Shedding of Covid mRNA Vaccine Components and Products From The Vaccinated to the Unvaccinated

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DEFINITION OF GENE THERAPY MEDICINAL PRODUCTS

- From the FDA's 2015 document on Gene Product Shedding Studies:

- *"Gene therapy products are all products that mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and that are administered as nucleic acids, viruses, or genetically engineered microorganisms.*

THE DEFINITION OF "SHEDDING"

From our Federal government, in this FDA document, the term "shedding" is defined as:

"*The release of viral or bacterial gene therapy products from the patient by any or all of the following routes: feces (feces); secretions (urine, saliva, nasopharyngeal fluids, etc.); or through the skin (pustules, lesions, sores).*"

FDA EMPHASIZES NEED FOR SHEDDING STUDIES

Shedding is distinct from biodistribution because the latter describes how a product is spread within the patient's body from the site of administration while the ***former describes how it is excreted or released from the patient's body.*** *Shedding raises the possibility of transmission of virus or bacteria based* ***gene therapy products*** *(VBGT) from* ***treated to untreated individuals*** *(e.g., close contacts and health care professionals).*

This guidance represents FDA's current thinking on how and when shedding data should be collected for VBGT and oncolytic products during preclinical and clinical development and how ***shedding data can be used to assess the potential for transmission to untreated individuals.***

FDA GUIDANCE ON DEVELOPMENT OF GENE THERAPIES

Shedding studies should be conducted for each VBGT or oncolytic product to provide information about the likelihood of transmission to untreated individuals because historical data alone may not be predictive of the shedding profile. Shedding data can be used to evaluate measures to prevent transmission. Shedding data collected during product development should provide a clear and comprehensive understanding of the shedding profile of VBGT or oncolytic products in the target patient population(s). Note that it may be appropriate to describe these data in the package insert for an approved Biologics License Application (BLA).

ANIMAL SHEDDING STUDIES ARE INSUFFICIENT

- Note that the FDA emphasizes the importance of doing ***human shedding studies*** and not just relying on animal studies.

- *To inform the design of human shedding studies, shedding data may be collected in animals following administration of the VBGT or oncolytic product. These data can help estimate the likelihood and potential shedding profile in humans, particularly when there is concern about transmission to untreated individuals.* ***However, such data cannot substitute for human shedding studies for several reasons.***

YET ANOTHER OMISSION OF THE FEDERAL REGULATORY APPROVAL PROCESS OF THE VACCINES

- *Any experiment involving the deliberate transfer of a nucleic acid to a human must be preceded by Institutional Biosafety Committee approval (document on the regulatory standards is here).*

WHY WERE SHEDDING STUDIES NOT DONE?

From the legal investigative work of Catherine Watts, Todd Callender, and Sasha Latypova:

- The vaccines were legally categorized as a “countermeasure”
- Operation Warp Speed was headed by a general from the Department of Defense
- Countermeasures do not require clinical evaluation
- All countermeasures require is a recommendation for use by the Director of the Health and Human Services Agency based on a judgement that “it may be effective."
- Many clinicians and researchers have been “screaming” for numerous types of studies that were not done:
  - Genotoxicity
  - Reproductive toxicity
  - Biodistribution
  - Insertional mutagenesis etc.

WHAT IS A LIPID NANOPARTICLE (LPN)?

- Terms like exosomes, lipid nanoparticles, extracellular vesicles, and nanoparticles are often used interchangeably

Exosome-like nanovesicles (ELNVs) are biological nanostructures of 40–150 nm, are secreted by most types of cells and ***relay information between cells and organisms across all three kingdoms of life****.1,2 Although earlier perceived to be cellular debris and hence undervalued, ELNVs are now acknowledged as crucial entities to regulate physiological functions of multicellular organisms in an intercellular transmission manner.*

Exosomes are EVs with a size range of ~40 to 160 nm (average ~100 nm) in diameter with an endosomal origin. For instance, the LNP's in the Covid MRNA vaccines are approximately 100 - 400 nm in size.

LIPID NANOPARTICLES CON'T

- Nanoparticles/exosomes/LNP's are tiny sacs enclosed by a lipid membrane which can contain any of the following: **proteins, metabolites, enzymes, growth factors, and nucleic acids**. You can also package drugs (and synthetic mRNA) into them in order to deliver their contents into recipient cells to effectively alter their biological response.

WHAT HAPPENS WHEN YOU INJECT LIPID NANOPARTICLES INTO THE BODY?

- In the recent leaked letter by the EMA, Executive Director, Emer Cooke, to the Chair of COVID-19 Special Committee, MEP Kathleen Van Brempt, Cooke begrudgingly admitted, *"that the lipid nanoparticles can distribute rather non-specifically to several organs such as liver, spleen, heart, kidney, lung and brain, with the liver appearing to be the organ where the lipid nanoparticles distribute most."*

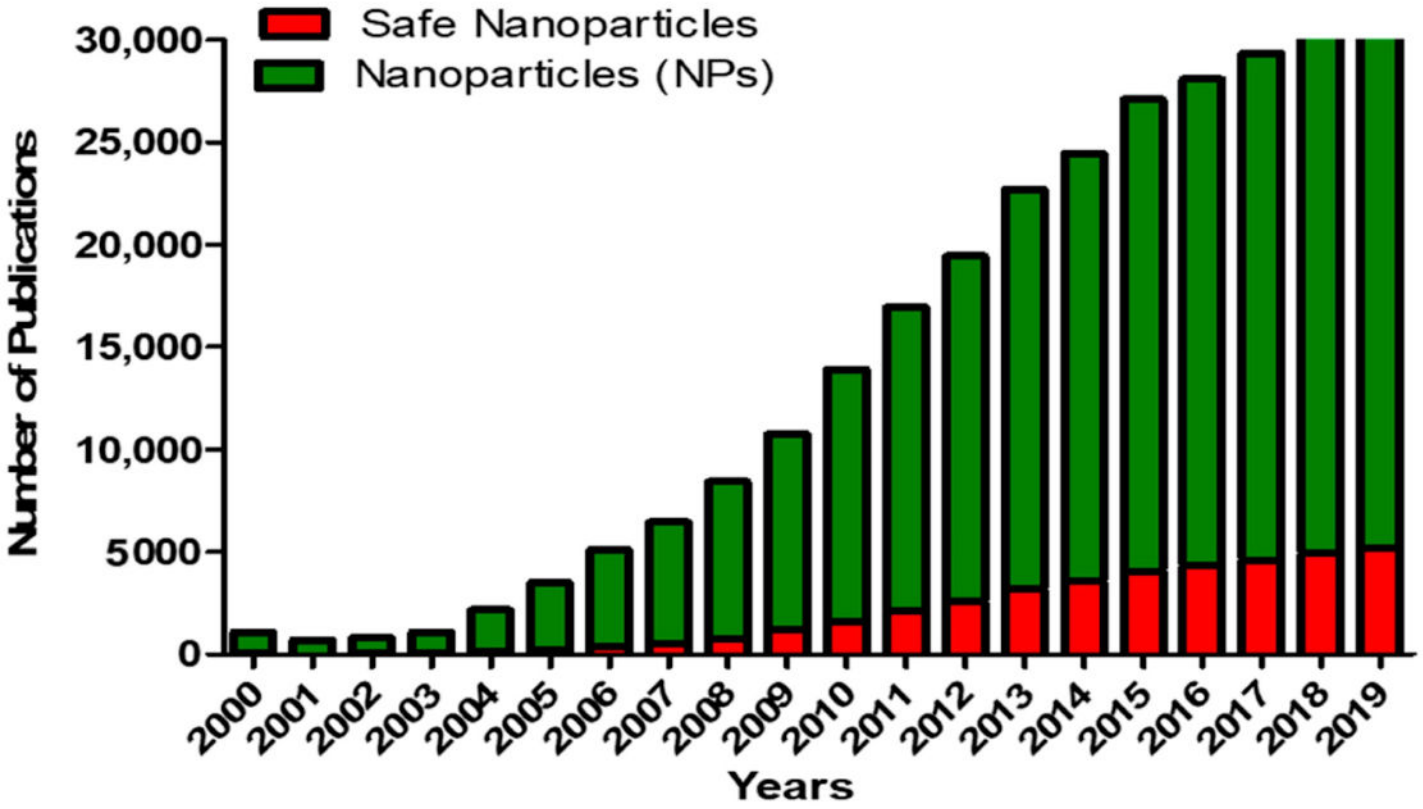
SO LNPS BIODISTRIBUTE WIDELY, BUT CAN THEY BE EXCRETED INTO THE ENVIRONMENT?

- LNP's or their natural equivalent, exosomes (a.k.a. extracellular vesicles (EVs)) **are able to be excreted through body fluids (sweat, sputum, breast milk) and to pass the transplacental barrier.** These exosomes are also able to penetrate by inhalation and through healthy or injured skin as well as orally through breast milk.

HOW MANY PRODUCTS USING NANOPARTICLES ARE THERE?

- *Due to their unique characteristics, nanoparticles are widely used in biomedical and industrial applications (Lee et al., 2007; Zhang et al., 2008; Das et al., 2009; Vance et al., 2015). **Currently, there are 1,814 marketed consumer products containing nanoparticles**, including antibiotics, food items, textiles, sports tools, and electronic materials, and the number is increasing steadily.*

GIVEN THE WIDE BIODISTRIBUTION AND EXCRETION POTENTIAL, HOW SAFE ARE NANOPARTICLES AS A THERAPEUTIC DELIVERY MECHANISM?



In every study or review paper I read, comments like this appear:

"More studies are needed to evaluate the safety of nanoparticle technology" appear.

RISKS OF NANOPARTICLES ARE MORE KNOWN THAN SAFETY

- *Despite the potential for clinical application, some studies have suggested that NPs can be toxic. These studies have demonstrated the ability of* ***NPs to accumulate in cells and induce organ-specific toxicity.*** *These studies, combined with the ever-increasing human exposure, demonstrate an urgent need for the design of safe NPs and the development of strict guidelines for their development with regards to toxicity testing.*

DID PFIZER KNOW OF SHEDDING RISKS?

- PFIZER TRIAL PROTOCOL LANGUAGE EXCLUDING PATIENTS WITH ”ENVIRONMENTAL EXPOSURES”

- Starting on p 67 of the protocol the investigator is instructed to report various "environmental exposures". These included
- 1)"A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception."
- 2) "A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact."
- 3) "A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception."
- 4) "A female is found to be breastfeeding while being exposed or having been exposed to study intervention (i.e., environmental exposure). An example of environmental exposure during breastfeeding is a female family member or healthcare provider who reports that she is breastfeeding after having been exposed to the study intervention by inhalation or skin contact."

WHAT THE PFIZER PROTOCOL LANGUAGE MEANS

- *This clearly means that any contact, including sexual contact with someone who has received the vaccines, exposes those who have not received the vaccines to the "intervention", i.e. mRNA. Exposure during breastfeeding had also to be immediately notified during the trial: it is assumed that the investigator is concerned that a breastfeeding mother could transmit the experimental mRNA to her baby if she received the vaccines directly or if she is "exposed to the study intervention by inhalation or skin contact."*

HAVE ANY GENE THERAPIES BEEN FOUND TO SHED?

- Shedding of LUXTURNA

  Transient and low level shedding of LUXTURNA may occur in patient tears. Advise patients and/or their caregivers on proper handling of waste material generated from dressing, tears, and nasal secretion, which may include storage of waste material in sealed bags prior to disposal. These handling precautions should be followed for up to 7 days following LUXTURNA administration.

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HOW CAN "SHED" NANOPARTICLES BE ABSORBED INTO THE BODY?

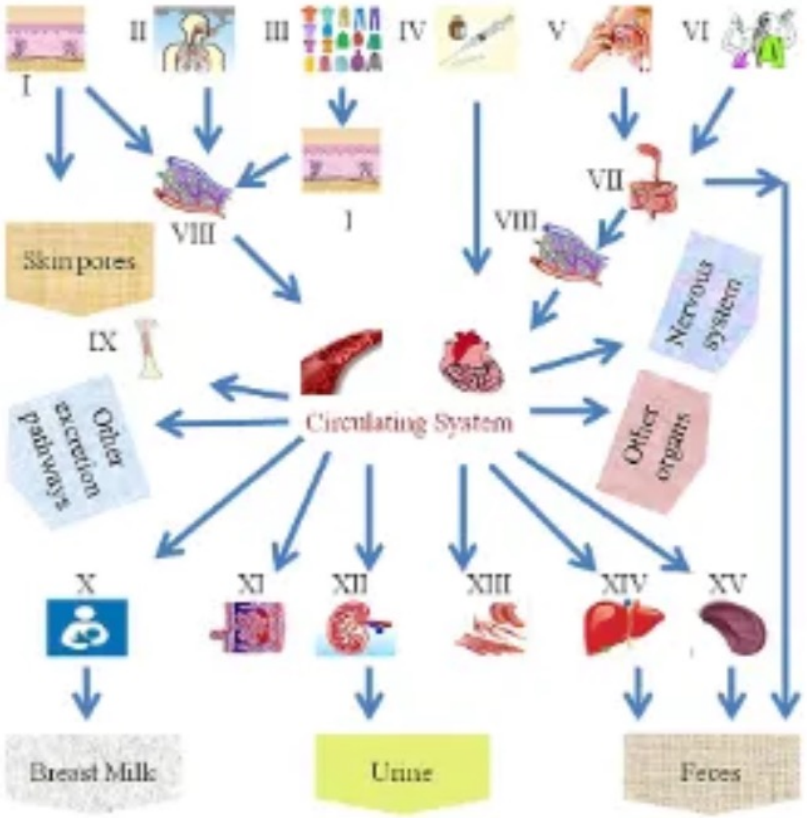


FIGURE 1. Scheme of the different exposure routes of nanoparticles in the human body. (I) Skin, (II) inhalation, (III) fabric, (VI) intravenous injection, (V) food intake, (VI) water intake, (VII) gastrointestinal tract, (VIII) lymph, (IX) bone marrow, (X) breast milk, (XI) placenta, (XII) kidney, (XIII) muscles, (XIV) liver, and (XV) spleen.

HOW LONG CAN mRNA LNPS, NAKED mRNA, OR SPIKE PROTEIN PRODUCT CIRCULATE IN THE BODY?

Table 1. Studies demonstrating persistence of vector-based vaccine constituents and/or derivative spike protein.

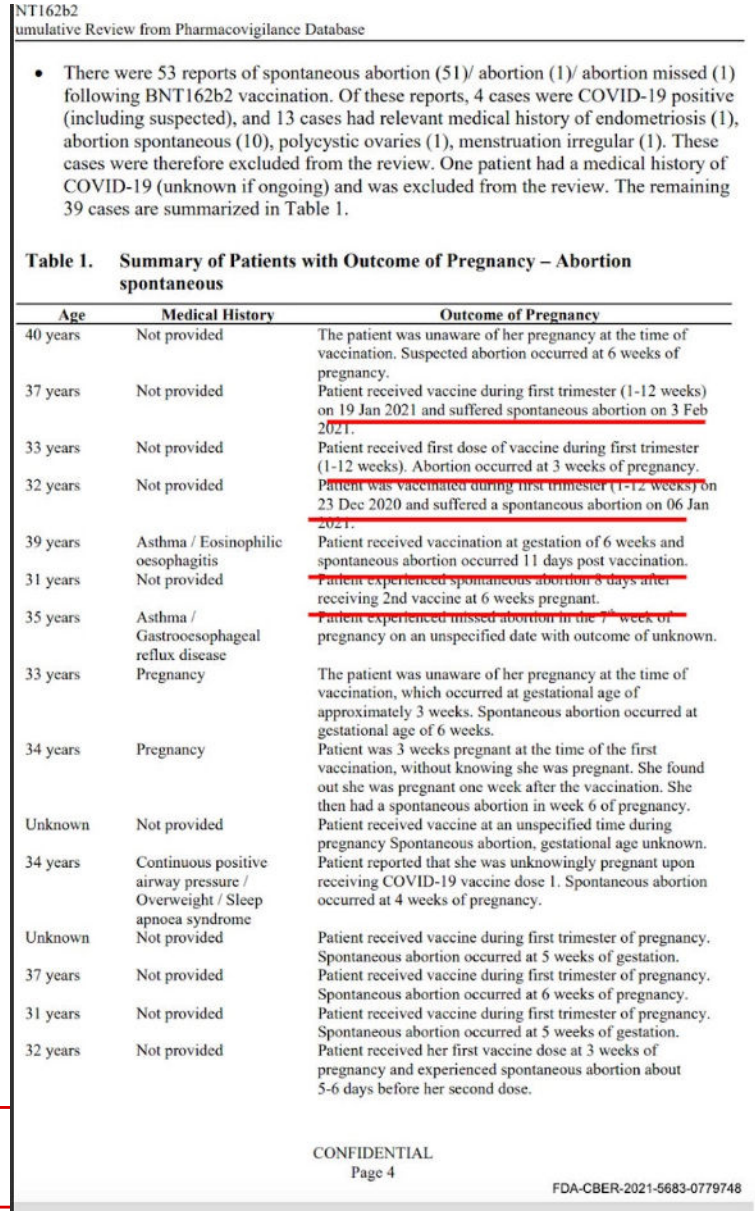
Author	Constituents/Tissue Type/Assay Technique	Duration Measured
Animal		
Pfizer (Japanese MoH) 2020 [46]	Radiolabelled LNP in plasma and tissues	140 h–14 days
Human		
Ogata et al. (2021) [52]	Spike protein and S1 subunit (assay)	3 days
Bansal et al. (2021) [57]	Spike Protein	4 months
Fertig et al. (2022) [50]	LNPs and mRNA	15 days
Röltgen et al. (2022) [53]	mRNA and Spike Protein in ipsilateral lymph nodes; 2–7 days post dose in blood	60 days
Yamamoto et al. (2022) [58]	Spike Protein in skin	3 months
Yonker et al. (2023) [54]	Spike Protein in blood	1–19 days *in cases of myocarditis*
Castruita et al. (2023) [51]	mRNA in plasma	28 days

In Covid mRNA vaccine studies, they have found that all vaccine components and products can be detected in the blood with studies reporting various time periods of 48 hours, one week, 14 days, 4 months, and up to 187 days (or longer).

SO, IF THEY CIRCULATE AND PERSIST IN THE BODY, CAN THEY CROSS THE PLACENTA?

- In one mouse study, they developed a PEG-ylated LNP similar to the COVID mRNA vaccines that could get to the uterus as a therapeutic delivery mechanism. Apparently, they succeeded. *The study conclusion: "These LNPs may provide a platform for in utero mRNA delivery for protein replacement and gene editing."*

EVIDENCE SUGGESTING THEY CAN CROSS THE PLACENTA



NT162b2
umulative Review from Pharmacovigilance Database

- There were 53 reports of spontaneous abortion (51)/ abortion (1)/ abortion missed (1) following BNT162b2 vaccination. Of these reports, 4 cases were COVID-19 positive (including suspected), and 13 cases had relevant medical history of endometriosis (1), abortion spontaneous (10), polycystic ovaries (1), menstruation irregular (1). These cases were therefore excluded from the review. One patient had a medical history of COVID-19 (unknown if ongoing) and was excluded from the review. The remaining 39 cases are summarized in Table 1.

Table 1. Summary of Patients with Outcome of Pregnancy – Abortion spontaneous

Age	Medical History	Outcome of Pregnancy
40 years	Not provided	The patient was unaware of her pregnancy at the time of vaccination. Suspected abortion occurred at 6 weeks of pregnancy.
37 years	Not provided	Patient received vaccine during first trimester (1-12 weeks) on 19 Jan 2021 and suffered spontaneous abortion on 3 Feb 2021.
33 years	Not provided	Patient received first dose of vaccine during first trimester (1-12 weeks). Abortion occurred at 3 weeks of pregnancy.
32 years	Not provided	Patient was vaccinated during first trimester (1-12 weeks) on 23 Dec 2020 and suffered a spontaneous abortion on 06 Jan 2021.
39 years	Asthma / Eosinophilic oesophagitis	Patient received vaccination at gestation of 6 weeks and spontaneous abortion occurred 11 days post vaccination.
31 years	Not provided	Patient experienced spontaneous abortion 8 days after receiving 2nd vaccine at 6 weeks pregnant.
35 years	Asthma / Gastrooesophageal reflux disease	Patient experienced missed abortion in the 7th week of pregnancy on an unspecified date with outcome of unknown.
33 years	Pregnancy	The patient was unaware of her pregnancy at the time of vaccination, which occurred at gestational age of approximately 3 weeks. Spontaneous abortion occurred at gestational age of 6 weeks.
34 years	Pregnancy	Patient was 3 weeks pregnant at the time of the first vaccination, without knowing she was pregnant. She found out she was pregnant one week after the vaccination. She then had a spontaneous abortion in week 6 of pregnancy.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy Spontaneous abortion, gestational age unknown.
34 years	Continuous positive airway pressure / Overweight / Sleep apnoea syndrome	Patient reported that she was unknowingly pregnant upon receiving COVID-19 vaccine dose 1. Spontaneous abortion occurred at 4 weeks of pregnancy.
Unknown	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 5 weeks of gestation.
37 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 6 weeks of pregnancy.
31 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 5 weeks of gestation.
32 years	Not provided	Patient received her first vaccine dose at 3 weeks of pregnancy and experienced spontaneous abortion about 5-6 days before her second dose.

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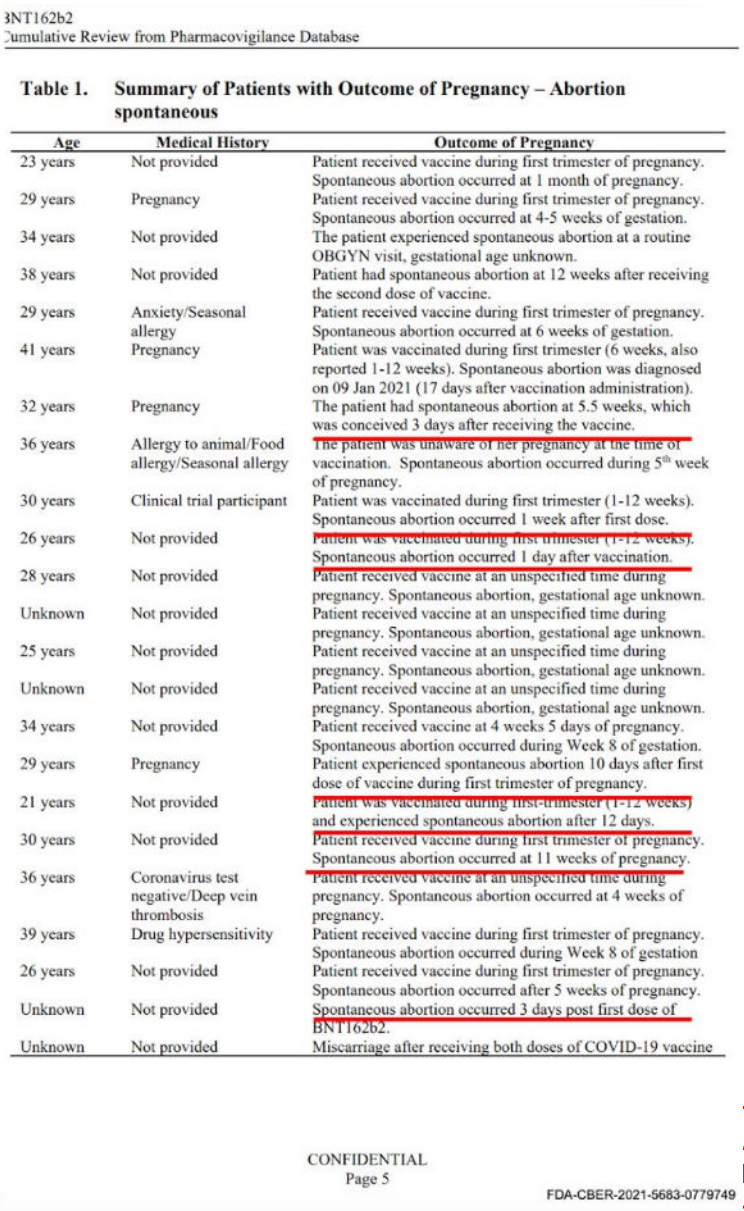

3NT162b2
Cumulative Review from Pharmacovigilance Database

Table 1. Summary of Patients with Outcome of Pregnancy – Abortion spontaneous

Age	Medical History	Outcome of Pregnancy
23 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 1 month of pregnancy.
29 years	Pregnancy	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 4-5 weeks of gestation.
34 years	Not provided	The patient experienced spontaneous abortion at a routine OBGYN visit, gestational age unknown.
38 years	Not provided	Patient had spontaneous abortion at 12 weeks after receiving the second dose of vaccine.
29 years	Anxiety/Seasonal allergy	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 6 weeks of gestation.
41 years	Pregnancy	Patient was vaccinated during first trimester (6 weeks, also reported 1-12 weeks). Spontaneous abortion was diagnosed on 09 Jan 2021 (17 days after vaccination administration).
32 years	Pregnancy	The patient had spontaneous abortion at 5.5 weeks, which was conceived 3 days after receiving the vaccine.
36 years	Allergy to animal/Food allergy/Seasonal allergy	The patient was unaware of her pregnancy at the time of vaccination. Spontaneous abortion occurred during 5th week of pregnancy.
30 years	Clinical trial participant	Patient was vaccinated during first trimester (1-12 weeks). Spontaneous abortion occurred 1 week after first dose.
26 years	Not provided	Patient was vaccinated during first trimester (1-12 weeks). Spontaneous abortion occurred 1 day after vaccination.
28 years	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
25 years	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
34 years	Not provided	Patient received vaccine at 4 weeks 5 days of pregnancy. Spontaneous abortion occurred during Week 8 of gestation.
29 years	Pregnancy	Patient experienced spontaneous abortion 10 days after first dose of vaccine during first trimester of pregnancy.
21 years	Not provided	Patient was vaccinated during first-trimester (1-12 weeks) and experienced spontaneous abortion after 12 days.
30 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 11 weeks of pregnancy.
36 years	Coronavirus test negative/Deep vein thrombosis	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion occurred at 4 weeks of pregnancy.
39 years	Drug hypersensitivity	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred during Week 8 of gestation
26 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred after 5 weeks of pregnancy.
Unknown	Not provided	Spontaneous abortion occurred 3 days post first dose of BNT162b2.
Unknown	Not provided	Miscarriage after receiving both doses of COVID-19 vaccine

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WHAT ABOUT BREAST MILK?

- This study in the Lancet reported on the breast milk of 11 women who were vaccinated with mRNA within 6 months of delivery. They found trace amounts of mRNA in 7 samples from 5 different participants at various times up to 48 hours post vaccination. The vaccine mRNA appeared in higher concentrations in the extracellular vesicles (exosomes) than in whole milk. Uh oh.
- Their conclusion: "**Our findings demonstrate that the COVID-19 vaccine mRNA is not confined to the injection site but spreads systemically and is packaged into breast milk extracellular vesicles.**"
- Another study found PEG (a component of the mRNA vaccine) as well as Covid vaccine mRNA in breast milk.

WOULDN'T ANY INGESTED mRNA OR LNPs BE DESTROYED BY STOMACH ACID?

- *It has been known for some years that mRNA encapsulated in extracellular vesicles is protected from gastric juices and can transfect intestinal cells. A recent review by Melnik and Schmitz confirms that milk EVs survive the extreme conditions of the gastrointestinal tract, are internalized by endocytosis, are bioavailable, reach the bloodstream, and penetrate peripheral tissue cells. Beyond integration into the genome, other concerns should arise such as provoking an "immunogenic" reaction to mRNA.*

BREAST MILK EXPOSURES

- From an eight-page confidential document of reports made to Pfizer by lactating women who were vaccinated.
- Reports graded as “non-severe Aes” occurred in 20% of the 215 lactating women reporting “exposure” to the vaccine.
- The report also documents 10 ***serious*** AEs, including facial paralysis (not listed under “serious” interestingly), lymphadenopathy (swelling of lymph nodes that could be associated with cancer), and blurred vision. Note these are all side effects of the vaccines reported by adults. Among infants, reports included skin exfoliation, rashes, swollen skin, and unspecified sickness. T

BREAST MILK "EXPOSURES"

- Pfizer documented numerous cases of strokes, convulsions, and respiratory failure among nursing babies, However, cases of the latter were excluded based on the following:

16.3.3.1.16. Respiratory AESIs

Search criteria - HLTs (All Path) Lower respiratory tract infections NEC; Respiratory failures (excl neonatal); Viral lower respiratory tract infections OR PTs Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Respiratory disorder.

Upon review, 4 cases were determined to be non-contributory and were not included in the discussion since these cases involved exposures to the vaccine during the mother's pregnancy or through breastfeeding.[99]

WHAT ABOUT EVIDENCE OF SHEDDING BETWEEN THE VACCINATED AND UNVACCINATED?

COVID vaccination and age-stratified all-cause mortality risk

Preprint · October 2021

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WHAT ABOUT EVIDENCE FOR SHEDDING BETWEEN VACCINATED AND THE UNVACCINATED?

- *Most associations show that vaccination in adults is correlated with increased mortality for the unvaccinated in the age group 0-14, (among 39 correlation coefficient values with unadjusted two-tailed P < 0.05,* ***32 are positive and 7 are negative****). This correlation increases from the week of vaccination until week 18 after vaccination, then disappears.* ***It indicates indirect adverse effects of adult vaccination on mortality of children of ages 0-14 during the first 18 weeks after vaccination.***
- They also found:
- *The euromomo.eu data also reveal an unexpected increase in mortality in children correlating with adult vaccination rates in the previous period.*

AND NOW FOR A DISCUSSION OF CLINICAL OBSERVATIONS OF SHEDDING

- Scott?
- Paul?