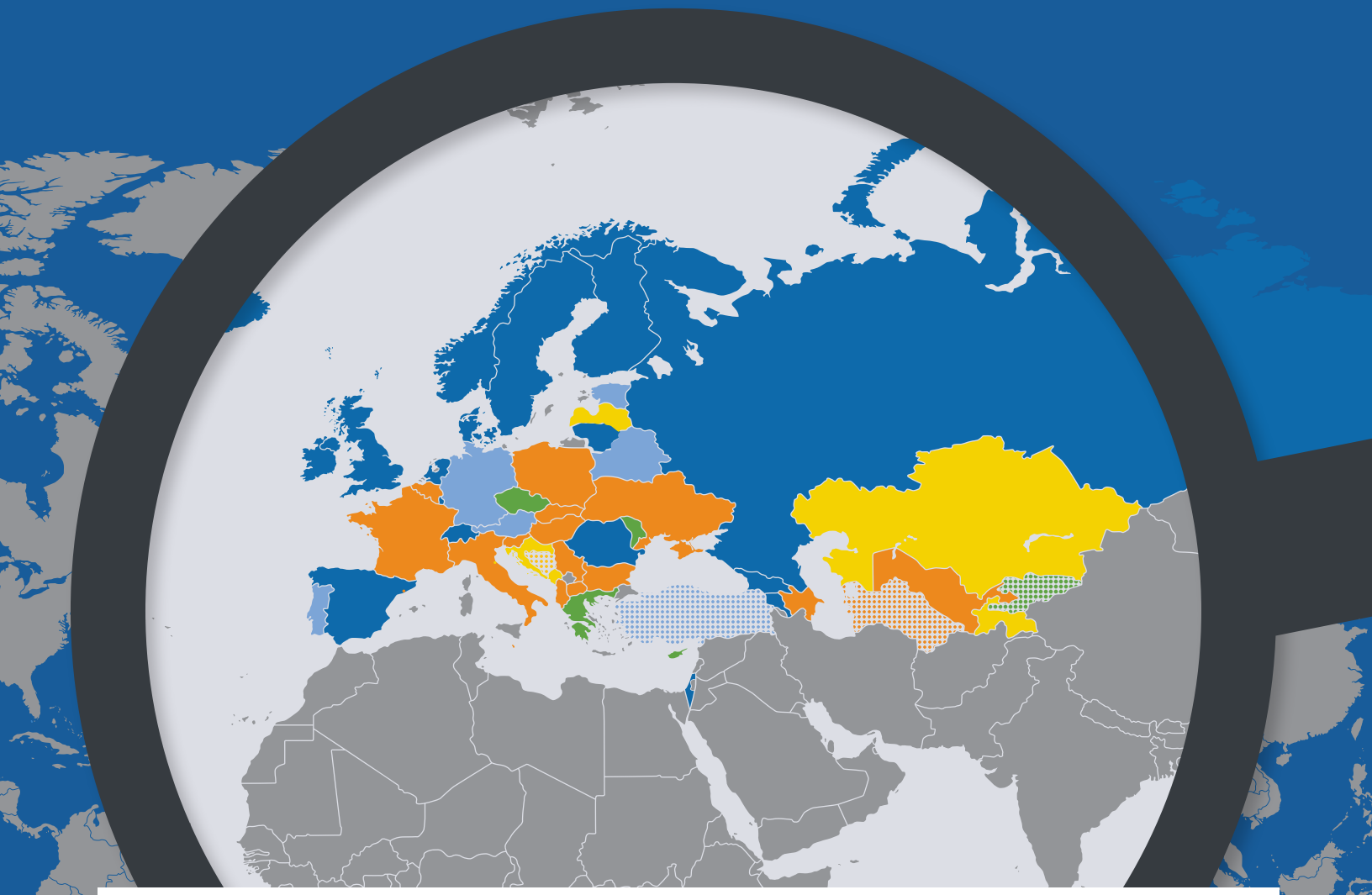
SABIN VACCINE INSTITUTE



Legislative Landscape Review:

Legislative Approaches to Immunization Across the European Region

December 2018

Acknowledgments

This report was made possible with support from Gavi, the Vaccine Alliance.

Prepared by:

Chris Bennett, Director of Policy, Sabin Vaccine Institute (former)

Bruce Gellin, President of Global Immunization, Sabin Vaccine Institute

Katie Gottschalk, Acting Executive Director, O'Neill Institute for National and Global Health Law, Georgetown University

Tara Hayward, Vice President of Resource Development & Policy, Sabin Vaccine Institute

Jamie Minchin, Associate, Sabin Vaccine Institute

Mariya Savchuk-Khatiwada, Consultant, Sabin Vaccine Institute

With Contributions by:

European Region Legislative Landscape Review Steering Committee

- Robb Butler, Senior Social Scientist: Vaccine Demand, UNICEF
- Niyazi Cakmak, WHO Regional Office for Europe
- Ana Gabriela Felix Garcia, Research Administrator, University of California, Berkeley
- Colette Selman, Regional Head EMRO-EURO-PAHO, Gavi, the Vaccine Alliance
- Stephanie Shendale, Technical Officer at World Health Organization, Expanded Programme on Immunization
- Joanna Wisniewska, Senior Programme Manager, Immunisation Financing & Sustainability, Gavi, the Vaccine Alliance

Editor: Kristin Morrell

Designer: büro svenja

Contents

Executive summary

In the last five years, Europe has experienced outbreaks and increased incidence of vaccine-preventable diseases, notably measles, across the region. This represents a marked change, since the World Health Organization (WHO) European Region had achieved an immunization coverage rate of almost 95 percent in the years 2012 to 2013 — 95 percent coverage is the rate at which communities are best protected against vaccine-preventable disease.[1] Since then, European Region countries have made notable changes to frameworks for immunization legislation, which are examined in detail in "Legislative Approaches to Immunization Across the European Region." This study, carried out by the Sabin Vaccine Institute (Sabin), is the first and only systematic review of immunization legislation that includes all 53 countries in the region and provides a comprehensive overview that can be used by countries as a point of reference when evaluating legislative frameworks for immunization law.

Legislative approaches to immunization in the European Region range from voluntary or recommended (the state asks that individuals seek out immunization) to mandatory (the state requires that individuals are immunized). What factors have led to success following mandated immunization law? What conditions have led to resistance to mandates? Which countries have high immunization coverage rates under legislation that recommends immunization? These are critical questions for decision makers in addressing public health concerns at the state level. Qualitative research with a survey of all 53 countries in the region resulted in a landscape review, legislative analysis and classification of the differing approaches to immunization legislation across the region.

Approaches to immunization legislation across the European Region are diverse and a matrix was developed to categorize country laws and policies and provide an overview of the degree of immunization oversight. A second tool was developed to further classify country immunization legislation with a scale ranging across five levels from *recommended* to *mandatory immunization with robust monitoring and follow-up*. The project also developed five country case studies, looking at the immunization legislation in two regions (the Baltic States and the Nordic countries) and three countries in depth (France, Moldova and Ukraine).

The project found that varied legislative approaches across the European Region do not point to any one "best approach." Instead, the research reinforces the principle that country context, capacity of the immunization system, economics, social dynamics, political realities and the constitutional relationship between a government and its citizens all play a role in how a country should approach its legislative framework for immunization. This study is a comprehensive analysis of European Region legislation on immunization that will serve as an important point of reference for countries considering changes to their legislative frameworks for immunization and paves the way for further analysis of the region.

Introduction

This study documents the current legislative environment for immunization in 53 European Region countries, providing an overview and analysis of legal provisions to inform policy decision making.

The World Health Organization's Regional Office for Europe (WHO/Europe)[2] has noted a decline in overall immunization coverage over the last decade.[3] The decline worsened in the period from 2010-2015, resulting in outbreaks, increased incidence of vaccine-preventable diseases such as measles and vaccine-preventable deaths beginning in 2016. While the decline was less than two percent over the five-year period, it represented a significant drop from the immunization coverage high of nearly 95 percent in the years 2012-2013. Following

[1] Understanding behaviours as a first step to addressing declining vaccination uptake in Europe [Internet]. Geneva: Euro.who.int; 2017. [Retrieved 16 November 2018, cited 2018 November 16] Available from http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/news/news/2017/10/understanding-behaviours-as-a-first-step-to-addressing-declining-vaccination-uptake-in-europe

[2] The WHO Regional Office for Europe is on of WHO's six regional offices around the world. It serves the WHO European Region, which comprises 53 countries, covering a vast geographical region from the Atlantic to the Pacific oceans (http://www.euro.who.int/en/about-us). We will refer to this area as the European Region throughout this document.

[3] WHO, Understanding behaviours as a first step to addressing declining vaccination uptake in Europe.

these outbreaks, decision makers in some countries (such as France, Germany, Italy, Lithuania and Romania) proposed legislative changes to strengthen existing immunization provisions.

The authors of this study have conducted a review of existing legislation in the European Region, paying close attention to mandatory immunization requirements, to contribute to a timely and increased understanding of the factors associated with these regional trends.

Legislative approaches to promote and expand immunization services vary widely across the European Region. With a geographic footprint stretching from Iceland to Russia to Turkey, the region includes 53 countries and more than 40 national languages. A wide array of cultures, diverse economic and political models and a web of legal and health systems impact the structure and effectiveness of public health programs, including immunization. This complexity is reflected in the varied national approaches to immunization. Across the region, legislation plays a key role in developing norms around immunization, outlining national immunization programs (NIPs), identifying the roles and responsibilities of stakeholders and codifying the rules, regulations and mandates for citizens.

"Legislative Approaches to Immunization Across the European Region" is the first systematic review of immunization legislation in the European Region that includes all 53 countries. This study is the first attempt to organize and categorize vaccine legislative frameworks at the national level across the entire region to allow for cross-country and sub-regional comparisons. In total, the study required the collection, review and categorization of hundreds of documents.

Through the development of five national and regional case studies, this study examines country legislative frameworks and highlights specific political and policy contexts that influence the effectiveness of a national immunization system. While some previous studies, such as the VENICE project,[4] provided a legislative overview of a subset of the region (29 countries in total) and others have focused on a single issue,[5] all have stopped short of classifying the variety of legislative approaches to immunization across the entire region.[6] The data collected and analyzed for this study is intended to serve policy makers by highlighting effective models, generating lessons learned and identifying challenges.

Project scope and focus

Sabin, in partnership with the O'Neill Institute for National and Global Health Law at Georgetown University (the O'Neill Institute) and with technical input from WHO, carried out this project with support from Gavi, the Vaccine Alliance (Gavi), to identify specific challenges with vaccine regulation and uptake. The project included a landscape review, legislative analysis and classification of the differing approaches to regulating vaccine uptake within individual countries.

Review and analysis of existing legislation focused on specific aspects of legislative frameworks: (1) approaches to requirements for immunization and (2) surveillance of and compensation for Adverse Events Following Immunization (AEFI). To conduct a meaningful analysis, the scope of the project was limited to: (1) European Region countries, (2) publicly available information on state and local level immunization programs and (3) legislative frameworks and court cases as they exist through October 2018.

To ensure that all appropriate data was collected for recommended and mandatory requirements for immunization and AEFIs, additional peripheral legislative provisions were identified and considered, but those determined to be

[4] Haverkate, Manon & D'Ancona, Fortunato & Giambi, C & Johansen, Kari & Lopalco, Pier & Cozza, Vanessa & Appelgren, E. (2012). Mandatory and recommended vaccination in the EU, Iceland and Norway: Results of the VENICE 2010 survey on the ways of implementing national vaccination programmes. Euro surveillance: bulletin européen sur les maladies transmissibles = European communicable disease bulletin.Euro Surveill. 2012 May 31. 17. 10.2807/ese.17.(22.). Pii: 20183-en.
[5] D'Ancona FP. HBV vaccination policies and recommendations in healthcare workers in Europe. Barcelone: Istituto Superiore di Sanitá; 2012. 20 p. Available from: http://www.vhpb.org/files/html/Meetings_and_publications/Presentations/BARS31.pdf;
[6] ASSET (Action plan on Science in Society related issues in Epidemics and Total pandemics). "Compulsory vaccination and rates of coverage immunisation in Europe" [Internet]. ASSET; 2016 January [cited 2018 Aug]. 6 p. Available from: http://www.asset-scienceinsociety.eu/reports/pdf/asset_dataviz_I.pdf

nonessential were not analyzed in detail, nor collected for the policy database that accompanies this study. This was a deliberate decision, made in consultation with external experts, to narrow the research focus and to keep the analysis relevant so that findings and insights are useful to policy makers.

The data collected and analyzed for this study includes stand-alone immunization laws, regulations and executive decrees, as well as relevant public health, healthcare and education-related laws with provisions on immunization. It does not include the broader "policy framework" for immunization such as ministry of health (MOH) policy guidelines, sub-national health authority policy and other policy guidance related to program and law implementation. As a comprehensive landscape review of immunization legislation in the European Region, the aim of the analysis was observational and not intended to provide specific recommendations.

Project objectives

By summarizing the variety of existing legislative frameworks and approaches to immunization in the European Region, the project provides an overview to policy makers that may empower them to make effective changes to immunization programs in their own countries. This project seeks to achieve three objectives: (1) analyze and categorize legislative frameworks in each country, (2) develop case studies providing context and in-depth analysis for specific countries or a subset of countries and (3) create a database of relevant documents (laws, regulations and policies) organized by country for public access and further analysis (see European Immunization Policy Database).

Glossary

Term	Definition
AEFI	Adverse Events Following Immunization
AEFI surveillance	Systems of the government that allow it to identify and track Adverse Events Following Immunization
coverage rate	The estimated percent of people who have received specific vaccines
European Region	World Health Organization European Region, comprises 53 countries across a vast geographical region from the Atlantic to the Pacific oceans
legislative framework	The acts, regulations, delegations, policies and procedures that together establish the rights and responsibilities of governments, companies or citizens
legislation	The exercise of the power and function of making rules (such as laws) that have the force of authority by virtue of their promulgation by an official organ of a state
Likert Scale: Assessing Levels of Immunization Legislation	A Likert Scale is the most widely used approach to scaling responses in survey research. Five classifications of immunization legislative frameworks across the European Region were developed by the study team
Recommended	Immunization is recommended; No mandatory provisions in either health- or education-related legislation and no enforcement provisions. Monitoring mechanisms are in place to assess coverage and provide data
Recommended with robust monitoring and follow-up	Immunization is recommended, with or without enforcement provisions. Robust monitoring and follow-up mechanisms are in place in the case of non-immunization
Recommended with mandatory requirements for school attendance	Immunization is recommended; Enforcement provisions are in place that can prevent a child from attending school if not immunized, effectively rendering immunization somewhat mandatory. Monitoring

	and follow-up mechanisms are in place to assess coverage and provide data
Mandatory immunization with monitoring and follow-up	Immunization is mandatory, with limited enforcement provisions. Monitoring and follow-up mechanisms are limited or do not exist
Mandatory immunization with robust monitoring and follow-up	Immunization is mandatory, with robust enforcement provisions. Robust monitoring and follow-up mechanisms are in place
mandate	In this study, the term mandate signifies an official requirement, codified in law, for a citizen to be vaccinated, or to vaccinate a dependent; however, in some cases the term mandate references a requirement on a government, codified in law, to provide healthcare, monitoring or funding for its citizens. The authors of this report delineate between the terms requirement and mandate, as a requirement is typically a necessity or prerequisite, and without legal standing or consequence
Matrix: Immunization Legislation	Developed by the project team to organize a basic framework categorizing country law and policy and provide an overview of the degree to which immunization is overseen by each country
monitoring system	Systems of a government that enable the identification of programmatic areas that are performing well and areas that need strengthening. For the purpose of this study, monitoring refers to the collection of immunization systems data on issues such as immunization coverage, planning, financing, surveillance, human resources, logistics management, outreach activities and safety
NIP	National Immunization Programs
state	An independent, sovereign government exercising control over a certain spatially defined and bounded geographic area

Methodology

Sabin assembled a project team to carry out the research study. This team included project management, technical and policy experts from Sabin, a lead consultant to manage the research and analysis portions of the project and research and legal analysis by the O'Neill Institute. The research presented in this document was conducted using qualitative methods, surveying all 53 participating countries from the European Region and 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.

Data collection process

The primary data collected for this project was qualitative and included legislative, regulatory and policy documents related to immunization. Data was collected in three stages. The first stage was through the administration of an electronic survey to national experts[7] based in each respective country, which included Expanded Program on Immunization (EPI) managers, heads of immunization or legal divisions within ministries of health and other national health experts. The main goal of the survey was to collect primary feedback from country experts. WHO/Europe shared its relevant contacts, which totaled 83 experts across the 53 countries in the region. In most cases, this included the EPI manager or another key immunization country expert. The research team received 27 complete responses and one incomplete response, representing 25 countries, translating into a response rate of close to 47 percent. The questions answered by respondent varied greatly. In some cases, multiple experts from the same country responded to the survey. For a copy of the survey and a detailed summary of all responses, see the Annex (Annex X, Annex XI).

[7] We will refer to this group as "national experts" throughout the project.

The second stage of data collection involved gathering all available and accessible primary legislative documents and authoritative secondary sources, such as parliamentary recommendations, articles, studies or comments. This stage involved in-depth desk research for each country, reviewing the following sources (representative, not exhaustive):

- MOH or EPI program website/webpages on immunization
- Ministry of justice/national registry of legislation webpages
- The European Centre for Disease Prevention and Control (ECDC) vaccine schedule reference website
- External repositories for legal instruments for a country or region
- The Vaccine European New Integrated Collaborative Effort (VENICE)
- The International Labor Organization's National Legislation database (NATLEX)
- Secondary sources, including international law and policy journals and reliable media accounts

The third and final stage of data collection involved follow-up outreach to national experts to verify results from the combined survey and desk research and to encourage additional responses. In situations where researchers could not find information related to specific criteria and had not received a survey response, the research team asked national experts to provide missing information.

Despite all efforts, gaps in the data collected remained. The research team consulted with members of the project steering committee who helped facilitate connections to additional relevant national experts to provide this information.

The project steering committee, comprised of immunization and regional experts from WHO/Europe, Gavi and UNICEF, was established to help oversee the project, provide advice for specific research decisions and facilitate communication with relevant country contacts. Specifically, the project steering committee reviewed and provided input into the project concept, survey questions and analysis categories.

Analysis process

A multi-step process was used to analyze the collected data. A preliminary review of the data was conducted by identifying key questions for categorizing country law and policy. Organized under eight questions that help identify the basic framework of rules codified in law to regulate immunization, the resulting matrix provides an overview of the degree to which immunization is overseen by the state for each country. A combination of desk research and survey data was used to complete the matrix. Given the subjective nature of the matrix's yes and no answers, a comprehensive master matrix was created to provide written justifications with links to primary documents to further explain answers to each question for every country. This analysis is summarized in the graphic "Matrix: Immunization Legislation" (Annex II).[8]

Using the Matrix, a second layer of analysis was conducted, establishing a "Likert Scale: Assessing Levels of Immunization Legislation," which provides a classification of countries ranging from a *recommended* approach to *mandatory immunization with robust monitoring and follow-up* (see Likert Scale). Five classifications of immunization legislative frameworks were identified based on underlying parameters. To help ensure consistency, these classifications were validated with external experts as well as the project steering committee.

A final level of analysis was conducted to identify and explore legislative frameworks of specific countries and carry out comparative analysis in more detail. This step culminated in the creation of five case studies. The selection of countries and themes for the case studies were influenced by several factors, including an analysis of preliminary findings to identify specific needs expressed by countries transitioning from Gavi financing and input from the project steering committee.

[8] There are approximately 10 countries that are missing 1-3 answers due to translation difficulties or lack of public information. Researchers declined to definitively categorize in these instances.

Findings

Wide variance in approaches to immunization legislation across the region

The data reveals a wide variety of approaches to immunization legislation in the region. Countries often base their immunization policies on the health context: epidemiology of vaccine-preventable diseases, age-specific morbidity and mortality, life expectancy, immunogenicity of vaccines, risk of AEFI, vaccine price and organization of the healthcare system. All these factors influence a country's approach to vaccines used, how they are financed and how services are organized.

Differences in political, historical, cultural and legal contexts are considerable and present some challenges when comparing approaches across countries. The Matrix includes a "right to health" question to provide a foundation for the remaining questions about the overarching legal context under which each country is governed. Accordingly, 38 countries have a constitutional right to health; meaning that in almost three-quarters of the countries in the region, the principal legal document recognizes an individual's legal right to health and establishes the state's responsibility to provide the highest attainable standard of physical and mental health to its citizens.[9]

It is important to reiterate that the drafting and adoption of a bill that renders immunization either recommended or mandatory for a particular group does not directly result in implementation by health professionals, nor does it ensure that the targeted population will comply with the law. How the law is interpreted and implemented by relevant health authorities is a key variable to consider when analyzing the legislation's impact. Additional considerations include physical availability of the vaccine, dependability and functioning of the supply chain, predictability and sustainability of the state's immunization financing and the technical expertise and training of healthcare professionals, along with other factors. As demonstrated in the Baltic States (Annex V) and Ukraine (Annex IX) case studies, understanding these related programmatic factors is critical when analyzing legislative frameworks for immunization. Often, these factors can support the underlying intent of legislation, as in the Baltic States, or, conversely, can undermine the intent to improve coverage rates, as in the case of Ukraine.

The Matrix shows the diversity of legislative frameworks for immunization in the region. The governments' commitment to immunization access from a legislative perspective is reflected in the provisions (1) mandating the government to provide immunization, (2) mandating government financing for vaccines, (3) mandating the government to monitor coverage and (4) intention to undertake AEFI surveillance and compensation. Two additional factors that help enforce the legislative provisions include establishing penalties for noncompliance as well as for mandatory immunization requirements for attending an educational institution. Finally, constitutional courts have also commented on the enforcement of legislation by directly ruling on whether provisions are constitutional and should be complied with. Each of these factors was considered and included in the Matrix.

Government provision and financing of vaccines

Our research highlighted a subtle distinction regarding government provision and financing of immunization within the legislative framework. As the Matrix demonstrates, almost all countries (50 out of 53), have a general provision stating that legislation requires the government to provide immunization services. However, a specific provision that the government must finance immunization services is only present in 45 out of 53 countries (and is unknown in one case, Turkey). While legislation mandating the government to provide immunization creates a legal obligation, it is further reinforced by legislative provisions that the government finance immunization and ensure supply of vaccines. Such legislative provisions not only enable easier access to vaccines for citizens, but also help to reinforce normative standards around immunization. In the three countries where the government is

[9] The Right to Health Fact Sheet No. 31 [Internet]. Geneva: The United Nations; June 2008 [cited 23 June 2018]. Available from: https://www.ohchr.org/Documents/Publications/Factsheet31.pdf

not mandated to finance immunization, Cyprus, Germany and Switzerland,[10] there is also no provision that the government provide immunization. All three countries also have recommended approaches to immunization in place. No contradiction exists because there is no obligation on the individual to be vaccinated and the government is not mandated to provide or finance immunization. [11, 12, 13, 14, 15]

Coverage monitoring

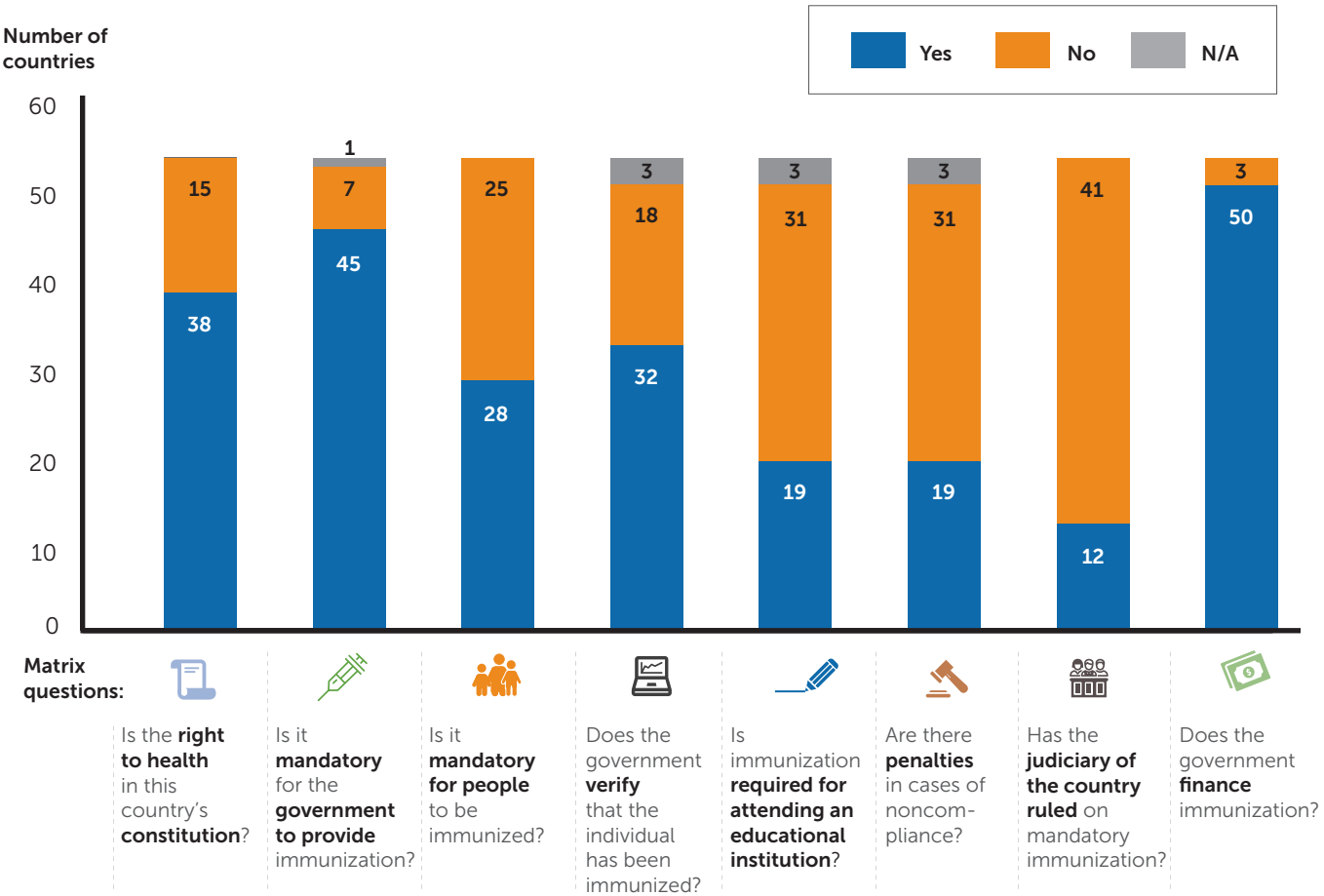
Immunization coverage is a widely used indicator of program performance, measured by registries, routine administrative reports or household surveys. Countries that have weak monitoring systems, where data is not easily available or reliable, are unlikely to demonstrate successful implementation of the NIP. In cases where monitoring is decentralized at the national level, regional coverage gaps are likely a challenge. If monitoring is linked to an e-registry, the government is better positioned to follow up with those refusing or delaying immunization. This is the case in all Nordic countries, and both Sweden and Denmark have successfully relied on monitoring and e-registry systems to address gaps in coverage and pockets of hesitancy. For example, Denmark uses a national registry system to send out written immunization reminders to parents who have not vaccinated their children. This method has resulted in an increase in coverage for certain vaccines (e.g., HPV). See the Nordic countries case study for more detail (Annex VIII).

In this sense, monitoring is needed to ensure compliance. Without a robust monitoring system for coverage in place, a government cannot verify whether the immunization provision is being implemented and cannot track those who refuse or delay immunization. While most countries do have monitoring systems, the reliability, regularity and accuracy of data vary widely. Over 60 percent of countries (33/53) have legislation regulating monitoring systems that are mandated to follow up on whether individuals have been immunized. This is relevant as it provides the opportunity for the government to carry out follow-ups with those who refuse or delay immunization, thus adding a layer of enforcement to the legislative framework. The availability of quality immunization coverage data, when linked to a national immunization registry, provides insight to help countries better understand the potential causes of outbreaks.

[10] Germany and Switzerland have statutory health insurance provisions in place, under which all recommended immunization costs are covered.
[11] Germany and Switzerland have reported significant numbers of measles cases in the recent outbreak, and a death in Switzerland in January 2017
[12] Anon. Young man dies of measles in Switzerland. Le News [Internet]. 24 March 2017 [cited 3 December 2018]. Available from: https://lenews.ch/2017/03/24/young-man-dies-of-measles-in-switzerland/
[13] DeVore V, Nguyen D. Measles outbreaks continue to plague Switzerland. SWI swissinfo.ch [Internet]. 28 Feb 2017 [cited 3 December 2018]. Available from: https://www.swissinfo.ch/eng/society/disease-data_measles-outbreaks-continue-to-plague-switzerland/42993356
[14] Boseley S. WHO warns over measles immunization rates as cases rise 300% across Europe. The Guardian [Internet]. 19 Feb 2018 [cited 3 December 2018]. Available from: https://www.theguardian.com/society/2018/feb/19/who-warns-over-measles-immunisation-rates-as-cases-rise-400-across-europe
[15] Lyneham C. Measles infection rate triples in Germany. DW [Internet]. 19 April 2018 [cited 3 December 2018]. Available from: https://www.dw.com/en/measles-infection-rate-triples-in-germany/a-43449784

Chart 1

Visual summary of country answers to the eight Matrix questions



AEFI surveillance and compensation

In several countries where legislation mandates that citizens be vaccinated, the occurrence of AEFI is also monitored and, in some instances, compensation is provided when an individual suffers negative consequences as a result of the immunization requirement (such as France,[16] Hungary,[17] Italy[18] and Slovenia[19]). These programs reflect a belief that it is fair and reasonable that an immunization program accept responsibility for and provide compensation to those who are injured by it,[20] thereby building and sustaining public confidence.[21] Even some countries without mandatory programs in place have legislation to provide compensation in cases of AEFI (Austria,[22] Denmark,[23] Finland,[24] Germany,[25] Iceland,[26] Norway,[27] Sweden,[28] Switzerland[29] and the United Kingdom[30]). Globally, the issue of compensation for harm or injury following the administration of vaccines remains a matter of debate, and at the time of the last global review (2011) only 19 countries provided compensation.[31] Even where legislative frameworks to address AEFI exist, their implementation differs across countries, shaped by historical specificities and legal traditions. This is further illustrated by the Nordic case study which shows the differences in AEFI compensation systems among countries which otherwise have very similar NIPs.

Our research shows that all countries have a surveillance system in place with either passive or mandatory reporting of AEFI, with more specific AEFI reporting bodies (such as national regulating bodies) and systems (pharmacovigilance) in about one-third of the surveyed countries (Annex III). These systems vary greatly, however, in the extent to which legislation supports them. In practical terms, factors such as a lack of reporting requirements for AEFI, a lack of coordination between the different levels of reporting (for example, if AEFI are captured at regional level, but not investigated further and not aggregated or followed up on at the national level) or a lack of follow-up once the AEFI is identified and confirmed, all impact the effectiveness of any legislative provision addressing AEFI.

Also, as described above, many countries do not have a compensation system in place for those who have suffered due to an AEFI (or they have lengthy and complex legal procedures that do not provide an effective way to obtain compensation). When adequate, AEFI surveillance and compensation can help build the public's trust in vaccines, since it demonstrates the government's willingness to take responsibility in case of unforeseen and unwelcomed adverse effects. Yet similar to monitoring systems, this aspect of NIPs often remains unclear or weak. For more information, refer to the Nordic countries case study, which delves more deeply into the issue of AEFI surveillance and compensation mechanisms. Some countries that have relatively weak disease monitoring

[16] *Dispositif de règlement amiable des dommages imputables à des vaccinations obligatoires* [Internet]. Paris: Office National d'Indemnisation des Accidents Médicaux; 2004 [cited August 2018]. Available from: http://www.oniam.fr/accidents-medicaux-vaccinations-obligatoires
[17] Boncz I, Sebestyen A. Compensation for vaccine injury in Hungary. *Lancet* 2006 Apr 8; 367(9517):1144
[18] Law no. 238 of 25 July 1997, modifications and additions to the Law no. 210 of February 25 1992, relating to compensation to those harmed by mandatory vaccinations, blood transfusions and blood products (in Italian). Rome: Ministry of Health; 1997.
[19] Zanoni G, Berra P, Lucchi I, Ferro A, O'Flanagan D, Levy-Bruhl D, et al. Vaccine adverse event monitoring systems across the European Union countries: time for unifying efforts. *Vaccine* 2009, May 26;27(25-26):3376-84.
[20] 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 March 12; 89:371-378.
[21] World Health Organization. Global Manual on Surveillance of Adverse Events Following Immunization [Internet]. Geneva: World Health Organization; 2014. 128 p.
[22] Act for the compensation of vaccination damages (Impfschadengesetz, BGBI nr. 371/1973) (in German). Vienna: Bundeskanzleramt; 1973.
[23] The Danish Liability for Damages Act. Copenhagen: Patientforsikringen; 2010.
[24] *Finnish Pharmaceutical Insurance Pool* [Internet site]. Helsinki: Finnish Pharmaceutical Insurance Pool; 2011. Available from: http://www.lvp.fi/en/
[25] *Protection against infection act (Infektionsschutzgesetz - IfSG), 1045; 20 July 2000*. Berlin: Federal Law Gazette; 2000. Available from: https://www.rki.de/EN/Content/infections/inf_dis_down.pdf?__blob=publicationFile
[26] Act on patient insurance no. 111/2000. Reykjavik: Ministry of Welfare; 2000.
[27] Patient Injury Act of 15 June 2001 no. 53 (in Norwegian). Oslo: Ministry of Health; 2001.
[28] The Undertaking (Indemnity rules). Stockholm: Lakemedelsforsakringen (LFF);2009
[29] Federal law from 18 December 1970 on communicable disease control (Epidemics act) 818.101. Berne: Federal Authorities of the Swiss Confederation; 1970.
[30] The Regulatory Reform (Vaccine Damage Payments Act 1979) Order 2002, Statutory Instrument 2002 no. 1592. London: Office of Public Sector Information; 2002.
[31] 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 March 12; 89:371-378.

and immunization coverage have been strengthening or introducing new elements into their systems (such as Armenia and Georgia) and others introduced penalties in an effort to increase compliance (such as Belgium and Croatia), accompanying the mandatory immunization provisions.

Penalties

Penalties for noncompliance must be considered when analyzing a mandatory legislative framework for immunization. According to our research, one-third of the countries (18/53) have introduced penalties to support enforcement of mandatory provisions. Although there have been examples of enforcement in Europe, penalties can be difficult to enforce, whether through monetary fines (such as Albania, Czech Republic and Slovenia) and even criminal charges for negligence (such as France). Apart from Cyprus, Germany and Moldova, all countries that have a mandatory approach also have penalties in place.

Mandatory immunization requirements for school attendance

Nineteen countries require a child to be immunized to attend school under education-related legislative provisions. When an immunization requirement is present to attend school, it is actually relevant to children under 24 months, the age group most vulnerable to childhood vaccine-preventable diseases. But because children enter school much later — typically beginning at five years old — the enforcement mechanisms do not enable timely follow-up with parents who delay immunization, or those who refuse it altogether. In these cases, the requirement exists but may not be adequately implemented. Approximately half of the countries (23/53) in this study do not require a child to be immunized to attend school and all of these follow the *recommended* or *recommended with robust monitoring and follow-up* approaches.

Cyprus and Moldova are classified with a *recommended with mandatory requirements for school attendance* approach. While it is possible to interpret the education-related provision as rendering immunization mandatory, in this study, immunization systems were evaluated and considered mandatory only if immunization- or health-related legislation included a vaccine mandate. In cases where health legislation contains provisions that stipulate that immunization is recommended, the approach is qualified as recommended, as is the case with Moldova and Cyprus. In Moldova, education-related provisions mandate immunization for school entry and the Constitutional Court has upheld this provision when challenged. While a case could be made that Moldova is an example of a mandatory framework, to distinguish this case from other countries, we chose to qualify the system as *recommended with mandatory requirements for school attendance*. See the Moldova case study (Annex VII) for more detail.

Germany is an outlier since it has a *recommended with robust monitoring and follow-up* approach and no immunization requirements for school attendance, yet a newly passed law introduces penalties in case of vaccine refusal. Documentation of immunization status is required for entry to kindergartens and schools. While failure to vaccinate does not constitute a reason for refusing to enroll children to kindergarten or school, the state may fine the family of the unvaccinated child. Please refer to the country frameworks section below (pages 18-21) for more detail.

Court rulings

For any legislative framework, how courts have interpreted the laws impacts how the framework is enforced. Reviewing court cases, regardless of the judicial outcome, can provide information and insights on a country's attitude toward vaccines, as the adjudication of such issues can reveal the local or national dialogue on immunization legislation.

The Matrix includes a question that explores whether a court has ruled on mandatory immunization legislation. Out of 53 countries, our project identified 10 whose constitutional courts have ruled on mandatory immunization cases. In seven out of 10 countries (Belgium, Croatia, France, Italy, Moldova, Slovakia and Switzerland), courts ruled in support of mandatory approaches prescribed in legislation. In Moldova, a recent court ruling upheld the introduction of mandatory immunization requirements for school attendance when challenged by parents that their children's right to education was being infringed upon. In Switzerland, a court supported mandatory regional

immunization requirements (Canton of Vaud) over the federal legislation which contains provisions making immunization voluntary.

In the Czech Republic, Lithuania and Turkey, courts ruled against a mandatory approach. Lithuania and Turkey have recommended approaches to immunization, while the Czech Republic has a *recommended with mandatory requirements for school attendance* approach. In Ukraine, the Constitutional Court has not ruled on this issue, although administrative provincial courts have ruled on it several times. The rulings in Ukraine have both supported and opposed a mandatory approach, creating some confusion as to the strength of mandatory immunization requirements.

The impact of court rulings on a legislative framework for immunization is important to policy makers. How courts interpret legislative provisions — in light of the broader constitutional framework in a country — is a consideration for policy makers, especially when working to strengthen immunization mandates. This nuance makes it difficult to classify a country's legislative framework. Therefore, the analysis that follows excludes the outcome of court cases. This situation is explored in the case studies of Moldova, Ukraine and the Baltic States, which all describe and partially analyze court rulings regarding mandatory immunization.

Analysis

Mandatory immunization is neither uniformly defined nor implemented across the region. The immunization programs, their legislative provisions and experience among different countries vary significantly, which makes defining "mandatory immunization" in discrete terms challenging. Looking across 53 very different cultural, economic, political and administrative contexts makes this even more challenging. Each country has a unique situation across a range of recommended and mandatory approaches.

Constitutional and legal frameworks vary across countries and immunization legislation is complicated, allowing for wide variance in provisions, enforcement mechanisms and interpretations. As a result, attempts to codify and categorize legislative frameworks can take many forms. For this review, we focused on analyzing and categorizing legislative frameworks in two ways that are useful for policy makers. First, we analyzed the breakdown of countries across the region based on the answers provided to the eight Matrix questions. Next, we conducted a more detailed analysis, weighing answers to the Matrix questions against other insights and variables identified during the research, to categorize the complete legislative framework for immunization into the five-category Likert Scale.

Categorizing country frameworks based on the answers to the eight Matrix questions

By categorizing countries on a legislative provision mandating that individuals be immunized, the split among the 53 countries is almost even, with 25 countries embracing recommended provisions and 28 mandatory ones. Most countries fall in middle range of the Matrix and embrace a mixed approach; only three out of 53 countries employ all eight mandatory provisions in the Matrix.

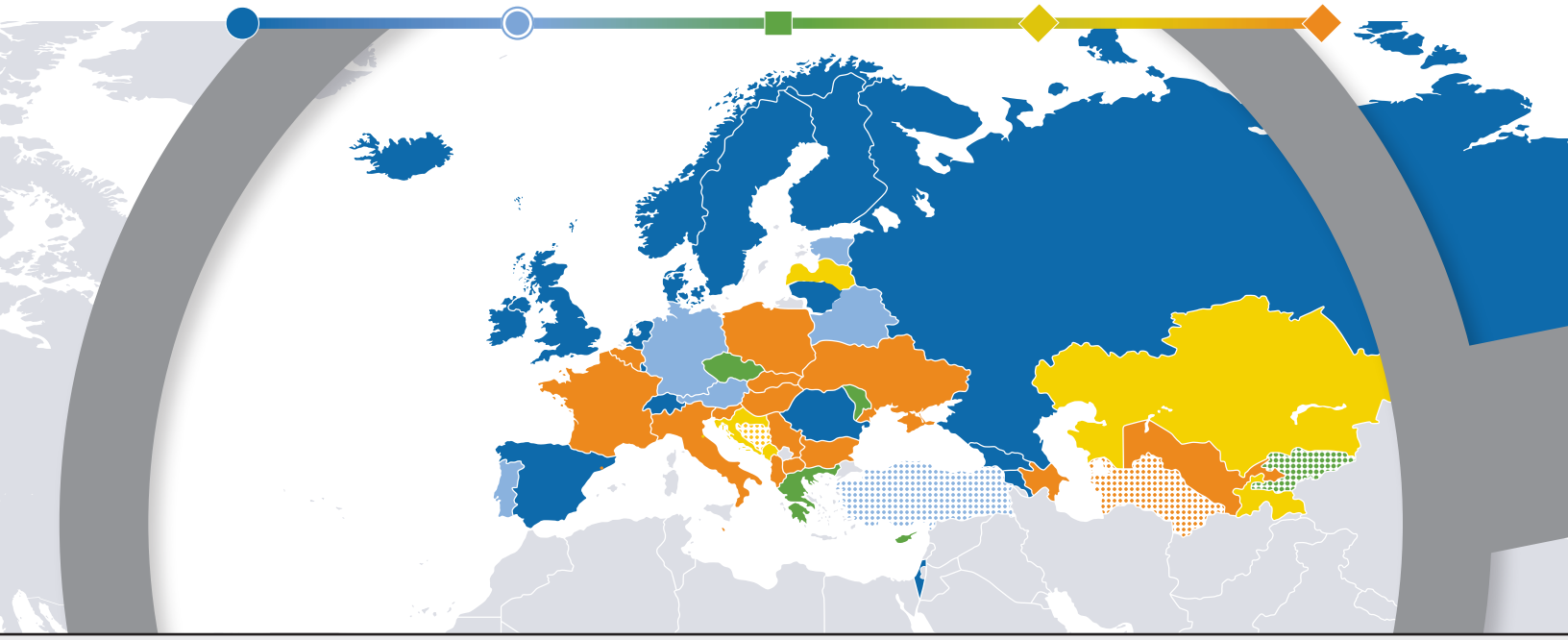
Creating a Likert Scale to capture and categorize the various approaches

Next, the team conducted a further, in-depth analysis using the Matrix and other research to develop a Likert Scale. In total, the team identified five categories in which all 53 countries fit. See Table 1 for a description of each category, followed by the Likert Scale: Assessing Levels of Immunization Legislation.

Table 1
Likert Scale: Assessing Levels of Immunization Legislation
Likert Scale Category Descriptions

APPROACH	CHARACTERISTICS	EXAMPLES
● **Recommended**	Immunization is recommended; No mandatory provisions in either health- or education-related legislation, and no enforcement provisions. Monitoring mechanisms are in place to assess coverage and provide data.	Denmark, Finland, Norway, Sweden, United Kingdom
◉ **Recommended with robust monitoring and follow-up**	Immunization is recommended, with or without enforcement provisions. Robust monitoring and follow-up mechanisms are in place in the case of non-immunization.	Austria, Estonia, Germany
■ **Recommended with mandatory requirements for school attendance**	Immunization is recommended; Enforcement provisions are in place that can prevent a child from attending school if not immunized, effectively rendering immunization somewhat mandatory. Monitoring and follow-up mechanisms are in place to assess coverage and provide data.	Cyprus, Greece, Moldova
◆ **Mandatory immunization with monitoring and follow-up**	Immunization is mandatory, with limited enforcement provisions. Monitoring and follow-up mechanisms are limited or do not exist.	Croatia, Latvia, San Marino
◆ **Mandatory immunization with robust monitoring and follow-up**	Immunization is mandatory, with robust enforcement provisions. Robust monitoring and follow-up mechanisms are in place.	Belgium, France, Italy

Likert Scale: Assessing Levels of Immunization Legislation



Recommended | **Recommended with robust monitoring and follow-up** | **Recommended with mandatory requirements for school attendance** | **Mandatory immunization with monitoring and follow-up** | **Mandatory immunization with robust monitoring and follow-up**

- Albania
- Andorra
- Armenia
- Austria
- Azerbaijan
- Belarus
- Belgium
- Bosnia and Herzegovina
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Georgia
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Israel
- Italy
- Kazakhstan
- Kyrgyzstan
- Latvia
- Lithuania
- Luxembourg
- Macedonia
- Malta
- Moldova
- Monaco
- Montenegro
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russian Federation
- San Marino
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Tajikistan
- Turkey
- Turkmenistan
- Ukraine
- United Kingdom
- Uzbekistan

*Researchers do not have sufficient information to place with confidence; probable area marked in light of coverage indicators

Level 1 – Recommended

On one end of the spectrum, we identify the *recommended* approach to immunization. 17 countries fit this category because they have no legislation creating an obligation to vaccinate, no enforcement provisions and no immunization requirements to attend educational institutions. Immunization is described as a right of individual choice throughout legislation. For this classification, monitoring mechanisms are in place to assess immunization coverage and provide data.

The United Kingdom's recommended approach

The United Kingdom (UK) introduced mandatory immunization in the 19th century,[32] but the government switched to a voluntary approach as the smallpox epidemic subsided and coverage levels improved. The UK has a flexible and strong program, with 88-98 percent coverage in 2017[33] and a clear right to immunization stated in the National Health Services' (NHS) Constitution (2012)[34] that stipulates the population's "right to receive vaccinations." Based on this mandate, the NHS can commission its partner agencies, Public Health England and the Department of Health, to comply with more than 10 "service specifications" on immunization to ensure delivery and funding of high-quality services. Immunization-related legislation is supported by evidence-based decision making system, multidisciplinary cooperation and a tailored and well-integrated communication strategy.[35] A results-based financing system is used that is regulated by contracts signed with family doctors. The UK delivers immunization in schools to improve immunization coverage among children and adolescents, which was especially successful during the introduction of the HPV vaccine. Additionally, the NHS actively cooperates with professional and charitable organizations and civil society to advocate for and promote immunization, for example through the provision of accurate and timely information and addressing parents' concerns regarding immunization.

Finland

Finland has a strong voluntary immunization program supported by regulations requiring health exams for children and requiring that providers offer counseling on vaccines. Government Decree 338 (2011) (see Database)[36] requires that municipal health systems ensure that children less than one year old have at least nine health exams annually and that children aged six years have at least six exams annually. During these visits, nurses meet with the child and his or her parents to review the child's health, development, social context and immunization status. If the family accepts immunization, nurses must also give recommended vaccines during this visit. Integrating immunization with other primary care services has led to higher coverage, lower costs per fully immunized child and less vaccine hesitancy. The Health Care Act (2010) (see Database),[37] Government Decree 338, and the Communicable Diseases Act (1986) (see Database)[38] place the responsibility of implementing the national immunization program on local municipalities. Each municipality collects taxes and provides a comprehensives package of child health services, including preventive interventions, such as immunization. Due to the integrated nature of child health clinic costs, there is no separate budget for immunization. However, by bolstering preventive health and primary care services, Government Decree 338 has encouraged municipalities to strengthen immunization funding.

[32] Finnegan G. "Mandatory Vaccination: Does it work in Europe?" [Internet] Vaccines Today; 2017 November 27. Available from: https://www.vaccinestoday.eu/stories/mandatory-vaccination-work-europe/
[33] Anon. United Kingdom of Great Britain and Northern Ireland: 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/gbr.pdf
[34] The NHS Constitution for England [Internet]. London: Department of Health and Social Care; 2015 Oct. Available from: https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england
[35] Salisbury D, Martin R, Van Damme P, Lopalco PL. Immunization in Europe. Vaccines 2013; (6) 1334-1352 Available from: https://doi.org/10.1016/B978-1-4557-0090-5.00068-9
[36] Government Decree 338 (2011) on maternity and child health clinic services, school and student health services and Preventative oral health services for children and youth (Health Care Act 2010). Helsinki: Ministry of Health and Social Affairs; 2011.
[37] Health Care Act no. 1326 (2010). Helsinki: Ministry of Health and Social Affairs; 2010.
[38] Communicable Diseases Act No. 583 Issued on 25 July 1986. Helsinki: Ministry of Health and Social Affairs; 1986.

Level 2 – Recommended with robust monitoring and follow-up

This next category along the spectrum includes five countries that also have no legal obligation to vaccinate. This classification includes measures that are designed to provide an incentive or motivate parents to vaccinate their children, as well as robust monitoring mechanisms that enable health professionals to track immunization and conduct follow-ups.

Germany

Germany has high immunization coverage ranging between 88-98 percent for most vaccines. The coverage for the first two doses of a measles-containing vaccine (MCV1 and MCV2) is quite high at 93 and 97 percent respectively.[39] In Germany, immunization is not required to attend school. In accordance with the Infectious Diseases Protection Law (IFSG),[40] the Federal Ministry of Health has appointed an independent expert committee for immunization recommendations called the Standing Vaccination Commission (STIKO). STIKO recommends vaccines that are of high value for the health protection of the individual and the general public to prevent communicable diseases (§ 20 (3) IFSG).[41] Immunization recommended by STIKO are covered by the statutory health insurance. The assessment and recognition of vaccine damage applies only to publicly recommended immunization (§ 60 IFSG).

In 2015, the law was amended[42] and parents now must submit information about the immunization status of their children and the guidance received from health professionals to kindergartens and schools. Failure to vaccinate does not constitute a reason for refusing to enroll children to kindergarten or school, but the educational institution is obliged to notify relevant healthcare agencies about unvaccinated children. Schools have the right to demand the child's expulsion. Based on the information provided by the school, the state may fine the family of the unvaccinated child.[43] In exceptional situations, the Ministry of Health of the Federal Republic of Germany or the local federal governments are also authorized by legal decree to compel segments of the population to be vaccinated.[44]

Level 3 – Recommended with mandatory requirements for school attendance

Four countries use this mixed strategy approach where immunization is recommended. Although no stand-alone statutory obligations to vaccinate exist, legal provisions require immunization to attend educational institutions. Immunization is recommended under the immunization- or health-related legislation, but education-related legislation provisions require immunization to attend school. This effectively renders immunization somewhat mandatory, since an unvaccinated child cannot attend an educational institution. Monitoring and follow-up mechanisms are in place to assess coverage and provide data.

Moldova is an effective illustration of this approach, since the country does not have mandatory immunization requirements per se, but immunization is required for school attendance, which creates a clear compulsion. Moldova's legislative framework for immunization is reviewed in more detail in the Moldova case study.

Cyprus

Cyprus has high immunization coverage, varying between 81 percent (Pneumococcal conjugate third dose, or PCV3) and 99 percent. MCV1 coverage is at 96 percent and MCV2 at 85 percent, with a dropout rate of around

[39] Anon. Germany: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited July 4, 2018]. Available from: http://www.who.int/immunization/monitoring_surveillance/data/deu.pdf
[40] Law on Prevention and Control of Infectious Diseases in humans (Infection Protection Act - IFSG), 2000 [statute on the Internet]. c2018 [cited 2018 July 7]. Available from: https://www.gesetze-im-internet.de/ifsg/IfSG.pdf
[41] Law on Prevention and Control of Infectious Diseases in humans (Infection Protection Act – IFSG - §20, 3), 2000 [statute on the Internet]. c2018 [cited 2018 July 7]. Available from: https://www.gesetze-im-internet.de/ifsg/IfSG.pdf
[42] Gesetz zur Modernisierung der epidemiologischen Überwachung übertragbarer krankheiten. Federal Law Gazette. 2017 Nov 24; 49: 2615.
[43] According to the existing policy, parents have the right to refuse vaccination, but this may result in a EUR 2500 fine (medical exemptions are accepted).
[44] Provided that an infectious disease with serious clinical consequences arises and it is estimated that an epidemic is spreading (Infectious Diseases Protection Law – IfSG – §20, 6, 7)

10 percent.[45] According to the Department of Primary Education, nine vaccines are required for school attendance: diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B and Meningococcal C. Additionally, if the child has not been vaccinated or if they require a booster, immunization will be carried out in school.[46] Once again, mandatory immunization is not mentioned in the health- or immunization-related legislation, but is in mandatory for school attendance.

Level 4 – Mandatory immunization with monitoring and follow-up

Under this approach, countries mandate immunization through legislative provisions, but do not legislate a specific enforcement provision. Monitoring and follow-up mechanisms are limited or do not exist. Six countries take this approach.

Latvia

As explored in the Baltic States case study, Latvia's NIP includes both recommended and mandatory vaccines. Section 30 of the Epidemiological Safety Law (1997) states that the Cabinet of Ministers determine which groups receive mandatory immunization and against which diseases. "Vaccine Regulation" No. 330 (2000) further clarifies this provision and states that "[w]ithin the framework of the State Immunisation Programme vaccination shall be mandatory for (3.1.) children." The legislation additionally stipulates that immunization must be monitored and verified, and that physicians must explain the advantages of immunization when vaccines are refused. Latvia employs an eHealth system to monitor and verify immunizations, though the system has experienced "substantial deficiencies" in the implementation. For instance, only 11 percent of health care professionals and pharmacists at the time of roll-out were informed or given guidelines on the eHealth project, severely limiting its efficacy.[47] Additionally, there are no required immunizations to attend educational institutions or penalties for noncompliance. Such limited enforcement provisions and monitoring mechanisms led to a classification as *mandatory immunization with monitoring and follow-up.*

Level 5 – Mandatory immunization with robust monitoring and follow-up

This approach – used in 17 countries – is on the far end of the spectrum and includes mandatory immunization provisions, together with robust financing, enforcement provisions and monitoring and follow-up mechanisms. Enforcement provisions can range from fines to incarceration.

Italy

Italy's coverage is slightly lower than that of its neighbors, between 83-97 percent.[48] Italy was an example of a *mandatory immunization with monitoring and follow-up* approach, due to lack of harmonization in vaccine policy at the national level (different vaccines were available in different regions), lack of monitoring and inconsistent financial provisions. With the introduction of new legislation, Italy has addressed some of these issues and moved into the *mandatory immunization with robust monitoring and follow-up* classification.

[45] Anon. Cyprus: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 2018 July 4]. Available from: www.who.int/immunization/monitoring_surveillance/data/cyp.pdf
[46] Ministry of Education and Culture (Cyprus). Procedures through which services are provided to citizens/businesses: Pupils' registration/transfer in Public Primary schools [Internet]. Cyprus: Ministry of Education and Culture; 2018 [cited Aug 2018]. Available from: http://www.moec.gov.cy/dde/en/infoserv_primary_registrations_ages_4_5.html
[47] Pulmanis E. Implementation of the eHealth Project in Latvia: Project audit perspective. State Audit Office of the Republic of Latvia. PM World Journal. 2018 October; 5(10). Available from: https://pmworldjournal.net/wp-content/uploads/2016/10/pmwj51-Oct2016-Pulmanis-eHealth-project-audit-perspective-featured-paper.pdf;
[48] Anon. Italy: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 2018 July 4]. Available from: www.who.int/immunization/monitoring_surveillance/data/ita.pdf

Under a law passed in 2017 (see Database),[49] the number of mandatory vaccines required increased from four to 11. The Livelli Essenziali di Assistenza (LEA), which is a financing mechanism and includes a list of essential services available to all residents free-of-charge for specific age cohorts, now includes an immunization plan and requires the 11 vaccines. Prior to the adoption of the new program, the immunization plans were decentralized with variability across regions. By centralizing immunization in the LEA, the Health Ministry has ensured that Italy's 19 regions and two autonomous provinces adhere to a uniform immunization calendar for the 11 antigens and all citizens receive the vaccines.

Slovenia

Slovenia has a robust immunization program with high coverage that varies between 93-98 percent.[50] In Slovenia, nine vaccines are mandatory in accordance with the program of "immunization and protection with drugs" (see Database).[51] Medical exemption is the only listed justification for vaccine refusal. To obtain a medical exemption, an individual must issue a formal request detailing the medical circumstances, which is then sent to the MOH where a commission will review it. The commission delivers its expert opinion to the MOH on whether a medical exemption should be granted.

Fines for noncompliance and refusal to vaccinate range from 41 to 417 Euros under the Infectious Diseases Law.[52] Kindergartens and schools cannot demand to see a child's immunization record, but they require a doctor's certificate certifying a child's fitness and ability to attend the educational institution, which includes their immunization status.

Importantly, Slovenia has a well-regulated compensation program for AEFI, where any person whose health is damaged by mandatory immunization — as evidenced by serious and lasting reduction of vital functions — is entitled to compensation. This reinforces the implementation of mandatory immunization in practice by guaranteeing compensation to individuals in cases of AEFIs; the implementation of mandatory immunization is reinforced and thereby strengthens the credibility of vaccines and confidence in the immunization program. A more in-depth description and illustration of AEFI compensation programs can be found in the Nordic countries case study.

Exceptions to classifications

Several countries in this study, notably Belgium and Switzerland, could not be easily classified in the Likert Scale. Belgium is classified with a *mandatory immunization with robust monitoring and follow-up* legislative approach, but it could be considered to have a *recommended with mandatory requirements for school attendance* approach. In such cases, a classification was selected by the study team to best reflect the country situation and based on data gathered for the Matrix. This additional detail — available in the Matrix — provides context for greater insight into the particular dynamics of each country.

Belgium has a high coverage rate for most vaccines, 85-99 percent, the lowest being for MCV2 at 85 percent.[53] The three distinct subnational regions in Belgium each manage their own immunization programs, yet the immunization schedule is identical across their geo-cultural boundaries and each region must comply with the National Health Council (NHC) recommendations. The NHC's recommended vaccines are provided at no cost by the regional authorities under their respective programs. The national recommendations for infant immunization include 11 antigens; polio vaccination is the only mandatory one for infants under a federal law dating back to 1958.[54] Documented confirmation of polio vaccination must be submitted to the municipal administration at 18

[49] Under a law passed in 2017, the number of mandatory vaccines required for entry into public schools and daycares increased from four to 11

[50] Anon. Slovenia: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 1 December 2018]. Available from: https://www.who.int/immunization/monitoring_surveillance/data/svn.pdf

[51] Constitutional court case law. (2018). Odlocitve.us-rs.si. Retrieved 16 November 2018, from http://odlocitve.us-rs.si/en/odlocitev/AN02772

[52] Slovenia - EFVV - European Forum for Vaccine Vigilance. (2018). EFVV - European Forum for Vaccine Vigilance [cited 16 November 2018]. Available from https://www.efvv.eu/slovenia-2/

[53] Anon. Belgium: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 2018 July 4]. Available from: www.who.int/immunization/monitoring_surveillance/data/bel.pdf

[54] Subnational immunization programmes in Belgium- Focus on hepatitis B. Brussels, Belgium: 7 November 2017. Available from: http://www.vhpb.org/files/html/Meetings_and_publications/Presentations/BRUS51B.pdf

months of age or parents/guardians will incur a penalty. The polio provision results in Belgium being classified as *mandatory immunization with robust monitoring and follow-up* on the Likert Scale.

As of January 1, 2017, Belgium's vaccine recommendations changed to use the hexavalent vaccine, which includes the inactivated polio vaccine (IPV) and five other antigens (diphtheria, tetanus, pertussis, Hib and hepatitis B), for immunizing infants, as IPV might simply not be available on its own. In practice, this could lead to either children being vaccinated with all six antigens to fulfill the mandatory polio requirement or some parents refusing vaccination with the hexavalent altogether (including polio) since it is a recommended vaccine. In this circumstance, the legislation is outdated and does not take into account the realities of the changing vaccine supply, the availability of certain vaccines and the changing nature of immunization practices (less jabs but more antigens administered). A similar situation occurred in France where three vaccines are mandatory, but only supplied in a hexavalent vaccine. See the France case study (Annex VI).[55]

There is a further difficulty in classifying Belgium, since its requirements around immunization for school attendance also differ among its regions. A school-aged child in the Wallonia (French) region must be vaccinated according to the procedures set out in Article 31 of the French Government's Decree of February 27, 2003[56] requiring immunization for polio, as well as six other antigens (diphtheria, pertussis, meningitis [Haemophilus influenzae type B, or Hib], measles, mumps and rubella).[57] The same Decree recommends, but does not require, three additional antigens (pneumococcal, Meningococcal C and hepatitis B). In contrast, there are no such requirements in the Flemish (Dutch) region or the German-speaking community. This legislative context makes it difficult to categorize Belgium. We have chosen to classify Belgium as a *mandatory immunization with robust monitoring and follow-up*, yet this classification can be challenged as not reflecting the whole country.

A similar difficulty with classification due to regional differences arises in Switzerland. There, federal legislation contains provisions making immunization voluntary; however, the Canton of Vaud (a region) makes immunization mandatory at the regional level. We chose to classify Switzerland as a *recommended* approach; however, the mandatory approach in one region is not reflected.

Building on the findings of previous studies

As noted, legislative changes to strengthen mandatory immunization requirements in several countries in the region (e.g., France and Italy) have followed recent measles outbreaks. A historical comparison of the legislative changes that have occurred in the region would allow us to gauge the magnitude of these changes. A previous study conducted in 2010 by the Vaccine European New Integrated Collaboration Effort (VENICE) network[58] provides an opportunity for such a historical comparison.

The VENICE survey considered 29 countries, including 27 European Union (EU) states, Iceland and Norway, to capture information regarding the degree to which immunization-related legislative provisions in the region were recommended (voluntary) or mandatory. One limitation cited by the VENICE survey was the lack of historical data that could be used for comparison and analysis, to determine if a change in policy can influence trends in immunization. Our research, which includes the 29 countries in the VENICE survey, helps fill this gap.

[55] Samia and Marc Lalere were charged under two legal provisions–a provision in the Code of Public Health (le code de la santé publique, art. L.3116-4) that imposes a fine of 3750 euros and up to six months in jail for those who do not receive, or allow those under their guardianship to receive mandatory vaccinations, including parents ("Le refus de se soumettre ou de soumettre ceux sur lesquels on exerce l'autorité parentale ou dont on assure la tutelle aux obligations de vaccination prévues aux articles L. 3111-2, L. 3111-3 et L. 3112-1 ou la volonté d'en entraver l'exécution sont punis de six mois d'emprisonnement et de 3 750 Euros d'amende").

[56] Anon. Summary report on immunization programs in Belgium: Vaccine European New Integrated Collaboration Effort (VENICE III) [Internet]. VENICE, 2008 [cited August 2018]. Available from: http://venice.cineca.org/documents/belgium_ip.pdf

[57] Subnational immunization programmes in Belgium- Focus on hepatitis B. Brussels, Belgium: 7 November 2017. Available from: http://www.vhpb.org/files/html/Meetings_and_publications/Presentations/BRUS51B.pdf

[58] ASSET (Action plan on Science in Society related issues in Epidemics and Total pandemics). "Compulsory vaccination and rates of coverage immunisation in Europe" [Internet]. ASSET; 2016 January [cited 2018 Aug]. 6 p. Available from: http://www.asset-scienceinsociety.eu/reports/pdf/asset_dataviz_I.pdf

The VENICE survey found in 2010 that, “In total 15 countries do not have any mandatory immunization; the remaining 14 have at least one mandatory immunization included in their programme.”[59] Eight out of the 15 countries that had mandatory provisions had a mixed approach, combining some recommended and some mandatory vaccines. In these eight countries, “recommended” indicated that vaccines are recommended for the entire population and mandatory was applied only to certain risk groups. In 2018, our study found that out of the same 29 countries, 16 do not have any mandatory immunization, while 13 have at least one included in their program. This is similar to the findings of the VENICE survey in 2010. Table 3 further illustrates this (Annex IV), showing historical changes in legislative frameworks across these countries.

Several significant changes have occurred within the NIPs of these countries. In most cases, countries have strengthened already existing mandatory provisions, for example, by increasing the number of mandatory vaccines (in France and Italy, by introducing mandatory immunization requirements for school attendance and/or introducing immunizations at schools (in Cyprus), by reducing the available exemptions (in France), or by speaking to the parents and reporting those who still refuse to vaccinate (in Germany). As a result, no visible change is reflected in their status in Table 3 from recommended to mandatory, although it is important to analyze whether the changes that occurred do have a significant impact on the program.

These legislative changes are recent, with most laws updated in 2017 and 2018. Therefore, the impact on coverage is difficult to assess. However, our study begins to examine the potential impact of these changes (see France case study). It is worth noting that the increase in Italian coverage rates for the first half of 2018 seems to point to a potential positive impact on the laws making more vaccines mandatory. Unfortunately, due to the shift in Italy’s governing elite in mid-2018, some of these legislative changes have been reversed and the impact on immunization is currently uncertain. Future analysis and research are necessary to assess the possible effect of the legislation in this situation.

Our study examined one of the conclusions of the VENICE survey stating that the data did not suggest any obvious relationship between immunization coverage and national policies on mandatory immunization. The VENICE survey stated that countries where a given vaccine is mandatory do not usually reach better coverage than neighboring or similar countries where there is no such legal obligation, as evidenced by the Baltic countries. We examined the immunization-related legislative provisions in the Baltic States (see Baltics case study) and noted that over the last decade, Latvia, with its mandatory approach, has consistently exhibited slightly higher coverage than Estonia and Lithuania, where immunization is voluntary. Although it is not possible to show causation with the current data, further research and analysis may provide insight on uptake provenance.

A more detailed analysis of the data across the two projects would help determine if countries using a more mandatory approach have realized improved or declining coverage. Additional analysis would also enable us to determine if the changes made in legislative approaches through the period of comparison were accompanied by changes in immunization coverage and, importantly, if the impact of legislative changes on coverage could then be isolated.

Conclusions

The landscape of legislative frameworks for immunization across the European Region is complex with a wide range of approaches, which have been classified in this study through five levels of immunization laws. On one end of the spectrum is a *recommended* approach while on the other end is *mandatory immunization with robust monitoring and follow-up*, which combines legal mandates with enforcement mechanisms. In the middle are three levels with frameworks that do not mandate immunization explicitly, but use various enforcement provisions — primarily school entry requirements and immunization coverage monitoring — to encourage immunization.

[59] Haverkate M, D’Ancona F, Giambi C, Johansen K, Lopalco PL, Cozza V, Appelgren E, on behalf of the VENICE project gatekeepers and contact points. Mandatory and recommended vaccination in the EU, Iceland and Norway: results of the VENICE 2010 survey on the ways of implementing national vaccination programmes. Euro Surveill. 2012;17(22):pii=20183. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20183

Wide variety across the region does not point to any one "best approach"

Analysis of varied legislative approaches across the European Region does not point to any one "best approach." Instead, our research reinforces the principle that country context, social dynamics, political realities and the constitutional relationship between a government and its citizens all play a role in how a country approaches its legislative framework for immunization. Further, the context of the broader immunization program such as financing, supply, program management, health system oversight and accountability, healthcare worker training and capacity, AEFI surveillance and no-fault compensation mechanisms, coverage monitoring, public communications, social norms and other factors all influence the success of legislative efforts to recommend or mandate immunization. Regardless of the approach, local and country context is critically important for policy makers to consider when evaluating the use of legislative tools to recommend or mandate immunization through law.

Impact of legislative approach on immunization coverage

While a correlation analysis was not part of the study scope, data gathered and presented in the Likert Scale helps to illustrate trends across the region and reinforces prior studies that indicate no identifiable correlation between legislative approach and immunization coverage rates.[60,61,62] In fact, data gathered for this study illustrates that some countries at the two opposing ends of our Likert Scale have the highest and most consistent coverage and the lowest number of outbreaks. Interestingly, a majority of countries fell into the middle range of our Likert Scale and have lower coverage rates. To provide further insight, the case studies explore a range of legislative approaches and coverage rates. Correlation between legislative approach and immunization coverage rates is a topic recommended for further research and advanced data analysis.

Need to look beyond health legislation for additional tools

Health legislation is just one aspect of a broader legislative framework for immunization. Identifying the legislative framework requires looking beyond health legislation to fundamental constitutional issues (role of government, rights of citizens) and immunization-related provisions in education-related legislation. Often education-related legislation can be helpful in enforcing school entry requirements and identifying opportunities to educate citizens about the benefits of immunization. See the legal memo in Annex for more detailed analysis (Annex I).

Need for more research

Leveraging the initial analysis and dataset to further assist country policy makers in understanding the connection between varying approaches to immunization legislation and coverage rates, future analysis could dive deeper into select country immunization legislation and track changes in legislation over time. Adding these two dimensions would enable correlations between legislation, policy and immunization coverage rates. Further analysis could focus on countries where legislative provisions have changed, and enough time has elapsed to identify the impact of these changes on coverage rates. An additional study on other aspects of the legislative framework for immunization (budgeting, program management, procurement, etc.) may complement and enrich the findings from this study and offer policy makers a wider range of tools to consider. Expanding this type of analysis to other regions or to more detailed sub-regional analysis could yield valuable results for other regions in the world struggling to maintain high immunization rates.

---

[60] Macdonald NE, Harmon S, Dube E, Steenbeek A, Crowcroft N, Opel DJ, et al. Mandatory infant & childhood immunization: Rationales, issues and knowledge gaps. Vaccine 2018;36:5811–8. doi:10.1016/j.vaccine.2018.08.042

[61] D.A. Salmon, S.P. Teret, C.R. MacIntyre, D. Salisbury, M.A. Burgess, N.A. Halsey Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future
Lancet, 367 (9508) (2006), pp. 436-442

[62] Haverkate M, D'Ancona F, Giambi C, Johansen K, Lopalco PL, Cozza V, et al. Mandatory and recommended vaccination in the EU, Iceland and Norway: results of the VENICE 2010 survey on the ways of implementing national vaccination programmes. Eurosurveillance 2012;17. doi:10.2807/ese.17.22.20183-en.

Limitations

A limitation to this research was the sheer scope and breadth of the research parameters across 53 countries in the European Region. While documenting specific legislation related to immunization was relatively straightforward, there were obvious limitations in the ability to analyze findings, conduct comparisons and fully investigate the detail and nuances that exist across 53 different countries. The case studies helped address this limitation, but further analysis with smaller elements of data may lead to useful findings.

Satisfying a threshold for survey responses was a challenge and limitation. Survey recipients were based on a list of key country contacts provided by WHO/Europe and email was the chosen method for outreach. Only a few of the experts were contacted via other methods such as phone calls; most simply responded electronically. Given this arrangement, the project assumed a rate of response of between 50 and 75 percent for the survey. We have reached an almost 50 percent response rate (47 percent, 25/53 countries) in terms of countries; however, not all surveys were complete (some questions were skipped) and not all answers were complete or clear enough to be used in the final analysis.

A further limitation was the lack of response on the part of many countries. Verification of data through the development of one-pagers was used to mitigate this issue, but the response rate was 15-20 percent and responses were not as complete as desired. For future survey efforts across the region, it will be critical to leverage networks and experience connecting with country representatives to increase the response rate.

Operating with more than 40 official languages used in the European Region was a challenge. Russian and English were the two working languages of the project. The research team relied on translation services for some documents and validating the accuracy of translations was an obstacle. A clear understanding of linguistic nuances was very important in the interpretation of legal documents, as even a small detail may have a strong bearing on the meaning and, more importantly, on the interpretation of a law.

Understanding country context is also important to assess and analyze how a law is implemented in practice. Consequently, even where authoritative secondary sources were identified for a legislative provision in place, in some instances the actual provision and its official translation could not be located to confirm the study results. To expand this project further and utilize primarily original legislative sources, extensive translation services would be required. However, given the authoritative nature of the secondary sources considered here (law review articles, international newspapers, etc.), the project team remains confident in the accuracy of the collected information.

Despite the limitations, the research team collected data on each of the 53 countries included in the analysis. The result is a comprehensive examination that included assessment and analysis of legislation, supporting documents, national constitutions, public regulations, decrees and other relevant information on country immunization programs. This led to a comprehensive review of legislation on immunization in the European Region that will serve as an important point of reference for countries considering changes to their legislative frameworks for immunization and pave the way for further analysis of the region.

Annex I: Europe's Immunization Tapestry: Legal Frameworks for Immunization

Increasingly, public health professionals have explored the potential of law to improve population health.[63] Experts and researchers typically utilize legislation, policy and regulation in their work; however, they are not characteristically included in the process, whereby science and theory are applied to law and policy.[64] While law and policy impact health systems, evolving health priorities also inform feedback for legislative changes. Understanding this dynamic interaction presents a useful dimension for evaluating public health systems and analyzing the context in which people make health decisions.

The development **of Legislative Approaches to Immunization across the European Region** and the **European Immunization Policy Database** are efforts to further our understanding of such interactions within the context of immunization policies and national immunization programs.

Legal analyses, such as those provided by the **O'Neill Institute for National and Global Health Law (O'Neill)**, deliver essential insights that add depth to public health work and research. A multidisciplinary approach helps to facilitate greater understanding of the wide variety of factors influencing what does and does not work in global public health. For its employment of a diverse set of technical experts, the Sabin study is a standout in the field in scope and quality.

Just as public health professionals do not start planning or analyzing a country's immunization program without having understood the disease burden and the characteristics of available vaccine products,[65] legal experts start by examining the layers of legal framework that surround and support the immunization program: Constitution, national law, regulation and policy and judicial decisions.

Diverging Paths at the Foundation: The Constitutional Right to Health

A nation's constitution is the first place to start a public health legal analysis. The constitution is the basis of a nation's laws and guides what government and citizens expect from each other. It determines if a government *should* make health care available or if a government *must* make health care available. If a government *must* provide a health care system for its citizens, we consider those citizens as having a specific human rights entitlement: the right to health.[66]

In Europe, many countries have adopted amendments or articles to their constitutions providing for a right to health care. For example:

- Albania's Constitution, Art. 55(1): Citizens enjoy in an equal manner the right to health care from the state.
    - This article neatly establishes a right to health care.
- Armenia's Constitution, Art. 85(1): Everyone shall, in accordance with law, have the right to health care; (2) The law shall prescribe the list of free of charge basic medical services and the procedure for the provision thereof
    - *This article both creates a right to health care and a government duty to provide certain medical services freely.*

Some countries have a constitutional provision for health insurance, but the right to health is not only a right to health insurance, because the latter does not guarantee access to health services unless supported by a sufficient system of health workforce and facilities. For instance:

[63] Gostin LO, Taylor AL. Global Health Law: A Definition and Grand Challenges. Public Health Ethics 2008;1:53–63. doi:10.1093/phe/phn005.
[64] Ibid.
[65] *Principles and Considerations for Adding a Vaccine to National Immunization Programme;* 2014 [Internet]. World Health Organization [cited 1 December 2018]. Available from: https://www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/. (2014)
[66] Statement by Dr. Tedros Adhanom Gebreyesus. *Health is a Fundamental Human Right;* 2017. World Health Organization [cited 1 December 2018]. Available from: http://www.who.int/mediacentre/news/statements/fundamental-human-right/en/

- Bulgaria's Constitution, Art. 52: 1) Citizens shall have the right to medical insurance guaranteeing them affordable medical care, and to free medical care in accordance with conditions and procedures established by law; 2) Medical care shall be financed from the state budget, by employers, through private and collective health-insurance schemes, and from other sources in accordance with conditions and procedures established by law; 5) The State shall exercise control over all medical facilities and over the production and trade in pharmaceuticals, biologically active substances and medical equipment.
    - Though the first provision only provides a right to insurance, because Bulgaria also requires government to provide medical facilities and equipment, this language establishes a right to health.

In addition, certain countries (such as Malta, San Marino) do not have a right to health written in their constitutions, but their governments have traditionally provided health care. Capturing this detail is essential toward understanding the public health legal frameworks of these countries. When comparing European states, these distinctions become important to the positioning of immunization programs.

Not every country has a constitution (such as United Kingdom, Israel, Austria) and rely instead on foundational laws. Other countries (such as Iceland) passed legislation for healthcare instead of amending their constitutions. Legislation can create rights like constitutions; however, the constitutional authority to create laws is different from a constitutional obligation to create *certain* laws.

Arranging Actions for Health Services: Law, Regulation and Policy

Laws, decrees, orders, regulation, policies and plans represent different levels of power and influence; however, collectively, they translate the constitutional protection of health into concrete arrangements of the health system. A nation's legislature creates laws (or "statutes"), which makes laws the most powerful instrument next to the constitution. Meanwhile, regulations (sometimes referred to as decrees) are drafted by executive-branch agencies and administrations, e.g. ministry of health. Regulations are not as strong as laws – which delimit what a government can or cannot do – but are otherwise influential since regulations state *how* a government will follow the law. For example, a ministry of health might regulate healthcare products by imposing a quality standard. Finally, policies and plans have little to no power by themselves and carry little legal "weight" but embody the strategy or direction of the health system.

Understanding law, regulation and policy and how they interact is important to any comprehensive study on immunization. For instance, German healthcare is renowned for its public-private hybrid system of governance. Under federal government oversight, private health insurance organizations provide health care services to most German citizens. The official Standing Committee on Vaccinations (STIKO), an independent group of experts appointed by the German Federal Ministry of Health, recommends vaccines to the health insurers. Yet, ultimately the insurers decide which, if any, vaccines to cover, though they are unlikely to ignore a STIKO recommendation in deference to STIKO's authority created by law. A country's legal structure shapes its healthcare system and the arrangements that determine the system's performance.

Drawing Boundaries of Authority: The Role of Courts

Throughout the study, O'Neill Institute researchers investigated whether or not the courts of a country had issued rulings on immunization. Researchers examined countries where courts have ruled on immunization issues (11/53) to monitor activities affirming or redrawing the legal boundaries in this area. For example, in Turkey in 2016, the courts ruled that the mandatory immunization law (first passed in 1930) was unconstitutional as a violation of both the rights of children and the rights of parents. Meanwhile, Slovakia's courts ruled that penalties for not vaccinating are constitutionally valid because the government has an obligation to promote health. The engagement of courts on these issues is a powerful indicator on whether a country has ongoing efforts in affirming or redrawing the boundaries of legal authority over national immunization.

Piecing It Together: Law and Public Health

What causes people to get vaccinated? What prevents them from doing so? Such are critical questions pursued by both public health professionals and legal experts in the immunization field. The public health community has

examined individual decision processes and social network factors leading to vaccine acceptance and refusal.[67] Meanwhile, the legal community analyzes the impact of national legal systems on decisions to vaccinate. Is a person more or less likely to vaccinate if a law mandates that they do so? Is a person more or less likely to vaccinate if there is no mandate but enrollment in public schools is contingent on immunization?

This study explores what the laws of 53 European Region countries say (on paper) and do (in practice) that promote or hinder immunization. Future efforts may pursue the harder question of whether immunization rates can be improved through *legally permissible* means.

[67] Dubé E, Macdonald NE. Vaccine Hesitancy. Oxford Research Encyclopedia of Global Public Health 2018. doi:10.1093/acrefore/978019063236

European Region Matrix:
Immunization Legislation

Is a right to health specifically enumerated in the country's primary legislative document, such as constitution? This does not include a state's establishment of universal health coverage, references to health care in secondary legislative documents, or any other legal instrumentality that is not the primary legislative document.

Does the country have specific legislation or a provision within legislation that requires the government to provide immunization to its population? This does not include legislation mandating vaccines to only specific groups (such as emergency personnel or the military) or in the instance of an emergency, and is independent of the actual provision of vaccines.

Does the country have legislation requiring that its population – adults and/or children – be immunized with one or more vaccines? Mandates for specific groups, such as emergency personal or the military, are not sufficient. The existence of the legislative mandate is independent of the government's ability to enforce the mandate through fines, fees and other means.

Is there a system for the reporting of an individual's immunization? This can include legislation requiring reporting from medical offices and other healthcare providers, electronic databases or other reporting systems as well as programs currently being piloted by the State, but does not include the mere existence of vaccine certifications if those records are kept and shared only between a patient and their doctor. This does not reflect actual verification by the government, but rather the ability to verify immunization if interested.

Is there legislation, or a provision within legislation, specifically mandating that children must be immunized to attend school?

Is there legislation mandating penalties, including detention, exclusion from schools or other social gatherings, or monetary fines, for non-compliant individuals (or their parents, where appropriate)? This question is only applicable in countries where the country has legislation requiring that its population be immunized.

Has a court in the country heard and ruled on a case involving mandatory immunization? Questions involving the state's ability to mandate immunization for its population, responsibility to provide immunization, and the requirement that children be immunized to attend school are the most common, but any judicial decision involving immunization is considered.

Does the country have specific legislation which requires the government to finance vaccines? This is independent of whether or not the government is actually paying for in country immunization programs, and focuses solely on the existence of mandating legislation.

European Region Matrix:
Immunization Legislation

COUNTRY A–B	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?	COVERAGE INDICATORS		MEASLES (cases, 7/2017–6/2018)
Albania	✓	✓	✓	✓	✓	✓		✓	DTP3	99%	2
									IPV	99%	
Andorra	✓	✓	✓	✓	✓			✓	DTP3	99%	0
									IPV	N/A	
Armenia	✓	✓						✓	DTP3	94%	19
									IPV	92%	
Austria	✓	✓		✓				✓	DTP3	90%	78
									IPV	N/A	
Azerbaijan	✓	✓	✓	✓	✓			✓	DTP3	95%	0
									IPV	96%	
Belarus	✓	✓		✓				✓	DTP3	97%	104
									IPV	98%	
Belgium	✓	✓	✓	✓	✓	✓	✓	✓	DTP3	98%	94
									IPV	N/A	
Bosnia and Herzegovina		✓	✓	✓	n/a	n/a		✓	DTP3	75%	50
									IPV	91%	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

European Region Matrix:
Immunization Legislation

COUNTRY B–F	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?	COVERAGE INDICATORS		MEASLES (cases, 7/2017–6/2018)
Bulgaria	✓	✓	✓		✓	✓		✓	DTP3	92%	11
									IPV	N/A	
Croatia	✓	✓	✓			✓	✓	✓	DTP3	92%	19
									IPV	N/A	
Cyprus					✓	✓			DTP3	97%	15
									IPV	N/A	
Czech Republic	✓	✓	✓		✓	✓	✓	✓	DTP3	96%	137
									IPV	N/A	
Denmark		✓		✓				✓	DTP3	98%	6
									IPV	N/A	
Estonia	✓	✓		✓				✓	DTP3	93%	10
									IPV	N/A	
Finland	✓	✓		✓				✓	DTP3	89%	13
									IPV	N/A	
France	✓	✓	✓	✓	✓		✓	✓	DTP3	96%	2741
									IPV	N/A	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

European Region Matrix:
Immunization Legislation

COUNTRY G–I	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?
Georgia				n/a				
COVERAGE INDICATORS	DTP3 91%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 1221	
Germany								
COVERAGE INDICATORS	DTP3 95%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 508	
Greece						n/a		
COVERAGE INDICATORS	DTP3 99%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 3192	
Hungary								
COVERAGE INDICATORS	DTP3 99%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 34	
Iceland								
COVERAGE INDICATORS	DTP3 89%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 1	
Ireland								
COVERAGE INDICATORS	DTP3 95%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 95	
Israel								
COVERAGE INDICATORS	DTP3 98%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 151	
Italy								
COVERAGE INDICATORS	DTP3 94%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 3343	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

European Region Matrix:
Immunization Legislation

COUNTRY K–M	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?	COVERAGE INDICATORS		MEASLES (cases, 7/2017–6/2018)
Kazakhstan	✓	✓	✓					✓	DTP3	99%	1
									IPV	99%	
Kyrgyzstan	✓	✓	✓	✓	n/a			✓	DTP3	92%	313
									IPV	N/A	
Latvia	✓	✓	✓	✓				✓	DTP3	98%	20
									IPV	N/A	
Lithuania	✓			✓			✓	✓	DTP3	94%	0
									IPV	N/A	
Luxembourg		✓			n/a			✓	DTP3	99%	2
									IPV	N/A	
Macedonia	✓	✓	✓	✓	✓	✓		✓	DTP3	91%	32
									IPV	97%	
Malta		✓	✓	✓		✓	✓	✓	DTP3	98%	0
									IPV	N/A	
Moldova	✓				✓	✓	✓	✓	DTP3	88%	37
									IPV	N/A	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

European Region Matrix:
Immunization Legislation

COUNTRY M–R	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?	COVERAGE INDICATORS		MEASLES (cases, 7/2017–6/2018)
Monaco	✓		✓	✓	✓			✓	DTP3	99%	N/A
									IPV	N/A	
Montenegro	✓	✓	✓			✓		✓	DTP3	87%	32
									IPV	95%	
Netherlands	✓	✓		✓				✓	DTP3	94%	28
									IPV	N/A	
Norway		✓		✓				✓	DTP3	96%	8
									IPV	N/A	
Poland	✓		✓	✓		✓		✓	DTP3	98%	95
									IPV	N/A	
Portugal	✓	✓	n/a	✓				✓	DTP3	98%	125
									IPV	N/A	
Romania	✓	✓						✓	DTP3	82%	1357
									IPV	N/A	
Russian Federation	✓	✓						✓	DTP3	97%	2099
									IPV	97%	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

European Region Matrix:
Immunization Legislation

COUNTRY S–T	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?
San Marino		✓	✓			✓		✓
COVERAGE INDICATORS	DTP3 86% · IPV N/A						MEASLES (cases, 7/2017–6/2018) 0	
Serbia	✓	✓	✓		✓	✓		✓
COVERAGE INDICATORS	DTP3 95% · IPV 98%						MEASLES (cases, 7/2017–6/2018) 5645	
Slovakia	✓	✓	✓	✓	✓	✓	✓	✓
COVERAGE INDICATORS	DTP3 96% · IPV N/A						MEASLES (cases, 7/2017–6/2018) 103	
Slovenia	✓	✓	✓		✓	✓		✓
COVERAGE INDICATORS	DTP3 94% · IPV N/A						MEASLES (cases, 7/2017–6/2018) 9	
Spain	✓	✓		✓				✓
COVERAGE INDICATORS	DTP3 98% · IPV N/A						MEASLES (cases, 7/2017–6/2018) 207	
Sweden		✓						✓
COVERAGE INDICATORS	DTP3 97% · IPV N/A						MEASLES (cases, 7/2017–6/2018) 49	
Switzerand							✓	
COVERAGE INDICATORS	DTP3 97% · IPV N/A						MEASLES (cases, 7/2017–6/2018) 63	
Tajikistan	✓	✓	✓	n/a		✓		✓
COVERAGE INDICATORS	DTP3 96% · IPV N/A						MEASLES (cases, 7/2017–6/2018) 13	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

European Region Matrix:
Immunization Legislation

COUNTRY T–U	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?
Turkey		n/a		n/a				
COVERAGE INDICATORS	DTP3 96%	IPV 93%					MEASLES (cases, 7/2017–6/2018) 338	
Turkmenistan					n/a	n/a		
COVERAGE INDICATORS	DTP3 99%	IPV N/A					MEASLES (cases, 7/2017–6/2018) N/A	
Ukraine								
COVERAGE INDICATORS	DTP3 50%	IPV 43%					MEASLES (cases, 7/2017–6/2018) 26,894	
United Kingdom								
COVERAGE INDICATORS	DTP3 94%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 947	
Uzbekistan								
COVERAGE INDICATORS	DTP3 99%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 6	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

Table 2
AEFI Surveillance in European Region

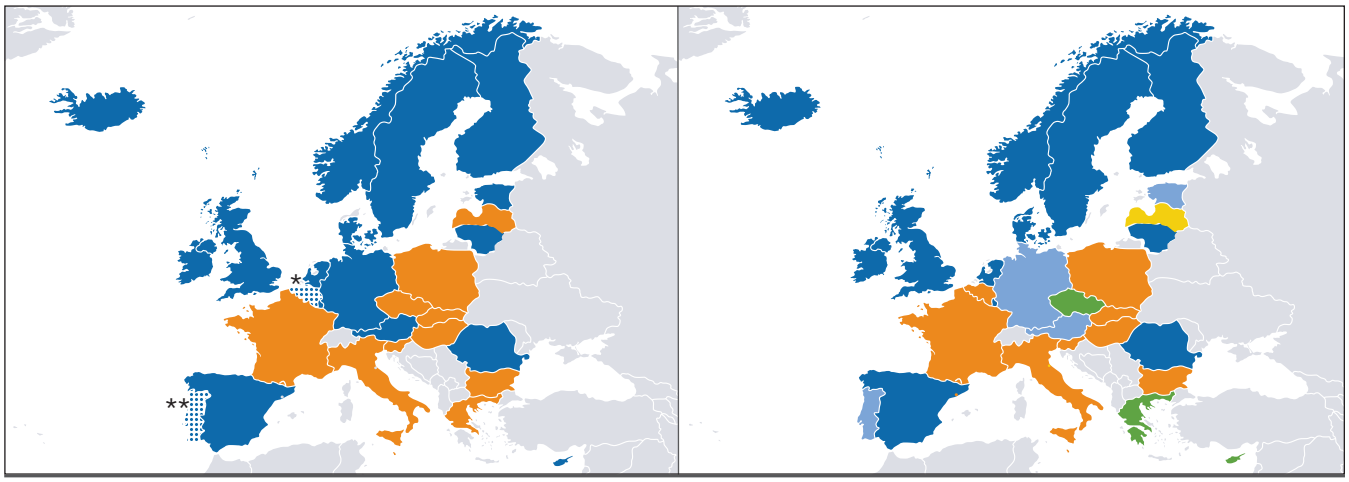
✓ YES ⊖ NO

COUNTRY	AEFI SURVEILLANCE	COUNTRY	AEFI SURVEILLANCE	COUNTRY	AEFI SURVEILLANCE
Albania	✓	Greece	✓	Poland	✓
Andorra	*	Hungary	✓	Portugal	✓
Armenia	⊖	Iceland	✓	Romania	✓
Austria	✓	Ireland	✓	Russian Federation	✓
Azerbaijan	✓	Israel	✓	San Marino	*
Belarus	⊖	Italy	✓	Serbia	✓
Belgium	✓	Kazakhstan	*	Slovakia	✓
Bosnia & Herzegovina	✓	Kyrgyzstan	✓	Slovenia	✓
Bulgaria	✓	Latvia	✓	Spain	✓
Croatia	✓	Lithuania	✓	Sweden	✓
Cyprus	✓	Luxembourg	✓	Switzerland	✓
Czech Republic	✓	Macedonia	⊖	Tajikistan	⊖
Denmark	✓	Malta	✓	Turkey	⊖
Estonia	✓	Moldova	✓	Turkmenistan	*
Finland	✓	Monaco	*	Ukraine	⊖
France	✓	Montenegro	✓	Uzbekistan	*
Georgia	✓	Netherlands	✓	United Kingdom	✓
Germany	✓	Norway	✓		

* Researchers did not have enough information to determine status in the country of an AEFI surveillance system

Table 3
Comparison of legislative provisions related to immunization for the VENICE survey (2010) and the Sabin review (2018)

VENICE findings (2010) **Sabin findings (2018)**



COUNTRY	VENICE	Sabin
Austria	Recommended	Recommended with robust monitoring and follow-up
Belgium	*	Mandatory immunization with robust monitoring and follow-up
Bulgaria	Mandatory	Mandatory immunization with robust monitoring and follow-up
Cyprus	Recommended	Recommended with mandatory requirements for school attendance
Czech Republic	Mandatory	Recommended with mandatory requirements for school attendance
Denmark	Recommended	Recommended
Estonia	Recommended	Recommended with robust monitoring and follow-up
Finland	Recommended	Recommended
France	Mandatory	Mandatory immunization with robust monitoring and follow-up
Germany	Recommended	Recommended with robust monitoring and follow-up
Greece	Mandatory	Recommended with mandatory requirements for school attendance
Hungary	Mandatory	Mandatory immunization with robust monitoring and follow-up
Iceland	Recommended	Recommended
Ireland	Recommended	Recommended
Italy	Mandatory	Mandatory immunization with robust monitoring and follow-up
Latvia	Mandatory	Mandatory immunization with monitoring and follow-up
Lithuania	Recommended	Recommended
Luxembourg	Recommended	Recommended
Malta	Mandatory	Mandatory immunization with robust monitoring and follow-up
Netherlands	Recommended	Recommended
Norway	Recommended	Recommended
Poland	Mandatory	Mandatory immunization with robust monitoring and follow-up
Portugal	**	Recommended with robust monitoring and follow-up
Romania	Recommended	Recommended
Slovakia	Mandatory	Mandatory immunization with robust monitoring and follow-up
Slovenia	Mandatory	Mandatory immunization with robust monitoring and follow-up
Spain	Recommended	Recommended
Sweden	Recommended	Recommended
United Kingdom	Recommended	Recommended

VENICE Recommended; Mandatory

Sabin Recommended; Recommended with robust monitoring and follow-up; Recommended with mandatory requirements for school attendance; Mandatory immunization with monitoring and follow-up; Mandatory immunization with robust monitoring and follow-up

* Belgium: Polio is mandatory, rest is recommended
** Portugal: Recommended (only diphtheria and tetanus are mandatory for special groups at risk)

The Baltic States:

A comparison of legislative approaches across three countries with similar historical, geographic and health contexts

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?
ESTONIA	YES	YES	NO	YES	NO	NO	NO	YES
COVERAGE INDICATORS	DTP3 93%	IPV N/A					**MEASLES** (cases, 7/2017–6/2018) **10**	
LATVIA	YES	YES	YES	YES	NO	NO	NO	YES
COVERAGE INDICATORS	DTP3 98%	IPV N/A					**MEASLES** (cases, 7/2017–6/2018) **20**	
LITHUANIA	YES	NO	NO	YES	NO	NO	YES	YES
COVERAGE INDICATORS	DTP3 94%	IPV N/A					**MEASLES** (cases, 7/2017–6/2018) **0**	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey * Information not available at this time

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

Introduction

As highlighted in the full report, *Legislative Approaches to Immunization Across the European Region*, a variety of contexts, policies, systems and capacities (organizational, managerial, financial, human resources) influence the effectiveness of immunization approaches. This case study is a comparative examination across the Baltic States of Estonia, Latvia and Lithuania, which share similarities including geographic proximity, common recent history (including independence from the Soviet Union in 1991) and high coverage rates but differ in their legislative approaches. Using the "Likert Scale: Assessing Levels of Immunization Legislation" developed by the Sabin Vaccine Institute (Sabin) for this study, the Baltic States fall under the following classifications:

- Estonia: *recommended with robust monitoring and follow-up*
- Latvia: *mandatory immunization with monitoring and follow-up*
- Lithuania: *recommended*

The Baltic States have similar traits that are useful for comparison. These include:

- **High immunization coverage:** 90-99 percent depending on vaccine and year of reference
- **Limited vaccine hesitancy:** Although immunization refusal has increased, vaccine hesitancy does not affect these countries to the same extent as many European neighbors
- **Government provision of vaccines**: In all three countries, the government is legally required to provide vaccines and vaccines are financed either by the state or through insurance schemes and are free for the target population
- **Joint Procurement:** Facing high vaccine prices due to a small market share, the Baltic States have initiated a joint procurement mechanism for purchasing vaccines

The purpose of this case study is to examine how Estonia, Latvia and Lithuania implement their immunization programs and how legislation is used to support these efforts. The analysis may be useful to policy makers to understand the legislative, financial and monitoring systems in place for successful immunization programs, each stemming from a different framework for immunization legislation.

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).

Context and findings

Political and economic challenges following the collapse of the Soviet Union at the beginning of 1990s had a significant impact on the health systems, and specifically immunization programs in the "communist bloc." The Baltic States faced a challenge given the dependency of their immunization systems on vaccines produced in the Russian Soviet Republic. Immunization programs were interrupted temporarily,

vaccine shortages were common and outbreaks occurred. Diphtheria outbreaks[1] and tuberculosis morbidity increased[2] significantly in all three Baltic States. The decrease in financing and deterioration in healthcare systems exacerbated the problems in tuberculosis control and treatment.[3]

Over the span of the next 10 years, Estonia, Latvia and Lithuania each introduced political and legislative changes. As a result, immunization programs began to improve, immunization rates increased and outbreaks became rare. High immunization coverage rates persisted despite the 2008-2009 financial crisis and the subsequent contraction of national economies. The Baltic States, each at its own pace, have prioritized immunization and introduced comprehensive legislative provisions to help regulate national immunization programs (NIPs). Yet, since 2010, each country has faced challenges related to vaccine hesitancy. Relative to other European countries, vaccine hesitancy and refusal rates have been low[4,5]: however, the trend is increasing and has affected immunization rates. Each country has worked to address the issue in its own way, and from a research perspective, this presents an opportunity for comparative study.

Estonia

Background and legislative landscape

In Estonia, the legislative framework for immunization is set under the Communicable Diseases Prevention and Control Act (2003) (See Database).[6] The national immunization scheme is defined by regulation of the Minister of Social Affairs, organized by the Health Board and financed by the independent Estonian Health Insurance Fund (EHIF) and the state budget.[7] Immunization of children is the responsibility of family doctors and school nurses. A committee advises which vaccines to include in the national immunization scheme.

The Ministry of Social Affairs and its agencies oversee Estonia's health system. The e-Health Foundation operates the national e-Health system, which is an information exchange platform that connects all providers and allows data exchange with various other databases. The platform enables patient access to health data.

Estonia is a strong performer in immunization, with coverage remaining high (93-99 percent) across the different vaccines over the past decade.[8] Recently immunization coverage has decreased slightly, falling below the recommended 95 percent, while simultaneously, vaccine refusals among parents have increased. In 2017, diphtheria-tetanus-pertussis (DTP3) coverage was at 93 percent. Parental refusal levels are a mere 3-3.9 percent, depending on the vaccine,[9] but like the rest of the world, vaccine hesitancy and refusal are trending upwards.

---

[1] Dittman S, Wharton M, Vitek C, Ciotti M, Galazka A, Guichard S, et al. Successful Control of Epidemic Diphtheria in the States of the Former Union of Soviet Socialist Republics: Lessons Learned. The Journal of Infectious Diseases. 2000 Feb; 181(1); S10-S22.
[2] Anon. The rise and spread of drug-resistant tuberculosis. The Lancet. 2008;371(9614):698
[3] National Institute for Health Development (Estonia). Health in the Baltic Countries 2015 [Internet]. Estonia: NIHD; 2015. 68 p. Report No. 24.
[4] Vaccination Programmes and Health Systems in the European Union [Internet]. Luxemborg: Expert Panel on effective ways of investing in Health (EXPH). European Commission; 2018 [cited December 2018]. Available from: https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/020_vaccinationpgms_en.pdf
[5] Larson H, Figueiredo A, Karafillakis E, Rawal M. State of Vaccine Confidence in the EU 2018 [Internet]. Luxemborg: European Commission; 2018 [cited December 2018]. Available from: https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018_vaccine_confidence_en.pdf
[6] Estonia Communicable Diseases Prevention and Control Act (2003)
[7] Banhard P. The Estonia Health Insurance System. Estonia: Estonian Health Insurance Fund; 2017 March 31. 16 p. Available from: https://www.haigekassa.ee/sites/default/files/pressile/presentation_riga_parliament_31032017_kodukale.pdf
[8] Anon. Estonia: 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/Estonia/immunization_country_profiles/immunization_est.pdf
[9] Filippova, I. Immunization in Estonia. Tallinn: VENICE; 2017 Jan 24. 40 p. Available from: https://intra.tai.ee/images/Immunization_in_Estonia__TAI__23.01.2017.pdf

In Estonia, vaccination is recommended (see Database)[10] with a Likert Scale classification as *recommended with robust monitoring and follow-up*. All vaccines included in the NIP are financed by the government and free of charge for all Estonian children (see Database).[11] Parents, guardians or legal representatives are empowered to make immunization decisions for their children and wards. However, if a parent refuses to vaccinate a child under the NIP, a written application is required.[12] Immunization issues are regulated by the Law on the Prevention and Control of Infectious Diseases and legal norms approved on its basis (see Database).[13] The Law on Occupational Health and Safety regulates immunization in the field of occupational health.

Financing

Estonia has been an early adopter of innovation in health, which has led to significant gains in efficiency and higher performance across the health sector, including immunization. Its health financing structure is one reason behind Estonia's robust immunization performance. Reforms in the early 1990s introduced the principles of a purchaser and provider split,[14] strengthening primary care by allowing free choice of provider and a significant level of provider autonomy in the Estonian health care system. In 1991, Parliament passed the Health Insurance Act (see Database),[15] which set the basis for a new financing source for healthcare. As a result, nearly all health services, including immunization,[16] are financed through a social health insurance system funded primarily by an earmarked payroll tax (similar to the system in Moldova, see Moldova case study for more information).[17] The Health Services Organization Act of 1994 laid the foundation for the organizational structure. After fundamental reforms in the mid-1990s, the focus shifted to incremental improvement of the health system. In 2001, the EHIF was established as the core independent public purchaser of health services.[18] The EHIF administers Estonia's health insurance system and covers the costs related to immunization (for vaccines included in the immunization schedule). A Health Services Organization Act and a new Health Insurance Act were adopted in 2001 and 2002 (see Database),[19] further improving the financing mechanism.

Estonia's social health insurance system combines per capita payment for primary healthcare with a pay-for-performance (P4P) program and additional financial incentives for achieving immunization coverage targets. P4P, also called the quality system (QS), was launched in 2006 as a voluntary quality-based financial incentive system. In the first year, 60 percent of family practices joined the program and by the end of 2008 enrollment rose to 78 percent.[20] One indicator for the program's achievement is the childhood immunization coverage rate.[21]

[10] Estonia Communicable Diseases Prevention and Control Act (2003)
[11] Public Health Act and Communicable Disease Prevention and Control Act (2003). The financing comes from the National Insurance Fund
[12] Ministry of Social Affairs Regulation No 116 (2003) (ПостановлениеМинистрасоциальныхдел No 116 от 31 октября2003 г. «Требованиякорганизациииммунизации») and Guidelines on the Organization of Immunization Services (27 October 2009): Available from: https://www.haigekassa.ee/uploads/userfiles/immkava_rakendusjuhis_vene_k.pdf
[13] Estonia Public Health Act and Communicable Disease Prevention and Control Act (2003) [statute on the Internet] c2018 [cited 2018 Aug 1].
[14] The purchaser–provider split (PPS) is a service delivery model in which third-party payers (purchasers of health care) are kept organizationally separate from service providers (e.g. hospitals). The operations of the providers are managed by contracts. One of the main aims of PPS is to create competition between providers leading to more efficiency and cost-saving. https://abetternhs.net/2011/01/18/commissioning-and-the-purchaser-provider-split/
[15] Health Insurance Act (Estonia) 2002 [statute on the Internet] c2018 [cited 2018 July]. Available from: https://www.riigiteataja.ee/en/eli/529122016002/consolide
[16] All vaccines included in the national immunization calendar are free for children (and DT vaccine for adults).
[17] Employers are obligated to pay social tax for employees of which includes 13 percent of gross wages for health insurance.
[18] Legislative documents regulating the establishment, financing and organization of the EHIF include: the Health Insurance Act (1991) and the Social Tax Act (see Database)
[19] Health Services Organization Act (2001) and Health Insurance Act (2002) (see Database)
[20] Eesti Haigekassa. Estonian Health Insurance Fund Annual Report 2008 [Internet]. Tallinn: Estonian Health Insurance Fund; 2008 [cited 2018 Aug]. 92 p. Available from: https://www.haigekassa.ee/uploads/userfiles/Majandusaasta%20aruanne%202008_ENG.pdf
[21] Merilind E, Salupere R, Vastra K, Kalda R. Pay for performance of Estonian family doctors and impact of different practice- and patient-related characteristics on a good outcome: A quantitative assessment. Medicina. 2016; 52(3): 192-198.

A study assessing the influence of P4P mechanisms on childhood immunization coverage[22] compared childhood immunization coverage rates of all Estonian family physicians in two groups, connected and not connected, to the QS during the observation period of 2006-2012.[23] It showed a significant difference between the two groups; doctors connected to the quality system met the 90 percent vaccination criterion more frequently compared to doctors not connected. And more importantly, "doctors not joined to the quality system were below the 90 percent vaccination criterion in all vaccinations listed in the Estonian State Immunization Schedule."[24] The study supports the argument that P4P mechanisms as a financial incentive encourages higher levels of childhood immunizations. Another study, assessing 11 P4P programs in Organisation for Economic Co-operation and Development (OECD) countries found that the P4P program in Estonia resulted in a modest increase in coverage rates for childhood immunization.[25, 26] Estonia has embraced P4P as a mechanism to encourage childhood immunization and help overcome vaccine hesitancy/refusal by incentivizing doctors.[27]

Political will and scientific support

In Estonia's case, political stability in the years following independence was a crucial factor for the success of the healthcare system reform, and in particular, the NIP. System reform benefited from the consensus and commitment of political parties, and there was minimal opposition to the introduction of healthcare and immunization reforms.[28] The Estonian Medical Association (EMA) also played a significant role in the successful initiation and implementation of health insurance reform.

Latvia

Background and legislative landscape

Latvia also has strong immunization program performance, with coverage rates ranging between 90-99 percent, depending on the vaccine, for the last decade.[29] The NIP expanded the number of antigens from 11 in 2008 to 14 in 2015. Like Estonia and Lithuania, Latvia experienced a decline in coverage beginning in 2012, but later rebounded. In 2017, DTP3 coverage was at 98 percent, up from 95 percent in 2012-2015.[30] Although the rates among the three countries are similar, Latvia has the highest coverage rates among the three Baltic States and is the only one with coverage at or above 95 percent between 2015 and 2017.

[22] Merilind E, Salupere R, Västra K, Kalda R. The influence of performance-based payment on childhood immunisation coverage. [Internet]. Current neurology and neuroscience reports. U.S. National Library of Medicine; 2015. Available from: https://www.ncbi.nlm.nih.gov/pubmed/25686796.

[23] Note: Immunisation coverage was calculated as the percentage of persons in the target age group who received a vaccine dose by a given age. From: Merilind E, Salupere R, Västra K, Kalda R. The influence of performance-based payment on childhood immunisation coverage. [Internet]. Current neurology and neuroscience reports. U.S. National Library of Medicine; 2015. Available from: https://www.ncbi.nlm.nih.gov/pubmed/25686796

[24] Merilind E, Salupere R, Västra K, Kalda R. The influence of performance-based payment on childhood immunisation coverage. [Internet]. Current neurology and neuroscience reports. U.S. National Library of Medicine; 2015. Available from: https://www.ncbi.nlm.nih.gov/pubmed/25686796

[25] How Provider Payment Approaches Affect Immunization Services [Internet]. Immunization Financing. Available from: https://www.immunizationfinancing.org/en/strategic-purchasing-and-procurement/how-provider-payment-approaches-affect-immunization-services#

[26] Paying for performance in health care. Implications for health system performance and accountability (2014) [Internet]. World Health Organization. World Health Organization; 2017. Available from: http://www.euro.who.int/__data/assets/pdf_file/0020/271073/Paying-for-Performance-in-Health-Care.pdf?ua=1

[27] Ministry not in favor of vaccination coercion measures [Internet]. Eesti Rahvusringhääling | ERR; 2017. Available from: https://news.err.ee/592617/ministry-not-in-favor-of-vaccination-coercion-measures

[28] Atun RA, Menabde N, Saluvere K, Jesse M, Habicht J. Introducing a complex health innovation--primary health care reforms in Estonia (multimethods evaluation). [Internet]. Current neurology and neuroscience reports. U.S. National Library of Medicine; 2006. Available from: https://www.ncbi.nlm.nih.gov/pubmed/16406131

[29] Anon. Immunization country profiles 2017 [Internet]. UNICEF DATA. 2018. Available from: https://data.unicef.org/wp-content/uploads/country_profiles/Latvia/immunization_country_profiles/immunization_lva.pdf

[30] Anon. Estonia: 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/Estonia/immunization_country_profiles/immunization_est.pdf

Latvia's NIP includes both recommended and mandatory vaccines resulting in a classification of *mandatory immunization with monitoring and follow-up*. While Section 30 of the Epidemiological Safety Law (1997)[31] states that the Cabinet of Ministers determine which groups receive mandatory immunization and against which diseases,[32] "Vaccine Regulation" No. 330 (2000)[33] further clarifies this provision and states that "[w]ithin the framework of the State Immunisation Programme vaccination shall be mandatory for (3.1.) children…" and then enumerates for which diseases.

Under the legislation, physicians must explain the advantages and disadvantages of immunization and obtain written refusal of services for those patients who decline. Section 32 of the Epidemiological Safety Law stipulates that health practitioners need to report complications observed as a result of the administration of a vaccine; however, there is no provision on compensation for potential damages. Paragraph 32 of the Vaccine Regulation states that "heads of educational institutions and social care institutions have a duty to request that a person to be educated or socially cared for, upon entering an educational or social care institution, submits a statement certified by a medical practitioner which shall specify which vaccines the person has received in conformity with the vaccination calendar of the State Immunisation Programme." In addition to the monitoring system, this is a verification mechanism to help ensure that children have been immunized. No provision is noted to prevent unvaccinated children from attending school.

Financing

The Law (1997) and Regulations (2000) guarantee that costs associated with mandatory vaccines, as well as complications arising from immunization, will be covered by state funds;[34] however, costs for recommended vaccines are not covered by the state budget. The Epidemiological Law (1997) reserves funding not only for vaccine purchase, but also for monitoring activities and routine program costs.

The Compulsory Health Insurance Agency is responsible for purchasing vaccines used in the official immunization program in Latvia. Mandatory health insurance is the basic level of medical assistance provided by the state, as laid out in Regulation No. 1046 "Health Care Organization and Financing Procedure," issued by the Cabinet of Ministers on December 19, 2006.[35] The state is obligated to insure basic healthcare services. State mandatory health insurance resources, in accordance with the Regulations, are financed by a state budget subsidy as outlined in the annual law, "On the State Budget," for healthcare. These resources guarantee the provision of healthcare services within fixed parameters. Latvia does not have a specific budget line for immunization, but the government can invoke the law, supported by the legal framework described above (see Database), to help justify funding requests and "costs associated with vaccination."[36] In practice, this can mean a delay or shortage of funds.

---

[31] Epidemiological Safety Law (1997). Latvia [Internet]. VENICE III. Available from: http://venice.cineca.org/documents/latvia_ip.pdf

[32] Within the framework of the State Immunisation Programme vaccination shall be mandatory for:
3.1. children – against tuberculosis, diphtheria, tetanus, whooping cough, poliomyelitis, measles, rubella, epidemic parotitis, b-type infection caused by Pfeiffer's bacilli (influenza bacteria), virus hepatitis type B;
3.2. adults – against diphtheria, tetanus; and
3.3. children and adults – against rabies after contact with animals or humans who are ill or are suspected of being ill with rabies.

[33] Vaccination Regulations [Internet]. Cabinet Regulation No. 330. Adopted 26 September 2000. Available from: www.vvc.gov.lv/export/sites/default/docs/LRTA/Citi/Cab._Reg._No._330_-_Vaccination_Regulations.doc

[34] Regulation No 330, Section I, par 6: "All expenditures related to the State ImmunisationProgramme and the vaccinations referred to in Paragraph 3 of these Regulations, their organisation, supervision and control, also to the acquisition of vaccines, drawing up of medical documentation, vaccine injection, as well as to the treatment of complications (side-effects) caused by vaccination which treatment has been included in the minimum of medical services to be provided for inhabitants specified in regulatory enactments, shall be financed from the State basic budget and the State special health care budget." Latvia's Epidemiological Law (1997) reserves funding not only for vaccine purchases but for monitoring activities and routine program costs, Chapter VI, Section 30: "Costs associated with vaccination against the referred to diseases shall be covered from the resources provided for such purpose in the annual State budget."

[35] State mandatory health insurance is the basic level of medical assistance provided by the state, as laid out in Regulations No. 1046 "Health Care Organization and Financing Procedure," issued by the Cabinet of Ministers on 19 December, in 2006.

[36] Republic of Latvia Vaccine Regulations No. 330 adopted 26 September 2000 [statute on the Internet].

As noted earlier, the Baltic States have been exposed to higher medical prices, including for vaccines, given the size of the small market they represent. To improve their negotiating position, reduce costs and guarantee access to the vaccines included in their national schedules, all three countries entered into a joint procurement agreement in 2012. It took some time to work out the process, however the end result was a 25 percent savings on price.[41]

Joint immunization procurement under the Baltic Partnership Agreement

On May 2, 2012 the three Baltic countries entered into an agreement (Baltic Partnership Agreement) to carry out joint tenders for purchasing medications and medical equipment as well as lending medications and medical equipment.[37] Since 2012, in times of need, the countries have used the Agreement to loan medications to each other and this has helped to alleviate serious shortages.

The joint procurement efforts, on the other hand, took more time to negotiate and implement. Collaboration around procurement began at the end of 2014, and to date, has focused solely on vaccines. All three countries have similar vaccine schedules and use the same preparations/dosages (given the size of the population, geographic distribution, etc.). The price range is also similar for all three given their purchase volumes, delivery schedules and development status. Pooled procurement would ideally result in a reduction in prices due to increased volumes and predictability of purchases/planning.

The first joint tender for the BCG vaccine, or bacille Calmette-Guerin, a vaccine for tuberculosis, was announced in 2015. It was organized in accordance with Latvia's Public Procurement Law, as Latvia was the lead partner. The tender was unsuccessful, with no submissions, since the only manufacturer who would have qualified under the technical specifications of the tender did not apply because the required doses could not be produced within the specified timeframe. It also became evident that several producers were not interested in participating in joint tenders for such a small market, so the three countries worked to refocus their procurement strategy.[38]

As a next step, Estonia and Latvia identified a rotavirus vaccine as the next most promising candidate for joint procurement (Lithuania's immunization program does not include the rotavirus vaccine in its schedule) and signed a two-year partnership agreement. Estonia became the lead partner for this round and the process was undertaken in accordance with its procurement provisions. The joint procurement for the rotavirus vaccine was announced on October 2016 and in February 2017, the Estonian Social Ministry and Latvian Health Ministry announced that it was successful, and as a result, both countries saved money. Estonia and Latvia purchased 61,000 doses of vaccine, of which 24,710 went to Estonia and 36,290 to Latvia. According to the Social Ministry, Estonia purchased the vaccines for a price 25 percent lower than it would have without the joint tender.[39] Latvia also entered a two-year partnership agreement with Lithuania for procurement of pneumococcal vaccines. Although further plans for procurement remain unclear, the governments have expressed interest to continue and increase the scope of joint procurement.[40]

[37] Partnership Agreement between the Ministry of Health of the Republic of Latvia, the Ministry of Social Affairs of the Republic of Estonia and the Ministry of Health of the Republic of Lithuania on Joint Procurements of Medicinal Products and Medical Devices and Lending of Medicinal Products and Medical Devices Procurable Centrally [Internet]. LIKUMI.LV. Available from: https://likumi.lv/doc.php?id=248008

[38] Espín J, Rovira J, Calleja Aet al., authors; Richardson E, Palm W, editors. How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe? [Internet] Copenhagen (Denmark): European Observatory on Health Systems and Policies; 2016. (Policy Brief, No. 21.) Policy brief. Available from: https://www.eu2017.mt/Documents/Programmes/PB21.pdf

[39] Estonia and Latvia jointly purchase rotavirus vaccine [Internet]. The Baltic Course | Baltic States news analytics. Available from: http://www.baltic-course.com/eng/baltic_states/?doc=127652

[40] Latvia to purchase vaccines jointly with Baltic neighbors [Internet]. The Baltic Times. Available from: https://www.baltictimes.com/latvia_to_purchase_vaccines_jointly_with_baltic_neighbors/

[41] Espín J, Rovira J, Calleja Aet al., authors; Richardson E, Palm W, editors. How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe? [Internet] Copenhagen (Denmark): European Observatory on Health Systems and Policies; 2016. (Policy Brief, No. 21.) Policy brief. Available from: https://www.eu2017.mt/Documents/Programmes/PB21.pdf

Lithuania

Background and legislative landscape

Like Estonia and Latvia, Lithuania went through a difficult period after the breakup of the Soviet Union and implemented new legislation and policies to establish a robust and efficient immunization program. The right to health is enshrined in the Constitution of Lithuania[42] and the government is required to provide immunization under the Health Systems Law, Art. 34, and the Law on Human Communicable Disease Prevention and Control.[43]

According to the NIP[44] and WHO/UNICEF coverage estimates,[45] immunization coverage under the Lithuanian program quickly improved and was between 94-99 percent for a number of vaccines until 2009. In a similar pattern to the other Baltic countries, this was followed by several years of growing hesitancy and a slight decrease in rates. Since 2012, immunization coverage improved, but it has not yet reached former high rates. In 2016-2017, coverage was at 94 percent, up from 93 percent in 2012-2015.

During the transition years, Lithuania introduced new legislation to help reorganize its health system and immunization program. The principal guidelines for public health services, including immunization, were outlined in the Health System Law (1994), the Lithuanian Health Program (1998-2010), with an updated version for 2014-2025,[46] and the National Public Health Strategy (2006-2013). In 2002, Parliament adopted the Public Health Care Law and the Public Health Monitoring Law.[47] The NIP has been largely regulated by the Health Systems Law[48] and the Law on Human Communicable Disease Prevention and Control,[49] as well as Ministerial decrees, orders and regulations based on this legislation.[50]

Immunization is *recommended* in Lithuania and all vaccines included in the national schedule are administered upon receiving consent.[51] Immunization policy is regulated by an official Immunization Calendar.[52] Health institutions report immunization data to public health centers.[53] Public health centers in turn report the aggregate data to the Center for Communicable Diseases Prevention and Control,[54] who is responsible for preparing recommendations for immunization, surveillance of vaccine-preventable

[42] The Constitution of Lithuania of 1992 with Amendments through 2016 [statute on the Internet]. C2018 [cited 18 August 2018]. Available from: https://www.constituteproject.org/constitution/Lithuania_2006.pdf?lang=en
[43] Lithuania Law on Human Communicable Disease Prevention and Control of July 1991 [statute on the Internet]. C2018 [cited 2 December 2018]. Available from: http://www.vaspvt.gov.lt/files/EN/LAW%20ON%20HEALTH%20SYSTEM.pdf
[44] Čaplinskienė I. Lithuanian Immunization Program – Vaccination Coverage Evaluation by the Effectiveness Criteria [Internet]. Health Policy and Management (Vol 1, No 6); 2014. Available from: https://www3.mruni.eu/ojs/health-policy-and-management/article/view/1712
[45] Anon. Immunization Country Profiles Lithuania 2017 [Internet]. UNICEF DATA. 2018. Available from: https://data.unicef.org/wp-content/uploads/country_profiles/Lithuania/immunization_country_profiles/immunization_ltu.pdf
[46] Lietuvos Respublikos Konstitucija. Resolution for Lithuanian Health Program Approval 2014-2025 (Legislation, 2014, No. 2014-09403). C2018 [cited July 2018]. Available from: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=476512
[47] Lithuania Public Health Care Law and the Public Health Monitoring Law of 3 July 2002 [statute on the Internet]. C2018 [cited 7 August 2018]. Available from: https://e-seimas.lrs.lt/portal/legalActPrint/lt?jfwid=191fum7z7o&documentId=914533008c8111e6a0f68fd135e6f40c&category=TAD
[48] Republic of Lithuania Law of the Health System of 1994.
[49] Republic of Lithuania Law on Human Communicable Disease Prevention and Control 25 September 1996 No. I-1553 [statute on the Internet]. C2018 [cited 18 August 2018]. Available from: https://e-seimas.lrs.lt/portal/legalActPrint/lt?jfwid=-g0zrzend5&documentId=TAIS.373789&category=TAD
[50]Ministerial Order: Action plan approval for reducing health inequalities in Lithuania 2014-2023 (Legislation, 2014, No. 2014-10332) http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=478355&p_tr2=2
[51] Law on Human Communicable Disease Prevention and Control. Article 11. Immuno-prophylaxis: **"**1. Immuno-prophylaxis may only be applied to persons with their consent, except for instances stipulated in other legal acts, and when they are incapable, upon obtaining the consent of their representatives according to the law. ". Law on Health System, Part 1, Chapter 2, Section 1, Art 38: http://www.litlex.lt/litlex/eng/frames/laws/Documents/164.HTM
[52] Latvia [Internet]. VENICE III. Available from: http://venice.cineca.org/documents/latvia_ip.pdf
[53] The Law on Public Health Monitoring of Republic of Lithuania (3 July 2002, No. IX-1023); The Law on Human Communicable Prevention and Control of Republic of Lithuania (25 September 1996, No. I-1553); Decision of Government of Republic of Lithuania on approval of the list of statistical indicators on children health (8 June 2004, No. 695). https://osp.stat.gov.lt/documents/10180/0/vaiku+profilaktiniai+skiepijimai_metainfo-EN
[54] Law on Human Communicable Disease Prevention and Control 25 September 1996, Chapter 2, Section1.

diseases, surveillance of Adverse Effects Following Immunization (AEFI) incidence, and monitoring and evaluation of immunization coverage at the national level.[55] With the rollout of the e-Health system, data collection may become even more accessible and efficient.

Financing

The Lithuanian Health Care System is based on mandatory health insurance (CHI) which is regulated by the Law on Health Insurance.[56] The state health insurance scheme is implemented by the National Health Insurance Fund (NHIF).[57] Those who are insured get their services covered by the Territorial Patient Funds from the NHIF.

Vaccines and other NIP costs are covered by the State budget.[58] Vaccines provided at no cost include: tuberculosis, Hepatitis B, pertussis, tetanus, diphtheria, Influenzae type b, poliomyelitis, measles, mumps and rubella. Vaccines are given to children within the first 24 hours after birth, at two, four and six months, six-seven years old, 12 years old and 15-16 years old.[59]

Analysis

The Baltic States have similarities in immunization systems — albeit with some differences in the degree of implementation — but the main difference is an immunization requirement. Estonia has *recommended with robust monitoring and follow-up*, in comparison to Latvia with *mandatory immunization with monitoring and follow-up*. Lithuania has a *recommended* approach.

In a comparison across the Baltic States, Estonia is positioned as an innovator and early adopter, based on the successful introduction of several new approaches to health and immunization. Estonia's innovation is exemplified by the electronic health information system (e-Health),[60] which facilities immunization coverage monitoring and AEFI surveillance, collection and analysis of data, as well as access to immunization records for patients, doctors and officials. This innovation has resulted in positive impact to Estonia's NIP, including better data for evidence-based decision making and the ability respond faster to crises and outbreaks.[61, 62]

Another monitoring mechanism used by both Latvia and Estonia is the requirement for a physician-signed official refusal by individuals declining immunization. This mechanism provides an opportunity for healthcare professionals to follow up with those refusing, supply more information and create another opportunity to vaccinate. In Estonia, where immunization is voluntary, this mechanism reinforces strong implementation and monitoring efforts and supports the country's classification as *recommended with robust monitoring and follow-up*. Latvia also has this mechanism in place, however, it is coupled with an

[55] Latvia [Internet]. VENICE III. Available from:http://venice.cineca.org/documents/latvia_ip.pdf
[56] The Republic Of Lithuania Law On Health Insurance. Available from:http://www.vlk.lt/sites/en/legislation/national-legislation/Documents/EN%20SDI%20aktuali%202014-07-10.pdf
[57] Health Insurance System [Internet]. National Health Insurance Fund under the Ministry of Health. Available from: http://www.vlk.lt/sites/en/health-insurance-in-Lithuania/health-insurance-system
[58] Law on Human Communicable Disease Prevention and Control 25 September 1996. Article 40. Special Features of the Funding of Communicable Diseases Prevention and Control from State Budget:The following shall be funded from the sum in the State Budget projected for healthcare:
1) according to the list approved by the Government, communicable diseases prevention and control measures are attributed to vital public healthcare measures;
[59] Medical Route In Lithuania [Internet]. Take Care Project. Available from: https://www.takecareproject.eu/upload/docs/Medical_route/MedicalRoute_LT_EN.pdf
[60] First country globally to do so. Estonia used its time as head of the EU Presidency to encourage other countries to adopt and implement eHealth.
[61] Why Estonia is a good place for eHealth (and why you should attend eHealth Tallinn). HIMSS Europe. (2018). Himss.eu. [cited 3 December 2018]. Available from: https://www.himss.eu/himss-blog/why-estonia-good-place-ehealth-and-why-you-should-attend-ehealth-tallinn
[62] Novek A. An Overview of Current Estonian Health Information System Architecture: Pitfalls and Prospects (13 October 2017). Tervise ja Healou Infosusteemide Keskus [cited 4 December 2018].

overall monitoring system that is weaker since it has not been properly introduced, established nor enforced.[63] As a result, Latvia is classified as a system with *mandatory immunization with monitoring and follow-up*.

As noted, Estonia implemented the P4P system thereby establishing a set of financial incentives for doctors. Immunization is an indicators of performance,[64] meaning doctors are incentivized to address the issue of refusals and encourage childhood immunization. There are potential drawbacks to this approach (such as data inflation), but the benefit is proactive dialog to address vaccine hesitancy and provide accurate information about immunization benefits, safety and risks. Neither Latvia nor Lithuania provide such healthcare provider incentives.

Latvia is the only Baltic State with a mandatory immunization approach, classified as *mandatory immunization with monitoring and follow-up*. Despite this mandatory requirement, other aspects of the NIP are weaker than Estonia's. For example, Latvia's healthcare system has historically been and remains one of the most under-funded in the European Union, and many citizens pay for services out-of-pocket.[65] Since lack of financing can undermine the quality of services provided, it is an important difference to take into account when comparing the three countries. Ongoing debate surrounds the proposed change from Social Health Insurance (SHI) in Latvia to a National Health Service (NHS) type system, which has hampered efforts to improve the financing situation. Monitoring is another relatively weak part of Latvia's system. Like Estonia and Lithuania, Latvia has working to adopt e-Health. Initiated in 2007, the project has experienced some setbacks and has not been fully implemented.

Political will is a primary driver of success in the introduction of legislative changes, regardless of a recommended or mandatory approach. Latvia, for example, has not developed the same level of political will and continuity as Estonia for its healthcare and by extension its immunization program reforms. Unlike Estonia, Latvia had a lot of political debate and experienced opposition to changes in the health sector. Managerial capacity, a clear and simple vision and a strong political backing were critical factors of success for the Estonian reforms. Latvia has not had such political will and support; many of the legislative and regulatory changes have not been implemented in a timely manner, efficiently or at all. In Estonia's case, political will contributed to successful NIP implementation. In many ways this is self-evident, as the introduction and implementation of law is easier in countries where there is support and harder where there is opposition.

In terms of immunization coverage, there are currently some differences across the Baltic States, with 93 percent coverage for DTP3 in Estonia, 94 percent in Lithuania and 98 percent in Latvia. This four to five percent difference cannot be easily attributed to a statistical error and the data is illustrative of an increasing trend. Aside from being statistically significant, the five percent difference puts Latvia above the 95 percent threshold for herd immunity. Latvia's figures increased significantly since the beginning of the decade, from 91 percent in 2012 to 98 percent in 2016-2017, Estonia's numbers actually decreased from 94 percent in 2012 to 93 percent in 2014-2017, while Lithuania's increased slightly from 93 percent in 2012 to 94 percent in 2016-2017. In the case of Estonia, it seems the mandatory provision, even with weaker implementation, resulted in higher coverage. However, Estonia is an illustrative example and this study does not provide justification for correlation between legislative approach and immunization coverage.

[63] Pulmanis E. Implementation of the eHealth Project in Latvia: Project audit perspective. State Audit Office of the Republic of Latvia. PM World Journal. 2018 October; 5(10). Available from: https://pmworldjournal.net/wp-content/uploads/2016/10/pmwj51-Oct2016-Pulmanis-eHealth-project-audit-perspective-featured-paper.pdf;
[64] Merilind E, Salupere R, Vastra K, Kalda R. Pay for performance of Estonian family doctors and impact of different practice- and patient-related characteristics on a good outcome: A quantitative assessment. Medicina. 2016; 52(3): 192-198.
[65] WHO notes on health system financing policy in Latvia: opportunities and challenges in light of international experience [Internet]. World Health Organization. 2016. Available from: http://www.vm.gov.lv/images/files/Latvia_meeting_report_WHO_2016_final_13_July_%281%29.pdf

The consensus of literature currently available on the relationship between legislative provisions and immunization coverage is that mandatory frameworks for immunization legislation do not result in higher coverage.[66,67,68] An ASSET[69] study conducted from 2007 to 2013 across 27 European countries to verify whether mandatory immunization in Europe is associated with better childhood immunization coverage rates concluded that countries where immunization was mandatory did not usually reach better coverage than neighboring or similar countries where there was no such legal obligation. The ASSET study referred to Latvia as an example "where vaccinations are mandatory, [but it] does not get better results than other Baltic countries." In contrast, this study has determined that Latvia does have a slightly better immunization coverage rate in the long-term and has fared better than its neighbors with recommended legislative approaches (Estonia and Lithuania). It is important to clarify that there are likely many factors behind Estonia's higher coverage rate and Estonia's legislative framework alone, is unlikely the cause.

Conclusion

Estonia, Latvia and Lithuania have established robust legal frameworks to support immunization programs and ensure that immunization is prioritized. Each of the Baltic States have reformed their health systems and NIPs to guarantee financing for vaccines, to improve data collection and monitoring systems, and to make procurement more efficient. All three countries are currently achieving relatively high coverage rates and are each developing ways to address vaccine hesitancy.

This case study illustrates that no one legislative approach alone leads to high immunization coverage. Furthermore, it reinforces the concept that legislative approaches to immunization must be tailored to country-specific needs, including political context and the strength of implementation programs. The success of immunization coverage in each country depends on a comprehensive approach to the immunization system.

Given the similarity in context across the Baltics States, the difference in legislative approaches and up to a five percent variance in immunization coverage rates, further study may be worthwhile to explore the relationship between legislative approaches and immunization coverage in Estonia, Latvia and Lithuania. Additional study may yield insight on the impact of recommended and mandatory legislative approaches on coverage, hesitancy and general strength of immunization programs.

[66] Shaw J, Mader EM, Bennett BE, Vernyi-Kellogg OK, Yang YT, Morley CP. Immunization Mandates, Vaccination Coverage, and Exemption Rates in the United States. Open Forum Infectious Diseases 2018;5. doi:10.1093/ofid/ofy130.
[67] ASSET (Action plan on Science in Society related issues in Epidemics and Total pandemics). "Compulsory vaccination and rates of coverage immunisation in Europe" [Internet]. ASSET; 2016 January [cited 2018 Aug]. 6 p. Available from: http://www.asset-scienceinsociety.eu/reports/pdf/asset_dataviz_I.pdf
[68] D.A. Salmon, S.P. Teret, C.R. MacIntyre, D. Salisbury, M.A. Burgess, N.A. Halsey Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future. Lancet, 367 (9508) (2006), pp. 436-442
[69] ASSET (Action plan on Science in Society related issues in Epidemics and Total pandemics). "Compulsory vaccination and rates of coverage immunisation in Europe" [Internet]. ASSET; 2016 January [cited 2018 Aug]. 6 p. Available from: http://www.asset-scienceinsociety.eu/reports/pdf/asset_dataviz_I.pdf

France:

Moving towards a more coercive approach to immunization

European Region Matrix: Immunization Legislation

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?
YES	YES	YES	YES	YES	NO	YES	YES

COVERAGE INDICATORS		
	DTP3	96%
	IPV	N/A

MEASLES (cases, 7/2017–6/2018)
2741

Answer Verified by Authoritative Secondary Sources Answer Verified by Survey * Information not available at this time

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

Introduction

France has had mandatory immunization legislation in place since the 1950s. A 2017 legislative change required additional mandatory vaccines and led to a classification of *mandatory immunization with robust monitoring and follow-up*, the highest level, on the "Likert Scale: Assessing Levels of Immunization Legislation" developed by the Sabin Vaccine Institute (Sabin) for this study. This differentiates France from most EU neighbors, except for Belgium and Italy, who generally follow more liberal approaches. Although vaccine coverage in France has not decreased significantly in recent years, the country has faced highly publicized measles outbreaks (in 2008-2011 and currently in 2016-2018). One possible reason behind the swift introduction of this legislative change is the political support of the Ministry of Health (MOH), and Minister of Health, Agnès Buzyn. Minister Buzyn, who assumed office May 17, 2017, is a strong and vocal supporter of mandatory immunization, and employed the use of evidence-based methods (surveys) and science-based arguments to support the introduction of the new legislation with the backing of medical societies and experts. Despite the swift passage of the legislation in 2017, France has a strong anti-vaccine movement. Like Greece, Italy and other countries in the World Health Organization (WHO) European Region,[1] populist movements spread anti-vaccine rhetoric and oppose mandatory vaccines. In France, populist politician Marine Le Pen's National Rally Party, formerly the National Front, opposes mandatory immunization and publicly questions vaccine safety.[2] If a populist movement should come to power in France, efforts to change the current mandatory law may occur, as they have in Greece and Italy where similar mandates have lost traction (and in Italy's case was overturned by the Senate) without sustained political support.

Since mandatory legislative changes were passed in 2017 in France, the focus of this study is the rationale and enabling factors behind the introduction of this legislation, as well as the process of adoption and accompanying measures that were put in place to strengthen compliance. Among these factors is the strong political will on the part of the current administration and the public consultations conducted prior to passing legislation. Given the recent passage of this legislation, this study cannot fully assess the impact on immunization coverage and outbreak trends, but the immediate impact and implementation of the 2017 legislation is examined.

Methodology

This study was carried out by the Sabin Vaccine Institute 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).

[1] The WHO Regional Office for Europe is one of WHO's six regional offices around the world. It serves the WHO European Region, which comprises 53 countries, covering a vast geographical region from the Atlantic to the Pacific oceans (http://www.euro.who.int/en/about-us). We will refer to this area as the European Region throughout this document.
[2] France looks to curb its growing anti-vaccination movement with a new law. (2017). The Verge. [cited 5 December 2018]. Available from https://www.theverge.com/science/2017/7/13/15964628/france-vaccination-skeptic-law-vaccine-mandate

Context and findings

Legislation

Since the 1950s, France has required that all children be vaccinated for diphtheria, tetanus and polio. In November 2017, France approved a new law mandating an additional eight vaccines (Hepatitis B, pertussis, pneumococcal, meningitis [Haemophilus influenzae type B, or Hib], meningitis C, measles, mumps and rubella) for all children under two years old. Effective January 2018, children must be vaccinated against 11 diseases. Those who have not had all their immunizations, including booster shots, will be refused admission to nurseries, schools and camps in France.

Rationale for introducing mandatory legislation: Measles outbreaks

Unlike other countries implementing mandatory vaccines as a response to falling rates of coverage, France has not seen a strong decline in its immunization rates.[3] Coverage rates for newer vaccines are below recommended levels, but have nonetheless increased steadily over time. The rate of meningitis C immunization, for example, has increased since introduction a decade ago, from just 48 percent among two-year-olds at the end of 2011 to 71 percent in the same group in 2016. [4] Overall, vaccine coverage in France for most diseases is high. At the same time, over the last six years, the coverage with booster shots has risen from a low of 67 percent in 2010, to 79 percent in 2016. [5] Further improvement is needed though. For example, 90 percent coverage is recorded for the first measles shot and only 79 percent coverage for the second.

Coverage numbers may make it difficult to explain why France has introduced coercive measures. However, the increasing number of measles cases and measles-related deaths are likely factors.[6] Since 2008, measles have caused 10 deaths in France.[7] France is among the countries with the highest number of measles cases and deaths in the European Region. It has recorded more than 2,600 cases of measles in 2018 (until September), including three deaths and high rates of hospitalization (22%).[8] It has faced large outbreaks in the past, including one where over 4,000 people were infected in 2011. [9,10] The

[3] Immunization country profiles 2017 [Internet]. UNICEF DATA. 2018. Available from: https://data.unicef.org/wp-content/uploads/country_profiles/France/immunization_country_profiles/immunization_fra.pdf
[4] Laws are not the only way to boost immunization [Internet]. Nature News. Nature Publishing Group; 2018. Available from: https://www.nature.com/articles/d41586-018-00660-y
[5] Immunization country profiles 2017 [Internet]. UNICEF DATA. 2018. Available from: https://data.unicef.org/wp-content/uploads/country_profiles/France/immunization_country_profiles/immunization_fra.pdf
[6] Ukraine restores immunization coverage in momentous effort to stop measles outbreak that has affected more than 12 000 this year [Internet]. World Health Organization. World Health Organization; 2018. Available from: http://www.euro.who.int/en/countries/ukraine/news/news/2018/05/ukraine-restores-immunization-coverage-in-momentous-effort-to-stop-measles-outbreak-that-has-affected-more-than-12-000-this-year; Mcneil DG. Measles Cases in Europe Quadrupled in 2017 [Internet]. The New York Times. The New York Times; 2018. Available from: https://www.nytimes.com/2018/02/23/health/measles-europe.html; Epidemiological update: Measles - monitoring European outbreaks, 15 September 2017 [Internet]. European Centre for Disease Prevention and Control. 2017. Available from: https://ecdc.europa.eu/en/news-events/epidemiological-update-measles-monitoring-european-outbreaks-15-september-2017; Measles outbreak in Ukraine kills two [Internet]. Medical Xpress - medical research advances and health news. Medical Xpress; 2018. Available from: https://medicalxpress.com/news/2018-01-measles-outbreak-ukraine.html
[7] Santi P, Assekour H. La loi pour rendre onze vaccins obligatoires sera examinée avant la fin de l'année [Internet]. Le Monde; 2017. Available from: https://www.lemonde.fr/sante/article/2017/07/05/la-loi-pour-rendre-onze-vaccins-obligatoires-sera-examinee-avant-la-fin-de-l-annee_5156364_1651302.html#EiCVqpwYzBcF8KAv.99
[8] France measles outbreak: babies hit hardest - VaccinesToday. (2018). VaccinesToday [cited 5 December 2018], Available from: https://www.vaccinestoday.eu/stories/france-measles-outbreak-babies-hit-hardest/; Measles cases hit record high in the European Region. World Health Organization (20 August 2018). Euro.who.int [cited 5 December 2018]. Available from http://www.euro.who.int/en/media-centre/sections/press-releases/2018/measles-cases-hit-record-high-in-the-european-region FOR
[9] Antona D, Lévy-Bruhl D, Baudon C, Freymuth F, Lamy M, Maine C, et al. Measles Elimination Efforts and 2008–2011 Outbreak, France. Emerging Infectious Diseases 2013;19:357–64. doi:10.3201/eid1903.121360.
[10] World Health Organization (WHO). WHO EpiData: A monthly summary of the epidemiological data on selected Vaccine-preventable diseases in the European Region [Internet]. Geneva: World Health Organization; 2018 [cited 5 December 2018]. [Table], Table 1: Reported measles cases for the period October 2017 — September 2018 (data as of 07 November 2018). Available from: http://www.euro.who.int/__data/assets/pdf_file/0004/386392/epi-data-oct2017-sept2018-eng.pdf?ua=1

country has committed to eliminating measles under the WHO Global Vaccine Action Plan[11] and European Vaccine Action Plan[12] goals.

In many countries, including France, the United States, the United Kingdom and others, these measles outbreaks could be due to the percent of vaccinated individuals falling below the 95 percent "herd-immunity" threshold which protects the rest of the population against infectious diseases like measles.[13] Herd-immunity is the concept that a community must be comprised of enough immune people so if a person contracts a contagious disease, the disease will not spread[14] among the large number of unvaccinated individuals. As noted above, in France the coverage for measles is at only about 79 percent. As several countries have faced vaccine-preventable disease outbreaks in the last couple of years, many have identified vaccine hesitancy or reluctance by parents to vaccinate their children as one of the causes behind the decreasing immunization coverage rates, France with a reported population hesitancy rate of 41% of surveyed citizens disagreeing that vaccines are safe.[15]

Process behind introducing the laws: Surveys and public consultations

Prior to introducing legislative measures, several of the European Region countries have commissioned some type of government mandated public consultation, or have surveyed their populations on the topic of immunization to better understand the causes of hesitancy and to strategize methods to increase vaccine demand, given the national context, population attitudes and other factors. France is one of these countries, and according to surveys, it is also one of the most vaccine-skeptical nations.[16] A recent survey showed that nearly one-third of the French population does not trust vaccines and only 52 percent believe that the benefits of vaccines outweigh their negative effects.[17] Vaccine hesitancy is also present among healthcare workers. About "16-43 percent of French family doctors said they never or only sometimes recommended some specific vaccines."[18]

Aware of these trends in France, a government committee was established to carry out a public consultation to further assess vaccine hesitancy.[19] The committee worked on the premise that "immunization has been a victim of its own success"– people do not see the necessity to vaccinate given the rarity of vaccine-preventable diseases. The perception of some is that the risk and negative side effects of immunization outweigh benefits and this belief is promoted by the anti-vaccine voices. In 2015, then Minister of Health Marisol Touraine (served as Minister of Health from 2012 to 2017), a vaccine supporter, tasked the government committee with launching a public consultation to field the viewpoints of vaccine critics and to encourage them to engage with public health professionals and experts on vaccines

[11] Global Vaccine Action Plan: Regional reports on progress towards GVAP-RVAP goals. Geneva: World Health Organization; 2016.
[12] European Vaccine Action Plan 2015-2020. Copenhagen, Denmark: WHO EURO; 2014.
[13] Funk, Sebastian. Critical immunity thresholds for measles elimination [Internet]. World Health Organization; 2017. Available from: http://www.who.int/immunization/sage/meetings/2017/october/2._target_immunity_levels_FUNK.pdf
[14] Plans P, Torner N, Godoy P, Jané M. Lack of herd immunity against measles in individuals aged <35 years could explain re-emergence of measles in Catalonia (Spain). International Journal of Infectious Diseases. 2014;18:81–3.
[15] Larson HJ, Figueiredo AD, Xiahong Z, Schulz WS, Verger P, Johnston IG, et al. The State of Vaccine Confidence 2016: Global Insights Through a 67-Country Survey. EBioMedicine 2016;12:295–301. doi:10.1016/j.ebiom.2016.08.042.
[16] Larson HJ, Figueiredo AD, Xiahong Z, Schulz WS, Verger P, Johnston IG, et al. The State of Vaccine Confidence 2016: Global Insights Through a 67-Country Survey. EBioMedicine. 2016;12:295–301; Cohen Sep J. France most skeptical country about vaccine safety [Internet]. American Association for the Advancement of Science; 2017. Available from: http://www.sciencemag.org/news/2016/09/france-most-skeptical-country-about-vaccine-safety
[17] Les Français font de moins en moins confiance aux vaccins [Internet]. Le Monde; 2016. Available from: https://www.lemonde.fr/sante/article/2016/10/24/les-francais-font-de-moins-en-moins-confiance-aux-vaccins-selon-une-etude_5018964_1651302.html; Katie Forster. France will make all vaccinations compulsory by law [Internet]. The Independent; 2017. Available from: http://www.independent.co.uk/news/world/europe/france-vaccination-mandatory-2018-next-year-children-health-measles-dying-anti-vaxxers-edouard-a7824246.html; Vaccins obligatoires: "Entre 10 et 20 millions d'euros", annonce Agnès Buzyn [Internet]. RTL.fr. Available from: https://www.rtl.fr/actu/politique/vaccins-obligatoires-entre-10-et-20-millions-d-euros-annonce-sur-rtl-agnes-buzyn-7789233053
[18] Why vaccination rates in the West are too low [Internet]. The Economist; 2016. Available from: https://www.economist.com/blogs/economist-explains/2016/03/economist-explains-2
[19] Présentation du rapport de conclusions du comité d'orientation [Internet]. Concertation Citoyenne Sur La Vaccination; 2016. Available from: http://concertation-vaccination.fr/wp-content/uploads/2016/11/DP-30.11-Concertation-citoyenne-sur-la-vaccination.pdf

and infectious diseases. This consultation came on the heels of a petition denouncing the use of aluminum adjuvants in vaccines that had reached a million signatures. The consultation curated the knowledge of medical experts, generated recommendations given by citizen juries of both laypeople and experts randomly polled, and fielded ideas solicited from an internet platform. Acting on the results of this unprecedented consultation, in November 2016 the organizing committee made several recommendations for reforming the country's vaccine policies.[20]

The committee recommended that the number of mandatory vaccines be temporarily increased and underlined that additional measures would be necessary to increase immunization coverage as well as restore confidence in vaccines. It recommended that mandatory health insurance fully cover the purchase of vaccines and that a compensation scheme covering adverse effects be established, since certain vaccines are mandatory. It also stated there must be sufficient supply of mandatory vaccines and that a new electronic immunization passport be implemented to improve monitoring. The government used these recommendations to back the introduction of a bill increasing the number of mandatory vaccines, as well as removing several exemptions.

Another factor influencing the passage of the legislation was the requirement issued by the State Council of France in 2017.[21] This requirement came after the Constitutional Court ruled that mandatory immunization is legal under the French Constitution. The constitutionality of the mandatory provision was raised by Samia and Marc Larères, who asked the Constitutional Court for a "priority preliminary ruling on the issue of constitutionality" (QPC) after a regional court in Auxere referred their case in January 2016.[22] In January 2016, the regional court sentenced the couple to a two-month suspended jail sentence for refusing to vaccinate their two young children.[23] The couple refused to vaccinate their children because non-mandatory vaccines were included in the hexavalent vaccine available.[24] In 2015, prior to the new legislation, only diphtheria, tetanus and polio were mandatory, however, the hexavalent vaccine available from vaccine suppliers in France included an additional three antigens against pertussis, Haemophilus influenzae type B and hepatitis B. The parents initially objected to this defacto mandatory immunization with six antigens, since a vaccine with only three mandatory ones was not available and single-antigen vaccines were not available. Later in the trial, the couple confirmed that they received the vaccines containing only the three mandatory antigens from Sanofi Pasteur, but still refused to vaccinate their children with a "toxic product." They were given a two-month suspended jail sentence. The case became high-profile in France, further fueling anti-vaccine and anti-establishment rhetoric.

Following the Larère case, the French State Council asked the MOH to draft new legislation and harmonize the legal provision with the available vaccine supply.[25] This harmonization likely was a factor in eight vaccines becoming mandatory to avoid future instances where non-mandatory vaccines are offered together with mandatory ones in a single polyvalent vaccine.

One of the arguments used against introducing mandatory immunization legislation is that it can cause a backlash in part of the population and/or lead to increased litigation which results in higher costs for the state. Carrying out a proper assessment of the population's attitudes and analyzing the causes behind

[20] Ward JK, Colgrove J, Verger P. Why France is making eight new vaccines mandatory. Vaccine. 2018; 36(14):1801–3.
[21] ILR, M., & ILR, M. (2018). Mandatory Vaccination in In France. MSU Internatonal Law Review. Retrieved 19 November 2018, from https://www.msuilr.org/msuilr-legalforum-blogs/2017/11/30/mandatory-vaccination-in-in-france
[22] Vaccination : deux mois de prison avec sursis contre les époux Larère. (7 January 2016). France Bleu [cited 5 December 2018]. Available from https://www.francebleu.fr/infos/faits-divers-justice/vaccination-2-mois-de-prison-avec-sursis-contre-les-epoux-larere-1452190526
[23] Browne R. French couple given suspended jail time for refusing to vaccinate children. Brisbane Times 2016. https://www.brisbanetimes.com.au/world/french-couple-jailed-jailed-for-refusing-to-vaccinate-children-20160108-gm1thy.html
[24] This legal "incoherence" was utilized in court, when Samia and Marc Larère were charged under two legal provisions for refusing to vaccinate their child. First, a provision in the Code of Public Health (*le code de la santé publique*, art. L.3116-4) that imposed a fine of 3,750 euros and up to six months in jail for those who do not receive— or allow those under their guardianship to receive —mandatory vaccinations.[24]And second, a provision in the Criminal Code that criminalizes neglect of parental duties "to the point of risking the health… of a minor child," with a fine of 30,000 euro and up to two years in prisons as penalty.
[25] Ward, Jeremy K., et al. "Why France Is Making Eight New Vaccines Mandatory." Vaccine, vol. 36, no. 14, 2018, pp. 1801–1803., doi:10.1016/j.vaccine.2018.02.095.

hesitancy and delays in immunization could potentially help, if not alleviate, these risks. France followed this path, using the conclusions and recommendations from the public consultation to implement legislative changes. Following the backlash to mandatory immunization legislation in Greece and Italy, which in Italy has resulted in the Senate overturning the Italian mandated immunization law,[26] the implementation of France's public communications strategy and sustained political will championed by the MOH for such a law may be critical factors to achieving high immunization coverage and mitigating vaccine hesitancy.

Process behind introducing the laws: Political will and support from the scientific community

Political will and the support of the scientific community were key elements in the success of France's legislative initiative. Minister Buzyn advocated for the introduction of mandatory vaccines as the only possible solution given the measles outbreaks.[27] She stated: "We are sending a very strong message to the public that the vaccine emergency is driven by fake news, which has spread misinformation about vaccine safety."[28] In her argument, she leaned on the results of the public consultation conducted in 2015 on vaccine hesitancy, and the conclusions and recommendations of the government committee. She provided further justification, citing recent opinion polls that showed that if DTP3 vaccine was made voluntary an additional 15 percent of parents would not vaccinate their children.[29]

In 2016, France conducted open citizen debates and created avenues to voice opinions and present critiques during the public consultation about the law and its contents, leading to greater acceptance on the part of the population. In 2017, French health professionals also mobilized in support of the ministerial initiative, 200 leading doctors signed a petition in June backing the draft legislation rendering 11 vaccines mandatory.[30] Furthermore, in the same year, the academic and medical societies and the Medical Academy – for the first time – took a stand in favor of immunization in 2017.[31] Elected officials also voted favorably; the bill was supported by an overwhelming majority during votes in the National Assembly and Senate.

[26] Roberts H. Italy Senate overturns mandatory vaccination law [Internet]. Financial Times; 2018. Available from: https://www.ft.com/content/afd472be-996c-11e8-9702-5946bae86e6d

[27] Agnès Buzyn : "Contre la théorie du complot, il n'existe malheureusement aucun vaccin" [Internet]. Franceinfo; 2018. Available from: https://www.francetvinfo.fr/sante/soigner/agnes-buzyn-contre-la-theorie-du-complot-il-nexiste-malheureusement-aucun-vaccin_2547043.html ; Faverau E. Vaccins : les onze injonctions d'Agnès Buzyn [Internet]. Liberation.fr; 2018. Available from: http://www.liberation.fr/france/2018/01/01/vaccins-les-onze-injonctions-d-agnes-buzyn_1619833; Vaccins obligatoires : "Entre 10 et 20 millions d'euros", annonce Agnès Buzyn [Internet]. RTL.fr. Available from: https://www.rtl.fr/actu/politique/vaccins-obligatoires-entre-10-et-20-millions-d-euros-annonce-sur-rtl-agnes-buzyn-7789233053; La ministre de la Santé assure que les adjuvants ne sont pas nocifs [Internet]. RTL.fr. Available from: https://www.rtl.fr/actu/debats-societe/vaccins-la-ministre-de-la-sante-assure-que-les-adjuvants-ne-sont-pas-nocifs-7789505216 ; Pourquoi Agnès Buzyn a fait des vaccins obligatoires une priorité du quinquennat [Internet]. RTL.fr. Available from: https://www.rtl.fr/actu/politique/pourquoi-agnes-buzyn-a-fait-des-vaccins-obligatoires-une-priorite-du-quinquennat-7790587864

[28] Which vaccines are mandatory in Italy? [Internet]. Vaccines Today; 2017. Available from: https://www.vaccinestoday.eu/stories/vaccines-mandatory-italy/

[29] Cot BD. Agnès Buzyn et les vaccins: "Je n'irai pas mettre un gendarme devant chaque crèche" [Internet]. LExpress.fr; 2017. Available from: https://www.lexpress.fr/actualite/societe/sante/agnes-buzyn-et-les-vaccins-je-n-irai-pas-mettre-un-gendarme-devant-chaque-creche_1964380.html

[30] Vaccins: 200 médecins lancent un appel pour une vaccination obligatoire [Internet]. LExpress.fr.; 2017. Available from: https://www.lexpress.fr/actualite/societe/sante/vaccins-200-medecins-lancent-un-appel-pour-une-vaccination-obligatoire_1922643.html

[31] Cot BD. Agnès Buzyn et les vaccins: "Je n'irai pas mettre un gendarme devant chaque crèche" [Internet]. LExpress.fr; 2017. Available from: https://www.lexpress.fr/actualite/societe/sante/agnes-buzyn-et-les-vaccins-je-n-irai-pas-mettre-un-gendarme-devant-chaque-creche_1964380.html

Measures to support the implementation and impact of legislation mandating immunization

Although stipulated under a separate decree[32] from the mandatory immunization law, French parents are now required to provide their child's immunization records upon kindergarten and school enrollment. If a child has not been vaccinated in accordance with the immunization calendar, they are required to catch up within a three-month period or provide a valid medical exemption.[33] France has, however, revoked the previous penalties[34] for non-compliance, that ranged from administrative to criminal (as was imposed on the Larères),[35] and instead is relying on monitoring and education campaigns for both parents and school or medical establishment workers. Additional measures will be made to persuade rather than impose this decision on the public. Minister Buzyn introduced an annual progress report that will be publicly available, showing the results of the new immunization measures.

Additionally, the Minister assured the public that all mandatory vaccines will be 100 percent funded, as per the Public Health Code,[36] with 65 percent of the price reimbursed by Medicare, and 35 percent by complementary insurance. "The additional cost for Medicare of the vaccine extension is estimated between 10 and 20 million euros," detailed the Minister.[37] The French government is also committed negotiations with vaccine suppliers to ensure the necessary stocks of vaccines are available.[38]

Aside from harmonizing the legislation to correspond to the realities of the vaccine supply, the legislative changes introduced by France also update their national immunization schedules in line with current health recommendations and ensure that the newly recommended vaccines are perceived to be as important for children as the previous mandatory ones. There is concern that the mandatory vaccines will be perceived as the only "important ones" to give to a child. This perception is reinforced in cases where the mandatory vaccine costs are fully financed, while the recommended vaccines are partially covered or not covered at all, as was the case in France prior to mandating the additional eight vaccines. Full financial coverage also helps to ensure that vaccines are equally accessible to all regardless of social, geographical or economic status.

The financial provisions covering the costs of the newly mandatory vaccines are an example of the additional measures introduced by or in conjunction with legislation to reinforce the implementation of the law. As described above, other accompanying measures included improved monitoring and stronger

[32] Décret n° 2018-42 du 25 janvier 2018 relatif à la vaccination obligatoire [Internet]. Légifrance; 2018. Available from: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000036543886&categorieLien=id
[33] Loi sur le financement de la Sécurité sociale (PFSS), l'article 49.
[34] A provision in the criminal code that criminalizes neglect of parental duties "to the point of risking the health… of a minor child", with a fine of 30,000 euros and up to two years in prisons as penalty (article 227-17: "Le fait, par le père ou la mère, de se soustraire, sans motif légitime, à ses obligations légales au point de compromettre la santé, la sécurité, la moralité ou l'éducation de son enfant mineur est puni de deux ans d'emprisonnement et de 30 000 euros d'amende").
[35] The new law removed the provision of the Public Health Code that foresaw a maximum of 6 months imprisonment and a 3750 euros fine for refusing to vaccinate your children with vaccines mandated by law.
[36] Article L3111-11"Vaccinations carried out by the institutions and organizations authorized under conditions defined by decree are free. Local and regional authorities may carry out vaccination activities under an agreement concluded with the State. This agreement specifies the objectives pursued, the categories of beneficiaries, the means implemented, the amount of the subsidy granted by the State, the data whose transmission to the State is mandatory, the methods for evaluating the actions undertaken as well as that, as the case may be, relations with other bodies working in the same field. Vaccinations carried out under this agreement are free. For the insured persons or their dependents, the expenses related to the vaccines are covered by the health insurance organizations to which they belong and, for the beneficiaries of the medical aid of the State, under the conditions provided for under V of Book II of the Code of Social Action and Families and in the manner provided for in Article L. 182-1 of the Social Security Code (see European Immunization Policy Database).
[37] Santi P, Assekour H. La loi pour rendre onze vaccins obligatoires sera examinée avant la fin de l'année [Internet]. Le Monde; 2017. Available from: https://www.lemonde.fr/sante/article/2017/07/05/la-loi-pour-rendre-onze-vaccins-obligatoires-sera-examinee-avant-la-fin-de-l-annee_5156364_1651302.html#EiCVqpwYzBcF8KAv.99
[38] Santi P, Assekour H. La loi pour rendre onze vaccins obligatoires sera examinée avant la fin de l'année [Internet]. Le Monde; 2017. Available from: https://www.lemonde.fr/sante/article/2017/07/05/la-loi-pour-rendre-onze-vaccins-obligatoires-sera-examinee-avant-la-fin-de-l-annee_5156364_1651302.html#EiCVqpwYzBcF8KAv.99 « Des discussions vont par ailleurs être engagées avec les laboratoires pharmaceutiques pour éviter les pénuries, concernant entre autres le vaccin contre l'hépatite B. Des pénuries qui, bien souvent, freinent la vaccination ».

provisions regarding immunization for school admission. These measures help with follow-up, ensuring that those who hesitate or delay are given another chance to immunize.

Analysis

Although French officials were able to garner political support to pass legislation mandating vaccines, the long-term effects on vaccine coverage are unclear. The key factors in the passage of this law were the widespread consultations and engagement between the public and medical experts, elimination of criminal penalties with simultaneous strengthening of school requirements, addressing further barriers to immunization, such as cost, by mandating full payment for the vaccines by the government and harmonizing the legislation in accordance with the available vaccine supply, as well as introducing public information education campaigns. After assessing the attitudes toward immunization among the population and among health professionals, France has recognized vaccines and public health as critical for investment and created single sources of publicly available, scientifically supported, reliable information for the public and introduced additional instruction opportunities for health professionals.

Minister Buzyn stressed that the coercive measures are a “last resort in the face of an emergency” and that the long-term goal for the French MOH is to change French attitudes towards immunization, educating and convincing the population that the benefits outweigh the associated risks. The results of the 2015 public consultation carried out by the government committee recommended that the mandatory measures be temporary and subject to review. Although the new legislation does not emphasize that the mandate is temporary, the French government has pledged to annually review the compliance with and impact of the new law and make the results of the evaluation public (starting in the last trimester of 2019).[39] Monitoring the implementation and impact will help assess whether the mandatory legislative provisions can increase vaccine coverage in France.

Given the reversal of vaccine mandates and poor enforcement in the European region, in the coming years France will need to continue to address vaccine hesitancy and monitor the rise of anti-vaccine movements. Publicizing the results of monitoring and evaluation measures should, in theory, increase confidence in these interventions and ensure government transparency.

One of the challenges of the introduction of more mandatory legislation in France is that it has united two unlikely groups against immunization, far right nationalists and far-left ecologists.[40] As noted earlier, Marine Le Pen, the conservative French politician, has raised doubts about the safety of vaccines and stated that she is opposed to the new mandatory law as it takes free will away from parents who are opposed to immunization. Anti-establishment parties from across the political spectrum have expressed sympathy with vaccine skeptics and have expressed mistrust of vaccines. This can lead to increased vaccine hesitancy, even in areas where coverage is high. Lack of political support will likely result in delays in adoption or weakening of legal provisions, whether they are mandatory or recommended, leading to a negative impact on coverage. The rise of populist, antiestablishment parties threatens to have further adverse effects as they support and legitimize vaccine refusal. If any of these groups are elected, they may overturn the mandatory provision. In Italy, this has already occurred and immunization is no longer mandatory.

[39] LOI n° 2017-1836 du 30 décembre 2017 de financement de la sécurité sociale pour 2018 (1) [Internet]. Légifrance; 2018. Available from: https://www.legifrance.gouv.fr/eli/loi/2017/12/30/CPAX1725580L/jo/texte
[40] Mandatory Vaccination in In France [Internet]. MSU Internatonal Law Review. Available from: https://www.msuilr.org/msuilr-legalforum-blogs/2017/11/30/mandatory-vaccination-in-in-france#_ftn17

Conclusion

Given the recent passage of 2017 mandatory legislation, it is premature to determine if changes in vaccine coverage rates are in part due to strengthening of the mandatory legislation. If in the future a change in coverage is significant and can be shown to have occurred after the introduction, assessing an association between the mandatory legislation introduced and changes in long-term coverage may be possible.

Even if such an association can be shown in the case of France, this does not indicate that similar vaccine mandates will work in other countries in the same way. Many factors need to be considered when reviewing the success of mandatory provisions, including the citizens' attitude toward and acceptance of coercive or mandatory legislation. In most countries reviewed in this study, the introduction of mandatory measures have led to public protests. Knowing that such a backlash is possible, France conducted research to assess the potential fallout, publicize the mandate prior to implementation and gauge whether its impact would be significant enough to negate the potential benefits.

Another factor when considering the success of mandatory law is the assessment of the overall need and immunization system capacity – the calculated burden of diseases and outbreaks, coverage trends, financing mechanisms and available supply, technical capacity to implement and monitor compliance, the education system and its respective reach and regulations. France conducted a thorough assessment to ensure the country had a robust immunization system in place. These and a host of other factors, many of them country-specific, need to be considered by countries contemplating similar changes prior to proposing legislation.

It is important to keep in mind that France enjoyed a favorable political environment and had strong immunization champions for the introduction of the mandates. Legislation introduced in other countries with comparably favorable circumstances, for example, Greece and Italy, was vulnerable to reversals and declining coverage when political dynamics shifted. Sustained political will is an important factor to consider as countries contemplate adopting immunization mandates; introducing legislation may be ineffective, short-lived or unacceptable to the population.

Moldova:

Reviewing a recommended approach with mandatory requirements for school attendance

European Region Matrix: Immunization Legislation

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?
YES	NO	NO	NO	YES	YES	YES	YES

COVERAGE INDICATORS		
	DTP3	88%
	IPV	N/A

MEASLES (cases, 7/2017–6/2018): **37**

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey * Information not available at this time

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

Introduction

The case of Moldova provides an interesting example of the benefits and challenges of a recommended approach that incorporates some mandatory requirements for specific groups. In Moldova, vaccines on the national immunization calendar are free and voluntary, although children must meet all routine immunization requirements to enter educational and other collective institutions. Moldova is classified as a *recommended with mandatory requirements for school attendance* approach on the "Likert Scale: Assessing Levels of Immunization Legislation" developed by the Sabin Vaccine Institute (Sabin) for this study. Although there is no mandatory provision in health- and immunization-related legislation, a provision addressing school entry exists in education-related legislation. An enforceability mechanism is implemented through the school or kindergarten entry restriction.

Moldova's National Immunization Program (NIP) is an example of a gradual approach to introducing new vaccines, with mechanisms in place to ensure that the government has adequate financing to pay for them and that coverage rates are sustained and improved over time. With planning organized through a five-year NIP, new vaccines have been added to the immunization calendar and accompanying measures have been introduced to ensure program viability.

Coverage trends

After declaring its independence from the Soviet Union in 1991 and adopting its constitution in 1994, Moldova's health programs, including the NIP, faced many challenges. However, immunization coverage was high (at or above 85 percent) from the end of the 1990s until a recent dip.[1] This strong performance is likely linked to the fact that Moldova has prioritized immunization through its legal framework by guaranteeing immunization as a public good, defining the immunization calendar and establishing general regulations for vaccine procurement and administration. Introduction of health insurance in 2004 improved financing of the health system, access to services and financial protection of the population.

However, around 2009, immunization rates started dropping and vaccine hesitancy became more pronounced. It has been observed not only among parents, but also among some nurses and doctors who have doubts about the effectiveness of vaccines. Parents and healthcare providers may also have a negative perception about the quality of some vaccines. Even though all vaccines available in Moldova are World Health Organization (WHO) prequalified products and follow recognized safety standards, some people believe that vaccines available through public providers are low quality and they prefer to go to private clinics for vaccination. Given such perceptions and the fact that the law[2] requires a child to be immunized prior to attending kindergarten, several parents have voiced concern that their children's right to education is being infringed upon. The Constitutional Court has upheld the mandatory immunization requirement for kindergarten attendance several times, ruling that it must be enforced in 2013,[3] and as recently as October 2018. However, this has not increased coverage,[4] illustrating that in this case, a purely legislative or coercive approach does not necessarily directly impact coverage. With the new NIP

[1] Anon. Moldova: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017. Available from: http://www.who.int/immunization/monitoring_surveillance/data/mda.pdf
[2] Law of the Republic of Moldova [Internet]. Law on State Supervision on Health, 2009. Available from: http://cis-legislation.com/document.fwx?rgn=27147
[3] In 2013 the Constitutional Court upheld the constitutionality of the vaccination requirement for educational institution attendance: https://www.balcanicaucaso.org/eng/Areas/Moldova/Resistance-in-Moldova-to-health-law-on-mandatory-vaccination-133929; in October 2018 the Constitutional Court held that the provisions of Article 52 para. (6) of the Law no. 10 of 3 February 2009 on State oversight of public health in that they are consistent with Articles 28, 35 and 16 of the Constitution: Press release of the Constitutional Court of Moldova - http://constcourt.md/libview.php?l=en&id=1317&idc=7&t=/Media/News/The-Constitutional-Courts-Solution-on-the-Issue-of-Childhood-Vaccination-and-Their-Access-to-Educational-and-Recreational-Institutions/
[4] Anon. Moldova: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017. Available from: http://www.who.int/immunization/monitoring_surveillance/data/mda.pdf

(2016-2020), the government introduced measures to improve communication and educate healthcare providers to increase vaccine uptake and counter vaccine hesitancy. For the first time, the NIP also included a budget for a communication strategy. With the communication strategy in place for such a short period of time, it is too soon to determine tangible impact in improving coverage.

With the current legislative framework for immunization, the government's commitment to immunization, including consecutive NIPs and interventions, and technical support from donors and partners, Moldova reversed a declining trend for the first time in the early 2000s. Authorities are retaining the current immunization requirements and supplementing them with a communications strategy. The goal of such renewed efforts is to bolster compliance with immunization requirements, improve health literacy among the population and ultimately, expand immunization coverage.

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, and 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).

Context and Findings

Immunization legislative framework

Moldova has clear and targeted legislative provisions that have helped prioritize immunization. Further, Moldova has prioritized immunization and leverages the NIP to help strengthen vaccine uptake which, to date, has negated the need to strengthen the legislative framework toward a stronger mandatory approach.

The right to health

Moldova's 1994 Constitution guarantees the right to health[5] (see Database) and requires the state to provide a basic level of health protection to all citizens. This is the foundation for the country's immunization policy (see Database).[6] In order to further improve health outcomes, the Parliament approved the Law on Mandatory Health Insurance (1998)[7] and introduced a state-funded free health service package in 1999.[8]

[5] Art 36 : «Right to Health Protection
(1) The right to health protection is guaranteed.
(2) The minimum health insurance provided by the State shall be free of charge.
(3) The structure of the national health security system and the means aimed at protecting the physical and mental health of the individual shall be provided for by organic law."
[6] Constitution of the Republic of Moldova Article 36 Right to Health Security July 29, 1994. Available from: http://www.wipo.int/wipolex/fr/text.jsp?file_id=427200#LinkTarget_1673
[7] Parliament of Republic of Moldova. Law On Mandatory Medical Insurance-No. 1585 (1998). Available from: http://www.law-moldova.com/laws/rus/obeazatelinom-meditsinskom-strahovanii-ru.txt [Accessed 5th March 2018].
[8] Law on the Minimum Package of Free-of-Charge Health Care Guaranteed by the State 1999: Chisinau, Moldova. 1999.

Health system financing and immunization

Given the economic challenges that Moldova faced after the collapse of the Soviet Union, limited funding was available to implement many of the laws that address immunization. The introduction of mandatory health insurance[9] (see Database) and the establishment of the National Health Insurance Company (CNAM) in 2004 (see Database)[10] improved financing of the health system, access to services and financial protection of the population. As a result of the introduction of mandatory health insurance, the financing scheme included the Government Health Insurance Fund, which now covers all expenses for the maintenance and overhead costs of healthcare facilities at the sub-national level (district and municipal levels), including items such as payroll, outreach efforts and immunization.[11]

The National Health Policy (2007-2016) (see Database) was followed by the Health System Development Strategy (2008-2017)[12] specifically aimed at expanding insurance coverage through financial incentives and requiring an insurance policy when renewing government-issued licenses. It also decreed that children should have universal access to essential health services, including immunization.

Strengthening surveillance and introduction of mandatory immunization for children to enroll in kindergarten

The Sanitary Epidemiological Service was traditionally oriented toward communicable disease prevention and control, regulation over exposure to risk factors, surveillance and law enforcement. In 2009, this entity was reformed by Law no. 10 on February 3, 2009 into the State Service for Public Health Surveillance.[13] The reformed State Service for Public Health Surveillance comprises the National Public Health Center, two municipal Public Health Centers (Chișinău and Bălţi) and 34 district Public Health Centers. The reform was oriented toward aligning national legislation and institutional structure and capacity with international and European community norms, International Health Regulations (2005) and to respond to new challenges that affect the population's health status. This included strengthening surveillance, prevention and control over communicable and non-communicable diseases, health promotion, information and health education, and assessment of the social determinants of health. Management of the NIP remains one of the leading areas of work of the State Service for Public Health Surveillance. The Law on State Surveillance of Public Health (see Database)[14] strengthened the government's ability to monitor communicable diseases and also introduced the requirement that children need to receive all vaccines included in the national schedule to enroll in kindergarten.

In accordance with Government Decision no. 705 dated September 6, 2017 on the creation of the National Public Health Agency and the reorganization of some legal entities,[15] the National Public Health Agency was created. The new Agency is an administrative and legal authority within the Ministry of Health, Labor and Social Protection and was created by merging a number of older authorities.[16] It remains to be seen how this reform will impact immunization, but the primary role given to the National

[9] Law on Mandatory Health Insurance 2004. Chisinau, Moldova.
[10] Law on Mandatory Health Insurance 2004. Chisinau, Moldova.
[11] Government of the Republic of Moldova. Comprehensive Multi-Year Plan for Immunization Programme 2011-2015. Chisinau, Moldova. Available from: http://www.nationalplanningcycles.org/sites/default/files/country_docs/Moldova/moldova-comprehensive_multi-year_plan_for_2011-2015_-_year_2011.pdf
[12] Republic of Moldova National Public Health Strategy 2014-2020. Chisinau, Moldova (2014)
[13] State Service for Public Health Surveillance Law No. 10 February 3, 2009. State Service for Public Health Surveillance. Chisinau, Moldova (2009)
[14] Law on State Surveillance of Public Health No. 10-XVI, 3 February 2009. State Service for Public Health Surveillance. Chisinau, Moldova (2009).
[15] Decision No. 705 on the creation of the National Agency for Public Health and the reorganization of some legal entities June 9, 2017. Official Gazette Nr. 329 art No: 809. Chisinau, Moldova 2017. Available from: http://lex.justice.md/md/371297/
[16] The merged authorities included National Assessment and Accreditation Council, National Center for Health Management, National Public Health Center, the municipal Public Health Centers from Chisinau and Balti, 34 district Public Health Centers and the Pharmaceutical and Medical Devices Inspectorate of the Medicines and Medical Devices Agency.

Public Health Agency suggest that immunization, as the key preventative intervention available to public health policy makers post-reform, should remain strong in Moldova.

Immunization-specific legislative provisions and the evolution of the NIP

The government specifically prioritized immunization through the implementation of several medium-term NIPs.[17] They helped define goals, objectives and targets in the area of preventing diseases by concerted immunization activities and commitments made by the National Government sectors and institutions, local authorities, civil society and international partners. The two latest NIPs also refer to "obligatory immunization."

The first ever NIP was approved for the period 1994-2000. This program introduced universal immunization against hepatitis B in newborns and adolescents and led to a 15.4-fold reduction in hepatitis B morbidity in children and adolescents (from 1002 cases in 1989 to 65 in 2004).[18] The immunization program for 2001-2005 represented a new phase and aimed at the permanent protection of the population against multiple infectious diseases, namely: polio, diphtheria, tetanus, pertussis, viral hepatitis B, measles, mumps, rubella and tuberculosis in children. The NIP for 2006-2010 guaranteed immunizations free of charge against 10 infectious diseases by adding meningitis (Haemophilusinfluenzaetype B, or Hib).

Immunization has been and remains one of the government's prioritized interventions and as a result, coverage increased to 95-98 percent in 2003-2007. However, the existence of vaccine hesitancy and anti-vaccine sentiment among parents and medical personnel,[19] and a decrease in coverage, became evident during the 2011-2015 NIP. The plan states: "Under the influence of the anti-vaccination propaganda, which has grown in the country since 2009, the level of immunization was reduced from 95-98 percent in 2003-2008 to 90-92 percent in 2015, lower in certain municipalities, as well as in the left bank of the Dniester (80-90 percent)."[20] The decreasing coverage has been partially attributed to anti-vaccine rhetoric and a lack of effective practices to educate parents and address their concerns. The coverage declined to 80-97 percent in 2015 and was even lower in certain municipalities.[21] The present NIP for 2016-2020 is the fifth, and aims at "eliminating or reducing morbidity, disability and mortality from preventable diseases by ensuing mandatory immunization for 13 antigens guaranteed by the state."[22] The goal is to achieve and sustain 95 percent immunization coverage by 2020. The Ministry of Health approved an accompanying Communication for Behaviour Change Strategy in February 2017, aiming to achieve high levels of sustained and equitable immunization coverage, improve public trust in vaccines and create higher demand for immunization.

[17] National Immunization Plans are passed by government decree and hence constitute legislation.
[18] Anon. Moldova: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017. Available from: http://www.who.int/immunization/monitoring_surveillance/data/mda.pdf
[19] Vaccine communication review in the Republic of Moldova "Communities of primary caregivers who question the quality and necessity of immunization are becoming an increasing challenge in the Republic of Moldova" [Internet]. World Health Organization Regional Office for Europe. 12 Oct 2014. Available from: http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/news/news/2014/12/vaccine-communication-review-in-the-republic-of-moldova
[20] Government of the Republic of Moldova. Comprehensive Multi-Year Plan for Immunization Programme 2011-2015. Chisinau, Moldova. Available from: http://www.nationalplanningcycles.org/sites/default/files/country_docs/Moldova/moldova-comprehensive_multi-year_plan_for_2011-2015_-_year_2011.pdf
[21] Anon. Moldova: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017. Available from: http://www.who.int/immunization/monitoring_surveillance/data/mda.pdf
[22] The program is elaborated in accordance with the provisions of the Health Protection Law no.411-XIII of 28.03.1995 (Monitor Rule Official of the Republic of Moldova , 1995, no.34 art.373) , Law no.10-XVI of February 3, 2009 on state public health surveillance (Official Gazette of the Republic of Moldova, 2009, No. 67, article 183), the Law no. 263-XVI of 27 October 2005 on the rights and responsibilities of the patient(Official Journal of Moldavian Mold Ova , 2005,n . 176-181 , art .867) , the National Health Policy, approved by the Government Decision no.886 of 6 August 2007 (Official Gazette of the Republic of Moldova, 2007, No. 127-130, Article 931), the National Public Health Strategy for 2014-2020, approved by the Government Decision no.1032 of 20 December 2013 and Recommendations of the World Health Organization

Analysis

Despite its commitment to immunization, a number of challenges threaten Moldova's progress and may prompt adjustments to the legislative framework for immunization.

Skewed perceptions of vaccines and vaccine hesitancy

As mentioned above, in 2009 with the Law on Public Health Surveillance, the government introduced the requirement that children be immunized in order to attend educational institutions. Protest has been a common reaction to the introduction of more compulsory clauses or legislation in every country where such clauses have been introduced. The introduction of legislation containing immunization as a requirement has led to protests in several countries, including France, Lithuania, Poland and Romania. In Moldova's case, vaccine hesitancy can be partially attributed to anti-vaccine campaigns in social media, parents not receiving sufficient information from family physicians and lack of awareness about the dangers of vaccine-preventable diseases.[23] The 2011-2016 NIP also mentions that anti-vaccine propaganda has grown in the country since 2009. In addition to parents' hesitancy, physicians have questioned the quality of vaccines administered in the public domain.[24] A recent article captured this viewpoint: "Laura Turcan works at the National Center for Preventive Medicine and says that Moldova meets all the conditions for risk-free immunization. However, she said she recognizes that private clinics often buy vaccines from countries with higher standards, where products are of better quality. 'Vaccines in public clinics are purchased with state funds, which are limited, so they are bought at cheaper prices and therefore are of lower quality. They are made in countries such as India, Vietnam and Indonesia, and often cause side-effects in children.'" [25]

Controversy surrounding school attendance provision

Great controversy in Moldova remains around the mandatory provisions for school attendance. After implementation of that provision, many parents felt their children's right to education was being infringed upon and submitted complaints to the Ombudsman's office. While parents submitted complaints that the law is unconstitutional, the Ministry of Education also opposed the provision.[26] In 2013, the Moldovan Centre for Human Rights filed a complaint at the Constitutional Court to challenge the constitutionality of such a requirement.

The constitutionality that conditions children's access to collectives, educational and recreational facilities by their immunization, under the Law on Public Health Surveillance, (Article 52 para. (6) of the Law no. 10 of February 3, 2009, [27] has been examined several times by Constitutional Court; the first time in 2013 and the last time as recently as October 2018. The Court examined the subject of compulsory immunization of the population from several perspectives, including alleged discrimination of non-vaccinated children compared to those vaccinated, in terms of access to educational institutions. In 2013,

[23] Gavi, the Vaccine Alliance. Moldova: Gavi support documents - Proposals, reports, plans, decision letters. Gavi, the Vaccine Alliance 1AD. https://www.gavi.org/country/moldova/documents/ (accessed November 17, 2018).
[24] Ghilascu N. Resistance in Moldova to health law on mandatory vaccination. Osservatorio balcani e caucaso transeuropa. 17 April 2013 [cited 7 July 2018]. Available from: https://www.balcanicaucaso.org/eng/Areas/Moldova/Resistance-in-Moldova-to-health-law-on-mandatory-vaccination-133929
[25] Ghilascu N. Resistance in Moldova to health law on mandatory vaccination. Osservatorio balcani e caucaso transeuropa. 17 April 2013 [cited 7 July 2018]. Available from: https://www.balcanicaucaso.org/eng/Areas/Moldova/Resistance-in-Moldova-to-health-law-on-mandatory-vaccination-133929
[26] Ghilascu N. Resistance in Moldova to health law on mandatory vaccination. Osservatorio balcani e caucaso transeuropa. 17 April 2013 [cited 7 July 2018]. Available from: https://www.balcanicaucaso.org/eng/Areas/Moldova/Resistance-in-Moldova-to-health-law-on-mandatory-vaccination-133929
[27] Namely Art. 52 para. (6) of Law No. 10 from 3 February 2009 on State Surveillance of Public Health, that stipulates, "Children access to collectives, educational and recreational facilities is conditioned by the fact of their systematic preventive immunization.

the Constitutional Court suspended the case[28] because there were no majority Court judges votes (a tie), and eventually the norm was maintained as being constitutional. In 2018, the constitutionality of Article 52 was once again challenged and was upheld to be constitutional by the Court in a ruling that was announced on October 30, 2018. The division of votes of constitutional judges in 2013 and the continued challenges to this provision demonstrate how complex and controversial the subject of immunization requirements for participation in educational institutions is and why it has been debated in several courts across Europe.

Examining the details of a constitutional challenge

In 2013, three judges found Article 52 to be constitutional. They based their decision on the legitimate aim pursued by the public authorities "to protect human lives and health" by ensuring "community immunity" as one of the most effective ways to prevent diseases and protect the population. Stating that the requirement for the compulsory immunization of children is proportionate to the purpose set forth, the judges concluded that "the differentiation between vaccinated and non-vaccinated children with regard to the access to collectives relies on objective criteria and does not deny equal protection under laws" (paragraph 143), hence the legislation is not discriminatory. The legislation allows an exception to the compulsory immunization only in case of medical contraindications (item 10 of Government Decision no. 1192 on the approval of the NIP for 2011-2015, December 23, 2010). The legislation does not provide exceptions from immunization for those who are against it due to religious or philosophical reasons. Those three judges did not consider the absence of such provisions unconstitutional, noting that "the state can adopt laws that stipulate compulsory immunization, because the freedom of the individual must sometimes be subordinated to the common well-being and may be subjected to the state control" (paragraph 159).

The three opposing judges found Article 52 unjustified and discriminatory in relation to children's access to education because systematic preventative immunization was a condition for children to access collectives, educational and recreational facilities. In their opinion, the state has various means to promote immunization for children, and by setting restrictions on the access to educational institutions for non-immunized children, the state failed to fulfill its obligations (paragraph 181 and 182).

In October 2018, the Constitutional Court ruled on case brought by the Parliamentarian Vladimir Odonostalco regarding the constitutionality of Article 52 (para. (6) of the Law no. 10 of February 3, 2009 on state oversight of public health and para. 21 subparagraph (1) let. e)), and the NIP for years 2016-2020 (approved by the Government Decision no. 1113 of October 6, 2016).[29] The challenged legal texts state that the admission of children to communities, educational and recreational institutions is being made contingent upon their systematic prophylactic immunization. The Court declared admissible the provisions of Article 52 para. (6) of Law no. 10 of February 3, 2009 on State oversight of public health and it declared constitutional the provisions of para. 21 subparagraph (1) let. e) of the NIP for 2016-2020 years. The constitutionality of the immunization requirement for attending educational and recreational institutions was therefore upheld. The judiciary supported mandatory immunization requirements in both cases, under the Law and the NIP.

[28] Constitutional Court, Judgement No.1 from 22 January 2013 on suspending the process for the review of the constitutionality of Art. 52 para. (6) of Law No. 10-XVI from 3 February 2009 on State Surveillance of Public Health.
[29] The Constitutional Court's Solution on Children's Vaccination and Their Access to Educational and Recreational Institutions. (2018). Constitutional Court of the Republic of Moldova [cited 4 December 2018].

Conclusion

Moldova's recommended approach to immunization law may be tested. As evidenced by challenges to the school entry restriction provision, public consensus is lacking on the introduction and strengthening of enforcement mechanisms supporting immunization. However, as recently as October 2018, the Constitutional Court upheld mandatory provisions for school attendance. While legal challenges and vaccine hesitancy likely make moves toward a mandatory legislative approach in Moldova unlikely; the recent outbreak of measles heightens the need to address declining or stagnant coverage rates.

If history is any guide, Moldova will likely continue to prioritize immunization through the implementation of a strong NIP and its current health reform to strengthen the health system. The 2016-2020 NIP includes behavioral change and communication plans, as well as a financing clause for the first time. Efforts are already underway to implement the communications plan and increase the opportunities for educating the public about vaccines in the media

A recent analysis conducted by Sabin identified additional areas where Moldova may implement changes to address public demand for immunization and increase coverage rates.[30] Improving communications about the benefits of immunization was recommended, including between healthcare providers and parents, as well as engaging government officials and parliamentarians to build support for immunization. More effective, accurate and timely coverage of immunization is needed in mainstream and social media, including public health experts as sources for media coverage. Furthermore, incentive mechanisms may be explored with family doctors to increase support for and champion immunization services. Finally, there is a growing recognition that clear guidelines are needed to address adverse events following immunization and minimize false contraindications.

Given the challenges to public confidence in vaccines and measles outbreaks following a period of reduced immunization coverage, the case study on Moldova demonstrates that in this situation, a purely legislative or coercive approach does not necessarily positively impact coverage. Ultimately, Moldova's experience may help illustrate the value of targeted activities to strengthen the immunization system rather than a wholesale change of the legislative framework for immunization. Moldova is attuned to challenges the country faces and has prioritized immunization at the national level through the National Health Strategy 2014-2020,[31] which states that "immunization coverage needs to be increased despite anti-vaccine propaganda."

http://www.constcourt.md/libview.php?l=en&idc=7&id=1317&t=/Media/News/The-Constitutional-Courts-Solution-on-Childrens-Vaccination-and-Their-Access-to-Educational-and-Recreational-Institutions/

[30] Sabin Vaccine Institute. Findings following a workshop held on September 6, 2018 in Chișinău with Moldovan immunization stakeholders on increasing public demand for immunization. Unpublished.

[31] Government of the Republic of Moldova. Comprehensive Multi-Year Plan for Immunization Programme 2011-2015. Chisinau, Moldova. Available from: http://www.nationalplanningcycles.org/sites/default/files/country_docs/Moldova/moldova-comprehensive_multi-year_plan_for_2011-2015_-_year_2011.pdf

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?
DENMARK	NO	YES	NO	YES	NO	NO	NO	YES
COVERAGE INDICATORS	DTP3 98%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 6	
FINLAND	YES	YES	NO	YES	NO	NO	NO	YES
COVERAGE INDICATORS	DTP3 89%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 13	
NORWAY	NO	YES	NO	YES	NO	NO	NO	YES
COVERAGE INDICATORS	DTP3 96%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 8	
SWEDEN	NO	YES	NO	NO	NO	NO	NO	YES
COVERAGE INDICATORS	DTP3 97%	IPV N/A					MEASLES (cases, 7/2017–6/2018) 49	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey * Information not available at this time

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

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.[1] 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.[2] 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.[3] Norway's coverage increased from 93 percent in 2007 to 96 percent in 2017.[4] Sweden's coverage has remained high throughout the decade with 97-98 percent between 2007 and 2017.[5]

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).

[1] Magnussen J, Vrangbaek K, Saltman R. Nordic Health Care Systems. Recent Reforms and Current Policy Challenges. Copenhagen: Open University Press, (2009).
[2] 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/
[3] Anon. Finland: 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/fin.pdf
[4] 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
[5] 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

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,[6] Finland,[7] Norway[8] and Sweden,[9] 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[10]	10
Finland[11]	11
Norway[12]	12
Sweden[13]	9

The Danish NIP is regulated by the Health Act (2010)[14] and additional decrees. The Health Act regulates immunization monitoring and the functioning of the Danish Vaccination Register.[15] An amendment in 2013[16] 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[17] indicated that recommended vaccines are provided free to all residents in Denmark by regional councils.

[6] The Danish childhood vaccination program. Danish Health Authority; 2018. Available from: The Danish childhood vaccination program. Danish Health Authority; 2018.
[7] Stuart Allt Web Design, Turku, Finland. Public Healthcare & Services in Finland. Finnish Education System: Enrolment Procedures, Vocational Training. https://www.expat-finland.com/living_in_finland/public_healthcare.html.
[8] Norway. VENICE III [Internet].Venice.cineca.org. N. p., 2018 [cited September 2018]. Available from: http://venice.cineca.org/documents/norway_ip.pdf
[9] Vaccinations - The Public Health Agency of Sweden [Internet]. (2018). Folkhalsomyndigheten.se. [citedSeptember 2018], Availablefrom:https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/
[10] 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).
[11] 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).
[12] 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).
[13] 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).
[14] 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
[15] Section 157a, the Health Act of 2010. The Danish Health Authority; 2010.
[16] 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
[17] 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).[18] An amendment enacted on March 1, 2017,[19] 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).[20] This statue 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.[21] 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,[22] 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.[23] The Norwegian Immunization Registry, SYSVAK, is a national Immunization Information System (IIS) administered by the Norwegian NIPH.[24] SYSVAK is legally anchored in the Norwegian law for Health Registries[25] and the SYSVAK regulation.[26]

The Swedish child immunization program is regulated by the Communicable Diseases Act (SFS 2004:168)[27] 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[28] regulates 13 factors that the Public Health Agency must consider when proposing changes in the NIP to the government.

[18] 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
[19] Finland: No jab, no job? [Internet] Vaccines Today [cited September 2018]. Available from: https://www.vaccinestoday.eu/stories/finland-no-jab-no-job/
[20] 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
[21] 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
[22] 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/
[23] Norway. VENICE III [Internet].Venice.cineca.org. N. p., 2018 [cited September 2018]. Available from: http://venice.cineca.org/documents/norway_ip.pdf
[24] 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
[25] 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
[26] 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
[27] 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
[28] 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

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,[29] 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: SoU7*[30]

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.[31]

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.[32] Finland, Norway and Sweden also consider the number of cases and healthcare visits to be an indicator of disease burden.[33]

Monitoring and AEFI surveillance

The countries also exhibit strong similarities in monitoring and AEFI surveillance. In Denmark, the Statens Serum Institut (SSI)[34] monitors the number of children who are immunized under the Danish childhood immunization program[35] 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.[36] The Danish Medicines Agency is responsible for collecting and

[29] Social Committee Report: Public Health Issues Summary 2016/17. Stockholm, Sweden. 2017. Available from: https://data.riksdagen.se/fil/77EB646D-37F9-4E33-9A89-331A5AA0E85A
[30] 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/
[31] 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
[32] 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/
[33] 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.
[34] Childhood vaccination programme. Danish Health Authority. Danish 2017. Available from: https://www.ssi.dk/English/PublicHealth/Vaccination/The Danish Childhood Vaccination Programme.aspx
[35] Vaccination. Forside – Sundhedsstyrelsen. Danish Health Authority. Danish 2018. Available from: https://www.sst.dk/en/disease-and-treatment/vaccination.
[36] 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.[37] A study has shown that the written reminders increase coverage among Danish children.[38] 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.[39] 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.[40] 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."[41] 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).[42]

[37] 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
[38] 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
[39] 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
[40] Soborg B. Addressing HPV vaccine hesitancy in Denmark. European Journal of Public Health 2017;27. doi:10.1093/eurpub/ckx187.036.
[41] 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/
[42] 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.[43] New technology such as text messaging and other electronic messages can be especially effective in adolescents.[44]

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.[45] 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.[46]

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.[47] The Vaccine Safety Unit of the THL has oversight of vaccine safety issues.[48] 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.[49]

Norwegian Immunization Registry, SYSVAK, is national, electronic immunization registry that records an individual's immunization status and immunization coverage in Norway.[50] 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

[43] 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
[44] 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
[45] 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.
[46] 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/
[47] 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
[48] 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.
[49] Rapola S. National immunization program in Finland. International Journal of Circumpolar Health 2007;66:382–9. doi:10.3402/ijch.v66i5.18310.
[50] 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[51], the Norwegian Law for Health Registries[52] and the SYSVAK regulation.[53] 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.[54] In compliance with Swedish law effective January 1, 2013,[55] healthcare providers are required to report all immunizations administered within the Swedish immunization programs to a national immunization registry.[56] 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.[57] 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

[51]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/
[52] 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
[53] 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
[54] 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/
[55] 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/
[56] 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
[57] 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.[58]

The Danish and Swedish vaccine compensation schemes were introduced in the 1970s, the Finnish one in 1980s, and the Norwegian one in the 1990s.[59] 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.[60] 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.[61] 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.[62]

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.[63] 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

[58] Hodges C. Nordic compensation schemes for drug injuries. J Consum Policy 2006; (29): 142-75. doi: 10.1007/s10603-006-9003-4
[59] 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
[60] Oldertz C. Security Insurance, Patient Insurance, and Pharmaceutical Insurance in Sweden. The American Journal of Comparative Law 1986;34:635. doi:10.2307/840326.
[61] Finnish Pharmaceutical Insurance Pool [Internet]. Helsinki: Finnish Pharmaceutical Insurance Pool; 2011. Available from: http://www.lvp.fi/www/page/lvp_www_2090
[62] 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
[63] 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,[64] Finland[65] and Sweden[66] 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.[67] In response to a more mandatory approach proposed in the Finnish Parliament, a new parliamentary group has been created solely to promote immunization.[68] Yet, to date, Finland has not introduced additional targeted information campaigns, unlike its neighbors, and 2017 coverage did not improved. 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. [69]

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.[70] 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.

[64] 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
[65] 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.
[66] 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.
[67] 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
[68] Riksdagen får vaccinationsgrupp [Internet]. (2017). Vasabladet.fi [cited September 2018] Available from: https://www.vasabladet.fi/Artikel/Visa/148728
[69] 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.
[70] Rehn M, Uhnoo I, Kühlmann-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

The Ukraine:

Exploring factors that undermine a strong legislative framework for immunization

European Region Matrix: Immunization Legislation

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?
YES	YES	YES	YES	YES	NO	YES	YES

COVERAGE INDICATORS			MEASLES (cases, 7/2017–6/2018)
	DTP3	50%	26,894
	IPV	43%	

◥ Answer Verified by Authoritative Secondary Sources ◥ Answer Verified by Survey * Information not available at this time

WHO-UNICEF estimates of immunization coverage. World Health Organization [data from 2017] [cited july 2018]. Available from: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html

Introduction

Using the "Likert Scale: Assessing Levels of Immunization Legislation," developed by the Sabin Vaccine Institute (Sabin), Ukraine receives the strongest ranking, *mandatory immunization with robust monitoring and follow-up*. Ukraine fulfills seven out of eight Matrix questions developed to categorize the degree to which immunization is overseen by the state, but does not have provisions which establish penalties for non-compliance. The Ukrainian Constitution guarantees the citizens' right to health. The government is mandated to provide and finance immunization, all citizens must be immunized and children require immunization to attend school. While there are no direct penalties for not immunizing children, the government verifies whether children have been immunized and uses immunization records as a requirement to be submitted prior to school attendance.

In practice, however, immunization coverage is much lower than would be expected from a review of the legislative framework. General mistrust of health authorities — specifically the negative perception of the safety and efficacy of vaccines — have led Ukraine to have some of the lowest coverage indicators in the European region. For example, immunization coverage indicators for Ukrainian children have declined from over 90 percent in the 1990s to only 70 percent in the 2000s and less than 50 percent in 2014.[1] Rates have improved since 2016; however, coverage remains very low for all vaccines.[2]

Understanding the factors that may undermine the intent of Ukraine's mandatory legislative framework for immunization is relevant for policy makers working to address low coverage rates. These factors are diverse, ranging from challenges to enforcing existing laws, backlash from some segments of the population and an overall lack of clarity on regulations. A good example of the confusion surrounding immunization policy is the mandate for school entry. Ukrainian courts have sent mixed messages on the mandatory nature of the law, with some administrative courts ruling that immunization mandates and school requirements are constitutional while other courts ruling the opposite.[3]

This case study will first examine the provisions that make up the national legislative framework for immunization. It will explore factors related to both legislation and to the broader immunization policy framework in the country that appear to be contributing to low coverage rates. Finally, the study will outline the various attempts by health authorities to address declining rates and analyze how changes to the legislative framework for immunization may help address some of the factors leading to low and declining coverage rates. Ultimately, this case study is exploratory and provides an overview of the legislative environment, it is not intended to provide prescriptive recommendations to policy makers.

For the sake of the analysis, we assume that a strong mandatory legislative framework supports an immunization system by providing more clarity on the roles and responsibilities of medical staff and of parents, increasing coordination between agencies, and signaling that immunization is a priority, ultimately leading to higher coverage rates. However, we do not claim that mandatory legislative provisions alone are sufficient to lead to higher coverage and we make no claims regarding causation of low coverage rates. Instead, we explore why the results are not as expected even though strong mandatory provisions are in place.

[1] Bagcchi S. Inadequate vaccine coverage fuels polio outbreak in Ukraine. The Lancet Infectious Diseases 2015;15:1268–9. doi:10.1016/s1473-3099(15)00367-9.
[2] Anon. Ukraine: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited July 4, 2018]. Available from: https://data.unicef.org/wp-content/uploads/country_profiles/Ukraine/immunization_country_profiles/immunization_ukr.pdf
[3] Anon. History of vaccination: legal nihilism and medical. Anteka Online 2018; 12. Available from: https://www.apteka.ua/article/451216

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).

Context and findings

Immunization in Ukraine

Ukraine's low coverage rates are likely the result of a variety of factors which are both internal and external to the immunization system. For example, recent political developments in Ukraine are likely to have influenced coverage rates. Ukraine has been involved in a conflict with Russia since 2014, which resulted in severe drops in coverage in the Eastern and Southern regions that have borne the brunt of the fighting. While the conflict is clearly one factor,[4] coverage numbers were dropping prior to 2014[5] and the World Health Organization (WHO) has been warning of potential polio outbreaks since as early as 2012.[6]

Ukraine's history as a Soviet Republic and the nature of its health system during the approximately 69 years of Soviet rule also likely impacts Ukraine's immunization rates. Ukraine has struggled to reform its healthcare system for decades following the end of Soviet rule, and financing for healthcare has been insufficient for many years. For immunization specifically, there is a lack of financing available for vaccines, as well as for the national immunization program (NIP). This is the result of relatively weak support for health in general and a lack of prioritization for immunization. Exacerbating these challenges, historically Ukraine has serious procurement challenges,[7] including non-transparent policies and processes, inflated prices and political corruption. This has led to both vaccine shortages and growing mistrust towards the NIP.[8]

Legislative framework

The legislative framework for health broadly, and immunization specifically, appears strong in Ukraine. Article 49 of the Ukrainian Constitution states that "everyone has a right to the health protection, medical care and medical insurance."[9] Health protection is provided by the government that finances the "socio-economic, medico-sanitation and health-prophylactic programs."[10] The Constitution declares healthcare to be free for all citizens, regardless of the scope of the medical problem.[11] Article 27 of the Law of Ukraine on "ensuring the sanitary and epidemic wellbeing of the population,"[12] declares that preventive

[4] Holt E. Health care collapsing amid fighting in east Ukraine. The Lancet 2015;385:494. doi:10.1016/s0140-6736(15)60186-6.
[5] WHO says Ukraine is at risk of polio outbreak as vaccine stockpiles dry up. The Pharmaceutical Journal 2014. doi:10.1211/pj.2014.20066444.
[6] Holt E. Ukraine at risk of polio outbreak. The Lancet 2013;381:2244. doi:10.1016/s0140-6736(13)61469-5.
[7] Fast Facts: Immunization. Kyiv, Ukraine: United Nations: Ukraine; 2014. Available from: http://www.un.org.ua/images/stories/FF_IMMUNIZATION.pdf
[8] Twigg JL. Ukraine's Health Sector Sustaining Momentum for Reform. Washington, DC: CSIS; 2017. Available from: https://www.csis.org/analysis/ukraines-health-sector
[9] Constitution of Ukraine with amendments and supplements borne December 8, 2004. Kyiv, Ukraine. 2004.
[10] Constitution of Ukraine, adopted at the Fifth Session of the Verkhovna Rada of Ukraine on 28 June 1996 and amended on 8 December 2004 by Law No. 2222-IV
[11] Lekhan V, Rudiy, V, Richardson E. Ukraine: health system review. Health Syst Transit 2012 (12).
[12] Закон України від 24 лютого 1994 р. № 4004-XII | Еженедельник АПТЕКА. (2011). Аптека online. Retrieved 18 November 2018, from https://www.apteka.ua/article/110989

immunization against tuberculosis, poliomyelitis, diphtheria, pertussis, measles, mumps and rubella are mandatory. Additionally article 12 of the Law of Ukraine regarding the "protection of the population against infectious diseases,"[13] clearly states and confirms that immunization against these diseases is mandatory and ensures that they are included in the national immunization schedule. Ministry of Health (MOH) Decree number 595 from September 16, 2011, that regulates the national immunization schedule, further supports this legislative arrangement.[14]

Challenges to the legislative framework

While the legislative framework for immunization is classified as *mandatory immunization with robust monitoring and follow-up*, a number of factors present challenges to achieving high coverage rates.

Immunization program is underfunded

Despite the constitutional right to health and legislation that indicates immunization is free for all citizens, the financing necessary for such a generous provision is not readily available under the current economic conditions in the country.[15] Collectively, the health system is underfunded, leaving the population reliant upon out-of-pocket payments and bribes for services.[16] In fact, 60 percent of Ukrainians believe that they "are able to get good healthcare only through bribes and connections."[17] Further, immunizations is not specifically prioritized in financing legislation and no dedicated national budget line item for immunization has been made since 2011.[18] The Procurement Law[19] (2016) identifies budgeted amounts necessary for immunization. However, due to limited budget availability, resources have not been made available in recent years. In 2015, Ukraine made an appeal for additional funds from external partners.[20] Vaccine purchasing is organized annually, which does not allow for multi-year forecasting and advance contracting with vaccine manufacturers. Reporting indicates that immunization funds are released late every year — not allowing the MOH enough time to complete necessary purchases — and the carryover legislative provision which covers only the first quarter of the next year, does not allow the MOH to hold another tender round and complete the procurement.[21]

Corruption and other procurement challenges

Corruption in the procurement sector in Ukraine takes many forms, including: "staging tenders among multiple companies controlled by one actual owner; collusion between independent companies to coordinate bids and increase prices; use of shell companies to purchase drugs overseas and sell them to the MOH at artificially high prices; and use of the Register of Bulk Release Prices, which should serve as a regulator, to overestimate tender prices by taking advantage of differential requirements for foreign and domestic drugs."[22]

---

[13] On protecting the population from infectious diseases No. 29, Article 228 (2000). Bulletin of the Verkhovna Rada of Ukraine. Kyiv, Ukraine. 2000.
[14] Ministry of Health Order from September 16, 2011 No. 595 On the Procedure for Prophylactic Vaccinations in Ukraine and Quality Control and Circulation of Medical Immunobiological Drugs. Kyiv, Ukraine. 2011.
[15] Luck J, Peabody J, Demaria L, Alvarado C, Menon R. Patient and provider perspectives on quality and health system effectiveness in a transition economy: Evidence from Ukraine. Social Science & Medicine 2014;114:57–65. doi:10.1016/j.socscimed.2014.05.0
[16] Danyliv A, Stepurko T, Gryga I, Pavlova M, Groot W. Is there a place for the patient in the Ukrainian health care system? Patient payment policies and investment priorities in health care in Ukraine. Society and Economy 2012;34:273–91. doi:10.1556/socec.34.2012.2.6.
[17] Bachmaha M. Vaccination Crisis in Ukraine: Its Origins and Consequences. KRYTYKA. (2018). M.krytyka.com. Retrieved 18 November 2018. Available from https://m.krytyka.com/en/ukraines-public-health-challenge/articles/vaccination-crisis-ukraine-its-origins-and-consequences#footnote32_owbkprf
[18] Twigg JL. Polio in Ukraine: Crisis, Challenge and Opportunity. Washington, DC: CSIS; 2016. Available from: https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf
[19] Vaccine Procurement Law 2016. Kyiv, Ukraine. 2016.
[20] Polio Outbreak in Ukraine, 2015-2016 Unique Challenges, Comprehensive Response [Internet]. Kyiv, Ukraine: UNICEF; 2016 [cited 1 December 2018]. Available from: https://www.unicef.org/ukraine/Polio_Outbreak_Report_Ukraine_FINAL_15_12_2016.pdf
[21] Twigg JL. Polio in Ukraine: Crisis, Challenge and Opportunity. Washington, DC: CSIS; 2016. Available from: https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf
[22] Who Makes Money on Epidemics of HIV/AIDS and Tuberculosis in Ukraine. Kyiv, Ukraine: Anti-Corruption Action Center; 2013.

The population believes that politicians prefer kickbacks from pharmaceutical companies over procurement of quality vaccines and other medical products, and that medical products manufactured in low-income or “third world” countries are of lesser quality and unacceptable.[23] The tendering and procurement practices for vaccines, other medications and medical devices have been notoriously nontransparent, controlled historically by oligarchs with high-level political connections and inflated prices.[24] Furthermore, “Ukrainian physicians also doubt the applicability of WHO guidelines and expertise in what they perceive as a distinct Ukrainian context, doubting vaccine quality in the absence of specific registration and testing in Ukraine, and worrying about locally unique allergens and poorly understood lingering impacts from Chernobyl.”[25]

Mistrust of vaccines

As a result of outdated training or a lack of training on immunization, in Ukraine, healthcare workers, including doctors and medical students, do not advocate effectively for immunization. Often, they rely on information obtained from the media, and not from scientific sources, and as a result, they cannot properly inform the population about methods, benefits and risks of immunization.[26] Even doctors who support the immunization program often do not show readiness to advocate for immunization due to a legal context where provisions are unclear and the environment does not prioritize immunization (as illustrated by the Prodanchuk case, see below). Also, the general population does not trust vaccines. According to the Vaccine Confidence Indicators, around 25 percent of the population disagree with the idea that vaccines are safe and over 15 percent do not think that vaccines are effective.[27]

[23] Twigg JL. Polio in Ukraine: Crisis, Challenge and Opportunity. Washington, DC: CSIS; 2016. Available from: https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf

[24] Semigina T, Mandrik O. Drug procurement in Ukraine: Is there a "window of opportunity"? Bulletin of the Academy of Labor, Social Relations and Tourism 2017;614:25–38.

[25] Twigg JL. Polio in Ukraine: Crisis, Challenge and Opportunity. Washington, DC: CSIS; 2016. Available from: https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf

[26] Survey conducted under the Brown University Ukraine Collaboration: “Almost 30% of the polled medical students believe that it is "better" for a child to get immunity, ill, rather than by vaccination. In addition, almost 60% of medical students reported that they believe that vaccines may cause autism. Both of these beliefs are not true and do not have a scientific basis”. Brown University Ukraine Collaboration was founded in 2011 and is a joint venture between the Brown University Center for AIDS Research (CFAR) and HIV health and service providers in Ukraine. The collaboration engages the resources of Brown University to work with Ukrainian health providers to address the challenges of the HIV/AIDS, tuberculosis (TB), other infectious diseases and public health issues among Ukraine’s most vulnerable groups. https://www.brown.edu/initiatives/global-health/brown-university-ukraine-collaboration

[27] The State of Vaccine Confidence: 2016 [Internet]. The Vaccine Confidence Project. 2018 [cited August 2018]. Vaccineconfidence.org. Available from http://www.vaccineconfidence.org/research/the-state-of-vaccine-confidence-2016/

The Prodanchuk Case

In May 2008, during a supplementary measles, mumps and rubella immunization campaign, a teenager from Kramatorsk died. The Attorney General's Office filed a lawsuit against the chief sanitary inspector, Mykola Prodanchuk, stating that he claimed excessive authority during the campaign.[28] Despite the fact that the subsequent investigation concluded that death was due to bacterial meningitis and was not related to the vaccine,[29] false allegations in the media caused public outrage over the immunization campaign and resulted in a widespread scare about vaccine side effects and a sharp drop in immunization coverage.[30] Over the next few days over a hundred children were hospitalized with symptoms wrongly attributed to vaccines.[31]

Whereas death and complications after any medical procedure require a thorough medical examination, the prosecution acted proactively to convince the public that the government was able to restore justice. Deputy Minister Prodanchuk was jailed for two months for his alleged involvement,[32] although the prosecutor's office could not provide evidence of his involvement in the death of the teenager. He was subsequently fired. As a result of the incident, “Protesters stormed the doors of the Ministry of Health. Legal aid non-governmental organizations reported an immediate spike in the number of parents seeking assistance in circumventing immunization requirements (by law, children cannot be enrolled in public schools without a certificate of immunization), and the Ministry of Health called a moratorium on measles, mumps and rubella vaccine distribution.”[33]

Media coverage of the event and contradictory government statements contributed to distrust among parents and healthcare professionals and further damaged confidence in health authorities and the state-run immunization program.[34] The combination of parental mistrust, and the Law on Infectious Diseases which states that children cannot be enrolled in school without a medical certificate showing they have been immunized,[35] has led some parents to purchase false vaccine certificates instead of vaccinating their child.[36] Kyiv physicians report that selling immunization records brings them more revenue than any other service they provide.[37] Other parents have noted discrepancies in the legal provisions regarding education and immunization in Ukrainian legislation and brought cases to court.

[28] “He had arranged for WHO/UNICEF to donate the vaccine as part of a one-time deal for delivery without prior registration in Ukraine. This contradicted a 2006 regulation requiring vaccines to be officially registered by country authorities prior to import and use, opening the door to widespread media accusations of tampering, conspiracy, and high-level corruption.” Twigg, J. L. (2016). Polio in Ukraine. Crisis, challenge, and opportunity.https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf

[29] Danilova, M. (2009). Vaccine scare threatens health in Ukraine. Associated Press. http://www.nbcnews.com/id/29875914/ns/health-health_care/t/vaccine-scare-ukraine-threatens-health/#.W2eujcKxWM8.

[30] Twigg JL. Polio in Ukraine: Crisis, Challenge and Opportunity. Washington, DC: CSIS; 2016. Available from: https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf

[31] Heidi Larson, “The Limits of Predictions: When No One Listens,” Vaccine Confidence Project, September 7, 2015. Available from: http://www.vaccineconfidence.org/the-limits-of-predictions-when-no-one-listens/.

[32] The physician who administered the vaccine was also imprisoned.

[33] Twigg JL. Polio in Ukraine: Crisis, Challenge and Opportunity. Washington, DC: CSIS; 2016. Available from: https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf

[34] Bazylevych M. Vaccination Campaigns in Postsocialist Ukraine: Health Care Providers Navigating Uncertainty. Medical Anthropology Quarterly 2011;25:436–56. doi:10.1111/j.1548-1387.2011.01179.x.

[35] Law on Infectious Diseases, Art. 15: Admission of children to upbringing, educational, rehabilitation, and other children's institutions shall be carried out in case of availability of a respective certificate issued by the health protection establishment where the child is under medical observation. Certificate shall be issued on the basis of results of medical examination of a child, provided that there are no medical contra-indications to his/her stay in this institution, and that he/she has undergone prophylactic vaccination in accordance with the vaccination calendar, and that he/she has not been in contact with anybody suffering from infectious diseases or with bacteria carriers. Children that have not undergone prophylactic vaccinations in accordance with the vaccination calendar shall not be allowed to attend children's institutions. In cases when prophylactic vaccinations have been made to children with violation of established terms due to medical contra-indications, with safe epidemic situation and upon decision to be taken by a conference of corresponding physicians such children may be admitted to a corresponding children's institution and attend such institution.

[36] Bachmaha M. Vaccination Crisis in Ukraine: Its Origins and Consequences. KRYTYKA. (2018). M.krytyka.com. Retrieved 18 November 2018. Available from https://m.krytyka.com/en/ukraines-public-health-challenge/articles/vaccination-crisis-ukraine-its-origins-and-consequences#footnote32_owbkprf

[37] How many doctors take bribes and how to avoid it. Segodnya.ua [2010 May 12]. Available from: https://www.segodnya.ua/newsarchive/za-chto-i-ckolko-vrachi-berut-vzjatki-i-kak-etoho-izbezhat.html

Complex and unclear policy prescriptions

Ukrainian legislative and regulatory provisions are complex, and in some cases unclear. Ukraine's complicated immunization guidelines have resulted in doctors interpreting contraindications for immunization in different ways, leading to wide variation in causes for delays or refusals. In some cases, seasonal colds have led to "reduced coverage by 5-10 percent" as a result of delays prescribed by doctors.[38] In other cases, doctors have a double record system where they will delay immunization of a child citing illness, but record that a child has been vaccinated and then circle back to that patient later when they deem they are healthy enough be vaccinated.[39] Some doctors are even nostalgic about the certainty and efficiency of the past Soviet era, where doctors' decisions were guided and guaranteed by a strong central apparatus.[40]

Contradictions present a challenge to the Ukrainian legislative framework for immunization. The Law of Ukraine on "Fundamentals of the Legislation on Health Care in Ukraine," Article 10,[41] specifies immunization as a duty of citizens. However, under the provisions of Article 43 preventive immunization is described as the right of individuals. The right to education is guaranteed in the Ukrainian Constitution (Article 53),[42] yet national healthcare legislation prevents those who are unvaccinated from attending school. The Constitutional Court has not ruled on the school immunization requirement yet, unlike in several other countries (such as Moldova,[43] Lithuania,[44] and Turkey[45]); however, parents have brought cases to Administrative Courts in several regions of the country to appeal the restrictions placed on attending school for unvaccinated children. Courts have not ruled consistently on the issue, and the same court (in Volyn Oblast, a providence in north-western Ukraine) ruled several times, and in some cases, the rulings contradicted each other.[46]

Lack of clarity of immunization legislation may also contribute to healthcare workers' hesitation to promote and administer vaccines. For example, laws stipulate that immunization be listed as the cause of death when a child dies within 30 days of receiving a vaccine, until an official investigation is conducted.[47] This regulation exposes physicians who administer vaccines to risk, as in the Prodanchuk case.[48] This legal environment creates a powerful disincentive for healthcare providers to advocate for immunization. The premise that the vaccine is at fault — without evidence — can lead to long delays in campaigns and further diminish trust in immunization. Several experts claim that the effects of the Prodanchuk case are still reflected today in the public perception and skepticism towards vaccines.[49]

[38] Twigg JL. Polio in Ukraine: Crisis, Challenge and Opportunity. Washington, DC: CSIS; 2016. Available from: https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf
[39] Ibid.
[40] Ibid.
[41] Law of Ukraine on Fundamentals of the Legislation on Health Care in Ukraine Article 10 2009. Kyiv, Ukraine. 2009
[42] Constitution of Ukraine, adopted at the Fifth Session of the Verkhovna Rada of Ukraine on 28 June 1996 and amended on 8 December 2004 by Law No. 2222-IV , https://web.archive.org/web/20120427012054/http://www.venice.coe.int/docs/2006/CDL%282006%29070-e.pdf
[43]More information in the Moldova case study
[44]More information in the Baltic case study
[45] Turkish courts strike blow against immunization program. (2018). Aa.com.tr [cited 4 December 2018] Available from: https://www.aa.com.tr/en/health/turkish-courts-strike-blow-against-immunization-program/575385
[46] What is especially interesting is that in one case the Volyn Administrative Court upheld the decision of the school to remove the child, (постановаВолинськогоокружногоадміністративногосудувід 02.07.2009 р. справіNo2A-18037/09/0370), but in two other cases the same court ruled the other way and since the children "were found to be in good health" allowed them access (справ № 2а-6501/09/0370, постанова від 16.03.2009 р. та № 2а/0370/2586/11, постанова від 12.10.2011 р.). However, in another case (справа № 2а/0370/2586/11, постанова від 12 жовтня 2011 р) the Court ruled that a child who has not been vaccinated cannot be given a certificate of attendance for school..
[47] Bachmaha M. Vaccination Crisis in Ukraine: Its Origins and Consequences. KRYTYKA. (2018). M.krytyka.com. Retrieved 18 November 2018. Available from https://m.krytyka.com/en/ukraines-public-health-challenge/articles/vaccination-crisis-ukraine-its-origins-and-consequences#footnote32_owbkprf
[48] The doctor who administered the vaccine was also fired.
[49] Twigg JL. Polio in Ukraine: Crisis, Challenge and Opportunity. Washington, DC: CSIS; 2016. Available from: https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160329_Twigg_PolioUkraine_Web.pdf

Difficulty in managing Adverse Effects Following Immunization (AEFIs)

Ukraine's policies on surveillance of adverse effects following immunization (AEFIs) are likely factors in low coverage rates. AEFIs may be ascribed to immunization without proof and healthcare workers may be held accountable without due cause. Protocols in cases of AEFIs may be unclear for healthcare professionals and health managers. Additional training on AEFI procedures may help lessen the perceived risk for those who administer the vaccines and can help address vaccine risks and cases of AEFIs in a timely manner. The Prodanchuk case described above provides an illustration of this circumstance.

An AEFI may also result in immunization campaigns being halted following media coverage of the AEFI event and increased public mistrust around immunization, as illustrated in the aforementioned Prodanchuk case in 2008. Such actions have contributed to low coverage and several deadly outbreaks (polio and measles). Healthcare staff familiar with procedures to follow in cases of AEFI can help provide a counter argument to the controversial media coverage and provide the population with a timely, reliable and evidence-based response, which in turn can help lessen the negative perceptions and rebuild trust. When issues go unaddressed or worse, the AEFI is linked to a vaccine, the effects on coverage may be severely negative and have lasting effects.

Analysis

Ukraine's efforts to address immunization challenges

Ukrainian policy makers have attempted to address some of the underlying factors that impact coverage rates with legislation. Healthcare system procurement reforms are well underway, while legislation for immunization financing and to support trust in vaccines (for example, by addressing previous corruption issues, informing patients about the provenance and quality of the available vaccines) are less advanced and more difficult to address.

Reforming procurement

Legislative reform to the procurement system in Ukraine has been a gradual process. A new Law on Public Procurement[50] was signed by President Poroshenko on February 17, 2016. With it, the ProZorro[51] platform (established in 2015) has resulted in more transparent contraction and open public disclosure online. Central authorities and state-owned enterprises adopted ProZorro in April 2016, with municipalities following in August.

Legislative reform takes time to implement and for the system to adapt to the new rules.[52] In an effort to speed up the procurement reform process and ensure more transparency in the short term, the MOH signed an agreement with international organizations (including UNDP and UNICEF) for the procurement

[50] Voznyuk O, Solohub V. Public Procurement in Ukraine. Thomas Reuters Practical Law (1 March 2013) [cited 4 December 2018]. Available from: https://uk.practicallaw.thomsonreuters.com/4-521-1646?transitionType=Default&contextData=(sc.Default)&firstPage=true&comp=pluk&bhcp=1

[51] Launched as a pilot in February 2015, the system uses our organization's Open Contracting Data Standard as a tool for structuring and analyzing contracts. Any information related to public procurement (annual plans, tender notices, bids, decisions of evaluation committees, contracts, etc.) is freely accessible online. In addition, new tools were developed, including anonymous auctions to help the government get better deals, and feedback systems to manage clarifications and complaints. https://www.open-contracting.org/2015/06/02/open_contracting_in_ukraine_a_collaborative_effort_for_procurement_reform/; http://www.me.gov.ua/Documents/Detail?lang=en-GB&id=4f2cb072-bac6-4ded-b564-5a00dd24511a&title=ReformOfStateProcurement

[52] For example the new procurement body under the MoH will only be established in 2019. Zhuk A. "Ukraine'S Health Sector Finally Healing Itself Of Corruption - Apr. 13, 2017." KyivPost. N. p., 2017. Web. 19 Nov. 2018. Available from: https://www.kyivpost.com/ukraine-politics/ukraines-health-sector-finally-healing-corruption.html

of medicines from the 2018 budget.[53, 54] The government also passed public procurement laws 2150[55] and 2151[56] in March 2015, allowing the government to procure medicines and vaccines through international organizations until 2020.[57] These measures were passed to change to a more transparent procurement system. Giovanna Barberis**,** the UNICEF Representative in Ukraine, stated that *"*UNICEF welcomes the opportunity to continue supporting the MOH through the procurement of life-saving vaccines and antiretroviral drugs to ensure reliable protection against infectious diseases for children and adults in Ukraine and access to continuous treatment for people living with HIV/AIDS. UNICEF will keep providing technical support to the government to create an effective and transparent national procurement system."[58] International procurement has already saved significant amounts of money for Ukraine,[59] and the procurement reform may contribute to increased trust in the immunization program, and eventually a rise in coverage indicators.

Strengthening mandatory immunization policy

In an effort to alleviate uncertainty and increase compliance, Ukrainian legislators attempted to use more coercive measures by enforcing the immunization requirement for access to primary education for children.[60] In some cases, parents faced criminal charges for refusing immunization of their children,[61] under Article 166 of the Criminal Codex of Ukraine. Several educational institutions were also taken to court for refusing admission of children lacking required immunizations,[62] but the Court rulings ranged in their interpretation from sustaining the right of the child to education to upholding enforcement of school mandates.

The issues around school mandates remain legally uncertain. The Ministry of Education, Youth and Sport attempted to clarify the situation by issuing a letter[63] in 2011, stating that: "the refusal of the head of a preschool educational institution in accepting a child to an institution without appropriate preventive immunizations is contrary to the current legislation of Ukraine. In the presence of appropriate medical certificates of the prescribed sample with the conclusion of the doctor, which states that the child may attend a preschool educational establishment, the head of the institution is obliged to accept the child to the institution." The letter did not have the weight of legislation, and it did not result in added clarity.

[53] Anon. "Ministry Of Health Signs Agreements With International Organizations For Procurement Of Medicine For The 2018 Budget - United Nations In Ukraine." Un.org.ua. N. p., 2018. Web. 19 Nov. 2018. Available from: http://www.un.org.ua/en/information-centre/news/4331-ministry-of-health-signs-agreements-with-international-organizations-for-procurement-of-medicine-for-the-2018-budget

[54] Ibid.

[55] Law No 2150 (269-VIII), http://patients.org.ua/en/2015/04/09/the-price-for-the-medicines-procured-by-the-international-organizations-for-state-programs-will-decrease-by-42/

[56] Law No 2151 (332 -VIII) " Law №2151 which enables the transfer of drug procurement to the international organizations. This law provides for the abolition of 7% VAT and 5% customs duty on drugs that will be procured by the international organization for the state budget". http://www.antiaids.org/eng/news/ukraine/state-procurements-of-drugs-and-vaccines-through-international-organizations-in-ukraine-will-happen-this-year-10528.html

[57] Parliament Passes Law on State Drug Procurement through International Organizations," Interfax-Ukraine, March 20, 2015. Available from: http://en.interfax.com.ua/news/general/256137.html

[58] Anon. "Ministry Of Health Signs Agreements With International Organizations For Procurement Of Medicine For The 2018 Budget - United Nations In Ukraine." Un.org.ua. N. p., 2018. Web. 19 Nov. 2018. Available from: http://www.un.org.ua/en/information-centre/news/4331-ministry-of-health-signs-agreements-with-international-organizations-for-procurement-of-medicine-for-the-2018-budget

[59] Overall, in 2015 Ukraine saved Hr 620 million ($23 million) compared to the 2014 prices (https://www.kyivpost.com/ukraine-politics/ukraines-health-sector-finally-healing-corruption.html)

[60] Law of Ukraine On Protection of the Population Against Infectious Diseases" of 6 April 2000 (as of 2009) no. 1645-III, VVR no. 29 (2000), Article 15(2). Kyiv, Ukraine. 2009.

[61] Berislavskyi regional court of Kherson oblast, case no. 1-124/2010 of 12 July 2010.

[62] Volyn district administrative court, case no. 2A-18037/09/0370 of 03 July 2009. Available from: https://pravoscope.com/act-postanova-2a-18037-09-0370-valyux-v-m-02-07-2009-ne-viznacheno-s

[63] About compliance with the order of admission of a
child to preschool educational institution; The letter of the Ministry of Education and Science of the Russian Federation # 1 / 9-389 (2011 May 25). Ministry of Education and Science of the Autonomous Republic of Crimea. Available from: http://osvita.ua/legislation/doshkilna-osvita/18791/

In 2014, the Ministry of Education, Youth and Sport and MOH collaboratively attempted to lift practical restrictions by issuing a joint regulation.[64] The regulation stated that children who do not receive required vaccines in accordance with the schedule of immunizations are not allowed to attend an educational institution. In cases when immunization is carried out under a delayed schedule due to medical contraindications, children may be admitted to a suitable kindergarten, provided the epidemiological situation permits and if parents obtain an official letter from their doctor stating that the child is healthy and fit to attend an educational institution. In cases where parents refuse immunization for their child, attendance is decided on a case-by-case basis by a medical advisory committee.

The practical implications of this regulation are challenging. The head of the educational institution is obliged to accept the child at the institution in the presence of an appropriate medical certificate. For children who have not received required vaccines (regardless of the reasons), the opinion of the medical advisory committee issued by a medical-preventive institution also is required, which states that the child is healthy and may attend an educational institution. If the medical advisory committee decides to bar a child who does not have immunization from attending an educational institution (in a complex epidemiological situation or due to individual circumstances), the local education authorities decide upon and provide the means of education for that child. In practice, this procedure remains confusing and complicated and may contribute to some parents finding it easier to obtain a falsified immunization certificate for their child.

Falsified certification sidesteps established legislation and undermines immunization campaigns in Ukraine, a country at high risk for outbreaks and where only an estimated 70-75 percent of the total population are vaccinated. The introduction of electronic monitoring mechanisms, similar to other countries in the region (for example, Estonia and Denmark), may help improve the oversight and follow-up, and reduce the use of falsified certificates.

Increasing financing

A constitutional provision[65] guarantees free access to immunization services for all, and Ukraine has also begun tackling the financing gaps that challenge the system. The parliament of Ukraine (Verkhovna Rada) adopted crucial legislation aimed at ensuring financing for healthcare in October 2017. Instead of guaranteeing free healthcare for all, the reform defined the scope of healthcare (including required immunizations) under the new healthcare package.[66] The legislation also introduced the “money follows the patient principle,” resulting in incentives for healthcare facilities to improve the quality of services they offer. Immunization is included and fully covered under the government benefits package, ensuring patient access to vaccines included in the national immunization program free of charge. This legislation is expected to help reduce out-of-pocket payments.

Conclusion

Ukraine has multiple mandatory immunization provisions in place, yet coverage numbers in the country are low. In its post-Soviet era riddled with civil unrest and corruption, the country has a significant amount of distrust toward the government, the healthcare system, healthcare professionals and also vaccines. Vaccine hesitancy and refusal occur in all types of systems, with voluntary (e.g., UK) and mandatory provisions (e.g., France), and can have a significant impact on coverage numbers, outbreaks and disease incidence. The reasons behind hesitancy vary depending on context. These factors, along with negative media coverage, an unclear government response to AEFIs, lack of transparency on vaccine

[64] Ministry of Education and Science of Ukraine together with the Ministry of Health of Ukraine wrote a letter dated 09/29/2014 № 1 / 9-500 / № 04.01.16 / 28103 "On the resolution of certain issues concerning enrollment in preschool and general educational institutions children who do not have mandatory preventive vaccinations”

[65] Article 49 of the Constitution of Ukraine, in which, in particular, it is stipulated that: “...medical services should be provided free of charge in State and community healthcare establishments...”, Constitution of Ukraine, adopted at the Fifth Session of the Verkhovna Rada of Ukraine on 28 June 1996 and amended on 8 December 2004 by Law No. 2222-IV

[66] Concept of the Healthcare Financing Reform in Ukraine. Kyiv, Ukraine: 2016. Available from: http://wb.moz.gov.ua/download/docfile/2b9213a4ac5e420/

procurement mechanisms, a lack of sustainable financing and an outdated legislative framework that in some cases is unclear, incomplete and poorly implemented, contribute to Ukrainian vaccine hesitancy or immunization refusal.

Ukraine has already begun an in-depth reform process of its healthcare system and the outcome will be important for the immunization program and coverage rates; however, several gaps relevant to building capacity of the immunization system remain. These include regulation of AEFIs, improving immunization monitoring, introducing and maintaining continuous education and skill building on immunization for health care workers, and dedicating a specific and guaranteed budget line for immunization. Additional efforts may include public communication campaigns to provide accurate information about immunization from reliable, evidence-based data and sources. This would likely help address misinformation spread by the media.

Despite Ukraine's classification as a *mandatory immunization with robust monitoring and follow-up*, immunization coverage is low. Even the fear of diseases such as polio and measles has not resulted in a significant and sustainable increase in coverage rates. Further coercive legislative approaches are unlikely to increase coverage; however, clarifying the immunization legislative framework may help address the issues at hand, while also elevating efforts to build capacity of the immunization system.

Annex X: Survey: Immunization-related legislation in the European Region

SURVEY DESCRIPTION:

Immunization-related legislative provisions in Euro-region countries focusing on:

- Compulsory immunization policies and their enforcement, and;
- Adverse-events following immunization (AEFI)

PURPOSE OF SURVEY:

Though neither sufficient nor necessary for the creation of sustainable programs, the process of creation of new legislation or updating existing laws and regulations can help countries identify and set immunization priorities at all levels (national, regional, local) and can signal a commitment to these priorities.
Consistent with the GVAP and EVAP recommendation that countries have legislative frameworks to support their immunization programs, this survey is the first step in Sabin's landscape analysis that aims to document and characterize existing immunization-related legislative provisions in the European region. This repository will be made accessible to countries looking for examples and strategies to strengthen their immunization systems through legislative approaches. A descriptive landscape analysis will summarize the findings from the region and be used to develop concrete case studies that can be used by countries to guide or inform their own strategies and approaches.

REMINDER:

Please be assured that your responses will be used for research purposes only and all responses to the questions will be kept strictly confidential; you will not be identifiable in any published results.

Section 1: Compulsory Immunization Policies and enforcement

1. Which vaccines are included in your national Expanded Immunization (EPI) program?

- ☐ Measles
- ☐ Rubella
- ☐ Cholera
- ☐ Meningococcal Disease
- ☐ Influenza
- ☐ Haemophilus influenzae type b
- ☐ Diphtheria
- ☐ Mumps
- ☐ Tetanus
- ☐ Hepatits A
- ☐ Pertussis
- ☐ Tuberculosis
- ☐ Hepatitis B
- ☐ Pneumococcal disease
- ☐ Typhoid fever
- ☐ Hepatitis E
- ☐ Poliomyelitis
- ☐ Tick-born encephalitis
- ☐ Rabies
- ☐ Varicella and herpes zoster (shingles)
- ☐ Human papillomavirus
- ☐ Rotavirus gastroenteritis
- ☐ Yellow fever
- ☐ Japanese encephalitis
- ☐ Malaria
- ☐ Dengue fever

2. Which vaccines are provided free of charge to children?

- ☐ Measles
- ☐ Rubella
- ☐ Cholera
- ☐ Meningococcal Disease
- ☐ Influenza
- ☐ Haemophilus influenzae type b
- ☐ Diphtheria
- ☐ Mumps
- ☐ Tetanus
- ☐ Hepatitis A
- ☐ Pertussis
- ☐ Tuberculosis
- ☐ Hepatitis B
- ☐ Pneumococcal disease
- ☐ Typhoid fever
- ☐ Hepatitis E
- ☐ Poliomyelitis
- ☐ Tick-born encephalitis
- ☐ Rabies
- ☐ Varicella and herpes zoster (shingles)
- ☐ Human papillomavirus
- ☐ Rotavirus gastroenteritis
- ☐ Yellow fever
- ☐ Japanese encephalitis
- ☐ Malaria
- ☐ Dengue fever

3. Please select those vaccines that are compulsory* for children to receive:
**Immunization is defined as compulsory (mandatory, obligatory) if every child is required to receive it by law, without the option for the parent/guardian to choose to accept it or not (notwithstanding available 'exemptions' – see question 6 below). This is in contrast to other vaccines that may be "recommended" even though parents/guardians may decide whether a child receives the vaccine in these cases.*

- ☐ Measles
- ☐ Rubella
- ☐ Cholera
- ☐ Meningococcal Disease
- ☐ Influenza
- ☐ Haemophilus influenzae type b
- ☐ Diphtheria
- ☐ Mumps
- ☐ Tetanus
- ☐ Hepatits A
- ☐ Pertussis
- ☐ Tuberculosis
- ☐ Hepatitis B
- ☐ Pneumococcal disease
- ☐ Typhoid fever
- ☐ Hepatitis E
- ☐ Poliomyelitis
- ☐ Tick-born encephalitis
- ☐ Rabies
- ☐ Varicella and herpes zoster (shingles)
- ☐ Human papillomavirus
- ☐ Rotavirus gastroenteritis
- ☐ Yellow fever
- ☐ Japanese encephalitis
- ☐ Malaria
- ☐ Dengue fever

4. Please specify the age group of the children for whom immunization is compulsory:

- ☐ 0-1 year
- ☐ 0-2 years
- ☐ 0-5 years
- ☐ 0-12 years
- ☐ 0-16 years

5. If a compulsory immunization requirement for children exists, are there any exemptions to it?

- ☐ Medical reasons
- ☐ Religious beliefs
- ☐ Personal beliefs
- ☐ "Moral" grounds

6. Are there compulsory vaccination requirements for other specific groups?

- ☐ Health workers
- ☐ Military
- ☐ Staff in educational institutions
- ☐ College students

7. Are there any legal provisions or policies stipulating that immunization (with certain vaccines) is compulsory for attending educational institutions (school, kindergarten, nursery, etc.)? If yes, please describe in the comment section.

- ○ Yes
- ○ No

Please specify and describe:

8. If immunization is compulsory for attending educational institutions, what is the penalty for noncompliance? (e.g., prevention from enrollment, requirement to remain home during outbreaks, etc.)

9. Are there penalties for the PARENT/GUARDIAN for not vaccinating a child in case of a compulsory immunization requirement? If yes, please specify what they are (e.g. administrative - fine, criminal, etc.)

- ○ Yes
- ○ No

Please specify and describe:

10. If such penalties exist, in which ways can they be enforced (e.g. through courts, by paying a fine, etc.)? Please describe.

11. Are there penalties for the HEALTH WORKER for not vaccinating a child in case of a compulsory immunization requirement? Please specify (e.g. administrative, criminal?)

- ○ Yes
- ○ No

Please specify and describe:

Section 2: Adverse events following immunization (AEFI)

12. Is there a surveillance system in place for tracking adverse events following immunization (AEFI)?
** AEFIs are defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.*
***AEFI surveillance is defined as monitoring, detecting and responding to adverse events following immunization (AEFI) and/or implementing appropriate and immediate action to correct any unsafe practices detected through the AEFI surveillance system, in order to lessen the negative impact on the health of individuals and the reputation of the immunization program.*

- ○ Yes
- ○ No

13. If such a surveillance system is in place, are there provisions for any compensation in cases of (serious) AEFIs? Please describe in your own words.

- ○ Yes
- ○ No

Please specify and describe:

14. Are you aware of any legislative changes that have been drafted, submitted or passed over the last 5 years which are related to or might have an impact on immunization programs? Please specify in your own words.

- ○ Yes
- ○ No

Please specify and describe:

15. In your opinion, is there a need for changing/updating or drafting new legislative provisions in order to improve your country's immunization program? Please elaborate.

Section 3: General- the following questions ask your opinion on immunization legislation issues and your country's overall approach to immunization

16. If yes, which areas do you think may benefit from a legislative reform? (For example: Updating the immunization schedule/calendar, designating certain vaccines compulsory or recommended, strengthening budgetary provisions, education requirements related to immunization status, improving surveillance systems, etc.) Please elaborate in your own words.

17. In your opinion, do you predict any negative consequences or resistance to implementing such legislative actions? Please comment below.

18. Beyond legislation cited above, does your country have another specific immunization-related legislation? *The term legislation is broadly defined and can include: laws, by-laws, decrees, amendments, regulations, and other types of provisions.

19. If you answered "yes", please share any legislative documents or written policies that you think are relevant to this study. They can be in the original language. Please include the name of the law/policy, or a hyperlink.

Annex XI: Survey Report: Immunization-related legislation in the European Region

Total Invitations: 83
Complete responses: 29
Countries invited: 53
Countries responded: 24

Countries responded:

Azerbaijan
Belgium
Croatia
Denmark
Estonia
Finland
France
Georgia
Hungary
Latvia
Lithuania
Moldova
Montenegro
Netherlands
Poland
San Marino
Slovakia
Slovenia
Spain
Sweden
Switzerland
Tajikistan
Ukraine
United Kingdom
Uzbekistan

Not responded:

Albania
Andorra
Armenia
Austria
Belarus
Bosnia and Herzegovina
Bulgaria
Finland
Cyprus
Czech Republic
Finland
France
Germany
Greece
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Luxembourg
Macedonia
Malta
Monaco
Norway
Portugal
Romania
Russia
Serbia
Turkey
Turkmenistan

Sabin Vaccine Institute
2175 K St, NW, Suite 400, Washington, DC 20037
+1 202 842 5025 sabin.org