Canadian Covid Care Alliance
Alliance canadienne pour la prévention et prise-en-charge de la covid
CCCA

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DO NO HARM

Protect Pregnancy & Breastfeeding

An extensively referenced Resource Guide reviewing up-to-date relevant research on COVID-19, the mRNA products used as vaccines in pregnant and breastfeeding women, safety concerns, and ethical considerations

It's easy to forget that pregnancy is a unique and exquisitely normal phase of health. If you're pregnant or breastfeeding, you may feel overloaded by information and advice. Public messaging repeatedly tells you to get a COVID-19 shot, one of the genetic mRNA products being used as vaccines. What do you know about these products? Do you have all the information you need to make an informed decision?

This Resource Guide was prepared to sort through the many questions expecting parents and their healthcare providers may have about use of these products in pregnancy and lactation. A team of experts in maternal care, clinicians, data analysts, and individuals who understand how challenging it can be to make informed choices have extensively reviewed available scientific research to produce this resource. Scientific studies on COVID-19 itself as well as information on the safety, necessity, and usefulness of the COVID-19 mRNA products in pregnancy are examined. The importance of adhering to ethical principles regarding the use of any product in pregnant and lactating women is discussed and the historical harms when these principles were ignored are noted. It may be reassuring to learn that up-to-date evidence suggests that healthy pregnant women with naturally acquired immunity are not at an increased risk of severe COVID-19, and that data shows that naturally acquired immunity is more protective than the mRNA products.

You will likely want to know how mRNA products might affect the reproductive system, pregnancy and lactation – and what little safety testing was done on these products before they were recommended in pregnant women. You may also want to know of the accumulating real-time safety concerns since the roll out of these mRNA products, the lack of evidence for short and long-term safety of mRNA products in pregnancy, and the risk of harms that you can see and cannot yet see. Finally, you may want to have a sense of the entangled interests that direct public health officials to promote these products in pregnant women. This Resource Guide has been developed to empower you as your baby's primary advocate to make an informed decision on how to protect your pregnancy. The reality is that consequences of your choices – whatever they are – will be borne by you and your baby.

Pregnancy – in fact the whole reproductive continuum – can be a beautiful, stressful, and/or a chaotic time – but it is undoubtedly a significant time in the life of a woman and her family. With the ongoing medicalization of life, it's easy to forget that pregnancy, childbirth, and lactation are all normal phases of life and are distinctly balanced states of health.

So much of well-being rides on healthcare choices, and this is especially true of the decisions made during pregnancy. Over the past three years, the level of stress has trended higher, and the emotional, physical and social support we used to be able to count on may feel more uncertain. Parents are often told what to think and feel when it comes to protecting their health and the health of their babies. Further complicating matters, healthcare professionals may not always be aware of available research to understand how it translates to individual persons and situations. This is a time when it is especially important that parents' questions, uncertainties, and concerns are taken seriously.

The quality of pregnancy and of reproductive health has critical implications for the future of humanity. It is important to ensure that any products used during pregnancy are safe. However, over the past two decades there has been increasing pressure from pharmaceutical companies to relax the regulatory guidelines[1,2] – often at the expense of ethical principles regarding clinical research, approval procedures, and the promotion of new drugs. Particularly concerning is the promotion of pharmaceutical products in women who are pregnant, breastfeeding or of childbearing age, without adequate safety or ethical considerations. The latest frenzied push is for the COVID-19 mRNA products being promoted as vaccines that continue to be recommended – sometimes even mandated in this group despite a lack of proven safety, known mechanisms of potential harm, and clear real-world safety signals.

We are a group of professionals and community members with decades of expertise in healthcare and research who care deeply about the physical and mental health of parents, their children and extended families. We believe that the life and health of our children – our future and their future – is too precious to risk by inaccurate messaging and uncertainties from inadequate science. We understand that it might be hard for expecting parents and healthcare providers to make sense of all the messaging regarding these products and their impact on the developing child. To address this gap, we have developed this Resource Guide – outlined with questions and considerations – aimed to sort through scientifically accurate and relevant information and present it in a way that is clear and understandable to parents and healthcare providers. It is our hope that making this information accessible may validate concerns and empower parents with the understanding they need to make informed decisions that respect their autonomy and honour the preciousness of life.

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1. The pregnancy continuum – Why is pregnancy important?

Pregnancy, birth, and the transition to parenting are among the most significant periods of life and may be experienced as intense, intimate, and challenging. At the same time, parents are often overwhelmed by messages that challenge their natural physiology as well as their capacity to make decisions about ways to best protect their children.

Humans have survived for eons without modern technology; and yet the medicalization of natural physiological processes has become a burden and sometimes interferes with parents' ability to protect young humans.

The natural capacity for the human body to heal and grow is reassuring. The generation of new life is formidable – whether that happens through spontaneous means or assisted reproduction and is an intricate, dynamically-timed web of encounters and connections. This continuum goes from preconception to fertilization to implantation through multiple critical as well as sensitive stages of differentiation, development, and growth in pregnancy followed by birth, breastfeeding, and postnatal development.[3-6]

Pregnancy is a unique and distinctly normal period. A mother's body naturally changes to provide for and accommodate the human being growing within her. Her immune system shifts to a healthy balance[7,8] that protects her and adapts to the unique life inside her with its distinct DNA (only half of which comes from her).

The main contributor to neonatal wellbeing is parental health, supported by nutrition and embracing positive environmental elements like sunshine and fresh air.[9,10]

Pregnancy is a sensitive period and also a time when the body is particularly vulnerable to substances, medications, and environmental toxins.[5,11]

2. Ethics – Why is ethical care so important during pregnancy and breastfeeding?

Healthcare systems are based on ethical codes that outline the obligations that healthcare professionals have to the people they serve. Traditionally clinicians have understood the weighty responsibility that comes with the unique relationship involved in providing health services to another human being. The four guiding principles of ethical practice are *autonomy, beneficence, justice, and non-maleficence*.[12]

Autonomy refers to a fundamental understanding of and respect for the dignity of each person as a worthy being with rightful values, decisions and choices. In practice, this means acting with the person's wellbeing at heart (beneficence), avoiding harm (non-maleficence), assuring the right to a fully informed consent that reflects one's dignity, values, and choices (autonomy), and also assuring that services are equally accessible for all (justice).[13-15]

Clinicians demonstrate compassionate and ethical care when they respect the physiological wonder of life and help a mother tune in to her own innate wisdom to make health decisions that are in line with her values and goals. This is done by providing valid, reliable, and accurate information for all interventions in the form of a risk-benefit analysis that outlines the potential short-term and long-term risks for mother and her offspring during a critical developmental period. Support for informed decision making is especially important during pregnancy. The multiple concurrent critical developmental processes, and the unique functions which take place during pregnancy, are exquisitely sensitive to environmental influences. Therefore, interference of any kind may have dire consequences for the current and future wellbeing of mother and child.[5]

Central to non-maleficence is the application of the ***precautionary principle***[16] – that is, to err on the side of caution or ***"first, do no harm"***. This means not recommending any intervention or substance without first undertaking extensive testing to prove its safety.

The history of harmful effects of substances and medications on mothers, and their children's health and longevity is undeniable. Fetal Alcohol Spectrum Disorder (FASD) is a well-known risk of alcohol consumption during pregnancy.[17] The link between the use of the acne drug isotretinoin (Accutane) and severe birth defects is now clearly understood.[18]

Despite the importance of following the precautionary principle, inadequately tested medications and substances have been recommended to pregnant mothers with disastrous effects. Thalidomide was prescribed in the early 1960s as a means of preventing morning sickness. This drug interfered with proper fetal limb development which resulted in devastating deformities that only became apparent at birth.[19] The destructive effects of diethylstilbestrol (DES), considered to be a "safe and effective" drug to help prevent miscarriage and avoid preterm labor, was prescribed to pregnant women from 1940-1971.[20-22] Reproductive abnormalities and/or cancers, only identified decades later, proved to be the consequences of this drug in mothers and their children. These effects may continue to have multigenerational impacts.[23] These real-life examples demonstrate why any research study involving pregnancy must be based on an ***ethical framework that ensures that the study prioritizes and demonstrates short and long-term safety of both mother and unborn child***.[24]

Limb defects caused by Thalidomide.

Health service providers and policy makers involved in maternal care are obligated to practice the precautionary principle in order to safeguard the immediate as well as the future health and wellbeing of mothers, their unborn, their newborn and young children. They must ensure that any substance recommended for use in pregnancy and breastfeeding has first undergone rigorous testing to clearly establish its safety before widespread use in the general population.

3. Science – What role does science play in maternal-child healthcare?

Scientific research is only one aspect of medicine or healthcare. It is meant to support clinical expertise and the client-practitioner therapeutic relationship. This relationship ideally respects a client's values and understands the relevant context, variables, and history of a client's health.

A respectful and caring therapeutic relationship is especially important during the intense and intimate experiences surrounding pregnancy and childbirth. Prioritizing "the science" to the exclusion of other critical factors in the healthcare relationship is problematic.[25]

Scientific inquiry involves the open questioning and investigation of uncertainties, hunches, and assumptions that need to be reviewed, investigated, and carefully reexamined. Furthermore, it is important to recognize that there are different types of studies, each with different designs, sample sizes, measures, strengths, and limitations to name a few. Research needs to be constructed to fit the situation and context being studied. Product safety cannot merely be assumed or declared. The randomized controlled trial (RCT) has been traditionally used as a gold standard and is generally needed to prove safety before a product is brought to market.[26] Demonstration of safety is determined through numerous carefully researched studies which have accurately assessed short and long-term outcomes. Other important considerations are the quality of the outcomes prioritized in addition to the length of the trial. Evaluating studies based on these research elements is essential in order to discern whether a safety claim is accurate or not.

4. Are the COVID-19 mRNA products like other vaccines?

The COVID-19 mRNA products are unlike previous vaccines.

These novel substances are actually synthetically altered foreign genetic material designed to modify the normal functioning of human cells.[27] In particular, they force human cells to produce the spike protein of the SARS-CoV-2 virus using information encoded in a highly modified messenger RNA (mRNA) version of the original viral spike gene.[28-30] The spike protein is a part of the SARS-CoV-2 virus that determines its infectivity and host immuno-inflammatory response[31-33] and it has been implicated in viral and non-viral inflammatory, immunological and thrombotic illness-causing mechanisms.[34-50] The presence of this foreign protein alarms the immune system, causing it to develop antibodies that will help identify and attack the spike protein on next presentation either as part of the SARS-CoV-2 virus or on the surface of human cells following viral exposure or the next mRNA injection.[29,51]

The Food and Drug Administration (FDA) defines gene therapy, or gene therapy products (GTPs), as any product that instructs cells to produce genetic material or a protein for treatment of a disease.[52,53] The FDA warns that GTPs can put people at an increased risk of undesirable, unpredictable, and delayed adverse outcomes and recommends up to 15 years of testing to establish safety.[54] The same testing standards should similarly be applied to the mRNA products being promoted as vaccines. These GTPs also utilize foreign DNA or RNA molecules in order to produce the desired responses. More recently, it has also been discovered that the mRNA products can be reverse transcribed into DNA[35] and that they may also contain plasmid DNA that can be translated into RNA.[36,37] Given our current understanding of the COVID-19 mRNA products, one might reasonably categorize them as products that modify genetic material regardless of their application.

At the time when the COVID-19 mRNA products were recommended for pregnant women, there were only two months of RCT data for adults, which is considerably shorter than the recommended 15 years for GTPs. In fact, the manufacturer, Moderna, indicated at the time that experience with the mRNA products was limited and suggested that their use should be restricted to research settings: "… mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines."[55] Hence, the research, especially around pregnancy and breastfeeding, seems to indicate that the current recommendation to use the COVID-19 mRNA products lack sufficient evidence of safety.

5. Are pregnant women at an increased risk of severe COVID-19?

5.1) The CDC's declaration that pregnant women are at increased risk of severe COVID-19 is primarily based on a large observational study done early in the pandemic. Observational studies look at how things change over time. While they may be good at detecting patterns, they are not very helpful in determining what is causing the trend. This study was conducted at a time when more aggressive strains of SARS-CoV-2 were circulating and levels of immunity in the general population were low. It found that pregnant women with symptomatic COVID-19, although at low risk of severe COVID-19 overall, had a higher risk of ICU admittance, invasive ventilation, and death compared to non-pregnant women with symptoms of the same age.[56] The study results were quickly used as a basis for classifying pregnant women as being at a high risk of severe outcomes even though the study was unable to prove that COVID-19 was the cause of their severe disease. Additionally, this study was poorly designed. The worst flaw was how it calculated rates of severe COVID-19 outcomes. The researchers only considered the confirmed symptomatic cases registered in their database rather than the total number of infections occurring in the population at that time. Using this smaller number, rather than the total number, as the denominator, inflated the rate of severe events making it seem like pregnant women were more at risk than they actually were. The analysis was also performed with large amounts of missing data; only a third of the pregnancy status and a quarter of the ICU status data were available for analyses. These factors bring the results of this study and others, conducted in a similar fashion, into question. The study also failed to emphasize that many of the severe outcomes occurred in women who were older, obese or had other health problems. Thus, the study results don't apply to most healthy pregnant women today.

5.2) More recent observational studies conducted early in the pandemic on obstetric wards with careful universal SARS-CoV-2 screening and well-designed databases capable of capturing very reliable pregnancy and ICU data came to a different conclusion.[57-59] The studies found that most women presenting for childbirth early in the pandemic tested negative (63% to 90%) and of those who tested positive most were without symptoms (72.6% to 98.1%). One very large prospective study assessed the outcomes of women without COVID-19 symptoms,[60] comparing those who tested positive for COVID-19 to those who tested negative and found comparable outcomes between the two groups. Only a small percentage of pregnant women actually tested positive for COVID-19 over the course of their pregnancy (2.4% of a total of 11,728 patients). Among those who did test positive, the majority (62%) did not have any symptoms. The pregnancy outcomes of asymptomatic test-positive pregnant women were comparable to those who tested negative. The authors conclude "pregnant women testing positive for SARS-CoV-2 at admission for delivery should be reassured by their healthcare workers in the absence of symptoms."[60] We now know with a high degree of certainty that *better quality studies indicate that the majority of pregnant women are at very low risk of severe COVID-19*.

5.3) During the past three years, most people have been either vaccinated, infected with SARS-CoV-2 and/or have recovered from COVID-19 at least once.[61] Close to 80% of Canadians have infection-acquired antibodies indicating that most have developed robust, broad, and long-lasting immunity.[61] A recent matched cohort trial from Qatar showed that immunity acquired by natural means dramatically reduces the risk of severe, critical, or fatal COVID-19 by 76% compared to the Pfizer or Moderna mRNA products.[62]

This means that studies that are used to designate pregnant women as at high risk of COVID-19 are outdated or no longer clinically relevant – given that now most pregnant women likely now have naturally acquired immunity that provides much better protection than mRNA products.

5.4) Additionally, it is well established that there are measures pregnant women can take to further bolster their healthy immune systems. An optimal vitamin D level supports a person's immune system to better fight respiratory illnesses.[63-68] Treatments such as hydroxychloroquine have also shown benefits and may be an option for those who do contract COVID-19.[69-75] Moreover, hydroxychloroquine has decades of safety data in pregnant women.[71,76]

6. Safety – Are these mRNA products safe for pregnant or breastfeeding women and their babies?

When evaluating pharmaceutical products – such as drugs, medications, vaccines, or other substances – for use during pregnancy or lactation, determining *safety* (for the mother, embryo, fetus, and nursing child) should take priority over considerations of their *effectiveness* (or whether the drug works).[24,77]

6.1) The thalidomide tragedy directly led to regulatory reforms in the U.S., the UK, and Canada, with laws that recognize the need to establish the safety of a product intended for humans prior to widespread use.[78,79] Regulatory authorities (such as Health Canada) require that manufacturers prove the safety (and efficacy) of a medical or pharmaceutical product before it goes on the market. This requires robust and scientifically sound data from highly regulated pre-clinical, clinical and finally RCT studies – the only type of study that is able to prove drug safety. Novel products first need to be assessed in non-pregnant people, then extensively in pregnant women and only then should the outcomes be used as the basis for any recommendation. In addition, these trials need to rigorously monitor both mother and child for major harms as well as for more subtle injury through the full length of the pregnancy and thereafter. The unfortunate generational harms of DES clearly indicated the need for long term follow up.[20,23] Anything less than this falls far short of the evidence needed to establish safety.

6.2) There is a concerning lack of robust and reliable RCT safety data showing that the COVID-19 mRNA genetic products as well as other recommended injections are safe in pregnant women. Notably, the UK Government Medicines & Healthcare products Regulatory Agency (MHRA) document dated December 2020 and updated January 6, 2023, still *advises that pregnant women and women who are breastfeeding should avoid the mRNA BNTa62b2/ Pfizer/ BioNTech products due to insufficient reassurance about the safety of those products*.[80] Preclinical studies are required to ensure that the injections don't harm the mother's or baby's genome, cause cancer, or harm reproductive health. Such studies were not conducted[81,82] and pregnant women were excluded from the RCTs needed to prove safety.[83,84] Of the women who later

were identified as pregnant over the course of Pfizer's study (n=50) and a total of 8 miscarriages were reported.[85] The studies used to support claims of reproductive and developmental safety found a statistically significant higher mean percentage pre-implantation loss in rats receiving the Pfizer mRNA product compared to controls. The studies also found a rat fetus with a malformed mouth and another with a malformed aorta in the mRNA product group and not the controls. Yet, these concerning findings were dismissed by authors.[86] Another report identified "wavy ribs" in those receiving the Moderna's mRNA products,[87,88] and the manufacturer's report acknowledged their connection to the mRNA injections.[87] These findings are at odds with FDA claims regarding Moderna mRNA products that there were "no vaccine-related fetal malformations or variations and no adverse effect on postnatal development".[89] The human RCTs were conducted in non-pregnant persons and the randomized assignment was dismantled at two months so there is no longer a control group for comparison. Thus, it is impossible to see if these genetic products are associated with short- and long-term harm in humans.[90] Health officials declared these COVID-19 mRNA products to be "safe" and recommended their use in pregnant women after they had only been on the market for four months. This declaration was done without proper supporting evidence and despite indicators that these products were associated with an increased risk of injury. Potential harms to mothers and offspring – our children – do not seem to have been considered.

6.3) Moreover, FDA's February 28, 2021, review of Pfizer's early pharmacovigilance safety database clearly showed that mRNA product (BNT162b2) injections may cause harm to mothers, pregnancy, lactation, and breastfeeding infants.[91] This review makes clear that this database cannot be used to calculate incidence rates or test hypotheses, but that it should be used to detect potential indicators of harm or safety signals. This raises the question of how much harm is acceptable before halting use of these products.

6.4) Despite a deficiency of safety data, these products continue to be declared as "safe" in pregnancy. Studies used to support these claims are generally of poor quality, consisting mainly of observational studies and voluntary registries. As such, they are only able to speculate that associations seen between suspected injuries and the mRNA product are not due to the COVID-19 mRNA products. The primary limitation of most of these studies is that they focus on short-term harms to the mother or only highly observable immediate harms such as miscarriage, stillbirth, preterm birth, or infant size at birth.[92-97] None of the studies monitored the health of the mother and child carefully enough – or long enough – to detect subtle but significant changes to maternal or infant bodily systems, including but not limited to, the reproductive, immune, or cardiovascular system. Additionally, these studies have significant statistical issues that further bring their findings into question: they lacked any reliable denominators; they lacked standardization; they lacked stratification of significant variables; they lacked adequate tracking and follow-up of participants; and they incorrectly interpreted what data is available.[92-97] Recently meta-analyses of these same observational trials have been published and have failed to establish safety risks for these COVID-19 mRNA products in pregnant women.[98-100] However, these analyses suffer from the same limitations as the observational trials and are no substitute for the robust and long-term RCT data that is required to prove product safety.

7. Effectiveness – Do these products work in pregnancy?

The claims made regarding the effectiveness of COVID-19 mRNA products promoted as vaccines in pregnant women are as unreliable as the safety claims. Consistent with ethical guidelines, pregnant women were not included in RCTs. The only information is on non-pregnant people whose immune system is distinctly different than that of pregnant women.[101-103] Therefore, one cannot draw conclusions about the impact these products would have on the immune system of a pregnant woman. Any statement about how well the COVID-19 products work in pregnant women based on RCTs conducted in non-pregnant persons is largely speculative.

7.1) Furthermore, the six-month RCT data for non-pregnant persons that was used as the basis for approving these COVID-19 mRNA products is now clinically irrelevant, because the studies were conducted when people had little exposure to COVID-19 and more virulent strains of SARS-CoV-2 were circulating. The virus changed over time. Also, many more people were likely exposed and developed natural immunity after the original RCT.[104] To assess whether the mRNA products are any better than naturally acquired immunity, a study would have to compare those who received two doses of the COVID-19 products to those who had recovered from COVID-19 twice. The actual RCT compared those who had had two COVID-19 doses to those who had never been exposed to COVID-19. As it is well established that immunity helps fight infection, this comparison would favor the mRNA products, but would fail to assess how they compare to naturally acquired immunity. It should be noted that the randomized part of the study was dismantled after two months, compromising its integrity as an RCT and making it impossible to know whether any benefits are long-lasting. Even so, the mRNA products did not prove to be very beneficial. Through 6 months of follow-up, the net benefit (Absolute Risk Reduction, ARR) seven days or more after the second dose was negligible; only 4% for symptomatic COVID-19 and 0.1% for severe COVID-19.[105-107]

7.2) Most public health authorities now recognize that the COVID-19 mRNA products are minimally effective. The CDC recently reported that the primary series - first two doses of the products – "provide minimal protection against infection and transmission"[108] and that the benefits of boosters are transient – in other words, these products do not work to previously accepted vaccine standards. They simply transiently restore the levels of spike-targeting antibodies, but for only a few months. These mRNA products continue to be promoted with the expectation that they protect against severe outcomes from COVID-19 and a presumed hope that some protection might extend to the unborn or newborn children via transfer of spike-antibodies through the placenta or breastmilk.[109] However, the evidence for these claims is shaky, especially given the widespread acquired natural immunity in the population and predominance of more benign variants of SARS-CoV-2. Antibody levels are not always indicative of durable protection from severe outcomes.[110,111] Further, these COVID-19 mRNA products have not been adequately tested in RCTs with pregnant women.[83,84,112-116] Limitations of the research include:

A) The observational studies considered are inadequate to establish a causal relationship between the benefits of the COVID-19 mRNA injections and prevention of severe infections in mothers or their (unborn) children.[117-120]

B) Most of these studies are less informative since they were assessing product effectiveness against variants that are no longer in circulation.[117-121]

C) The absolute number of hospitalizations in mothers was so low that when calculating the absolute risk reduction in hospitalization the decrease was as low as 0.1-0.2% despite reportedly large reductions in relative risk.[119]

D) The studies did not account for differences in natural immunity, type of birth, and whether mothers were breastfeeding or not – all of which have impacts on immunity and health. In other words, these COVID-19 products do not clearly show additional protection against severe infection.

7.3) Given that the apparent benefits of the COVID-19 mRNA products are short-lived, boosters have been promoted as a means of preventing severe COVID-19. However, claims of booster effectiveness have not been based on quality RCTs, but rather on poor-quality observational studies that used an unreliable measure for determining COVID-19 infection status[122-128] or studies that measure spike antibody levels.[129-132] Studies promoting boosters during pregnancy also failed to take into account the cumulative impact that receiving multiple doses of these products may have on the immune system and the developing child. Each additional booster may decrease immune function and the body's ability to protect itself. The bivalent booster being advised for pregnant women is particularly problematic. For the BA.4/5 booster, no clinical trials were done at all, but recommendations relied on data from 8 mice and poor-quality clinical data from an entirely different booster, the BA.1 booster. Additionally, the BA.1 study was of incredibly poor quality: the authors asked the wrong questions, measured the wrong endpoints, misinterpreted effectiveness, and misrepresented safety. Beyond that, the data presented in ***the BA.1 study actually shows an increased level of COVID-19 infection with the Omicron booster as compared with the original booster*** in those not recently infected.[133]

8. What are some of the known factors of concern and plausible ways they might cause harm?

There are known factors about these COVID-19 mRNA injections that are worrisome – especially around issues of fertility, pregnancy, and the health and development of the born/unborn babies. These COVID-19 mRNA products are designed to cross naturally protective barriers to get into cells, to interact with the cells' protein producing machinery, and to stimulate inflammation to cause an immune reaction. The strength of the inflammatory response to these injections, and the resulting tissue damage may be greater if the mother already has natural immunity, or has already received a previous dose of an mRNA product.

8.1) Lipid nanoparticles (LNPs) are unnatural "fat pockets" used to import the synthetic mRNA cargo into cells. LNPs are specifically designed to cross protective barriers in the body. Two of the protective barriers that keep people healthy are the blood-brain barrier and the placental barrier. Pfizer's own data established that LNPs distribute throughout the body and concentrate in particular organs, including the liver, spleen, adrenal glands and ovaries (Table 1).[134] Widespread distribution of these products to multiple organs, including the brain, heart, lungs, liver, eyes, and testes was also seen in Moderna's biodistribution data.[135] ***Given these products' engineered ability to breech protective barriers, and given that certain LNPs have been shown to selectively accumulate in mice placentas***, there is legitimate concern that – in the case of pregnant or breastfeeding mothers – the LNPs and their harmful cargo might get into the bodies of born or unborn babies at potentially critical phases of their development. The data in this regard is equivocal. Interference during the development of the brain, organ, and immune system could directly impact the survival, health, and wellbeing of these young ones over a lifespan. Apart from whatever substance they carry into specific organs and cells, the ***LNPs themselves are known to be inflammatory and toxic***.[136,137]

Sample	Mean total lipid concentration (µg lipid equivalent/g (or mL) (3 males and 3 females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Adrenal glands	0.271	1.48	2.72	2.89	6.80	13.80	18.20
Bone marrow (femur)	0.479	0.96	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
Heart	0.282	1.03	1.40	0.99	0.79	0.45	0.55
Kidneys	0.391	1.16	2.050	0.924	0.590	0.426	0.425
Liver	0.737	4.63	11.00	16.50	26.50	19.20	24.30
Lung	0.492	1.21	1.83	1.50	1.15	1.04	1.09
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
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.30
Pancreas	0.081	0.21	0.414	0.380	0.294	0.358	0.599
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264
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
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112
Spleen	0.334	2.47	7.730	10.300	22.100	20.100	23.400
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.000
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.446

Table 1
SARS-CoV-2 mRNA Product (BNT162, PF-0 7302048): 2.6.5.5B. Adapted from Pharmacokinetics: ***organ distribution***, report number: 185350, Pages 6-7

8.2) ***The mRNA material*** carried into the cells by the LNPs is also a known cause for concern. Even the manufacturer, Moderna, acknowledged that actual experience with their mRNA products was limited at the time of rollout and use should have been restricted to research settings. Moderna specifically noted, "… mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines."[55]

8.2.1) ***The mRNA material*** (carried into the cells by the LNPs) is not natural and has been synthetically engineered ***to be longer lasting*** than natural viral mRNA. With each injection, an overwhelming amount of spike protein is produced in the body, much more than what would occur with SARS-CoV-2 infection. Tens of trillions of LNPs may be injected with each COVID-19 mRNA injection and each single LNP can carry multiple copies of the longer-lasting spike mRNA. In turn, individuals receiving these injections could produce hundreds of trillions of copies of the spike proteins throughout their body.[138] This is a matter of concern as the spike protein is highly bioactive and can trigger hyper-inflammation.[139] It is also similar to numerous other biotoxins,[140] and may contribute to autoimmune inflammatory responses[141] such as those associated with myocarditis.[142] Circulating spike proteins have been found in the bloodstream for months after injection.[143]

8.2.2) A recent research letter in JAMA Pediatrics highlighted that the ***COVID-19 mRNA product has been detected in breast milk***.[144] The clinical significance of these inflammatory compounds passing into a child's digestive system has not been fully investigated. Previous studies on nursing mothers who have received these mRNA products have shown adverse events in 7.1% of breastfed infants,[109] and an observational safety study conducted in U.S., 1.2% of pregnant or lactating women reported unexplained "issues" with their breastmilk-fed infant after vaccination.[145] The FDA review of Pfizer's early pharmacovigilance safety data base demonstrates similar concerning findings.[134] Multiple factors in breastfeeding, including but not limited to maternal antibodies passed through breastmilk, contribute to immune function and development in nursing babies.[146,147] The complexity and the uncertainty about the duration and impact of all of the products, mRNA or other, or byproducts including spike protein, that may be secreted in breastmilk should be cause for pause – especially for any products that have not been proven safe in infants. Although JAMA authors suggest that mothers interrupt breastfeeding for two days following vaccination, this recommendation seems rather arbitrary and the precautionary principle would dictate that vaccination should be avoided until extensive safety testing is conducted to protect the breastfeeding continuum.

8.2.3) There are ***variations in the sizes*** of the synthetic mRNA molecules and other ***apparent "impurities"*** in COVID-19 injection vials.[148] The degree to which these "impurities" are immunoreactive and the impact the varied-sized mRNA molecules have on the human immune system is also unknown.[149,150] In addition, there is mounting evidence that the bacterial plasmid DNA used to manufacture the mRNA in the lipid nanoparticles is a significant contaminant.[151,152]

8.2.4) ***Molecular mimicry*** occurs when a protein attacked by the immune system resembles a human protein. This ***may lead to an increased risk of autoimmune*** (an immune reaction against a person's own healthy proteins) ***conditions***.[153] Similarities between the spike protein and human proteins may lead to an autoimmune reaction, which ***may affect reproduction***. A study published in American Journal of Reproductive Immunology found that the spike protein shares partial similarities with 27 human proteins that relate to essential reproductive functions necessary for achieving and maintaining a successful pregnancy – oogenesis, uterine receptivity, decidualization, and placentation.[154] As reported by a Finnish whistleblower,[155] an autoimmune-type reaction against some of these 27 proteins could potentially impair reproduction and may account for the observed decrease in health of oocytes, sperm cells, and embryos in in-vitro fertilization clinics following the mass rollout of these mRNA products. In men, two doses of the Pfizer/BioNTech COVID-19 product was associated with a 15.4% temporary decline in total sperm concentration and motility.[156]

8.2.5) The controversial question of ***whether mRNA sequences delivered by vaccination can become part of the human genome*** needs to be addressed. There is evidence that it can occur,[81,157,158] that production of DNA copies of vaccine mRNA inside cells has been demonstrated,[159] and that genome integration has occurred with SARS-CoV-2 sequences.[160] These events have been associated with increased levels of biological elements that promote genomic instability and inflammation and their continued stimulation can lead to immune disorders.[81,159,160] A study published in PLOS Pathogens showed that in mice, "the mRNA-LNP vaccine platform induces long term immunological changes, ***some of which can be inherited by the offspring"*** (emphasis added).[161] The effect on the immune system in human offspring – including defence against infections as well as a propensity toward allergy and autoimmune disorders – is at this stage completely unknown.

As noted, multiple studies indicate that there are many concerning mechanisms of action and potential harms associated with mRNA substances and similar products. The precautionary principle – "first, do no harm" – would suggest that the best course of action for pregnant and/or breastfeeding mothers would be to avoid these products all together.

9. What are some of the disturbing safety signals?

Most concerning are the accumulating safety signals – and the apparent reluctance to fully investigate them. In the first 3 months of the rollout, Pfizer submitted a worldwide safety report to the Food and Drug Administration (FDA) in April 2021 reporting on the safety of the COVID-19 mRNA products. This report documented 1,223 mRNA product-suspected adult deaths and 28 fetal or newborn deaths.[91] Based on these findings, Pfizer concluded that there was insufficient information to establish the safety of these products in pregnant and lactating women.

Vaccine surveillance systems like the U.S. Vaccine Adverse Events Reporting System (VAERS),[162] UK Medicines & Healthcare Products Regulatory Health Research Agency (MHRA) Yellow Cards,[163] European Medicines Agency (EMA) EudraVigilance,[164] and World Health Organization (WHO) VigiAccess[165] were established to monitor suspected adverse events in the general population following the approval of vaccines that had been previously exhaustively studied for five to ten years and had fully characterized safety profiles. These passive systems were not designed to properly determine the safety profile of a drug or determine the frequency of an adverse event. The VAERS database may only capture as few as 1% of actual adverse events.[166] If you look at this chart going back to 1990, the miscarriages/stillbirths related to vaccines by year were low until the mRNA injections came out in 2021, then they absolutely skyrocketed (Figure 1).

Figure 1
Reports of miscarriage and stillbirths from VAERS[162]

That said, all four major adverse event surveillance databases contain significant numbers of reproductive-related and pregnancy-related adverse outcomes.

	VAERS	MHRA	VigiAccess (WHO)	EudraVigilance (Pfizer only)
Total Reports	1,424,789	464,072	4,429,975	1,132,795
Pregnancy / Puerperium / Perinatal			12,413	2876
Miscarriages	5055	821	5959	1994
Fetal deaths			548	150
Stillbirths	193	23	231	60

Table 2
Reported Pregnancy-related Adverse Events on International Databases up to October 10, 2022 (source: HART's Open Letter to RCOG, RCM & UKHSA)[167]

9.1) A study currently in preprint by Dr. James Thorp (a U.S. specialist in fetal-maternal medicine) compares VAERS reported suspected ***pregnancy-related adverse outcomes*** after the COVID-19 mRNA products to those reported after influenza vaccinations.[168] The study found much higher rates of miscarriages, fetal disorders, fetal growth abnormalities, low amniotic fluid, and fetal death/ stillbirth following the mRNA injections as compared to the traditional flu vaccines.[168] As shown in Figure 2, adverse event (AE) reporting ratios ranged from 5 to more than 1,000 times with most between 10- and 100-fold greater – this means the sheer number of events being reported after mRNA product administration is considerably higher than anything previously seen with other vaccines. There is no question that comparing adverse outcomes of two different products has its limitations. Nevertheless, the number of reports indicating the possibility of fetal injury is truly troubling and should alone prompt an urgent halt to the use of mRNA products during pregnancy.

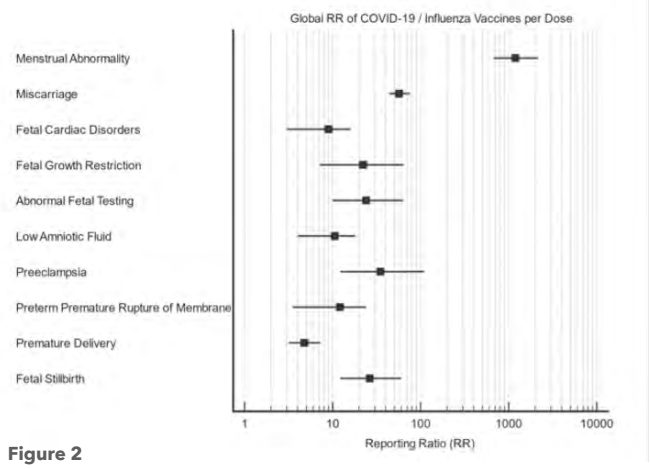

Figure 2
Global Reporting Ratios (RRs) of Adverse Events (AEs) for COVID-19 Vaccination vs. Influenza Vaccination by Dose Given.

9.2) An ***increased infant mortality rate*** was seen in Scotland in 2021 (Figure 3). This increase mostly related to ***spikes in neonatal deaths***, which seem to have followed closely with recent maternal injections of the mRNA products (Figure 4). This correlation is especially remarkable considering not all pregnant women were vaccinated with these products. These spikes in neonatal deaths continued into 2022 and have been acknowledged as concerning.[169] In May 2022, unsupported assertions were made that the "the COVID-19 mRNA product, which studies have consistently shown to be safe in pregnancy, was not a factor [in these neonatal deaths]."[170] This cannot be known from the available evidence. Such an assertion would require transparent studies free from the unexamined biases that often plague most publications on this subject to date. Given how closely the increase in neonatal deaths followed the mRNA product rollout, it would seem the most ethical response would be to halt the manufacture and distribution of the mRNA products and immediately identify and investigate potential causes.

This phenomenon of increased neonatal deaths is not limited to Scotland. Spikes in neonatal death rates in 2021 were also observed in analysis of data from a major Israeli health insurer. Quarterly rates nearly tripled in Q2 and Q4, following recommendation of COVID-19 mRNA products in February 2021 and 2021's booster vaccination campaign, respectively.[171]

Figure 3
Infant Mortality Rates by Week in Scotland 2015 – 2022[172]

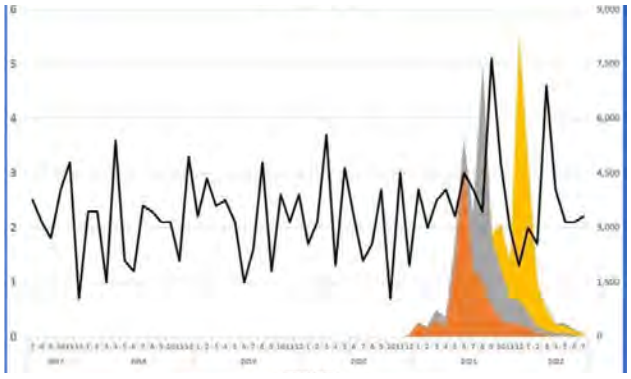

Figure 4
Neonatal Deaths and COVID-19 mRNA product (dose (D) 1 – 3) in Pregnancy in Scotland[172]

9.3) Several studies have reported ***fetal heart stress*** after the mother received the COVID-19 mRNA product. These fetal heart issues appear to be similar to the myocarditis and pericarditis known to occasionally follow COVID-19 injections in children.[173,174] Historically, myocarditis in babies has been exceedingly rare and yet between June 2022 and March 2023 there was an unprecedented surge of ***severe myocarditis in newborns and infants*** in the UK.[175] The important question of whether the babies and/ or their mothers had received any mRNA product will likely go unaddressed.[175]

9.4) According to a CDC study, there has been a ***significant increase in U.S. maternal mortality rates*** of about 50% in 2021 relative to previous years (2019 and 2020).[176] This represents the largest increase in recent years and happened despite the introduction of the COVID-19 mRNA products purportedly meant to protect pregnant women.

9.5) ***Menstrual abnormalities and bleeding*** are among the adverse effects known to be associated with the COVID-19 mRNA injections in women.[177,178] "Symptoms" of immune thrombocytopenia (ITP), an immune mediated drop in platelets that can cause bruising and/ or bleeding, have been found in young Saudi women (ages 19-29 years) after receiving the COVID-19 mRNA vaccines, and were more severe with Moderna than Pfizer. Authors emphasize that these results were similar to findings of studies carried out in Germany, Israel, and Africa.[179] These types of immune issues and clotting disorders are particularly concerning for young women as these have been associated with infertility and recurrent miscarriages.[180]

9.6) The ***global drop in birthrates*** in countries with highly COVID-19 vaccinated populations is another concerning indicator of potential harm. In the first half of 2022, birth rates appear to have fallen significantly in highly vaccinated countries throughout Europe, with a decline of more than 4% in 15 countries and more than 10% in seven countries.[181-184] At least two analyses have identified a temporal association between large declines in birthrate and COVID-19 vaccination.[182,184] Continuing to vaccinate without fully investigating whether the drop in birthrate is linked to the mass roll-out of mRNA injections is unsettling.

9.7) It is important to question whether there are ***increased safety risks with repeated shots.*** Currently, some pregnant or lactating women have received a 4th or 5th shot and the FDA has recently approved the 4th shot (i.e., first booster) for infants (> 6 months).[185] This is occurring without adequate safety data.

10. Does the messaging and medical advice follow scientific evidence?

10.1) The media has promoted publications that claim mRNA product safety. As discussed in section 6.4, the studies used to support these claims are observational studies or meta-analyses of observational trials. These studies are unable to establish safety and do not sufficiently monitor both mother and child for potential harms through the full length of the pregnancy and thereafter. Additionally, conflicts of interest, where pharmaceutical companies have vested interests in these products, may have significantly impacted the integrity of studies that are said to suggest mRNA product safety and effectiveness.

10.2) Problematic publications on purported safety continue. Here are a few examples. A large Canadian study published in The Lancet concluded that the COVID-19 injections had "a good safety profile in pregnancy" based on a follow-up period of only seven days.[94] An appropriate analysis would follow safety through pregnancy and up to two years of child development. A BMJ publication that claimed efficacy of the mRNA injections in pregnancy for birth outcomes was among other observational studies. This publication used a long list of co-variables and statistical assumptions rather than actually matching the variables in the groups of people being compared.[92] A systematic review and meta-analysis, co-authored by the current president of the Royal College of Obstetrics and Gynecology UK and others with significant acknowledged conflicts of interest, declared the use of the mRNA products during pregnancy to be effective in improving perinatal outcomes.[186] However, the observational studies used to support these claims were not sufficiently robust to support these conclusions.[187] ***There are no reliable statistics proving safety in pregnancy at this time.***

10.3) Fundamental ethical considerations in the research process have been circumvented in the past three years. Evidence overwhelmingly indicates that these mRNA products marketed as vaccines to women of childbearing age – and to pregnant and/ or breastfeeding mothers – are not needed, lack effectiveness (i.e., they don't work), and have plausible mechanisms of harm in addition to glaring, real-world indicators of potential harm (i.e., they have not been fully proven safe). Taken together, all of these issues indicate that the safety information available to healthcare providers and the people they serve regarding these mRNA products is inadequate, misunderstood or misleading.

11. Does the healthcare system prioritize the safety of a mother and her baby?

Traditionally, health delivery systems were designed with the wellbeing of the recipient in mind.

However, over the years other interests have taken precedence, shifting the focus away from person-centered care to what is broadly deemed "the best interests of the community". Healthcare systems have tended to depersonalize care in the service of efficiency and affordability. Large healthcare systems are complex and have multiple layers and many profit-minded stakeholders,[188] including pharmaceutical companies. Entangled interests[189,190] of safety, efficiency, influence,[191,192] and profit inevitably complicate matters and can lead to competing priorities.[193]

Vaccines are among the most lucrative pharmaceutical products, as their use can be rationalized in both the healthy and the sick on an ongoing basis, especially the use of vaccines for respiratory illnesses.[194] In both the U.S. and Canada, vaccine manufacturers are often shielded from liability[195] and during the COVID-19 crisis, the COVID-19 mRNA products received emergency use approval, such that, unlike other products, they were not required to prove safety prior to use in the general population.[189] Even more concerning is that it appears that government organizations like the U.S. Department of Health and Human Services (HHS) gave millions of dollars to the American College of Obstetricians and Gynecologists (ACOG) to participate in a state of the art marketing campaign called the COVID-19 Community Corps,[196] which subverted trusted relationships to promote these under-tested mRNA products in pregnant women rather than uphold informed consent.[197]

Pharmaceutical companies and vaccine manufacturers play a large role in designing and running the studies needed for drug approval and promotion. Intentionally or unintentionally, competing financial interests[198,199] can compromise research design, data collection, and conclusions leading to an over emphasis on product benefits and minimization of product risks. When there are concerns about the safety of a pharmaceutical product, it may require significant legal action to make research data available for review.[200,201] What can get lost in the push to develop, regulate, and deploy incredibly lucrative new products in record time is the actual living, breathing human beings and their born and unborn children who might be harmed by their use.

Protecting pregnancy

Pregnant and breastfeeding women, their babies, reproductive health, and indeed our future, are too precious to risk injury due to under-tested products. Pregnancy is a unique and exquisitely normal phase of health. Nature's intricate design and wisdom have sustained life throughout the millennia. Relationships and engaging with the living world around and within are what nourish life.

The precautionary principle: ***"First, do no harm",*** implores practitioners to avoid interventions, impositions, or interferences in pregnancy and natural processes that have not been proven safe and without fully weighing potential consequences to mothers and their babies. Logically, this principle would lead to an immediate pause to the use of COVID-19 products marketed as vaccines in women of childbearing age, and during pregnancy and breastfeeding. The clear real-world safety signals and the absence of data on long-term safety outcomes support the notion that these substances pose too many risks for mothers and children. Similarly, the evidence reviewed indicates these mRNA products are not needed and may be doing more harm than good. Pregnant women, breastfeeding mothers, or women of childbearing age deserve to know and to act on this information without fear of how they will be treated in response to the questions they ask or the decisions they make.

Life is precious. Protect pregnancy and breastfeeding. Do no harm.

About Us

The Canadian Covid Care Alliance provides independent, science-based evidence to empower Canadians.

Our alliance of independent Canadian doctors, scientists and healthcare practitioners is committed to providing top-quality and balanced evidence-based information to the Canadian public about COVID-19 so that hospitalizations can be reduced, lives saved, and our country safely restored as quickly as possible.

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References

1. van der Graaf R, van der Zande ISE, den Ruijter HM, et al. Fair Inclusion of Pregnant Women in Clinical Trials: an Integrated Scientific and Ethical Approach. Trials 2018;19:78.
2. Baylis F. Pregnant Women Deserve Better. Nature 2010;465:689-90.
3. Government of Canada - Public Health Services. Pregnancy. 2023. (Accessed April 6, 2023, at https://www.canada.ca/en/public-health/services/pregnancy.html.)
4. Marshall JE, Raynor MD. Myles' Textbook for Midwives E-Book: Elsevier Health Sciences; 2014.
5. Siegler RS, Saffran J, Eisenberg N, Gershoff ET. Prenatal Development and the Newborn Period. How children develop (6th ed). New York NY: MacmillanLearning; 2020:40-77.
6. Health Canada. Family-centred Maternity and Newborn Care: National Guidelines. 2022. (Accessed May 15, 2023, at https://www.canada.ca/en/public-health/services/maternity-newborn-care-guidelines.html.)
7. Mor G, Cardenas I. The Immune System in Pregnancy: a Unique Complexity. Am J Reprod Immunol 2010;63:425-33.
8. Svensson-Arvelund J, Ernerudh J, Buse E, et al. The Placenta in Toxicology. Part II: Systemic and Local Immune Adaptations in Pregnancy. Toxicol Pathol 2014;42:327-38.
9. McAlpine JM, McKeating DR, Vincze L, Vanderlelie JJ, Perkins AV. Essential Mineral Intake During Pregnancy and Its Association With Maternal Health and Birth Outcomes in South East Queensland, Australia. Nutr Metab Insights 2019;12:1178638819879444.
10. Zuccarello D, Sorrentino U, Brasson V, et al. Epigenetics of Pregnancy: Looking Beyond the DNA Code. J Assist Reprod Genet 2022;39:801-16.
11. Moore KL, Persaud TVN, Torchai MG. The Developing Human: Clinically Oriented Embryology. 11th ed. North York ON: Elsevier; 2019.
12. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 8th ed. New York, NY: Oxford University Press; 2019.
13. Parikh N. Your Rights As A Patient. 2023. (Accessed April 6, 2023, at https://canadianhealthadvocatesinc.ca/blog/your-rights-as-a-patient/.)
14. Canadian Medical Association. CMA Code of Ethics and Professionalism. 2018. (Accessed April 6, 2023, at https://policybase.cma.ca/viewer?file=%2Fmedia%2FPolicyPDF%2FPD19-03.pdf#page=1.)
15. American Medical Association. AMA Principles of Medical Ethics. 2001. (Accessed April 6, 2023, at https://code-medical-ethics.ama-assn.org/principles.)
16. Kriebel D, Tickner J. Reenergizing Public Health Through Precaution. Am J Public Health 2001;91:1351-5.
17. O'Neil E. The Discovery of Fetal Alcohol Syndrome. Embryo Project Encyclopedia 2011:05-9.
18. Roche. Accutane (Isotretinoin Capsules) Data Safety Document 2008. (Accessed April 6, 2023, at https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/018662s059lbl.pdf.)
19. Thalidomide Victims Association of Canada. The Tragedy of Thalidomide in Canada: The Canadian Tragedy. (Accessed April 6, 2023, at https://thalidomide.ca/en/the-canadian-tragedy/.)
20. Zamora-León P. Are the Effects of DES Over? A Tragic Lesson from the Past. Int J Environ Res Public Health 2021;18.
21. Kinch RA. Diethylstilbestrol in Pregnancy: An Update. Can Med Assoc J 1982;127:812-3.
22. National Cancer Institute. Diethylstilbestrol (DES) Exposure and Cancer. 2021. (Accessed May 13, 2023, at https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/des-fact-sheet.)
23. Des Daughter. DES – The Drug to Prevent Miscarriage Ruins Lives of Millions. 2017. (Accessed April 6, 2023, at https://www.hormonesmatter.com/des-drug-to-prevent-miscarriage-ruins-lives-of-millions/.)
24. Chervenak FA, McCullough LB. An Ethically Justified Framework for Clinical Investigation to Benefit Pregnant and Fetal Patients. Am J Bioeth 2011;11:39-49.
25. Cheng R. Covid-19 Highlights the Shortcomings of Evidence-based Medicine. J Orthomol Med. 35: 1-7. 2020.
26. Justice Laws Canada. Food and Drug Regulations (C.R.C., c. 870). 2023. (Accessed May 1, 2023, at https://laws-lois.justice.gc.ca/eng/regulations/C.R.C._c._870/index.html.)
27. ModernaTX Inc. SPIKEVAX - Product Monograph. 2022. (Accessed April 6, 2023, at https://assets.ctfassets.net/qjie68e5s6cv/5D9QY4rECv8o5QzmWpXZfV/e23f3d7aab0c2351ca0bcebb571b2123/Product_Monograph_SPIKEVAX_EN_17Mar2022.pdf.)

References (cont.)

28. Centers for Disease Control and Prevention. Overview of COVID-19 Vaccines. 2023. (Accessed June 1, 2023, at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html.)

29. Bettini E, Locci M. SARS-CoV-2 mRNA Vaccines: Immunological Mechanism and Beyond. Vaccines (Basel) 2021;9.

30. Xu S, Yang K, Li R, Zhang L. mRNA Vaccine Era—Mechanisms, Drug Platform and Clinical Prospection. Int J Mol Sci 2020;21:6582.

31. Almehdi AM, Khoder G, Alchakee AS, Alsayyid AT, Sarg NH, Soliman SSM. SARS-CoV-2 Spike Protein: Pathogenesis, Vaccines, and Potential Therapies. Infection 2021;49:855-76.

32. Baldari CT, Onnis A, Andreano E, Del Giudice G, Rappuoli R. Emerging Roles of SARS-CoV-2 Spike-ACE2 in Immune Evasion and Pathogenesis. Trends Immunol 2023;44:424-34.

33. Lamers MM, Haagmans BL. SARS-CoV-2 Pathogenesis. Nature Reviews Microbiology 2022;20:270-84.

34. Yu J, Yuan X, Chen H, Chaturvedi S, Braunstein EM, Brodsky RA. Direct activation of the alternative complement pathway by SARS-CoV-2 spike proteins is blocked by factor D inhibition. Blood 2020;136:2080-9.

35. Kulkarni HS, Atkinson JP. Targeting complement activation in COVID-19. Blood 2020;136:2000-1.

36. Wang H, Chen Q, Hu Y, et al. Pathogenic antibodies induced by spike proteins of COVID-19 and SARS-CoV viruses. (preprint) 2021;doi:10.21203/rs.3.rs-612103/v1.

37. Colaco C. Thrombosis, Spike and Complement activation in COVID19 (Response to: Thrombosis after covid-19 vaccination). BMJ 2021;373:n958/rr-6.

38. Lei Y, Zhang J, Schiavon CR, et al. SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2. Circ Res 2021;128:1323-6.

39. Biancatelli RC, Solopov P, Sharlow ER, Lazo JS, Marik PE, Catravas JD. The SARS-CoV-2 Spike Protein Subunit 1 induces COVID-19-like acute lung injury in K18-hACE2 transgenic mice and barrier dysfunction in human endothelial cells. Am J Physiol Lung Cell Mol Physiol (online ahead of print) 2021;doi:10.1152/ajplung.00223.2021.

40. Suzuki YJ, Gychka SG. SARS-CoV-2 spike protein elicits cell signaling in human host cells: Implications for possible consequences of COVID-19 vaccines. Vaccines 2021;9:36.

41. Theoharides TC. Could SARS-CoV-2 Spike Protein Be Responsible for Long-COVID Syndrome? Mol Neurobiol 2022;59:1850-61.

42. Abdulla ZA, Al-Bashir SM, Alzoubi H, Al-Salih NS, Aldamen AA, Abdulazeez AZ. The Role of Immunity in the Pathogenesis of SARS-CoV-2 Infection and in the Protection Generated by COVID-19 Vaccines in Different Age Groups. Pathogens 2023;12:329.

43. Vojdani A, Vojdani E, Kharrazian D. Reaction of Human Monoclonal Antibodies to SARS-CoV-2 Proteins With Tissue Antigens: Implications for Autoimmune Diseases. Front Immunol 2020;11:617089.

44. Zheng Y, Zhao J, Li J, et al. SARS-CoV-2 Spike Protein Causes Blood Coagulation and Thrombosis by Competitive Binding to Heparan Sulfate. Int J Biol Macromol 2021;193:1124-9.

45. De Michele M, d'Amati G, Leopizzi M, et al. Evidence of SARS-CoV-2 Spike Protein on Retrieved Thrombi from COVID-19 Patients. J Hematol Oncol 2022;15:108.

46. Atyabi SMH, Rommasi F, Ramezani MH, et al. Relationship Between Blood Clots and COVID-19 Vaccines: A Literature Review. Open Life Sciences 2022;17:401-15.

47. Ryu JK, Sozmen EG, Dixit K, et al. SARS-CoV-2 Spike Protein Induces Abnormal Inflammatory Blood Clots Neutralized by Fibrin Immunotherapy. bioRxiv 2021:2021.10.12.464152.

48. Grobbelaar Lize M, Venter C, Vlok M, et al. SARS-CoV-2 Spike Protein S1 Induces Fibrin(ogen) Resistant to Fibrinolysis: Implications for Microclot Formation in COVID-19. Biosci Rep 2021;41.

49. Li W, Roytenberg R, DeHart A, Denning K, Yue H. SARS-CoV-2 Spike Protein Enhanced Thrombosis is Inhibited by Tipiracil in Mice. Research and Practice in Thrombosis and Haemostasis Conference; 2022.

50. Kircheis R. Coagulopathies after Vaccination against SARS-CoV-2 May Be Derived from a Combined Effect of SARS-CoV-2 Spike Protein and Adenovirus Vector-Triggered Signaling Pathways. Int J Mol Sci 2021;22:10791.

51. Matsumura T, Takano T, Takahashi Y. Immune Responses Related to the Immunogenicity and Reactogenicity of COVID-19 mRNA Vaccines. Int Immunol 2022;35:213-20.

References (cont.)

52. U.S. Department of Health Human Services - Food and Drug Administration - Center for Biologics Evaluation Research. Long Term Follow-Up After Administration of Human Gene Therapy Products. 2020. (Accessed May 15, 2023, at https://www.fda.gov/media/113768/download.)

53. U.S. Food and Drug Administration. What is Gene Therapy? 2018. (Accessed April 6, 2023, at https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy.)

54. U.S. Food and Drug Admnistration. Long Term Follow-Up After Administration of Human Gene Therapy Products - Guidance for Industry. 2020. (Accessed April 6, 2023, at https://www.fda.gov/media/113768/download.)

55. ModernaTX Inc. Quarterly Report Pursuant to Secrion 13 or 15(d) of the Securities Exchange Act of 1934. 2020. (Accessed April 6, 2023, at https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm.)

56. 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. Morb Mortal Weekly Rep 2020;69:1641.

57. Maru S, Patil U, Carroll-Bennett R, et al. Universal Screening for SARS-CoV-2 Infection Among Pregnant Women at Elmhurst Hospital Center, Queens, New York. PLoS One 2020;15:e0238409.

58. Sutton D, Fuchs K, D'alton M, Goffman D. Universal Screening for SARS-CoV-2 in Women Admitted for Delivery. N Engl J Med 2020;382:2163-4.

59. Woods KL, Gabasan A, Schwing D, Wagner B, Eiland L, Camins B. 539. Prevalence of Symptomatic and Asymptomatic COVID-19 Infection in Pregnant Women and Their Infants in an Urban Hospital. Open Forum Infectious Diseases; 2020 2020: Oxford University Press. p. S337.

60. Cruz-Lemini M, Ferriols Perez E, de la Cruz Conty ML, et al. Obstetric Outcomes of SARS-CoV-2 Infection in Asymptomatic Pregnant Women. Viruses 2021;13:112.

61. COVID-19 Immunity Task Force. Seroprevalence in Canada. 2023. (Accessed May 31, 2023, at https://www.covid19immunitytaskforce.ca/seroprevalence-in-canada/.)

62. Chemaitelly H, Ayoub HH, AlMukdad S, et al. Protection from Previous Natural Infection Compared with mRNA Vaccination Against SARS-CoV-2 Infection and Severe COVID-19 in Qatar: a Retrospective Cohort Study. Lancet Microbe 2022;3:e944-e55.

63. Borsche L, Glauner B, Mendel vJ. COVID-19 Mortality Risk Correlates Inversely with Vitamin D3 Status, and a Mortality Rate Close to Zero Could Theoretically Be Achieved at 50 ng/mL 25(OH)D3: Results of a Systematic Review and Meta-Analysis. Nutrients 2021;25.

64. Ooi S-L, Pak S-C. Nutraceuticals in Immune Function. Molecules 2021;26:5310.

65. Balla M, Merugu GP, Konala VM, et al. Back to Basics: Review on Vitamin D and Respiratory Viral Infections Including COVID-19. J Community Hosp Intern Med Perspect 2020;10:529-36.

66. Charan J, Goyal JP, Saxena D, Yadav P. Vitamin D for Prevention of Respiratory Tract Infections: A Systematic Review and Meta-analysis. J Pharmacol Pharmacother 2012;3:300-3.

67. Anitua E, Tierno R, Alkhraisat MH. Current Opinion on the Role of Vitamin D Supplementation in Respiratory Rnfections and Asthma/COPD Exacerbations: A need to Establish Publication Guidelines for Overcoming the Unpublished Data. Clin Nutr 2022;41:755-77.

68. Gallagher JC. Vitamin D and Respiratory Infections. The Lancet Diabetes & Endocrinology 2021;9:54-6.

69. Sisti G, Schiattarella A, Sisti A. Treatment of COVID-19 in Pregnancy with Hydroxychloroquine and Azithromycin: a case report. Acta Biomed 2020;91:e2020123.

70. Ryan GA, Purandare NC, McAuliffe FM, Hod M, Purandare CN. Clinical Update on COVID-19 in Pregnancy: A Review Article. J Obstet Gynaecol Res 2020;46:1235-45.

71. Bérard A, Sheehy O, Zhao JP, Vinet E, Quach C, Bernatsky S. Chloroquine and Hydroxychloroquine Use During Pregnancy and the Risk of Adverse Pregnancy Outcomes Using Real-World Evidence. Front Pharmacol 2021;12:722511.

72. Derwand R, Scholz M. Does Zinc Supplementation Enhance the Clinical Efficacy of Chloroquine/Hydroxychloroquine to Win Today's Battle against COVID-19? Med Hypotheses 2020;142:109815.

73. Gasmi A, Peana M, Noor S, et al. Chloroquine and Hydroxychloroquine in the Treatment of COVID-19: the Never-ending Story. Appl Microbiol Biotechnol 2021;105:1333-43.

74. Rios SS, Resende CN, Peixoto AB, Júnior EA. Treatment of COVID-19 Disease in Pregnancy and Breastfeeding. Сеченовский вестник 2021;12:44-54.

References (cont.)

75. Bermas BL, Gianfrancesco M, Tanner HL, et al. COVID-19 in Pregnant Women With Rheumatic Disease: Data From the COVID-19 Global Rheumatology Alliance. The Journal of Rheumatology 2022;49:110-4.

76. Naveau T, Lichau O, Barnetche T, Blanco P, Truchetet M-E, Richez C. O7 Safety of Chloroquine and Hydroxychloroquine During Pregnancy: A Systematic Literature Review and Meta-analysis. Archives of Disease in childhood; 2020.

77. Götestam Skorpen C, Hoeltzenbein M, Tincani A, et al. The EULAR Points to Consider for Use of Antirheumatic Drugs Before Pregnancy, and During Pregnancy and Lactation. Ann Rheum Dis 2016;75:795-810.

78. U.S. Government. Public Law 87-781 - Oct 10, 1962. 1962. (Accessed April 6, 2023, at https://www.govinfo.gov/content/pkg/STATUTE-76/pdf/STATUTE-76-Pg780.pdf.)

79. UK Government. Medicines Act 1968. 1968. (Accessed April 6, 2023, at https://www.legislation.gov.uk/ukpga/1968/67/contents.)

80. UK Government Medicines & Healthcare products Regulatory Agency. Summary of the Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech. 2023. (Accessed April 6, 2023, at https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine.)

81. Acevedo-Whitehouse K, Bruno R. Potential Health Risks of mRNA-based Vaccine therapy: A Hypothesis. Med Hypotheses 2023;171:111015.

82. McCullough PA, Bernstein I, Jovanovic S, McLeod D, Stricker RB. Lack of Compelling Safety data for mRNA COVID Vaccines in Pregnant Women. 2021. (Accessed May 15, 2023, at https://www.trialsitenews.com/a/lack-of-compelling-safety-data-for-mrna-covid-vaccines-in-pregnant-women.)

83. Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med 2021;384:403-16.

84. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med 2020;383:2603-15.

85. U.S. Food and Drug Administration. FDA-CBER-2021-5683-0218504 - Appendix 16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age. 2021. (Accessed May 15, 2023, at https://media.ellinikahoaxes.gr/uploads/2022/08/rs125742_S1_M5_5351_c4591001-interim-mth6-adverse-events.pdf.)

86. Bowman CJ, Bouressam M, Campion SN, et al. Lack of Effects on Female Fertility and Prenatal and Postnatal Offspring Development in Rats with BNT162b2, a mRNA-based COVID-19 Vaccine. Reprod Toxicol 2021;103:28-35.

87. U.S. Food and Drug Administration. Re: FDA FOIA Request 2021-4379; Judicial Watch, Inc. v. U.S. Department of Health and Human Services, 21-cv-2418. 2022. (Accessed May 15, 2023, at https://justthenews.com/sites/default/files/2022-08/Moderna%20trial%20records%20FDA%20FOIA.pdf.)

88. Piper G. COVID Vaccine Trials Document Birth Defects, Lost Pregnancies, FOIA Requests Reveal. 2022. (Accessed May 15, 2023, at https://justthenews.com/government/federal-agencies/covid-vaccine-trials-document-birth-defects-lost-pregnancies-foia.)

89. U.S. Food and Drug Administration. Summary Basis for Regulatory Action - SPIKEVAX. 2022. (Accessed May 15, 2023, at https://www.fda.gov/media/155931/download.)

90. Cyranoski D. Why Emergency COVID Vaccine Approvals Could Pose a Dilemma. Nature 2020;588:18-9.

91. Pfizer. 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports (Report to the FDA). 2021. (Accessed May 15, 2023, at https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf.)

92. Fell DB, Dimanlig-Cruz S, Regan AK, et al. Risk of Preterm Birth, Small for Gestational Age at Birth, and Stillbirth after Covid-19 Vaccination During Pregnancy: Population Based Retrospective Cohort Study. BMJ 2022;378:e071416.

93. Fell DB, Dhinsa T, Alton GD, et al. Association of COVID-19 Vaccination in Pregnancy With Adverse Peripartum Outcomes. JAMA 2022;327:1478-87.

94. Sadarangani M, Soe P, Shulha HP, et al. Safety of COVID-19 Vaccines in Pregnancy: a Canadian National Vaccine Safety (CANVAS) Network Cohort Study. Lancet Infect Dis 2022;22:1553-64.

95. Ruderman RS, Mormol J, Trawick E, et al. Association of COVID-19 Vaccination During Early Pregnancy With Risk of Congenital Fetal Anomalies. JAMA Pediatr 2022;176:717-9.

96. Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. N Engl J Med 2021;384:2273-82.

References (cont.)

97. Kharbanda EO, Haapala J, DeSilva M, et al. Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy. JAMA 2021;326:1629-31.

98. Shafiee A, Kohandel Gargari O, Teymouri Athar MM, Fathi H, Ghaemi M, Mozhgani SH. COVID-19 Vaccination During Pregnancy: A Systematic Review and Meta-analysis. BMC Pregnancy Childbirth 2023;23:45.

99. Rahmati M, Yon DK, Lee SW, et al. Effects of COVID-19 Vaccination During Pregnancy on SARS-CoV-2 Infection and Maternal and Neonatal Outcomes: A Systematic Review and Meta-analysis. Rev Med Virol 2023;33:e2434.

100. Carbone L, Trinchillo MG, Di Girolamo R, et al. COVID-19 Vaccine and Pregnancy Outcomes: A Systematic Review and Meta-analysis. Int J Gynaecol Obstet 2022;159:651-61.

101. Devvanshi H, Kachhwaha R, Manhswita A, Bhatnagar S, Kshetrapal P. Immunological Changes in Pregnancy and Prospects of Therapeutic Pla-Xosomes in Adverse Pregnancy Outcomes. Front Pharmacol 2022;13:895254.

102. MacLean MA, Wilson R, Thomson JA, Krishnamurthy S, Walker JJ. Immunological Changes in Normal Pregnancy. Eur J Obstet Gynecol Reprod Biol 1992;43:167-72.

103. Abu-Raya B, Michalski C, Sadarangani M, Lavoie PM. Maternal Immunological Adaptation During Normal Pregnancy. Front Immunol 2020;11:575197.

104. Our World in Data. Coronavirus (COVID-19) Cases. 2023. (Accessed May 14, 2023, at https://ourworldindata.org/covid-cases.)

105. Canadian Covid Care Alliance. The Pfizer Inoculations For COVID-19 – More Harm Than Good – PDF. 2021. (Accessed April 6, 2023, at https://www.canadiancovidcarealliance.org/media-resources/the-pfizer-inoculations-for-covid-19-more-harm-than-good/.)

106. Thomas SJ, Moreira ED, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine Through 6 Months. N Engl J Med 2021;385:1761-73.

107. Bridle B, Martins I, Mallard B, et al. Concerns Regarding the Efficacy and Safety for BNT162b2 mRNA Coronavirus Disease (COVID-19) Vaccine through Six Months. www.CanadianCovidCareAlliance.org 2022:1-10.

108. Massetti GM. Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Healthcare Systems—United States, August 2022. MMWR Morbidity and Mortality Weekly Report 2022;71.

109. National Institute of Child Health and Human Development. Drugs and Lactation Database (LactMed®) [Internet]. Bethesda (MD): COVID-19 Vaccines [Updated 2023 Jan 19]. 2023. (Accessed April 6, 2023, at https://www.ncbi.nlm.nih.gov/sites/books/NBK565969/.)

110. Centers for Disease Control and Prevention. Interim Guidelines for COVID-19 Antibody Testing in Clinical and Public Health Settings. 2022. (Accessed November 2022, 2022, at https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html.)

111. U.S. Food and Drug Administration. Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety Communication. 2021. (Accessed November 28, 2022, at https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety.)

112. Zhu F, Zozaya C, Zhou Q, De Castro C, Shah PS. SARS-CoV-2 Genome and Antibodies in Breastmilk: A Systematic Review and Meta-analysis. Arch Dis Child Fetal Neonatal Ed 2021;106:514-21.

113. Pace RM, Williams JE, Järvinen KM, et al. Characterization of SARS-CoV-2 RNA, Antibodies, and Neutralizing Capacity in Milk Produced by Women with COVID-19. mBio 2021;12.

114. Rottenstreich A, Zarbiv G, Oiknine-Djian E, Zigron R, Wolf DG, Porat S. Efficient Maternofetal Transplacental Transfer of Anti-Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Spike Antibodies After Antenatal SARS-CoV-2 BNT162b2 Messenger RNA Vaccination. Clin Infect Dis 2021;73:1909-12.

115. Paul G, Chad R. Newborn Antibodies to SARS-CoV-2 Detected in Cord Blood After Maternal Vaccination - a Case Report. BMC Pediatr 2021;21:138.

116. Gray KJ, Bordt EA, Atyeo C, et al. Coronavirus Disease 2019 Vaccine Response in Pregnant and Lactating Women: a Cohort Study. Am J Obstet Gynecol 2021;225:303.e1-.e17.

117. Badell ML, Dude CM, Rasmussen SA, Jamieson DJ. Covid-19 Vaccination in Pregnancy. BMJ 2022;378:e069741.

118. Goldshtein I, Nevo D, Steinberg DM, et al. Association Between BNT162b2 Vaccination and Incidence of SARS-CoV-2 Infection in Pregnant Women. JAMA 2021;326:728-35.

119. Dagan N, Barda N, Biron-Shental T, et al. Effectiveness of the BNT162b2 mRNA COVID-19 vaccine in pregnancy. Nat Med 2021;27:1693-5.

References (cont.)

120. Morgan JA, Biggio JRJ, Martin JK, et al. Maternal Outcomes After Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection in Vaccinated Compared With Unvaccinated Pregnant Patients. Obstet Gynecol 2022;139:107-9.

121. Our World in Data. SARS-CoV-2 Sequences by Variant, Jan 30, 2023. 2023. (Accessed February 16, 2023, at https://ourworldindata.org/grapher/covid-variants-bar?country=USA~GBR~ESP~ZAF~ITA~DEU~FRA~CAN~BEL~AUS.)

122. Al Bayat S, Mundodan J, Hasnain S, et al. Can the Cycle Threshold (Ct) Value of RT-PCR Test for SARS CoV2 Predict Infectivity Among Close Contacts? Journal of Infection and Public Health 2021;14:1201-5.

123. Borger P, Malhotra RK, Yeadon M, et al. External Peer Review of the RTPCR Test to Detect SARS-CoV-2 Reveals 10 Major Scientific Flaws at the Molecular and Methodological Level: Consequences for False Positive Results. Eurosurveillance 2020.

124. Braunstein GD, Schwartz L, Hymel P, Fielding J. False Positive Results With SARS-CoV-2 RT-PCR Tests and How to Evaluate a RT-PCR-Positive Test for the Possibility of a False Positive Result. J Occup Environ Med 2021;63:e159-e62.

125. Infectious Disease Society of A, Association for Molecular P. IDSA and AMP Joint Statement on the Use of SARS-CoV-2 PCR Cycle Threshold (Ct) Values for Clinical Decision-making - Updated March 12, 2021. 2021.

126. Stang A. The Performance of the SARS-CoV-2 RT-PCR Test as a Tool for Detecting SARS-CoV-2 Infection in the Population. J Infect 2021;83:237-79.

127. Hirsch O, Bergholz W, Kisielinski K, Giboni P, Sönnichsen A. Methodological Problems of SARS-CoV-2 Rapid Point-of-care Tests When Used in Mass Testing. AIMS Public Health 2022;9:73-93.

128. Mina MJ, Peto TE, García-Fiñana M, Semple MG, Buchan IE. Clarifying the Evidence on SARS-CoV-2 Antigen Rapid Tests in Public Health Responses to COVID-19. The Lancet 2021;397:1425-7.

129. Chalkias S, Harper C, Vrbicky K, et al. A Bivalent Omicron-Containing Booster Vaccine against Covid-19. N Engl J Med 2022;387:1279-91.

130. Chalkias S, Eder F, Essink B, et al. Safety, Immunogenicity and Antibody Persistence of a Bivalent Beta-containing Booster Vaccine against COVID-19: A Phase 2/3 Trial. Nat Med 2022;28:2388-97.

131. Hoge S. mRNA-1273.214 Moderna COVID-19 Investigational Bivalent Vaccine (Original + Omicron) - Presentation to the Vaccines and Related Biological Products Advisory Committee, June 28, 2022. 2022. (Accessed May 31, 2023, at https://www.fda.gov/media/159492/download.)

132. Swanson KA. Pfizer/BioNTech COVID-19 Omicron-Modified Vaccine Options - Presentation to the Vaccines and Related Biological Products Advisory Committee, June 28, 2022. 2023. (Accessed May 31, 2023, at https://www.fda.gov/media/159496/download.)

133. Canadian Covid Care Alliance. Omicron Booster: Five Fatal Study Flaws (Video). 2022. (Accessed April 6, 2023, at https://www.canadiancovidcarealliance.org/media-resources/omicron-booster-five-fatal-study-flaws-video/.)

134. Pfizer. SARS-CoV-2 mRNA Vaccine (BNT162, PF-0 7302048): 2.6.5.5B. Pharmacokinetics: organ distribution, report number: 185350, Pages 6-7. (Accessed April 6, 2023, at https://ia802305.us.archive.org/28/items/pfizer-confidential-translated/pfizer-confidential-translated.pdf.)

135. European Medicines Agency - Committee for Medicinal Products for Human Use (CHMP). Assessment Report - COVID-19 Vaccine Moderna 2021. (Accessed April 6, 2023, at https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf.)

136. Rose J. Effect of LNPs on RBCs to Render them Dysfunctional - Is Obvious. 2022. (Accessed April 6, 2023, at https://jessicar.substack.com/p/effect-of-lnps-on-rbcs-to-render?r=16nb0w&utm_campaign=post&utm_medium=email.)

137. Ndeupen S, Qin Z, Jacobsen S, Bouteau A, Estanbouli H, Igyártó BZ. The mRNA-LNP Platform's Lipid Nanoparticle Component Used in Preclinical Vaccine Studies is Highly Inflammatory. iScience 2021;24:103479.

138. Sutton WJH, Branham PJ, Williamson YM, et al. Quantification of SARS-CoV-2 Spike Protein Expression from mRNA Vaccines Using Isotope Dilution Mass Spectrometry. Vaccine 2023.

139. Murata K, Nakao N, Ishiuchi N, et al. Four cases of Cytokine Storm After COVID-19 Vaccination: Case Report. Front Immunol 2022;13:967226.

140. Karrow NA, Shandilya UK, Pelech S, et al. Maternal COVID-19 Vaccination and Its Potential Impact on Fetal and Neonatal Development. Vaccines (Basel) 2021;9.

References (cont.)

141. Samsudin F, Raghuvamsi P, Petruk G, et al. SARS-CoV-2 Spike Protein as a Bacterial Lipopolysaccharide Delivery System in an Overzealous Inflammatory Cascade. J Mol Cell Biol 2023;14.

142. Baumeier C, Aleshcheva G, Harms D, et al. Intramyocardial Inflammation after COVID-19 Vaccination: An Endomyocardial Biopsy-Proven Case Series. Int J Mol Sci 2022;23.

143. Bansal S, Perincheri S, Fleming T, et al. Cutting Edge: Circulating Exosomes with COVID Spike Protein Are Induced by BNT162b2 (Pfizer-BioNTech) Vaccination prior to Development of Antibodies: A Novel Mechanism for Immune Activation by mRNA Vaccines. J Immunol 2021;207:2405-10.

144. Hanna N, Heffes-Doon A, Lin X, et al. Detection of Messenger RNA COVID-19 Vaccines in Human Breast Milk. JAMA Pediatr 2022;176:1268-70.

145. Kachikis A, Englund JA, Covelli I, et al. Analysis of Vaccine Reactions After COVID-19 Vaccine Booster Doses Among Pregnant and Lactating Individuals. JAMA Network Open 2022;5:e2230495-e.

146. Camacho-Morales A, Caba M, García-Juárez M, Caba-Flores MD, Viveros-Contreras R, Martínez-Valenzuela C. Breastfeeding Contributes to Physiological Immune Programming in the Newborn. Front Pediatr 2021;9:744104.

147. Cabinian A, Sinsimer D, Tang M, et al. Transfer of Maternal Immune Cells by Breastfeeding: Maternal Cytotoxic T Lymphocytes Present in Breast Milk Localize in the Peyer's Patches of the Nursed Infant. PLoS One 2016;11:e0156762.

148. Rose J. RNA Integrity in the Context of the COVID-19 Shots. 2022. (Accessed April 6, 2023, at https://open.substack.com/pub/jessicar/p/rna-integrity-in-the-context-of-the?r=16nb0w&utm_campaign=post&utm_medium=email.)

149. Tinari S. The EMA Covid-19 Data Leak, and What It Tells Us About mRNA Instability. BMJ 2021;372:n627.

150. Seneff S, Nigh G. Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19. International Journal of Vaccine Theory, Practice, and Research 2021;2:38-79.

151. McKernan K. Pfizer and Moderna Bivalent Vaccines Contain 20-35% Expression Vector and are Transformation Competent in E. Coli. 2023. (Accessed May 31, 2023, at https://anandamide.substack.com/p/pfizer-and-moderna-bivalent-vaccines.)

152. McKernan K, Helbert Y, Kane LT, McLaughlin S. Sequencing of Bivalent Moderna and Pfizer mRNA Vaccines Reveals Nanogram to Microgram Quantities of Expression Vector dsDNA per Dose. OSF Preprints 2023; April 10, doi:10.31219/osf.io/b9t7m.

153. Nunez-Castilla J, Stebliankin V, Baral P, et al. Potential Autoimmunity Resulting from Molecular Mimicry between SARS-CoV-2 Spike and Human Proteins. Viruses 2022;14.

154. Dotan A, Kanduc D, Muller S, Makatsariya A, Shoenfeld Y. Molecular Mimicry Between SARS-CoV-2 and the Female Reproductive System. Am J Reprod Immunol 2021;86:e13494.

155. Parikka H. Acknowledgement of Personal Responsibility or Blind Obedience: Reflections from Finland 2023. 2023. (Accessed June 20, 2023, at https://worldcouncilforhealth.substack.com/p/reflections-from-finland.)

156. Gat I, Kedem A, Dviri M, et al. Covid-19 Vaccination BNT162b2 Temporarily Impairs Semen Concentration and Total Motile Count Among Semen Donors. Andrology 2022;10:1016-22.

157. Domazet-Lošo T. mRNA Vaccines: Why Is the Biology of Retroposition Ignored? Genes (Basel) 2022;13.

158. Kyriakopoulos AM, McCullough PA, Nigh G, Seneff S. Potential Mechanisms for Human Genome Integration of Genetic Code from SARS-CoV-2 mRNA vaccination: Implications for Disease. J Neurol Disord 2022;10:519.

159. Aldén M, Olofsson Falla F, Yang D, et al. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. Curr Issues Mol Biol 2022;44:1115-26.

160. Zhang L, Richards A, Barrasa MI, Hughes SH, Young RA, Jaenisch R. Reverse-transcribed SARS-CoV-2 RNA Can Integrate Into the Genome of Cultured Human Cells and Can Be Expressed in Patient-Derived Tissues. Proceedings of the National Academy of Sciences 2021;118:e2105968118.

161. Qin Z, Bouteau A, Herbst C, Igyártó BZ. Pre-exposure to mRNA-LNP Inhibits Adaptive Immune Responses and Alters Innate Immune Fitness in an Inheritable Fashion. PLoS Pathog 2022;18:e1010830.

162. National Vaccine Information Center - MedAlerts.org. Search VAERS Database. 2023. (Accessed April 6, 2023, at https://medalerts.org/vaersdb/index.php.)

163. UK Government - Medicines and Healthcare products Regulatory Agency. Coronavirus (COVID-19) Vaccines Adverse Reactions. 2023. (Accessed April 6, 2023, at https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions.)

References (cont.)

164. European Medicines Agency. EudraVigilance. 2023. (Accessed April 6, 2023, at https://dap.ema.europa.eu/analytics/saw.dll?PortalPages.)

165. World Health Organization. VigiAccess - WHO Collaborating Center for International Drug Monitoring. 2023. (Accessed April 6, 2023, at http://vigiaccess.org/.)

166. Lazarus R. Electronic Support for Public Health-Vaccine Adverse Event Reporting System (esp: Vaers)-Final Report. (Prepared by Harvard Pilgrim Healthcare, Inc. Under Grant No. R18 Hs017045). 2011. (Accessed April 6, 2023, at https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.)

167. Health Advisory and Recovery Group. Safety Concerns re: Covid-19 Vaccinations In Pregnancy - Open Letter to RCOG, RCM & UKHSA. 2022. (Accessed April 6, 2023, at https://www.hartgroup.org/safety-concerns-re-covid-19-vaccinations-in-pregnancy/.)

168. Thorp JA, Rogers C, Deskevich MP, et al. COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function (preprint). 2022. (Accessed May 15, 2023, at https://www.preprints.org/manuscript/202209.0430/v1.)

169. BBC News. Investigation into Spikes in Newborn Baby Deaths in Scotland. 2022. (Accessed April 6, 2023, at https://www.bbc.co.uk/news/uk-scotland-63097142.)

170. BBC News. Fresh Probe into Spike in Newborn Baby eaths in Scotland. 2022. (Accessed April 6, 2023, at https://www.bbc.com/news/uk-scotland-61448963.)

171. Guetzkow J. Data on Neonatal Deaths from Major Israeli Health Insurer Shows Huge Spikes. 2022. (Accessed April 5, 2023, at https://jackanapes.substack.com/p/data-on-neonatal-deaths-from-major?utm_source=post-email-title&publication_id=747747&post_id=92306949&isFreemail=true&utm_medium=email.)

172. Public Health Scotland. COVID-19 Wider Impacts on the Healthcare System. 2022. (Accessed April 6, 2023, at https://scotland.shinyapps.io/phs-covid-wider-impact/.)

173. Abdallah W, Rechdan JB, Lakkis R, et al. Fetal Supraventricular Tachycardia and Maternal COVID-19 Vaccination: Is there any Relationship? Future Sci OA 2022;8:Fso812.

174. Mattos S, Chaves M, Freitas C, et al. Fetal Pericardial Effusion After Maternal COVID-19 Vaccination: a Fortuitous Association? Prenatal Cardiology 2022.

175. Evans O. WHO Warns of 'Unusual' Surge in Severe Myocarditis in Babies in England and Wales. 2023. (Accessed May 31, 2023, at https://www.theepochtimes.com/who-warns-of-unusual-surge-in-severe-myocarditis-in-babies_5271536.html.)

176. Hoyert DL. Maternal Mortality Rates in the United States, 2020. 2022. (Accessed May 15, 2023, at https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm.)

177. Parotto T, Thorp J, Hooker B, et al. COVID-19 and the Surge in Decidual Cast Shedding. G Med Sci 2022;3:107- 17.

178. Rose J. Update on Fertility Data & VAERS. 2022. (Accessed April 6, 2023, at https://worldcouncilforhealth.org/multimedia/dr-jessica-rose-fertility-vaers/.)

179. Said KB, Al-Otaibi A, Aljaloud L, et al. The Frequency and Patterns of Post-COVID-19 Vaccination Syndrome Reveal Initially Mild and Potentially Immunocytopenic Signs in Primarily Young Saudi Women. Vaccines (Basel) 2022;10.

180. Fertility Institute of Hawaii. Recurrent Miscarriages and Fertility Treatment Options. 2023. (Accessed April 6, 2023, at https://www.ivfcenterhawaii.com/fertility-diagnoses/recurrent-miscarriages/.)

181. Hagemann R. Decline of Live Births in Europe. 2022. (Accessed April 6, 2023, at https://www.initiative-corona.info/fileadmin/dokumente/Geburtenrueckgang-Europe-EN.pdf.)

182. Kanton Bern Conseil-exécutif. Intervention Parlementaire: Baisse du Nombre de Naissances d'une Ampleur Jamais Vue en 150 ans - Est-ce dû à la Vaccination Contre le COVID-19? - Réponse du Conseil-exécutif 2022.RRGR.299 2022. (Accessed June 29, 2023, at https://www.rrgr-service.apps.be.ch/api/rr/documents/document/50b42d40a9cc43eb9f23998b50e218e4-332/15/RRB-02.11.2022-fr.pdf.)

183. Hagemann R. Geburtenrückgang in den Schweizer Kantonen - 13.08.2022. 2022. (Accessed June 29, 2023, at https://www.aletheia-scimed.ch/wp-content/uploads/2022/08/Geburtenrueckgang-in-den-Schweizer-Kantonen_13082022.pdf.)

184. Bujard M, Andersson G. Fertility Declines Near the End of the COVID-19 Pandemic: Evidence of the 2022 Birth Declines in Germany and Sweden. 2022. (Accessed July 7, 2023, at https://www.bib.bund.de/Publikation/2022/Fertility-declines-near-the-end-of-the-COVID-19-pandemic-Evidence-of-the-2022-birth-declines-in-Germany-and-Sweden.html?nn=1219558.)

References (cont.)

185. U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Bivalent Pfizer-BioNTech COVID-19 Vaccine as Booster Dose for Certain Children 6 Months through 4 Years of Age. 2023. (Accessed April 5, 2023, at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-bivalent-pfizer-biontech-covid-19-vaccine-booster-dose.)

186. Prasad S, Kalafat E, Blakeway H, et al. Systematic Review and Meta-analysis of the Effectiveness and Perinatal Outcomes of COVID-19 Vaccination in Pregnancy. Nat Commun 2022;13:2414.

187. Frenton N. Statistical Illusion of Better Pregnancy Outcomes for Vaccinated Women. 2022. (Accessed April 6, 2023, at https://www.normanfenton.com/post/the-statistical-illusion-of-better-pregnancy-outcomes-for-vaccinated-women.)

188. Lübbeke A, Carr AJ, Hoffmeyer P. Registry Stakeholders. EFORT Open Rev 2019;4:330-6.

189. Health Canada. Draft Guidance on Advanced Therapeutic Products Framework: Developing Tailored Requirements, Schedule G. 2023. (Accessed May 14, 2023, at https://www.canada.ca/en/health-canada/programs/consultation-draft-guidance-advanced-therapeutic-products-framework/developing-tailored-requirements-schedule-g.html.)

190. Thorp M, Thorp J. FOIA Reveals Troubling Relationship between HHS/CDC & the American College of Obstetricians and Gynecologists. 2023. (Accessed May 14, 2023, at https://www.americaoutloud.com/foia-reveals-troubling-relationship-between-hhs-cdc-the-american-college-of-obstetricians-and-gynecologists/?utm_source=copy&utm_medium=website&utm_campaign=SocialSnap.)

191. Health Canada. Regulatory Innovation for Health Products: Overview. 2023. at https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/strategies-initiatives/health-products-food-regulatory-modernization.html.)

192. Brill-Edwards M. OGGO Meeting No. 64 - Standing Committee on Government Operations and Estimates. 2023. (Accessed May 14, 2023, at https://parlvu.parl.gc.ca/Harmony/en/PowerBrowser/PowerBrowserV2/20230428/-1/39119.)

193. Palmer G. The Politics of Breastfeeding: When Breasts Are Bad for Business: Pinter & Martin Publishers; 2009.

194. Douglas RG, Samant VB. The Vaccine Industry. Plotkin's Vaccines 2018:41-50 e1.

195. Gilmore R. Coronavirus Vaccine Makers Are Shielded from Liability. Here's Why Officials Say That's Normal. 2020. (Accessed May 14, 2023, at https://globalnews.ca/news/7521148/coronavirus-vaccine-safety-liability-government-anand-pfizer/.)

196. Weber MA, Backer TE, Brubach A. Creating the HHS COVID-19 Public Education Media Campaign: Applying Systems Change Learnings. J Health Commun 2022;27:201-7.

197. U.S. Department of Health and Human Services. COVID-19 Public Education Campaign. 2023. (Accessed May 14, 2023, at https://wecandothis.hhs.gov/about.)

198. Eren Vural I, Herder M, Graham JE. From Sandbox to Pandemic: Agile Reform of Canadian Drug Regulation. Health Policy 2021;125:1115-20.

199. Health Canada. Report from Canada's Economic Strategy Tables: Health and Biosciences. 2018. (Accessed May 15, 2023, at https://ised-isde.canada.ca/site/economic-strategy-tables/en/report-2018/report-canadas-economic-strategy-tables-health-and-biosciences.)

200. Greene J. 'Paramount Importance': Judge Orders FDA to Hasten Release of Pfizer Vaccine Docs. 2022. (Accessed May 14, 2023, at https://www.reuters.com/legal/government/paramount-importance-judge-orders-fda-hasten-release-pfizer-vaccine-docs-2022-01-07/.)

201. Informed Consent Action Network. V-Safe Data. 2023. (Accessed May 14, 2023, at https://icandecide.org/v-safe-data/.)