

Dear recipients

Ministry of Social Affairs and Health: ministers and registry
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This letter is ONLY FOR INFORMATION to the following actors, who will also be informed of the STM answers to the questions raised:

The Finnish Population Federation

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REQUEST FOR INFORMATION ON THE IMPACT OF COVID-19 VACCINATION ON THE FERTILITY, PREGNANCY AND THE HEALTH OF THE UNBORN CHILD

Covid-19 vaccination is offered as a safe and effective option for pregnant women and women planning to become pregnant, those of childbearing age and children. Any offer or recommendation for vaccination should always be based on scientific justification. In this information request, Save the Children in Finland is an independent medical association and asks questions about pregnancy, fertility, fetal and child health and monitoring. THL has informed pregnant women, women planning to become pregnant and breastfeeding women on its website about the use of the Covid-19 vaccine. The THL claims that pregnant women are among the most seriously ill risk group for severe coronavirus disease.

We ask on what research data are the following guidelines and claims made by the THL based?

1. You can have the Covid-19 vaccine at any stage of pregnancy.
2. The Covid-19 vaccine protects pregnant women from coronavirus infection and severe disease.
3. The vaccinated mother is less likely to transmit coronavirus to her newborn after delivery than an unvaccinated woman.
4. Studies already published on the widespread use of the vaccine in pregnant women in different countries do not indicate any particular safety concerns for the pregnant woman or the developing fetus.
5. The vaccine does not excrete in breast milk. Corrected later: Some breastfeeding mothers may excrete very small amounts of mRNA in milk within two days after vaccination. mRNA is digested by enzymes in the baby's digestive tract and is not transferred to muscle cells, such as when the vaccine is injected.
6. RNA is destroyed in the human body within about two days.
7. The structures of RNA and DNA are very different. Therefore, the mRNA in the Covid-19 vaccine cannot integrate to the DNA of the cells of the vaccinee. mRNA vaccine cannot therefore modify the human genome. In addition, the mRNA in the vaccine degrades rapidly in the body.

8. We would also like to know how, in concrete terms, is the monitoring of adverse effects carried out?

For each of the Covid-19 vaccine safety monitoring methods mentioned by THL, what is the written guidelines for each of the groups involved in the monitoring of the vaccine?

The THL website provides the following information:

The authorities also closely monitor the safety of Covid-19 vaccines for both children and adults after the introduction of the vaccines. Monitoring is carried out both in Finland and internationally (THL). Safety monitoring and adverse reaction assessment are carried out at national and international level cooperation.

Participants in the work

- the authorities
- marketing authorisation holders of the vaccine
- national and international expert organisations

The following are also involved in the detection and reporting of adverse reactions

- doctors
- vaccinators
- pharmacy staff, i.e. pharmacists
- vaccinated people

We ask THL to answer the following questions on pharmacodynamics, and we would like each question to be answered with a reference (Questions 9-13)

9. What is known about the biodistribution of Covid-19 vaccines?
10. To which organs does the vaccine concentrate?
11. What is the safety data on lipid nanoparticles (LNP) for pregnant women?
12. Does LNP, spike protein encoding mRNA or spike protein pass through the placenta?
13. Where does LNP, mRNA or spike protein enter the fetus?

We also ask THL to answer the following questions on fertility (Questions 14-16)

14. What is the cause of the reported menstrual irregularities in vaccinated women?
15. How do you monitor the impact of the vaccine on fertility in the following target groups:
 - a) women and men of fertile age
 - b) vaccinated children
 - (c) children born during pregnancy to vaccinated women
16. how do you monitor the dose-dependent effect on fertility?

To questions on genetic effects (Questions 17-18)

17. Can mRNA be integrated into the oocyte or sperm genome or genetic material be transferred by any other mechanism to offspring? If you think that this event is not even theoretically possible, please provide a scientific justification for this using the latest molecular biological data.
18. What is known about the epigenetic effects of the Covid-19 vaccine on germ cells?

To questions on prenatal monitoring (Questions 19-20)

19. Exactly how are adverse effects of vaccination monitored in the fetus?
20. In practice, how do you monitor for miscarriages, uterine deaths, possible illnesses or malformations and the vaccine?

To the questions on monitoring the health of live-born children (Questions 21-22)

21. How and for how long is the effect of prenatal vaccination on the health of the newborn child monitored?
22. What written instructions are given to patients, doctors (neonatal doctors, paediatricians, fertility doctors, obstetricians), other medical staff (including midwives) and vaccinators?

We also want to know what kind of guidance you give to those providing fertility treatment (the tissue establishments) (Questions 23-27)

23. What guidance has FIMEA given to the tissue establishments it supervises to monitor the

potential adverse effects of mRNA vaccine?

24. We are asking to see your guidance for fertility treatment providers (the tissue establishments) providing conception services, how they should monitor the adverse effects.

25. What are the instructions for traceability between the mRNA vaccine and the gametes/embryos/born child?

26. What is the documentation for follow-up and traceability of the mRNA vaccine?

27. How does the THL monitor compliance with the conditions of the Fertility Treatment Act for the mRNA vaccine?

In the case of mRNA in the following sections of the Act:

a) 4§ of the Fertility Treatment Act

General restrictions on the use of reproductive embryos

The use of embryos in fertility treatment is prohibited:

1) gametes and embryos whose genetic heritage has been compromised

b) 8§ of the Fertility Treatment Act

Obstacles to the administration of fertility treatment

Fertility treatment may not be administered if:

5) it is obvious that a balanced development of the child cannot be ensured.

28. Finally, we want to know how informed consent is implemented in the context of Covid-19 vaccinations?

To summarise, there are 28 separate questions in this request for information. We require clear answers to each question in the written guidelines and in the source materials.

We also require precise scientific justification with sources for the claims on your website, for each claim separately; questions 1-7

In the absence of the requested reference, guidance or other requested explanation, please provide a reply to the absence of such information.

Our request is based on the Health Care Act and the Infectious Diseases Act of the Ministry of Social Affairs and Health and the THL, Fimea and the newly established administrative bodies under the THL and Fimea and, in particular, on the advisory obligations imposed on the organisations of the Welfare Regions and, in particular, on the the request for information on which they are based. The above-mentioned authorities are subject to a health care quality of healthcare and patient safety and to provide information when this is required and advice is requested, in particular by health professionals who wish to ensure patient safety.

This document and the responses received will be published on <https://pelastetaansuomenlapset.fi/>

Respectfully

Espoo 31.1.2023

Save the Children of Finland

Independent team of doctors and researchers

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