

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

December 2018

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

▼ Answer Verified by Authoritative Secondary Sources

▼ Answer Verified by Survey

Introduction

Using the “[Likert Scale: Assessing Levels of Immunization Legislation](#),” developed by the Sabin Vaccine Institute (Sabin), 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 2014⁵ 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, Rudyi, 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 Law¹⁹ (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_owbkrpf

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_owbkrpf

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

Complex and unclear policy prescriptions

Ukrainian legislative and regulatory provisions are complex, and in some cases unclear. Ukraine's complicated immunization and regulatory 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 to 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 Turkey⁴⁵); 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 province 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, (постанова Волинського окружного адміністративного суду від 02.07.2009 р. у справі № 2А-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 (справа № 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 Procurement⁵⁰ was signed by President Poroshenko on February 17, 2016. With it, the ProZorro⁵¹ 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](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 2150⁵⁵ and 2151⁵⁶ 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 letter⁶³ 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.antiids.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 Berislavskiy 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-viznachenno-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 provision⁶⁵ 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.

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