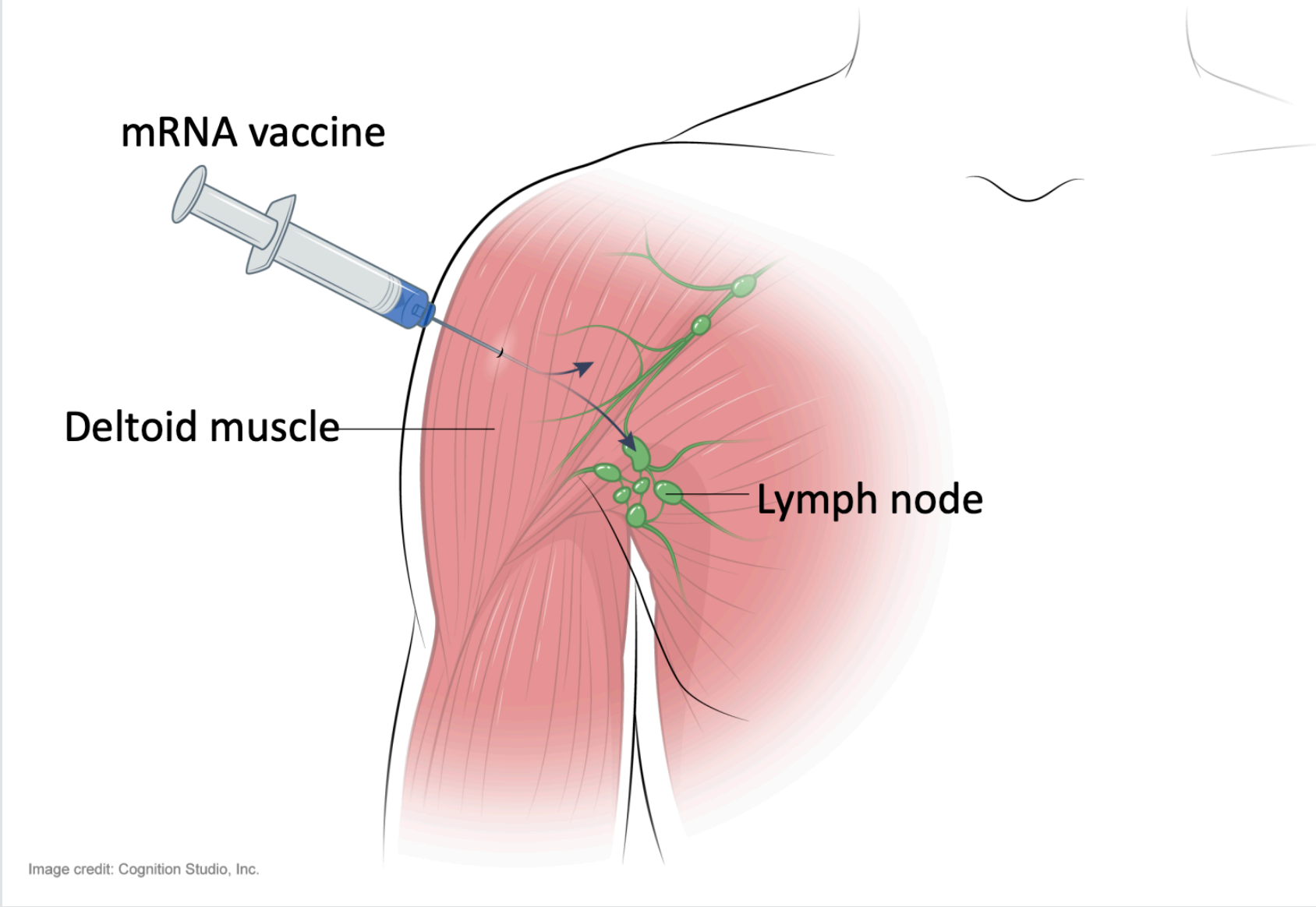
## DES – Diethylstillbestrol

- Synthetic estrogen
- Prescribed between 1940 -1971
- Prevent Miscarriage and PTL
- Stopped use in pregnancy 1950s
- Continued use to stop lactation, for emergency contra-
  caption, menopause
- 1971 linked in utero exposure to clear cell carcinoma
  and twice the risk for cervical dysplasia

# Thalidomide

- First marketed in 1957 in West Germany
- Morning sickness
- 1961 birth defects estimate 10,000 (40 % died at birth)
- Limb, eye, urinary tract, heart problems
- Frances Kelsey (FDA) prevented entry into US market
- Currently approved for use for cancer and Leprosy

# Intended Biodistribution

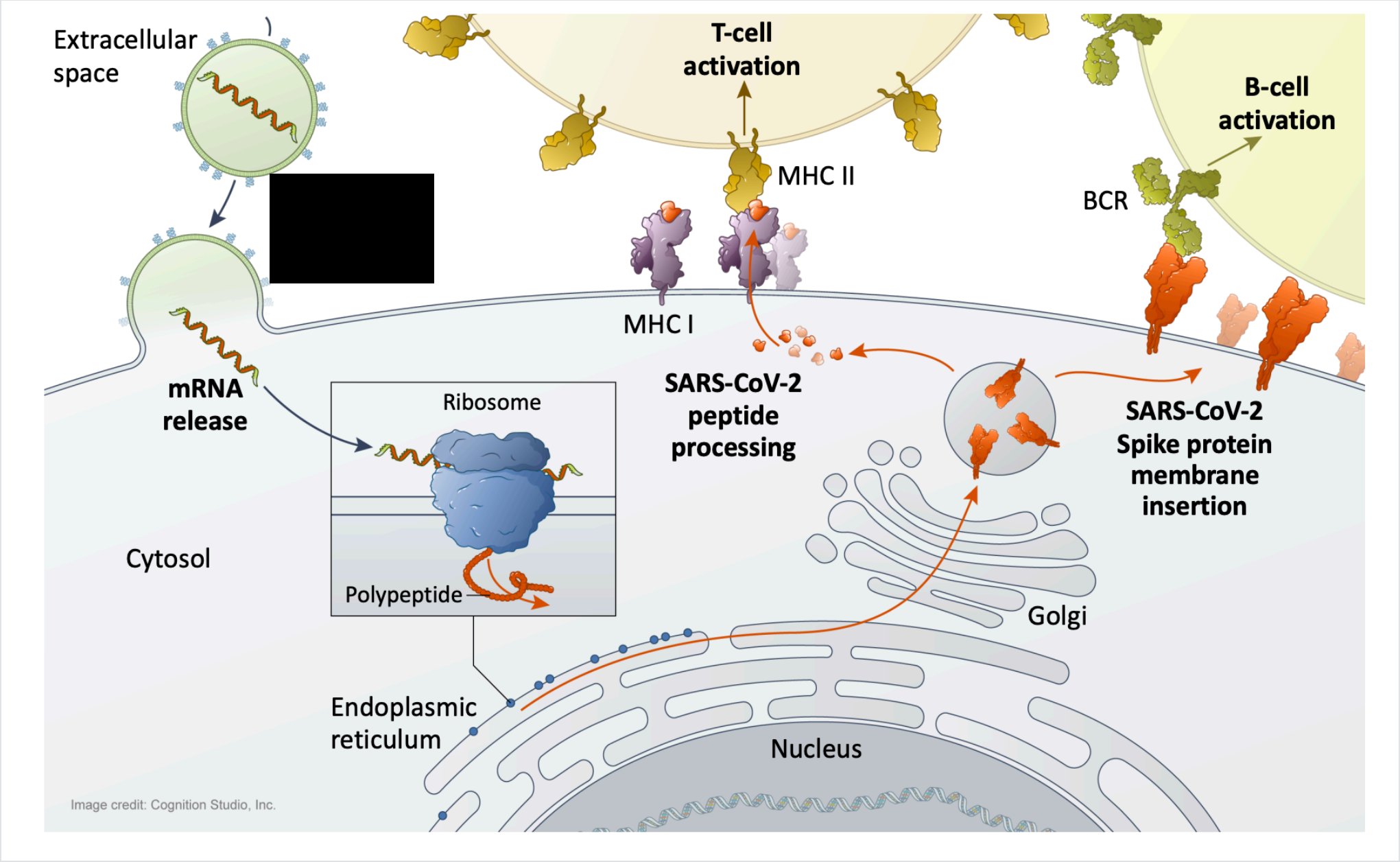


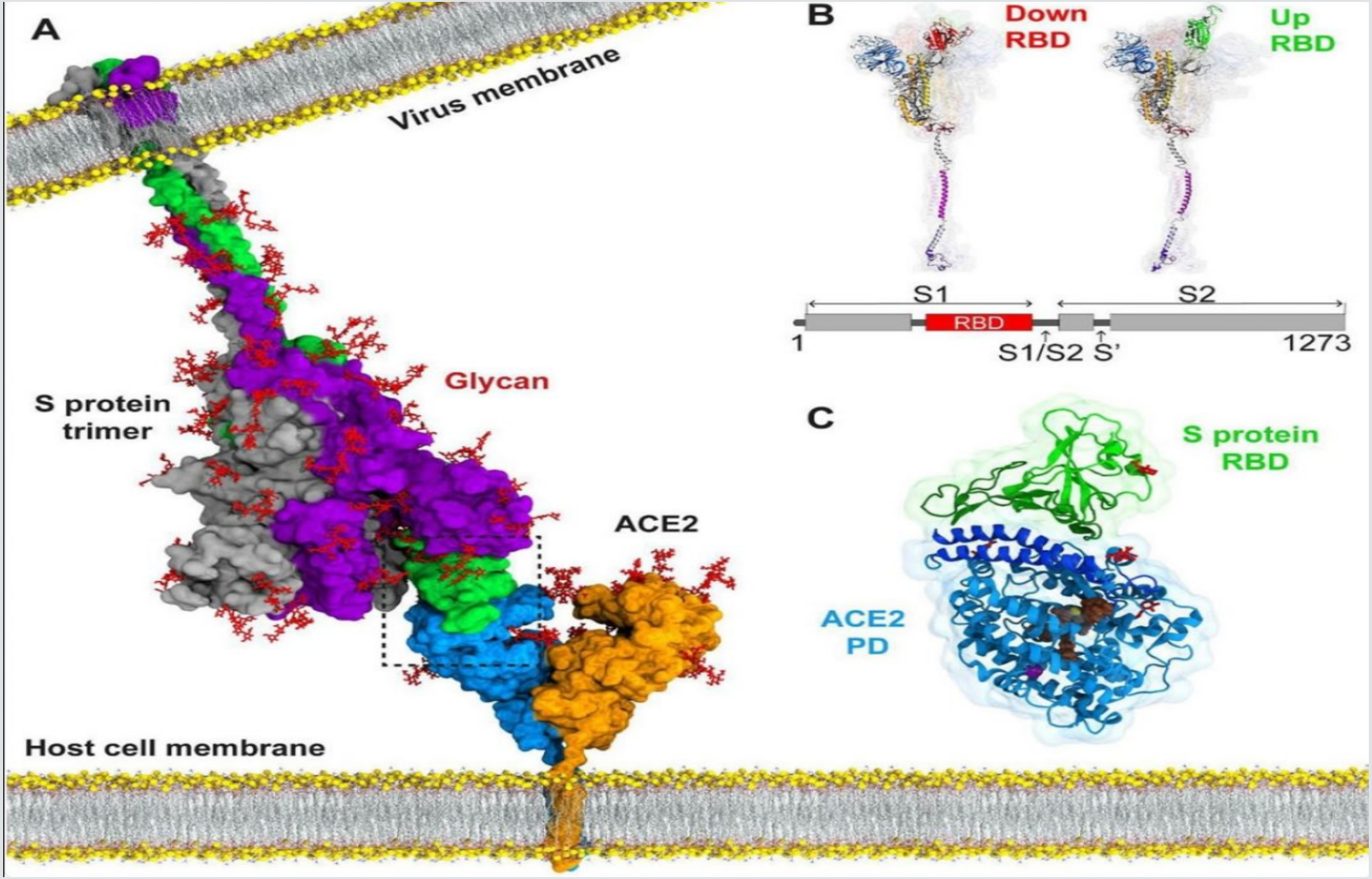
| | |
|---|---|
| Method of Administration: | Intramuscular injection |
| Dose: | 50 µg [$^3$H]-08-A01-C0 (lot # NC-0552-1) |
| Number of Doses: | 1 |
| Detection: | Radioactivity quantitation using liquid scintillation counting |
| Sampling Time (hour): | 0.25, 1, 2, 4, 8, 24, and 48 hours post-injection |

| Sample | Mean total lipid concentration (µg lipid equivalent/g (or mL) (males and females combined) | | | | | | | % of administered dose (males and females combined) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0.25 h | 1 h | 2 h | 4 h | 8 h | 24 h | 48 h | 0.25 h | 1 h | 2 h | 4 h | 8 h | 24 h | 48 h |
| Adipose tissue | 0.057 | 0.100 | 0.126 | 0.128 | 0.093 | 0.084 | 0.181 | -- | -- | -- | -- | -- | -- | -- |
| Adrenal glands | 0.271 | 1.48 | 2.72 | 2.89 | 6.80 | 13.8 | 18.2 | 0.001 | 0.007 | 0.010 | 0.015 | 0.035 | 0.066 | 0.106 |
| Bladder | 0.041 | 0.130 | 0.146 | 0.167 | 0.148 | 0.247 | 0.365 | 0.000 | 0.001 | 0.001 | 0.001 | 0.001 | 0.002 | 0.002 |
| Bone (femur) | 0.091 | 0.195 | 0.266 | 0.276 | 0.340 | 0.342 | 0.687 | -- | -- | -- | -- | -- | -- | -- |
| Bone marrow (femur) | 0.479 | 0.960 | 1.24 | 1.24 | 1.84 | 2.49 | 3.77 | -- | -- | -- | -- | -- | -- | -- |
| Brain | 0.045 | 0.100 | 0.138 | 0.115 | 0.073 | 0.069 | 0.068 | 0.007 | 0.013 | 0.020 | 0.016 | 0.011 | 0.010 | 0.009 |
| Eyes | 0.010 | 0.035 | 0.052 | 0.067 | 0.059 | 0.091 | 0.112 | 0.000 | 0.001 | 0.001 | 0.002 | 0.002 | 0.002 | 0.003 |
| Heart | 0.282 | 1.03 | 1.40 | 0.987 | 0.790 | 0.451 | 0.546 | 0.018 | 0.056 | 0.084 | 0.060 | 0.042 | 0.027 | 0.030 |
| Injection site | 128 | 394 | 311 | 338 | 213 | 195 | 165 | 19.9 | 52.6 | 31.6 | 28.4 | 21.9 | 29.1 | 24.6 |
| Kidneys | 0.391 | 1.16 | 2.05 | 0.924 | 0.590 | 0.426 | 0.425 | 0.050 | 0.124 | 0.211 | 0.109 | 0.075 | 0.054 | 0.057 |
| Large intestine | 0.013 | 0.048 | 0.093 | 0.287 | 0.649 | 1.10 | 1.34 | 0.008 | 0.025 | 0.065 | 0.192 | 0.405 | 0.692 | 0.762 |
| Liver | 0.737 | 4.63 | 11.0 | 16.5 | 26.5 | 19.2 | 24.3 | 0.602 | 2.87 | 7.33 | 11.9 | 18.1 | 15.4 | 16.2 |
| Lung | 0.492 | 1.21 | 1.83 | 1.50 | 1.15 | 1.04 | 1.09 | 0.052 | 0.101 | 0.178 | 0.169 | 0.122 | 0.101 | 0.101 |

| Sample | Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined) | | | | | | | % of Administered Dose (males and females combined) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0.25 h | 1 h | 2 h | 4 h | 8 h | 24 h | 48 h | 0.25 h | 1 h | 2 h | 4 h | 8 h | 24 h | 48 h |
| Lymph node (mandibular) | 0.064 | 0.189 | 0.290 | 0.408 | 0.534 | 0.554 | 0.727 | -- | -- | -- | -- | -- | -- | -- |
| Lymph node (mesenteric) | 0.050 | 0.146 | 0.530 | 0.489 | 0.689 | 0.985 | 1.37 | -- | -- | -- | -- | -- | -- | -- |
| Muscle | 0.021 | 0.061 | 0.084 | 0.103 | 0.096 | 0.095 | 0.192 | -- | -- | -- | -- | -- | -- | -- |
| Ovaries (females) | 0.104 | 1.34 | 1.64 | 2.34 | 3.09 | 5.24 | 12.3 | 0.001 | 0.009 | 0.008 | 0.016 | 0.025 | 0.037 | 0.095 |
| Pancreas | 0.081 | 0.207 | 0.414 | 0.380 | 0.294 | 0.358 | 0.599 | 0.003 | 0.007 | 0.014 | 0.015 | 0.015 | 0.011 | 0.019 |
| Pituitary gland | 0.339 | 0.645 | 0.868 | 0.854 | 0.405 | 0.478 | 0.694 | 0.000 | 0.001 | 0.001 | 0.001 | 0.000 | 0.000 | 0.001 |
| Prostate (males) | 0.061 | 0.091 | 0.128 | 0.157 | 0.150 | 0.183 | 0.170 | 0.001 | 0.001 | 0.002 | 0.003 | 0.003 | 0.004 | 0.003 |
| Salivary glands | 0.084 | 0.193 | 0.255 | 0.220 | 0.135 | 0.170 | 0.264 | 0.003 | 0.007 | 0.008 | 0.008 | 0.005 | 0.006 | 0.009 |
| Skin | 0.013 | 0.208 | 0.159 | 0.145 | 0.119 | 0.157 | 0.253 | -- | -- | -- | -- | -- | -- | -- |
| Small intestine | 0.030 | 0.221 | 0.476 | 0.879 | 1.28 | 1.30 | 1.47 | 0.024 | 0.130 | 0.319 | 0.543 | 0.776 | 0.906 | 0.835 |
| Spinal cord | 0.043 | 0.097 | 0.169 | 0.250 | 0.106 | 0.085 | 0.112 | 0.001 | 0.002 | 0.002 | 0.003 | 0.001 | 0.001 | 0.001 |
| Spleen | 0.334 | 2.47 | 7.73 | 10.3 | 22.1 | 20.1 | 23.4 | 0.013 | 0.093 | 0.325 | 0.385 | 0.982 | 0.821 | 1.03 |
| Stomach | 0.017 | 0.065 | 0.115 | 0.144 | 0.268 | 0.152 | 0.215 | 0.006 | 0.019 | 0.034 | 0.030 | 0.040 | 0.037 | 0.039 |
| Testes (males) | 0.031 | 0.042 | 0.079 | 0.129 | 0.146 | 0.304 | 0.320 | 0.007 | 0.010 | 0.017 | 0.030 | 0.034 | 0.074 | 0.074 |
| Thymus | 0.088 | 0.243 | 0.340 | 0.335 | 0.196 | 0.207 | 0.331 | 0.004 | 0.007 | 0.010 | 0.012 | 0.008 | 0.007 | 0.008 |
| Thyroid | 0.155 | 0.536 | 0.842 | 0.851 | 0.544 | 0.578 | 1.00 | 0.000 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 |
| Uterus (females) | 0.043 | 0.203 | 0.305 | 0.140 | 0.287 | 0.289 | 0.456 | 0.002 | 0.011 | 0.015 | 0.008 | 0.016 | 0.018 | 0.022 |
| Whole blood | 1.97 | 4.37 | 5.40 | 3.05 | 1.31 | 0.909 | 0.420 | -- | -- | -- | -- | -- | -- | -- |
| Plasma | 3.97 | 8.13 | 8.90 | 6.50 | 2.36 | 1.78 | 0.805 | -- | -- | -- | -- | -- | -- | -- |
| Blood:Plasma ratio[a] | 0.815 | 0.515 | 0.550 | 0.510 | 0.555 | 0.530 | 0.540 | -- | -- | -- | -- | -- | -- | -- |

# mRNA vaccine Mechanism of action




A
Virus membrane
Glycan
S protein
trimer
ACE2
Host cell membrane
B
Down
RBD
Up
RBD
S1
S2
RBD
1
S1/S2
S'
1273
C
S protein
RBD
ACE2
PD

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

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ABSTRACT

**BACKGROUND**

Many pregnant persons in the United States are receiving messenger RNA (mRNA) coronavirus disease 2019 (Covid-19) vaccines, but data are limited on their safety in pregnancy.

**METHODS**

From December 14, 2020, to February 28, 2021, we used data from the "v-safe after vaccination health checker" surveillance system, the v-safe pregnancy registry, and the Vaccine Adverse Event Reporting System (VAERS) to characterize the initial safety of mRNA Covid-19 vaccines in pregnant persons.

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Shimabukuro at the Immunization Safety Office, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30329, or at tshimabukuro@cdc.gov.

*The members of the CDC v-safe COVID-19 Pregnancy Registry Team are listed in

**RESULTS**

A total of 35,691 v-safe participants 16 to 54 years of age identified as pregnant. Injection-site pain was reported more frequently among pregnant persons than among nonpregnant women, whereas headache, myalgia, chills, and fever were reported less frequently. Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 (13.9%) were pregnancy losses and 712 (86.1%) were live births (mostly among participants vaccinated in the third trimester). Adverse neonatal outcomes included preterm birth (in 9.4%) and small size for gestational age (in 3.2%); no neonatal deaths were reported. Although not directly comparable, calculated proportions of adverse pregnancy and neonatal outcomes in persons vaccinated against Covid-19 who had a completed pregnancy were similar to incidences reported in studies involving pregnant women that were conducted before the Covid-19 pandemic. Among 221 pregnancy-related adverse events reported to the VAERS, the most frequently reported event was spontaneous abortion (46 cases).

**CONCLUSIONS**

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.

UNACCEPTABLE JESSICA

# Real time obstetrician/ gynecologist's data on new patients and miscarriages for 2021 and 2022 (and now 2020 for baseline)

Direct from the horse's mouth...

JESSICA ROSE
NOV 18, 2022 AT 9:02 AM

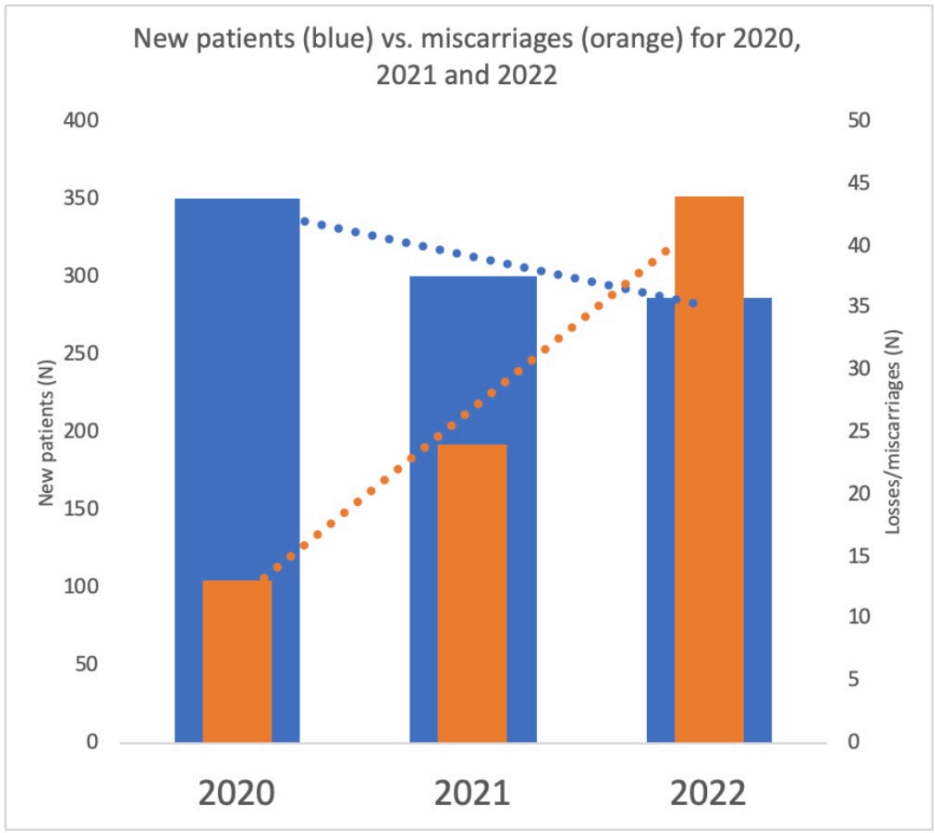
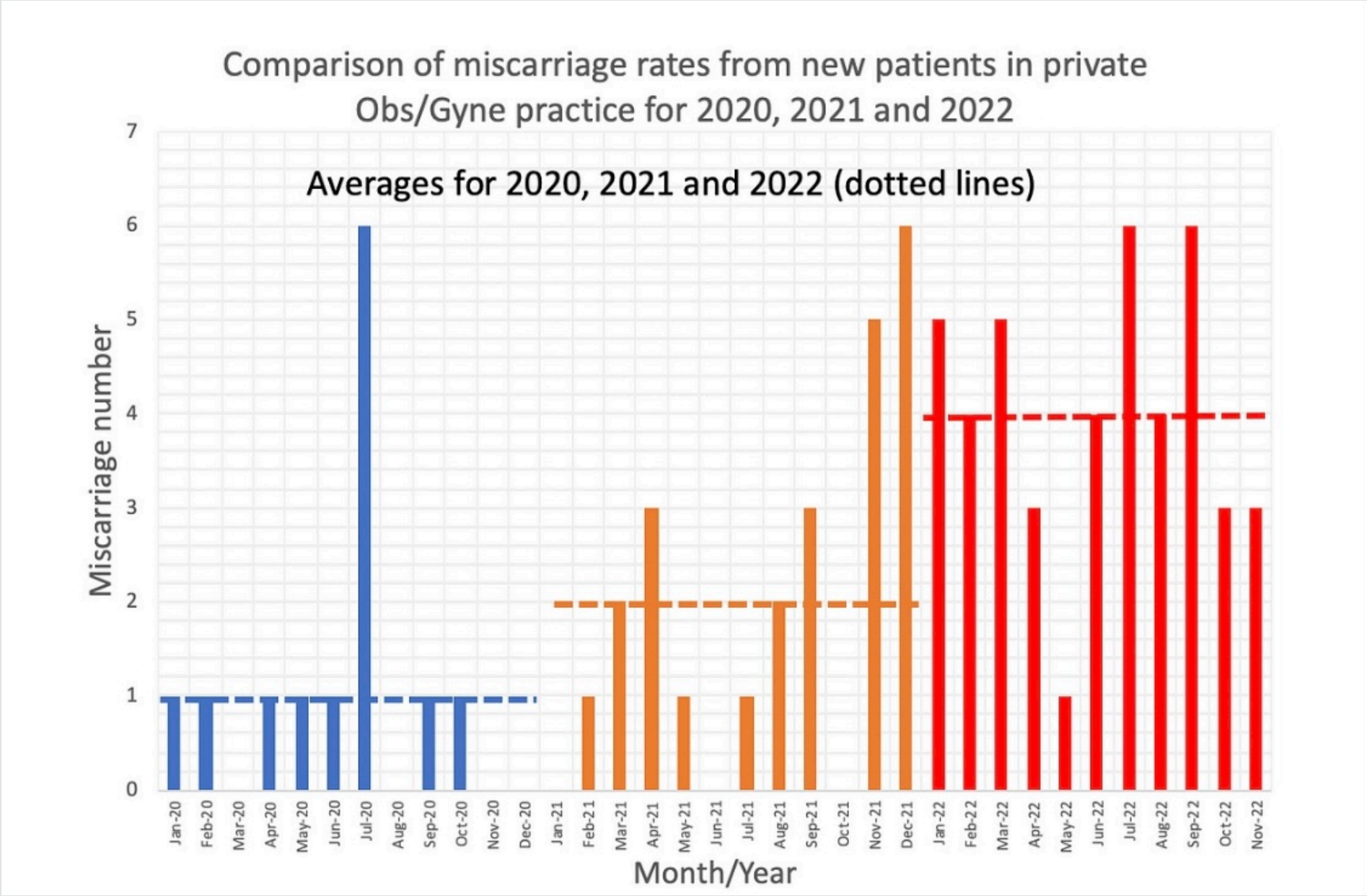



Figure i: New patients versus miscarriages for 2020, 2021 and 2022.


Comparison of miscarriage rates from new patients in private Obs/Gyne practice for 2020, 2021 and 2022
Averages for 2020, 2021 and 2022 (dotted lines)
Miscarriage number
0
1
2
3
4
5
6
7
Jan-20
Feb-20
Mar-20
Apr-20
May-20
Jun-20
Jul-20
Aug-20
Sep-20
Oct-20
Nov-20
Dec-20
Jan-21
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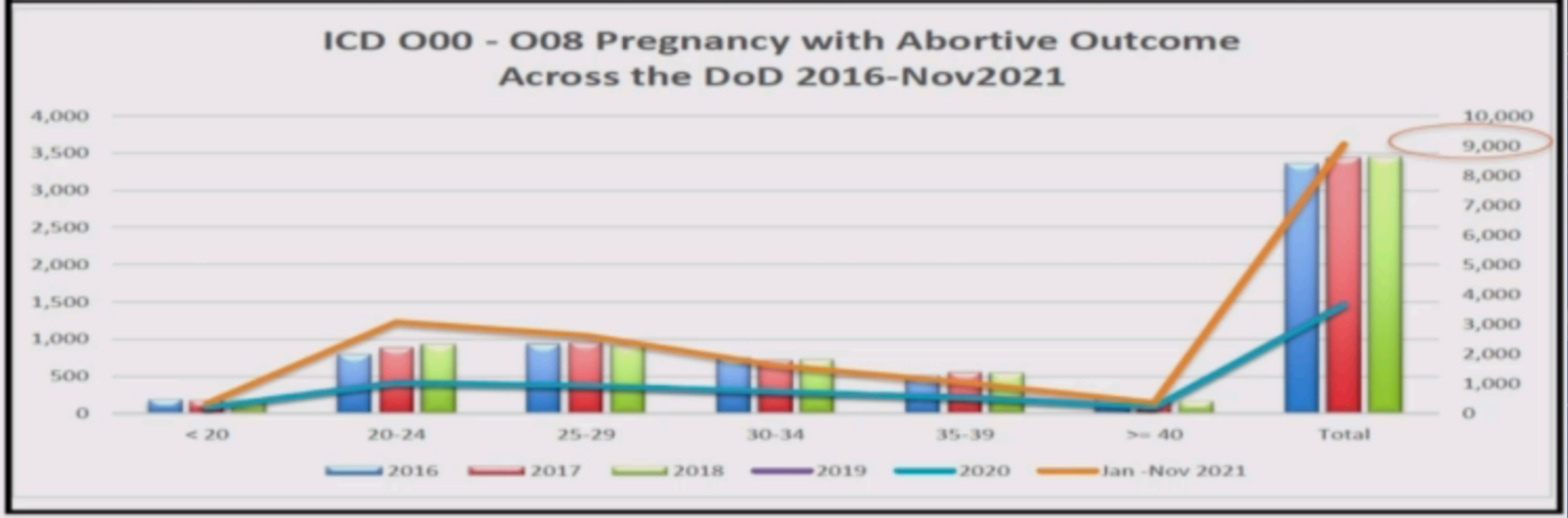
Feb-22
Mar-22
Apr-22
May-22
Jun-22
Jul-22
Aug-22
Sep-22
Oct-22
Nov-22
Month/Year

## ICD O00 - O08 Pregnancy with Abortive Outcome

| Counts | 2016 | 2017 | 2018 | 2019 | 2020 | Jan -Nov 2021 |
|---|---|---|---|---|---|---|
| < 20 | 187 | 176 | 177 | 201 | 206 | 343 |
| 20-24 | 794 | 888 | 931 | 1,052 | 1,013 | 3,079 |
| 25-29 | 934 | 949 | 913 | 935 | 941 | 2,625 |
| 30-34 | 741 | 715 | 721 | 715 | 744 | 1,620 |
| 35-39 | 509 | 553 | 543 | 561 | 525 | 1,037 |
| >= 40 | 192 | 161 | 164 | 218 | 214 | 362 |
| Total | 3,357 | 3,442 | 3,449 | 3,682 | 3,643 | 9,066 |



# Other Issues in Pregnancy:

- Pre Eclampsia / Gestational Hypertension
- Oligohydramnios
- Post Partum Hemorrhages
- Stillbirths (Dr. Thorp)

Other Issues Gynecology:

- Breast Cancer
- Abnormal Pap Smears increased 15%
- Infertility
- Abnormal Uterine Bleeding

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Public Health | Research

# COVID-19 and the surge in Decidual Cast Shedding

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# Abstract

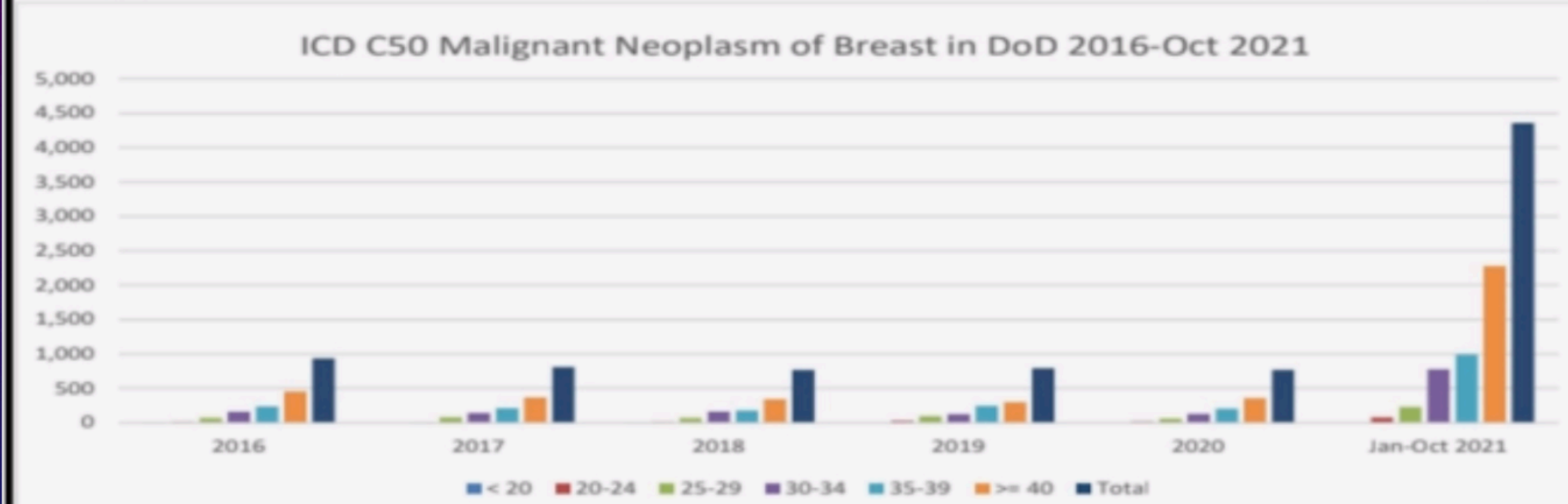
**Background:** The purpose of this study is to report on the unprecedented rise in decidual cast shedding (DCS) that occurred in 2021. DCS is historically a rare gynecological event, with less than 40 cases reported in the medical literature over the last 109 years. Previous journal articles on DCS were usually case studies; population prevalence data is non-existent.
**Methods:** The MyCycleStory℠ survey was distributed via social media from May 16th, 2021, through December 31, 2021. The total sample size for analysis was 6049 with 89.1% of the participants responding within the first 3.5 months of the 7.5 months duration of the study. In parallel to the survey study, a Google Trends search was completed for search frequencies of relevant keyword terms including “decidual cast” and “decidual cast covid vaccine.”
**Results:** In the survey, 292 women (4.83 % of the sample) reported having experienced DCS. The mean age of these predominantly non-Hispanic white women was 36.1 ± 0.5 (SEM) years. Eleven percent were taking hormonal contraceptives, 94.3% considered themselves healthy and 96.2% reported that menstrual irregularities started in 2021. According to Google metadata, search terms for "decidual cast shedding" substantially increased during the months of April, May, and June 2021. These peaks in searches represented a 2000% increase over the first quarter of 2021.
**Conclusions:** There was a significant increase in self-reported DCS in the latter part of 2021 compared to all pre-pandemic cases. More research is urgently needed to investigate the factors contributing to DCS in 2021 and whether this trend is continuing.



**Keywords:** Decidual Cast Shedding, COVID-19 pandemic, COVID vaccine adverse reactions, spike protein shedding, menstrual abnormality

ICD C50 Malignant neoplasm of breast

| Counts | 2016 | 2017 | 2018 | 2019 | 2020 | Jan-Oct 2021 |
|---|---|---|---|---|---|---|
| < 20 | 1 | 0 | 1 | 0 | 0 | 0 |
| 20-24 | 14 | 11 | 12 | 26 | 18 | 78 |
| 25-29 | 71 | 79 | 69 | 94 | 60 | 230 |
| 30-34 | 160 | 142 | 165 | 126 | 128 | 779 |
| 35-39 | 234 | 210 | 177 | 247 | 203 | 993 |
| >= 40 | 454 | 368 | 342 | 299 | 357 | 2,277 |
| Total | 934 | 810 | 766 | 792 | 766 | 4,357 |

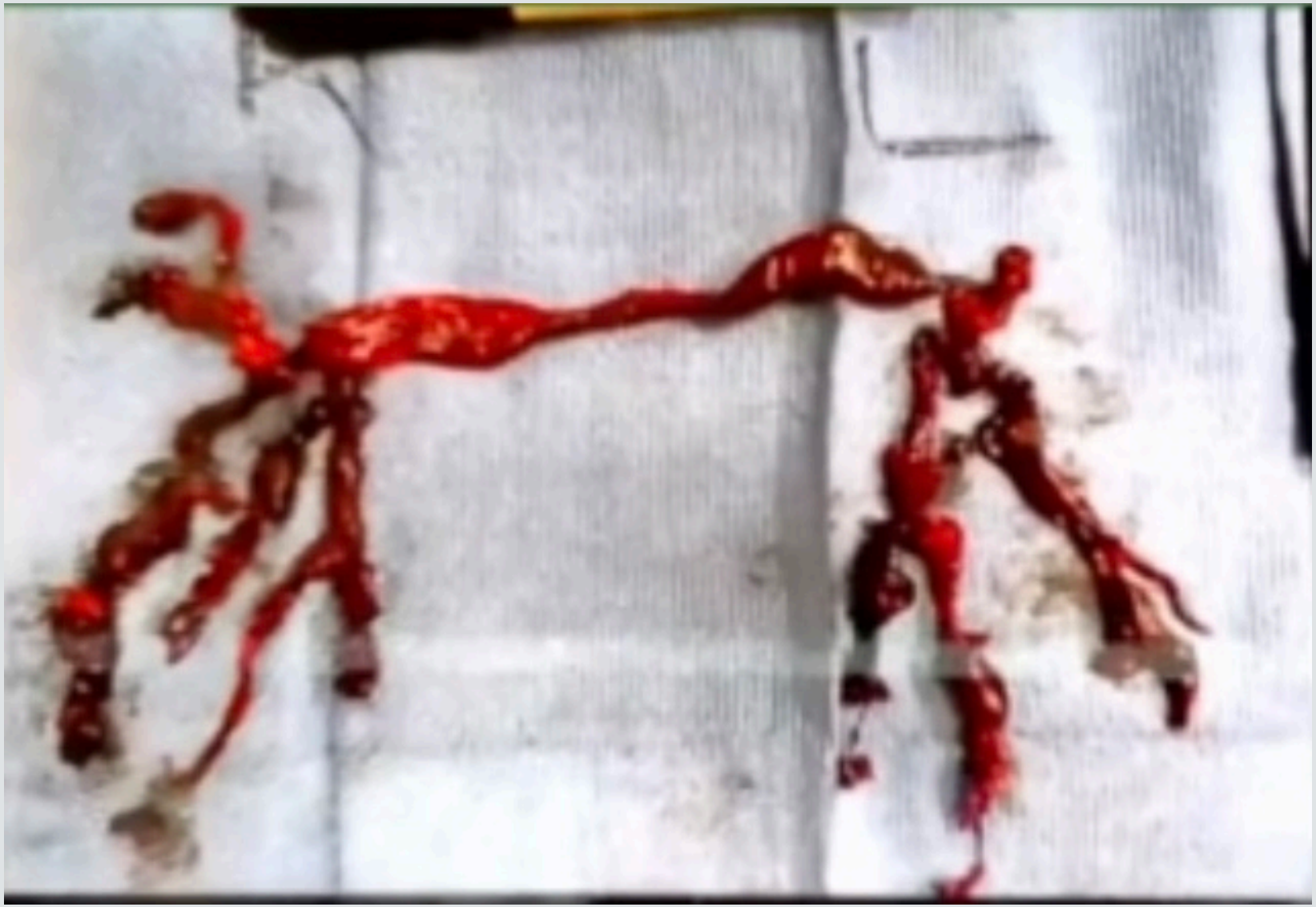



Source: DMSS 1/19/2022

Rate calculated in counts per 1,000 persons per year. Data with unknown values excluded.

* Selected Diagnoses:

C50 Malignant neoplasm of breast



Original Research

# Pregnancy and the Risk of In-Hospital Coronavirus Disease 2019 (COVID-19) Mortality

*Beth L. Pineles, MD, PhD, Katherine E. Goodman, JD, PhD, Lisa Pineles, MA, Lyndsay M. O'Hara, PhD, MPH, Gita Nadimpalli, MD, MPH, Laurence S. Magder, PhD, Jonathan D. Baghdadi, MD, PhD, Jacqueline G. Parchem, MD, and Anthony D. Harris, MD, MPH*



**OBJECTIVE:** To evaluate whether pregnancy is an independent risk factor for in-hospital mortality among patients of reproductive age hospitalized with coronavirus disease 2019 (COVID-19) viral pneumonia.

**METHODS:** We conducted a retrospective cohort study (April 2020–May 2021) of 23,574 female inpatients aged 15–45 years with an International Classification of Diseases, Tenth Revision, Clinical Modification diagnosis code for COVID-19 discharged from 749 U.S. hospitals in the Premier Healthcare Database. We used a viral pneumonia diagnosis to select for patients with symptomatic COVID-19. The associations between pregnancy and in-hospital mortality, intensive care unit (ICU) admission, and mechanical ventilation were analyzed using propensity score–matched conditional logistic regression. Models were matched for age, marital status, race and ethnicity, Elixhauser comorbidity score, payer, hospital number of beds, season of discharge, hospital region, obesity, hypertension, diabetes mellitus, chronic pulmonary disease, deficiency anemias, depression, hypothyroidism, and liver disease.

**RESULTS:** In-hospital mortality occurred in 1.1% of pregnant patients and 3.5% of nonpregnant patients hospitalized with COVID-19 and viral pneumonia (propensity score–matched odds ratio [OR] 0.39, 95% CI 0.25–0.63). The frequency of ICU admission for pregnant and nonpregnant patients was 22.0% and 17.7%, respectively (OR 1.34, 95% CI 1.15–1.55). Mechanical ventilation was used in 8.7% of both pregnant and nonpregnant patients (OR 1.05, 95% CI 0.86–1.29). Among patients who were admitted to an ICU, mortality was lower for pregnant compared with nonpregnant patients (OR 0.33, 95% CI 0.20–0.57), though mechanical ventilation rates were similar (35.7% vs 38.3%, OR 0.90, 95% CI 0.70–1.16). Among patients with mechanical ventilation, pregnant patients had a reduced risk of in-hospital mortality compared with nonpregnant patients (0.26, 95% CI 0.15–0.46).

**CONCLUSION:** Despite a higher frequency of ICU admission, in-hospital mortality was lower among pregnant patients compared with nonpregnant patients with

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*Each author has confirmed compliance with the journal's requirements for authorship.*

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*Co-corresponding author: Jacqueline G. Parchem, MD, Division of Maternal-Fetal Medicine, Department of Obstetrics, Gynecology and Reproductive Sciences,*

Message Detail

Date: 7/13/2022 3:53:09 PM
Category:
Subject: Statement Regarding Misinformation and Disinformation and Medical Professionalism

Mark Unread

The American Board of Obstetrics and Gynecology (ABOG) issued a statement regarding Dissemination of COVID-19 Misinformation on September 27, 2021. The following statement reiterates and expands ABOG's position.

Patients rely on physicians to practice medicine based on fact-based scientific data. ABOG standards and policies for certification and maintenance of certification have clear expectations about medical professionalism and professional standing that physicians agree to as part of the certification process. Intentionally providing misinformation and disinformation that may harm patients or public health does not meet these agreed-upon standards and may be grounds for adverse action on an OB GYN's certification status.

Free speech is a right in our country, and medical providers may practice according to their conscience and religious, moral, and ethical values. Diplomates are not required to provide services that conflict with these values. Facts, science, and evidence-based medicine are critically important guides to OB GYN clinical practice. The dissemination of misinformation and disinformation not only involves COVID-19, but is a threat to the access to and the ability to provide legal and safe evidence-based comprehensive reproductive health care, including contraception and abortion. Opinions publicized by OB GYNs about COVID-19, reproductive health care, and abortion should reflect the specialty's commitment to scientific and clinical excellence and to the needs of our patients.

Misinformation and disinformation about contraception and abortion can create false narratives about essential safe practices in the specialty. In addition, false or misleading information from board-certified medical professionals can also be used to advocate for legislation, regulations, criminal code, and health policy. ABOG considers the dissemination of misinformation and disinformation that may threaten the health of the patients who place their trust in its diplomates to be a violation of medical professionalism.

ABOG will review reports of dissemination of misinformation and disinformation about COVID-19, reproductive health care, contraception, abortion, and other OB GYN practices that may harm the patients we serve or public health. Eligibility to gain or maintain ABOG certification may be lost if ABOG determines that diplomates do not meet the standards that they have agreed to meet and that the public deserves and expects.

Committee Opinion No. 390

December 2007

# **Ethical** Decision Making in Obstetrics and Gynecology*

**Ethical** Decision Making in Obstetrics and Gynecology* ... and frameworks have emerged: virtue-based **ethics**, an **ethic** of care, feminist **ethics**, communitarian **ethics**, and case-based reasoning, all of ... **Professional codes** and commentaries may offer some guidance about how to resolve such ... **Ethically**, breaches of confidentiality also may be justified in rare cases to protect others from ...

As previously noted, one of the most important elements of informed consent is the patient's capacity to understand the nature of her condition and the benefits and risks of the treatment that is recommended as well as those of the alternative treatments (30). A patient's capacity to understand depends on her maturity, state of consciousness, mental acuity, education, cultural background, native language, the opportunity and willingness to ask questions, and the way in which the information is presented. Diminished capacity to understand is not necessarily the same as legal incompetence. Psychiatric consultation may be helpful in establishing a patient's capacity, or ability to comprehend relevant information. Critical to the process of informing the patient is the physician's integrity in choosing the information that is given to the patient and respectfulness in presenting it in a comprehensible way. The point is not merely to disclose information but to ensure patient comprehension of relevant information. Voluntariness—the patient's freedom to choose among alternatives—is also an important element of informed consent, which should be free from coercion, pressure, or undue influence (31).

Possible mechanisms:

- Dr. Yeadon and Dr. Sucharit Bhakdi – Syncitium?
- Inflammation—LNPs and/or Spike?
- Endocrine– ovary/testes or pituitary origin?
- Clotting (micro)

Nazeeh Hanna, MD, et al demonstrated mRNA in breastmilk, Sept. 2022.

Could intact mRNA cross to fetuses?

LNPs cross the placental barrier -- ?? Female fetuses

Early Treatment Denied

- HCQ
- Ivermectin
- Monoclonal Antibodies
- Neutraceuticals

Good Prognosis