Report of the working group for improving vaccination activities

REPORTS AND MEMORANDUMS OF THE MINISTRY OF SOCIAL AFFAIRS AND HEALT 2019:53

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Report of the working group for improving vaccination activities

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Tiivistelmä

Rokotusohjelmalla on olennaisesti vähennetty monien tartuntatautien aiheuttamaa kuolleisuutta ja tautitaakkaa. Kansainvälisesti arvioituna Suomen rokotuskattavuus on edelleen hyvä. Erityisenä haasteena on kuitenkin kattavuuden alueellinen sekä rokotekohtainen vaihtelu, joka vähentää rokotuksista saatavaa hyötyä, ja voi altistaa väestön epidemioille.

Rokotteilla estettävien tautien hävitessä osalla väestöstä ei ole enää käsitystä tautien vakavuudesta ja rokotteiden tuomasta hyödystä. Internet ja sosiaalinen media mahdollistavat rokotusten hyötyä kyseenalaistavan ja mahdollisia haittoja liioittelevan tiedon levittämisen. Rokotusluottamuksen heikkenemisen lisäksi myös terveyspalvelujärjestelmän haasteet voivat johtaa siihen, että osa väestöstä jää vaille riittävää rokotussuojaa.

Asiantuntijaryhmän tehtävänä oli selvittää miten rokotusohjelman kattavuutta voidaan parantaa. Kehittämisvaihtoehtoja tarkasteltiin lainsäädännön ja käytännön rokotustoiminnan näkökulmista. Ryhmä arvioi perusoikeuksiin liittyen myös eräitä lasten ja perheiden sosiaaliturvaetuuksia, varhaiskasvatus- ja koulutuspalveluja sekä mahdollisuutta muuttaa rokotustoiminnan vapaaehtoisuutta koskevaa lainsäädäntöä.

Työryhmä esittää useita toimenpiteitä, joilla voitaisiin edelleen parantaa rokotuskattavuutta. Ehdotukset kohdistuvat palvelujärjestelmän kehittämiseen, tiedon lisäämiseen koulutuksen avulla, rokotteita ja rokottamista koskevan viestinnän parantamiseen, rokotustoiminnan toteutumista koskevan tutkimuksen vahvistamiseen sekä lainsäädännön kehittämiseen.

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Referat

Vaccinationsprogrammet har i väsentlig grad bidragit till att minska den dödlighet och sjukdomsbörda som orsakas av många smittsamma sjukdomar. I internationell jämförelse är vaccinationstäckningen i Finland alltjämt god. En särskild utmaning är dock det faktum att täckningen varierar mellan olika regioner och vacciner. Detta minskar nyttan av vaccinationerna och kan leda till att befolkningen utsätts för epidemier.

I och med att sjukdomar som kan förhindras genom vaccination försvinner förlorar en del av befolkningen uppfattningen om hur allvarliga dessa sjukdomar är och vilken nytta vaccinerna ger. Via internet och sociala medier kan man enkelt sprida information som ifrågasätter nyttan av vaccinationer och överdriver deras möjliga skadliga effekter. Utöver ett försvagat förtroende för vaccinationer kan också utmaningar i hälsovårdssystemet leda till att en del av befolkningen inte får ett tillräckligt vaccinationsskydd.

Sakkunniggruppen hade till uppgift att utreda hur man kunde förbättra vaccinationsprogrammets täckningsgrad. Olika utvecklingsförslag granskades utgående från lagstiftningen och den praktiska vaccinationsverksamheten. Gruppen bedömde med tanke på de grundläggande rättigheterna också vissa sociala förmåner för barn och familjer, tjänster för småbarnsfostran och utbildningstjänster samt möjligheten att ändra lagstiftningen om vaccinationsverksamhetens frivilliga karaktär.

Arbetsgruppen föreslår flera olika åtgärder genom vilka vaccinationstäckningen kan förbättras ytterligare. Förslagen går ut på att utveckla servicesystemet, öka kunskapen genom utbildning, förbättra kommunikationen om vacciner och vaccinationer, stärka forskningen om genomförandet av vaccinationsverksamheten och utveckla lagstiftningen.

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Abstract

The Finnish national vaccination programme has significantly reduced the mortality rate and disease burden caused by many infectious diseases. From an international perspective, vaccination coverage is good in Finland. However, the coverage varies between regions and vaccines, which diminishes the benefits of vaccination and may expose the population to epidemics.

Disappearance of some infectious diseases as result of vaccination has led to situation where part of the population lacks understanding of the severity of vaccine-preventable diseases and the benefits of vaccination. The internet and social media enable spreading information that questions the benefits of vaccination and exaggerates the risks of vaccines. In addition to weakened trust in vaccination, also current challenges in the healthcare services may lead to inadequate vaccination coverage of part of the population.

The expert working group was appointed to examine, from legislative and practical perspectives, how to improve coverage of the vaccination programme. The group also considered matters related to fundamental rights: social benefits for families and children, early childhood education and other educational services, as well as possibilities to amend legislation on voluntary vaccination.

The working group proposes several actions to improve the vaccination coverage in Finland. The proposals focus on developing the service system, increasing knowledge through education, improving communication on vaccination, strengthening research on promotion of vaccination activities, and developing the relevant legislation.

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TO THE MINISTRY OF SOCIAL AFFAIRS AND HEALTH

On 16 January 2019, the Ministry of Social Affairs and Health established a working group to investigate the development of vaccination activities.

Based on international assessment, Finland has good vaccination coverage. Around one per cent of the age group of children born will end up completely unvaccinated, and there has not been a significant growth in the share of unvaccinated children. In spite of the overall good vaccination coverage, the protection provided by vaccines to the population is challenged by variation in the coverage between regions and specific vaccines. A lack of appropriate vaccinations undermines the benefits brought by the national vaccination programme to national health and may expose the population to epidemics.

The statutory national vaccination programme was the starting point for the efforts of the working group. The vaccination programme has significantly reduced the mortality and disease burden caused to Finns by many communicable diseases and has even managed to fully eradicate certain diseases. The aim of the vaccination programme is to provide as comprehensive vaccination coverage to the population as possible. When enough people are vaccinated, the risk for contracting and further spreading diseases is reduced. This also allows protecting the few people who cannot be vaccinated due to reasons such as age or a chronic illness. The vaccinated person's protection is also improved as a result of this phenomenon known as herd immunity. The national vaccination programme also provides efficient protection against transboundary disease and epidemic threats.

The national vaccination programme is based on thorough research evidence on the health impacts and cost effectiveness of vaccinations. The programme is estimated to save the costs incurred to society by at least EUR 100 million every year. This makes the vaccination programme one of the most effective methods of preventive health care.

Extensive national unanimity on the significance and usefulness of the vaccination programme has helped maintaining a high vaccination coverage among the population. The vaccination programme has resulted in practically eradicating many of the diseases prevented with vaccines in Finland. Paradoxically, this has led to the parents of families with children potentially no longer understanding the severity of the diseases and the health benefits brought by the vaccinations. The internet and social media have facilitated the spread of information questioning the benefits of vaccinations and exaggerating their potential risks. The extensive measles epidemics and related deaths detected in a number of European countries are an alarming example of how a decline in the trust in vaccinations has contributed to the return of communicable diseases.

In addition to the drop in the population's trust in vaccinations, many challenges in the health service system may also lead to providing part of Finland's population with insufficient vaccination coverage. In the future, the increase in the number of unvaccinated people and regional variation in vaccination coverage may also lead to the spread of communicable diseases and significant threat of an epidemic in Finland. In recent years, the measles infections contracted abroad have caused many extensive exposure situations around Finland. Effective measures for combating the infections have succeeded in limiting the number of further infections.

In accordance with the assignment given to the extensive group of experts, the group has examined how the coverage of the vaccinations free of charge included in the national vaccination programme could be maintained and further improved in Finland (appendix 1). The group has explored development alternatives from both legal and practical – particularly family-oriented – perspectives, assessing measures such as utilising the maternity package and developing maternity and child health clinic activities to strengthen positive attitudes towards vaccinations. Similarly, the group has assessed certain social welfare benefits, education and early childhood education and care services as well as the opportunities for changing the legislation concerning the voluntariness of vaccination activities from the viewpoint of fundamental rights. In its efforts, the working group has taken into account the latest available knowledge of the factors affecting vaccination coverage.

The working group proposes a number of measures that could further improve vaccination coverage and the protection provided to the population by vaccines. The proposed measures are focused on developing the service system, increasing awareness through training, improving the communications on vaccines and vaccination, strengthening the research in vaccination activities, and developing the legislation related to the vaccination activities.

The working group was chaired by Director Kari Ilmonen of the Ministry of Social Affairs and Health. Head of Unit Taneli Puumalainen of the National Institute for Health and Welfare was the vice chair. The members included Senior Officer for Legal Affairs Annika Juurikko, Ministerial Adviser Arja Ruponen, Chief Physician Ritva Halila, Senior Officer for Legal Affairs Susanna Rahkonen, Ministerial Counsellor, Health/Medical Affairs Anni Virolainen-Julkunen and Senior Government Adviser Liisa Katajamäki of the Ministry of Social Affairs and Health; Senior Adviser for Legislative Affairs Eerikki Nurmi of the Ministry of Education and Culture; and Senior Researcher Jonas Sivelä and Research Manager Tuovi Hakulinen of the National Institute for Health and Welfare. Other members of the working group included Senior Medical Advisor Jan Löfstedt of the Social Insurance Institution of Finland, Bishop Emeritus Wille Riekkinen, Medical Director Pia-Maria Sjöström of the Jakobstad Department of Social Services and Health Care, Paediatric Infectious Diseases Specialist Tea Nieminen of the Hospital District of Helsinki and Uusimaa, Professor of Law Suvianna Hakalehto of the University of Eastern Finland, Professor of Medical Ethics Veikko Launis of the University of Turku, Work Environment Specialist Anna Kukka of the Tehy Union of Health and Social Care Professionals in Finland, Development Manager Aija Saarinen of the Finnish Association of Public Health Nurses, and Leading Expert Esa Iivonen of the Mannerheim League for Child Welfare. The secretary of the working group was Senior Specialist Mia Kontio of the National Institute for Health and Welfare, and Professor of Constitutional Law Tuomas Ojanen of the University of Helsinki served as the group's permanent specialist.

The working group worked from 19 January to 31 March 2019 and convened six times in total. After completing its work, the working group submitted its report to the Minister of Social Affairs and Health on 15 May 2019.

In Helsinki, 15 May 2019

Kari Ilmonen	Taneli Puumalainen
Annika Juurikko	Arja Ruponen
Ritva Halila	Susanna Rahkonen
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1 The national vaccination programme and vaccination coverage in Finland

The vaccination programme has significantly reduced the mortality and disease burden caused to Finns by communicable diseases. The programme has succeeded in fully eradicating some contagious diseases. The aim of the vaccination programme is to provide as comprehensive vaccination coverage to the population as possible. The high vaccination coverage and the herd immunity it provides reduces the risk of the spread of communicable diseases, which protects not only the vaccinated person, but also those who cannot be vaccinated for reasons such as age or serious chronic illnesses. The national vaccination programme also provides the population with protection against transboundary epidemics.

The national vaccination programme in Finland

The national vaccination programme is based on the Communicable Diseases Act (1227/2016). The central government procures the vaccines included in the vaccination programme, and municipalities are responsible for the implementation of vaccinations. The National Institute for Health and Welfare steers and supports the implementation of the vaccination programme, and monitors the effects of vaccinations. The statutory duties of various agents are described in appendix 2. The Decree of the Ministry of Social Affairs and Health on Vaccinations (149/2017) describes the vaccinations included in the vaccination programme and their target groups in further detail (appendix 3). The vaccines included in the national vaccination programme are free of charge and getting the vaccinations is voluntary. According to the Communicable Diseases Act, provisions on organising compulsory vaccination can nonetheless be issued by Government decree, if comprehensive vaccination is necessary to prevent the spread of a generally hazardous communicable disease capable of causing substantial harm to the life and health of the population or a part thereof. A compulsory vaccination may also be focused on a certain part of the population, a group or age class.

The national vaccination programme is based on thorough research evidence on the impacts of vaccinations at the level of individuals and the population, and an estimate

of the cost effectiveness of vaccines. For instance, the MMR vaccine against measles, mumps, and rubella is estimated to annually prevent on average 53,000 cases of measles, 37,000 cases of mumps, and 27,000 cases of rubella[1,2]. Without the vaccinations, these diseases would cause several fatalities each year, leading to over 450 years of potential life lost, and at least 14,000 doctor's appointments in primary health care alone. The MMR vaccines also prevent thousands of serious complications, including encephalitis, meningitis, myocardial, hearing and sight impairments, miscarriages and infertility. The annual savings resulting from the MMR vaccination are estimated to total at EUR 40 million, while the national vaccination programme is evaluated to save over EUR 100 million in health care costs.

Vaccination coverage

Vaccination coverage provides information of the share of the population or a certain age or risk group that has been vaccinated. The National Institute for Health and Welfare follows the vaccination coverage and the effects of vaccinations using a national vaccination register[3]. The register is based on vaccination data recorded in different patient records systems, which are transferred in real time to the vaccine register maintained by the National Institute for Health and Welfare through Avohilmo, a treatment notification system of primary health care. The register data cover vaccinations given in primary health care since 2009. While data on children's vaccinations has good coverage, the omission of data on vaccinations given in the private sector and particularly in private occupational health care from the vaccination register significantly hampers assessing the implementation of adults' vaccinations. Data on vaccinations given in specialised medical care will also be included in the national vaccination register in 2019. The aim is to expand the data collection to also apply to vaccinations given in the private sector and occupational health care. Once the use of the

[1] Salo, Heini; Kilpi, Terhi. National vaccination program – a success story of public health and economy. Duodecim 2017; 133: 977–83
[2] Tuuli Karppinen: Terveyshyötyjen diskonttaaminen terveydenhuollon taloudellisissa arvioinneissa ja MPR-rokotusohjelman kustannusvaikuttavuus vuosina 1995–2015. Master's thesis [in Finnish]
[3] The National Institute for Health and Welfare's Vaccination coverage web page – up-to-date vaccination coverage status per vaccine and region

My Kanta system (https://www.kanta.fi/en/citizens) is expanded to registration purposes, members of the general public will have an opportunity for checking their vaccine data using the My Kanta service.

Overall, vaccination coverage is good among Finnish children[4]. Only around one per cent of children have not received any of the vaccinations included in the national vaccination programme by the age of three. Only 0.5 per cent of children that have reached school age have not been given the basic vaccinations. There has been no significant change in the share of unvaccinated children in recent years. According to register data, on average, the 5-in-1 vaccine series is started for 99 per cent of children born in 2016. The vaccine series protects children against diphtheria, tetanus, pertussis, polio and diseases caused by the haemophilus bacterium. The rotavirus vaccine series was started for 92 per cent and the pneumococcal conjugate vaccine series for 96 per cent of children. Approximately 96 per cent of children were given the MMR, or measles, mumps and rubella, vaccination. The vaccination coverage for the HPV vaccine against the human papillomavirus among girls is around 70 per cent. Depending on the vaccine, the share of children receiving the full series of vaccinations is a few per cent lower than the share of those starting the series. This is significant from the perspective of the protection provided by vaccinations to the population, as an interrupted series of vaccinations does usually not provide long-term protection.

There is clear regional variation in the vaccination coverage. In around one third of municipalities, the coverage of the MMR vaccine is below 95 per cent, at the lowest at 65–80 per cent. Individual municipalities whose vaccination coverage is clearly below the national average are scattered around Finland. The prevention of measles epidemics typically requires 95–97 per cent vaccination coverage. To prevent a local epidemic, those in close contact with the person affected by the disease must also be vaccinated. Effective measures to combat the disease, launched at an early stage, including the treatment of the affected person in isolation, and tracking down and quarantining those exposed to the illness prevent the extensive spread of the disease. The better the vaccination coverage, the less there is need to take these measures, which saves societal expenditure.

[4] The National Institute for Health and Welfare (2019). Children's vaccination coverage has improved – protection against measles has increased the most (in Finnish).

2 Vaccine confidence and hesitancy in Finland

Based on current knowledge, Finland's vaccination coverage and vaccine confidence are at a very good level despite the fact that vaccine hesitancy is often discussed in the media and the public arena. Only a tiny portion (around one per cent) of Finns will categorically refrain from all vaccines[5]. Persons may end up not getting vaccinated due to medical reasons, based on their beliefs of the risks and reliability of vaccines, or poor accessibility or ease of use of vaccination services. These observations are based on the data included in the national vaccination register as well as information collected of the cooperation between the National Institute for Health and Welfare and the municipalities, for instance.

Making a decision on vaccinations is a multifaceted issue, and practical reasons may contribute very significantly to a person's choice to stay unvaccinated. Such reasons may include a long distance to a child health clinic or health centre, impractical opening hours, forgetting an appointment, poorly available information about municipal vaccination services, and problems with booking an appointment[6]. People's confidence in vaccination may be diminished by factors related to society, culture and individuals, such as differences in people's understanding of risks, i.e. how individuals perceive the risks related to diseases, therefore negatively affecting their vaccination decision. Polarity and inequality in society may strengthen such beliefs. People's decisions are also influenced by the polarisation caused by online search engines and social media algorithms, resulting in filter bubbles and isolation of individuals or population groups. Finland also has certain active agents whose actions on social media and public events may have enhanced hesitation related to vaccines[7]. Vaccine hesitancy and anti-vaccine attitudes are usually based on a concern of the safety of vaccines or not knowing the extent of the risks related to diseases[8].

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[5] The National Institute for Health and Welfare (2019). Children's vaccination coverage has improved – protection against measles has increased the most (in Finnish).
[6] MacDonald NE, The SAGE Working Group on Vaccine Hesitancy (2015). Vaccine hesitancy: definition, scope and determinants. Vaccine, 33:4161–4.
[7] Sivelä, J. et al. (2018). Käsitykset rokotuksista ja rokotuskattavuuteen vaikuttavat tekijät. Suomen lääkärilehti 10 (73): 648–652.
[8] Eve Dubé et al. (2013) Vaccine hesitancy, Human Vaccines & Immunotherapeutics, 9(8): 1763–1773, DOI: 10.4161/hv.24657

In the autumn of 2018, a report examining vaccine confidence in EU member states was published. According to the report, attitudes towards vaccines and vaccination are generally positive in Europe. The report places Finland among the countries viewing vaccines and vaccination with most confidence and positivity[9].

Thanks to the countries' high vaccination coverage, few studies on vaccine confidence and hesitancy are available in Finland and other Nordic countries. Even through vaccination coverage and vaccine confidence are currently at a good level in Finland, there are risks related to the increasing anti-vaccination attitudes at the international level. As a result, it is appropriate to strengthen the current operating methods by also putting more efforts into increasing research-based and evidence-based measures in Finland.

Vaccination coverage has been successfully strengthened in Finland and around the world by improving the availability of vaccination services, developing approaches for health care professionals to encounter vaccine hesitancy, and increasing information provision about vaccines and the diseases prevented with these to both the general public as well as health care professionals. At the international level, so called "nudging" efforts, used to motivate people to make health-promoting choices, have also led to positive experiences. Nudging can include pre-booked vaccination or child health clinic appointments, and free influenza vaccines provided at workplaces without needing to book an appointment[10].

[9] Larson, H. et al. (2018) The State of Vaccine Confidence in the EU: 2018.
[10] Benartzi S, et al. (2017). Should governments invest more in nudging? Psychological Science, 28: 1041–1055.

3 International views and experiences of vaccination coverage and confidence

Particularly Western countries perceive anti-vaccine views and vaccine hesitancy as a growing health threat. Indeed, the World Health Organisation (WHO) listed *vaccine hesitancy* as one of its ten major threats to global health in 2019[11]. The term *vaccine hesitancy* refers to different reasons affecting people's choice to stay unvaccinated, including hesitation and refusal to take vaccinations, but also more extensively to reasons related to the availability of vaccination services and people's beliefs concerning risks[12].

In 2012, the World Health Organisation (WHO) set the target of having all people in the world covered by vaccination services by the year 2020 regardless of where they were born, who they are and where they live. In recent years, different EU institutions have made numerous decisions and set multiple targets for safeguarding good vaccination coverage in Europe [13, 14, 15]. Based on these goals, recommendations and decision, the Council of the European Union adopted a recommendation by the Council of the European Union on the development of vaccination activities, strengthened cooperation against vaccine-preventable diseases and improving vaccine confidence in the EU in December 2018[16].

The EU Joint Action on Vaccination (EU-JAV), a three-year project launched in August 2018, develops and determines the conditions for implementing the goals set in the recommendation by the Council of the European Union[17]. To strengthen vaccination

[11] WHO (2019). Ten threats to global health in 2019.
[12] MacDonald NE, The SAGE Working Group on Vaccine Hesitancy (2015). Vaccine hesitancy: definition, scope and determinants. Vaccine, 33:4161–4.
[13] Council conclusions on childhood immunisation: successes and challenges of European childhood immunisation and the way forward
[14] Council conclusions on childhood immunisation: successes and challenges of European childhood immunisation and the way forward
[15] Shortage of acellular pertussis-containing vaccines and impact on immunisation programmes in the EU/EEA (first update)
[16] COUNCIL RECOMMENDATION on strengthened cooperation against vaccine-preventable diseases
[17] European joint action on vaccination

coverage, the project creates means for sharing research knowledge related to vaccination activities and confidence, and joint good practices in Europe. Finland is actively involved in the EU-JAV project. Finland is in charge of leading the section on vaccination confidence and hesitancy, and participates in implementing several other sub-projects.

Based on an initiative by the National Institute for Health and Welfare, a Nordic Vaccine Hesitancy group was established in November 2018. Experts working in vaccine confidence and hesitancy from all Nordic public health institutions were invited to participate in the group. The purpose of the group is to share current information and experiences of vaccination confidence and hesitancy as well as related work and measures between Nordic public health institutions. The group also plans structures for cooperation, also on a tight schedule if necessary.

Other Nordic countries have been implementing projects particularly related to improving confidence in vaccinations in recent years. Denmark, where the coverage of the HPV vaccine plunged from around 90 per cent to less than 40 per cent after 2014, launched the Stop HPV project in 2016 to increase vaccination coverage[18]. The project succeeded in restoring confidence in the vaccine and improving vaccination coverage. The project utilised versatile communications, including hiring two people to reply to questions on vaccinations submitted through social media. The project was carried out in cooperation with the Danish National Institute of Public Health, Danish Medical Association and the Danish Cancer Society.

In June 2018, the Public Health Agency of Sweden, Folkhälsomyndigheten, was commissioned to carry out a project aiming to strengthen the activities and communications related to vaccination. The project investigates the reasons for staying unvaccinated, customises communications materials, and develops tools for encountering vaccine-hesitant people. The annual budget of the project, spanning from July 2018 until December 2020, is SEK 5.5 million (equivalent to around EUR 520,000)[19].

[18] Denmark campaign rebuilds confidence in HPV vaccination; Stop HPV
[19] Uppdrag om att förbättra barns skydd mot smittsamma sjukdomar 2018-2020

4 The main themes and perspectives of the working group's discussions

From an international perspective, attitudes towards vaccination are highly positive in Finland. Only a very small portion of Finland's inhabitants refuse vaccinations for themselves or their children.

In addition to the moral/ethical considerations presented at the beginning of this chapter, the working group addressed a number of legal standpoints as well as practical reasons and situations recognised to underlie the choice to stay unvaccinated. The following section presents perspectives which could be partly summarised as clear proposals for measures or at least determined as worthy of further examinations.

Vaccine opposition and hesitancy from moral and ethical perspectives

The ethical questions related to vaccine opposition can be divided into three groups: understanding the reasons for opposing vaccinations, influencing anti-vaccination attitudes, and the moral acceptability of vaccine opposition.

The first two subjects have been the topic of academic and health policy discussion for a long time by now. The understanding of the individual and communal factors increasing or reducing vaccine opposition has significantly grown in recent years. However, the discussion on the ethics of vaccination has paid less attention to the moral acceptability of vaccine opposition.

People avoid vaccines for a number of reasons. Many of the diseases prevented with vaccines have been practically eradicated as a result of vaccination. People are no longer able to remember or know what sort of damage diseases such as pertussis, diphtheria or measles can cause. It is understandable that the relationship between the benefits and harm caused by vaccines is blurred. The fact that even specialists are not always unanimous about the hazard caused by the diseases further confuses the situation.

Fears related to vaccines are another reason for avoiding vaccination. As with any medical agents, vaccines carry a risk for different reactions and adverse effects. For

some people, vaccines cause mild symptoms of an inflammatory disease, such as soreness and swelling of the vaccination site or fever. These symptoms are considerably milder compared to the effects caused by the disease without vaccination. Nevertheless, some serious adverse events may occur. The epidemiological connection between the so-called swine flu vaccine and the onset of narcolepsy has caused a lot of fear and worry, particularly in Finland. Even though this was a globally rare and highly exceptional phenomenon, it takes time for the related fear to subside.

The fear of the serious adverse effects of vaccines is also bred by statements without a basis in reality that have reached, or will reach, a wide audience. The most famous of these is probably an article published in an influential medical journal suggesting that there is a link between the MMR vaccine and autism. The author of the article later admitted having falsified the research data. Despite the fact that the article was proven to be incorrect and was withdrawn from the publication, it nonetheless resulted reducing vaccination coverage for years, particularly in the United Kingdom. This resulted in a number of measles epidemics, children falling severely ill, and even deaths, in the country.

Brand new fears have emerged in connection with the HPV vaccination. Some parents struggle understanding the significance of vaccinating young girls when the aim is to prevent a viral infection that would only lead to cervical cancer after years, or even decades, have passed.

In the increasingly international world, there are also apparent ideological suspicions towards vaccines, anti-vaccine behavioural patterns justified with various beliefs, and tensions caused by cultural differences, even between family members.

The emotional reactions related to vaccination are often more severe than in the context of other forms of medication and health care. When discussing with a person with a suspicious regard of vaccines, listening to and understanding the person’s worries and leaving him or her with an experience of being heard is of primary importance. The perspectives of those with a hesitant attitude towards vaccination help developing the national vaccination programme. Appropriate information about the diseases prevented with vaccines, and the safety and potential adverse effects of vaccines compared to the harm caused by the diseases that the vaccines prevent, and flexibility in

vaccination arrangements can help individual people and families in accepting and receiving vaccines. There is also reason to provide information about the risks caused by staying unvaccinated, which threaten the children of the person reluctant to vaccinate as well as the members in his or her community who cannot be vaccinated for health reasons.

The question of the value basis and moral justifications of interventions promoting population health and welfare is among the trickiest issues related to vaccination ethics. This is a complex and theoretically controversial issue, and it is not easy to elaborate on individual, justifiable aspects. Generally speaking, the aspects concerning moral justification have emphasised either consequentialist (utilitarian) viewpoints or the freedom and self-determination of the individual. However, the recent international discussion has paid increasing attention to aspects concerning human dignity.

The perspectives of human dignity supporting a national vaccination programme are built upon deontological ethics that put emphasis on solidarity and reciprocation. According to these views, providing sufficient vaccination coverage – safeguarding herd immunity – is a kind of a moral obligation.

The perspectives based on human dignity can also be examined from several viewpoints. The first justification for opposing vaccinations is applicable to a viewpoint concerning convictions and worldviews. The thoughts of anti-vaccination parents acting based on different ideologies cannot be merely put to question on the basis of their worldview possibly not conforming to scientific facts but, instead, is based on an alternative belief system and spiritual orientation. The fact that a person is not fully committed to science-based thinking may not suffice as a reason for morally questioning his or her decision. However, parents' decision to refuse vaccination can be challenged with a practical viewpoint: is it right that the parents with anti-vaccination attitudes prioritise their worldviews over the health of their own or other people's children? In the worst-case scenario, this means invalidating the suffering of more vulnerable children or other people in a way that opens the actions to moral criticism.

On the other hand, it can be seen that some parents cannot accept the potential, through very rare, adverse effects of vaccines, and will therefore refuse to vaccinate themselves and their children. This way of thinking might be propelled by the fact that these parents and children benefit from the herd immunity provided by the vaccinated

adults and children living in their local environment, allowing them to avoid exposure to the adverse effects of vaccines. Whether this choice is respectful to human dignity and ethically responsible is left to consideration.

The basis of Finland's national vaccination programme, based on voluntariness, respects human dignity and the individuals' self-determination. However, from a perspective of ethics and respect for human dignity, there is moral leeway for society to even employ tough measures in exceptional situations. In conflicts, there is need to assess which is the best solution from the perspective of the situation on the whole. The matter must be solved in a manner respecting the right of self-determination while at the same time taking seriously the duty of the state to protect its citizens, particularly children, from communicable diseases, which could be prevented through vaccination.

There are ethical grounds for particularly drawing attention to the right of children to a healthy life. Preventing serious adverse health effects, and keeping children alive and healthy take priority over the beliefs and convictions of individual guardians. If necessary, the responsibility will fall on the authorities, who must think of the best interest of children. However, under normal conditions, imposing penalties could be interpreted as a form of blackmail, which could affect those most vulnerable in society, which would only result in more opposition. Making a service compulsory is prone to foster anti-authority attitudes. By contrast, dialogue and appropriate information on the significance of vaccination remind people of sharing responsibility, also for herd immunity. This may lead to a clearer view with significant ethical, health-based and financial effects: vaccinating children against communicable diseases free of charge is a privilege.

Arguments related to voluntary and compulsory vaccination

A variety of means can be employed in strengthening vaccination coverage. When the reason for staying unvaccinated is related to practical arrangements, it is the easiest to influence. In addition to using positive measures, such as improving services and increasing correct information, the public discussion has presented introducing an obligation for vaccinating and penalties for neglecting this responsibility.

Vaccination programmes can be voluntary, compulsory, or partly compulsory. A compulsory vaccination programme would require imposing penalties for vaccine rejection. In connection with determining these penalties, there would be need to consider the effectiveness of the chosen penalty on different population groups (e.g. a financial sanction) or targeting them at the individual level (e.g. restricting rights, child/parent/adult). The imposed penalties could involve fines, withholding child benefits, refusal to admit a child to a day-care centre or school, or tax-related penalties to the parents of unvaccinated children.

The discussion on making vaccination programmes compulsory is often underlined by a considerable worry about the decline of vaccination coverage. The majority of EU countries have a voluntary vaccination programme. No reliable research findings indicate that vaccination coverage would categorically improve if a voluntary vaccination programme was made fully or partly compulsory [20]. The scientific community has also expressed a worry that making a vaccination programme compulsory could increase negative attitudes towards vaccination and emphasised that other aspects should be primarily invested in, including the availability of the vaccination service, and related communications and training[21, 22].

Since 1998, Australian families have been refused the right to a child benefit if the child has not been vaccinated in accordance with the national vaccination programme. The so-called "*No Jab No Pay*" legal amendment that entered into force in 2016 made the act stricter by removing the right to refuse vaccines based on conscientious objections. Some of the country's states simultaneously introduced the so-called "*No Jab No Play*" policy refusing the right of unvaccinated children to participate in early childhood education and care. By March 2018, MMR vaccine coverage among five-year-olds had increased from 92.6 per cent to 94.3 per cent. However, measuring the direct impacts of the legal amendments on vaccination coverage is difficult, as other measures aiming to

[20] Compulsory vaccination and rates of coverage immunisation in Europe
[21] Betsch, C et al. (2016) Detrimental effects of introducing partial compulsory vaccination: experimental evidence Eur J Public Health, 26 (3): 378–381
[22] Leask, J. and Danchin, M. Imposing penalties for vaccine rejection requires strong scrutiny. Journal of Paediatrics and Child Health 53 (2017) 439–444.

strengthen vaccination coverage were taken in Australia at the same time. These included the introduction of reminder systems, implementation of campaigns, and improvement of the reliability of the vaccination coverage register.[23]

Vaccinations are not currently compulsory in Finland. However, section 54 of the Communicable Diseases Act (1227/2016) includes the authority to issue a decree on compulsory vaccinations, if comprehensive vaccination is necessary to prevent the spread of a generally hazardous communicable disease capable of causing substantial harm to the life and health of the population or a part thereof in accordance with section 47 of the Act. A compulsory vaccination may also be limited to a certain part of the population, a group or age class. While this authorisation issued by the provision has never been used, it has been retained in the Act for the purpose of highly exceptional disruptions in health care. For example, such a situation could emerge in the context of a smallpox epidemic resulting from bioterrorism.

It can be presumed that the effects of making vaccines compulsory on the vaccination coverage would be controversial, particularly in the long period. The provision issued in section 48 of the Communicable Diseases Act on the vaccination of employees and students to protect patients has been implemented in some parts of the country in a way that has resulted in some of the staff feeling pressured to take the vaccine. This fear of losing one's job has led to an increase in vaccine hesitancy and questioning the benefits brought by vaccines.

Making vaccines compulsory would also result in having to solve questions regarding the accuracy and detail in which the provisions on the compulsory vaccinations should be issued in the Act, how the implementation of the provisions would be organised, and what sort of a penalty would be correctly proportioned to the severity of neglecting vaccines. As making vaccines compulsory would mean imposing a restriction on the right of self-determination, personal freedom and integrity, as well as intervening in the right of individuals to make choices concerning themselves and their body, which is considered a private matter, the acceptability, correct proportioning and necessity of compulsory vaccination should be examined in relation to the achieved benefits. At the same time, it

[23] MacDonald, N. et al. (2018) Mandatory infant & childhood immunization: Rationales, issues and knowledge gaps. Vaccine, 36 (39): 5811–5818

should be evaluated whether vaccination coverage can be improved with other measures that do not require limiting fundamental and human rights or at least include less severe limitations to fundamental rights compared to compulsory vaccination. As making vaccines compulsory would require imposing fairly far-reaching restrictions to fundamental rights, it is clear that vaccines cannot be made compulsory if there are other means to improve vaccination coverage.

Vaccination from the perspective of fundamental rights and the rights of the child

When assessing the need for compulsory, or obligatory, measures, the key premise is to primarily achieve the goals set by society with measures other than the restriction of fundamental rights. The effectiveness, acceptability and necessity as well as correct proportions of the measures is always considered in connection with obligatory measures.

Increasingly targeting the compulsory regulation of vaccination activities would require the issuance of an act and further specifying the matter with a decree. The regulation should pay extensive attention to several provisions and contents included in the Constitution of Finland: human dignity and the freedom and rights of the individual, equality and non-discrimination and the rights of children, the right to life, personal freedom and integrity, protection of private life, educational rights, the duty of the public authorities to promote the health of the population, and protection under law, and good governance. The individual's right of self-determination also plays a key role as it is linked to several fundamental rights, particularly the provisions of section 7 of the Constitution of Finland concerning the right to life, personal liberty and integrity, and section 10 of the right to privacy.

Similarly, the obligations imposed by vaccination activities must be examined through the conditions concerning restricting fundamental rights, as making vaccines compulsory would require imposing far-reaching restrictions to fundamental rights. In this case, the issues to consider include the requirements on issuing provisions in an act and their accuracy and definitions, the acceptability of the restriction, the integrity of the core area of fundamental rights, legal protection, and the compulsory nature of human rights.

In practice, a particularly essential issue in the assessment of the vaccination obligation would concern the requirement of the acceptability of the restriction to fundamental rights and particularly the correct proportion of this limitation: the restrictions must be necessary for the achievement of the set objective and their scope must be correctly proportioned to the legal priority and the weight of the societal interest underlying the restriction.

Key aspects in considering the circumstances when a vaccine could be made compulsory would concern issues such as the danger posed by the disease. An increase in the general hazard caused by the disease would also strengthen the prerequisites for making vaccines compulsory. However, an impact assessment concerning matters such as information about the efficiency of the vaccination in combating each illness should always be performed. The correct proportions and necessity of the compulsory vaccination would also have to be considered separately for each situation.

The best interest and rights of the child form a specific basis for assessing the vaccination obligation. The requirement to protect the life and health of an underaged person is unconditional. The risk for endangering the health and life of a child lays a strong legal basis which also overrides the rights of parents for the child's custody and education. The Act on the Status and Rights of Patients (785/1992) should be clarified in this area to lay down clearer provisions on safeguarding the implementation of the best interest and rights of the child as well as taking into account the views of underaged children and their parents or other guardians regarding the vaccines given to the child.

The United Nations Convention on the Rights of the Child sets a special requirement for taking the best interests and rights of the child into account in all decision-making related to children. Similarly, under section 6 (3) of the Constitution of Finland, children shall be treated equally and as individuals and they shall be allowed to influence matters pertaining to themselves to a degree corresponding to their level of development. The right of the child to health has been considered a necessary requirement for the implementation of the fundamental and human rights of the child. The maintenance of health requires health services provided to the child, including the security to health provided by vaccines. Similarly, according to the Convention on the Rights of the Child, parents and the child must be provided with information and instruction on maintaining the child's health. This should also include comprehensive and high-quality vaccination counselling.

The best interest of the child is the primary objective, therefore also laying the foundation for the health care legislation and practical health care activities concerning the child. This must be visible in selecting care alternatives and solving possible conflicts of interest related to this process. Similarly, whenever exploring new legislative solutions, their effectiveness must be assessed from the perspectives of the implementation of the best interest and rights of the child. The regulation of vaccination must pay attention to both the implementation of the rights of the child as well as respecting the rights of the guardians.

The Act on Child Custody and Right of Access (361/1983) issues provisions on child custody as well as the duties and rights of guardians to make arrangements on the child's care. Provisions have been laid down on the guardian's rights to decide on their child's issues and also contain matters related to health care. The primary role of the decision-making authority of the child's parents is strong and includes a presumption that the guardian will act in the best interest of the child.

According to the Act on Child Custody and Right of Access, the child's guardians are primarily responsible for child custody together. Provisions have been separately laid down for derogations. However, vaccination has not been perceived to be included within the scope of these grounds for derogations.

The child has the right to express his or her opinion and for this to be taken into account to the extent possible based on the child's age and level of development. This is already required under section 6(3) of the Constitution of Finland. The Act on the Status and Rights of Patients also includes a strong obligation according to which if a minor patient owing to his or her age and level of development can decide on the treatment given to him or her, he or she has to be cared in mutual understanding with him or her. In such situations, guardians are not entitled to prevent vaccinating the child, for instance. Similarly, under the Act on the Status and Rights of Patients, the guardian of a minor shall not have the right to forbid any care which may be required to avert a threat to the child's life or health. However, it must be possible to clearly indicate this threat.

The Act on the Status and Rights of Patients does not include regulation in a situation where the child's guardians have varying views on the arrangements for the child's

care. The Parliamentary Ombudsman has considered the lack of regulation as a deficiency that should be corrected with an amendment to the Act on the Status and Rights of Patients. Nonetheless, it is clear under section 9 (4) of the Act on the Status and Rights of Patients that the guardians of a minor do not have the right to forbid any care which may be required to avert a threat to the patient's life or health.

The protection of family life is a widely recognised right under which the guardians have the primary right and responsibility for taking care of their child's welfare, raising children, and deciding on the personal matters that concern them. Under legislation, guardians have strong autonomy, which must also be protected based on the Convention on the Rights of the Child. However, under the Convention on the Rights of the Child, the best interest of the child and the protection of his or her life and health has more weight than the views of guardians if the actions by the guardians put the best interest of the child, and particularly the protection of his or her life and health, at risk. As a result, the assessment of vaccination, particularly in the context of children, must not only separately consider and take into account the interests of the child and his or her guardians as well as their common interest, but also the implementation of the rights of all children and the population as a whole.

The working group was also tasked with considering whether linking **child benefits** to children's vaccinations could lead to more parents vaccinating their children in accordance with the national vaccination programme. The measures discussed by the working group have included a so-called child benefit bonus, which would be paid once the child has received vaccines in accordance with the national vaccination programme and, alternatively, reducing the child benefit as a penalty for neglecting vaccinations.

Both of these alternatives include the problem that as the vaccines included in the vaccination programme are primarily given when the child is little, the decision-making concerning the child's vaccination is a responsibility of the guardian; however, the consequence of the guardian's choice, i.e. reducing the child benefit or paying a so-called vaccination bonus, would target the child benefit whose explicit purpose is to protect the child's care and custody.

If the aim of reduction in the child benefit was to cause a deterrent effect, it should probably be substantial, such as completely withholding the benefit for a set period of time.

The right of the child to social welfare and a sufficient standard of living as well as supporting families are fundamental and human rights. Reducing or completely withholding the child benefit from a family would cause a decline in the child's fundamental and human rights based on the activities by his or her guardians. The child would not be vaccinated, as a result of which the implementation of his or her health rights would be incomplete, and his or her family's right to social protection, and through this, possibly the child's sufficient standard of living, would also be restricted.

Reducing or withholding the child benefit would also be a problematic measure from the perspective of children's mutual equality. A significant reduction of the child benefit or fully withholding the benefit would put the unvaccinated child to a financially unequal position compared to other children.

The child benefit is not dependent on income. As a result, the reduction or withholding child benefits due to opting out of vaccinating the child would also impact families differently. It can be assumed that reducing the benefit would be more likely to increase families' willingness to vaccinate the smaller the family's total income. This would result in putting families in an unequal position regarding the effectiveness of the penalty.

The additional condition on vaccinating included in the child benefit would also cause problems related to restricting and implementing the provisions: to which group would the new condition apply (those currently receiving child benefits or children born after the condition's entry into force)? A further point of consideration would involve what would happen in situations such as the placement of the child outside of his or her family or in case of a divorce resulting in transferring the child's custody from a parent with a positive attitude towards vaccinations to a parent with a negative one. EU legislation could also pose further challenges to the new regulation concerning child benefits, producing an obligation to pay child care benefits for a child residing abroad in certain situations. The vaccination programmes of states covered by EU regulation may not correspond to one another.

From the perspective of fundamental and human rights, granting additional child benefit or other benefit for children who have been vaccinated under the vaccination programme is less problematic. Nevertheless, the impacts of granting the benefit might remain relatively insubstantial. Meanwhile, the costs of the so-called vaccination bonus might end

up being high, as Finland has good vaccination coverage. At the end of 2017, child benefits were paid for slightly over one million children.

It can be estimated that vaccination coverage could be more effectively promoted with the same financial resource using other measures, such as strengthening education, guidance and services. The aforementioned measures could also more effectively increase families' general wellbeing compared to the additional income resulting from vaccinating the child.

It is difficult to justify including additional conditions related to vaccinations to the legislation concerning the benefits from the perspective of the basic goals set for the benefits. The goal of the recent projects aiming to develop social security has also been simplifying and clarifying the social security system. Including different effectiveness targets in the same mechanism does not support the aforementioned general objectives for developing social security. In fact, the effect of the new conditions would be contradictory to the current objectives set for developing the system.

The Constitution of Finland guarantees for everyone the right to receive indispensable subsistence and care. Basic social assistance is the last-resort form of social welfare assistance linked to the provisions of the Constitution of Finland granted to families. The purpose of social assistance is to mend the situations where a person is in need of support but is for some reason unable to make a living by primary means, such as care provided by the person with a duty to maintain. Under the Child Maintenance Act, the child is entitled to receive sufficient maintenance from his or her parents. Neglecting the maintenance obligation is not grounds for withholding a child's social assistance.

When determining the need for social assistance, all forms of income, including child benefits, are taken into account as a rule. However, this has been taken into account in scaling the basic component for children. For low-income families, the basic social assistance would compensate for the income loss caused by the reduction of the child benefit, as a result of which cutting the benefit would not achieve the intended effect. What is more, there is also no accurate, evidence-based knowledge of the impacts of financial penalties on people's behaviour.

The share of completely unvaccinated children who have reached school age is around 0.5 per cent in Finland. With this in mind, using the child benefit system as a means to

promote vaccination coverage would be a disproportionately strenuous and probably rather ineffective means. The new conditions set for child benefits would also increase the administrative burden caused to families, municipalities and the Social Insurance Institution of Finland.

Refusing to admit unvaccinated children in schools or early childhood education and care has also been presented as a measure for safeguarding vaccination coverage. From the perspective of fundamental and human rights, imposing restrictions on the right to attend early childhood education and care is considerably problematic, as this would have consequences on the child's development, education and welfare. The right to basic education free of charge under section 16 (1) of the Constitution of Finland provides the right for everyone to both basic education and education free of charge.

The right to basic education free of charge is a key fundamental right and human right, and restricting it through an act would require extremely serious grounds. From the perspective of an unvaccinated child, the situation would be disproportionate if the child would be refused vaccination based on a decision by his or her guardians as well as early childhood education and care or basic education based on a decision by society.

According to the Communicable Diseases Act, a person who is ill or justifiably suspected of being infected with a generally hazardous communicable disease may be ordered to stay away from day care and education for a fixed period (section 57). This requires that the spread of the disease cannot be prevented by other measures. According to the provision, the decision on absence from work, day care, or educational institution must be revoked at once, when the person is no longer spreading the infection. A person who has been exposed, or is justifiably suspected of having been exposed, to a generally hazardous communicable disease may be ordered into quarantine (section 60), for instance, in his or her own home. Both provisions are concerned with both vaccinated and unvaccinated individuals. Such restrictive measures related to an acute and severe epidemic are clearly more lenient in restricting fundamental and human rights compared to the categorical refusal to admit unvaccinated children to early childhood education and care and basic education.

Making vaccination compulsory or making vaccination a condition for receiving a benefit or service would also result in new questions concerning **tort liability legislation** in case

vaccines were suspected to have caused some sort of harm. The issues subject to consideration would include issuing provisions on the no-fault liability of the state.

5 Conclusions and proposed measures by the working group

5.1 Developing the service system

Improving the availability and accessibility of maternity and child health clinic services

In Finland, maternity and child health clinics are responsible for vaccinating under-school-aged children and pregnant women, and providing vaccination counselling for families. School health care is in charge of vaccinating school-aged children. The Joint external evaluation of IHR core capacities of the Republic of Finland (WHO-IHR Joint External Evaluation, 2017)[24] noted that the maternity and child health clinic system is a key factor for good vaccination coverage among children. The operating conditions for high-quality maternity and child health clinic activities must be protected. There is need for sufficient human resources for the maternity and child health clinic services. In 2017, the public health nurse staffing levels in compliance with national recommendations were reached in 54 per cent of health centres; the corresponding rate for physicians was 33 per cent[25]. In school health care, the goal for public health nurse staffing was accomplished in 88 per cent, and for physicians in only 8 per cent, of health centres. This shortage of staff results in many municipalities struggling in providing the statutory health examinations by child health clinics and school health

[24] WHO 2017. Joint external evaluation of IHR core capacities of the Republic of Finland. Mission report, March 2017.
[25] Wiss K, Hakamäki P, Hakulinen T, Hietanen-Peltola M, Ikonen J, Saaristo V, Saukko N & Ståhl T. 2018. Äitiys- ja lastenneuvolan sekä koulu- ja opiskeluterveydenhuollon henkilöstövoimavarat terveyskeskuksissa 2004–2017 (in Finnish).THL, Tutkimuksesta tiiviisti (Research in brief), November 2018.

care[26]. The appointments are also not always implemented in accordance with the relevant government decree (338/2011)[27] and national instructions[28] in terms of their content and scope. From the perspective of organising vaccination activities, this means that there is often not enough time for counselling and discussing with the child's parents[3].

Ensuring the human resources for maternity and child health clinic services improves vaccination activities when the possibly missing vaccine doses can be given flexibly and there is enough time to discuss with parents sceptical about vaccinating with a public health nurse and physician. The implementation of the statutory service can also be supported with more efficient monitoring than currently.

An increase in uncommon working hours can lead to practical difficulties of families to find suitable appointment times in maternity and child health clinics. The accessibility of maternity and child health clinics should also be further developed by utilising the results of surveys exploring the needs of service users more than currently. Workable local operating models can include developing the accessibility of the clinics' appointment booking system and telephone services, expanding the clinics' opening hours to evenings and weekends, outpatient clinic services, as well as providing vaccinations flexibly also to others than the clinic's local clients.

- ***The health care operating units will provide more flexible opportunities for vaccinating than currently***
- ***Including SMS reminders of booked appointments for vaccinations and at maternity and child health clinics in electronic appointment booking systems***

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[26] **, Pelkonen M. 2018. Up-to-date practices and long traditions. Follow-up study of maternity and child health clinic and school health care services. 2016−2017. Report 11/2018. National Institute for Health and Welfare (THL). Hakulinen T, Hietanen-Peltola M, Vaara S, Merikukka M**

[27] Government Decree on maternity and child health clinics, pupil and student health care, and preventive oral health care for children and young people 338/2011.

[28] Maternity and child health clinics, pupil and student health care, and preventive oral health care. Grounds and application directives for Decree (380/2009). Ministry of Social Affairs and Health publication 2009:20.

- ***Municipalities will ensure that their maternity and child health clinic activities and school health care will have enough staff to enable the implementation of decree (338/2011)***
- ***The National Supervisory Authority for Welfare and Health and the regional state administrative agencies will include compliance with the Government Decree on maternity and child health clinic services (338/2011) in their supervisory programmes***

Strengthening the role of physicians in the vaccination activities of maternity and child health clinics and school health care

According to section 6 of the Ministry of Social Affairs and Health on vaccinations (149/2017), physicians are in charge of the planning and implementation of vaccination activities. In practice, the vaccinations for children included in the national vaccination programme are typically given by public health nurses. Public health nurses usually have excellent knowledge base of vaccines and the diseases prevented with vaccination. Discussing with parents with a hesitant attitude towards vaccination may require the active involvement of both a public health nurse and a physician. Some parents could also benefit from discussions with a paediatrician or a specialist in infectious diseases.

Some municipalities use operating models that involve a public health nurse booking a separate discussion with a child health clinic or school health care physician if the parents wish to know more or are suspicious about vaccines. Parents refusing the vaccines offered to their child have also been provided with an opportunity to meet a paediatrician. Developing and widely utilising these or equivalent local operating models improve families' opportunities for discussing possible concerns related to vaccines with experts.

- ***Strengthening the role of physicians in vaccination counselling***
- ***Ensuring that parents with a hesitant attitude towards vaccines get an opportunity to discuss their child's vaccination with a child health clinic physician and, if necessary, a paediatrician***

Enhancing vaccination among adults

The vaccination programme for adults consists of periodic boosters to tetanus–diphtheria vaccines. The first boosters are implemented as a combination vaccine which also includes protection against diphtheria. The purpose of the vaccine is to boost the protection of parents and, through them, babies against diphtheria. An annual influenza vaccine is also offered to adults in at-risk groups and those over 65 years old. Vaccination coverage is usually lower among adults and older people compared to little children. However, assessing the vaccination coverage is difficult, as a significant share of vaccination takes place in occupational health care and the private sector, from where the vaccination data will not be submitted to the national vaccination register. Boosting adults' vaccines requires well-functioning primary health care with sufficient resources. People must be able to book an appointment for a vaccine without a considerable delay.

- ***Primary health care resources are strengthened to allow booking a vaccination appointment without delay***
- ***Health care operating units will provide more flexible opportunities for getting vaccinations than currently***
- ***The validity of protection by vaccination will be verified at occupational health checks***

Developing information systems and monitoring

The development work of electronic patient systems will create new opportunities for enhancing vaccination activities. Reminder and alarm systems notifying users of missing vaccines enable complementing vaccinations at every health care appointment. Some health centres already use automatized SMS reminders of booked appointments. In the future, corresponding messages can be also used to remind people of the vaccines they have not yet gotten. It would also be appropriate to construct the reminder system as part of the My Kanta service, allowing users to personally check their vaccination protection status and possible need for a booster, and book an appointment for vaccination using the electronic service.
The national vaccination register allows up-to-date monitoring of vaccination coverage at the level of municipalities, health centres, and hospital districts. The register can

also be used to follow whether children have received vaccines in accordance with the vaccination schedule. Including data from other registers also allows using the vaccination register to monitor vaccination coverage in other language groups and based on different socioeconomical background variables. Using the register data in steering vaccination activities must be further enhanced at the national level as well as in municipalities and hospital districts.

- ***Determining alarms for missing vaccines concerning vaccinations in patient record systems at the national level***
- ***Health care operators will ensure that software supplier will create an SMS reminder and alarm feature for missing vaccines in their patient record systems***
- ***Developing the data transfer between the vaccination register and the Kanta service for the use of both health care professionals and the general public; the My Kanta service will allow users to actively follow their personal vaccination protection***
- ***The population group specific monitoring of the vaccination coverage will be enhanced, and data suitable for local utilisation is increased***

5.2 Education services and training for health care professionals

The Student Welfare Act (1287/2013) regulates basic education, general upper secondary education, and vocational education and training. Pupil and student welfare services must be implemented as multidisciplinary, systematic cooperation with education services, students and their guardians as well as other partners if necessary. The curricula for basic and upper secondary education must include information about vaccination and the diseases prevented with vaccines.

The National Vaccination Competence Module (2 cr + 1 cr) developed by the National Institute for Health and Welfare and universities of applied sciences is currently extensively included in the basic studies of public health nurses. All the practical work placements of public health nursing studies include practical vaccination training. The course is usually optional for nurses, midwives and paramedics, and many only complete the basic section of the course. Including the module in full in the compulsory

qualification criteria of midwifery, nursing and paramedic education must be investigated. A separate national training module must be organised for developing vaccination competence and knowledge of communicable diseases among practical nurses. The basic and further studies of physicians should also include more training on vaccination as well as contents developing interpersonal skills.

There is need for further increasing the supplementary training for health care professionals already employed in the health sector. The National Vaccination Competence Module is also well-suited for supplementary training purposes. The online-based training must also be supported with contact learning, for example on the techniques used in motivating interviews that aim at improving the health care professionals' capacity in encountering hesitation and hesitant parents.

- ***Increasing knowledge and education on vaccinations in basic education and upper secondary education***
- ***Including more information about vaccination in the basic and supplementary training of all health care professions***

5.3 Communication work promoting vaccine information and confidence

Previously, the confidence in health care operators was founded on authority. This is no longer the case, which must also be taken into account in communications aiming to strengthen vaccine confidence. Currently, trust is based on the transparency of research activities, monitoring and the structures related to vaccines, providing information openly and in a timely manner, the interactive and responsive involvement of the population (listening and appropriately responding to the worries and questions of the general public) and the accessibility of information, ensuring that people find the vaccine information they are looking for smoothly and from reliable sources.

Many diseases preventable through vaccination have been practically eradicated, which has led to a gradual decline in the knowledge and understanding of the necessity and usefulness of vaccines. Understanding the significance of vaccination in the prevention of diseases is part of general civic knowledge, which must be maintained through constant communications.

The information, attitudes and practical decisions on vaccination can be crucially influenced by communications that build trust and are provided at the correct time. The continuity of a customer relationship increases trust, as a result of which sharing of information about children's vaccinations must occur in a continuum from the maternity clinic to child health clinic and school health care. In addition to the information provided by a public health nurse, reliable information published in the client's mother tongue must be available to families on the website of the National Institute for Health and Welfare and municipalities as well as in brochures handed out to families.

In Finland, health promotion and the implementation of the national vaccination programme are among the municipality's basic tasks. Particularly smaller municipalities have insufficient resources for providing sufficient communications about vaccination. Despite the fact that the National Institute for Health and Welfare supports and steers the vaccination programme at the international level, the institute's communications are mainly focused on supporting the work of health care professionals. According to the Communicable Diseases Act, the tasks of the National Institute for Health and Welfare include providing the population with recommendations for preventing infection and spread of disease (section 7), which is precisely what communicating about vaccination is. The communications must reach an extensive range of population and language groups, occur in multiple communication channels, and construct cooperation networks between different agents. In addition to the usefulness of vaccines, the contents of communications must take into account key questions related to vaccination safety.

- ***The National Institute for Health and Welfare will increase its communications about vaccination aimed at both health professionals as well as the general public***
- ***The significance of vaccinating will be demonstrated by providing clear information about the diseases preventable through vaccination, their symptoms and possible complications***
- ***The communications about vaccination will take different population and language groups into account more comprehensively than currently***
- ***Enabling the use of the maternity package as one of the channels of communicating about vaccination aimed at families***

- ***Establishing a group to determine the best way to disseminate information for families about the child's overall wellbeing as part of the maternity package***

5.4 Studying the reasons affecting vaccination coverage and vaccine confidence

The improvement of vaccine coverage requires follow-up and research knowledge of the reasons that affect vaccination coverage and vaccine confidence as well as the expected effectiveness of different measures. There is also need to investigate the operating conditions and related barriers in the service system more strongly than currently.

The currently ongoing Joint Action on Vaccination project of the EU member countries examines the factors affecting vaccination coverage and charts good practices for strengthening the vaccination coverage. Nevertheless, evidence-based measures also always require local research data collected of each country's population groups.

Allocating funding by the Academy of Finland and other agents to research in vaccination coverage and vaccine confidence would significantly promote Finnish knowledge base and preconditions for developing operating approaches and tools for strengthening vaccination coverage and confidence.

- ***Allocating sufficient research funding to the research of the factors affecting vaccination coverage and vaccine confidence and the development of related measures***

5.5 Developing legislation

As such, the currently valid legislation provides a sufficient and correct frame to vaccination activities. However, the legislation should be clarified and its accuracy improved in certain parts.

In some of his decisions concerning the vaccination of a child[29, 30], the Parliamentary Ombudsman has noted that there is reason to improve the accuracy of the legislation in certain areas. According to section 6 of the Act on the Status and Rights of Patients, if a major patient cannot decide on the treatment given to him or her, the patient has to be given a treatment that can be considered to be in accordance with his or her personal interests. However, there is no equivalent provision on a situation where the views of the legal representatives, close family members or other loved ones of an underaged child unable to decide on the treatment given to him or her vary from one another. In practice, this has led to situations where a child has not been vaccinated if one of his or her guardians has opposed it. As a result, there is need to clarify the regulation (the Act on the Status and Rights of Patients) to take into account the best interests of the child and the obligation for protecting the child's life and health, particularly in circumstances where the child's guardians have different views of vaccinating the child.

The provision, marketing and use of alternative treatments not based on research evidence has increased in Finland. In the future, this may also result in a decline in confidence in vaccinations among the population. There is no legislation on regulating alternative treatments in Finland. For instance, in Sweden, cancer patients, pregnant women or children aged under 8 years old may only be treated by persons with lawful health care training. In the future, a similar act should also be prepared in Finland.

The omission of vaccine data from the private sector from the national vaccination register severely complicates the assessment of vaccination protection and coverage among the adult population. Provision on a binding obligation for transferring vaccination data via an electronic user interface to the vaccine register maintained by the National Institute for Health and Welfare must be issued to all social and health care units.

- ***The legislation on the rights of the child and guardians will be clarified, taking into account the best interest of the child and the obligation to***

[29] Decision by the Parliamentary Ombudsman: Guardians' permission to their child's swine flu vaccine (in Finnish)
[30] Decision by the Parliamentary Ombudsman: The implementation of the HPV vaccination campaign (in Finnish)

protect the child's life and health. Particular attention will be paid to situations where the parents have varying views of the child's vaccinations (Act on the Status and Rights of Patients).

- ***Preparing legislation concerning alternative treatments will be started immediately***
- ***The vaccination register will be developed by introducing binding legislation concerning the transfer of vaccination data***

Appendices

1. Decision on establishing the working group
2. Legislation concerning vaccines and health examinations
3. Basic vaccination programme for children of child health clinic age and vaccination programme for adults

Appendix 2

Legislation concerning vaccines and health examinations

Communicable Diseases Act (1227/2016, https://www.finlex.fi/fi/laki/kaannokset/2016/20161227)

The purpose of the Communicable Diseases Act

According to *section 1 of the Communicable Diseases Act* (Objectives), the objective of the Act is to prevent communicable diseases and their spread, as well as to prevent harmful effects caused by these diseases to people and the society.

National vaccination programme

The vaccines given in Finland included in the national vaccination programme are based on *section 44 of the Communicable Diseases Act.* The national vaccination programme includes free vaccinations given to protect the public from infectious diseases. According to section 44, the contents of the vaccination programme are set by the Ministry of Social Affairs and Health, after consulting experts specialised in vaccines and vaccination.

Under the Act, the municipalities must provide vaccinations included in the national vaccination programme. Participation in the vaccinations is voluntary.

The National Institute for Health and Welfare guides the implementation of the national vaccination programme and other general vaccinations, monitors the coverage and effects of the vaccinations, conducts research, and submits proposals to develop the national vaccination programme.

The detailed rationale for section 44 in government proposal HE 13/2016vp notes e.g. the following. The purpose of the national vaccination programme is to accomplish a good vaccination coverage to both individual and the population as a whole. For the accomplishment of these objectives, the vaccination programme means systematically offering vaccinations which, in practice, municipalities provide in maternity and child health clinics, school health care, and other activities of health centres. Vaccinations are primarily comprehensively provided for age groups. However, vaccines

against some diseases, such as tuberculosis, are currently only offered to those belonging to risk groups. A seasonal influenza shot is currently offered based on risk determined by the person's age as well as medical risk, and also to part of social and health care staff and medical care personnel. Implementing the vaccinations in the national vaccination programme as comprehensively as possible is an important objective that does not only protect the vaccinated person but also the rest of the population.

Compulsory vaccinations

Under *section 47 of the Communicable Diseases Act* (Compulsory vaccination), provisions on organising compulsory vaccinations can be issued by Government decree, if comprehensive vaccination is necessary to prevent the spread of a generally hazardous communicable disease capable of causing substantial harm to the life and health of the population or a part thereof. A compulsory vaccination may also be limited to a certain part of the population, a group or age class. Municipalities must arrange the compulsory vaccinations referred to in the section.

According to the detailed rationale for section 47 in the government proposal, the provision concerning compulsory vaccination was proposed to be issued in accordance with the Communicable Diseases Act of 1986. While this authorisation issued by the provision has never been used, it should be retained in the Act for the purpose of highly exceptional disruptions in health care. Such a situation could emerge in the context of a smallpox epidemic resulting from bioterrorism.

Adverse effects

Under *section 51 of the Communicable Diseases Act* (Monitoring the effects of vaccinations and investigating identified or suspected adverse reactions), the National Institute for Health and Welfare must monitor the efficiency, effects, and safety of vaccines used in the vaccinations, and take measures to investigate a diagnosed or suspected adverse reaction to a vaccine or vaccination.

According to *section 53 of the Communicable Diseases Act* (Recording the notifications of adverse reactions to vaccines and vaccinations), the Finnish Medicines Agency records all received notifications of adverse reactions to vaccines and vaccinations in its national Adverse Reaction Register to ensure pharmaceutical safety as well as the safety of patients. This information comprises the identification data of the

person receiving the vaccination, information on the person submitting the notification and information on the administered vaccinations, including the vaccine's batch data and data on the identified or suspected adverse reaction.

Provisions on the register are laid down in the Medicines Act (395/1987), and the Act on National Personal Data Registers for Health Care (556/1989) and the related Decree (774/1989).

Vaccines free of charge

According to *section 81 of the Communicable Diseases Act (Vaccines free of charge),* the municipality e.g. receives the vaccines used for the vaccinations referred to in sections 44(1) and 47 free of charge. The central government is responsible for the incurred costs.

Health protection violation

According to *section 88 of the Communicable Diseases Act* (Reference to the Criminal Code), the penalty for a health protection violation is laid down in Chapter 44, section 2 of the Criminal Code of Finland (39/1889). This applies to vaccinations when a person refuses to take a compulsory vaccination ordered based on section 47 of the Communicable Diseases Act.

Ministry of Social Affairs and Health Decree on vaccinations (149/2017, https://www.finlex.fi/fi/laki/kaannokset/2017/20170149)

Section 1 of the Decree (Vaccines and vaccinations included in the national vaccination programme) notes that the vaccines used in the national vaccination programme and the vaccinations given for the purpose of protecting different population groups against communicable diseases have been listed in the appendix of the Decree. The basic vaccination programme for children and adolescents and the vaccination programme for adults have been attached to the present report.

According to *section 6 of the Decree* (Vaccination), a physician is in charge of planning and implementing vaccination activities. A vaccine shot may only be administered by a physician or a nurse, public health nurse or midwife who has completed appropriate vaccination training.

Section 7 of the Decree (Reporting data on vaccination in patient records) notes that the given vaccinations must be reported in the patient records using a vaccine monitoring template or an equivalent section in an electronic data processing system. The date of vaccination, name of vaccine, batch number, injection site, vaccination method, and person administering the shot are reported on the form or in the data processing system.

Government Decree on maternity and child health clinics, pupil and student health care, and preventive oral health care for children and young people (338/2011, https://www.finlex.fi/fi/laki/kaannokset/2011/20110338)

Section 14 of the Government Decree (General health care counselling) notes that the local authorities shall provide health care counselling as referred to in section 13 of the Health Care Act in accordance with the individual needs and developmental attainments of local residents, in cooperation with individuals and their families so as to enable them to strengthen their resources, apply information in practice and take responsibility for their own health. Health care counselling shall include evidence-based information. Health care counselling may be provided individually, in groups or in communities.

Section 14 (2) notes that health care counselling must support
parenthood and intimate partner relationships and also enhance the social support networks of families. It must also support the promotion of the health, including mental health, and psychosocial well-being of individuals and their families, including in the area of vaccinations in accordance with the national vaccination programme and infection prevention.

According to *section 9 of the Government Decree* (Regular health examinations), the local authorities shall provide:
1) at least one extensive health examination for each family expecting a baby

2) at least nine (9) health examinations for each child during the first 12 months of life; these shall include six health examinations conducted by a public health nurse, two health examinations jointly conducted by a physician and a public health nurse when the child is 4 to 6 weeks old and 8 months old, and an extensive health examination when the child is 4 months old

3) at least six (6) health examinations for each child between the ages of 1 and 6, including extensive health examinations at the ages of 18 months and 4 years; one of these health examinations shall include a public health nurse’s estimation of the child’s oral health, and

4) a health examination for schoolchildren during each school year, of which the examinations in the 1st, 5th and 8th grades shall be extensive health examinations.

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