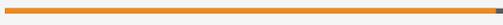
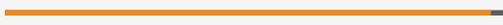


# Legislative Landscape Review: Legislative Approaches to Immunization across the European Region

December 2018

## The Nordic countries of Denmark, Finland, Norway and Sweden: The recommended approach in practice

### European Region Matrix: Immunization Legislation

COUNTRY	Is the right to health in this country's constitution?	Is it mandatory for the government to provide immunization?	Is it mandatory for the people to be immunized?	Does the government verify that the individual has been immunized?	Is immunization required for attending an educational institution?	Are there penalties in cases of noncompliance?	Has the judiciary of the country ruled on mandatory immunization?	Does the government finance immunization?
<b>Denmark</b> 	NO	YES	NO	YES	NO	NO	NO	YES
COVERAGE INDICATORS		DTP3  98%					MEASLES (cases, 7/2017–6/2018)	6
		IPV  N/A						
<b>Finland</b> 	YES	YES	NO	YES	NO	NO	NO	YES
COVERAGE INDICATORS		DTP3  89%					MEASLES (cases, 7/2017–6/2018)	13
		IPV  N/A						
<b>Norway</b> 	NO	YES	NO	YES	NO	NO	NO	YES
COVERAGE INDICATORS		DTP3  96%					MEASLES (cases, 7/2017–6/2018)	8
		IPV  N/A						
<b>Sweden</b> 	NO	YES	NO	NO	NO	NO	NO	YES
COVERAGE INDICATORS		DTP3  97%					MEASLES (cases, 7/2017–6/2018)	49
		IPV  N/A						

Answer Verified by Authoritative Secondary Sources

Answer Verified by Survey

## Introduction

Using the “[Likert Scale: Assessing Levels of Immunization Legislation](#)” developed by the Sabin Vaccine Institute (Sabin) for this study, the Nordic countries of Denmark, Finland, Norway and Sweden all receive the *recommended* classification. The Nordic countries are comparable in terms of demographics, disease burden, healthcare systems with tax-based funding, public ownership and operation of hospitals, universal access to immunization and comprehensive coverage.<sup>1</sup> Furthermore, the national immunization programs (NIPs) of the Nordic countries are similarly organized. Immunization is voluntary in all four countries and vaccines included in the NIPs are provided free of charge to children. Children are immunized in childcare centers and later in schools, but there are no immunization requirements for school entry. Disease, coverage and monitoring systems are well-established, reliable and provide detail at national and sub-national levels. Furthermore, compensation systems are in place in cases of Adverse Effects Following Immunization (AEFI).

National immunization rates have been historically high in all four countries, though current coverage rates and trends are starting to differ. The diphtheria-tetanus-pertussis (DTP3) vaccine serves as an example of this recent variance among the Nordic countries. DTP3 coverage ranged from 89-98 percent across the countries in 2017. Denmark’s DTP3 coverage figures steadily increased from 87 percent in 2007 to 98 percent in 2017.<sup>2</sup> Finland’s DTP3 coverage was high at 97-99 percent between 2007 and 2015, but slipped from 95-92 percent in 2016, and further decreased to 89 percent in 2017.<sup>3</sup> Norway’s coverage increased from 93 percent in 2007 to 96 percent in 2017.<sup>4</sup> Sweden’s coverage has remained high throughout the decade with 97-98 percent between 2007 and 2017.<sup>5</sup>

This case study aims to explore factors that differentiate immunization approaches in the Nordic countries, including legislation and factors related to immunization system capacity.

## Methodology

This study was carried out by Sabin in partnership with the O’Neill Institute for National and Global Health Law, Georgetown University. The research presented in this document was conducted using qualitative methods, surveying 53 participating countries from the European Region, as well as complementary desk research. Additional information was collected from authoritative secondary sources and from insights provided by national experts and members of the project steering committee. A comprehensive overview of legislation, supporting documents, national constitutions, public regulations, decrees and other relevant information on country immunization programs examined are now publicly available on Sabin’s [European Immunization Policy Database](#) (Database).

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<sup>1</sup> Magnussen J, Vrangbaek K, Saltman R. Nordic Health Care Systems. Recent Reforms and Current Policy Challenges. Copenhagen: Open University Press, (2009).

<sup>2</sup> Anon. Denmark: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 4 July 2018]. Available from: <http://www.who.int/features/2018/hpv-vaccination-denmark/en/>

<sup>3</sup> Anon. Finland: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 4 July 2018]. Available from: [http://data.who.int/immunization/monitoring\\_surveillance/data/fin.pdf](http://data.who.int/immunization/monitoring_surveillance/data/fin.pdf)

<sup>4</sup> Anon. Norway: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 4 July 2018]. Available from: [http://www.who.int/immunization/monitoring\\_surveillance/data/nor.pdf](http://www.who.int/immunization/monitoring_surveillance/data/nor.pdf)

<sup>5</sup> Anon. Sweden: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 4 July 2018]. Available from: [https://data.unicef.org/wp-content/uploads/country\\_profiles/Sweden/immunization\\_country\\_profiles/immunization\\_swe.pdf](https://data.unicef.org/wp-content/uploads/country_profiles/Sweden/immunization_country_profiles/immunization_swe.pdf)

# Context and findings

## Structure of NIPs and legislation

In the Nordic countries, vaccines included in the NIPs are recommended and provided free of charge to children. In Denmark,<sup>6</sup> Finland,<sup>7</sup> Norway<sup>8</sup> and Sweden,<sup>9</sup> immunization services are offered and organized by the municipal health centers. Before starting school, children are offered immunizations within the framework of child health services and well-baby clinics. Immunizations offered during school-age are the responsibility of the school health services.

COUNTRY	# of Vaccines Included in the NIP
Denmark <sup>10</sup>	10
Finland <sup>11</sup>	11
Norway <sup>12</sup>	12
Sweden <sup>13</sup>	9

The Danish NIP is regulated by the Health Act (2010)<sup>14</sup> and additional decrees. The Health Act regulates immunization monitoring and the functioning of the Danish Vaccination Register.<sup>15</sup> An amendment in 2013<sup>16</sup> allowed for the Register to be used in following up with parents who did not immunize their children, by sending them written reminders. A 2018 Decree on Free Immunization Against Certain Contagious Diseases<sup>17</sup> indicated that recommended vaccines are provided free to all residents in Denmark by regional councils.

<sup>6</sup> The Danish childhood vaccination program. Danish Health Authority; 2018. Available from: The Danish childhood vaccination program. Danish Health Authority; 2018.

<sup>7</sup> Stuart Allt Web Design, Turku, Finland. Public Healthcare & Services in Finland. Finnish Education System: Enrolment Procedures, Vocational Training. [https://www.expats-finland.com/living\\_in\\_finland/public\\_healthcare.html](https://www.expats-finland.com/living_in_finland/public_healthcare.html).

<sup>8</sup> Norway. VENICE III [Internet]. Venice.cineca.org. N. p., 2018 [cited September 2018]. Available from: [http://venice.cineca.org/documents/norway\\_ip.pdf](http://venice.cineca.org/documents/norway_ip.pdf)

<sup>9</sup> Vaccinations - The Public Health Agency of Sweden [Internet]. (2018). Folkhalsomyndigheten.se. [cited September 2018], Available from: <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/>

<sup>10</sup> <https://www.sst.dk/en/disease-and-treatment/vaccination/childhood-vaccination-programme> : diphtheria, tetanus, pertussis, varicella, poliomyelitis, Haemophilus influenzae type b (Hib), pneumococcal, measles, mumps, rubella. Girls are also offered a vaccine against the human papillomavirus (HPV).

<sup>11</sup> <https://thl.fi/en/web/vaccination/national-vaccination-programme/vaccination-programme-for-children-and-adolescents>: diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type b (Hib), measles, mumps, rubella, rotavirus, varicella, pneumococcal, hepatitis B, human papillomavirus (HPV).

<sup>12</sup> Rotavirus, diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type b (Hib), hepatitis B, pneumococcal, measles, mumps, rubella. Girls are also offered a vaccine against the human papillomavirus (HPV).

<sup>13</sup> Vaccinations. The Public Health Agency of Sweden [Internet]. (2018). Folkhalsomyndigheten.se. [cited September 2018], Available from: <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/>

Diphtheria, tetanus, pertussis, poliomyelitis, infections caused by Haemophilus influenzae type b (Hib), measles, mumps, rubella and pneumococcal. Hepatitis B is offered by county councils to all children as well. Girls are also offered a vaccine against the human papillomavirus (HPV).

<sup>14</sup> LBK nr 913 af 13/07/2010 Gældende (Sundhedsloven) Offentliggørelsesdato: 15-07-2010 Indenrigs-og Sundhedsministeriet Available from: <http://www.stfnet.dk/Love/Sundhedsloven%20LBK%20nr%20913%20af%2013.pdf>

<sup>15</sup> Section 157a, the Health Act of 2010. The Danish Health Authority; 2010.

<sup>16</sup> Law Amending the Health Act, Section 1 of Law No. 904 of 4 July 2013. The Danish Health Authority; 2013. Available from: <https://www.retsinformation.dk/forms/r0710.aspx?id=160482>

<sup>17</sup> Legislative Decree No. 191 of 28 February 2018. The Danish Health Authority; 2018. Available from: <https://www.retsinformation.dk/pdfPrint.aspx?id=160482>

Finland's NIP is regulated under the Communicable Diseases Act (1227/2016).<sup>18</sup> An amendment enacted on March 1, 2017,<sup>19</sup> underwent several rounds of consultation and resulted in changes, including improved monitoring. Additionally, statutes concerning immunization of employees working in the social and health fields were changed to mandate that personnel who are in direct contact with high-risk groups (e.g., children under age one, the elderly over age 65, and the sick) must be immunized for influenza, measles, varicella and pertussis (see Database).<sup>20</sup> This statute also provides penalties for refusal to be immunized. On December 2, 2018, Finland's Minister of Education Sanni Grahn-Laasonen proposed making childhood immunization a condition for payment of state child and family benefits as a mechanism to increase immunization coverage.<sup>21</sup> At the time of this study, no legislative changes have been made but Minister's Grahn-Laasonen's proposal hints that Finland may introduce new penalties for immunization refusal.

Norway's NIP is regulated by provisions included in the Infectious Disease Control Act,<sup>22</sup> and immunization is voluntary and free of charge. The decision to introduce a new vaccine into the NIP is carried out by the Ministry of Health and Care Services, based on advice from the National Institute of Public Health (NIPH). The program is introduced at the national level but services are provided by local municipality healthcare providers and administered by nurses. All vaccines under the NIP are purchased by the Norwegian Institute of Public Health and are distributed to local providers.<sup>23</sup> The Norwegian Immunization Registry, SYSVAK, is a national Immunization Information System (IIS) administered by the Norwegian NIPH.<sup>24</sup> SYSVAK is legally anchored in the Norwegian law for Health Registries<sup>25</sup> and the SYSVAK regulation.<sup>26</sup>

The Swedish child immunization program is regulated by the Communicable Diseases Act (SFS 2004:168)<sup>27</sup> and regulations issued by the Public Health Agency of Sweden. The Communicable Diseases Act stipulates that a communicable disease shall be covered by a NIP, if the vaccine is expected to effectively prevent a communicable disease from spreading, and if it is cost effective and sustainable. The corresponding Ordinance<sup>28</sup> regulates 13 factors that the Public Health Agency must consider when proposing changes in the NIP to the government.

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<sup>18</sup> Communicable Disease Decree No. 786 (1986 October 31). Ministry of Social Affairs and Health, Finland. Helsinki, Finland. 1986. Available from: [http://www.finlex.fi/fi/laki/kaan/nokset/1986/en19860786\\_20101059.pdf](http://www.finlex.fi/fi/laki/kaan/nokset/1986/en19860786_20101059.pdf)

<sup>19</sup> Finland: No jab, no job? [Internet] Vaccines Today [cited September 2018]. Available from: <https://www.vaccinestoday.eu/stories/finland-no-jab-no-job/>

<sup>20</sup> Communicable Disease Decree No. 786 (1986 October 31). Ministry of Social Affairs and Health, Finland. Helsinki, Finland. 1986. Available from: [http://www.finlex.fi/fi/laki/kaannokset/1986/en19860786\\_20101059.pdf](http://www.finlex.fi/fi/laki/kaannokset/1986/en19860786_20101059.pdf)

<sup>21</sup> Minister proposes child benefits be tied to vaccine requirements [Internet] Uutiset [cited December 2, 2018]. Available from : [https://yle.fi/uutiset/osasto/news/minister\\_proposes\\_child\\_benefits\\_be\\_tied\\_to\\_vaccine\\_requirements/10536101](https://yle.fi/uutiset/osasto/news/minister_proposes_child_benefits_be_tied_to_vaccine_requirements/10536101)

<sup>22</sup> The Act Relating to the Control of Communicable Diseases. County Social Welfare Boards. Oslo, Norway. Available from: <https://www.fylkesnemndene.no/en/what-does-fylkesnemndene-do/the-contagious-diseases-protection-act/>

<sup>23</sup> Norway. VENICE III [Internet]. Venice.cineca.org. N. p., 2018 [cited September 2018]. Available from: [http://venice.cineca.org/documents/norway\\_ip.pdf](http://venice.cineca.org/documents/norway_ip.pdf)

<sup>24</sup> Trogstad L, Ung G, Hagerup-Jenssen M, Cappelen I, Haugen I L, Feiring B. The Norwegian immunisation register – SYSVAK. Euro Surveill. 2012;17(16):pii=20147. <https://doi.org/10.2807/ese.17.16.20147-en>

<sup>25</sup> Lov om helseregistre og behandling av helseopplysninger (helseregisterloven) LOV-2014-06-20-43. [Act of 20 June 2014 No. 43 relating to personal health data registries]. Available from: <https://lovdata.no/dokument/NL/lov/2014-06-20-43>

<sup>26</sup> Lov om helseregistre og behandling av helseopplysninger (helseregisterloven) - Lovdata. (2018). Lovdata.no. [cited 3 December 2018] FOR-2003-06-20-739. Available from: [https://lovdata.no/dokument/SF/forskrift/2003-06-20-739?q=sysvak\\_forskriften](https://lovdata.no/dokument/SF/forskrift/2003-06-20-739?q=sysvak_forskriften)

<sup>27</sup> Disease Prevention Act SFS No. 168 (2009). Ministry of Social Affairs. Stockholm, Sweden. 2009. Available from: [http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/smittskyddslag-2004168\\_sfs-2004-168](http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/smittskyddslag-2004168_sfs-2004-168)

<sup>28</sup> Infectious Disease Regulation SFS No. 255 (2004). Ministry of Social Affairs. Stockholm, Sweden. 2004. Available from: [http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/smittskyddsforordning-2004255\\_sfs-2004-255](http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/smittskyddsforordning-2004255_sfs-2004-255)

### **Sweden's attempt to introduce mandatory immunization**

The Riksdag, or Swedish parliament, received a proposal that called for mandatory immunization in 2016. In March 2017, it voted against this proposal based on the recommendation of the Parliament Social Committee,<sup>29</sup> which said, "The general vaccination program has a good coverage, and most children are protected against measles and polio, for example. There is, however, skepticism about vaccinations, both the vaccinations included in the basic program and others. In our view, however, it is of societal interest that the vaccination program is implemented in its entirety, and many of the myths and incorrect data circulating about the vaccination program need to be treated and pinned. We therefore consider that the government should provide the appropriate authority with the task of designing an information campaign on the benefits and necessity of the childhood vaccination program." *Riksdag Social Committee report 2016/17: SoU*<sup>30</sup>

### **Decision making on new vaccine introduction**

The decision making structure for the introduction of new vaccines is similar across all four countries. Each country has established a National Immunization Technical Advisory Groups (NITAGs) for vaccine introduction decision making, chaired by national public health institutions with broad representation from the medical and public health communities. These NITAGs evaluate evidence and provide recommendations to policy makers. The final decision to introduce the vaccine is then made by the national government.<sup>31</sup>

Despite similarities in decision making processes and burdens of disease, the countries have reached different decisions on new vaccine introduction. For example, Finland, Norway and Sweden have introduced rotavirus vaccines into their NIPs; however, in Denmark a decision was made against introducing the rotavirus vaccine. All four countries evaluate the burden of disease as part of decision making. Denmark also considers the "severity factor," which for rotavirus, evaluated the low mortality and benign course of most cases of infection as an argument against introduction.<sup>32</sup> Finland, Norway and Sweden also consider the number of cases and healthcare visits to be an indicator of disease burden.<sup>33</sup>

### **Monitoring and AEFI surveillance**

The countries also exhibit strong similarities in monitoring and AEFI surveillance. In Denmark, the Statens Serum Institut (SSI)<sup>34</sup> monitors the number of children who are immunized under the Danish childhood immunization program<sup>35</sup> as well as surveillance the diseases on the childhood immunization schedule. Since 1996, the Danish Vaccination Register (DDV) contains information on all immunizations given in the childhood immunization program.<sup>36</sup> The Danish Medicines Agency is responsible for collecting and

<sup>29</sup> Social Committee Report: Public Health Issues Summary 2016/17. Stockholm, Sweden. 2017. Available from: <https://data.riksdagen.se/fil/77EB646D-37F9-4E33-9A89-331A5AA0E85A>

<sup>30</sup> Did Sweden Ban Mandatory Vaccination? [Internet]. VAXOPEDIA. N. p., 2018 [cited July 2018]. Available from: <https://vaxopedia.org/2018/05/16/did-sweden-ban-mandatory-vaccination/>

<sup>31</sup> St-Martin G, Lindstrand A, Sandbu S, Fischer TK. Selection and Interpretation of Scientific Evidence in Preparation for Policy Decisions: A Case Study Regarding Introduction of Rotavirus Vaccine Into National Immunization Programs in Sweden, Norway, Finland, and Denmark. *Frontiers in Public Health* 2018;6. doi:10.3389/fpubh.2018.00131

<sup>32</sup> Selection and Interpretation of Scientific Evidence in Preparation for Policy Decisions: A Case Study Regarding Introduction of Rotavirus Vaccine Into National Immunization Programs in Sweden, Norway, Finland, and Denmark, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5960676/>

<sup>33</sup> St-Martin G, Lindstrand A, Sandbu S, Fischer TK. Selection and Interpretation of Scientific Evidence in Preparation for Policy Decisions: A Case Study Regarding Introduction of Rotavirus Vaccine Into National Immunization Programs in Sweden, Norway, Finland, and Denmark. *Frontiers in Public Health* 2018;6. doi:10.3389/fpubh.2018.00131.

<sup>34</sup> Childhood vaccination programme. Danish Health Authority. Danish 2017. Available from:

[https://www.ssi.dk/English/PublicHealth/Vaccination/The Danish Childhood Vaccination Programme.aspx](https://www.ssi.dk/English/PublicHealth/Vaccination/The%20Danish%20Childhood%20Vaccination%20Programme.aspx)

<sup>35</sup> Vaccination. Forside – Sundhedsstyrelsen. Danish Health Authority. Danish 2018. Available from: <https://www.sst.dk/en/disease-and-treatment/vaccination>.

<sup>36</sup> Suppli CH, Rasmussen M, Valentiner-Branth P, Mølbak K, Krause TG. Written reminders increase vaccine coverage in Danish children - evaluation of a nationwide intervention using The Danish Vaccination Register, 2014 to 2015. *Eurosurveillance* 2017;22. doi:10.2807/1560-7917.es.2017.22.17.30522

analyzing the AEFI information. In compliance with 2014 legislation, data from the DDV was linked with other administrative registers to allow the SSI to send written reminders to parents of children with missing immunizations.<sup>37</sup> A study has shown that the written reminders increase coverage among Danish children.<sup>38</sup> The Danish Health Authority also collaborates internationally on monitoring AEFI.

Starting in 2013, the Danish Medicines Agency received an increasing number of reports of suspected AEFI due to human papillomavirus (HPV) immunization of young girls.<sup>39</sup> As a result, Denmark saw an increase in public concern over the safety of the HPV vaccine and a dramatic decrease in vaccine uptake from 79 percent in birth cohort 2000 to 17 percent in birth cohort 2003.<sup>40</sup> According to the World Health Organization (WHO), “Since 2014, HPV vaccination coverage among 12-year-old Danish girls has decreased dramatically from around 90 percent in previous cohorts to below 40 percent due to safety concerns about the vaccine.”<sup>41</sup> In 2016, in order to understand why parents of girls were postponing immunization, the Danish Health Authority conducted an analysis and found that nearly all parents who doubted whether to vaccinate their daughters had heard stories about the suspected side-effects, primarily through social media and online sources. In 2017, the Danish Health Authority, the Danish Cancer Society and the Danish Medical Association launched a campaign called “Stop HPV, Stop Cervical Cancer.” Armed with knowledge about the sources of information for parents, the campaign not only published articles about how to prevent cervical cancer in traditional news sources (newspapers and magazines), but also started a Facebook page to help answer parent questions and share stories. The campaign has helped build confidence in the vaccine and reminds people that the risk of contracting cervical cancer far outweighs the risk of AEFIs (see Written Reminders).<sup>42</sup>

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<sup>37</sup> Proposal Act amending the Health Act can be found here:

<https://www.ft.dk/samling/20161/lovforslag/L132/index.htm>; <https://www.retsinformation.dk/Forms/R0710.aspx?id=131918>

<sup>38</sup> Sociodemographic predictors are associated with compliance to a vaccination-reminder in 9692 girls age 14, Denmark 2014–2015 <https://www.sciencedirect.com/science/article/pii/S2211335518300238>

<sup>39</sup> Valentiner-Branth P. Prevention and control of HPV and HPV related cancers: the Danish experience. Vienna, Austria: Stans Serum Institute; 2018. Available from:

[https://www.ages.at/download/0/0/a00df22e71ad1b6ab84022774280e7e28c632fa3/fileadmin/AGES2015/Service/AGES-Akademie/2018-01-17\\_ASM\\_New\\_Year\\_s\\_Lecture\\_2018/HPV\\_denmark\\_vienna.pdf](https://www.ages.at/download/0/0/a00df22e71ad1b6ab84022774280e7e28c632fa3/fileadmin/AGES2015/Service/AGES-Akademie/2018-01-17_ASM_New_Year_s_Lecture_2018/HPV_denmark_vienna.pdf)

<sup>40</sup> Soborg B. Addressing HPV vaccine hesitancy in Denmark. *European Journal of Public Health* 2017;27. doi:10.1093/eurpub/ckx187.036.

<sup>41</sup> Anon. Denmark: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 4 July 2018]. Available from: <http://www.who.int/features/2018/hpv-vaccination-denmark/en/>

<sup>42</sup> stophpv.dk - Sammen mod HPV og livmoderhalskræft. (2018). Stophpv.dk. Retrieved 19 November 2018, from <http://www.stophpv.dk/>

**Written reminders: The Danish approach to increasing immunization rates for HPV and MMR**

Studies show that several interventions are effective in increasing vaccine uptake and, specifically, reminders may be useful in the case of adolescents who tend to visit medical facilities less regularly than young children.<sup>43</sup> New technology such as text messaging and other electronic messages can be especially effective in adolescents.<sup>44</sup>

To increase immunization coverage under the NIP, the Danish Parliament introduced a reform in May 2014 to allow the SSI to issue written reminders to parents of children who lack one or more immunizations. Reminders are issued when the child turns two, six and a half and 14 years old. Parents are reminded on all immunizations included in the NIP, except if the child is lacking pneumococcal or meningitis (*Haemophilus influenzae* type B, or Hib) immunization. The reminder is sent to the parent in custody of the child. If the parents have joint custody, but do not share the same address, the reminder is sent to both parents. Reminders have been found to increase the immunization coverage of several vaccines, including the second dose of the measles, mumps and rubella (MMR) vaccine, which correlated with a five percent rise in coverage for children aged seven.<sup>45</sup> Denmark documented its successful approach and has shared it with other countries that are also struggling with low HPV coverage and when faced with introducing a new vaccine into their NIP.<sup>46</sup>

In Finland, the National Institute for Health and Welfare (THL) carries out surveillance of vaccine-preventable diseases, as well as the implementation and safety of the immunization program.<sup>47</sup> The Vaccine Safety Unit of the THL has oversight of vaccine safety issues.<sup>48</sup> The unit monitors the safety and the quality of the vaccines in Finland and maintains a register for AEFI reported by health care personnel. According to national regulations, healthcare workers must report all serious AEFI. The online register enables real-time evaluation of incidents and severity of possible AEFI linked to each vaccine.<sup>49</sup>

Norwegian Immunization Registry, SYSVAK, is national, electronic immunization registry that records an individual's immunization status and immunization coverage in Norway.<sup>50</sup> Established in 1995 to replace its precursor that was in place since 1976, SYSVAK is administered through the child immunization program and includes personal details such as an individual's name, Norwegian personal identity number, address, vaccine given and immunization date. SYSVAK is regulated by the Personal Health

<sup>43</sup> Suppli CH, Dreier JW, Rasmussen M, Andersen A-MN, Valentiner-Branth P, Mølbak K, et al. Sociodemographic predictors are associated with compliance to a vaccination-reminder in 9692 girls age 14, Denmark 2014–2015. *Preventive Medicine Reports* 2018;10:93–9. doi:10.1016/j.pmedr.2018.02.005

<sup>44</sup> Suppli CH, Dreier JW, Rasmussen M, Andersen A-MN, Valentiner-Branth P, Mølbak K, et al. Sociodemographic predictors are associated with compliance to a vaccination-reminder in 9692 girls age 14, Denmark 2014–2015. *Preventive Medicine Reports* 2018;10:93–9. doi:10.1016/j.pmedr.2018.02.005

<sup>45</sup> Suppli CH, Rasmussen M, Valentiner-Branth P, Mølbak K, Krause TG. Written reminders increase vaccine coverage in Danish children - evaluation of a nationwide intervention using The Danish Vaccination Register, 2014 to 2015. *Eurosurveillance* 2017;22. doi:10.2807/1560-7917.es.2017.22.17.30522.

<sup>46</sup> Anon. Denmark: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 4 July 2018]. Available from: <http://www.who.int/features/2018/hpv-vaccination-denmark/en/>

<sup>47</sup> National vaccination programme - Vaccination - THL. (2018). The National Institute for Health and Welfare (THL), Finland [cited September 2018] Available from: <https://thl.fi/fi/web/vaccination/national-vaccination-programme>

<sup>48</sup> Postila V, Kilpi T. Use of vaccine surveillance data in the evaluation of safety of vaccines. *Vaccine* 2004;22:2076–9. doi:10.1016/j.vaccine.2004.01.020.

<sup>49</sup> Rapola S. National immunization program in Finland. *International Journal of Circumpolar Health* 2007;66:382–9. doi:10.3402/ijch.v66i5.18310.

<sup>50</sup> About the Norwegian Immunisation Registry SYSVAK [Internet]. (2011). Norwegian Institute of Public Health. [cited September 2018] Available from: <https://www.fhi.no/en/hn/health-registries/norwegian-immunisation-registry-sysvak/norwegian-immunisation-registry-sys/>

Data Registration Act<sup>51</sup>, the Norwegian Law for Health Registries<sup>52</sup> and the SYSVAK regulation.<sup>53</sup> All NIP immunizations must be registered on the SYSVAK. Registration of vaccines given outside the NIP requires consent from the person being vaccinated.

### **Norway: The rule engine**

To calculate the real-time immunization coverage and the extent to which the NIP recommendations are followed, SYSVAK uses a built-in rule engine. The rule engine is a tool that helps calculate coverage on national, regional, municipality or district levels using the National Registry's information on residency. The rule engine was developed to improve the quality of data in SYSVAK. Quality lists can be produced at municipality and district levels, and identify unvaccinated children, as well as children who are not fully vaccinated according to the NIP. The lists are forwarded to the responsible health personnel in all municipalities and districts for further follow-up. However, there is no requirement or clear guidance on how the follow-up is conducted.

In Sweden, the Public Health Agency monitors immunization coverage, informs the public about the immunization program and administers the immunization registry.<sup>54</sup> In compliance with Swedish law effective January 1, 2013,<sup>55</sup> healthcare providers are required to report all immunizations administered within the Swedish immunization programs to a national immunization registry.<sup>56</sup> The Medical Products Agency is responsible for monitoring vaccine safety and reviewing reports of AEFI.

The Public Health Agency of Sweden uses the immunization registry to identify areas of low coverage. In 2013, the Agency carried out a pilot study using the WHO European Region Tailoring Immunization Programmes (TIP) method among three identified groups at risk for outbreaks of measles and rubella: the anthroposophic community in Järna, located south of Stockholm; the Somali communities in Rinkeby and Tensta, northern Stockholm; and undocumented migrants in Stockholm and Gothenburg.<sup>57</sup> As a result of the pilot, several targeted communication and education initiatives, including a "peer-to-peer" project, in-depth vaccinology education for healthcare professionals and targeted information about the importance of being vaccinated with MMR before travelling abroad, were developed and are being implemented (an update was not available at the time of this study).

## **Compensation schemes**

It is important to note, that in addition to strong surveillance of AEFI, the four countries also have comprehensive compensation schemes in place. Vaccine-injury compensation programs were

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<sup>51</sup> Act on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) No. 24. Ministry of Health and Care Services (18 May 2001). Oslo, Norway. Available from:

<https://www.regjeringen.no/en/topics/health-and-care/public-health/Act-of-18-May-2001-No-24-on-Personal-Health-Data-Filing-Systems-and-the-Processing-of-Personal-Health-Data-Personal-Health-Data-Filing-System-Act-/id224129/>

<sup>52</sup> Lov om helseregistre og behandling av helseopplysninger (helseregisterloven) LOV-2014-06-20-43. Act of 20 June 2014 No. 43 relating to personal health data registries. Ministry of Health and Care Services. Available from:

<https://lovdata.no/dokument/NL/lov/2014-06-20-43>

<sup>53</sup> Forskrift om innsamling og behandling av helseopplysninger i Nasjonalt vaksinasjonsregister (SYSVAK-registerforskriften) FOR-2003-06-20-739. [Regulations concerning the collection and processing of health data in the national immunisation register (SYSVAK Registry Regulations)]. Ministry of Health and Care Services. Oslo, Norway. Available from:

[https://lovdata.no/dokument/SF/forskrift/2003-06-20-739?q=sysvak\\_forskriften](https://lovdata.no/dokument/SF/forskrift/2003-06-20-739?q=sysvak_forskriften)

<sup>54</sup> Surveillance of communicable diseases - The Public Health Agency of Sweden. Public Health Agency of Sweden. (2018).

Folkhalsomyndigheten.se. Available from: <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/surveillance-of-communicable-diseases/>

<sup>55</sup> Vaccination register and vaccination coverage - The Public Health Agency of Sweden. (2018). Folkhalsomyndigheten.se.

Available from: <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/vaccination-register-and-vaccination-coverage/>

<sup>56</sup> Sveriges Riksdag. Act (2012:453) about registers for national vaccination programs. The Public Health Agency of Sweden [Document on the Internet] 2012 [cited 2015 June 9]. Available from: <http://rkrattsdb.gov.se/SFSdoc/12/120453.PDF>

<sup>57</sup> Barriers and motivating factors to MMR vaccination in communities with low coverage in Sweden Implementation of the WHO's Tailoring Immunization Programmes (TIP) Method. Folkhalsomyndigheten. 2018. Available from:

<https://www.folkhalsomyndigheten.se/contentassets/5db4b41a40f94e98b0e1d0d4a596bae8/barriers-motivating-factors-mmr-vaccination-communities-low-coverage-sweden-15027.pdf>

established to ensure that individuals who are adversely affected by vaccines in the interests of the community are adequately compensated and receive any needed care. These schemes have been shown to function efficiently when operating alongside well-established, comprehensive national social welfare systems in the Scandinavian countries. In these countries, vaccine-injury compensation schemes have been found to have a relatively low administrative cost, especially compared to civil litigation cases.<sup>58</sup>

The Danish and Swedish vaccine compensation schemes were introduced in the 1970s, the Finnish one in 1980s, and the Norwegian one in the 1990s.<sup>59</sup> In Denmark and Norway, the vaccine-injury scheme is administered by the Department of Health, whereas the Finnish and Swedish schemes are voluntary for pharmaceutical companies and are not operated by the government. In Sweden, the insurance industry and government collaborated to establish a Swedish vaccine-injury compensation scheme to which all pharmaceutical companies and importers voluntarily pay contributions.<sup>60</sup> Similarly in Finland, all pharmaceutical manufacturers formed the Finnish cooperative for the indemnification of medicine-related injuries and negotiated with the insurance sector to establish its own voluntary scheme.<sup>61</sup> In Norway, although the scheme is government run, it is also funded by contributions from the pharmaceutical industry. Finland, Norway and Sweden use a manufacturers' levy to fund their vaccine-injury compensation schemes.<sup>62</sup>

## Analysis

A trend across legislative and programmatic approaches could not be identified that explains the differences in immunization coverage among the Nordic countries. For example, in Sweden, a voluntary approach was maintained following a proposal to pass a more mandatory approach. Despite this, Sweden has maintained high coverage rates. On the opposite end, Finland introduced an updated Communicable Diseases Act that requires social and health personnel working in direct contact with high-risk groups to be immunized and includes penalties for refusal.<sup>63</sup> Despite these efforts, rates have been declining.

The review of NIP communications in each of the Nordic countries demonstrates how important it is that the population be informed of the risks and benefits of immunization. This is not a new finding, but the case study provides some additional comparative illustrations of the different methods used by these four countries. This case study supports the idea that in countries that have worked to address hesitancy through targeted information campaigns — with follow-up targeting groups that displayed lower immunization coverage — the immunization rate has either been sustained (Sweden) or improved (Denmark), whereas in countries where monitoring was carried out, but communication efforts to follow-up with the population were limited (Norway) or no further information follow-up was undertaken (Finland), coverage has not risen as significantly (Norway) or has fallen (Finland).

Monitoring systems act as a diagnostic. All four Nordic countries have strong monitoring systems, enabling identification of potential causes of declining immunization rates. Leveraging monitoring

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<sup>58</sup> Hodges C. Nordic compensation schemes for drug injuries. *J Consum Policy* 2006; (29): 142-75. doi: 10.1007/s10603-006-9003-4

<sup>59</sup> Looker C, Kelly H. No-fault compensation following adverse events attributed to vaccination: a review of international programmes. *Bulletin of the World Health Organization* 2011;89:371–8. doi:10.2471/blt.10.081901

<sup>60</sup> Oldertz C. Security Insurance, Patient Insurance, and Pharmaceutical Insurance in Sweden. *The American Journal of Comparative Law* 1986;34:635. doi:10.2307/840326.

<sup>61</sup> Finnish Pharmaceutical Insurance Pool [Internet]. Helsinki: Finnish Pharmaceutical Insurance Pool; 2011. Available from: [http://www.lvp.fi/www/page/lvp\\_www\\_2090](http://www.lvp.fi/www/page/lvp_www_2090)

<sup>62</sup> Looker C, Kelly H. No-fault compensation following adverse events attributed to vaccination: a review of international programmes. *Bulletin of the World Health Organization* 2011;89:371–8. doi:10.2471/blt.10.081901

<sup>63</sup> The government's proposal for the Parliament as an infectious disease and some related laws HE 13/2016 - Hallituksen esitykset [Internet]. FINLEX (2018). Finlex.fi. [cited September 2018]. Available from: <https://www.finlex.fi/fi/esitykset/he/2016/20>

systems, studies conducted by Denmark,<sup>64</sup> Finland<sup>65</sup> and Sweden<sup>66</sup> have shown that parts of the population (whether vulnerable populations, e.g., immigrants or parents in specific regions) either lack information or make their decisions regarding immunization based on misinformation provided in media sources. Sweden conducted an analysis of the reasons behind lower immunization rates among immigrant populations in several areas of the country and undertook a targeted information campaign. Similarly, Denmark has conducted an analysis to discover the reasons behind HPV vaccine hesitancy and addressed it through a targeted information campaign. Denmark has also introduced a system of written reminders as a follow-up mechanism with parents of unvaccinated or under-vaccinated children. Both of these tactics had positive results, and Sweden saw its immunization rates maintained, while Denmark saw a significant improvement.

Finland on the other hand has seen a decline in its coverage numbers and significant differences in coverage between different parts of the country. Coverage has dipped as low as 70 percent as parents hesitate or delay taking their children to be immunized. These trends have been evident in the Ostrobothnia region and the Åland Islands, and in parallel, these regions have experienced an increase in the number of pertussis cases.<sup>67</sup> In response to a more mandatory approach proposed in the Finnish Parliament, a new parliamentary group has been created solely to promote immunization.<sup>68</sup> Yet, to date, Finland has not introduced additional targeted information campaigns, unlike its neighbors, and 2017 coverage did not improve. Similarly, although SYSVAK has been used in Norway to identify under-vaccinated or unvaccinated children, no known targeted information or follow-up campaigns have been initiated to date.<sup>69</sup>

## Conclusion

While limited in scope, this case study helps to illustrate that countries with a *purely recommend* legislative approach can attain high levels of immunization coverage and the strength of an immunization system is critical to improving and sustaining coverage. One important factor is the existence of a reliable, universal monitoring system that can be used to track coverage, disease incidence and AEFIs, identifying regions or populations where coverage may be low or declining. Another effective mechanism is proactively addressing a lack of information on immunization, or misinformation spread by traditional and social media or by healthcare professionals. Experiences in Sweden and Denmark have shown targeted information campaigns, through a medium that the audience most relies on and trusts, influences coverage.<sup>70</sup> Systems that automate reminders to the under-vaccinated or unvaccinated population have also been an effective approach used in the Nordic countries. The study suggests that activities to follow up and implement targeted information efforts result in a positive impact on coverage in countries with a voluntary approach to immunization.

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<sup>64</sup> Amdisen L, Kristensen ML, Rytter D, Mølbak K, Valentiner-Branth P. Identification of determinants associated with uptake of the first dose of the human papillomavirus vaccine in Denmark. *Vaccine* 2018;36:5747–53. doi:10.1016/j.vaccine.2018.08.006

<sup>65</sup> Hagerup-Jenssen M, Kongsrud S, Riise ØR. Suboptimal MMR2 vaccine coverage in six counties in Norway detected through the national immunisation registry, April 2014 to April 2017. *Eurosurveillance* 2017;22. doi:10.2807/1560-7917.es.2017.22.17.30518.

<sup>66</sup> Grandahl M, Tydén T, Gottvall M, Westerling R, Oscarsson M. Immigrant women's experiences and views on the prevention of cervical cancer: a qualitative study. *Health Expectations* 2012;18:344–54. doi:10.1111/hex.12034.

<sup>67</sup> Frustrated and disappointed: One father asks why Finland won't make childhood vaccines compulsory [Internet]. Yle Uutiset [cited September 2018] Available from:

[https://yle.fi/uutiset/osasto/news/frustrated\\_and\\_disappointed\\_one\\_father\\_asks\\_why\\_finland\\_wont\\_make\\_childhood\\_vaccines\\_compulsory/10023122](https://yle.fi/uutiset/osasto/news/frustrated_and_disappointed_one_father_asks_why_finland_wont_make_childhood_vaccines_compulsory/10023122)

<sup>68</sup> Riksdagen får vaccinationsgrupp [Internet]. (2017). Vasabladet.fi [cited September 2018] Available from:

<https://www.vasabladet.fi/Artikel/Visa/148728>

<sup>69</sup> Hagerup-Jenssen M, Kongsrud S, Riise ØR. Suboptimal MMR2 vaccine coverage in six counties in Norway detected through the national immunisation registry, April 2014 to April 2017. *Eurosurveillance* 2017;22. doi:10.2807/1560-7917.es.2017.22.17.30518.

<sup>70</sup> Rehn M, Uhnoo I, Kühnmann-Berenzon S, Wallensten A, Sparén P, Netterlid E. Highest Vaccine Uptake after School-Based Delivery - A County-Level Evaluation of the Implementation Strategies for HPV Catch-Up Vaccination in Sweden. *Plos One* 2016;11. doi:10.1371/journal.pone.0149857

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