



Cooperative Biological Engagement Program, Defense Threat Reduction Agency

CBEP Country Assessment: Ukraine



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TABLE OF CONTENTS

1	CBEP EXECUTIVE SUMMARY.....	1-1
2	INTRODUCTION AND BACKGROUND	2-1
3	HUMAN HEALTH SECTION.....	3-1
3.1	Overview of Health System Governance.....	3-1
3.2	National Legislative and Regulatory Framework	3-2
3.3	Budget and Funding Mechanisms	3-5
3.4	Human Health System Priorities.....	3-8
3.5	International Standards Compliance.....	3-8
3.6	Human Health System Overview	3-9
3.6.1	Disease Detection	3-9
3.6.2	Laboratory Diagnostics	3-15
3.6.3	Epidemiological Analysis and Investigation	3-19
3.6.4	Reporting and Communications	3-25
3.6.5	National and Regulatory Frameworks.....	3-30
3.6.6	Facility-Level Biorisk Management Systems and Culture.....	3-33
3.6.7	Pathogen Consolidation and Security.....	3-38
4	ANIMAL HEALTH SECTION.....	4-1
4.1	Overview of Health System Governance.....	4-1
4.2	National Legislative and Regulatory Framework	4-2
4.3	Budget and Funding Mechanisms	4-3
4.4	Health Priorities.....	4-3
4.5	International Standards Compliance.....	4-5
4.6	Animal Health System Overview	4-6
4.6.1	Disease Detection	4-6
4.6.2	Laboratory Diagnostics	4-10
4.6.3	Epidemiological Analysis and Investigation	4-14
4.6.4	Reporting and Communications	4-17
4.6.5	National and Regulatory Frameworks.....	4-21
4.6.6	Facility-Level Biorisk Management Systems and Culture.....	4-22
4.6.7	Pathogen Consolidation and Security.....	4-24
5	ONE HEALTH	5-1
	APPENDIX I: Stakeholders Interviewed	I-1
	APPENDIX II: Description of Stakeholders	II-1
	APPENDIX III: Relevant Legislation in Ukraine.....	III-1
	APPENDIX IV: Notifiable Diseases in Ukraine (2001).....	IV-1
	APPENDIX V: Notifiable Animal Diseases in Ukraine.....	V-1
	APPENDIX VI: Endemic, Notifiable, and Transboundary HUMAN Diseases in Ukraine ...	VI-1
	APPENDIX VII: Endemic, Notifiable, and Transboundary Animal Diseases in Ukraine	VII-1
	APPENDIX VIII: Acronyms	VIII-1
	APPENDIX IX: Gaps	IX-1

HIGHLIGHTS

Highlight 1: Primary Care in Ukraine	3-10
Highlight 2: Hospital Comparison	3-12
Highlight 3: Health Service Delivery in Conflict Areas.....	3-14
Highlight 4: National Accreditation Agency of Ukraine.....	3-17
Highlight 5: Kyiv City Laboratory.....	3-18
Highlight 6: Kyiv Regional Hospital	3-18
Highlight 7: Lviv OLC and General Directorate of SES	3-20
Highlight 8: Epidemiology in Ukraine.....	3-20
Highlight 9: Disease-Specific Surveillance Systems.....	3-22
Highlight 10: Reporting Challenges at Healthcare Facilities	3-25
Highlight 11: Kyiv City Sanitary Epidemiological Station and Laboratory	3-29
Highlight 12: Kyiv Regional Hospital	3-35
Highlight 13: Lviv OLC.....	3-37
Highlight 14: Veterinary Degree at National Agrarian University	4-8
Highlight 15: Training at IECVM and IVM.....	4-8
Highlight 16: ASF Outbreak	4-9

EXHIBITS

Exhibit 1: Ukraine Assessment Team Composition.....	2-1
Exhibit 2: Cooperative Biological Engagement Program Metrics Pillars	2-2
Exhibit 3: Oblasts of Ukraine.....	3-1
Exhibit 4: Ukrainian Health System Divisions and Roles	3-2
Exhibit 5: Selected Human Health Legislation	3-3
Exhibit 6: Selected Laboratory Legislation.....	3-4
Exhibit 7: Selected IT Legislation.....	3-5
Exhibit 8: Calendar of Annual Budget Process.....	3-5
Exhibit 9: Health Expenditures by Country	3-7
Exhibit 10: Cooperative Biological Engagement Program Metrics Pillars	3-9
Exhibit 11: Health Workers in Ukraine per 100,000 Population, Selected Years.....	3-11
Exhibit 12: Ukraine Burden of Disease 2012.....	3-13
Exhibit 13: Command Structure of Human Laboratory Network	3-15
Exhibit 14: Public Health Center Under MoH Decree 604.....	3-16
Exhibit 15: Disease Surveillance Administrative Units	3-20
Exhibit 16: Human Health System Biosurveillance Concept of Operations in Ukraine (Current)	3-26
Exhibit 17: Human Health System Biosurveillance Concept of Operations in Ukraine (Anticipated).....	3-27
Exhibit 18: EIDSS Capabilities.....	3-29
Exhibit 19: Selected BS&S Legislation	3-31
Exhibit 20: Equivalent U.S. National Institute of Health Risk Groups and Ukraine Pathogen Groups for Pathogens with High Risk	3-32

Exhibit 21: Structure of SVPS of Ukraine	4-1
Exhibit 22: Animal Healthcare Legislation.....	4-2
Exhibit 23: Areas in Strategic Plan Relevant to Animal Health	4-4
Exhibit 24: List of Priority Animal Diseases	4-4
Exhibit 25: Administrative Structure of the Laboratory System	4-10
Exhibit 26: Lviv RDVL System of Quality Control	4-11
Exhibit 27: Flow of Pathogenic Samples Through the Animal Laboratory Network	4-12
Exhibit 28: Disease Surveillance Administrative Units	4-14
Exhibit 29: Animal Health System Biosurveillance Concept of Operations in Ukraine (Current)	4-18
Exhibit 30: Animal Identification and Registration System.....	4-19
Exhibit 31: Animal Identification and Registration System Architecture.....	4-20
Exhibit 32: Veterinaria.....	4-20
Exhibit 33: Stakeholders	II-2

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Executive Summary



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1 CBEP EXECUTIVE SUMMARY

The Cooperative Biological Engagement Program (CBEP) Ukraine Country Assessment Report delivers a baseline analysis of the human and animal health systems' structure as well as an analysis of biosurveillance (BSV) and biosafety and biosecurity (BS&S) infrastructure, processes, and gaps. This assessment provides data for CBEP's short- and long-term strategic plans with Ukraine and for programmatic metrics.

An 11-member team of interdisciplinary subject matter experts (SME) conducted the assessment using three phases of data collection: (1) open-access research, (2) stakeholder telephone interviews, and (3) in-country validation (interviews and selected site visits). Data from these three phases has been analyzed and organized into human and animal health sections. Each section includes an overview of system governance, national and legislative regulatory framework, budget and funding mechanisms, systems priorities, and international standards compliance. This is followed by a description of Ukraine's capabilities and gaps, aligned to the seven CBEP BSV and BS&S metrics pillars: disease detection, laboratory diagnostics, epidemiological analysis and investigation, reporting and communications, national and regulatory frameworks, facility-level biorisk management systems and culture, and pathogen consolidation and security. The final section describes One Health capabilities and gaps. A brief summary of the human and animal health sectors, as well as a combined overview of BSV and BS&S capabilities and gaps, is outlined below.

Background

Since 2014, Ukraine has been moving toward a Western model of governance structures and health practices. As a result, both the human and animal health systems have undertaken a series of reforms to reorganize central authorities and enhance service provision. However, the country continues to face considerable challenges in this process, including a struggle to overcome entrenchment in Soviet-era ideologies, profound economic issues, and a rigid approach to regulation. While there are prominent gaps in the system, often compounded by the challenges noted, there are opportunities for the Ukrainian government and its supporters to continue the path to sustainability and internationally-accepted standards.

Human Health Overview

Ukraine is at moderate risk for transboundary incursions of two pathogens of security concern from neighboring countries: highly pathogenic avian influenza (HPAI) virus from Poland and Russia, and *Brucella* spp. from Romania and Russia. Endemic pathogens of security concern are *Bacillus anthracis*, *Clostridium botulinum*, *Francisella tularensis*, *Rickettsia* spp, *Coxiella burnetii*, Crimean Congo hemorrhagic fever (CCHF) virus, and tick-borne encephalitis virus.

Ukraine is challenged by an uneven distribution of healthcare workers, access to primary care, and funding for healthcare services. Furthermore, Ukraine has not reported progress toward the World Health Organization's (WHO) International Health Regulations 2005 (IHR [2005]) implementation in the last 5 years. Currently, the only IHR (2005) core capacity that has been developed is legislation related to infectious diseases. In an effort to stimulate effective reforms, MoH has identified four priorities for the Ukrainian health system: (1) shifting to a primary care service and delivery model that emphasizes preventive care, (2) reallocating financial resources.

more efficiently, (3) restructuring healthcare system governance, and (4) strengthening essential health system inputs, particularly the workforce.

Animal Health Overview

The structure of the animal health system in Ukraine is similar to the human health system. Current animal system reform aims to partially decentralize certain functions of the veterinary services; this includes formation of a new veterinary entity—the State Service on Food Safety and Consumer Protection (SSFSCP)—and transfer of financial responsibility to oblast and rayon levels. Ukraine has a substantial veterinary regulatory framework based on the Soviet model, but the majority of existing regulations no longer adequately address the country’s present animal health situation or its political evolution, and despite recent updates to regulations still do not fully align with international standards. Lack of financial resources and antiquated facilities and equipment exacerbate the situation and impinge on SSFSCP’s ability to monitor and respond to disease events. Modern epidemiological methods and disease data do not drive SSFSCP’s allocation of disease surveillance resources.

Ukraine is at moderate to high risk of transboundary disease incursion due to the constant movement of animals and people across borders. The highest disease threats caused by pathogens of security concern are HPAI, classical swine fever, and foot-and-mouth disease (FMD). Diseases of security concern present in the country either in the wild or in domestic animal populations include anthrax, Newcastle disease, tularemia, and African swine fever (ASF). SSFSCP’s limited management of veterinary disease burdens—even those not of a security concern—represents a major risk because the agricultural sector represents such a significant portion of Ukraine’s economy.

Ukraine is a member of the World Organisation for Animal Health (OIE) and consistently reports disease data to OIE. In 2015 SSFSCP informed the OIE of registered ASF cases and 1 case of CSF via immediate notifications submitted to OIE. SSFSCP also submitted six-month and annual reports. Accuracy of the data reported to OIE is uncertain because of potential underreporting of disease data within Ukraine.

CBEP Metrics Pillars: Capabilities and Gaps

Disease Detection

The human and animal health systems remain predominantly centralized. Disease detection capabilities for human and veterinary practitioners are, in general, adequate for diseases caused by pathogens that are regularly seen in the country, but lacking for diseases less commonly seen. Both human and animal health services are delivered through the public and private sectors. The public sector is primarily responsible for disease detection in both health systems. The animal private health sector is much more prominent than the human health private sector, which is small and exists predominantly only in large cities. While the overall number of human health workers in Ukraine is sufficient, their geographical distribution is uneven; in contrast, the distribution of veterinary services is well-balanced across the country. There have been ongoing efforts to improve access to care through establishment of primary healthcare in Ukraine, but this system has not yet been fully implemented. In terms of education and training, physicians in Ukraine obtain a basic medical degree in 6 years and then pursue postgraduate education in a specialty. Veterinarians receive standardized training, although veterinary

institutions offer varying degrees of hands-on training. Continuing education is mandatory for both physicians and veterinarians, who have major roles in reporting infectious diseases. Human hospitals and clinics follow disease-specific protocols, but there are no clinical guidelines for diseases caused by pathogens of security concern. The animal health system has disease protocols for several CBEP diseases of security concern, but these protocols are not updated on a regular basis and some have not been updated since the Soviet era. The leading causes of the human healthcare burden are related to noncommunicable diseases, although human immunodeficiency virus (HIV), tuberculosis (TB), and hepatitis C remain significant communicable disease concerns. ASF and rabies are the primary sources of animal health infectious disease burden.

Laboratory Diagnostics

While historically the human health laboratory network has been aligned directly under the authority of MoH, the newly established Public Health Center (PHC) under MoH will become the direct administrator of the network going forward. The basic framework of the laboratory referral network will not change with the reforms, and the authority to conduct specialized testing for especially dangerous pathogens (EDPs) will be retained by the national institutes. Rayon- and oblast-level laboratories will continue to screen pathogens and refer Group I–II pathogens to national laboratories for confirmation. Other significant system modifications include establishment of a national quality office and a national training program; standardization of procedures; and consolidation of resources, including testing facilities and their functions. Within the animal health laboratory system, the State Veterinary Phytosanitary Service (SVPS) was the previous authority of the network, but SSFSCP is absorbing SVPS as part of a reorganization of the Service. The structure of the animal referral network will remain the same, with rayon- and oblast-level laboratories screening Group II–IV pathogens and referring samples for confirmation to the State Scientific Research Institute for Laboratory Diagnostics and Veterinary Sanitary Expertise (SSRILDVSE or ILD). The animal health laboratory system needs effective quality management and coordinated staff training. Both human and the animal health laboratory networks lack significant funding to maintain equipment and reagent inventories.

Epidemiological Analysis and Investigation

MoH and SVPS have structured, regionalized approaches to disease surveillance and epidemiological analysis for the human and animal health systems. The primary limitation of the disease surveillance system in both sectors is that Ukraine follows the classical Soviet paradigm of epidemiology that focuses on disinfection of surfaces and liquidation of disease. Analyses are mainly descriptive; there is a lack of epidemiological analyses to make inferences, determine risk factors, and investigate the etiology of a disease. Consequently, there are no baseline data to establish alert or epidemic thresholds. Outbreak investigation and response are heavily regulated by protocols that are both disease-specific and often outdated. Response measures follow the Soviet model, which does not assess the association between exposures and outcomes. There are rosters of individuals who may be deployed as part of a response team during an outbreak, but in many cases, operating procedures (SOPs) for communication or mobilization of an outbreak response team are inadequate. These challenges limit the ability to detect emerging outbreaks, associate exposures to outcomes, and optimize preparedness for outbreak response.

Reporting and Communications

Disease monitoring in Ukraine is conducted primarily through passive surveillance; however in the animal health system, ASF, HPAI, and Newcastle disease are part of active surveillance programs. In the human health system, active surveillance is conducted for TB and HIV/acquired immune deficiency syndrome (AIDS) and occurs through siloed programs that are not integrated or that have minimal coordination with national surveillance data. Ukraine has an extensive list of notifiable diseases which includes the OIE list of notifiable animal diseases, but veterinary health authorities are also considering a list of select priority diseases indicated in the EU Association Agreement. The list of human diseases is currently under revision to align with the notifiable diseases of the European Union (EU). Case definitions are newly adopted in the human health system and have been historically absent in the animal health system, but efforts are under way to implement case definitions consistent with EU and OIE standards. Disease reporting depends largely on a laborious paper-based system that is time-consuming and prone to human error and inconsistency; there is no unified electronic system to incorporate human and animal health disease data. However, there are plans to deploy the Electronic Integrated Disease Surveillance System (EIDSS) to integrate disease reporting and surveillance. Underreporting is a significant challenge to timely and complete reporting. Animal owners and veterinary health officials, in particular, expect negative consequences for failing to prevent an outbreak, which disincentivizes reporting disease cases. Moreover, a sizeable, informal economy exists in the agricultural sector, which is comprised of “backyard farms” that do not adhere to biorisk management practices that larger, commercial farms do. Although SSFSCP reports notifiable disease events transparently, these factors result in an incomplete understanding of the country’s disease burden and limits preparedness to respond to emerging outbreaks.

National and Regulatory Frameworks

Ukrainian BS&S legislation for the human and animal health systems is out-of-date, and regulations are fragmented among various laws and decrees. Ukraine has ratified the Cartagena Protocol on Biosafety and the Biological Weapons Convention, and reports on their implementation. While these documents provide oversight for the regulation of GMOs and biological weapons, additional country-specific legislation is necessary to provide comprehensive BS&S oversight for handling and storing pathogens of security concern. Ongoing reforms of the human and animal health systems offer significant opportunity to align Ukrainian regulations with international BS&S guidelines. MoH has established a working group to draft new BS&S legislation that will address human and zoonotic pathogens, supporting improvements to both the human and animal systems. Risk assessments are not presently used to determine appropriate BS&S measures, which leads to inadequate biocontainment measures throughout the country. Limited funding for laboratories, specifically for implementation of BS&S practices, presents a major challenge for developing and implementing BS&S regulations that align with international guidelines.

Facility-Level Biorisk Management Systems and Culture

Compliance with national regulations is a clear priority for human and animal laboratories and clinical facilities, but few facilities take additional measures to align with WHO and EU guidelines. Facilities document plans and procedures in accordance with national regulations, such as for the proper use of laboratory equipment, but they often neglect biosafety. Incidents, accidents, and subsequent corrective actions are poorly documented and tracked, resulting in inaccurate records that inhibit the ability to identify and effect necessary improvements. Funding limitations hinder the ability of entities to develop and sustain infrastructure, train BS&S and laboratory personnel, procure and properly maintain safety equipment, and provide appropriate personal protective equipment (PPE). Despite these constraints, the biosafety culture at the facility level is relatively strong: personnel demonstrate awareness of BS&S and an understanding of current policies, procedures, and international regulations

Pathogen Consolidation and Security

Ukraine has identified and consolidated pathogens of security concern into several institutions. While further consolidation has encountered resistance from institutional leadership, health system reforms aim to facilitate further consolidation. Ukraine does not have legislation to regulate the control of pathogens of security concern, and significant gaps exist in biosecurity capabilities. Physical security measures at human facilities exist primarily at national institutions that have been engaged with external stakeholders. However, a lack of adequate funding and maintenance has resulted in much of the donated equipment either falling into disrepair or being disabled for cost savings. In general, physical security measures at animal facilities are better than those at their human counterparts. Material control and accountability, personnel security, transportation security, and information security require significant improvement to secure dangerous pathogens, but steady funding sources remain the major constraint in implementing and sustaining such biosecurity measures.

One Health

The One Health concept has limited recognition and understanding in Ukraine. Although human and veterinary health professionals are aware of the concept, no legislation or One Health programs have been established and the concept is not extensively practiced. There is no common list of notifiable zoonotic diseases or pathogens, the flow of information on zoonotic risk factors between sectors is minimal, and defined communication protocols are not in place. In the event of a zoonotic outbreak, an ad hoc Anti-Epizootic Committee assembles from appointed members of various government agencies; however, this interagency group does not participate in trainings or exercises on a routine basis. Without an inclusive One Health strategy, there is no institutional coordination to ensure efficient use of scarce resources and to optimize intersectoral and interdisciplinary disease prevention and control. However, Ukraine joined the U.S. Global Health Security Agenda in September 2015 in which both SSFSCP and the MoH participate.

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Introduction and Background



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2 INTRODUCTION AND BACKGROUND

CBEP engages partner nations in different regions of the world to strengthen their ability to detect, diagnose, and report diseases and assess related biological safety and security concerns. CBEP conducts baseline assessments to determine health system gaps and plan appropriate engagement strategies. This CBEP Country Assessment: Ukraine, hereafter referred to as “assessment report,” delivers a baseline analysis of Ukraine’s human and animal health system structure, and BSV and BS&S infrastructure, processes, and gaps, focused on CBEP goals. The assessment report provides baseline data for CBEP’s programmatic metrics and promotes the development of evidence-based, partner-specific engagement strategies.

Methodology

An 11-member team of interdisciplinary SMEs¹ (Exhibit 1) employed a three-phase approach to collect data: (1) open-access research, (2) stakeholder telephone interviews, and (3) in-country validation (interviews and selected site visits).

Exhibit 1: Ukraine Assessment Team Composition

Team Member	Role
Mr. Kevin Garrett	Country Manager, Ukraine
Dr. Nino Kharaishvili	Lead, Country Assessments Project
Ms. Bethany Danyluk	Team Lead, Ukraine Assessment
Dr. Maureen Cruz	Epidemiologist
Mr. Justin Edwards	Laboratory Diagnostics Specialist
Ms. Jennifer Mitchell	Management Analyst
Mr. Bikram Nagra	Information Technology Specialist
Ms. Janet Reynolds	Clinical Specialist
Dr. Yazmin Rodriguez	Veterinary Specialist
Mr. Jeffrey Russin	Biosafety Specialist
Dr. Justin Taylor	Biosecurity Specialist

The team used the previously developed assessment tool, including standardized questionnaires for BSV and BS&S, to target and collect raw data. Following the data collection process, the team analyzed and synthesized its findings as described below:

- **Phase 1—Open Access:** The team conducted open-access research using published literature, CBEP documents, and stakeholder websites to identify data gaps to address in subsequent stages.
- **Phase 2—Stakeholder Interviews:** The team conducted telephone interviews with United States Government, international, and in-country stakeholders to confirm Phase 1 findings and uncover information not available via open-access research.
- **Phase 3—In-Country Interviews:** The SME team visited Kyiv, Ukraine, from February 1 to February 5, 2016, and Lviv, Ukraine, from February 8 to February 10, 2016, to validate findings with national, oblast, and rayon stakeholders; strengthen understanding of BSV and BS&S systems; and collect additional data. Appendix I provides a complete list of organizations the team visited.

Limitations

This assessment report presents key findings to guide CBEP’s future planning efforts in Ukraine. However, it has limitations. It targets entities, processes, and enablers consistent with CBEP’s objectives and mission space and is not an assessment of Ukraine’s overall human and animal healthcare systems. The assessment report provides recommendations and supports the development of country-specific strategy documents that include suggestions and proposed solutions to selected gaps.

Analysis and Structure of Report

The assessment report begins with a section describing several overarching themes that emerged during the interviews and that highlight factors that have shaped Ukrainian health systems. The body of the report contains three main sections: human health, animal health, and One Health. Both the human and animal health sections discuss Ukraine’s national legislative and regulatory frameworks, budget and funding mechanisms, system priorities, international standards compliance, and overall systems. Subsections in the health system overviews analyze the country’s capacities, capabilities, and gaps in terms of the seven CBEP BSV and BS&S metrics pillars identified in Exhibit 2. Highlight boxes appear throughout the assessment report to share anecdotal or pertinent information.

Exhibit 2: Cooperative Biological Engagement Program Metrics Pillars

Biosurveillance	Biosafety and Biosecurity
<ul style="list-style-type: none">• Disease Detection• Laboratory Diagnostics• Epidemiological Analysis and Investigation• Reporting and Communication	<ul style="list-style-type: none">• National-Level Regulatory Frameworks• Facility-Level Biorisk Management Systems and Culture• Pathogen Consolidation and Security

Each subsection begins with a summary of major findings and a brief description of the metric pillar status within Ukraine. The subsection concludes with a fact-based analysis of each metric pillar in terms of CBEP’s scope and a list of gaps. Recommendations throughout the report are designed to address system-specific issues and note the root cause(s) of each existing gap.

Background

Ukraine is still emerging from decades of entrenchment in the Soviet system. The 2014 revolution, precipitated by a popular rejection of increasing Russian influence in favor of alignment with the West, enabled Ukraine to sign and ratify the EU Association Agreement in July 2014. The agreement obligates Ukraine to undertake reforms in multiple sectors, including healthcare, to align governance structures and economic policies with EU recommendations and standards as an initial step toward EU accession. However, Ukraine’s health systems still reflect the Soviet paradigm, typified by centralized control, excessive regulation, and a focus on curative care. Moreover, Ukraine’s economy is still in the midst of prolonged recession, making it difficult to finance necessary reforms.

Emerging Identity

The Ukrainian people made a clear choice to align with the West during the 2014 revolution that ousted Russian-leaning president, Viktor Yanukovich. Since that time, the new class of leaders has adopted a pro-reform, pro-EU platform that culminated in the ratification of the EU Association Agreement in 2014. Among other requirements, the agreement calls for improvements in Ukraine's public health and animal health sectors to address shared concerns about infectious and noninfectious diseases, to ensure Ukrainian traded goods meet EU safety standards, and to promote environmental and occupational health and safety.² Compliance with the agreement to increase EU integration is a key driver of Ukraine's reforms. However, lingering Soviet mindset and influence among officials, policymakers, and practitioners still largely shapes institutional governance. Adapting to the new, more European approach, such as use of modern epidemiological surveillance, requires a shift in mindset among these key actors. It will take time and effort for all levels of Ukraine's health systems, from central government officials to mid-level staff to local physicians, to adapt to this new mindset.

Health Reform

In August 2014, MoH initiated development of the *National Health Reform Strategy for 2015–2020*. The proposed strategy is a component of the National Action Plan of Reforms, which was declared by presidential order in January 2015. The objective of the health reforms is to transform the post-Soviet healthcare system into a more relevant system that will improve the quality of and access to healthcare, and to mitigate financial risks for the Ukrainian people.

MoH Order No. 604 (2015) and Cabinet of Ministers Resolution No. 442 (2015) form the basis of the health system reforms. Order 604 establishes the national PHC, which subsumes a number of state laboratories, epidemiology stations, and other institutions. At the time of this assessment, the PHC was not fully functional; a draft of the new structure, based on the recommendations of the European Centre for Disease Prevention and Control (ECDC), is currently under discussion. Resolution No. 442 consolidates the state veterinary epidemiological organizations into one body, SSFSCP, under the Ministry of Agrarian Policy and Food (MoAPF). Subsequent sections of the assessment report provide more detail on the reforms, their status, and how they affect each metrics pillar.

Economy

Ukraine's economy suffered greatly from the global economic crisis in 2008. The country's recession deepened in 2014 when conflict near the Russian border disrupted activity in the industrial areas of the east and weakened both consumer and investor confidence. At the same time, accumulated public debt was high, the currency sharply devalued, and security and defense spending increased. The full-year decline of the gross domestic product (GDP) in 2014 was 6.8 percent. Most sectors were affected, including industry (-10.1 percent year-over-year), wholesale trade (-15.0 percent), and construction (-21.7 percent). Agriculture was the only real growth sector in 2014, with a 2.8-percent increase year-over-year.³

In March 2015, the International Monetary Fund (IMF) approved an Extended Fund Facility loan of approximately \$17.5 billion (USD) for a 4-year period. These funds will support the Ukrainian government's economic program, which aims for sustainability of external support, a

strengthening of public finances, and creation of a path to economic recovery. By July 2015, the IMF stated there were already signs of improvements in exchange rate stabilization and a moderation in economic decline. The same press release also noted that “momentum needs to be sustained, as significant structural and institutional reforms are still needed to address economic imbalances that held Ukraine back in the past,” making sure the loan is used, in part, to maintain the progress planned in ongoing governmental reforms.⁴ Although the IMF has committed its financial support, the budget crisis still looms in Ukraine.

Root Causes of Health System Gaps

Despite reform efforts, several overarching systemic challenges persist. First, Ukraine remains overregulated and undergoverned. Even small changes to processes and procedures require a specific regulation that must be approved/registered with the Ministry of Justice before legislative action can take place. Second, ideological conflict between purveyors of the conventional and reform mindset pose a continuing challenge to progress. Some stakeholders in Ukraine do not feel that the reform process is transparent or inclusive and are actively resisting reorganization efforts, while others see reforms as a positive change that will streamline organization and reduce corruption. Without an effective, consistent communications strategy in place, these ideological tensions threaten to further delay the reform process.

Many of the themes commonly seen across government institutions in Ukraine contribute to persistent gaps in the human and animal health systems. The gaps discussed in this assessment can be grouped into areas of root cause. By identifying the root cause of current issues, the origin of problems is more clearly visible, affording an accurate yet simple picture of areas within the system that need to be addressed. Furthermore, quantifying the gaps that fall into each root cause area is effective in identifying the areas for which changes and improvements will have the greatest effect.

The following five root causes derived from the above themes are potential reasons for the challenges Ukraine currently faces in healthcare.

1. **Ideology:** The country is caught between those who cling to a prescriptive, Soviet-era mindset and those who are seeking progress and change, generating tension between the new and old regimes. For example, legacy structures in some institutions allowed overstaffing and underemployment; leaders and staff are now resisting reforms as it is unclear if they will continue to remain employed in the reorganized administrations.
2. **Funding:** Significant economic troubles greatly affect budgets from the national to the rayon level, leaving ministries and facilities unable to meet all needs. The Ministry of Finance is unable to approve ministry budget requests in full, leaving institutions to prioritize needs. As a result, long-term goals are often neglected in favor of immediate necessities. For example, training, equipment, supplies, and consumables are not prioritized in allotted budgets.
3. **Legislation and regulations:** There is a plethora of laws, decrees, and orders on particular topics, causing confusion regarding the sheer volume of directives. Many of these regulations have not been updated since the Soviet era; some topics, which clearly need governing policies, have none. For example, regulations require obsolete methods of personal protective equipment, including reusable “anti-plague suits.”

4. Governance: Institutions often lack a strong administrative structure, leading to insufficient oversight, enforcement of duties and requirements, or communication among entities. For example, the laboratory network does not have a quality management system.
5. Education and training: Many modern methods are not taught in certain specialties, training and educational curricula are inconsistent, and practical experience is not always offered, creating variations in demonstrable capabilities. For example, epidemiologists are trained in Soviet techniques and have limited opportunities to learn internationally-accepted epidemiological methods.

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Human Health Section



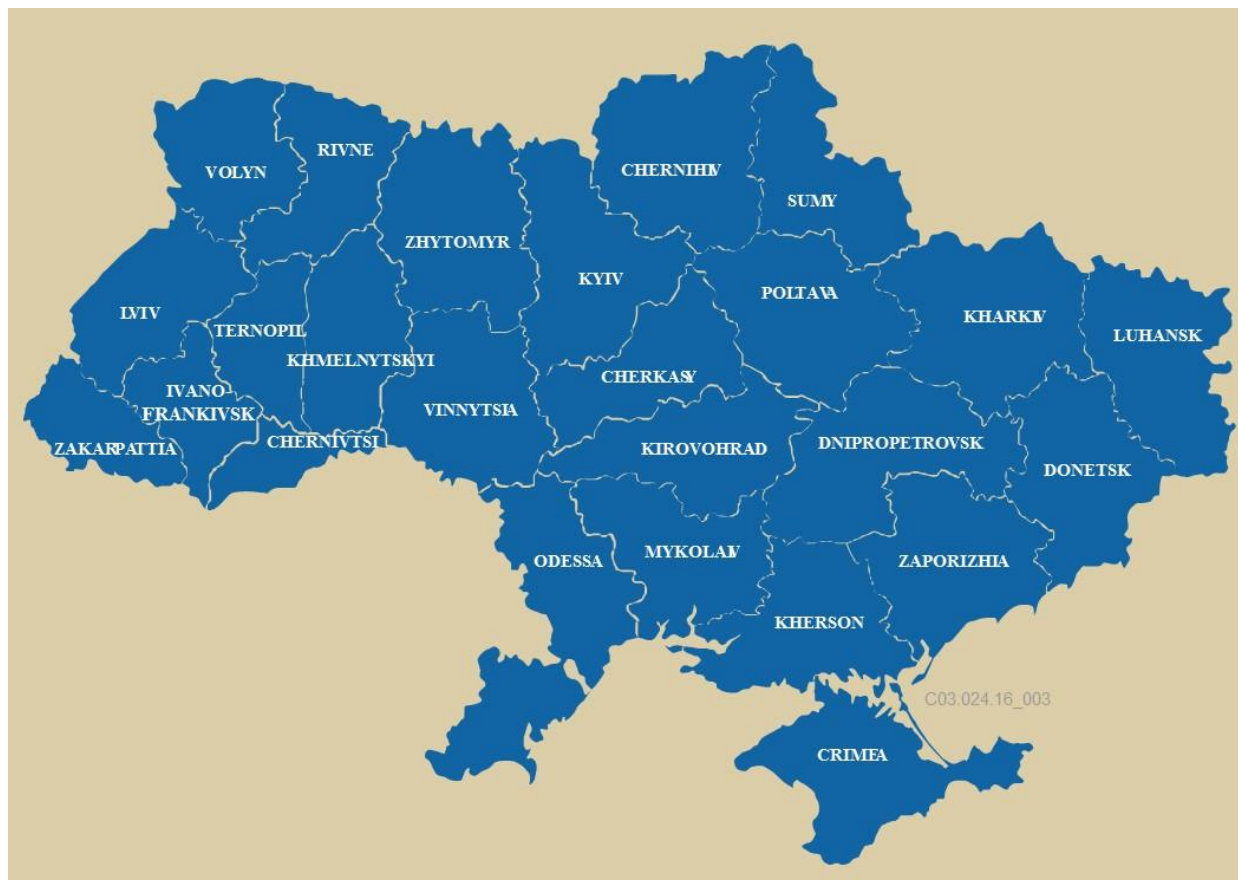
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3 HUMAN HEALTH SECTION

3.1 Overview of Health System Governance

Ukraine is a unitary state in Eastern Europe with an area of 603,550 square kilometers/233,032 square miles. The country is made up of 24 oblasts (regions) (see Exhibit 3) and two cities with a special status, Kyiv and Sevastopol. Oblasts are further divided into rayons (districts), which are composed of urban settlements, rural settlements, and villages.

Exhibit 3: Oblasts of Ukraine⁵



The healthcare system is organized around the three administrative levels: (1) central, (2) oblast, and (3) rayon, with MoH serving as the central authority. The country has retained a large number of facilities in parallel health systems.⁶ The military health system (under the Ministry of Defense) mirrors the civilian structure.⁷

Although Ukraine has been moving toward a more decentralized model through reforms, the healthcare system remains relatively centralized. For example, the move to the PHC was an effort toward decentralization with authority and decision making moving to the oblast and rayon levels, but review of the proposed organizational structure reveals a still highly centralized system. Also, the healthcare finance system remains somewhat centralized. Some powers have devolved to the oblast and rayon level. Funding flows from a consolidated state budget to MoH and then to oblast and rayon hospitals, and while the oblast and rayon health authorities are

responsible for managing healthcare facilities, they are dependent on their local level governments for financial accounting and management. This has created a disconnect between programmatic and budgetary authority. Future decentralization entails a plan to implement a system for purchasing services at the oblast and rayon levels. Exhibit 4 outlines the current relationship and the responsibilities and/or functions of each of the three basic administrative levels.

Exhibit 4: Ukrainian Health System Divisions and Roles

Administrative Division	Responsibilities/Function
Central—MoH	<p>Serves as the leading body that develops and implements health policy; directly manages and/or funds the following:</p> <ul style="list-style-type: none"> • National specialized state-owned health facilities • Allocation of resources (particularly staffing) for healthcare facilities⁸ • Development and approval of state quality standards and clinical protocols⁹ • Organization and implementation of the mandatory accreditation of healthcare facilities¹⁰ • Enforcement of guidelines (norms) for all healthcare facilities across the country (e.g. number of infectious disease physicians, surgeons, and nurses per number of beds)¹¹ • National programs • Planning of healthcare services at oblasts and rayons
Oblast—Regional healthcare authorities	<p>Is responsible for managing health service delivery, including finances, within their oblast¹² including the following:</p> <ul style="list-style-type: none"> • Implementation of national health policies within their territory • Responsibility for regional healthcare facilities, which primarily provide specialized and highly specialized tertiary services as well as outpatient, preventive, and emergency care services • Provision of accreditation of facilities within their region • Monitoring of primary healthcare services¹³ • Approval of local clinical protocols
Rayon—District healthcare authorities	<p>Is responsible for managing health service delivery, including finances, within their catchment area, including the following:</p> <ul style="list-style-type: none"> • Responsibility for rayon and rural hospitals, which provide basic inpatient care and primary health clinics, and polyclinics, which provide basic secondary level primary and preventive care • Administration of accreditation of facilities within their rayon • Approval of local clinical protocols

3.2 National Legislative and Regulatory Framework

Ukraine has numerous laws that govern the human health sector. However, many of these laws reflect the Soviet era, system, and mindset and are not suitable for the health needs of the modern population and as Ukraine seeks further European integration.

The Verkhovna Rada is the main law-making body in Ukraine. This unicameral parliament is tasked with both creating new laws and amending the Constitution of Ukraine. Once the Rada passes a law, the President of Ukraine must sign it before it takes effect. A ministry can also issue orders or regulations to govern within its scope; the Ministry of Justice must approve and register these orders before they can be implemented.

Given Ukraine’s current state of reform, several existing laws need to be updated, and new laws will need to be passed to form the basis of public health system. The three main human health laws

that most critically need revision to address modern practices are “The Law of Ukraine on Ensuring Sanitary and Epidemiological Welfare,” “The Law of Ukraine on Protection of Population Against Infectious Diseases,” and “Fundamentals of the Legislation of Ukraine on Healthcare.” Once these primary laws are updated, orders and regulations can follow to guide processes or requirements in specific functional areas. Exhibit 5 lists some important Ukrainian human health legislation.

Exhibit 5: Selected Human Health Legislation

Regulation	Description
The Law of Ukraine on Ensuring Sanitary and Epidemiological Welfare (No. 4004-XII, 1994)	Regulates sanitary and epidemic safety assurance, and defines the respective rights and obligations of public authorities, enterprises, institutions, organizations, and individuals. It also prescribes the organization of the State Sanitary Epidemiological Service (SSES) and the execution of state governed sanitary-epidemic supervision. ¹⁴
The Law of Ukraine on Protection of Population Against Infectious Diseases (No. 1645-III, 2000)	Governs the organizational and functional basis for activities of state bodies, bodies of local self-government, enterprises, institutions, and organizations aimed at preventing the emergence or spread of infectious disease. It also defines the rights, obligations, and responsibilities of legal entities in protecting the public from infectious diseases. ¹⁵
Fundamentals of the Legislation of Ukraine on Healthcare (No. 2801-XII, 1992)	Establishes the main principles of healthcare; guarantees the right of every citizen of Ukraine to have healthcare; defines the rights of patients; assigns the implementation of state healthcare policy to bodies of state executive power; and notes the financing of healthcare will be done at the expense of the state budget, budgets of local and regional self-government, medical insurance funds, charity funds, and any other sources not expressly prohibited by law. ¹⁶
On the Establishment of the Institution “Public Health Center of the Ministry of Health of Ukraine” (No. 604, 2015)	Establishes the state institution governing public health issues, the PHC, as a separate legal entity by merging state enterprises and agencies, including national laboratories (Lviv Research Institute of Epidemiology and Hygiene [LRIEH], Ukraine Center for Socially Dangerous Disease Control [UCDC], Ukrainian Center for Disease Control and Monitoring [UCDCM], Ukrainian Research Anti-Plague Institute [URAPI]) and the oblast and rayon laboratory centers of the SSES. ¹⁷
On Optimization of Central Executive Bodies (No. 442, 2014)	Merges the SVPS with functions of the State Inspectorate for Consumer Protection and the State Sanitary Epidemiological Service to establish the new state institution, the SSFSCP. ¹⁸
On the Development and Implementation of Medical and Technological Documents on Medical Care Standardization in the System of the Ministry of Health of Ukraine (No. 751, 2012)	Guides the development and standardization of clinical guidelines and protocols and their digitization.
On Comprehensive Measures for the Implementation of Family Medicine in the Health Care System, Cabinet of Ministers of Ukraine 20 June 2000 N 989	Lays out a detailed plan for phased transition of primary healthcare based on family medicine over the course of 2000–2005.
On the Strategy for Sustainable Development “Ukraine–2020” Decree №5/2015 President of Ukraine	Provides for the implementation of 62 reforms and development programs. The goal for healthcare reform is a radical, systemic reform, aimed at creating a system focused on the patient, able to provide healthcare for all citizens of Ukraine at the level of developed European countries. The reform would increase personal responsibility of citizens for their own health, provision of free choice of healthcare services of good quality, the provision of targeted assistance to the most vulnerable populations, creating a business friendly environment in the healthcare market.
Action Programme of the Cabinet of Ministers of Ukraine approved by the Verkhovna Rada of Ukraine on December	Includes action for healthcare reform that would include the following: <ul style="list-style-type: none"> • Elimination of corruption schemes in procurements in the health system • Transformation and upgrade of the hospital network, creating a unified

Regulation	Description
11, 2014, № 26-VIII	<p>three-tier system (local hospitals—regional hospitals—national reference centers)</p> <ul style="list-style-type: none"> • Deregulation of the pharmaceutical market • Passage of the legislation on health insurance

Ukraine has bilateral agreements with 22 countries, including most neighboring nations, for assistance in case of a national emergency.¹⁹ These agreements, concluded between the Cabinet of Ministers and the government of the other country, specifically cite cooperation in “emergency prevention and response,” “mutual assistance in case of emergencies,” or “prevention of emergency situations.”²⁰

There are a number of laws pertaining to surveillance and diagnostic testing of infectious diseases. Some of these laws, including those listed below in Exhibit 6, designate UCDCM Central Sanitary Epidemiological Station (CSES) as the central authority or laboratory carrying out certain functions and activities. With the reforms resulting in changes in certain administrative and diagnostic functions, some laws may need amendments in situations where CSES or other institutions will no longer be fulfilling certain responsibilities.

Exhibit 6: Selected Laboratory Legislation

Regulation	Description
14.12.1992 № 183 “About the mode of pathogenic microorganisms”	Establishes regulation and control of pathogenic Group I–IV organisms and materials through the establishment of the Central Regime Commission. ²¹
23.06.1998 № 168 “About creation of laboratory network from diagnostics of poliomyelitis and acute flaccid paralyses”	Improves surveillance of poliomyelitis and cases of acute flaccid paralysis in the framework of the WHO program to eliminate polio by 2000 and certification of Ukraine as a territory free of poliomyelitis. Among other things, the law served to create a network of laboratory diagnosis of polio. ²²
03.08.1999 № 192 “On measures to improve the bacteriological diagnosis of diphtheria in Ukraine”	Strengthens diagnosis of diphtheria by standardizing procedures and quality control, providing testing resources, designating qualified testing centers, and by other means. ²³
30.12.2003 № 631 “On the establishment of the laboratory network for the diagnosis of measles, rubella and mumps”	Improves epidemiological surveillance of measles, rubella, and mumps in the framework of the WHO program to eliminate measles by 2007 and certification of Ukraine as a territory free of measles. Among other things, the law served to create a network of laboratory diagnosis of measles, rubella, and mumps. ²⁴
23.07.2003 № 342 “On measures to prevent diseases for tularemia”	Improves anti-epidemic and preventive measures for tularemia by establishing CSES as a reference laboratory for the diagnosis of tularemia, as well as establishing public health control measures to prevent infection. ²⁵
19.05.2006 № 306 “On the establishment of the Reference Centre for Molecular Diagnostics of Infectious Diseases Ministry of Health of Ukraine”	Improves the fight against dangerous infectious diseases and to ensure coordination of methodology and practice and implementing measures for sanitary protection in Ukraine from the introduction and spread of infectious diseases and their timely diagnosis. Establishes and defines the functions and activities of the Reference Center for Molecular Diagnostics of Infectious Diseases Ministry of Health of Ukraine as part of CSES. ²⁶
20.07.2006 № 501 “Regarding Sentinel surveillance for rotavirus infection”	Establishes sentinel surveillance and diagnostic testing for rotavirus, including designating an approved list of medical institutions in the network. ²⁷
05.04.2007 No. 167 “Approval of the Guidelines ‘Determination of the Sensitivity of Microorganisms to Antibiotics’”	Implements the main provisions of the “Global Strategy WHO containment of resistance to antimicrobial agents” to reduce the prevalence of antibiotic-resistant microorganisms, particularly in healthcare settings; reducing morbidity and mortality from infectious diseases caused by resistant strains; ensuring effective antimicrobial therapy and improved methods of determining microbial resistance to antimicrobial drugs used in healthcare institutions of the country; and harmonizing them with international requirements. ²⁸

Regulation	Description
04.12.2009 № 922 “On the organization of virological studies of influenza and acute respiratory viral infections in Ukraine during a pandemic”	Establishes CSES as the central laboratory for the diagnosis of influenza and acute respiratory viral infections. Designates authority to CSES to coordinate institutions of the SSES for virological diagnosis of influenza and SARS. ²⁹
12.12.2013 №1080 “About the improvement of organization of sentinel control after bacterial meningitis”	Addresses the further improvement of sentinel epidemiological surveillance of bacterial meningitis by standardizing guidelines, defining institutions for surveillance, and establishing CSES as the central laboratory for diagnostic testing. ³⁰

Ukraine has very broad information technology (IT) laws and decrees that contain provisions for protecting an individual’s personal and sensitive data, including health information (Exhibit 7). There are no laws, however, specifically designed to guard personal health data and/or health information systems.

Exhibit 7: Selected IT Legislation³¹

Regulation	Description
The Law on Protection of Personal Data (No. 2297-VI, 2011)	Protects generally against unlawful processing and unauthorized access of personal data about race, ethnicity, political opinions, religious beliefs and world outlooks, membership in political parties and professional unions, criminal convictions, health, sex life, and biometric or genetic information ³²

For BS&S laws and regulatory frameworks, see the National and Regulatory Frameworks subsection within the Health Systems Overview section. Appendix III provides a comprehensive list of regulations.

3.3 Budget and Funding Mechanisms

*The national budget of Ukraine follows an elaborate process before it is passed into law each year. The laws regulating the process and preparation of the budget include the Constitution of Ukraine, the Budget Code of Ukraine, the Law on the Accounting Chamber, and the Annual Law on the State Budget of Ukraine.*³³

The budget has state and local components. The state budget includes all central government income and expenditures, plus grants and transfers to the local levels. Local budgets include the cities of Kyiv and Sevastopol, plus the budgets of oblasts, rayons, cities, city districts, villages, rural settlements, and towns. The Ministry of Finance prepares a draft budget, with input from individual ministries, which requires approval from the Cabinet of Ministers, the Verkhovna Rada, and the President of Ukraine.³⁴ The annual budget calendar is shown in Exhibit 8.

Exhibit 8: Calendar of Annual Budget Process³⁵

By March 15	National Bank of Ukraine submits to the Verkhovna Rada and Cabinet of Ministers projected monetary indicators for the forthcoming budget year.
By March 20	Ministry of Finance prepares a draft Budget Declaration for the forthcoming year and submits it to Cabinet of Ministers. Line ministries and other central public authorities (CPAs) submit to State Budget Department of the Ministry of Finance data estimates on structural changes that occurred in line ministries and other CPAs and their budget holders since the previous year and request additional expenditures in the upcoming year due to new policy/legislation.
By April 1	Cabinet of Ministers considers and approves the Budget Declaration and submits it to the Verkhovna Rada of Ukraine within a 3-day period.

May-August	Ministry of Finance fixes expenditure for the upcoming year, as well as expenditure benchmarks for two out-years for ministries and other CPAs, and brings them to the attention of line ministries.
	Line ministries and other CPAs submit budget requests (electronically) where they break down expenditures by and within the programs, and, if needed, demand and motivate additional sources.
	State Budget Department analyzes budget requests and holds meetings with line ministries and other CPAs on state budget parameters for the coming year.
	The Local Budgets Department of the Ministry of Finance calculates and makes known to the local governments subnational revenue forecasts, amounts of inter-budgetary transfers, and indicators used for defining the transfers.
	The Ministry of Finance prepares a forecast of the consolidated budget on key revenue, expenditure, financing, and debt parameters for a period of 3 years following the budget year for the approval of the Cabinet of Ministers
September	The Ministry of Finance submits the draft Budget Law to the Cabinet for consideration.
By September 15	The Cabinet of Ministers of Ukraine approves the Budget Bill and submits it along with relevant materials to the Verkhovna Rada and the President of Ukraine.

The annual budget process requires MoH and other ministries to write program “passports” based on specific line items provided in their budget request to the Ministry of Finance. The passports include information on funds, people in charge of funds, objectives for funds, and other program characteristics. In addition, the passports guide program implementation and outline performance indicators needed for evaluation. Ministries must report mid-year and at the end of each year to the Ministry of Finance on the performance of passports.³⁶ These passports indicate a ministry’s budget priorities for the fiscal year. In 2015, MoH did not place priority on most communicable or reportable diseases. With one exception—laboratory research in epidemiological welfare for outbreaks or epidemics—MoH passports mainly focused on management and leadership of various functions, training and education of healthcare personnel, and socially dangerous diseases (i.e., tuberculosis, HIV/AIDS).³⁷ IHR 2005 implementation is not a separate line item in the MoH budget; however, MoH has allocated funds in 2016 for IHR 2005 core capacities such as surveillance and laboratory.

Health Expenditures

Ukraine’s health expenditures as a percentage of its GDP are relatively high for the region (see Exhibit 9 for comparative expenditures in the region.) Even at only 4 percent, Ukraine ranks higher than several other countries and lower than only Moldova.³⁸ Ukraine spent 4.2 percent of its GDP on health expenditures in 2013 (the most recent year available), 4.1 percent of GDP in 2012, 4.1 percent of GDP in 2011, and 4.4 percent of GDP in 2010.³⁹

Exhibit 9: Health Expenditures by Country⁴⁰



Because of Ukraine's current economic situation, most public sector entities do not receive funding commensurate with actual needs. Hospitals receive as little as 40 percent of proposed yearly budgets. Funding often covers (minimal) salaries and is insufficient to sustain facility operational needs such as utilities and building maintenance. As a result, many healthcare facilities are struggling to balance the costs of patient care with internal human resources, equipment, and other administrative expenses.

Health Insurance

The Ukrainian constitution guarantees that free medical care will be available to all Ukrainian citizens and registered residents. In practice, however, public funds remain limited for healthcare. Only basic provisions are free; out-of-pocket health expenditure (percent of private expenditure on health) totaled 94 percent in Ukraine in 2013.⁴¹ This high percentage has significant implications for equity in the health system. The out-of-pocket monies include informal payments for services that should be free as patients try to ensure better quality or more attentive care. Private health insurance is scarce in Ukraine, and the providers that do exist are very small. There are small social insurance funds managed by the government that are designed to provide protection against occupational accident and disease risks; for-profit private insurance funds comprising employer contributions; voluntary schemes purchased by individuals; and Sickness Funds, a nonprofit health insurance scheme. Most Ukrainians cannot afford voluntary insurance; in 2008, only 8 percent of the total Ukrainian workforce and 25 percent of the Kyiv workforce had some form of voluntary medical insurance. All health insurances combined provide marginal healthcare financing for the country.^{42,43,44,45}

Poor, insufficient public health financing can lead to patients being reluctant to seek healthcare services, which in turn can delay infectious disease detection and could result in underreporting of diseases of security concern. Eventually, MoH would like to move the country toward a private insurance model that would provide additional healthcare financing; however, this may be years in the future as other reforms must take place first.

3.4 Human Health System Priorities

Ukraine's health priorities have been shaped by guiding principles and directives from the WHO Framework, IHR 2005, and the EU Association Agreement. These documents outline standards and processes that will help modernize Ukraine's health system and bring it into alignment with European and other international models. Accordingly, MoH has developed its *National Health Reform Strategy for 2015–2020*, which provides a structure for Ukraine's healthcare vision, priorities, objectives, and key measures for developing a “people-centered,” “outcomes-oriented,” and “implementation-focused” system.⁴⁶ The strategy calls for a complete “overhaul” of the current system within the following domains:

- **Service Production and Delivery**—MoH will gradually shift to a system focused on primary healthcare rather than the current inefficient combination of family medicine, hospitals, and specialty care. The new model will emphasize disease prevention over curative care and restructure certain systems and processes such as disease monitoring and surveillance, food safety, and laboratory diagnostics.
- **Health Financing**—Ukraine will rely on tax revenues to fund the public health system but seek to allocate public resources more efficiently by moving toward a system of service reimbursement and resource pooling, supporting development of the private sector, and shifting toward output-based purchases. Universal health insurance is a long-term goal.
- **Stewardship and Governance**—MoH will adopt a more strategic, policymaking role while relinquishing service provision and delivery responsibilities. It will also focus on transparency and accountability while supporting public–private partnerships and provider autonomy.
- **Essential Health System Inputs**—Ukraine will undertake reforms designed to strengthen its health workforce, including improving training and education, and to bolster the use of health information systems and technology.⁴⁷

As part of the reforms, MoH has convened working groups which align with these priorities: (1) financing health systems; (2) primary healthcare; (3) new forms of governance; financing, and resource management for the hospital sector; and (4) a new system of public health.⁴⁸ The working groups are tasked with developing a path forward for each domain in consultation with MoH and international partners.

MoH strategic priorities seem to partially align with its 2015 budget passport programs. Several passports mention leadership and management in health and health service, organization and regulation of institutions and healthcare measures, and improving health for the people of Ukraine. These budget line items could support MoH goals for service production and delivery and stewardship and governance.

3.5 International Standards Compliance⁴⁹

Ukraine has not reported current progress toward IHR 2005 implementation to WHO. Current reforms and the opportunity to align with EU standards are prompting the development of activities that will advance IHR 2005 compliance. The new PHC under MoH will have a division responsible for coordinating activities toward this goal.

Ukraine has not reported progress toward IHR 2005 implementation in the last 5 years. Before the health reforms, it was unclear who was tasked with monitoring IHR 2005 compliance. In 2014, MoH order No. 503 established an expert group on IHR 2005 that will be responsible for coordinating and monitoring activities that align with compliance. This working group is anticipated to be seated within the newly established PHC and will be under the supervision of MoH. The lack of an administrative or functional entity to monitor IHR 2005 compliance has likely contributed to the lack of discernible progress toward compliance and the absence of data reported to WHO.

In 2015, WHO provided comments on central coordination of activities that align with IHR 2005 compliance. Comments include WHO's expectation that the PHC will have a division that is responsible for coordinating with WHO. This is consistent with MoH's plan for the PHC to be the IHR 2005 national focal point (NFP). Ukraine may have up to five NFPs, and it is unclear whether all NFPs will be at the PHC. The lack of a designated NFP to date limits efficient and effective national coordination of emergency response systems and international reporting of health emergencies. It also increases the burden on the national surveillance system to assess and respond to national health events and risks.

Compliance with IHR 2005 is measured as progress against core capacities. Progress is self-reported, so there is no standardized procedure for evaluating progress. The EU-Ukraine Association Agreement specifically mentions the need for Ukraine to build capacity against cross-border health threats through implementation of IHR. Currently, the only IHR 2005 core capacity that has been developed is legislation related to infectious diseases.

3.6 Human Health System Overview

The Human Health System Overview section provides an assessment of Ukraine's BSV and BS&S status using the CBEP BSV and BS&S metrics pillars in Exhibit 10.

Exhibit 10: Cooperative Biological Engagement Program Metrics Pillars

Biosurveillance	Biosafety and Biosecurity
<ul style="list-style-type: none"> • Disease Detection • Laboratory Diagnostics • Epidemiological Analysis and Investigation • Reporting and Communication 	<ul style="list-style-type: none"> • National-Level Regulatory Frameworks • Facility-Level Biorisk Management Systems and Culture • Pathogen Consolidation and Security

3.6.1 DISEASE DETECTION

The Ukrainian healthcare system strives to become more decentralized and flexible. The healthcare system comprises both public and private facilities, with most hospitals and clinics publicly owned. Despite the availability of medical education programs and an adequate overall number of health workers, the geographical distribution is uneven, with most practicing in the urban areas. This is at least partially due to aging of the workforce and new graduates choosing to work outside the state health system or seeking opportunities abroad.

Health Service Delivery

Ukraine has both a public and private healthcare sector, and while public service is available in both rural and urban areas, private healthcare is almost exclusively available in Kyiv and large cities. Inpatient and outpatient services are offered in both the public and private facilities, with specialty services more widely available in urban areas.^{50,51} The majority of the Ukrainian population lives in the urban areas where it can access a wide range of services.⁵² Although reform proposing a primary care gatekeeping model began in 2010, it has been broadly opposed by patients who continue to access the system wherever they choose.⁵³ In most areas, this first possible contact with the healthcare system includes an ambulance service staffed by a physician, which can be called for evaluation of non-life-threatening illness.

Highlight 1: Primary Care in Ukraine

In 2000, Ukraine introduced a new primary healthcare model in an effort to reform primary care based on the principles of family medicine. The model relied on family doctors practicing in polyclinic facilities, mostly in rural areas, and serving as referral points for secondary level specialists.⁵⁴ However, in 2010, Ukraine was still far short of the targeted number of family doctors. Ukraine again introduced efforts to reorient the system to prioritize and strengthen primary care. A general-practitioner-led system was attempted, with physicians assigned to a panel of patients according to the physician's qualification and area served, clear patient pathways, and strong gatekeeping. The primary aim was to reduce unnecessary use of specialist services, but patients broadly opposed gatekeeping, and self-referral to hospitals (effectively bypassing primary care) continued to be a major source of inefficiency in the system. In 2011, several oblasts began pilot projects to look for gaps in the system and to strengthen primary care. Overall goals for access to primary care in Ukraine still have not been reached, with much of the work derailed by the political instability and the conflict in the eastern part of the country. In 2015, MoH announced primary care as one of the objectives for moving toward a European system of healthcare and, more recently, has listed primary care as one of its top three system priorities. As part of the reforms, MoH has convened a working group on primary healthcare to analyze the current situation and formulate a plan for necessary improvement.

Ukraine has an extensive healthcare infrastructure both in terms of numbers of facilities and hospital beds, which is high by international standards. There were 5.4 hospitals/100,000 population in 2009.⁵⁵ The country has also retained a large number of facilities in parallel health systems. For example, Ukraine has 22 military hospitals servicing 250,000 members of the armed forces and their families.

The primary point-of-care providers in Ukraine are physicians and nurses; nurses are not autonomous but function in a supportive role.⁵⁶ The country is facing serious challenges in shortages of physicians, particularly in rural areas and in primary care. Poor social conditions and infrastructure in rural areas make positions there difficult to fill; healthcare workers generally prefer to work in private facilities, despite fewer employment opportunities, because of the low wages, low status, and poor working conditions associated with the public sector.⁵⁷ Exhibit 11 lists the number of health workers in Ukraine per 1,000 population, for the years 2005 through 2010, including percentage changes year over year.

Exhibit 11: Health Workers in Ukraine per 100,000 Population, Selected Years⁵⁸

	2005	2006	2007	2008	2009	2010	% Change 2005–10
Doctors (all types, excluding dentists)	174,143	175,417	175,046	175,616	176,754	175,752	0.9%
<i>% change from previous year</i>		0.7%	-0.2%	0.3%	0.6%	-0.6%	
Practicing physicians, clinical medicine	150,185	149,990	149,053	149,020	149,392	149,618	-0.4%
<i>% change from previous year</i>		-0.1%	-0.6%	0.0%	0.2%	0.2%	
Family doctors	4,975	5,825	6,815	7,772	8,112	8,140	63.6%
<i>% change from previous year</i>		17.1%	17.0%	14.0%	4.4%	0.3%	
Nurses, midwives, and feldshers	367,163	365,138	362,389	360,119	360,414	358,492	-2.4%
<i>% change from previous year</i>		-0.6%	-0.8%	-0.6%	0.1%	-0.5%	
Dentists	20,588	20,539	20,509	20,582	20,894	21,313	3.5%
<i>% change from previous year</i>		-0.2%	-0.1%	0.4%	1.5%	2.0%	
Laboratory specialists	35,091	35,258	35,417	35,238	35,672	35,389	0.8%
<i>% change from previous year</i>		0.5%	0.5%	-0.5%	1.2%	-0.8%	
Management staff	12,357	12,511	12,612	12,297	12,412	12,532	1.4%
<i>% change from previous year</i>		1.2%	0.8%	-2.5%	0.9%	1.0%	

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Doctors in rural areas are burdened by the number of patients they must attend and many are leaving their practices. The medical workforce is also aging rapidly as new graduates choose to work outside the state health system or seek opportunities abroad. Complicating this is the fact that primary care and family medicine are not top choices among medical students upon graduation; the number of newly trained primary care doctors barely offsets the number who leave their posts each year. Measures have been taken by MoH in the form of sending new graduates to work in underserved areas and specialties, and introducing benefits for healthcare workers in rural areas, such as the waiving of utility payments, but these incentives have not brought the desired results.^{59,60} Without the needed number of primary care physicians, particularly in the rural areas, patients do not have access to the care they need. This in turn can lead to infectious disease diagnosis being delayed or missed, and cases not being reported.

Ukraine's 18 schools of medicine offer medical degrees to students. In addition, most medical schools offer master's, doctorate, or post-diploma degrees or training in infectious disease or preventive medicine. Physicians must undergo a mandatory recertification program every 5 years, and there are medical universities and post-graduate facilities that provide various kinds of postgraduate education to fulfill this obligation. Infectious disease detection and reporting classes are not a requirement for recertification program, and the quality of training materials used is not known.

Infection Control and Safety

Infection control in healthcare system varies among the facilities. Challenges are mostly associated with inadequate supply of PPE and/or its incorrect use. Hospitals report that MoH has national infection control guidelines, particularly for PPE, hand washing, disinfection, decontamination, and waste disposal, but not all clinicians are aware of or follow them.

Moreover, health personnel are largely unfamiliar with the concept of EDPs and necessary precautions. This situation could lead to cases not being handled correctly, contribute to nosocomial infections, and result in further outbreak spread.

Highlight 2: Hospital Comparison

Oleksandrivska City Clinical Hospital is the largest hospital in Kyiv and the only MoH hospital in Ukraine with an EDP unit. There are two infectious disease units, on different levels in the separate infectious disease building. The building was remodeled in 2012. Patients access the building via separate entrances according to disease condition. The isolation rooms have ultraviolet lights and external exits, and some are equipped with negative air pressure. Physicians use local protocols adapted from MoH and WHO guidelines for the diagnosis and treatment of infectious diseases. Staff are also well-versed in the process for reporting infectious diseases. The hospital has four laboratories, with one serving as an express laboratory housed in the infectious disease building. The hospital and laboratories are clean, and all staff have been trained on cleaning methods. Clinical and laboratory staff, including physicians, have all needed PPE and are specially trained in its use based on their job descriptions, with supplemental training provided by URAPI. The hospital follows strict national protocols for waste management.

In contrast, Lviv Regional Clinical Hospital, a very large old hospital, shows little evidence of remodeling. The facility does not have an infectious disease unit; all patients with suspected or confirmed infectious disease are transferred to other hospitals, except for obstetrical patients with infections, who are placed in isolation in regular patient rooms on the obstetrics unit. The hospital has staff who understand the process for reporting infectious diseases and an epidemiologist who monitors nosocomial infection but not disease trends. The campus also has four laboratories. The largest clinical laboratory appeared to be clean, but floors in each of its room were made of small pieces of wood with large crevices between each, which would make thorough cleaning and disinfecting difficult. PPE at the hospital and its laboratories is often in short supply, and training is inconsistent. The hospital also develops local protocols and has paper medical records, but there was no mention of a system for auditing to assure adequate documentation or adherence to the protocols. Protocols exist for waste management, but biological hazardous waste is present in the trash containers outside the hospital, and body parts sometimes are literally carried “across the street for disposal.”

Clinical Guidelines

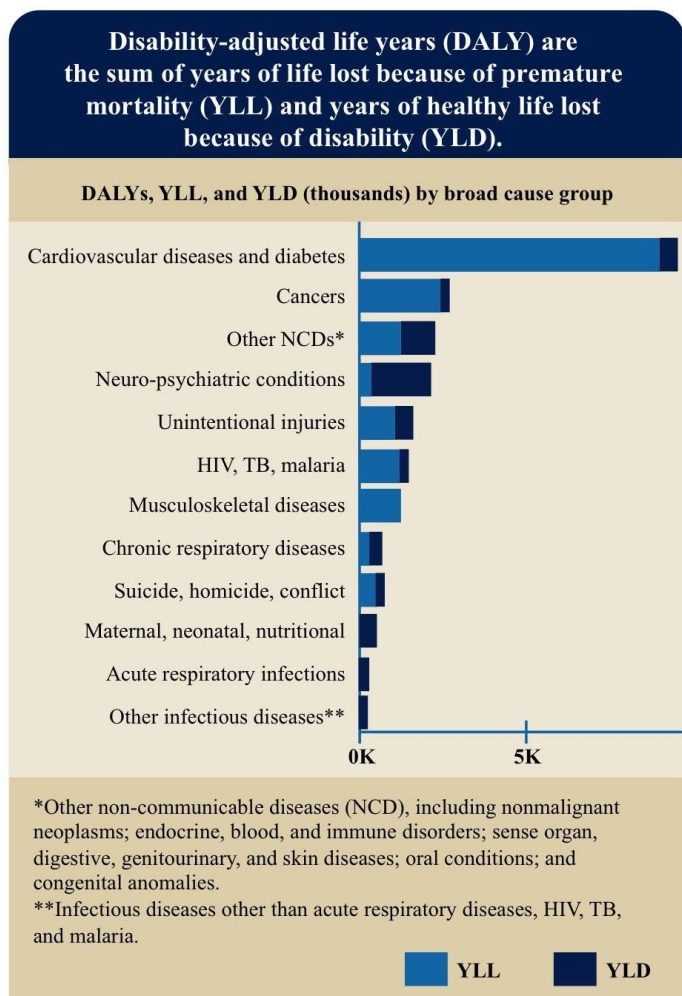
In 2012, MoH approved Order 751 that covered the adaptation and development of clinical guidelines. The order designated the MoH Department of Quality Control of Medical Services to oversee implementation of these documents, with participation of the State Expert Centre. It also prescribed development of the Registry of Medical and Technological Documents on Standardization of Care.⁶¹ The registry has since been developed, and clinical guidelines have been posted, including for infectious diseases such as hepatitis C, influenza, and acute respiratory infections, but no guidelines are posted for diseases of security concern.

Hospitals in Ukraine adapt and use MoH or WHO guidelines to develop local protocols used to diagnose and treat infectious diseases. Physicians receive some training on use of protocols during basic university study, and some hospitals audit medical records for compliance, but there is no indication that practicing physicians receive training on new protocols. It would be helpful if physicians had access to continuous training and education programs or activities.

Disease Burden

The leading causes of healthcare burden in Ukraine are related to noncommunicable diseases, although HIV, TB, and hepatitis C remain concerns. The major causes of mortality in 2012 were cardiovascular disease, cancer, and external causes, including accidents and poisonings; these three causes accounted for 84 percent of all deaths in Ukraine.⁶² (See Exhibit 12.)

Exhibit 12: Ukraine Burden of Disease 2012⁶³



Bacillus anthracis, measles virus, *Leishmania* parasites, West Nile virus, *Clostridium botulinum*, rubella virus, *Leptospira*, mumps virus, *Francisella tularensis*, *Rickettsia* spp., *Coxiella burnetii*, CCHF virus, and tick-borne encephalitis virus are considered endemic pathogens in Ukraine.^{64,65,66,67} Because of outbreaks in neighboring countries, notable transboundary pathogens of security concern in Ukraine are HPAI virus and *Brucella* spp.⁶⁸ Appendix VI provides a list of endemic, notifiable, and transboundary human disease in Ukraine.

Multiple outbreaks of communicable diseases have occurred during the past decade, but only one (anthrax) was caused by a pathogen of security concern.⁶⁹ The HIV/AIDs epidemic has had far greater impact, however, because it stressed the functioning of the healthcare delivery system and also pointed out barriers and weaknesses in the system that impeded the rapid scale-up of an

effective response.⁷⁰ The TB epidemic in Ukraine, characterized by widespread multidrug resistant and extensively drug resistant tuberculosis, relatively high mortality from inappropriately or untreated TB, and increasing TB/HIV co-infection, has been costly in Ukraine.⁷¹ The country is particularly worried about rabies and, more recently, about polio after it was announced in September 2015 that the disease had paralyzed two children in the southwestern region of Trans-Carpathia.⁷²

Highlight 3: Health Service Delivery in Conflict Areas

In April 2014, armed conflict erupted in the Donbas area of eastern Ukraine as a result of Russia's hybrid war against Ukraine, heavily displacing local civilian populations. For those who remained, there was a disruption of basic services, including electricity, water, fuel, communications, and healthcare. Regions with new populations found an already stretched healthcare system burdened to the breaking point. Medications, medical supplies, and personnel were in short supply, and the risk of diseases outbreaks was high. With the help of outside agencies the situation has improved, but the Russian aggression against Ukraine has disrupted disease surveillance and reporting, resulting in missed cases of infectious disease. A dependable healthcare system throughout the affected region will likely not be restored for years to come.

Gaps: Disease Detection

Gap	Explanation	Root Cause	Recommendations
Healthcare Worker Distribution	There is an uneven geographical distribution of healthcare workers with most practicing in the urban areas.	Funding	Form a multisectoral working group to discuss ways to mitigate the scarcity, misdistribution, and turnover of the healthcare workforce. Topics of discussion would include identification of where the needs are in the country, specific recruitment and retention efforts, budgeting/funding sources, and role of universities in preventing "brain drain."
Primary Healthcare Structure	There have been ongoing efforts to improve access to care through the establishment of primary healthcare in Ukraine. The system, however, has not yet reached its goal, especially in the rural areas.	Governance	Work with MoH and the Primary Healthcare Working Group to implement strategies to further stated primary healthcare access priority.
Physician Continuing Education	Mandatory recertification for physicians does not require any courses in disease detection or reporting.	Legislation and Regulation, Education and Training, Funding	Form working group with government and medical education facility representation to create legislation for mandatory inclusion of disease detection and reporting in recertification classes and to discuss funding sources.
Infection Control Practices	Healthcare providers are unaware of national infection control guidelines and/or do not always follow them.	Education and Training, Funding	Convene working group with government, hospital, clinic, and medical education facility representation to determine whether there is a lack of guidelines and the quality of existing guidelines, and to develop a plan for distribution, education, and compliance with the use of infection control guidelines.
Clinical Guidelines	Clinical guidelines do not exist for diseases caused by pathogens of security concern. Hospitals develop	Ideology, Education and Training	Collaborate with State Expert Center to develop clinical guidelines for diseases caused by pathogens of security concern.

Gap	Explanation	Root Cause	Recommendations
	local protocols for diagnosis and treatment of diseases, and it is reported that they are approved by local healthcare departments, but this process could lead to nonstandardized care. While physicians receive training in their basic education, there is no system to educate on new protocols and no systematic auditing for compliance.		Collaborate with oblast and rayon healthcare departments toward standardization of local protocols. Discuss with universities and post-graduate facilities how the education of new protocols can be assured. Work with a group of hospitals to establish auditing to assure accurate use of clinical guidelines/protocols. Work with MoH to discuss/encourage possible needed legislation.

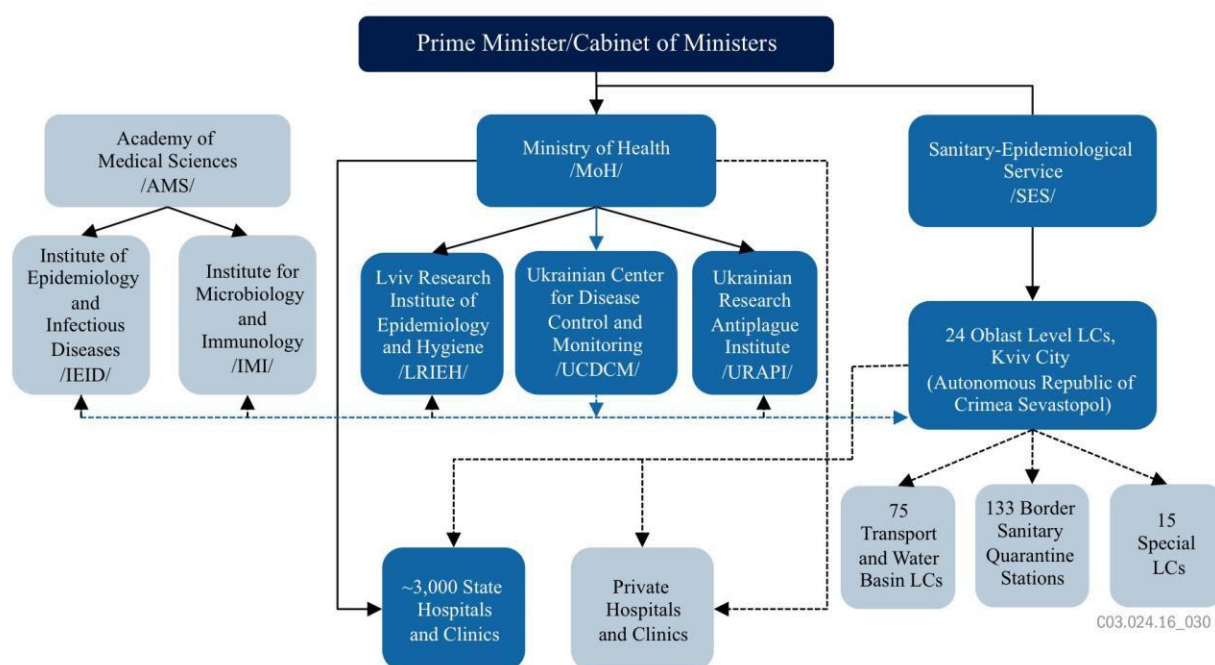
3.6.2 LABORATORY DIAGNOSTICS

The central laboratories, which include UCDCM, URAPI, and the LRIEH, act as confirmatory centers for Group I–II pathogens. Under the current laboratory network, hospitals or clinic laboratories (if in-house clinic laboratories exist) test collected samples for infectious diseases. Rayon-level laboratories test environmental samples for Group III–IV pathogens. The PHC intends to retain laws pertaining to the laboratory referral network for EDPs.

Structure of Laboratory Network

The public health laboratory network is primarily composed of rayon, oblast, and national laboratories—all under the authority of MoH. Exhibit 13 provides a diagram of the current network structure (pre-reform).

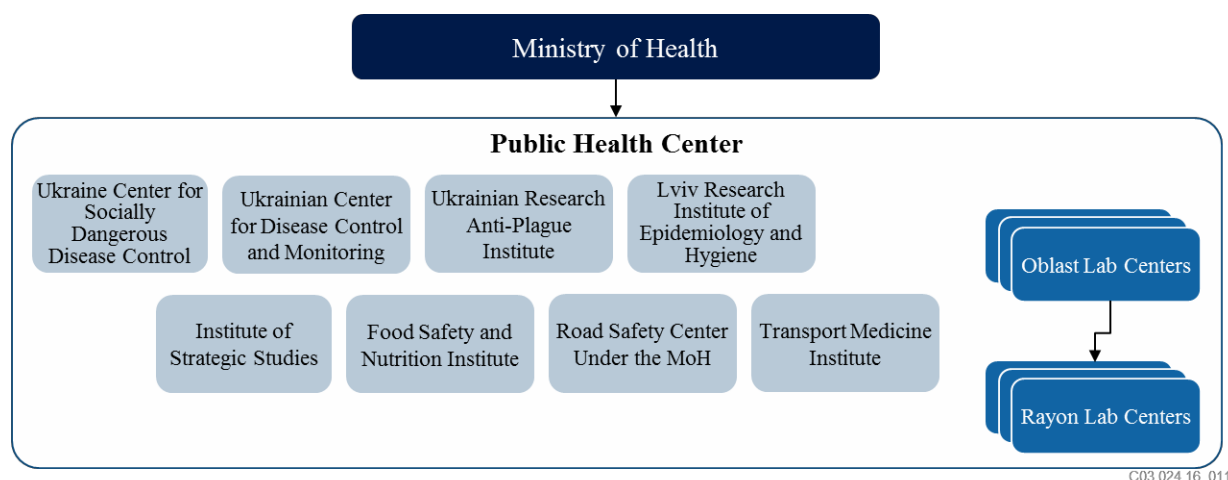
Exhibit 13: Command Structure of Human Laboratory Network⁷³



The public health laboratory network is expected to be strengthened under MoH Decree No. 604, which mandates establishment of the PHC. Anticipated areas of improvement include laboratory quality management, coordinated programmatic training, consolidation of resources, biosafety

and biosecurity, laboratory accreditation, and a network-wide laboratory information management system. Exhibit 14 is a diagram of the entities being reorganized under the PHC.

Exhibit 14: Public Health Center Under MoH Decree 604⁷⁴



At the moment, the national laboratory network does not have a strategic plan providing a comprehensive understanding of the goals and priorities of the system. The strategic plan would increase the level of transparency regarding the system’s future direction, set the course for a defined number of years, and also leverage future assistance from stakeholders with an interest in strengthening laboratory capacity for the Ukraine network. As the PHC working group on the reforms concludes its discussions and begins moving toward implementation, developing the strategic plan should be a priority and presents a prime opportunity for support/engagement.

Quality Management System

Historically, the Metrology and Calibration Unit of UCDCM has performed quality management by conducting yearly audits in oblast laboratories to ensure laboratory equipment was calibrated according to the regulations and to verify implementation of quality control measurements. UCDCM also provided external quality assessments to oblast laboratories. While UCDCM’s oversight served an important role, the system still lacked a central quality office to ensure standardization of procedures and quality management. With the establishment of the Quality Control Unit under the PHC, such a national office will exist, which will not only oversee internal quality control and compliance with metrological requirements but also will work to standardize national SOPs and develop a national external quality assessment scheme (EQAS).

A needed component of the EQAS is the inclusion of proficiency testing and evaluation exercises for EDPs. In addition, the development of national SOPs for all procedures, most especially procedures related to EDPs, would be necessary to ensure effective functioning of the laboratory system. Achieving ISO 17025 accreditation for all CBEP-supported laboratories is a priority of the PHC.

Highlight 4: National Accreditation Agency of Ukraine

The National Accreditation Agency of Ukraine (NAAU) issues ISO 17025 accreditation to qualified human and animal laboratories. NAAU is an associate member of the European Cooperation for Accreditation and a cooperating member of the International Laboratory Accreditation Cooperation and the International Accreditation Forum. Because NAAU is the only agency within the former Soviet Union countries that meets all international laboratory standards, it is well-suited to provide its services to other laboratories in the region, which might enhance Ukraine's capabilities as a regional leader. Strengthening of NAAU's capacities may provide a unique opportunity to improve quality standards in Ukraine and other regional nations.

Human Resource Development

The training program for the laboratory network needs enhancement because there is currently no national, standardized laboratory training program in Ukraine. While UCDCM, URAP, LRIH, and regional laboratories under SSES have provided important trainings, lack of coordination and standardization of trainings is a weakness in the system. The PHC intends to establish a national training program that will include a national training center and international cooperation for laboratory instruction and field epidemiology training. The program is expected to include trainings for sample collection, packaging, and shipping; BS&S; and SOPs for diagnostic testing. The training program should also include a laboratory quality management training program for laboratory supervisors and leading staff. In addition, there will be a post-graduate unit within the PHC that will coordinate post-graduate training and continuing education through medical credits, seminars, conferences, and other meetings. National laboratories may conduct specialized technical training in partnership with universities. Establishment of the training center and development of national trainings for the aforementioned subjects, including development of a core curriculum to standardize minimum training and continuing education, will be an important next step in establishing a strong laboratory network.

Consolidation of Resources

One of the greatest needs for the laboratory system is to determine accurate resource requirements for effective and efficient the PHC structure and functioning. The current state of resources leaves most laboratories poorly equipped to respond effectively to a public health emergency. While EDP laboratories have the needed equipment for rapid detection of infectious diseases, these laboratories are underfunded and can neither maintain reagent kits nor afford to maintain the equipment, including biosafety cabinets (BSC). In addition, the infrastructure of some laboratories is severely outdated and in extremely poor condition, which increases the biosafety, occupational safety, and biosecurity risks to the facility and of the pathogens they screen and store. Optimizing the system through consolidating laboratory resources would increase efficiency of resources and capacities to maintain laboratories, including allocating funds to modernize outdated facilities.

Highlight 5: Kyiv City Laboratory

The Kyiv City Laboratory serves as the central reference laboratory for the city of Kyiv. It provides quality oversight for the 10 district bacteriological laboratories and additional laboratories within the city. Because of its population size and status as a major transportation hub, Kyiv requires strong epidemiological surveillance and laboratory response for disease detection. While the Kyiv City Sanitary Epidemiological Station (SES) and central laboratory fulfill these functions, laboratory capacities are diminished owing to the poor conditions of the laboratory facility. Building infrastructure is dilapidated, and the equipment is outdated. In addition, there are severe inadequacies in biosafety engineering controls, such as poorly maintained BSCs and air handling systems. Because this is an EDP laboratory, these conditions fail to meet international biosafety standards. This creates a significant risk to both personnel and the surrounding environment. As part of ongoing discussions on laboratory consolidation, the Kyiv City Laboratory should be a consideration, potentially transferring its laboratories to the newly constructed building on its campus. While other laboratories are being considered for this new facility, consideration should be given to consolidating functions for all laboratories under discussion, so that reference testing needs can be fulfilled for both national and Kyiv city disease detection at the new facility.

Laboratory Information System

The Ukrainian healthcare system lacks a broadly used laboratory information management system (LIMS); consequently, implementation of LIMS is inconsistent across healthcare facilities. Some facilities, such as the Kyiv Regional Hospital, have installed LIMS and use the software for sample management, data entry, instrument integration, internal data exchange, auditing/chain of custody, barcoding, reagent inventory, quality control, and diagnostic laboratory result report generation. However, where a LIMS is absent, laboratories use paper-based logbooks and/or generic software tools such as Microsoft® Excel.

Highlight 6: Kyiv Regional Hospital

Kyiv Regional Hospital uses an elaborate web-based LIMS known as MEGAabikc. Twenty triage units within the hospital are able to access the LIMS to register the patient, generate patient identification, and create sample barcodes. Once the laboratory receives the sample, it is able to scan the barcode and update sample status, enabling tracking of samples as they move through various departments throughout the hospital. The laboratory at the hospital contains 13 different analyzers, most of which can communicate directly with the LIMS, which helps eliminate user errors. The results can be printed, emailed, and/or made available over the telephone for patients and doctors. The LIMS also tracks quality control, and laboratory staff can export their quality control data for comparison purposes. MEGAabikc is interoperable with other information systems such as hospital information systems and electronic disease surveillance and reporting systems.

Gaps: Laboratory Diagnostics

Gap	Explanation	Root Cause	Recommendations
Laboratory Quality Management System	With no national quality office, Ukraine has struggled with consistent oversight for compliance with quality standards. In addition, there is no national EQAS, and	Governance	Support the new Quality Unit under the PHC, which should improve quality oversight for the laboratory network. Support efforts to improve the laboratory

Gap	Explanation	Root Cause	Recommendations
	there is a lack of standardization of procedures and laboratory training, including training for sample collection and transport, working with EDPs, and laboratory quality management.		quality management system, including developing a national EQAS, training, and standardization of national procedures.
Human Resources Development	There is no national training program or office to coordinate required trainings for laboratory staff.	Governance	Support PHC's efforts to fill this gap through its training center. The training program will include trainings for sample collection, packaging, and shipping; biosafety and biosecurity; and SOPs for diagnostic testing.
Equipment Maintenance Practices	The culture of equipment maintenance is generally absent, leaving equipment idle, unsafe to use, or potentially producing inaccurate test results.	Funding	Incorporate maintenance of equipment into regulations. Include preventive maintenance agreements in the annual budget. Encourage establishment of biomedical engineering departments within MoH to routinely maintain equipment.
Reagents and Consumables	Expenditures on diagnostic kits and consumables are limited.	Funding	Leverage scientific expertise and functionality of the Institute of Veterinary Medicine (IVM) and State Sanitary Control Institute of Biotechnology and Strains of Microorganisms (SSCIBSM) to manufacture diagnostic kits for PHC upon validation and approval.
Electronic Laboratory Reporting System	There is no system wide implementation of LIMSs.	Governance	Identify LIMS utility and install system in a select number of sites.

3.6.3 EPIDEMIOLOGICAL ANALYSIS AND INVESTIGATION

Ukraine has a structured, regionalized approach to disease surveillance and epidemiological analysis. Data collection and data analyses are conducted by different entities, which is a key challenge in coordinating disease detection and response efforts. There are no baseline data to establish alert or epidemic thresholds. The quality of surveillance data is generally poor because disease reporting is often incomplete. Outbreak responses are heavily regulated by outdated decrees. Staff are trained under the Soviet paradigm of epidemiology, which emphasizes descriptive statistics rather than the analyses of surveillance data to determine risk factors or disease trends.

System Description

SSES, which was composed of SESs in each oblast and rayon, has historically managed disease surveillance and outbreak response by collecting surveillance data and submitting it to UCDCM for statistical analysis. In 2011, SSES acquired status as an individual state executive body, and in 2014, it was ordered to be liquidated in accordance with Cabinet of Ministers Resolution No. 442. MoH Order No. 604 divided the surveillance and laboratory functions of SSES, and it was subsumed by the PHC, which will report directly to MoH. Under the planned reforms, PHC will become the central entity to collect and analyze disease data from the rayon, oblast, and central levels depicted in Exhibit 15.

Exhibit 15: Disease Surveillance Administrative Units

Administrative Level	Administrative Unit (Current)	Administrative Unit (Post-Reform)	Unit Description (Current and Post-Reform)
Central	SSES/UCDCM	PHC	Collects, aggregates, and analyzes disease data for 24 oblasts and 2 cities with special status.
Oblast	Oblast SES/ Oblast Laboratory Center (OLC)	PHC	Collects and aggregates data from rayons within the oblast and conducts epidemiological investigations.
Rayon	Rayon SES	PHC	Collects daily morbidity data from local health facilities and conducts epidemiological investigations.

Highlight 7: Lviv OLC and General Directorate of SES

In 2012, Lviv SES divided into the Lviv OLC/SES and the General Directorate SES. On paper and in practice, these two entities are separate but are both governed by the Chief of the General Directorate SES. Reform regulations have created some functional redundancy in the system and a lack of understanding of roles and responsibilities. Surveillance data are sent to the OLC/SES, but the General Directorate SES is responsible for the enforcement of sanitary control measures. Prior to the reforms, OLC/SES would monitor surveillance data and implement sanitary measures to control outbreaks. Reform legislation terminated the response functions of the OLC/SES and transferred them to the General Directorate SES; consequently, the OLC/SES cannot legally take appropriate measures based on its disease monitoring capacity, despite its capability to do so. Similarly, the General Directorate SES is responsible for responding to outbreaks but does not have a complete picture of the epidemiological situation because it does not receive surveillance data. Generally, personnel at these institutes hold a negative opinion of this restructuring and the overall impact of the health reforms. Staff from both the OLC/SES and General Directorate SES expressed frustration with the structure and compared it with having “one head with two bodies.” This structure has generated inefficiency and reduced efficacy of the public health system. This communication barrier impedes disease detection and response and heightens vulnerability to widespread outbreaks.

Human Resources

There are roughly 2,000 epidemiologists in Ukraine, which translates into approximately 9 epidemiologists per 200,000 population. Kyiv City has 2 or 3 epidemiologists in each of its 10 districts. Although this exceeds the U.S. Centers for Disease Control and Prevention (CDC) recommendation of 1 epidemiologist per 200,000 population, it is important to understand that the epidemiologist role in Ukraine is different from that in Western countries (see Highlight 8).

Highlight 8: Epidemiology in Ukraine

Epidemiology in Ukraine (and most former Soviet Union countries) developed independently from epidemiology as a discipline in western countries. Most western countries use analytical epidemiology, in which biostatistical analyses are performed on surveillance data to make inferences and determine risk factors, investigate the etiology of a disease and modes of transmission, and assess the association between exposures and outcomes (i.e., why and how an outbreak emerged). In contrast, Ukraine uses descriptive epidemiology and has adopted the classical Soviet paradigm of epidemiology that focuses on ecological measures to prevent or liquidate infectious diseases. Statistical analyses are primarily basic and descriptive; data are used to describe patterns among cases and in populations (i.e., who, what, where, and

when an outbreak emerged). Descriptive epidemiology can be used to generate hypotheses, but analytic epidemiology is needed to test hypotheses. As a result, Ukraine does not perform advanced epidemiological functions such as trend analysis, forecasting, and assessment of risk factors. For example, surveillance data in Ukraine consist of morbidity and mortality data broken down by categories (e.g., age, location). In addition, excessive regulation/legislation impedes epidemiological monitoring in Ukraine.

At the time of the assessment, there was an ongoing influenza epidemic. Influenza surveillance data were reported daily to the SES and categorized by age, oblast, pregnancy, or hospitalization status, etc. These data were compared with alert thresholds in outdated legislation that has not changed since the Soviet era. If the threshold was reached, sanitary control measures were implemented as specified by the legislation. Alert thresholds for influenza are specific to the time of the season (e.g., the alert threshold for the first week of flu season is different from that of the fourth week of flu season) and were calculated based on retrospective analyses. With thresholds fixed into legislation, disease data are evaluated against potentially outdated metrics. This limits the ability to detect emerging disease outbreaks, associate exposures to outcomes, and optimize preparedness for outbreak response.

Epidemiologists' responsibilities include data collection to monitor the public health situation and trends, epidemiological investigation of cases (including interviewing patients and contacts, examining household and environmental conditions, collecting samples for laboratory testing), implementing control and preventive measures in line with national legislation and guidelines, and aggregating epidemiological data for statistical analyses. Epidemiologists prepare reports of summary statistics to submit up the administrative hierarchy. Oblast hospitals ideally have an epidemiologist who supervises reporting to the SES. Recent funding constraints have prevented hospitals from filling this staff epidemiologist position (see Highlight 10 in Reporting and Communications).

Analysis of Collected Data

UCDCM is responsible for aggregating and conducting statistical analyses of national surveillance data on reportable diseases to develop recommendations for controlling and preventing diseases. The Center for Medical Statistics at MoH collects data from UCDCM and other surveillance networks (e.g., TB, AIDS, sexually transmitted infection) and generates reports, which are not publicly available. The Center for Medical Statistics is required to send data to the State Statistics Service of Ukraine, which is part of the Ministry of Economy. The State Statistics Service may use these data to determine how resources have been used. Reports from the Center for Medical Statistics are not routinely published, but the center may issue reports for a fee. The State Statistics Service publishes annual statistical bulletins on healthcare and morbidity in Ukraine. These bulletins report statistics on select infectious diseases of security concern (e.g., anthrax, HPAI), but there are no indicators of anomalous disease patterns.

Although disease data are routinely collected on reportable diseases, data are often incomplete (i.e., underreported), and there is no quality control of the data. Jurisdictions do not always report surveillance data in a timely and complete manner. These data are not used to identify disease patterns, implicate a source of disease, or determine statistical outcomes, including risks and rates. The incomplete reporting practices render the quality of disease data as generally poor, with the possible exception of the TB and AIDS data that are collected by separate surveillance systems. Analytical epidemiological techniques and relevant biostatistical tests are not conducted. Rayon and oblast SESs conduct analyses on collected surveillance data to determine

vaccination plans or resources needed for sanitary measures. SSES uses Microsoft® Excel for basic analysis. Only specialized health programs use sophisticated analytical tools (e.g., EpiInfo, e-TB Manager).

Highlight 9: Disease-Specific Surveillance Systems

MoH established UCDC to conduct epidemiological and programmatic surveillance of TB and HIV/AIDS. It has a network of regional HIV/AIDS centers and a system of regional TB clinics and laboratories. These surveillance systems are siloed vertical systems that operate in parallel with the national surveillance system. The TB and HIV programs have benefited from international assistance and are able to employ surveillance tools such as EpiInfo and e-TB Manager, a web-based tool that integrates all data across all aspects of TB control. These modern tools allow staff to conduct relevant epidemiological risk analyses. Thus, data analyses for these diseases are different from those of diseases monitored by the national surveillance system. TB and HIV are the only diseases in Ukraine for which active surveillance is conducted. The Global Fund will be phasing out its support of the TB and HIV programs, putting the sustainability of UCDC activities at risk. As part of the reform process, there is a plan to integrate the TB and HIV surveillance systems into the national system, but this plan has not yet been fully developed or implemented.

Collected data are used to develop sanitary control measures at the central level that are passed down to subordinate administrative levels. It was widely acknowledged that surveillance data are not used to inform administrative and programmatic public health decisions. Data analyses are used to project resources needed for control measures, and not for determining priority diseases, conditions, or risk factors.

Outbreak Investigation

SSES oversees outbreak investigation and response at all administrative levels. Determination of an outbreak by the rayon or oblast SES is based on case thresholds specified in national regulations. There is an abundance of disease-specific regulations that define an outbreak threshold and the number of cases for which an investigation should be initiated. The regulations also specify what sanitary control measures to implement for each disease. When the SES observes that cases have reached the threshold for an outbreak, it notifies the hospitals in its jurisdiction that an outbreak has been declared. In effect, hospitals cannot discern from their own data that there is an outbreak and consequently, do not initiate precautions. Hospitals rely on the SES to announce that there is an outbreak and that the hospital should prepare to receive and treat patients. This delays detection of and response to an outbreak. By the time the SES notifies a hospital of an official outbreak, the disease may have propagated farther than is manageable by a local hospital or healthcare facility.

Epidemiologists from the local SESs initiate epidemiological investigations using paper-based forms. SES staff conduct an investigation for each reported case of a notifiable disease under surveillance. Ideally, an investigation team consists of an epidemiologist, an assistant, a hygiene specialist, a laboratory specialist, and, depending on the situation, may also include a specialist such as a bacteriologist or virologist. If the outbreak is suspected to be caused by an EDP, the response team that is deployed is staffed with an epidemiologist with specialized training in EDPs. The number or identity of epidemiologists who have completed this specialized EDP training is uncertain. The epidemiological investigation team visits the outbreak site to interview

contacts, outline boundaries, collect samples, conduct disinfection measures, and monitor patients. SES completes a standard investigation form.

Epidemiologists conduct site visits and interviews typically in less than a day. Investigations that are prompted by immediate notification (e.g., suspected EDP) are completed and presented to public health authorities the following day. By law, epidemiologists are required to investigate all reported cases of notifiable diseases. There are approximately 67 notifiable diseases (Appendix IV), including enteric diseases, for which large numbers of cases are reported annually. With constrained resources and a shortage of trained staff, it is unclear whether field investigation of each case is feasible as mandated by legislation. There may be cases for which no resources are available to conduct an investigation, leading to the possibility of further spread of disease. Moreover, even if all reported cases were investigated, the institutionalized underreporting of cases that persists would continue to pose a public health risk.

SES determines and executes control measures in accordance with disease-specific legislations. The surveillance arm of the SES works closely with the laboratory arm to determine control measures based on confirmed laboratory results.

MoH has no dedicated emergency operations center (EOC) for health emergencies. The National and Regional Comprehensive Civil Protection Code and Response Plan details the emergency preparedness and response functions of an EOC. This Civil Code defines the criteria for an emergency situation and describes the responsibilities of the State Emergency Services of Ukraine (formerly Ministry of Emergencies) and MoH during an emergency. There are SOPs and bylaws for MoH that require notifying the State Emergency Services of Ukraine during a public health emergency, but they do not describe how it has to be done. The planned PHC will have an Outbreak Investigation Unit. Members of the PHC Outbreak Investigation Unit will be responsible for revising legislation and will focus on developing SOPs and defining responsibilities during an investigation.

Training and Education

Currently, epidemiology and disease surveillance training is limited to the postgraduate level because of funding constraints. Some medical schools (e.g., P.L. Shupyk National Medical Academy of Postgraduate Education, Odessa National Medical University, Kyiv Medical Institute) offer epidemiology courses in their curricula, but epidemiology training is not standardized across medical schools. Two Ukrainians are currently enrolled in the CDC Field Epidemiology and Laboratory Training Program in Tbilisi, Georgia.

In 2009 through 2012, Walter Reed Army Institute of Research (WRAIR) conducted a train-the-trainer course to instruct Ukrainian trainers on investigative and analytical techniques in epidemiology. The course participants subsequently found employment with SSES or in academia. The seven trainers proceeded to train more than 200 epidemiologists using the training modules of the epidemiology course. Approximately half of the seven trainers continued to work within the national health system after the training concluded in 2012. However, at the time of the assessment, the employment status of the trainers and the trainees was not known. MoH is planning to incorporate the WRAIR epidemiology training modules into university curricula, but they have not yet been formally adopted and implemented.

There are 60 to 100 students currently enrolled in institutionalized (i.e., university) epidemiology programs, but there is no funding to enroll new cohorts. Every 5 years, epidemiologists must complete a recertification course at a national graduate medical academy. SSES has an annual in-service training plan in which the staff rotate through CSES in Kyiv to refresh their skills. CSES also provides trainings for physicians and other staff working with patients with infectious diseases.

Training and retention of personnel is a persistent issue. There is high staff turnover because of low wages, and the health reform process has further affected the development of human resources. The first round of reforms resulted in the loss of 30 percent of personnel in the healthcare system and limited the hiring of new epidemiologists. Most of the staff that were laid off were close to retirement age, so the remaining staff are less experienced personnel who are overburdened and underpaid. The remaining staff were trained under the Soviet paradigm of epidemiology and have limited ability to conduct investigations and analyze surveillance data according to internationally accepted methods. The capabilities of the current workforce are a significant barrier to the timeliness, accuracy, and quality of data, as well as the ability to conduct analysis and outbreak investigation. The current reforms of the health system aim to streamline disease surveillance and modernize the epidemiological workforce. The human resource strategy for the new reforms will be developed after the new structure of the health system is in place and staffing needs are determined.

Gaps: Epidemiological Analysis and Investigation

Gap	Explanation	Root Cause	Recommendation
System Coordination and Integration	Functional units within the surveillance system do not coordinate efforts effectively. One unit collects data, but legislation prevents it from implementing control measures.	Funding, Governance	Improve the integration among the surveillance subsystems to eliminate duplication of functions and inappropriate use of resources.
Analysis of Disease Trends	Data analysis consists of descriptive statistics. There is minimal analysis of disease data to understand disease trends and risk factors.	Education and Training, Ideology	Develop advanced modern analytic capabilities that are capable of analyzing trends, determining risk factors, etc. Provide advanced training and apprenticeship of key analytical epidemiologists.
Data Quality	Data quality is poor, and there are no mechanisms to monitor the quality of data.	Education and Training, Ideology	Train epidemiologists on methods to monitor and evaluate data quality.
Baseline Disease Data	Baseline data exist only for influenza, TB, and HIV/AIDS. There is minimal baseline data for other diseases to inform alert or epidemic thresholds.	Education and Training, Ideology	Train epidemiologists to generate baseline data and calculate thresholds.
Human Resources	Reforms have significantly reduced personnel, and there is a low retention rate of trained graduates in the public health system, causing existing staff to be overburdened. Current staff capabilities are limited to outdated Soviet techniques in surveillance and disinfection.	Funding, Education and Training	Redistribute and optimize staff functions, implement mechanisms for retaining qualified staff.
SOPs for Outbreak Investigation and	The guidelines for responding to an outbreak are outdated and mired in	Governance	Train personnel on appropriate analytical and investigative epidemiological

Gap	Explanation	Root Cause	Recommendation
Response	legislation.		methods; develop SOPs for investigation of diseases of public health importance.

3.6.4 REPORTING AND COMMUNICATIONS

Ukraine has a passive disease surveillance system driven by reporting of notifiable diseases. As part of the planned reforms of the health system, the list of notifiable diseases will be revised to be more in alignment with EU standards. The reporting system is paper-based, with data entered into electronic spreadsheets at the oblast level. Underreporting is a significant problem, and the quality of the data is generally inadequate, which hinders the country's ability to detect and respond to disease outbreaks.

Disease Surveillance System

Disease monitoring in Ukraine is conducted primarily through passive surveillance. The process is initiated by a patient seeking medical care. Regulation No. 157 stipulates that healthcare institutions are required to report notifiable diseases to the rayon SES immediately and to notify public agencies of a change of diagnosis within 12 hours. Hospitals are required to report other disease data to the local SES daily, but the extent to which this is implemented is unclear and intermittent at best. Depending on the suspected pathogen, the healthcare facility may perform diagnostic tests internally, or send samples directly to the OLC or to a designated national reference laboratory. Similarly, the patient may be transferred to a regional or specialty hospital (e.g., infectious disease hospital).

The rayon SES sends information and samples to the OLC. Reporting through the public health centers is paper-based with data managed in Microsoft® Excel. A separate paper form must be filled out for each case. Paper forms (form 58 and register 60) are old normative documents. If there is a suspected zoonotic disease, the rayon or oblast SES should notify its counterparts in the veterinary health system, but there are no clear lines of communication or a known protocol for this process. The SES at the rayon level aggregates morbidity data and generates summary statistics that are sent monthly to the oblast SES which, in turn, aggregates data from the rayons and sends a monthly summary report to UCDCM. UCDCM aggregates data and submits them to MoH, which determines what data to report to WHO.

There are significant, widespread challenges to accurate reporting. The system of passive surveillance is rife with underreporting—the expectation of negative consequences for generating poor results (i.e., punishment for failing to prevent an outbreak) is a disincentive for reporting disease cases. This makes it impossible to ensure total compliance by healthcare providers and ultimately affects the quality of data and the country's biosurveillance capacity. Another challenge is the use of outdated reporting forms that do not correspond to international guidelines. Collecting disease data using a paper system is laborious, time-consuming, and prone to human error and inconsistency.

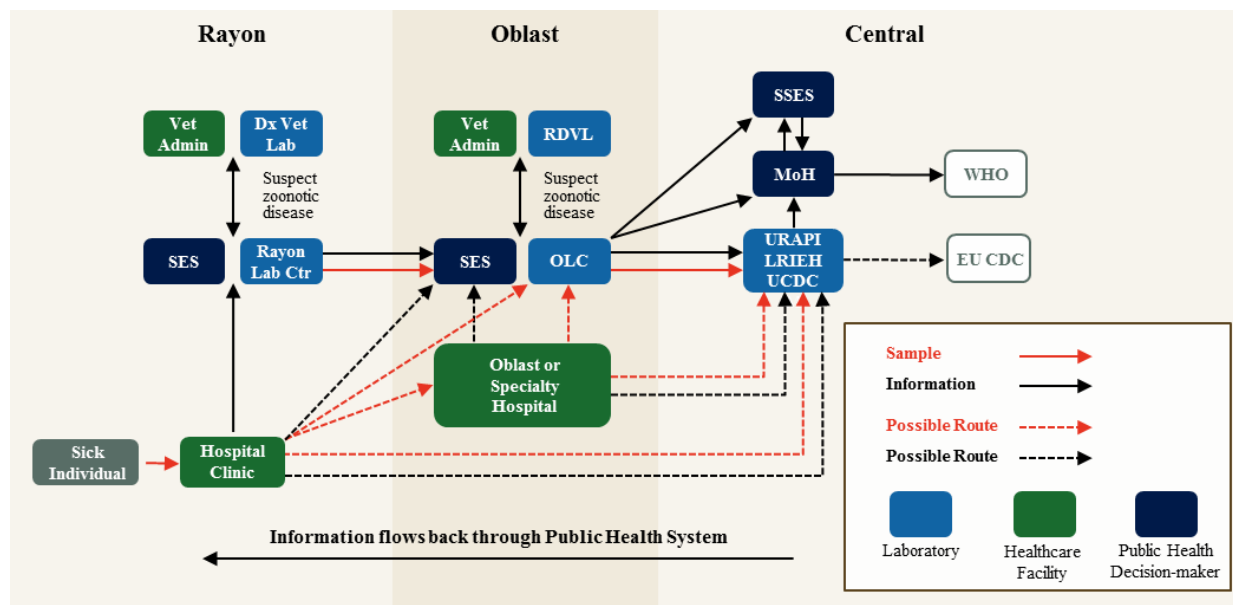
Highlight 10: Reporting Challenges at Healthcare Facilities

Historically, oblast hospital staff relied on the epidemiologist to know which diseases should be reported and to ensure the quality and accuracy of reporting. Current funding constraints have prevented the

staffing of this position in hospitals, so clinicians fulfill this function in the absence of an epidemiologist in many places. This adds an additional burden to clinicians' already busy schedules and has caused further delays in reporting, has affected the quality of reported data, affects the SES's ability to detect and respond to disease outbreaks, and detracts from physicians' clinical responsibilities and performance.

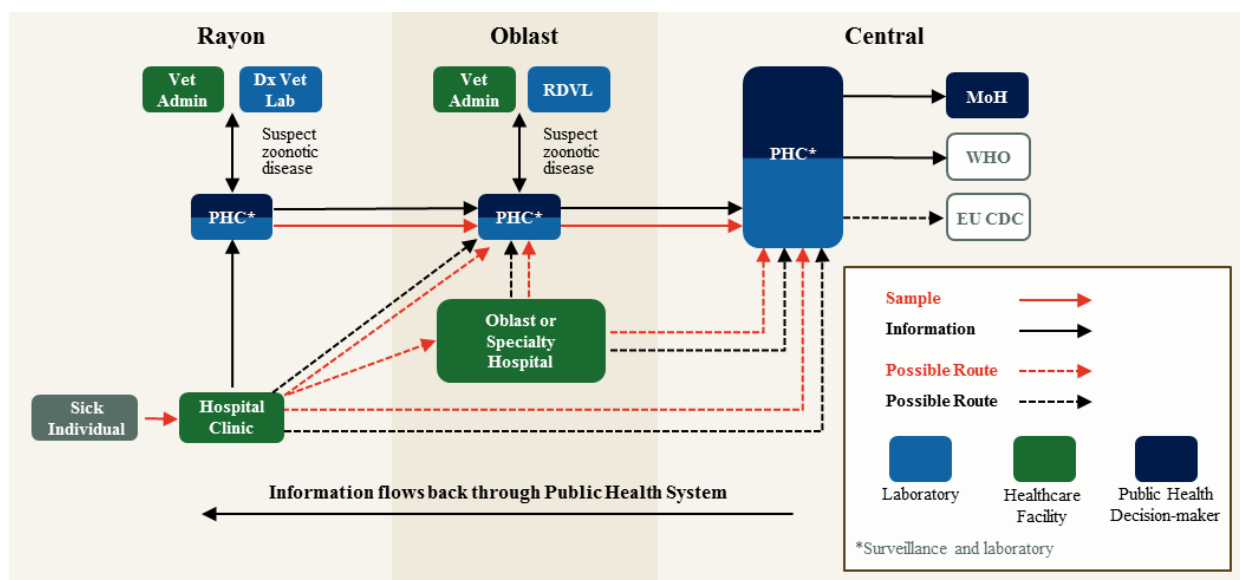
The Concept of Operations (CONOPs) for routine surveillance system, with the current and envisioned flow of information and samples is shown in Exhibit 16 (Current) and Exhibit 17 (Anticipated).

Exhibit 16: Human Health System Biosurveillance Concept of Operations in Ukraine (Current)



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Exhibit 17: Human Health System Biosurveillance Concept of Operations in Ukraine (Anticipated)



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Each unit displayed in the diagrams plays a distinct role in disease reporting. The main roles and functions of various units participating in disease reporting and communication are—

- Healthcare facility—Performs initial clinical diagnosis, aiding disease detection. Takes samples, orders laboratory tests, and records information about disease cases for further reporting.
- SES—Collects case counts from healthcare facilities, implements sanitary control measures to eliminate infectious diseases, and reports surveillance data to UCDCM for analysis.
- Laboratory Center—Receives samples from healthcare facilities and conducts diagnostic or confirmatory testing of patient samples. Reports tests results to clinicians.

The anticipated reforms of the health system will charge the PHC with oversight of both surveillance and laboratory functions and reporting to international organizations. Eventually, the PHC will be the main health surveillance agency at all administrative levels.

The military health sector reports data to the national surveillance system at the central level. Military medical units and hospitals report directly to one of the five regional MoD SESs. The frequency of routine reporting is unknown, but suspected EDPs are reported immediately by telephone to the regional MoD SES and MoH. The oblast MoD SES reports to the main MoD SES in Kyiv, which conducts analyses on collected surveillance data and sends an annual report to MoH. If a military hospital treats a civilian in a conflict zone, the patient is referred to a civilian hospital, and the reporting process is initiated there.

Other Types of Surveillance

As in most countries, passive surveillance is the primary form of disease surveillance in Ukraine. Active surveillance is conducted only for TB and HIV/AIDS, and occurs through siloed programs that are sponsored by international organizations that have minimal coordination with the national surveillance scheme. The active surveillance system for TB and HIV/AIDS has amassed a significant amount of high-quality data, but these data are not integrated into the national surveillance data. The only known syndromic surveillance is conducted for acute flaccid paralysis and with WHO support. Because international donors conduct their in-country engagements via the active and syndromal surveillance programs, it is uncertain how these programs will be sustained with the funding and human resource constraints of the country.

Notifiable Diseases

Ukraine employs a notifiable disease list that is included in Cabinet of Ministers Decree No. 157 (2001) (see Appendices III and IV). The working group on public health reforms has prepared changes to the current list of notifiable diseases to comply with EU standards, but the specific nature of these changes is not known. In addition to the notifiable disease list, the country uses disease-specific regulations that contain disease descriptions and diagnostic criteria.

In 2015, MoH approved a list of case definitions (suspect, probable, and confirmed) for communicable diseases on the current notifiable disease list to improve epidemiological surveillance and also to align with the EU Association Agreement. This list does not include all diseases caused by pathogens of security or transboundary concern, but it does include anthrax, Ebola, and other hemorrhagic fevers. The approved list integrates case definitions into clinical, laboratory, and epidemiological diagnostic criteria, but there is little information on whether they have been integrated into clinical guidelines. It is likely that they have not, given that the case definitions were adopted only recently and not all diseases have case definitions. Many epidemiologists are unaware of or unfamiliar with these case definitions, and it is not mandatory to use them.

Ukraine does not conduct surveillance of non-notifiable diseases, which limits its capacity to add new notifiable diseases to the current list and to identify diseases that may need to be monitored throughout the country.

Electronic Disease Reporting and Analysis

MoH understands the importance of electronic disease surveillance systems but does not have a centralized electronic reporting and surveillance tool. Individual healthcare facilities have taken steps toward implementing electronic disease surveillance systems. However, information and communication technology (ICT) infrastructure resources and funding determines individual healthcare facilities' ability and method of reporting. Currently, some reporting is done on paper (mostly at rayon-level facilities) and some on various autonomous electronic systems (mostly at oblast-level facilities). In general, healthcare facilities have assigned data entry specialists and epidemiologists for entering data into these information systems. Local software developers typically develop these autonomous systems, which have limited scope of scalability, functionality, and interoperability. Healthcare entities depend greatly on cooperation of these local software developers to support addition, alteration, or elimination of any functionality of

their systems. Highlight 11 describes one of these systems, currently deployed at the Kyiv City Sanitary Epidemiological Station and Laboratory. In addition, some facilities use programs such as Microsoft® Excel and Excel-based sheets for reporting.

Highlight 11: Kyiv City Sanitary Epidemiological Station and Laboratory

Kyiv City Sanitary Epidemiological Station and Laboratory has deployed a pilot web-based reporting and surveillance tool for the rayon. This system is able to monitor brucellosis, cholera, shingles, Lyme disease, and other areas, such as air and water quality, morbidity rates, and radiation on an interactive geographical information system. This electronic system was developed by a locally contracted IT specialist group and specifically developed to cater to Kyiv Rayon. Epidemiologists are able to use a webpage form (based on form no. 58) for data entry to report and monitor local population. This system is able to generate Microsoft® Excel-based data sheets from routine surveillance that can be sent to external entities. Presently, this system is not integrated with any other entities or other systems.

The TB and HIV programs have successfully deployed information systems such as e-TB Manager. e-TB Manager is a web-based tool that integrates all data across all aspects of TB control, including information about patients, medicine, laboratory diagnostic and testing, treatment, and trends. e-TB Manager is currently deployed at rayon, oblast, and national levels.

Overall, the health informatics field lacks standardization, and there are no elaborate data exchange standards such as Health Level Seven and Clinical Documentation Architecture (communication standards used internationally for interoperability purposes). Ukrainian healthcare officials plan to pilot the Electronic Integrated Disease Surveillance System (EIDSS). Deploying EIDSS will standardize and benefit the reporting and surveillance capabilities significantly. EIDSS's capabilities are highlighted in Exhibit 18.

Exhibit 18: EIDSS Capabilities

System Name	Description							
Electronic Integrated Disease Surveillance System (EIDSS)	EIDSS can support and strengthen disease surveillance and monitoring for human and animal healthcare facilities. EIDSS is interoperable with other health information systems and uses international data exchange standards.							
	Type of Surveillance	Capability	Platform(s)	Operating System	Data base	Open Source	User	Donor
	Passive, Vector, Syndromic	Reporting, Surveillance, Data Analysis, Notification, Laboratory Analysis, Geographical Information System	Desktop application, Web application, Mobile Web application, Android application	Windows XP, Vista, Windows 7, Windows 8, Windows Server 2003, 2008 R2 (x64), Server 2012 (x64)	MS SQL Server 2008 R2 Express Edition	Yes	MoH, MoAPF	DTRA

Gaps: Reporting and Communications

Gap	Explanation	Root Cause	Recommendation
Outdated Notifiable	The current list of notifiable diseases	Legislation	Update normative/legislative base to

Gap	Explanation	Root Cause	Recommendation
Disease List	does not include emerging diseases or pathogens of international health concern. Daily reporting of more than 60 conditions is very costly and brings little benefit.		prioritize notifiable diseases, include recently emerging priority diseases, and eliminate those of low national priority.
Timely and Complete Reporting	Underreporting is a persistent problem. Reporting of outbreaks is discouraged owing to fear of punishment for failing to prevent or control them. The reporting system is laborious and paper-based.	Ideology, Governance	Establish a web-based reporting system, preferably capable of conducting basic quality checks, analytic functions, and generating key alerts. Offer incentives for reporting; enforce penalties for not reporting.
Parallel Surveillance Systems	TB and HIV surveillance data are siloed; these data are collected and analyzed independently of national disease data.	Funding, Governance	Develop standards for incorporating data from other systems into the national surveillance system.
Integration of Case Definitions into Clinical Guidelines	Protocols exist for reporting diseases, but without uniform case definition, clinicians may use various criteria for case reporting.	Legislation, Governance, Ideology	Integrate case definitions into clinical protocols, particularly for disease of security concern.
Data Sharing Between Rayons and Oblasts	Flow of information is linear from the lowest administrative level to the central level. Oblasts do not know the epidemiological situation in neighboring oblasts, which could delay disease detection.	Governance	Develop communication protocols between rayons and oblasts, or provide access to data from other oblasts.
Data Exchange Standards	There are no data exchange standards.	Governance	Develop data exchange protocols and standards to improve interoperability of information systems.
ICT Infrastructure	There is a lack of consistent ITC infrastructure.	Funding	Upgrade healthcare facilities to support basic IT functionality. Provide computers, electricity, and Internet/network capabilities.

3.6.5 NATIONAL AND REGULATORY FRAMEWORKS

Ukrainian BS&S national and regulatory frameworks reflect the previous era and do not align with international guidelines. Insufficient funding is a major challenge in implementing BS&S guidelines. Reforms to the human health system present an opportunity to update frameworks to align with international guidelines.

While Ukraine has ratified the Cartagena Protocol on Biosafety and has a corresponding national biosafety framework, the regulations focus exclusively on genetically modified organisms (GMO) and are not applicable for laboratories or healthcare facilities handling infectious pathogens. Ukraine is also a state party to the Biological Weapons Convention, which prohibits the possession and proliferation of biological weapons.

In 2015, a commission for BS&S, which was part of the National Security Council, was created to develop a national BS&S strategy, but limited funding led to the dissolution of the commission, and the strategy was never adopted. Ukraine's BS&S legislation is out-of-date, and regulatory frameworks do not align with international BS&S guidelines; current regulations are fragmented between State Sanitary Rules and MoH orders. The Central Regime Commission,

which works with the Oblast Regime Commissions of SSES, enforces BS&S regulations (Exhibit 19).

Exhibit 19: Selected BS&S Legislation⁷⁵

Regulation	Description
Law of Ukraine on Provision of Sanitary and Epidemiological Wellbeing of Population (VRU—02/24/94, last amended—12/23/2015)	This law determines the rights and obligations of state bodies, companies, organizations, and citizens. The law also establishes procedures for the organization of the SES and implementation of the SSES in Ukraine. ⁷⁶
Law of Ukraine on the State System of Biosafety at the Time of Creating, Testing, Transporting, and Using Genetically Modified Organisms (VRU-2007, last amended—04/09/2014)	This law regulates relations among executive authorities, producers, suppliers, developers, researchers, scientists, and consumers of GMOs and products generated according to technologies that involve their development, generation, testing, research, transportation, import, export, market placement, release into the environment, and use within Ukraine to ensure biological and genetic safety. ⁷⁷
Law of Ukraine on State Control Over International Transfers of Military Goods and Dual-Use Goods (VRU—2003, last amended—07/01/2014).	This law regulates activities related to international transfers of military goods and dual-use materials (including biological materials) to prevent proliferation and use in terrorist and illegal activities. ⁷⁸
Decree of the Commission on Biosafety and Biosecurity at the National Security and Defense Council of Ukraine (under the Order of the President of Ukraine No. 220 as of 04/6/2009)	This decree recognizes the importance of biological safety in Ukraine to combat bioterrorism, regulate GMOs, and maintain public health. ⁷⁹
State Public Health Regulations, 2008	This regulation was developed on the basis of regulation 22.06.99 #1109 and applies to the organization of laboratory operations during research of material containing agents in groups I–IV in which polymerase chain reaction (PCR) methods are used. ⁸⁰
Instruction on Storage, Maintenance, Sale, Import to Ukraine and Export of Strains of Microorganisms, Toxins and Poisons of Animal and Plant Origin that are Used for Medical and Scientific Needs, the ORDER of the Ministry of Agrarian Policy of Ukraine and the State Department of Veterinary Medicine No. 70 as of 12/04/2002	This order regulates the storage, maintenance, delivery, importation, and exportation of microorganisms, toxins, and poisons of plant and animal origin that are used in veterinary medicine and science. The order classifies pathogens into groups, regulates which facilities may work with different pathogen groups, and provides requirements for working with the respective pathogens. ⁸¹
State Sanitary Rules 9.9.5-080-2002 “Rules of Organization and Safe Work in Laboratories (Divisions) of Microbiological Profile”	This regulation defines safe working conditions for laboratory personnel working with pathogens in groups I–IV. It aims to properly contain materials and prevent laboratory-acquired infections. It also allows for institutions to implement additional regulations to further improve safety, as long as compliance with national regulations is maintained. This document replaced USSR MoH regulations. ⁸²
State Sanitary Rules 9.9.5-064-2000 “Procedure to Grant the Permission for the Work with Microorganisms of I–IV Groups of Pathogenicity and Recombinant DNA”	This regulation defines conditions that institutions must meet to receive work permits to legally work with microorganism in groups I–IV. ⁸³
State Sanitary Rules 9.9.5-03599 “Safe Working With Microorganisms of Groups I–II of Pathogenicity”	This regulation applies to all entities and personnel carrying out work with microorganisms in groups I and II and sets requirements for room planning, equipment, safe methods of work, accident plans, utility supply, training, and occupational health for personnel. ⁸⁴
Decree No. 1300 On the Development of State System of Deposition of Strains of Microorganisms, 17 August 1999	This decree approves the regulations to control the number of institutions that store stocks of pathogens and toxins. ⁸⁵
Decree No. 35 of the Chief State Sanitary Doctor of the Ukraine, 1 July 1999	This decree approved the State sanitary norms and rules “Hygienic classification of work in terms of hazard and danger environment factors, severity and intensity of the work process.” This regulation focuses on the

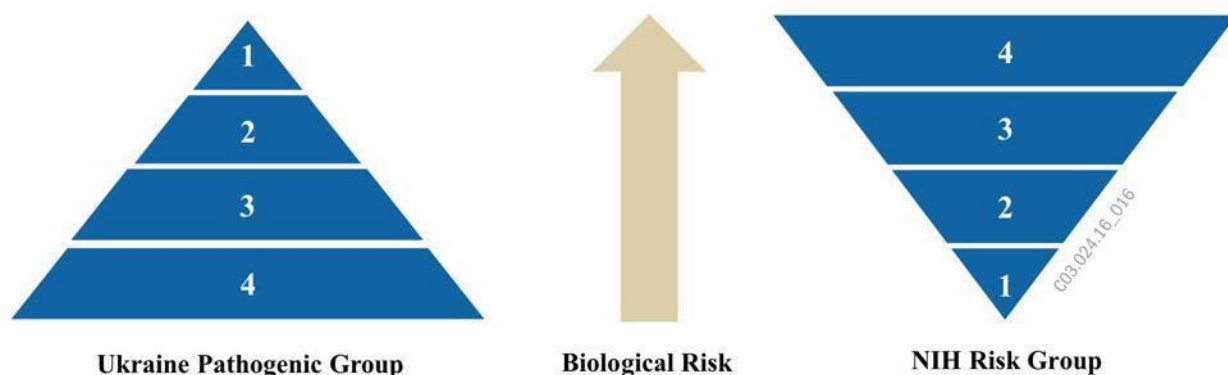
Regulation	Description
	hygienic assessment of workplace conditions, requiring facilities to meet standards and provide PPE to personnel in hazardous working conditions. ⁸⁶
Decree No. 705 On the State System of Deposition of Strains of Microorganisms, 12 October 1994	This decree approves the resolution proposed by the National Academy of Sciences to regulate the deposit, registration, recording, and storage of microorganisms for the purposes of obtaining a patent. ⁸⁷
Regulation on Procedure of Storage, Work and Transfer of the Cultures of Bacteria, Viruses, Rickettsia, Fungies, Protozoa, Micoplasma, Bacterial Toxins, and Poisons of Biological Origin, 18 May 1979	This regulation provides for material accountability, laboratory safety, material transfer, storage, and unauthorized distribution of cultures, toxins, and poisons. ⁸⁸

Ukraine categorizes agents into four different pathogenic groups, with “I” being the highest risk and “IV” being the lowest risk (Exhibit 20). Ukraine classifies pathogens of security concern into groups I and II as EDPs, but many Select Agents (as defined by the U.S. system) are absent. Biocontainment measures are based on the risk group rather than risk assessments, which may result in use of excessive or insufficient biocontainment measures for the laboratory activities. Leadership, laboratory staff, and hospital staff are generally aware of existing BS&S regulations, but insufficient funding and outdated directives often impede alignment with international guidelines because facilities cannot afford to procure and maintain safety equipment or adhere to internationally accepted BS&S standards.

Ongoing reforms have strengthened the movement to update national BS&S legislation to align with international guidelines. The National Security Council currently has an advisor dedicated to BS&S reforms. While there is significant support from MoH leadership for updating BS&S regulations, internal support from government leadership and external support from international donors is needed to draft and implement the updated regulations.

Exhibit 20: Equivalent U.S. National Institute of Health Risk Groups and Ukraine Pathogen Groups for Pathogens with High Risk

Pathogen	Ukraine Pathogen Group	NIH Risk Group
Ebola and Marburg viruses	1	4
<i>Yersinia pestis</i>	1	3
Lassa, Machupo viruses	1	4
Variola major and Variola minor viruses (Smallpox)	1	4
Crimean-Congo Haemorrhagic Fever virus	1	4
<i>Bacillus anthracis</i>	2	2
<i>Brucella abortus</i> , <i>Brucella melitensis</i> , <i>Brucella suis</i>	2	3
<i>Francisella tularensis</i>	2	3
<i>Burkholderia mallei</i> , <i>Burkholderia pseudomallei</i>	2	3
Highly Pathogenic Avian Influenza (HPAI) virus	3	3
Hendra, Nipah virus	4	4



Ukraine has a biosafety association that hosts annual events, including a symposium in 2015 and a conference in early 2016. In addition to government working groups and international support, the national biosafety association is a valuable asset for BS&S reform. The chair of the biosafety association is the advisor to the president on BS&S reforms, providing a direct avenue for the association to apply valuable expertise and communicate information and feedback directly to the Ukrainian government. While the biosafety association is active, efforts to strengthen the organization and broaden their capacity to involve even more laboratory personnel and other stakeholders is important to facilitate dissemination of information, including updated regulations and changes to national policies, to laboratories and clinical facilities throughout the country.

Gaps: National Legislative and Regulatory Framework

Gap	Explanation	Root Cause	Recommendation
Dangerous Pathogen Regulations	Biosecurity regulations do not exist for pathogens of security concern.	Ideology	Develop regulations for pathogens of security concern that are similar to the U.S. Select Agent Program or Comité Européen de Normalisation (CEN) Workshop Agreement 15793.
Outdated National BS&S Regulations	BS&S regulations are outdated and do not align with international guidelines.	Ideology	Develop regulations that align with international BS&S guidelines.
Fragmented BS&S Regulations	BS&S regulations are fragmented between different ministries.	Legislation and Regulation	Consolidate BS&S regulations.
Biosafety Level (BSL) Guidelines	Risk groups and risk assessments are not used to determine biocontainment. Internationally accepted BSL guidelines are not used.	Legislation and Regulation	Develop regulations that identify pathogen risk groups and require risk assessments to determine biocontainment.

3.6.6 FACILITY-LEVEL BIORISK MANAGEMENT SYSTEMS AND CULTURE

Human health laboratories and healthcare facilities implement policies according to national regulations. A formal risk assessment process is not used. Financial limitations are a widespread challenge that frequently affects day-to-day operations and capacity to implement appropriate biosafety measures. Poor financing particularly affects training, facility infrastructure, staffing of BS&S personnel, and biosafety equipment maintenance. Facilities that receive international assistance are unable to sustain improvements to infrastructure and equipment.

Human Resource Development

Laboratories assign biosafety responsibilities to a designated staff member, although the role may not always be held in an official capacity. These duties are typically assigned in addition to a staff member's regular responsibilities within the laboratory. Laboratory leadership often indicated that biosafety is included within the job description of all personnel; therefore, all personnel are collectively responsible for biosafety. While it is important for all personnel to employ sound biosafety practices, absence of dedicated BS&S personnel may result from a system in which these responsibilities are broadly assigned as a substitute for a biosafety officer. A biosafety officer should be clearly designated at laboratory facilities, and it is critical that these personnel are supported with the means to further develop BS&S expertise and apply their skills and knowledge to develop facility biorisk programs. Healthcare facilities typically rely on the expertise of senior nursing staff to administer training and implement BS&S policies and procedures in their individual units. Designated training personnel who possess biosafety expertise could serve to improve BS&S in healthcare facilities.

Laboratory and clinical personnel are aware of the need for BS&S education and training. Although new-hire and annual refresher training incorporate BS&S topics, specific BS&S training does not typically occur in facilities across the country. Gaps in BS&S training can be addressed by creating uniform BS&S training curricula for the country. Standardized, clear, and comprehensive biosafety legislation and guidelines will play a significant role in addressing this concern, when they are developed.

Laboratory personnel receive initial training based on their job responsibilities. This training typically incorporates topics such as PPE use, decontamination procedures, and incident response procedures (e.g., a spill, needle stick, or other emergency). Many facilities include practical components in training and competency evaluation programs. In addition, laboratory personnel must often go through a period of mentorship, during which they perform all work alongside a more experienced laboratorian until they demonstrate a satisfactory level of competency and ability to conduct work autonomously. Many facilities conduct refresher trainings on an annual or more frequent basis, with some facilities conducting training as regularly as every 3 months. Biosafety is incorporated into these trainings; however, the frequency with which biosafety is incorporated is not standardized, and personnel receive training on national regulations, not international best practices.

Clinic and hospital training does not generally include formal biosafety components. Clinic and hospital training does not generally include formal biosafety components. Procedures such as PPE use, sample collection, and waste handling are covered during onboarding training. Beyond initial training, these procedures are occasionally covered in periodic continuing education trainings. Continuing education training is organized and initially administered to senior nurses, who are then responsible for providing the training to the nurses and other personnel in their unit. Biosecurity does not appear to be addressed in training administered to clinical staff.

Laboratories have received BS&S training by international partners; CBEP-sponsored training has included basic biosafety instruction, as well as safe shipping and handling training. Personnel occasionally attend international conferences and seminars to receive training, although regular attendance at such events can tax already limited financial resources because of the costs of

travel, lodging, and conference fees. The URAPI facility and staff have provided training for other institutions within the country, including UCDCM and healthcare facilities.

Facility Infrastructure

Laboratories that were upgraded or constructed as part of CBEP engagement are in good physical condition, although many of these facilities, including UCDCM and LRIEH, do not sustain critical BS&S features that were installed, such as heating, ventilation, and air conditioning; security; and backup power systems. Many of Ukraine's public health laboratories are located in buildings that need maintenance, repair, and upgrade. Buildings often have damaged walls or peeling paint, and floors are generally constructed of porous material, which does not align with international guidelines that require surfaces to be easy to decontaminate. Nevertheless, public health laboratory spaces observed during this assessment are clean and uncluttered. Floor space and surfaces are mostly accessible for cleaning, and laboratories have adequate space for personnel to safely move around the facility and operate equipment.

Highlight 12: Kyiv Regional Hospital

The laboratory at Kyiv Regional Hospital is in particularly good condition. While this laboratory does not work with EDPs, it has very good infrastructure and does not appear to have received international assistance. In the absence of clear legislation, laboratories such as the Kyiv Regional Hospital may be considered as a resource to assist other facilities in improving BS&S.

Facilities face challenges in sustaining utility services such as electricity. Cost-saving efforts to minimize the use of utilities present a threat to safety and security because many components of laboratory infrastructure critical to BS&S are not used appropriately owing to the cost of operation. For example, when present, air handling equipment is rarely in use. Efforts to further conserve electricity by limiting the use of lighting may also result in occupational hazards to personnel. Frequent blackouts also threaten the continuous supply of power, which is best addressed by backup generators that are present at some facilities. However, this equipment carries the additional burden of maintenance, testing, and fuel supply, which some facilities are unable to financially support. Municipal water quality is also a concern because it has caused damage to autoclaves, presumably owing to high salt and mineral content in the supply. When such damage occurs, facilities often do not have the resources readily available to support repairs. Water softening systems are available to improve the quality of water used in autoclaves, although most facilities do not currently have the means to purchase and maintain this equipment.

MoD SES laboratories, which CBEP has not engaged, have particularly poor infrastructure. Laboratories reside in buildings that are not originally designed to support laboratory capacities and are otherwise dilapidated, creating numerous hazards and rendering the facilities unfit for work with pathogenic material, particularly EDPs. Building designs lack proper airflow and hinder safe sample flow processes.

Observed hospitals with infectious disease units are generally in good condition. Buildings are often dated but appear structurally sound and well-maintained. Walls and windows are intact, and electric supply does not appear to be a problem because facilities are able to support the cost

of usage and, in some cases, have functioning backup generators to use in the case of power outage.

Biosafety Equipment

The condition of biosafety equipment such as BSCs and autoclaves varies greatly among facilities. Many laboratories that conduct work that requires the use of a BSC to align with international guidelines do not have the equipment available. Laboratories that have received CBEP assistance have modern equipment but often face problems with sustainability. On the other hand, some laboratories that have not been engaged by CBEP and work with EDPs, or could potentially receive EDP samples, have old, outdated, or inadequate equipment. In some facilities, laboratory equipment was unplugged and appeared to be rarely used, potentially owing to maintenance issues or in an effort to conserve power and reduce operational overhead costs.

There is no national BSC certification program, and outdated certification is a common problem across laboratories. The Kyiv OLC performs testing and calibration internally, but the personnel conducting these testing procedures are not properly trained or certified. In addition, equipment used to certify the cabinets may not be properly calibrated.

PPE, which includes gowns, shoe covers, gloves, eye protection, and respiratory protection, is present in most facilities; however, overall stock is limited. To comply with national regulations (specifically State Sanitary Rule 9.9.5.03599), facilities must maintain “anti-plague suits” for work with certain infectious material. This legacy regulation requires facilities to purchase supplies of antiquated, unsuitable, and costly PPE. Regulatory requirement updates are an opportunity to enable facilities to seek more economical PPE solutions that provide better personnel protection and align with international guidelines.

Biosafety and Biosecurity Documentation

Documented BS&S policies focus on compliance with national regulations, which may not align with international guidelines. Some facilities implement additional, internal policies and procedures that align with international guidelines; however, these policies are not subject to national regulations and may not be subject to inspection or regular review.

Policies and procedures are not based on a formal risk assessment process. Clearly documenting risk assessments will help to identify hazards and personnel at risk, determine gaps in current policies and procedures that leave risks unmitigated, and outline what needs to be done to improve BS&S. Conducting agent-specific risk assessments will also assist facilities in determining the biological agents with which they have the ability to safely work based on facility capacities, or what improvements must be made to increase capacity.

Laboratories and hospitals have SOPs and emergency response procedures. SOPs documenting the instructions for use of equipment are frequently posted on walls in the relevant area of the laboratory, hand washing procedures are frequently posted near sinks and doorways, and biohazard signage is posted on doorways and on equipment such as freezers and incubators. However, additional biohazard signage is needed to mark all appropriate doors and equipment will improve alignment with international guidelines. Training records are maintained for up to 5

years and are typically kept in paper logbooks. Paper records are kept in an administrative space outside the active laboratory.

Highlight 13: Lviv OLC

Personnel at the Lviv OLC speak knowledgeably about SOPs and the methods used to maintain records. A biosafety manual, incident response procedures, detailed training records, and log of incidents are stored in an administrative office within the laboratory. Documents are organized and can be quickly referenced and discussed. The facility also holds regular refresher training, with sessions occurring every 3 months. Despite funding limitations consistent with other laboratories, the laboratory is organized, clean, and well-maintained by staff members.

Healthcare facilities draft SOPs independently; however, MoH mandates that procedures for hand washing, PPE use, waste disposal, and decontamination align with national regulations. Protocols used for the clinical treatment of disease are often pathogen-specific, leading to a large number of active protocols and creating the potential for PPE requirements to be inconsistent if all documents are not carefully and regularly reviewed. Strengthened BS&S training for healthcare personnel may improve knowledge and understanding of appropriate PPE and assist personnel in choosing consistent, appropriate equipment for dealing with a range of pathogens.

Most assessed facilities indicate that laboratory incidents (e.g., a spill of infectious material) are very rare or have never occurred. It is unlikely that incidents do not occur, but facilities might underreport or maintain poor records. Improved systems in which incidents are documented and addressed will be helpful for the development and improvement of SOPs.

Biological Waste Management

Facilities are required to comply with national regulations, enforced by SSES, for the treatment and disposal of hazardous waste. Methods for waste treatment include an onsite autoclave, the use of chemical disinfectant followed by onsite incineration, or removal by a third-party, certified waste removal service. Liquid waste is often poured into the municipal sewage system, although this should only occur if proper disinfection procedures are strictly adhered to and procedures are in compliance with all national regulations and international guidelines regarding disposal of hazardous waste.

Laboratories use metal containers that can be autoclaved and reused to internally transport and treat waste. Biohazard waste containers were not observed in all laboratories, and unmarked bags were sometimes used within marked or unmarked containers. Although waste disposal methods must meet national requirements, methods are inconsistent, vary among laboratories, and do not align with WHO guidelines.

Waste disposal is a significant concern owing to deficiencies in equipment and infrastructure. Improperly functioning autoclaves increase the risk of waste being incorrectly decontaminated and handled in an unsafe manner. Autoclave tape, used to seal bags of waste and indicate that the cycle has reached the appropriate minimum temperature during processing, was observed to be used in some facilities. While autoclave tape is a cost-effective method to verify temperature, it does not verify steam or pressure, two important factors of autoclave cycles. Furthermore,

facilities that use onsite incinerators may experience similar issues with waste being improperly disposed of because of equipment malfunction.

Gaps: Facility-Level Biorisk Management Systems and Culture

Gap	Explanation	Root Cause	Recommendation
Defined BS&S Roles	Roles and responsibilities of BS&S personnel are not clearly defined.	Funding, Legislation and Regulation	Support PHC to develop updated legislation that aligns with international guidelines. Assist with resources needed to support onsite biosafety officers.
Formally Assigned BS&S Personnel	Biosafety officer positions are not filled by dedicated BS&S personnel with formal biosafety training.	Funding, Training and Education	Recruit staff with experience in BS&S. Provide opportunities for personnel filling BS&S positions to attend trainings and conferences to further expertise.
Formal BS&S Training	Current legislation and governing entities do not provide clear training requirements, or clear legislation on which to focus training.	Training and Education, Legislation and Regulation	Provide advisory assistance to implement training programs that incorporate updated BS&S regulations.
Facility Infrastructure	Facilities are located in old buildings with numerous infrastructure and utility issues. Infrastructure improvements made during previous engagement have not been sustained.	Funding	Focus engagements on facilities at which the government is likely to support ongoing operations beyond CBEP engagement.
Equipment Maintenance	Facilities do not have resources to maintain, repair, or replace biosafety equipment.	Funding	Assist with resources to upgrade equipment and facilitate development of long-term maintenance plans.
Formal Risk Assessment Process	Policies and procedures are not based on formal risk assessment process	Training and Education, Legislation and Regulation	Implement national regulations that require the employment of best practices and international guidelines. Train BS&S staff and principal investigators to understand and conduct risk assessments.
Incident Reporting	There is no system in place to report and track laboratory incidents.	Legislation and Regulation	Provide advisory assistance to incorporate into updated BS&S legislation.
BS&S Signage	Not all facilities display proper signage indicating biohazard areas.	Legislation and Regulation	Provide advisory assistance to incorporate requirements into updated BS&S framework. Provide signage materials to facilitate alignment with WHO regulations.

3.6.7 PATHOGEN CONSOLIDATION AND SECURITY

Ukraine faces security challenges due to conflicts in several oblasts and multiple facilities with collection pathogens of security concern, both of which highlight the need to store pathogens securely. Ukraine does not have a system to ensure security of pathogens, which may lead to vulnerabilities.

Criminal activity, conflicts with pro-Russian separatists in multiple oblasts, the annexation of Crimea by Russia, a newly formed government, and large numbers of civil protests present security threats within Ukraine. Ukraine has several facilities, such as UCDCM, LRIEH, and URAPI, which contain collections of pathogens of security concern. Stored pathogens include *Bacillus anthracis*, *Francisella tularensis*, *Coxiella burnetti*, HPAI virus, *Yersinia pestis*, *Brucella* spp., *Burkholderia mallei*, *Rickettsia prowazekii*, CCHF virus, and eastern equine encephalitis virus. While Ukraine does have regulations for work with EDPs (Group I and II

pathogens), the regulations are not equivalent to the U.S. Select Agent program or the CEN Working Agreement 15793, and significant gaps exist in all aspects of biosecurity, including physical security, transportation security, information security, material control and accountability, and personnel reliability. Implementation of a biosecurity program designed for Ukraine would greatly improve pathogen security.

Research and Storage of Pathogens of Security Concern

Collections of pathogens of security concern are stored at facilities that conduct research and diagnostics such as UCDCM, LRIEH, and URAPI. Pathogen consolidation has been previously initiated through collaborations with international partners, but competition between institutions resulted in an unwillingness to consolidate pathogens to limited facilities. The reorganization of the health system and merging of laboratories under the PHC presents an opportunity to consolidate pathogens because UCDCM, LRIEH, and URAPI will report to the PHC.

Clinical and hospital laboratories have limited capacity to confirm infectious diseases and send samples from potential cases of EDPs to central laboratories for confirmation. Because clinical samples are destroyed after testing or referred to other laboratories, samples are not stored in clinical and hospital laboratories, which greatly reduces the number of pathogen collections.

Physical Security

International partners have engaged national- and a select few oblast-level institutions to implement physical security measures, including security grilles on windows, electronic access control, onsite guards, closed-circuit television (CCTV), volumetric sensors, and integrated alarm systems. Significant gaps, such as incomplete perimeter fencing; windows without bars; and broken or deactivated access controls, CCTV, and alarm systems, exist at most facilities. Although most facilities have bars on the first floor and sometimes second floor windows, first floor windows are occasionally left unbarred, which would allow easy access for an intruder. The electronic access control systems at several facilities were not functioning, and the absence of mechanical keyed locks presents a serious vulnerability because many doors to laboratories and pathogen collections are unsecured. Lack of maintenance and fluctuations in the power supply that damage electronics affect electronic access control systems. Some facilities also intentionally disable electronic access control systems, volumetric sensors, CCTV, and alarm systems to reduce electricity consumption because the laboratories are often unable to afford electric bills. Funding limitations at the institutes pose a major challenge for implementing and sustaining physical security measures.

Material Control and Accountability

Several institutions maintain large collections of pathogens of security concern, but material control and accountability of these collections are limited. Pathogens are accounted for using paper logbooks, and inventories are not always accurately maintained. Freezer equipment for pathogen storage is outdated and in danger of failing. At least one facility visited during the assessment does not have appropriate equipment for long-term storage and regularly cultures pathogens to maintain stocks. Frequent culturing of pathogens increases access to isolates and the chances of accidents or thefts. Several facilities use wax seals to monitor access to collections of pathogens, which is an outdated technique. Presently, there is a deployment plan for Pathogen

Asset Control Systems (PACS) at LRIEH, URAPI, and UCDCM. Implementation of PACS is projected to be completed by July 2016 for these facilities. Although Ukrainian officials have a strong interest in further implementing PACS, no additional sites are currently planned. Modern freezer equipment and PACS at target pathogen repositories would improve material control and accountability, but difficulties with maintaining constant electricity owing to finances and infrastructure must be taken into account to ensure sustainability.

Personnel Security

Personnel reliability programs do not exist at facilities, and investigations into laboratory staff are generally limited to verifying professional and academic records. Staff do not wear identification badges at most facilities, and visitors are only occasionally required to sign in. Pay for both laboratory staff and security guards is low, which may lead to increased susceptibility to coercion. A full personnel reliability program may be difficult to implement given the limited resources, but implementing background checks would be the first step to ensure that only suitable staff have access to pathogens of security concern.

Information Security

Sample inventory records are retained in paper logbooks rather than electronic systems. Although the logbooks are stored within the laboratory, they are not stored securely in lockable filing cabinets. Procedures for managing sensitive information, including securing and destroying documents, are not used. Implementing a password-protected electronic system or securing documents in locked containers would improve information security.

Transportation Security

Laboratory staff who have training on sample packaging conduct sample transport. Samples that potentially contain infectious agents are generally triple packaged, although not to International Air Transport Association standards, and are delivered to laboratories. Laboratories have dedicated sample receipt areas and do not accept samples that incorrectly packaged. Received samples are documented in paper logbooks, but detailed chain of custody records are not maintained, which may lead to vulnerabilities during sample transport. Providing sample transport training and maintaining chain of custody records would improve transportation security.

Gaps: Pathogen Consolidation and Security

Gap	Explanation	Root Cause	Recommendations
Pathogen Consolidation	Several institutes have large collections of pathogens of security concern, and institutional leadership opposes consolidation for political reasons.	Ideology	As institutes merge under the PHC, identify target facilities to serve as repositories and initiate pathogen consolidation.
Physical Security	Security features such as grilles on windows, electronic access control, CCTV, volumetric sensors, and integrated alarm systems are broken or not in use.	Funding, Legislation and Regulation	Identify mechanisms to support maintenance and sustainment of security features.
Material Control and	Paper logbooks are used to track samples of pathogens of security	Funding, Legislation and Regulation	Implement PACSs at select facilities, which will improve pathogen inventory

Gap	Explanation	Root Cause	Recommendations
Accountability	concern, creating difficulties in maintaining an accurate inventory and chain of custody. Wax seals, which are an outdated technique, are used to monitor access to pathogens.		and tracking.
Personnel Security	Personnel do not undergo background checks to ensure suitability prior to accessing pathogens of security concern.	Funding, Legislation and Regulation	Develop system for verifying academic and professional backgrounds of personnel and for performing criminal background investigations.
Transportation Security	Chain of custody records are not maintained during sample transport, which may lead to loss or theft of material.	Funding, Legislation and Regulation	Develop procedures for chain of custody during sample transport.

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Animal Health Section



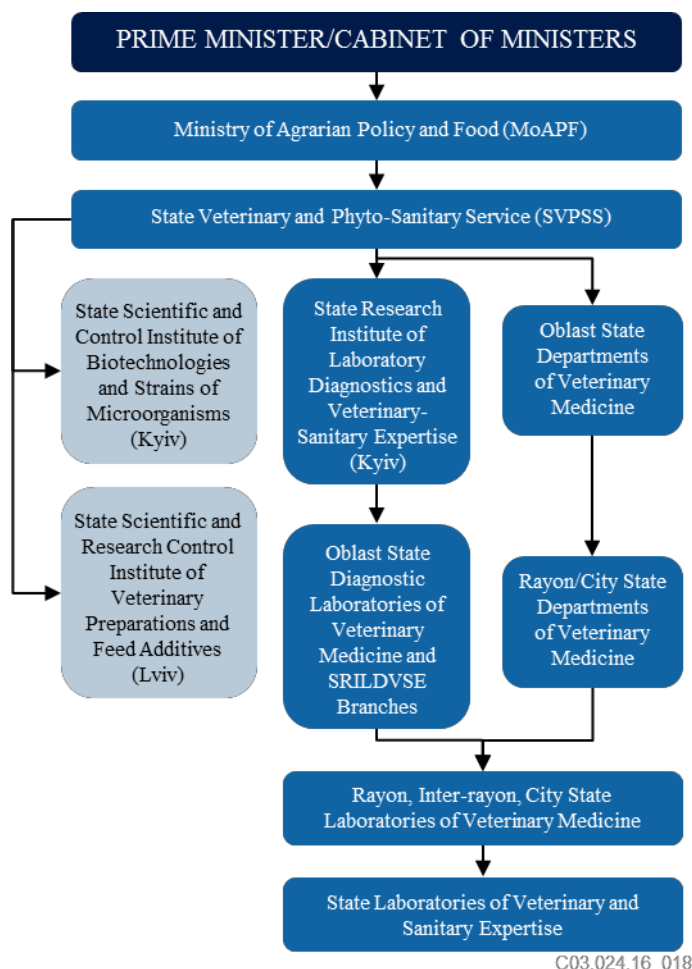
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4 ANIMAL HEALTH SECTION

4.1 Overview of Health System Governance

Like its human health system counterpart, the animal health system is divided into three administrative levels: central, oblast, and rayon. Under MoAPF, SVPS manages the animal health system via the oblast and rayon administrative services and serves as the national authority for veterinary regulation. SVPS also oversees state and private veterinarians, and food inspection service at all levels (see Exhibit 21).⁸⁹

Exhibit 21: Structure of SVPS of Ukraine



With current reforms, SVPS remains the main veterinary authority for policy and oversight; however, oblast and rayon veterinary administrative departments are now responsible for direct management of finances. SVPS continues to manage financing of regional and local food inspection, diagnostic testing, and disinfection. SVPS also administers a central network of laboratories composed of SSRILDVSE and its four branches, regional diagnostic veterinary laboratories⁹⁰ (RDVL), and rayon, and city laboratories.⁹¹ The newly formed SSFSCP will be responsible for food safety, inspections, sanitary and epidemiological services, and consumer protection.⁹²

4.2 National Legislative and Regulatory Framework

Similar to the human sector, animal health laws and regulations need to be modernized in response to ongoing reforms. Once primary laws are updated or created, orders and regulations can follow to guide processes or requirements in specific functional areas. Appendix III contains a more inclusive list of laws and regulations governing Ukraine’s animal health sector.

The primary law governing animal public health is *The Law of Ukraine on Veterinary Medicine* and its amendments. This law determines the “authority of state bodies, rights and obligations of legal entities and natural persons in the field of ensuring veterinary and epizootic welfare, animal quarantine, and establishes the procedure for providing state veterinary control.” It will need swift modification to reinforce and reallocate authorities in alignment with the new structure for veterinary services.⁹³

In accordance with Cabinet Resolution 442, SSFSCP will be responsible for food safety, inspections, sanitary and epidemiological service, and consumer protection.⁹⁴ SSFSCP will continue to have oversight of policies and regulations, but oblast veterinary authorities will manage the structure and finances of the veterinary medicine system. SVPS will continue to perform a series of audits of regional and local veterinary medicine departments, clinics, and diagnostic laboratories to determine which institutions will remain under the new reorganization. In addition, the development of a law on practice of private medicine is currently underway. The purpose of this law is to transfer the veterinary managing authority and finances to the oblast and rayon levels. Exhibit 22 lists some of Ukraine’s essential animal healthcare legislation.

Exhibit 22: Animal Healthcare Legislation⁹⁵

Regulation	Description
The Law of Ukraine on Veterinary Medicine (No. 2498-XII, 1992)	This law sets forth the legal, organizational, and financial basis of veterinary medicine in Ukraine. It determines the requirements relating to veterinary-sanitary quality and safety of animal products, the rights and obligations of legal entities and persons in the field of ensuring veterinary and epizootic welfare, animal quarantine, and the conduct of state veterinary-sanitary control and supervision. The law notes that state administration of veterinary medicine will be carried out by the Cabinet of Ministers and its specifically authorized central body of executive power on agricultural policy issues, plus its territorial bodies and regional services. ⁹⁶
On Optimization of Central Executive Bodies (No. 442, 2014)	This Cabinet of Ministers resolution merges SVPS with functions of the State Inspectorate for Consumer Protection and SSES to establish SSFSCP. ⁹⁷
Resolution 2015 of October 28, r. № 871 Kyiv on the Establishment of the Territorial Bodies of the State Service for Food Safety and Consumer Protection	This Cabinet of Ministers resolution reorganizes the territorial bodies of SVPS, the State Inspectorate for Consumer Protection, and the SSES by joining their respective territorial bodies with SSFSCP. ⁹⁸
Decree No. 464 On approval of the State Veterinary and Phytosanitary Service of Ukraine	This decree establishes the official functions of SVPS. ⁹⁹
Order No. 81 of the Ministry of Agrarian Policy and Food validating the Regulation on prophylaxis of African swine fever	This order was formulated after the introduction of ASF into the country and describes the measures that must be taken to prevent the spread of the disease in swine production facilities, among private animal owners, and in the wild. ¹⁰⁰

For BS&S laws and regulatory frameworks, see the National and Regulatory Frameworks subsection within the Health Systems Overview section. Appendix III provides a comprehensive list of regulations.

4.3 Budget and Funding Mechanisms

Animal health budgets must go through the same bottom-up process as human health budgets, ultimately being passed into law by the Rada and approved by the President of Ukraine. Although Ukraine's economy is supported significantly by agrarian practice, budget priorities do not reflect the country's interest in the health of its livestock population.

Budget Process

Currently, rayon-level veterinarians create proposals for priority state-mandated vaccinations, preventive active surveillance programs, and required budgetary and human resources needs. These proposals go to oblast-level veterinary departments, who add any additional resources needed and then submit them to the State Committee for Veterinary Medicine of Ukraine. This committee compiles all proposals and subsequently reviews, adds content, amends, and incorporates them into a national plan for veterinary services. The committee presents the national veterinary budget plan to the Cabinet of Ministers at the budgetary session to receive operational funding allocations. Once the budget is approved, funds are allocated throughout the veterinary service structure.¹⁰¹ Moving forward, decentralization of funding will change the budget process because local levels will no longer be able to rely on transfers of funds from central authorities. Information on specific budget priorities for MoAPF was not available; as such, it is not clear whether the budget for 2016 has taken such measures into account.

Health Expenditures

Ukraine's specific expenditures on animal health are not known. The entire MoAPF budget has decreased from 2015 to 2016.¹⁰² This substantial decrease is partially the result of the change in how rayon- and oblast-level veterinary services will now be funded under the reforms; however, it is not clear what portion of this reduction will directly affect animal health programs or services, particularly because fee for service for veterinary activities accounts for most of the veterinary budget.

4.4 Health Priorities

MoAPF agricultural and animal health priorities focus on food security, agriculture, livestock development, and export of agriculture products. Ukraine's strategic plan does not directly address disease control or eradication efforts as priorities. SVPS recognizes a number of infectious diseases of importance because of their zoonotic potential and the danger they pose to humans and animals.

MoAPF's *Strategy for Agriculture and Rural Development, 2015–2020* outlines its objectives to increase Ukraine's competitiveness and promote agricultural development in ways that conform to EU and international standards. Ukraine must undertake several strategic modernization measures under the EU Association Agreement. It is expected to align the food safety, animal

health, and phytosanitary laboratories with EU requirements and establish an early warning system for the safety of human food and animal feed, animal health, and plant health as part of the prescribed sanitary and phytosanitary measures.¹⁰³ The strategic plan focuses on areas such as corruption, MoAPF reorganization, land reform, taxation, research, education, and food security, but does not specifically mention national animal health priorities (Exhibit 23). Two priorities that affect animal health are food security and agri-food chain development.¹⁰⁴

Exhibit 23: Areas in Strategic Plan Relevant to Animal Health

Area Addressed	Action
Structural Organization	Create an authority responsible for formulating and implementing national regulations with respect to animals and food products.
Regulations	Formulate and implement a law for veterinary medicine private practice; draft regulations pertaining to safety of food products in line with EU standards.
Training	Formulate specialized training at higher educational institutions in the areas of implementation of state policy on food safety and food market operators.

SVPS priorities focus on the reforms, the creation of a new service, and the transfer of human resource finances to the local level. SVPS noted several reportable infectious diseases that are of great national importance to the country because of their zoonotic spread potential, the danger level they pose to humans and animals, and the potential of economic losses (Exhibit 24).¹⁰⁵

Exhibit 24: List of Priority Animal Diseases

Priority Disease	Outbreak Action Plan
African Swine Fever (ASF)	Created and Implemented
Highly Pathogenic Avian Influenza (HPAI)	Created and Implemented
Classical Swine Fever	N/A
Newcastle Disease	N/A
Anthrax	N/A
Foot-and-Mouth Disease (FMD)	N/A
Brucellosis	N/A
Blue Tongue	N/A
Rabies	N/A
Bovine Tuberculosis	N/A
Bovine Leukemia	N/A
Trichinella	N/A
Bovine Spongiform Encephalopathy	N/A
Salmonellosis	N/A
Crimean Congo Hemorrhagic Fever (CCHF)	N/A

SVPS has recognized HPAI, swine influenza, and ASF as major threats to the veterinary health system, and as a result, implemented a response action plan for all veterinary jurisdictions in the country to follow. Subordinate jurisdictional levels are aware of the priority disease list, but it is not clear if they use it. In addition to the national priority diseases, each oblast is responsible for collecting disease data from each rayon. Historic annual data collected is used to formulate oblast-specific anti-epizootic plans for local priority diseases. The anti-epizootic plan is used to

project what preventive measures are needed (e.g., vaccines, anthelmintics), and it is also considered a disease-monitoring data collection tool.

4.5 International Standards Compliance

Until 2015, Ukraine demonstrated compliance with OIE disease reporting guidelines. The ongoing restructuring of the veterinary health system has compromised the disease notification process and has resulted in Ukraine being currently noncompliant with OIE disease reporting, with the exception of ASF. OIE completed a Performance of Veterinary Services (PVS) evaluation mission in 2007, but the results of the evaluation are not yet publicly available. Ukraine is eligible for a follow-up PVS evaluation mission.

Ukraine is a member of the OIE and aims to comply with disease reporting guidelines in a timely manner. As an OIE member, Ukraine must notify the World Animal Health Information Database by fax or email within 24 hours of the following events:

- The first occurrence of a listed disease, infection, or infestation in a country, a zone, or a compartment
- The recurrence of a listed disease, infection, or infestation in a country, a zone, or a compartment following the final report that declared the outbreak ended
- The first occurrence of a new strain of a pathogen of a listed disease, infection, or infestation in a country, a zone, or a compartment
- A sudden or unexpected change in the distribution of or increase in incidence or virulence of, or morbidity or mortality caused by, an etiological agent of a listed disease, infection, or infestation present within a country, a zone, or a compartment
- An occurrence of a listed disease, infection, or infestation in an unusual host species.

Mandatory weekly reports subsequent to a notification provide additional information on the evolution of the disease event that necessitated the notification. Biannual reports regarding the absence, presence, and evolution of listed diseases, infections, or infestations of epidemiological significance are also required.

For the period 2010 to 2014, Ukraine consistently reported the status of OIE-listed diseases (Appendix V) to the OIE. Since September 2 of 2015, Ukraine has not been compliant with OIE reporting. The lack of recent reporting to OIE is likely a result of the veterinary health system restructuring; a diminished workforce and unclear roles and responsibilities of agencies in the current and anticipated structure have disrupted the disease notification and response process. Moreover, data within reports to OIE for the period 2010 to 2014 may be biased because of underreporting of cases and outbreaks within the country. The reported data are of poor quality because they are often incomplete. As a result, Ukraine lacks a clear picture of the epidemiological situation and cannot prepare appropriately for health events.

At Ukraine's request, OIE completed a PVS evaluation mission in 2007, but the report is not publicly available.¹⁰⁶ As of September 2015, Ukraine was eligible for a PVS evaluation follow-up mission but had not requested one.¹⁰⁷

4.6 Animal Health System Overview

The Animal Health System Overview section provides an assessment of Ukraine's BSV and BS&S status using the CBEP BSV and BS&S metrics pillars (see Exhibit 10 of the Human Health Section).

4.6.1 DISEASE DETECTION

Ukraine has an abundance of state veterinarians in the country with varying degrees of disease detection skills. State veterinarians perform most disease detection and investigation; veterinary paraprofessionals, who are known as technicians, have a minor role in disease detection and are limited to assisting state veterinarians in their daily duties. Overall, veterinary training varies by teaching institution, with some veterinary schools lacking necessary clinical training; as such, practical training often takes place at the workplace after graduation.

Human Resources

The majority of Ukraine's 54,000 veterinarians serve in the public sector.¹⁰⁸ State veterinarians at the local level are at the forefront of disease detection activities, tasked with preventive care, management of chronic disease, surgical procedures, disease detection, and outbreak investigation.

Private veterinarians work at large farms or operate in private practice. However, their duties are limited to preventive care measures such as vaccination, anti-parasite prevention, administration of treatments, and elective surgical procedures. Private veterinarians are not permitted to collect suspect pathogenic samples from animals and must rely on the state veterinarians to conduct these specific tasks, which can delay case investigation and response.

State veterinarians are supported by veterinary technicians. Veterinary technicians have a limited role in disease detection; most of their duties involve assisting veterinarians in routine daily tasks. Veterinary technicians must obtain education at vocational schools.

Infrastructure

State veterinarians provide services at veterinary points, stations, and veterinary clinics. These three entities offer the same services but differ in the number of personnel and patients, with veterinary clinics seeing the most patients and the veterinary points seeing the fewest. Veterinary clinics serve larger cities, while veterinary stations and veterinary points serve towns and villages, respectively. State veterinarians who perform ambulatory services have access to ambulatory vehicles specially fitted to carry tools, medications, and containers for their daily duties, although availability of these specially equipped vehicles varies among rayons. State veterinarians can provide ambulatory services to large farming operations and smaller, family-operated ventures. Vehicle decontamination between farm calls is standard procedure, and disinfection supplies are readily available. Local veterinary hospitals' equipment is dated but functional.

Ukraine has developed an electronic animal identification and traceability system designed to protect the food chain and align with EU regulations (see additional information in Reporting and Communications section and in Exhibit 30). The registry system has several functions: it

stores data on owners (individual and commercial); traces intra/international movement of registered animals; and stores medical information, disease outbreak information, and information at slaughter (if applicable). Farmers and other livestock owners must register large and small ruminants, equines, and swine; failure to comply results in penalties, although these are rarely enforced. Although the system is well developed, lack of farmer compliance reduces its efficacy.

Clinical Guidelines

Clinical guidelines exist in the form of orders, which are legislated guidelines formulated primarily by SVPS. Veterinarians in academia, research institutions, and public and private practice can suggest revisions and offer formulations of guidelines via an online forum; however, intake or incorporation of suggestions is not the norm, and ultimately SVPS determines the final content of the clinical guidelines. There are approximately 70 orders for veterinarians' use. They are not revised or updated frequently and include imprecise instructions on preventive disease measures and disease control procedures.¹⁰⁹ Although clinical guidelines are disease-specific, they do not explicitly state timelines for onset of disease response or reporting schemes and do not include all the information needed to be considered a proper guideline. Some guidelines have been adopted from the Soviet era and need to be updated. The guidelines (orders) are available online; veterinarians who participated in the assessment process are aware of those guidelines and indicate that they use them appropriately.

SVPS has formulated a joint action plan against swine influenza, ASF, and HPAI. This action plan has more specific guidance in the event one of those diseases is suspected. The action plan describes timelines for personnel response and actions they should take, including how much time it should take to notify SVPS, when and which level of veterinary service should arrive at the site, the timeline for sample collection and submission to the laboratory, preventive measures, initial quarantine measures, disinfection procedures, and subsequent monitoring. These diseases were chosen for the action plan based on the transboundary risk and danger to humans and animals they present. Oblast and rayon veterinary services personnel gave the impression they were familiar with the action plan and that all veterinarians in the country were also aware. A standardized, more inclusive disease protocol guideline that includes not only guiding decisions and criteria regarding diagnosis, management, and treatment of disease, but also specific timelines for communication and response is recommended to improve the quality of disease protocols.

Professional Societies, Medical Education and Training

There are 12 veterinary schools in Ukraine. The Ministry of Education confers veterinary school accreditation based on criteria provided in the Law of Ukraine on Higher Education.¹¹⁰ Several accredited veterinary schools offer additional training for veterinarians who choose to specialize. Veterinary programs vary in curriculum despite the mandate that all institutions abide by established curriculum standards. Because each veterinary institution designs its own curriculum, graduating veterinarians may reflect different levels of training, particularly with respect to hands-on instruction and experience.

The most notable veterinary medicine association in Ukraine is the Association of Veterinary Specialists of Ukraine. It was created to promote improvement in veterinary services in Ukraine,

assist new veterinary graduates in finding employment, propose curricula changes at veterinary schools, and interact with international organizations to support the exchange of new information.¹¹¹ Nevertheless, the Association of Veterinary Specialists of Ukraine has an advisory role to SVPS and provides limited advocacy for veterinarians in the country.

Highlight 14: Veterinary Degree at National Agrarian University

Bila Tserkva National Agricultural University provides a 6-year program to obtain a veterinary degree—a 4-year basic veterinary program, followed by 1 year of specialized training, and 1 year of master's training. Basic course topics include infectious and zoonotic disease recognition, especially recognition of EDPs; food safety; and laboratory diagnostics. The university offers specialized courses of study in veterinary medicine, veterinary diagnostics, food inspection, and veterinary pharmacy. Students have the choice of doing rotations (hands-on training) at the school and also at private farms or commercial entities under the supervision of senior veterinarians. Veterinary education needs to be standardized to ensure consistent quality of new graduates given that not all veterinary institutions can offer the same amount or level of hands-on training.

Veterinarians are required to complete continuing education (CE) courses every 5 years based on their areas of interest. Topics for CE include handling infectious diseases, border and slaughterhouse inspections, laboratory diagnostic procedures, and preventive care. Veterinarians must pass a test to continue practicing veterinary medicine. Paraprofessionals are not required to take mandatory CE or be licensed. A statutory governing body and a national examination and licensing program for all veterinary graduates does not exist in Ukraine, but has proven useful in other western countries for validating basic competencies in veterinary medicine.

State veterinarians receive additional training on an ad hoc basis. The National Academy of Agrarian Sciences (NAAS) and its subordinate institutes, IVM and Institute of Experimental and Clinical Veterinary Medicine (IECVM), have provided veterinary training for animal health workers in infectious diseases, biosafety practices, and laboratory diagnostics.¹¹² Foreign partners, such as the Food and Agriculture Organization of the United Nations (FAO) have also provided ad hoc trainings in zoonotic and infectious diseases and, most recently, in control and prevention of ASF. The system could benefit from additional trainings in disease recognition, proper sample handling, biosafety practices, and disease control.

Highlight 15: Training at IECVM and IVM

IVM and IECVM are subordinates of NAAS. Although independent and not directly associated with MoAPF or SVPS, these institutes are authorized to conduct diagnostic testing for several pathogens of security concern, including HPAI virus, classical swine fever virus, and ASF virus. At the request of SVPS, IVM and IECVM can also assist in outbreak investigations by collecting samples and performing diagnostic testing. The institutes function primarily as academic/research facilities by studying various animal diseases, developing diagnostic methodology, and providing training to veterinary professionals in the country.

Disease Burden

Endemic pathogens in Ukraine include a varied group of bacterial, viral, and parasitic microorganisms, some of which are also pathogens of security concern. Some of diseases caused by endemic pathogens of security concern include anthrax, Newcastle disease, tularemia, Q

fever, and ASF.¹¹³ The transboundary risk of disease in Ukraine is moderate to high because Ukraine's semi-porous borders allow free movement of wildlife, such as wild boar. Wild boar crossings may have caused Ukraine's recent ASF outbreak. There is also extensive legal and illegal cross-border movement of people, who often travel with meat and meat-products from their countries of origin.¹¹⁴ Important transboundary pathogens of security concern that pose a threat to Ukraine include brucellosis, HPAI, and FMD. In particular, brucellosis is endemic in Russia, and border crossing of people and animals is frequent. Ukraine is declared free of brucellosis since the late 1980s, and therefore, there is no vaccination requirement for animals. The disease remains a moderately high transboundary risk for Ukraine, however, because of its endemicity in neighboring countries.

There is an underfunded compensation system that is non-inclusive of all diseases for farmers who have lost livestock as a result of disease control efforts; farmers fear such eradication disease efforts because of their economic consequences. As such, disease detection may be delayed owing to lack of reporting by farmers.

Highlight 16: ASF Outbreak¹¹⁵

Ukraine has reported cases of ASF since 2012. MoAPF and SVPS prioritized ASF control and have implemented several control measures, such as increasing the number of swine inspections for large farms, small-scale operations, and individuals who own swine, establishing ban of movement of swine or their meat products and strict disinfection measures. While the control measures significantly decreased the number of cases of ASF, some assessment participants indicated that ASF cases are greatly underreported. ASF was likely introduced by the movement of people from Russia carrying infected meat and meat products¹¹⁶. Other theories suggest that wild boar crossing borders may be the source. Despite disease control measures and increased border surveillance along the border with Russia, new outbreaks are periodically detected in the wild boar population and reported to OIE.

Gaps: Disease Detection

Gap	Explanation	Root Cause	Recommendations
Continuing Education Requirements	CE is mandatory for veterinarians every 5 years.	Legislation and Regulation, Training and Education	CE is intended to further advance knowledge and keep veterinarians up to date on the latest advancements in the veterinary field. Require CE at least every 1 to 3 years, ideally yearly.
Professional Licensure	State veterinarians are not required to take a national licensing examination upon graduation, which results in variability in general veterinary knowledge among veterinary practitioners. Private veterinarians are required to obtain a license to practice; however, the only requirements to obtain a license are personal identification information and veterinary diploma. An examination is not required.	Governance, Training and Education	Assemble a working group to create a statutory body to establish a standardized national veterinary licensing exam. Licensing exam is intended measure student's competencies to be able to practice veterinary medicine. Ideally, license all veterinarians (state and private).
Private Veterinarians	Private veterinarians are only allowed to deliver preventive care.	Legislation and Regulation	Create a working group to revise private veterinarians' role in disease detection and revise current laws/regulations.

Gap	Explanation	Root Cause	Recommendations
Clinical Guidelines	Clinical guidelines (orders) exist for a large number of diseases; however, these guidelines are not comprehensive and are not revised frequently.	Legislation and Regulation, Governance	Create a working group composed of higher and lower jurisdictional levels, academia, and researchers to standardize creation and revision of clinical guidelines.
Compensation	Farmers do not receive compensation in the event of a disease outbreak that requires the elimination of a herd or flock; consequently, farmers delay contacting the veterinary services rather than reporting the earliest signs of a disease outbreak.	Funding, Legislation and Regulation	Create a working group to formulate compensation regulations for farmers who lose livestock as a result of a public health emergency. Elevate to Cabinet of Ministers for consideration.
Standardized Veterinary Education	There is a lack of clinical or hands-on training by some veterinary schools.	Training and Education, Governance	Create a statutory body that has oversight for accreditation of veterinary schools in the country.

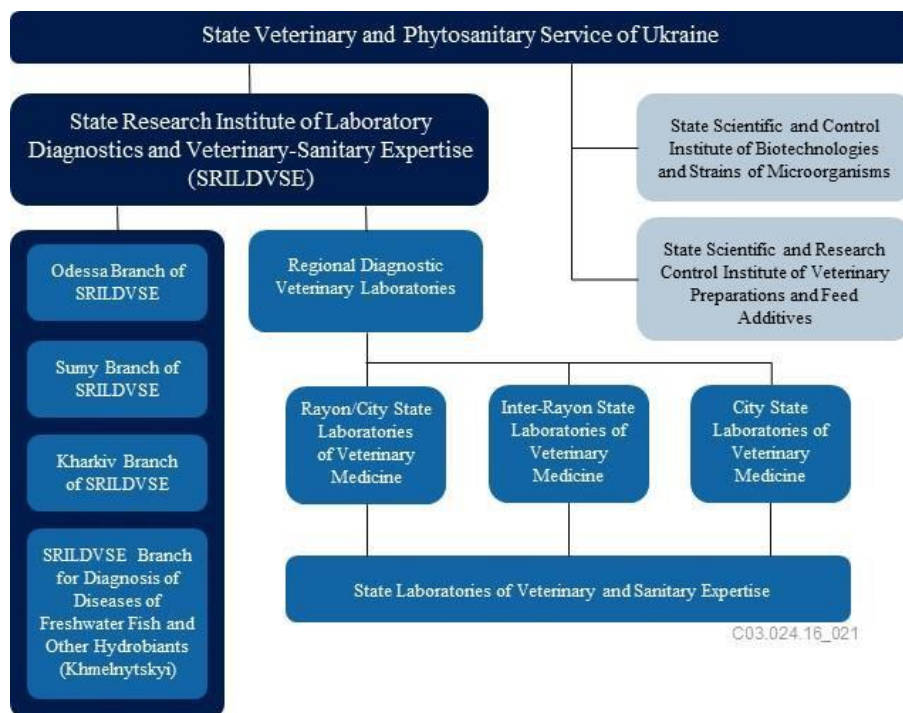
4.6.2 LABORATORY DIAGNOSTICS

The Cabinet of Ministers of Ukraine Decree No. 442, approved in September 2014, merged SVPS, the State Inspectorate for Consumer Protection, and SSES to establish the SSFSCP; however, the future of the animal laboratory system is still unclear. Because SSFSCP subsumed SVPS, it is unclear how the SVPS animal laboratory referral network might be restructured.

Structure of Laboratory Network

The animal laboratory network is primarily composed of rayon, oblast, and national laboratories all under the authority of the SVPS of Ukraine. Exhibit 25 provides a schematic of the present administrative structure of the laboratory system.

Exhibit 25: Administrative Structure of the Laboratory System¹¹⁷

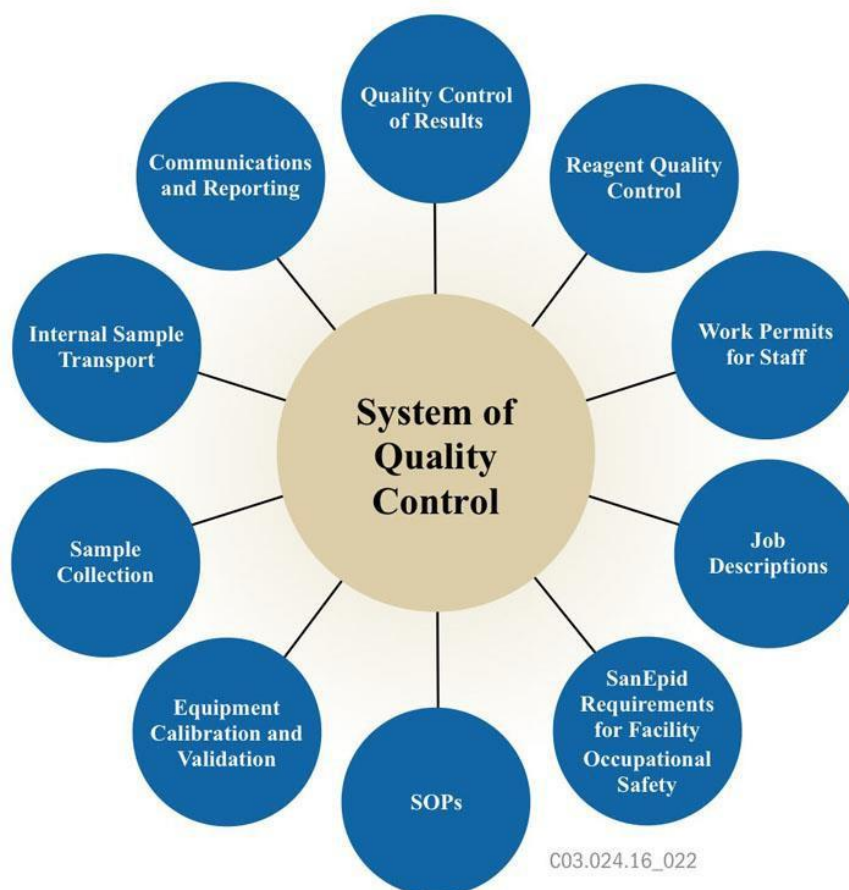


Quality Management System

SSRILDVSE is the lead laboratory network agency. It provides methodological guidance and support to veterinary laboratories in Ukraine, and also audits the RDVLs for compliance with quality control and calibration standards. SSRILDVSE also participates in external quality assessments (proficiency testing) provided by OIE and EU Reference Laboratories, and prepares quality assessments for the specialists within the SVPS network. However, there is no quality system in place to update and standardize diagnostic SOPs and procedures for sample collection. Moreover, no oversight or standardized assessment schemes are provided to ensure compliance with sample collection and transport. SSRILDVSE requires quality oversight strengthening, or a separate national quality office should be established to enhance laboratory quality management for the network. SSRILDVSE and all RDVLs are accredited in accordance with ISO 17025 by NAAU.

Similar to the human laboratory network, RDVLs provide quality oversight to rayon laboratories within their oblasts through audits and methodological assessments. The Lviv RDVL established a laboratory quality management program that could be a model for oblast leadership. In addition, Lviv RDVL has adapted regulations and procedures to conform to international guidelines. Exhibit 26 provides a diagram illustrating the Lviv RDVL's quality control system.

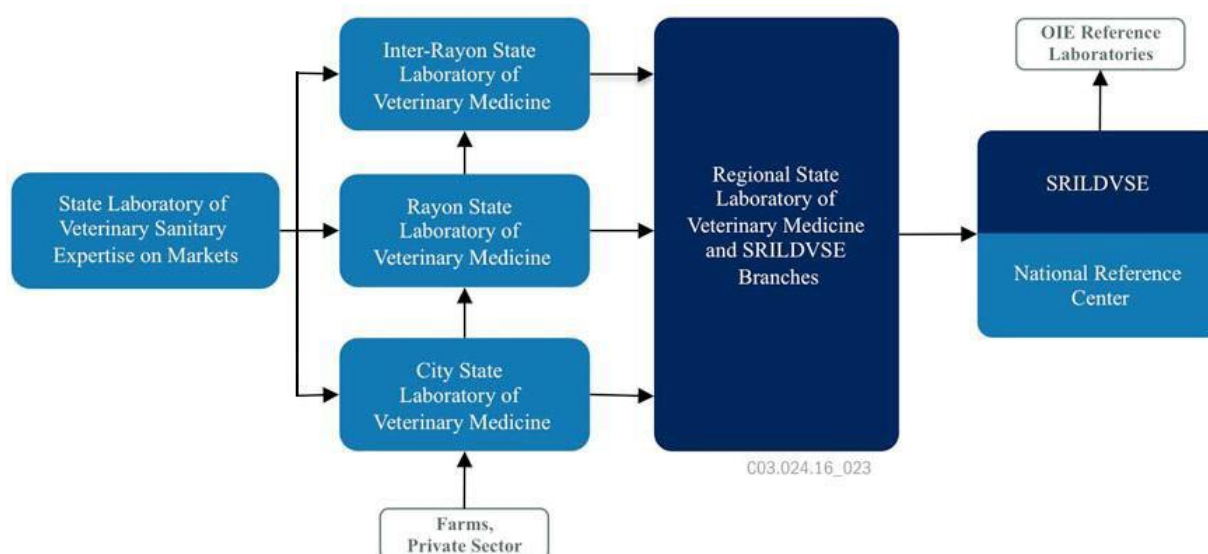
Exhibit 26: Lviv RDVL System of Quality Control



Sample Referral

Under the current framework, local farmers and private and state veterinarians submit samples to city, rayon, and inter-rayon laboratories. Suspected Group II EDPs are sent for confirmation to RDVLs or SSRILDVSE oblast branches. Should additional confirmation be required, RDVLs and SSRILDVSE oblast branches refer samples to SSRILDVSE, which can also refer them to OIE reference laboratories. Exhibit 27 provides a diagram of the flow of pathogenic samples through the animal laboratory network. A more comprehensive overview of sample flow is illustrated in the veterinary system CONOPS.

Exhibit 27: Flow of Pathogenic Samples Through the Animal Laboratory Network¹¹⁸



Human Resource Development

Ukraine does not have a standardized, coordinated national training program for laboratory professionals. However, individual entities at multiple levels, including SSRILDVSE, IVM, and the RDVLs, provide training on certain skills to targeted sets of laboratory specialists, who are then equipped to transfer this knowledge to workers at other facilities and other levels. For example, in connection with ASF outbreaks in Ukraine, SSRILDVSE organizes sample collection and transport workshops and practical trainings for RDVL specialists. These specialists train other specialists from the rayon facilities to collect and transport infectious materials. In addition, IVM's Research Training Center for Animal Disease Diagnostics (RTCADD) is capable of providing training in virology, bacteriology, chemical toxicology, molecular diagnostics, and biosafety and biosecurity; however, there is no cooperation between the SVPS and IVM for using RTCADD to train specialists from the SVPS laboratory network. Instead, RTCADD has provided non-laboratory-specific biosafety and biosecurity training for personnel within the Security Services, State Emergency Services, and MoD.

As the veterinary system proceeds with reforms, a national training program should be established that includes developing a core curriculum among the agrarian universities and the NAAS and its research institutes. A coordinated training program would optimize resources and ensure laboratory network staff receive all of the required trainings consistently. Moreover,

consideration should be given to develop a national EQAS for Group II–IV pathogens within the animal laboratory system.

Reagent Supplies

One of the greatest impacts of financial constraints is laboratories' inability to maintain inventory for molecular diagnostic testing kits. Within the SVPS laboratory network, this severely limits the ability to provide timely test results using modern methodologies. SSCIBSM develops diagnostic kits for anthrax, salmonellosis, and ASF that are currently only used for research and commercial purposes. In addition, Ukrainian institutes have developed diagnostic kits, but these kits were not approved for diagnostic testing; instead, SVPS procures kits independently from other manufacturers. Leveraging the potential diagnostic kit resources for use in the SVPS network would increase efficiency and sustainability within the veterinary laboratory network.

Laboratory Information Management Systems

The EU has supported installation of a comprehensive LIMS at the Kyiv and Lviv RDVLs, with plans to deploy LIMS in all oblasts by fall 2016. Bravo IT Center, a local developer, created the LIMS, which complies with ISO/IEC 17025. Along with typical LIMS functionality, such as sample tracking, quality control, reagent inventory, and regulatory documents, this system also stores equipment maintenance logs. It is capable of barcoding samples, but the Lviv RDVL is not using this function. Instead, there is an electronic logbook for assigning unique identifiers and registering and tracking samples. The LIMS is interoperable with other information systems and will further enhance the laboratory system and health informatics in Ukraine.

Gaps: Laboratory Diagnostics

Gap	Explanation	Root Cause	Recommendation
Laboratory Quality Management System	With no national quality office, Ukraine has struggled with consistent oversight for compliance with quality standards. In addition, there is a lack of standardization of procedures and laboratory training, including training for sample collection and transport, working with EDPs, and laboratory quality management.	Governance	Support efforts to improve the laboratory quality management system, including developing a national EQAS, training, and standardization of national procedures.
Human Resources Development	There is no national training program or office to coordinate required trainings for laboratory staff.	Governance, Training and Education	Develop a national training program for detection and identification of organisms that includes EDP training on diagnostic procedures and sample collection and transport.
Equipment Maintenance Practices	The culture of equipment maintenance is generally absent, leaving equipment idle, unsafe to use, or potentially producing inaccurate test results.	Legislation and Regulation, Funding,	Incorporate maintenance of equipment into regulations. Include preventive maintenance agreements in the annual budget.
Reagents and Consumables	Expenditures on diagnostic kits and consumables are limited.	Legislation and Regulation, Funding,	Leverage internal scientific expertise and functionality to manufacture diagnostic kits for SVPS upon validation and approval.

4.6.3 EPIDEMIOLOGICAL ANALYSIS AND INVESTIGATION

SVPS oversees all epidemiological analysis and investigation in the veterinary health system. Analyses are descriptive and are not used to determine risk factors or alert thresholds. Outbreak investigation and response are tied to legislated protocols that are disease-specific and not up to date. There is a roster of individuals who may be called on when there is an outbreak, but mobilization of an Anti-Epizootic Committee is ad hoc, and there are no SOPs for communication or mobilization of an outbreak response team.

System Description

Currently, SVPS is the central authority for disease surveillance data collection and analysis. The planned reforms, however, designate the SSFSCP as the central entity to collect and analyze disease data from the rayon, oblast, and central levels depicted in Exhibit 28.

Exhibit 28: Disease Surveillance Administrative Units

Administrative Level	Administrative Unit (Current)	Administrative Unit (Post-Reform)	Unit Description (Current and Post-Reform)
Central	SVPS	SSFSCP	Collects, aggregates, and analyzes disease data
Oblast	RDVL	RDVL	Collects surveillance data and performs diagnostic testing
Rayon	Rayon Diagnostic Veterinary Laboratory	Rayon Diagnostic Veterinary Laboratory	Collects surveillance data and performs diagnostic testing

The veterinary health system is heavily regulated. There are regulations that determine the outbreak thresholds and reporting timelines (usually within 24 hours of detection) for specific diseases. However, not all diseases have reporting timelines specified in the regulations, and adherence with reporting timelines is inconsistent. Case definitions do not exist, but disease-specific regulations have descriptions of symptoms and other criteria that can be used to diagnose diseases. Regulations also indicate what control measures to implement for a specific disease.

Human Resources

There are no formally trained epidemiologists in the veterinary health system. Rather, veterinarians perform epidemiological surveillance functions and collect disease data, conduct investigations, and implement preventive and sanitary control measures. They also prepare reports of the epidemiological situation in their respective territories and submit them to the central level.

Staffing is a complex issue. There are discrepancies in the official number and actual number of personnel on staff. For example, at the State Veterinary Service in the Kyiv oblast, there are only 98 administrative employees even though the current structure requires 222 administrative employees.¹¹⁹ This disparity may indicate understaffing and unmet administrative capabilities.

Training and Education

Epidemiology courses are part of the curricula at veterinary schools, but they mainly focus on managing infectious diseases via sanitary control measures and disinfection of surfaces and environments. Veterinarians have engaged in trainings on veterinary epidemiology offered abroad. For example, in 2012, a delegation of veterinarians participated in a workshop on wildlife disease surveillance sponsored by the National Wildlife Disease Program and the U.S. Department of Agriculture. As mentioned, all veterinarians (public and private) are required to take professional development trainings at least once every 5 years. This is especially applicable to private veterinarians who have to complete a full professional development course at accredited veterinary schools to renew their licenses.

General epidemiology courses are available only at the postgraduate level. Institutionalized epidemiology training for veterinarians does not include modern analytical and investigative methods in epidemiology. However, the faculty at some veterinary schools has begun to accept the value of statistics in determining disease trends and creating epidemic thresholds. In 2016, a cohort of veterinarians from Bila Tserkva National Agricultural University will train in biostatistics in an OIE-organized program in Lyon, France. Based on this training, the faculty plans to develop a manual on biostatistics to use at the university. The initiation and implementation of biostatistics training is a step forward for the veterinary health surveillance system and is an indicator of the willingness to shift toward analytical methods of epidemiological investigation and analysis.

Analysis of Aggregated Reports

The central-level Division of Epizootic Monitoring under SVPS performs all data analyses. The software used for analysis is called One Vet. Analyses are mainly descriptive statistics such as disease prevalence; data collected over time are not used to determine disease trends or to derive baseline data.

The oblast-level Veterinary Service's Anti-Epizootic Actions Department is responsible for epizootic monitoring and control. The oblast Veterinary Service aggregates data collected at the rayon level submits them to SVPS in an annual report. SVPS aggregates the data and uses it to determine which diseases should be monitored the following year. The process of reporting an outbreak is described in the Reporting and Communication section of this chapter.

Data quality is generally poor as a result of underreporting. Many disease cases are not reported at all—for example, farmers fear their animals will be killed as a result, particularly without adequate compensation for the loss—and the data that are reported are not timely or complete. Institutionalized underreporting is exacerbated by the loss of surveillance stations in the territories near the eastern border. Thus, the data are an inaccurate measure of the disease prevalence in the country.

Outbreak Investigation and Response

The state veterinarian at the rayon level initiates an outbreak investigation and quarantine measures within 24 hours of detection of a suspected case. An outbreak is determined by comparing the number of cases with the thresholds specified in regulations. There are disease-specific protocols that guide activities and measures to implement during outbreaks. Many of

these protocols have not been updated to address current needs (e.g., PPE that aligns with international guidelines, multisectoral communication plans) or capabilities (e.g., electronic information systems). Responders reference these protocols during an outbreak, but it is unknown how closely they follow them. There are rosters of veterinary personnel who may be deployed as part of an outbreak response team, but there are no formal SOPs for mobilizing a team. In the event of a zoonotic outbreak, an Anti-Epizootic Committee is assembled ad hoc within 24 hours of a suspected case. This committee has representatives from the veterinary service, law enforcement, the Ministry of Finance, State Emergency Service, and MoH. The Committee convenes to make decisions pertaining to outbreak response and bases its decisions on the protocols in existing regulations. If a zoonotic outbreak is suspected, the Regional Department of Veterinary Medicine reports to the local public health center (i.e., rayon SES or OLC), and each entity reports to its respective authorities.

The timeliness of outbreak response is tied into regulation. For example, the regulation for responding to an ASF outbreak has detailed descriptions of what actions to take and when to take these specific actions. The veterinary service is responsible for implementing this regulation and controlling the outbreak. There is a similar regulation for HPAI, but these are the only two diseases for which specific actions are held to a notification timeline.

Recent large-scale outbreaks of ASF have revealed weaknesses in the country’s epidemiological capacity and the repercussions of the conflict in the eastern territories. Border stations have been either destroyed in the conflict or personnel have evacuated. This has opened the already porous borders to transboundary movement of disease and further weakened the surveillance capabilities in these regions. Beyond the border vulnerabilities, the nation’s surveillance system and outbreak investigation and response capabilities are significantly constrained by a lack of funding and outdated regulations that do not promote real-time disease detection and response. For example, the veterinary service has limited ability to fight disease outbreaks because of its inability to pay indemnity for animals that must be culled. This disincentive for farmers to report diseases results in a misinformed national surveillance system that is unprepared to respond to emerging disease threats. Response efforts themselves are limited because they are rooted in the outdated discipline of sanitary epidemiology that focuses on disinfection rather than modern methods in epidemiology that focus on identifying the cause of a disease and eliminating it at its source. Overall, these limitations have resulted in further propagation of disease that could have been prevented and additional strain on exceedingly limited resources.

Gaps: Epidemiological Analysis and Investigation

Gap	Explanation	Root Cause	Recommendation
SOPs for Outbreak Response	The guidelines for responding to an outbreak are outdated, and not all disease-specific protocols are driven by timelines.	Legislation and Regulation, Governance	Establish protocols for mobilizing an outbreak response team.
Veterinary Epidemiologists	Epidemiologists are not part of the veterinary health system, and the existing epidemiology training received by veterinarians is not on par with international standards.	Ideology, Training and Education, Ideology	Train veterinarians in modern analytical and investigative methods in epidemiology. Integrate veterinary epidemiologists into the national surveillance system.
Analysis of Disease Trends	Analysis occurs only at the central level, and there is no analysis of	Ideology, Training and Education	Train veterinary epidemiologists in analytic and investigative epidemiology.

Gap	Explanation	Root Cause	Recommendation
	disease data to understand disease trends and risk factors.		
Baseline Disease Data	There are no baseline data to inform alert or epidemic thresholds.	Ideology, Training and Education	Train epidemiologists to generate baseline data and calculate thresholds.
Case Definitions	Standardized case definitions do not exist; clinicians may use various criteria for case reporting.	Legislation and Regulation, Governance, Ideology	Develop standardized case definitions for priority diseases, reportable diseases, and diseases of security concern. Integrate case definitions into clinical protocols.
Human Resource Capacity	Training in epidemiological analysis is not robust in internationally accepted epidemiological methods.	Training and Education	Provide advanced training and apprenticeships for key analytical epidemiologists.

4.6.4 REPORTING AND COMMUNICATIONS

Ukraine conducts primarily passive surveillance on priority diseases in the country and extends active surveillance activities to ASF, HPAI, and Newcastle disease. The notification system is primarily paper-based. Electronic tools are used to manage surveillance data and not for notification or alert purposes. As such, outbreaks are not reported in a timely manner. Rayon and oblast veterinary services receive reports of aggregated surveillance data after an outbreak has already occurred. This results in a limited understanding of the disease burden and limited preparedness to respond to emerging outbreaks. Ukraine has adopted the OIE notifiable disease list but also reports on a certain number of diseases to the EU in accordance with the EU Association Agreement.

Disease monitoring in Ukraine is done mainly through passive surveillance, with immediate reporting of notifiable diseases. Ukraine uses the OIE notifiable disease list (Appendix V) as its national list of reportable diseases, although some of the diseases listed, particularly those caused by EDPs, are not present in Ukraine. This suggests a disconnect between the local and central levels regarding awareness and communication of the epidemiological situation, and indicates a need to reach consensus on priority diseases for the country.

MoAPF and the predecessor to SVPS established the disease priority list many decades ago, and their determination was not made based on disease prevalence or data collected. The disease priority list has not been revised since it was established. More in-depth analysis of the data collected could be better used to determine current disease priorities along with diseases that pose a current transboundary risk or need control measures. Recently, the EU Association Agreement with Ukraine led to a selection of diseases from the OIE list that should be considered the notifiable disease list in Ukraine. These diseases are indicated in Appendix V with an asterisk (*). Diseases on the EU list that are not on the OIE list are swine vesicular disease, vesicular stomatitis, and enterovirus encephalomyelitis.

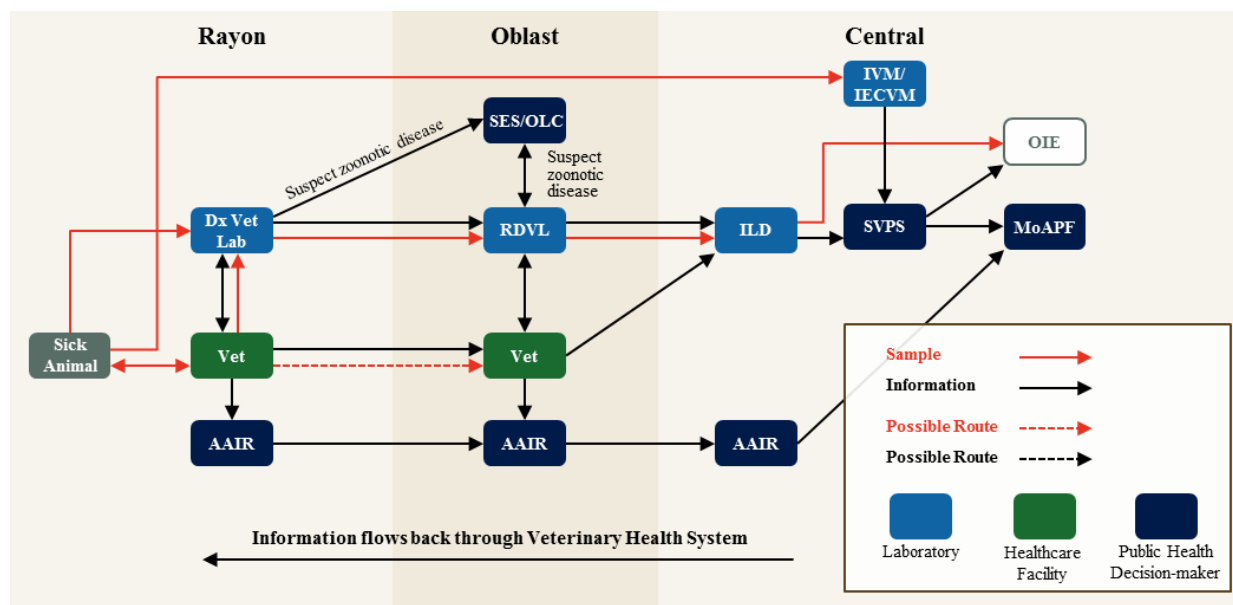
Active surveillance is conducted for ASF, HPAI, and Newcastle disease. Classical case definitions do not exist, but a number of disease-specific protocols and guidelines are tied into regulations to assist diagnosis. These national regulations are available to veterinarians at all levels.

There is currently no funding to support wildlife or vector surveillance, but soil samples from animal burial sites have been tested for traces of anthrax. Surveillance (i.e., pre- and post-mortem inspection) is also conducted at animal facilities that process raw materials, large farms, and meat processing facilities. The frequency and completeness of these surveillance activities is unknown.

System Description

The CONOPs for the current state of the routine surveillance system in Ukraine, with flow of case information and samples, is shown in Exhibit 29.

Exhibit 29: Animal Health System Biosurveillance Concept of Operations in Ukraine (Current)



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In the current system, the process begins when a farmer reports a sick animal to a local veterinarian who takes samples and notifies relevant agencies. Private veterinarians are not authorized to collect animal samples, but must contact the state or public veterinary service to collect samples and initiate an investigation. The local state veterinarian reports to the Rayon Laboratory of Veterinary Medicine and also to the rayon-level Agency for Animal Identification and Registration (AAIR), which, in turn, report to their counterparts at the oblast level, the RDVL, and the oblast-level AAIR. Oblast entities report information up to central-level AAIR and SSRILDVSE, which pass information on to SVPS, MoAPF, and OIE. In the anticipated (post-reform) system, SSFSCP will replace SVPS as the central agency that collects and analyzes surveillance data. The Rayon Laboratory of Veterinary Medicine and RDVL may also report to the oblast-level Public Health Center/OLC if a zoonotic disease is detected.

Veterinarians report cases using standardized paper forms. Some might use Microsoft® Excel to record cases and case data, but collecting data in spreadsheets is not widely used to track cases. Underreporting is a persistent problem. Many cases are not reported because of the potential financial consequences for both the farmer and public health official. It is unclear whether cases are reported from all jurisdictions, but the conflict at the eastern border of Ukraine has hindered

surveillance efforts in that region, and underreporting has been a persistent challenge. The reorganization of the administration may affect surveillance and communication. However, the integration of the SSES and the SVPS might facilitate an improved intersectoral relationship.

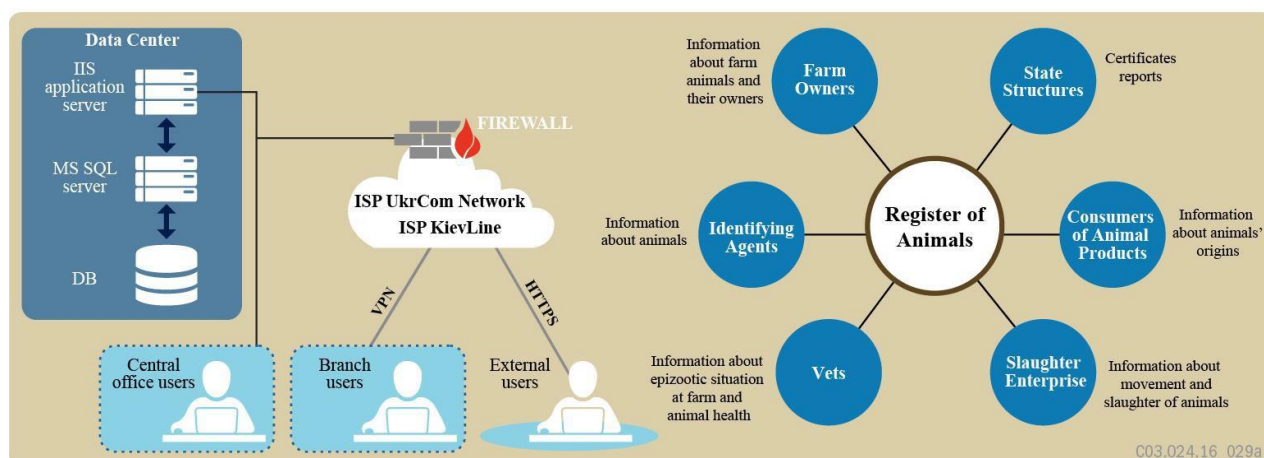
Electronic Disease Reporting and Analysis

Ukraine has two major electronic information systems for animal healthcare but there is no electronic disease reporting and/or surveillance system in Ukraine. The first system, the Animal Identification and Registration System, is able to identify, register, trace, and store information (demographics, vaccination, and disease information). Ukrainian law requires animals (large and small ruminants, swine, cattle, and equines) to be registered in this system, issued an ear tag, and later issued a passport. There are laws/policies that mandate the animal's information be updated in this system upon transaction of that animal. This system is elaborate enough to display all of the recorded data on an interactive built-in geographical information system. The interactive map is able to display epizootic situation by oblasts and rayons, and users may click certain areas of the map and can get information about the amount and percentage of infected animals. There is also an additional disease module that is able to record additional disease data. However, this module has not been fully adopted. The animal identification and registration system is described in Exhibit 30 and illustrated in Exhibit 31.

Exhibit 30: Animal Identification and Registration System

System Name	Description							
Animal Identification and Registration System	Animal Identification and Registration Agency has deployed this information system to electronically register and trace animals in Ukraine.							
	Type of Surveillance	Capability	Platform(s)	Operating System	Database	Open Source	User	Donor
	N/A	Surveillance; Notification; Geographical Information System	Desktop application, Web application, Mobile Web application, Android application.	Windows XP, Vista, Windows 7, Windows 8, Windows Server 2003, 2008 R2 (x64), Server 2012 (x64)	MS SQL Server	No	Animal Identification and Registration System	N/A

Exhibit 31: Animal Identification and Registration System Architecture



Veterinaria, a web-based system available at rayon, oblast, and central levels, is the other electronic tool used to store animal health data. Veterinaria is not integrated with any LIMS, but veterinarians can include laboratory results as an attachment to the animal's file. Data that veterinarians record at the rayon and oblast level are available to the central level, but oblasts and rayons do not have access to data from other oblasts and rayons. SVPS and SSRILDVSE have access to all recorded data across Ukraine. Veterinaria is not used for reporting, notification, and/or surveillance purposes. Exhibit 32 summarizes characteristics of Veterinaria.

Exhibit 32: Veterinaria

System Name	Description							
Veterinaria	Veterinaria is a web-based system that is available at the rayon, oblast, and central levels. This system is able to store information such as vaccination, anthelmintics, disease, and laboratory results and serves as a database of animal health records.							
	Type of Surveillance	Capability	Platform(s)	Operating System	Database	Open Source	User	Donor
	N/A	Electronic health records, animal health database	Web application	N/A	No information available	No	SVPS, SSRILDVSE, Veterinarians	N/A

Presently these systems are not used for reporting and surveillance, and data recorded in both of these systems are not analyzed or used for surveillance. Deploying EIDSS can enable disease reporting and surveillance. (EIDSS's capabilities are highlighted in the human section in Exhibit 18.) There are plans to deploy an EIDSS pilot at several animal healthcare facilities. Following the pilot phase, MoAPF is hoping to further expand EIDSS to more facilities and integrate with human healthcare. This will significantly support the One Health initiative and improve Ukraine's ability to control disease outbreaks.

Gaps: Reporting and Communications

Gap	Explanation	Root Cause	Recommendations
Timely and Complete Reporting	Underreporting is a primary challenge; farmers fear that their herds will be culled, and veterinary health professionals fear that failing to control an outbreak would result in termination.	Ideology, Governance	Establish an electronic reporting system and incentives for reporting.
Data Sharing Between Rayons and Oblasts	Oblasts do not know the epidemiological situation in neighboring regions, oblasts could delay disease detection.	Governance	Develop communication protocols between rayons and oblasts, or provide access to data from other oblasts. Improve communication from the national level down to the local level.
Priority Disease List	Reporting all the OIE notifiable diseases is costly and time consuming.	Legislation, Regulation, Funding	Update legislation to prioritize a select number of emerging diseases of security concern.
Data Exchange Standards	There are no data exchange standards.	Governance	Develop data exchange protocols and standards to improve interoperability of information systems.
ICT Infrastructure	There is a lack of consistent ICT infrastructure.	Funding	Upgrade healthcare facilities to support basic IT functionality. Provide computers, electricity, and Internet/network capabilities.

4.6.5 NATIONAL AND REGULATORY FRAMEWORKS

As with the human system, Ukrainian BS&S national and regulatory frameworks for animal health are outdated and do not align with international guidelines. Insufficient funding is a major challenge in implementing BS&S guidelines. Reforms to the human and animal health system present an opportunity to update frameworks to align with international guidelines.

Similar to the situation regarding the human health system, longstanding Ukrainian BS&S legislation and regulatory frameworks do not align with international BS&S guidelines. The ratification of the Cartagena Protocol on Biosafety does not affect animal laboratories because the regulations focus exclusively on GMOs. SVPS and MoH legislation regulates BS&S, and there is fragmentation between regulations. The Central Regime Commission, along with regional Regime Commissions of SSES, enforces BS&S regulations. Although leadership, laboratory staff, and veterinary staff are aware of BS&S regulations, challenges such as insufficient funding, outdated regulations that result in the inability to procure and maintain safety equipment, and the requirement to follow outdated BS&S procedures, prevent alignment with international guidelines within the animal health system. The challenges with BS&S regulations lead to difficulties in working safely and securely with pathogens. Ongoing reforms in the human and animal health systems, along with the goal to strengthen BS&S, have the potential to result in national BS&S regulations that align with international guidelines.

Gaps: National and Regulatory Frameworks

Gap	Explanation	Root Cause	Recommendation
Pathogens of Security Concern Regulations	Biosecurity regulations do not exist for pathogens of security concern.	Legislation and Regulation	Develop regulations for pathogens of security concern that are similar to the US Select Agent Program or CEN

Gap	Explanation	Root Cause	Recommendation
			Workshop Agreement 15793.
Outdated National BS&S Regulations	BS&S regulations are outdated and do not align with international guidelines.	Ideology, Legislation and Regulation	Develop regulations that align with international BS&S guidelines.
Fragmented BS&S Regulations	BS&S regulations are fragmented between different ministries.	Legislation and Regulation	Consolidate BS&S regulations.
BSL Guidelines	Risk groups and risk assessments are not used to determine biocontainment. Internationally accepted biosafety level guidelines are not used.	Legislation and Regulation	Develop regulations that identify pathogen risk groups and require risk assessments to determine biocontainment.

4.6.6 FACILITY-LEVEL BIORISK MANAGEMENT SYSTEMS AND CULTURE

As with the human health system, veterinary laboratories and clinics employ procedures based on legacy BS&S legislation. Formal risk assessments are not used. Funding at veterinary laboratories is a significant concern, especially because the current reforms have further limited funding that will be available to facilities from the state level. With such limited financial resources, it is difficult for facilities to support BS&S. Despite financial limitations, veterinary facilities are generally well-maintained by personnel.

Human Resource Development

Animal laboratory facilities do not have full-time biosafety officer positions or advanced trainings of current staff members because of a severe shortage in funding. Biosafety responsibilities are incorporated into the job duties of other staff members who typically do not have formal biosafety training.

In veterinary laboratories, occupational safety training is incorporated into new employee training, and components of biosafety are incorporated into sample-specific trainings and refresher trainings, including proper use of PPE, sample handling, and decontamination. Laboratory staff display an awareness of regulations as well as international guidelines. Personnel also receive training on and review the procedures for proper equipment use. Mentorship programs help properly train staff before they are permitted to carry out procedures autonomously. Annual trainings occur at oblast and rayon levels. Action plans for disease-specific response, such as ASF, are developed at the national level and communicated to oblasts, and trainings for these plans are carried out at the oblast level. Other trainings are also organized at the oblast level and provided to lower-level laboratories. OIE and FAO have periodically assisted in training efforts, and biosafety training was provided as part of CBEP engagement in 2011 and 2013.

Facility Infrastructure

Physical structures of veterinary laboratories appear to be in good condition. In general, country-wide utility problems that affect human health laboratories also affect animal health facilities. Major components of laboratory infrastructure, such as air handling equipment and backup generators are installed, although maintenance and fuel supply are ongoing concerns.

Establishing local maintenance providers and reliable fuel sources are critical needs to increase sustainability.

If a greater number of laboratories are privatized, as MoAPF has indicated may occur, laboratory infrastructure may become more challenging to regulate, standardize, and monitor. Private facilities may begin activities using facilities that were originally built for different capacities, may use buildings that vary greatly in general condition, or simply may not have knowledge of the appropriate regulations and guidelines to properly design a facility. Clear communication of national-level regulations and requirements will be critical to improving infrastructure in current buildings as well as achieving appropriate infrastructure in new facilities.

Biosafety Equipment

Most laboratory equipment is in good condition, although maintenance and equipment certification continue to pose challenges because of limited funding and expertise. BSCs do not receive routine maintenance and certification from trained technicians. Laboratories in large cities have greater access to trained maintenance and repair resources for their autoclaves, while laboratories in rural areas may struggle with finding local resources and expertise. Figures demonstrate that with the extremely limited 2016 funding outlook, regular maintenance and repair will be a significant challenge.

As a general practice, PPE is available and used properly within laboratories, and is also worn when samples are received at facilities. PPE supplies for outbreak response are kept stocked in each rayon. These materials are maintained in quick response bags that can be rapidly deployed.

In observed laboratories, incident response equipment, such as spill cleanup supplies, was often not immediately visible in assessed facilities, but staff advised that they understood spill response procedures and where to obtain response supplies. Eyewash station materials were not present in all laboratory spaces.

Materials used for safe storage and transport of samples align with international best practices. Primary and secondary containers are available for use in sample transport when a sample is received and when it is necessary to transport samples within the laboratory.

BS&S Documentation

A risk assessment process is important for documentation and improvement of BS&S, but a clear process is not used. As in human health facilities, a sound risk assessment process would serve to mitigate hazards while facilitating alignment with international BS&S guidelines.

SOPs are posted within laboratories, and staff are expected to review and follow procedures for proper use of equipment, facilitating good biosafety practices, as well as otherwise correct use of equipment. SOPs serve primarily to assist in aligning with national regulations and international best practices. Incident response plans developed at laboratories and procedures, such as spill response, also align with international best practices. Appropriate signage is often present on main laboratory doors and equipment, such as freezers and incubators, but additional signage on interior doors and additional pieces of equipment is needed to comply with international guidelines.

Biological Waste Management

Animal health laboratories and clinics are required to comply with national waste management regulations. Laboratories that work with EDPs treat waste and incinerate waste onsite. Non-EDP waste is sent offsite using a contracted waste removal service. Proper maintenance and operation of equipment, such as autoclaves and incinerators, are critical factors in the appropriate disposal of biological waste.

Biohazardous waste receptacles are present in some laboratory spaces. Staff indicated that biohazardous waste is always placed in marked containers and disposed of in accordance with regulations. Proper handling and disposal of biological waste during field sample collection was not confirmed.

Gaps: Facility-Level Biorisk Management Systems and Culture

Gap	Explanation	Root Cause	Recommendation
BS&S Roles and Responsibilities	Facilities do not have full-time biosafety officers.	Legislation and Regulation, Funding	Provide advisory assistance to improve alignment with international guidelines. Assist with resources needed to hire or train biosafety officers.
Formal BS&S Training	Formal training is needed to consistently and properly instruct personnel on BS&S. In healthcare facilities, disease-specific training is burdensome and may lead to inconsistent BS&S practices.	Legislation and Regulation, Governance, Funding, Training and Education	Provide assistance to implement training programs that incorporate updated BS&S regulations.
Equipment Maintenance	Limited funding will limit the ability to properly maintain equipment.	Legislation and Regulation, Funding	Assist with resources to upgrade equipment and facilitate development of long-term maintenance plans.
Formal Risk Assessment Process	Policies and procedures are not based on formal risk assessment process	Legislation and Regulation, Training and Education	Implement national regulations that require the employment of best practices and international guidelines. Train BS&S staff and principal investigators to understand and conduct risk assessments.
BS&S Signage	Not all facilities display proper signage indicating biohazard areas.	Legislation and Regulation	Provide signage materials to facilitate alignment with WHO regulations.

4.6.7 PATHOGEN CONSOLIDATION AND SECURITY

Ukraine faces security challenges as a result of conflicts in several areas and multiple facilities with collections pathogens of security concern, which highlights the need to securely store pathogens. Ukraine does not have a system to ensure security of pathogens, which may lead to vulnerabilities.

Ukraine handles collections of pathogens of security concern at SSCIBSM, IVM, and SSRILDVSE, which share a campus, as well as IECVM. Stored pathogens include *Bacillus anthracis*, *Francisella tularensis*, *Coxiella burnetti*, ASF virus, HPAI, *Yersinia pestis*, *Brucella* spp., Newcastle disease virus, *Burkholderia mallei*, *Rickettsia prowazekii*, CCHF virus, and eastern equine encephalitis virus. The animal system has gaps in biosecurity similar to the human

system which include physical security, transportation security, information security, material control and accountability, and personnel reliability.

Research and Storage of Pathogens of Security Concern

Collections of pathogens of security concern are stored at facilities that conduct research and diagnostics such as SSCIBSM, IVM, and IECVM.

Veterinary hospital laboratory testing is limited to basic microbiological and serological tests, and potential cases of EDPs are sent to central laboratories for confirmation. After testing, clinical samples are destroyed or referred to other laboratories, so collections of samples are limited.

Physical Security

National institutions, such as SSCIBSM, IVM, SSRILDVSE, and IECVM; and regional laboratories, such as Kyiv RDVL and Lviv Oblast laboratory; have physical security measures similar to human institutions. The measures are often a result of engagements with international partners and include perimeter fencing, security grilles on windows, electronic access control, onsite guards, CCTV, volumetric sensors, and integrated alarm systems. Access controls include radio frequency card readers and mechanical locks. Some gaps in physical security exist at facilities that may lead to vulnerabilities. Fencing at the SSCIBSM, IVM, and SSRILDVSE campus is decorative and not tall enough to prevent an individual from easily scaling the fence. The fencing does not form a continuous barrier around the perimeter, allowing easy access for intruders. While most first floor windows have security grilles, windows are occasionally left unbarred, leading to easy access for an intruder. Access controls are generally used properly with exceptions, such as the disabling of access controls to laboratories at SSRILDVSE and keys being left in doors at multiple facilities. While both human and animal facilities at the national level have similar physical security, the animal facilities' security features are better maintained and functional. Limitations with funding still pose a threat to sustaining physical security measures.

Material Control and Accountability

Material control and accountability are limited to paper logbooks and inventories that are not always accurately maintained. Samples are stored in approximately 12 freezers, many of which are outdated and prone to failure. Wax seals are used to monitor access to the collection of pathogens, which is an antiquated technique that has limited ability to track access. There is a deployment plan for PACS for the veterinary field at SSCIBSM, IVM, and IECVM. Select staff have received training for PACS; therefore, they may only require limited additional training. Modern freezer equipment to consolidate pathogens into fewer freezers and PACS to track pathogens would significantly improve material control and accountability.

Personnel and Information Security

Similar to the human system, personnel reliability programs do not exist besides verification of staff's professional and academic records. Laboratory leadership understands the need for personnel security, but limited resources prevent the implementation of criminal background investigations. Access to pathogen collections at SSCIBSM is limited to select staff, but more in-

depth background investigations would strengthen personnel reliability. As with the human system, information security is also limited because laboratories use unsecured paper logbooks to keep track of pathogens. Implementation of PACS would substantially improve information security.

Transportation Security

The animal system has equipment for sample transport such as refrigerated containers and dedicated vehicles. Samples are transported by farmers, veterinarians, and laboratory staff, who generally follow regulations on sample packaging and transport. In transportation to the laboratory and within the laboratory, chain of custody is not always maintained, leading to vulnerabilities during sample transport. Samples are received in dedicated spaces within laboratories, which do not accept improperly packaged samples. Providing sample transport training and maintaining chain of custody records would improve transportation security.

Gaps: Pathogen Consolidation and Security

Gap	Explanation	Root Cause	Recommendations
Physical Security	Gaps in physical security, such as incomplete fencing and missing grilles on windows, lead to vulnerabilities at facilities. Maintenance for BS&S measures, such as access control and alarm systems, is limited because of inadequate funding, which increases the likelihood for failure.	Legislation and Regulation, Funding	Assess physical security measures to identify gaps and address gaps. Identify mechanisms to maintain existing physical security measures.
Material Control and Accountability	Paper logbooks are used to track samples of pathogens of security concern creating difficulties in maintaining an accurate inventory and chain of custody. Wax seals, which are an outdated technique, are used to monitor access to pathogens.	Legislation and Regulation, Funding	Implement PACS at select facilities to improve pathogen inventory and tracking.
Personnel Security	Personnel do not undergo background checks to ensure suitability prior to accessing pathogens of security concern.	Legislation and Regulation, Funding	Develop a system for verifying academic and professional backgrounds of personnel and for conducting criminal background investigations.
Transportation Security	Chain of custody records are not maintained during sample transport, which may lead to loss or theft of material.	Legislation and Regulation, Funding	Develop procedures for chain of custody during sample transport.

One Health



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5 ONE HEALTH

The One Health concept in Ukraine exists at a theoretical level, where concepts are understood to varying degrees, but not practiced. No particular government entity or group is tasked with One Health activities in the country nor are there any policies or decrees related to One Health. If a zoonotic disease outbreak occurs, an ad hoc Anti-Epizootic Committee is assembled. The Anti-Epizootic Committee is composed of members of different government agencies, such as MoH, MoAPF, State Emergency Service of Ukraine (formerly Ministry of Emergencies), Ministry of Finance, and Ukrainian law enforcement. This committee is responsible for developing a plan of action.

Multisectoral Collaboration

There is no defined protocol for reporting and communications between the human and animal health systems. Regulations determine the number of cases needed to officially declare an outbreak. If a zoonotic disease outbreak occurs, multisectoral communication or reporting is conducted on an ad hoc basis. There is no common list of notifiable zoonotic diseases or pathogens. The MoH PHC's vision after the reforms is that in the event of a zoonotic disease outbreak, communication protocols will be established with their veterinary counterparts; however, this is still in the developing stages. The absence of official, defined reporting protocols may directly affect timely response to a public health emergency and may delay the proper designation of duties.

Limited information exchange occurs between the human and veterinary healthcare systems. Veterinary clinics notify the local SES of zoonotic cases to help determine outbreaks. However, SES is not obligated to notify the veterinary health sector of zoonotic cases. Although the Agency of Animal Identification and Registration is responsible for livestock registration, epizootic disease investigation, and safe food products, it reports no One Health efforts in Ukraine.

There are annual interagency exercises in the country. Previous exercises have included nuclear attack and HPAI pandemic. These exercises involve emergency response staff from four to five oblasts and occur every year. A national exercise has not occurred since 2008, when the country conducted an exercise to respond to an HPAI outbreak. The abundance of regulations that define the procedures to be followed during an outbreak has created the perception that exercises are somewhat unnecessary. Without regular exercises, emergency personnel may not be able to maintain specialized skills and gaps in capabilities or response plans.

Training

While they are aware of the One Health concept, medical and veterinary universities in Ukraine have only a few joint research projects, a joint microbiology textbook being written by Bogomolets National Medical University and educators on the veterinary side, and an occasional advisory role, but no joint training efforts or joint classes. The One Health concept is not a discipline in the medical educational curricula; rather it is referenced in the courses that are offered. In Lviv, veterinarians and the phytosanitary service have started to work on determining how to incorporate One Health standards into education and programs; but the project remained

incomplete owing to a lack of communication. A lack of both human and economic resources was reported by both the human and veterinary sides as the cause.

Outbreak Response

Multisectoral collaboration between public health officials and veterinary services during an outbreak is minimal. Collaborative efforts have included a multisectoral exercise on HPAI, but such efforts have been infrequent. At the national level, each sector implements its own preparedness and response plans that are based on disease-specific legislated protocols (i.e., there are no joint SOPs). During a zoonotic outbreak, the Cabinet of Ministers assembles an ad hoc Anti-Epizootic Commission to develop joint recommendations on control measures. This Commission has representatives from MoAPF, MoH, and the State Emergency Service. At the oblast and rayon levels, coordination occurs as needed (e.g., rabies cases, salmonella outbreaks). Algorithms to respond to a zoonotic disease outbreak do not exist in Ukraine. The lack of multisectoral coordination for outbreak response results in inefficient use of resources and delayed detection and response to zoonotic outbreak.

Gaps: One Health

Gap	Explanation	Root Cause	Recommendations
Multisectoral Communications	There is no formal protocol for inter-agency communication. Communications are reactive and ad hoc during outbreaks.	Legislation and Regulation	Form a multisectoral working group to create legislation that would clarify communication and disease reporting roles prior to and during an outbreak.
One Health in Training Curricula	The One Health educational approach does not exist between the human and animal sectors.	Funding, Training and Education	Form a working group with both human and veterinary medical universities to create joint educational efforts.
Trained Outbreak Response Teams	There is a shortage of trained interdisciplinary teams and staff to manage outbreaks and conduct investigations.	Funding, Training and Education	Create a roster of trained personnel from both sectors who can form a team that can respond to a zoonotic outbreak.
Zoonotic Pathogens/ Disease List	A list of common zoonotic pathogens or diseases does not exist.	Legislation and Regulation	Develop a list of priority zoonotic diseases and pathogens that require intersectoral notification.
Outbreak Exercises	Intersectoral outbreak exercises do not exist.	Training and Education	Develop workshops or exercises to assess response capacity to zoonotic disease threats.
One Health Legislation	One Health legislation does not exist.	Legislation and Regulation	Form a multisectoral working group to create One Health legislation.

Appendices



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APPENDIX I: STAKEHOLDERS INTERVIEWED

Organization	Bureau	Telecom	In-Country
American Medical Center, Lviv			X
Bila Tserkva National Agricultural University			X
Bila Tserkva Laboratory of Veterinary Medicine			X
Bila Tserkva Veterinary Hospital			X
Black & Veatch		X	X
Boholomets National Medical University	Rector's Office, Epidemiology Department, Infectious Disease Department		X
Consultative and Diagnostics Center			X
CRDF Global		X	
Danylo Halytskyi Lviv State Medical University			X
Defense Threat Reduction Office—Kyiv		X	
Institute of Biology			X
Institute of Experimental and Clinical Veterinary Medicine (IECVM)			X
Institute of Veterinary Medicine (IVM)		X	X
General Directorate Sanitary Epidemiological Service, Lviv Oblast			X
General Directorate of Veterinary Medicine in Lviv Oblast			X
Kyiv City Sanitary Epidemiological Station (SES)/Rayon Level SES			X
Kyiv Oblast Hospital of Veterinary Medicine			X
Kyiv Oblast Laboratory Center (OLC) and SES in Kyiv Oblast			X
Kyiv Regional Hospital #1			X
Kyiv Regional Veterinary Diagnostic Laboratory (RDVL)			X
Lviv City Department of Veterinary Medicine			X
Lviv City Hospital of Veterinary Medicine			X
Lviv OLC/SES			X
Lviv Regional Clinical Hospital			X
Lviv RDVL			X
Lviv Research Institute of Epidemiology and Hygiene (LRIEH)			X
Metabiota		X	
Ministry of Agrarian Policy and Food (MoAPF)			X
Ministry of Defense (MoD)	Sanitary Epidemiological Station, Kyiv		X
Ministry of Defense (MoD)	Sanitary Epidemiological Station, Lviv		X
Ministry of Foreign Affairs	Biological Threat Reduction		X
Ministry of Health (MoH)			X
Ministry of Health (MoH)	Public Health Center Working Group		X
Ministry of Health (MoH)	Department of Reform Coordination		X

Organization	Bureau	Telecom	In-Country
National Accreditation Agency of Ukraine (NAAU)			X
Oleksandrivska City Clinical Hospital			X
Sharpe Solutions, LLC		X	
St. Paraskeva Medical Center			X
Science and Technology Center of Ukraine (STCU)			X
Shupyk Academy of Postgraduate Study			X
State Emergency Service of Ukraine			X
State Sanitary Control Institute of Biotechnology and Strains of Microorganisms (SSCIBSM)			X
State Sanitary Epidemiological Service (SSES)			X
State Scientific and Research Institute for Laboratory Diagnostics and Veterinary and Sanitary Expertise (SSRILDVSE)			X
State Telemedicine Center			X
State Veterinary Service Bila Tserkva Rayon			X
State Veterinary and Phytosanitary Service (SVPS)			X
Ukrainian Center for Disease Control and Monitoring (UCDCM)			X
Ukraine Center for Socially Dangerous Disease Control (UCDC)			X
Ukraine Medical Association			X
Ukrainian Research Anti-Plague Institute (URAPI)			X
Ukrainian State Agency of Animal Identification and Registration			X
United States Centers for Disease Control and Prevention (CDC)	Division of Global HIV/AIDS	X	
United States Department of State (DOS)	Biological Engagement Program (BEP)	X	
Walter Reed Army Institute of Research (WRAIR)		X	

APPENDIX II: DESCRIPTION OF STAKEHOLDERS

Several major stakeholder groups influence the human and animal health systems in Ukraine. They include government entities, key academic entities, professional organizations, and international donor and advisory organizations. Exhibit 33 at the end of this appendix contains a more extensive list of stakeholders.

Human

Government Entities

The Ministry of Health (MoH) governs human health policies and strategies, sets general health policies at the central level, and regulates the health system, national programs, and hospitals. MoH has an international relations division that plays a role in health cooperation with other countries and international organizations, such as World Health Organization (WHO).

The State Sanitary Epidemiology Service (SSES), which falls directly under the Cabinet of Ministers, currently conducts epidemiological surveillance at the central level and through its oblast and rayon extensions. After reform implementation, the newly established Public Health Center (PHC), administered by MoH, will assume responsibility for surveillance of infectious and non-infectious diseases.

Academic Entities

Bogolomets National Medical University is one of the most notable and influential public medical school in Ukraine. Founded in 1841, the university provides training for a student body of 12,000-13,000. Its Department of Infectious Disease offers an internship and clinical residency and holds affiliation with Oleksandrivska Clinical Hospital, the only hospital in Ukraine with an especially dangerous pathogens (EDP) patient unit. Bogolomets has assisted MoH in the development of clinical protocols for infectious diseases. They have expressed interest in supporting, through training in their Department of Health Informatics, the development and implementation of software for the reporting of infectious diseases in Ukraine.

Nongovernmental Organization (NGO) and Donor Entities

Several international donors contribute to Ukraine's human health system.

- **European Centers for Disease Control (ECDC):** ECDC is helping to drive the current health reforms in Ukraine by providing advice and assistance in restructuring the system. MoH is in the process of implementing recommendations, including establishment of the PHC, from ECDC's recent assessment of Ukraine's health system.
- **International Monetary Fund (IMF):** IMF authorized a loan to Ukraine of \$17.5 billion (USD) over a 4-year period in an effort to set the country on the path to economic recovery.
- **The World Bank:** The World Bank currently funds an e-Health Initiative intended to create interoperable electronic reporting systems nationwide and a project to eliminate gaps in healthcare and provide diagnostic and consultative centers according to population needs.
- **WHO:** WHO is working on several projects in Ukraine: 1) to strengthen disease surveillance response, including laboratory capacities and technical guidance on priority

public health issues and threats; 2) to strengthen the Syndromic Disease Early Warning System to collect information on epidemic-prone diseases; and 3) to organize and work with donors to provide health services in the Donetsk and Luhansk oblasts and establish the Mobile Emergency Primary Health Care Units in Donbas.

Animal

Government Entities

The State Veterinary and Phytosanitary Service (SVPS) resides under the Ministry of Agrarian Policy and Food (MoAPF) and currently serves as the central authority for policymaking and implementation of veterinary practices. The agency governs subordinate entities down to the oblast and rayon levels. SVPS is also part of outbreak investigations, is a provider of training and continuing education, and is responsible for providing reports to the World Organisation for Animal Health (OIE).¹²⁰ Moving forward, the functions of the SVPS and some functions of the SSES will be performed by the newly established State Service on Food Safety and Consumer Protection (SSFSCP), which will continue to align under the MoAPF.

Academic Entities

- The National Academy of Agrarian Sciences (NAAS) and its subordinates, the Institute of Veterinary Medicine (IVM) and the Institute of Experimental and Clinical Veterinary Medicine (IECVM), are under the direct oversight of the Cabinet of Ministers and are research institutions for veterinary medicine.¹²¹ These institutes provide support to academic institutions and post-graduate training for higher education with respect to animal diseases. They also directly support the animal health system by assisting SVPS during outbreak investigation if support is requested.
- State Scientific Control Institute of Biotechnology and Strains of Microorganisms (SSCIBSM) provides support to the animal health system by developing tools for diagnostic testing of pathogens, storing and preserving pathogen strains, and providing post-graduate training in areas such as microbiology, infectious diseases, and immunology.¹²²

NGO and Donor Entities

Several international donors contribute to Ukraine's animal health system.

- **Food and Agriculture Organization of the United Nations (FAO):** FAO has assisted with programs to improve livestock traceability, emergency prevention systems for transboundary diseases, and prevention and control of African swine fever (ASF).
- **United States Department of Agriculture Agricultural Research Service (USDA-ARS):** USDA-ARS has collaborated with Ukrainian entities on projects involving response to highly pathogenic avian influenza (HPAI) and surveillance systems for ASF.
- **OIE:** OIE supports diagnostic testing confirmation of Ukrainian samples and has assisted in providing training personnel to help prevent and control ASF.

Exhibit 33: Stakeholders

Organization	Domain	Key project, activities and progress, or role
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Organization	Domain	Key project, activities and progress, or role
Bila Tserkva National Agricultural University	Animal	Bila Tserkva is one of several veterinary educational institutions training future veterinarians in Ukraine. The university is authorized by SVPS to provide continuing education to veterinary professionals.
Black & Veatch	Animal/ Human	Black & Veatch is the Biological Threat Reduction Integration Contractor (BTRIC) for the Defense Threat Reduction Agency (DTRA).
Bogolomets National Medical University	Human	Bogomolets National Medical University currently has 12,000-13,000 students. The university began, long before the creation of an independent Department of Epidemiology, training medical students in the basics of fighting infectious diseases. The university offers an internship and clinical residency through the Department of Infectious Disease with clinical affiliation at Oleksandrivska Clinical Hospital, which has the only infectious disease unit for diseases caused by EDPs. More recently the University took part in adapting course material organized by Black & Veatch for DTRA.
CRDF Global	Animal	CRDF was primarily engaged in 2014 and 2015 through the Department of State's (DOS) Biological Engagement Program (BEP) on biosafety and biosecurity projects with IECVM and IVM.
Danylo Halytskyi State Medical University	Human	Danylo Halytskyi State Medical University is the oldest medical university in Ukraine. The university trains 19,000 students annually at the undergraduate, graduate, and post-graduate levels. Infectious disease and epidemiology courses are included in the curriculum beginning at the undergraduate level. The university plans to be involved in training of the particulars of the new reforms for disease reporting.
Deutsches Akkreditierungsstelle GmbH (DakKS)	Animal	DakKS is the national accreditation body in Germany. The organization performs laboratory research and diagnostic studies with SSRILDVSE.
Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ)	Human	GTZ supports Ukraine's reform process currently by providing support for the public administration, chambers of commerce, and subject matter experts.
European Bank for Reconstruction and Development (EBRD)	Human	EBRD currently has 363 projects in Ukraine with a focus on strengthening energy efficiency and energy security, unlocking the country's agricultural and industrial potential, providing quality infrastructure, and strengthening the financial sector. EBRD also assisted in implementing a project to raise awareness and mitigate the risks of ASF.
European Union (EU)	Animal/ Human	Ukraine signed an Association Agreement with the EU and its member states in 2014, which is the first step toward EU accession. Multiple provisions in the agreement are guiding reforms in Ukraine in both the human and animal health systems.
Food and Agriculture Organization of the United Nations (FAO)	Animal	FAO has engaged with Ukraine on emergency prevention systems for transboundary animal diseases and plant pests, as well as on the development of national capacity building. Some past projects include improved traceability of livestock and livestock products and support to the emergency prevention system for transboundary animal and plant pests and diseases. FAO also partnered with OIE and USDA to provide training to veterinarians and laboratory personnel from Ukraine and several other countries to prevent and control ASF.
Global Fund	Human	Ukraine has one of the most serious human immunodeficiency virus (HIV) epidemics in Eastern Europe, and is also among the high-burden multidrug-resistant tuberculosis (TB) countries and high TB/HIV co-infection burden countries. The goal of the joint TB/HIV Global Fund program in Ukraine is to contain the TB and HIV epidemics and reduce TB- and HIV-related morbidity and mortality by investing in community and health system to strengthen as well as expand equitable access to high quality prevention, treatment, and care.
Institute of Biology	Human	The Institute of Biology is an academic institution with B.S., M.S., and Ph.D. programs of study in numerous fields of biology. The Institute has only Biosafety Level (BSL) 1 capacity and does not work with pathogenic

Organization	Domain	Key project, activities and progress, or role
		material. Students collaborate with offsite entities for additional experience as a component of graduate education programs. The facility has a limited role in BS&S.
Institute of Experimental and Clinical Veterinary Medicine (IECVM)	Animal	IECVM is the main research institution for veterinary medicine under NAAS.
Institute of Veterinary Medicine (IVM)	Animal	IVM provides scientific and methodological support for the prevention of biological risks and threats concerning livestock.
International Federation of Red Cross and Red Crescent Societies (IFRC)	Human	IFRC provides aid in the Donbas region, including locating missing family members.
International Medical Corps (IMC)	Human	IMC is currently helping to restore healthcare services in the Donbas region.
International Monetary Fund (IMF)	Animal/ Human	IMF approved an Extended Fund Facility loan of approximately \$17.5 billion (USD) for a 4-year period in March 2015. The loan is aimed at helping Ukraine achieve some level of economic recovery.
Lviv Research Institute of Epidemiology and Hygiene (LRIEH)	Human	Within the human health system of Ukraine, LRIEH provides research and diagnostics for EDPs caused by Group II viruses and rickettsia, and diseases caused by Group III bacteria.
Lyon National Veterinary School	Animal	Veterinarians from Bila Tserkva National Agricultural University have a 1-year training agreement with Lyon National Veterinary School. Starting in 2016, veterinarians from Ukraine will attend an introductory biostatistics course in Lyon. Knowledge gained from this course will be used to develop a biostatistics manual.
Medecins Sans Frontieres (MSF)	Human	MSF was providing medical care in the Donbas region, but in September 2015, separatists ousted foreign aid organizations and only allowed Red Cross to continue working.
Medlabsecure	Human/ Animal	Medlabsecure is a European project that has provided grants to laboratories with an interest in preventing vector-borne and emerging diseases.
Metabiota	Animal/ Human	Metabiota has conducted projects in Ukraine in both the human and animal health spheres. Projects have included training, laboratory renovation, and research.
Ministry of Agrarian Policy and Food (MoAPF)	Animal	MoAPF is the main policymaking body for agrarian practices, including animal health.
Ministry of Defense (MoD), Sanitary Epidemiological Stations (SES)	Human	MoD is responsible for the health of 250,000 members of the armed services and their families. The ministry has five SESs in the country, and three of them include laboratories. The disease data collected through each SES are ultimately reported to the MoH on a yearly basis.
Ministry of Foreign Affairs (MFA)	Animal/ Human	The MFA directs relations with other states and international organizations. The ministry has a biological threat reduction section that works closely with DTRA Cooperative Biological Engagement Program (CBEP), the G7 Global Partnership, and the Global Health Security Agenda.
Ministry of Health (MoH)	Human	MoH is the primary policymaking body for human health in Ukraine. The ministry is undertaking extensive reforms at this time.
Ministry of Health (MoH), Public Health Center (PHC) Working Group	Human	The PHC Working Group first convened at the end of 2015 to help guide the MoH reforms and restructuring called for in MoH order #604 and Cabinet of Ministers resolution #871. The group has a first draft plan under discussion with various stakeholders. The PHC will be based on already existing organizations (SSES, UCDCM, Ukrainian Research Anti-Plague Institute [URAPI], LRIEH, etc.); it is intended to bring the function of surveillance back under the control of MoH and will cover both infectious and non-infectious diseases.

Organization	Domain	Key project, activities and progress, or role
Ministry of Health (MoH), Department of Reform Coordination	Human	The Department of Reforms provides strategic planning and analysis of measures and functions of the MoH
National Accreditation Agency of Ukraine (NAAU)	Animal /Human	NAAU is the accreditation agency of Ukraine for both human and animal laboratories. Laboratory accreditation issuance includes ISO 17025.
Sharpe Solutions, LLC	Animal /Human	Sharpe Solutions supported the BTRIC in several human and animal health projects: URAPI renovations; laboratory training, management, and emergency response training; and IVM and IECVM physical security and biosecurity assessments.
Science and Technology Center of Ukraine (STCU)	Animal/ Human	STCU is an international government entity, jointly governed by Canada, the EU, Ukraine, and the United States, that funds and facilitates collaborative nonproliferation research and activities in Eastern Europe, Central Asia, the United States, and the EU. STCU has scaled back its activities due to political turmoil in Ukraine.
Shupyk Academy of Postgraduate Study		Shupyk is a prominent medical post-graduate medical education and research facility in Kyi. There are 81 departments in the academy that provide both theoretical and practical trainings to students. According to the local stakeholders, post graduate studies are provided by only three institutions in Ukraine and one
Soros Foundation	Human	The Soros Foundation has provided tens of millions of dollars to Ukrainian NGOs to assist them in transforming the country into a more “open” and “democratic” society.
State Emergency Service of Ukraine (SESU)	Animal/ Human	SESU is the central executive body under the Cabinet of Ministers charged with implementing state policy in civil protection, protection of people and territories in emergencies, and prevention and elimination of emergencies. SESU has responded to HPAI, influenza, and ASF outbreaks in recent years.
State Sanitary Control Institute of Biotechnology and Strains of Microorganisms (SSCIBSM)	Animal	SSCIBSM serves as the national center for strains of microorganisms in Ukraine, storing and maintaining 700 strains of microorganisms. In addition to scientific research and diagnostic tools development, it serves as the national reference center for rabies.
State Sanitary Epidemiological Service (SSES)	Human	The SSES is the central body responsible for monitoring and controlling disease outbreaks in Ukraine. It prevents and eliminates disease and environmental contamination by improving hygienic and sanitary conditions. In 2011, SSES separated from MoH and became an individual state executive body. Subsequently, SSES was ordered to be liquidated and its functions subsumed under the PHC and SSFSCP.
State Sanitary Epidemiological Service (SSES), Sanitary Epidemiological Stations (SES)	Human	SESs are local stations that are responsible for epidemiological and public health interventions during a health crisis. SESs are located in the oblasts and rayons. They report disease data to higher administrative levels and conduct investigations and implement control measures during disease outbreaks.
State Sanitary Epidemiological Service (SSES), Oblast Laboratory Centers (OLC)	Human	OLCs are the regional laboratory centers for the EDP laboratory network. In addition to diagnostic testing, they provide oversight and training to rayon laboratories in their respective oblasts.
State Scientific and Research Institute for Laboratory Diagnostics and Veterinary and Sanitary Expertise (SSRILDVSE)	Animal	SSRILDVSE conducts scientific studies of Group II pathogens and serves as the central veterinary laboratory for confirmatory diagnostic testing of samples referred by Regional Diagnostic Veterinary Laboratories (RDVL) and other subordinate laboratories.
State Veterinary and Phytosanitary Service (SVPS)	Animal	SVPS is currently an agency under MoAPF that oversees, regulates, and performs the majority of the animal biosurveillance-related activities in the country.
State Veterinary and Phytosanitary Service (SVPS), Regional Diagnostic Veterinary	Animal	RDVLs are the regional laboratory centers for the EDP animal laboratory network. In addition to diagnostic testing, they provide oversight and training to rayon laboratories in their respective oblasts.

Organization	Domain	Key project, activities and progress, or role
Laboratories (RDVL)		
Swiss Agency for Development and Cooperation (SDC)	Human	The SDC's active involvement in Ukraine extends to governance and peacebuilding, improvements in healthcare, the prevention of noncommunicable diseases, and other development efforts. The agency current has specific projects to further the process of decentralization; assist in drawing up and implementing healthcare reforms; promote healthier lifestyles toward prevention of noncommunicable diseases; and provide emergency assistance in the form of products for purifying drinking water, medicines, and medical consumables and medical instruments.
Ukrainian Center for Disease Control and Monitoring (UCDCM)	Human	UCDCM is in charge of identification and classification of pathogenic biological agents, and also serves as an analytical and diagnostic confirmation center for MoH. It provides confirmatory testing for <i>B. anthracis</i> , <i>F. tularensis</i> , and <i>Brucella</i> species. UCDCM also collects statistical information concerning environmental and clinical sample testing in OLCs.
Ukraine Center for Socially Dangerous Disease Control (UCDC)	Human	UCDC was established in 2012 and works in coordination with several NGOs to improve the management of national efforts to combat HIV/AIDS, TB, and other socially dangerous diseases. UCDC implements policy and monitors and evaluates programs such as the national TB program, national HIV/AIDS program, and the reference laboratories for HIV/AIDS and TB.
Ukraine Medical Association (UMA)	Human	UMA advocates on behalf of its physician members in areas such as professional development, increasing practical skills, and improving medical education. The association also seeks to privatize the majority of the health system in Ukraine, allowing physicians career outlets that are not state-controlled. Only about 18,000 of Ukraine's 180,000 physicians are currently association members.
Ukrainian Red Cross	Human	The Ukrainian Red Cross provides a wealth of services to the citizens of Ukraine, including shelter; disaster and crisis management; and health services such as first aid, emergency response, epidemic control, health promotion and prevention, psychosocial care, and community empowerment.
Ukrainian Research Anti-Plague Institute (URAPI)	Human	URAPI is the MoH's main research and methodological entity responsible for responding to Group I and II pathogens and newly identified infectious diseases.
Ukrainian State Agency of Animal Identification and Registration	Animal	The agency's primary goals are to provide safe, healthy livestock products for the population; control epizootic situation; and register and identify animals. Through its electronic system, it is able to identify, trace, and track animal movement throughout Ukraine. There are laws/policies that mandate that animals be registered with this agency through 1 of its 22 animal registration branches.
United Nations High Commissioner for Refugees (UNHCR)	Human	UNHCR provides support required to enable the health sector to fill in the health system's gaps and to respond to the increasing needs of the people in the Donbas region.
United States Agency for International Development (USAID)	Human	USAID programs in Ukraine focus primarily on good governance, economic growth, strengthened health services, and humanitarian assistance.
United States Centers for Disease Control and Prevention (CDC)	Human	The CDC office in Ukraine was established in 2010. Its primary focus is developing the capacity of government and nongovernment institutions to respond to the AIDS epidemic by providing technical assistance to partners to implement large Global Fund grants. Two Ukrainians are currently enrolled in CDC's Field Epidemiology Training Program.
United States Department of Agriculture (USDA)		USDA provided financial support to FAO to conduct trainings for veterinarians and laboratory personnel from Ukraine and several other countries to prevent and control ASF.
United States Department of Agriculture (USDA), Agricultural	Animal	USDA-ARS has collaborated with IECVM on projects related to HPAI and conducted a project aimed at establishing a sustainable surveillance system

Organization	Domain	Key project, activities and progress, or role
Research Service (ARS)		for ASF in the country.
United States Department of State (DOS), Biological Engagement Program (BEP)	Animal/ Human	DOS BEP supports the STCU to engage scientists in cooperative research and has provided funding for biosecurity improvements at IVM and IECVM. DOS BEP partnered with USDA-ARS to reduce the potential for dual-use technologies, counter bioterrorism, improve laboratory capacity, build sustainability, and support long-term threat reduction.
United States President's Emergency Plan for AIDS Relief (PEPFAR)	Human	In 2011, PEPFAR supported Ukraine in providing care and support to 14,100 HIV-positive individuals (including TB/HIV) and counseling and testing to 23,800 individuals.
Walter Reed Army Institute of Research (WRAIR)	Human	WRAIR is not currently conducting any projects in Ukraine, but previously provided training and training materials on surveillance and epidemiology.
The World Bank	Human	The World Bank currently funds an e-Health Initiative in Ukraine that aims to create interoperable electronic reporting systems nationwide. It is also financing a project aimed to eliminate gaps in healthcare and provide diagnostic and consultative centers according to what is needed (e.g., primary care, cardiovascular care, and oncology services).
World Health Organization (WHO)	Human	WHO is working to strengthen disease surveillance response, including laboratory capacities and technical guidance on priority public health issues and threats. WHO is also working to strengthen the Syndromic Disease Early Warning System to collect information on epidemic-prone diseases; develop public health interventions; and prevent, detect, and respond to epidemic-prone diseases; prepare emergency medical supplies and materials to ensure timely response to disease outbreaks. WHO has also been involved in organizing and working with donors to provide health services in the Donetsk and Luhansk oblasts, and establishing the Mobile Emergency Primary Health Care Units in Donbas.
World Organisation for Animal Health (OIE)	Animal	OIE is the international organization responsible for improving animal health worldwide. Ukraine reports to OIE the status of diseases listed on the OIE's notifiable disease list. In addition, SSRILDVSE has sent samples for diagnostic testing confirmation to OIE reference laboratories. OIE also partnered with FAO to provide training to veterinarians and laboratory personnel from Ukraine and several other countries to prevent and control ASF.

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APPENDIX III: RELEVANT LEGISLATION IN UKRAINE

Law	Domain	Title	Description
N/A, 1979	Human	Regulation on Procedure of Storage, Work and Transfer of the Cultures of Bacteria, Viruses, Rickettsia, Fungies, Protozoa, Micoplasma, Bacterial Toxins, and Poisons of Biological Origin	This regulation provides for material accountability, laboratory safety, material transfer, storage, and unauthorized distribution of cultures, toxins, and poisons. ¹²³
No. 2498-XII, 1992	Animal	The Law of Ukraine on Veterinary Medicine	This law sets forth the legal, organizational, and financial basis of veterinary medicine in Ukraine. It determines the requirements relating to veterinary-sanitary quality and safety of animal products, the rights and obligations of legal entities and persons in the field of ensuring veterinary and epizootic welfare, animal quarantine, and the conduct of state veterinary-sanitary control and supervision. The law notes that state administration of veterinary medicine will be carried out by the Cabinet of Ministers and its specifically authorized central body of executive power on agricultural policy issues, plus its territorial bodies and regional services. ¹²⁴
No. 2801-XII, 1992	Human	Fundamentals of the Legislation of Ukraine on Healthcare	Establishes the main principles of healthcare; guarantees the right of every citizen of Ukraine to have healthcare; defines the rights of patients; assigns the implementation of state healthcare policy to bodies of state executive power; and notes the financing of healthcare will be done at the expense of the state budget, budgets of local and regional self-government, medical insurance funds, charity funds, and any other sources not expressly prohibited by law. ¹²⁵
No. 705, 1994	Human	On the State System of Deposition of Strains of Microorganisms	This decree approves the resolution proposed by the National Academy of Sciences to regulate the deposit, registration, recording, and storage of microorganisms for the purposes of obtaining a patent. ¹²⁶
No. 4004-XII, 1994	Human	The Law of Ukraine on Ensuring Sanitary and Epidemiological Welfare	Regulates sanitary and epidemic safety assurance, and defines the respective rights and obligations of public authorities, enterprises, institutions, organizations, and individuals. It also prescribes the organization of the State Sanitary Epidemiological Service (SSES) and the execution of state governed sanitary-epidemic supervision. ¹²⁷
No. 35, 1999	Human	Decree No. 35 of the Chief State Sanitary Doctor of the Ukraine	This decree approved the State sanitary norms and rules “Hygienic classification of work in terms of hazard and danger environment factors, severity and intensity of the work process.” This regulation focuses on the hygienic assessment of workplace conditions, requiring facilities to meet standards and provide PPE to personnel in hazardous working conditions. ¹²⁸
No. 1300, 1999	Human	On the Development of State System of Deposition of	This decree approves the regulations to control the number of institutions that store stocks of pathogens

Law	Domain	Title	Description
		Strains of Microorganisms	and toxins. ¹²⁹
No. 989, 2000	Human	On Comprehensive Measures for the Implementation of Family Medicine in the Health Care System, Cabinet of Ministers of Ukraine	Lays out a detailed plan for phased transition of primary healthcare based on family medicine over the course of 2000–2005.
No. 1645-III, 2000	Human	The Law of Ukraine on Protection of Population Against Infectious Diseases	Governs the organizational and functional basis for activities of state bodies, bodies of local self-government, enterprises, institutions, and organizations aimed at preventing the emergence or spread of infectious disease. It also defines the rights, obligations, and responsibilities of legal entities in protecting the public from infectious diseases. ¹³⁰
State Sanitary Rules 9.9.5-064, 2000	Human	Procedure to Grant the Permission for the Work with Microorganisms of I–IV Groups of Pathogenicity and Recombinant DNA	This regulation defines conditions that institutions must meet to receive work permits to legally work with microorganism in groups I–IV. ¹³¹
No. 70, 2002	Human/ Animal	Instruction on Storage, Maintenance, Sale, Import to Ukraine and Export of Strains of Microorganisms, Toxins and Poisons of Animal and Plant Origin that are Used for Medical and Scientific Needs	This order regulates the storage, maintenance, delivery, importation, and exportation of microorganisms, toxins, and poisons of plant and animal origin that are used in veterinary medicine and science. The order classifies pathogens into groups, regulates which facilities may work with different pathogen groups, and provides requirements for working with the respective pathogens. ¹³²
State Sanitary Rules 9.9.5-080, 2002	Human	Rules of Organization and Safe Work in Laboratories (Divisions) of Microbiological Profile	This regulation defines safe working conditions for laboratory personnel working with pathogens in groups I–IV. It aims to properly contain materials and prevent laboratory-acquired infections. It also allows for institutions to implement additional regulations to further improve safety, as long as compliance with national regulations is maintained. This document replaced USSR MoH regulations. ¹³³
State Sanitary Rules 9.9.5-153, 2008	Human	The Organization of Laboratories’ Work in the Case of Investigation of Materials Containing the Biological Pathogenic Agents by Molecular-Genetic Methods	This regulation was developed on the basis of regulation 22.06.99 #1109 and applies to the organization of laboratory operations during research of material containing agents in groups I–IV in which polymerase chain reaction (PCR) methods are used. ¹³⁴
No. 220, 2009	Human	Decree of the Commission on Biosafety and Biosecurity at the National Security and Defense Council of Ukraine (under the Order of the President of Ukraine)	This decree recognizes the importance of biological safety in Ukraine to combat bioterrorism, regulate GMOs, and maintain public health. ¹³⁵
No. 604, 2015	Human	On the Establishment of the Institution “Public Health Center of the Ministry of Health of Ukraine”	Establishes the state institution governing public health issues, the PHC, as a separate legal entity by merging state enterprises and agencies, including national laboratories (Lviv Research Institute of Epidemiology and Hygiene [LRIEH], Ukraine Center for Socially Dangerous Disease Control [UCDC], Ukrainian Center for Disease Control and Monitoring [UCDCM], Ukrainian Research Anti-

Law	Domain	Title	Description
			Plague Institute [URAPI]) and the oblast and rayon laboratory centers of the SSES. ¹³⁶
No. 442, 2014	Human/ Animal	On Optimization of Central Executive Bodies	Merges the SVPS with functions of the State Inspectorate for Consumer Protection and the SSES to establish the new state institution, the SSFSCP. ¹³⁷
No. 751, 2012	Human	On the Development and Implementation of Medical and Technological Documents on Medical Care Standardization in the System of the Ministry of Health of Ukraine	Guides the development and standardization of clinical guidelines and protocols and their digitization.
No. 5, 2015	Human	On the Strategy for Sustainable Development “Ukraine–2020,” President of Ukraine	Provides for the implementation of 62 reforms and development programs. The goal for healthcare reform is a radical, systemic reform, aimed at creating a system focused on the patient, able to provide healthcare for all citizens of Ukraine at the level of developed European countries. The reform would increase personal responsibility of citizens for their own health, provision of free choice of healthcare services of good quality, the provision of targeted assistance to the most vulnerable populations, creating a business friendly environment in the healthcare market.
No. 26-VIII, 2014	Human	Action Programme of the Cabinet of Ministers of Ukraine approved by the Verkhovna Rada of Ukraine	Includes action for healthcare reform that would include the following: <ul style="list-style-type: none"> • Elimination of corruption schemes in procurements in the health system • Transformation and upgrade of the hospital network, creating a unified three-tier system (local hospitals—regional hospitals—national reference centers) • Deregulation of the pharmaceutical market • Passage of the legislation on health insurance
No. 464, 2011	Animal	On approval of the State Veterinary and Phytosanitary Service of Ukraine	This decree establishes the official functions of SVPS. ¹³⁸
No. 442, 2014	Human/ Animal	On Optimization of Central Executive Bodies	This Cabinet of Ministers resolution merges SVPS with functions of the State Inspectorate for Consumer Protection and SSES to establish SSFSCP. ¹³⁹
No. 1103-16, 2007	Human/ Animal	Law of Ukraine on the State System of Biosafety at the Time of Creating, Testing, Transporting, and Using Genetically Modified Organisms	This law regulates relations among executive authorities, producers, suppliers, developers, researchers, scientists, and consumers of GMOs and products generated according to technologies that involve their development, generation, testing, research, transportation, import, export, market placement, release into the environment, and use within Ukraine to ensure biological and genetic safety. ¹⁴⁰
No. 549-IV, 2003		Law of Ukraine on State Control Over International Transfers of Military Goods and Dual-Use Goods	This law regulates activities related to international transfers of military goods and dual-use materials (including biological materials) to prevent proliferation and use in terrorist and illegal activities. ¹⁴¹
No. 81, 2014	Animal	Regulation on prophylaxis of	This order was formulated after the introduction of

Law	Domain	Title	Description
		African swine fever	ASF into the country and describes the measures that must be taken to prevent the spread of the disease in swine production facilities, among private animal owners, and in the wild. ¹⁴²
No. 4004-XII, 1994	Human	Law of Ukraine on Provision of Sanitary and Epidemiological Wellbeing of Population	This law determines the rights and obligations of state bodies, companies, organizations, and citizens. The law also establishes procedures for the organization of the SES and implementation of the SSES in Ukraine. ¹⁴³
State Sanitary Rules 9.9.5-035, 1999	Human	Safe Working With Microorganisms of Groups I–II of Pathogenicity	This regulation applies to all entities and personnel carrying out work with microorganisms in groups I and II and sets requirements for room planning, equipment, safe methods of work, accident plans, utility supply, training, and occupational health for personnel. ¹⁴⁴

APPENDIX IV: NOTIFIABLE DISEASES IN UKRAINE (2001)

Immediately Notifiable Diseases	
Cholera	Poliomyelitis acute
Typhoid	Rabies
Paratyphoid A,B,C	Tick-borne encephalitis spring and summer*
Other Salmonella infections	Hemorrhagic fever*
Bacterial dysentery (shigellosis), including bacteriologically confirmed	Measles
Enteritis caused by the pathogen Yersinia enterocolitica	Viral hepatitis, including hepatitis A, hepatitis B, hepatitis C
Enteritis, colitis, gastroenteritis, food poisoning, due to other established agents, including campylobacteriosis, rotavirus enteritis	The disease caused by the human immunodeficiency virus (HIV)
Acute intestinal infection caused by unidentified pathogens and accurately identified food poisoning	Mumps epidemic
Tuberculosis of the respiratory system, including destructive	Infectious mononucleosis
Tularemia*	Malaria, first diagnosed
Anthrax*	Ascariasis
Brucellosis*	Trichuriasis
Leptospirosis	Enterobiasis
Catalepsy	Himenolipidoz
Diphtheria	Trematodozy
Scarlet fever	Pediculosis
Varicella	Scabies
Rubella	Acute upper respiratory infections multiple or unspecified localization
Congenital rubella	Influenza (seasonal)
Pertussis, including parakashyluk	Carriers of human immunodeficiency virus (HIV)
Meningococcal disease	Holders agents of dysentery
Legionellosis	Holders agents of typhoid and paratyphoid A,B,C
Gonorrhea acute and chronic	Carriers of toxigenic strains of diphtheria
Lyme disease	Holders netoksykohennyh strains of diphtheria
Psittacosis	Holders of cholera agent
Rickettsial, including epidemic typhus*	Parazytonosiyi malaria
Bryl, tick-borne typhus, Q fever*	Viral meningitis

* indicates diseases caused by pathogens on the U.S. Federal Select Agents and Toxins List

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APPENDIX V: NOTIFIABLE ANIMAL DISEASES IN UKRAINE

Multiple species Diseases, Infections, and Infestations	Cattle Diseases and infections
<ul style="list-style-type: none"> • Anthrax • Bluetongue* • Brucellosis (<i>Brucella abortus</i>) • Brucellosis (<i>Brucella melitensis</i>) • Brucellosis (<i>Brucella suis</i>) • Crimean Congo haemorrhagic fever • Epizootic haemorrhagic disease • Equine encephalomyelitis (Eastern) • Foot and mouth disease* • Heartwater • Infection with Aujeszky's disease virus • Infection with <i>Echinococcus granulosus</i> • Infection with <i>Echinococcus multilocularis</i> • Infection with rabies virus • Infection with Rift Valley fever virus* • Infection with rinderpest virus* • Infection with <i>Trichinella</i> spp. • Japanese encephalitis • New world screwworm (<i>Cochliomyia hominivorax</i>) • Old world screwworm (<i>Chrysomya bezziana</i>) • Paratuberculosis • Q fever • Surra (<i>Trypanosoma evansi</i>) • Tularemia • West Nile fever 	<ul style="list-style-type: none"> • Bovine anaplasmosis • Bovine babesiosis • Bovine genital campylobacteriosis • Bovine spongiform encephalopathy • Bovine tuberculosis • Bovine viral diarrhoea • Enzootic bovine leukosis • Haemorrhagic septicaemia • Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis • Infection with <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i>SC (Contagious bovine pleuropneumonia)* • Lumpy skin disease* • Theileriosis • Trichomonosis • Trypanosomosis (tsetse-transmitted)
Sheep and Goat Diseases and Infections	Equine Diseases and Infections
<ul style="list-style-type: none"> • Caprine arthritis/encephalitis • Contagious agalactia • Contagious caprine pleuropneumonia • Infection with <i>Chlamydophila abortus</i> (Enzootic abortion of ewes, ovine chlamydiosis) • Infection with peste des petits ruminants virus* • Maedi-visna • Nairobi sheep disease • Ovine epididymitis (<i>Brucella ovis</i>) • Salmonellosis (<i>S. abortusovis</i>) • Scrapie • Sheep pox and goat pox* 	<ul style="list-style-type: none"> • Contagious equine metritis • Dourine* • Equine encephalomyelitis (Western) • Equine infectious anaemia • Equine influenza • Equine piroplasmosis • Glanders* • Infection with African horse sickness virus* • Infection with equid herpesvirus-1 (EHV-1) • Infection with equine arteritis virus • Venezuelan equine encephalomyelitis*
Swine diseases and infections	Avian diseases and infections
<ul style="list-style-type: none"> • African swine fever* • Infection with classical swine fever virus* • Nipah virus encephalitis • Porcine cysticercosis • Porcine reproductive and respiratory syndrome • Transmissible gastroenteritis 	<ul style="list-style-type: none"> • Avian chlamydiosis • Avian infectious bronchitis • Avian infectious laryngotracheitis • Avian mycoplasmosis (<i>Mycoplasma gallisepticum</i>) • Avian mycoplasmosis (<i>Mycoplasma synoviae</i>) • Duck virus hepatitis • Fowl typhoid

Multiple species Diseases, Infections, and Infestations	Cattle Diseases and infections
	<ul style="list-style-type: none"> • Infection with avian influenza viruses* • Infection with influenza A viruses of high pathogenicity in birds other than poultry, including wild birds • Infection with Newcastle disease virus* • Infectious bursal disease (Gumboro disease) • Pullorum disease • Turkey rhinotracheitis
Lagomorph diseases and infections	Bee diseases, infections and infestations
<ul style="list-style-type: none"> • Myxomatosis • Rabbit haemorrhagic disease 	<ul style="list-style-type: none"> • Infection of honey bees with <i>Melissococcus plutonius</i>(European foulbrood) • Infection of honey bees with <i>Paenibacillus larvae</i>(American foulbrood) • Infestation of honey bees with <i>Acarapis woodi</i> • Infestation of honey bees with <i>Tropilaelaps</i> spp. • Infestation of honey bees with <i>Varroa</i> spp. (Varroosis) • Infestation with <i>Aethina tumida</i> (Small hive beetle).
Other diseases and infections	
<ul style="list-style-type: none"> • Camelpox • Leishmaniosis 	
Fish diseases	Mollusc diseases
<ul style="list-style-type: none"> • Epizootic haematopoietic necrosis* • Infection with <i>Aphanomyces invadans</i>(epizootic ulcerative syndrome) • Infection with <i>Gyrodactylus salaris</i> • Infection with HPR-deleted or HPR0 infectious salmon anaemia virus* • Infection with salmonid alphavirus • Infectious haematopoietic necrosis • Koi herpesvirus disease • Red sea bream iridoviral disease • Spring viraemia of carp • Viral haemorrhagic septicaemia* 	<ul style="list-style-type: none"> • Infection with abalone herpesvirus • Infection with <i>Bonamia exitiosa</i> • Infection with <i>Bonamia ostreae</i>* • Infection with <i>Marteilia refringens</i>* • Infection with <i>Perkinsus marinus</i> • Infection with <i>Perkinsus olseni</i> • Infection with <i>Xenohaliotis californiensis</i>
Crustacean diseases	Amphibians
<ul style="list-style-type: none"> • Crayfish plague (<i>Aphanomyces astaci</i>) • Infection with Yellowhead virus • Infectious hypodermal and haematopoietic necrosis • Infectious myonecrosis • Necrotising hepatopancreatitis • Taura syndrome • White spot disease • White tail disease 	<ul style="list-style-type: none"> • Infection with <i>Batrachochytrium dendrobatidis</i> • Infection with ranavirus

* indicates diseases that should be considered the notifiable in Ukraine, per the EU Association Agreement

APPENDIX VI: ENDEMIC, NOTIFIABLE, AND TRANSBOUNDARY HUMAN DISEASES IN UKRAINE

Disease/ Pathogen	Priority	HHS/ USDA Select Agent List	Endemic	Trans- boundary	Description	Source
Avian Influenza virus	Yes (Group III)	Yes	No	Yes	There is considerable human public health risk and transboundary concern for Ukraine due to the presence of the disease in neighboring Poland and Russia. There are guidelines with comprehensive recommendations to help Ukrainian healthcare workers establish sentinel site surveillance for severe respiratory disease and seasonal influenza. The MoH follows WHO's guidance for national pandemic planning.	^{145, 146, 147}
<i>Bacillus anthracis</i>	Yes (Group II)	Yes	Yes	No	<i>Bacillus anthracis</i> is found naturally in soil and commonly affects domestic and wild animals. Humans get anthrax when they breathe in spores, eat contaminated food, drink contaminated water, or inadvertently inoculate spores into the skin. There was one human case of anthrax in Ukraine in 2012.	^{148, 149, 150}
Botulism	Yes (Group II)	Yes	Yes	No	Botulism is a rare but serious, potentially fatal paralytic illness caused by a nerve toxin produced by the <i>Clostridium</i> bacterium. There were two outbreaks of botulism reported in Ukraine in 2015.	^{151, 152, 153}
Brucellosis	Yes (Group II)	Yes	No	Yes	The natural hosts for the <i>Brucella</i> organism are mammals: sheep, goats, swine, cattle, dogs, and marine mammals. <i>Brucella</i> can cause illness in humans exposed to the organism. Ukraine is at moderate risk for transboundary incursion due to the presence of the disease in neighboring Romania and Russia.	^{154, 155}
Cholera	Yes (Group II)	No	No	No	Cholera is an acute, diarrheal illness caused the bacterium <i>Vibrio cholera</i> , spread by ingestion of contaminated food or water. The infection is often mild, but can be life threatening. Ukraine's last outbreak was in 2009, but there is increased concern for reemergence in the conflict areas.	^{156, 157, 158}
<i>Coxiella burnetii</i>	Yes (Group II)	Yes	Yes	No	Q fever is a worldwide disease caused by the bacteria <i>Coxiella burnetii</i> . The primary reservoirs are cattle, sheep, and goats. Humans can be infected by inhaling air containing the organism, by tick bites, or by ingestion of unpasteurized milk or dairy products. There have been no cases of Q Fever reported in Ukraine in the last 10 years.	^{159, 160}
Crimean Congo Hemorrhagic	Yes (Group I)	Yes	Yes	No	The geographic distribution of Crimean Congo Hemorrhagic Fever (CCHF) coincides with that of <i>Hyalomma</i> ticks. The primary CCHF	^{161, 162}

Disease/ Pathogen	Priority	HHS/ USDA Select Agent List	Endemic	Trans- boundary	Description	Source
Fever virus					virus vector has been found in several countries including Ukraine. CCHF is of particular concern due to its high mortality rate.	
<i>Ebola</i>	Yes (Group I)	Yes	No	No	There have been trainings in many regions of Ukraine on detecting suspected cases of Ebola and procedures and precautions to take. The Ministry of Health (MoH) website contains information about Ebola and what the country is doing to prevent and prepare for cases.	¹⁶³ , ¹⁶⁴ , ¹⁶⁵
<i>Francisella tularensis</i>	Yes (Group II)	Yes	Yes	No	The presence of the natural foci of <i>F. tularensis</i> has been found in wild animals in Ukraine. Given the history of tularemia and its persistence in animal hosts, there is the possibility of (re)emergence in human populations.	¹⁶⁶ , ¹⁶⁷
Hepatitis C	Yes (Group II)	No	No	No	Hepatitis C is a concern for Ukraine because of its high prevalence. Approximately 3 to 8 percent of Ukraine's population is infected (about 1.3–5 million people). Treatment protocols have been created and funds from both the Ukrainian government and outside sources have been allocated for programs on prevention, diagnosis, treatment, and registration of affected patients.	¹⁶⁸ , ¹⁶⁹
HIV/AIDS including carriers	Yes (Group II)	No	No	No	HIV/AIDS prevention and treatment has long been a priority concern in Ukraine. It is estimated that 1.6 percent of the population is living with HIV/AIDS; the prevalence of the disease in Ukraine is among the highest in the WHO European region. There are many international organizations working in the Ukrainian health sector focusing their activities on the HIV/AIDS epidemic.	¹⁷⁰ , ¹⁷¹
Lassa	Yes (Group I)	Yes	No	No	Lassa fever is an acute viral hemorrhagic illness that currently occurs only in West Africa. The Lassa virus is transmitted to humans via contact with food or household items contaminated with rodent urine or feces, but person-to-person infections and laboratory transmission can also occur. Similar to Ebola, there is risk of transmission to Ukraine and other countries through global travel.	¹⁷² , ¹⁷³
Leishmaniasis	No	No	Yes	No	Leishmaniasis is a parasitic disease caused by infection with <i>Leishmania</i> parasites, which are spread by the bite of phlebotomine sand flies. There are two types of the disease: visceral (can be fatal) and cutaneous. While notification is mandatory, the disease is likely underreported in Ukraine. There is no awareness among doctors, and no protocol to follow for diagnosis and treatment, resulting in late and missed diagnoses. Medications for treatment are difficult to obtain, and there is no national control program.	¹⁷⁴ , ¹⁷⁵

Disease/ Pathogen	Priority	HHS/ USDA Select Agent List	Endemic	Trans- boundary	Description	Source
Leptospirosis	Yes (Group II)	No	Yes	No	Leptospirosis is a bacterial disease caused by bacteria of the genus <i>Leptospira</i> . In humans, it can cause no symptoms or a wide range of symptoms which sometimes mimic other diseases. Without treatment, leptospirosis can lead to serious and sometimes fatal complications. Leptospirosis is reported in all administrative territories of Ukraine almost every year. However, there has been a downward trend in the number of cases since 2001.	176, 177
Malaria, first diagnosed	Immediately Notifiable	No	No	No	Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected female mosquitoes. Ukraine is concerned about malaria because all the factors are there for it to reemerge. There are no units that monitor the water and the mosquito population is high.	178, 179
Measles	Immediately Notifiable	No	Yes	No	Deterioration of socio-economic conditions in Ukraine created the threat of the spread of communicable diseases, including vaccine-preventable diseases such as measles. Measles was targeted for elimination in Ukraine, but there continued to be outbreaks as recently as 2014. The conflict in the eastern part of the country carries significant public health risk and requires changing tactics of surveillance and epidemiological control against measles.	180, 181, 182
Meningococcal disease	Immediately Notifiable	No	No	No	Meningococcal meningitis is a serious bacterial infection of the thin lining around the brain and spinal cord. There was an outbreak of meningitis in Ukraine in the Lviv and Zhytomyr regions in July 2013. A total of 29 cases of meningitis affecting both children and adults were reported.	183, 184, 185
Mumps epidemic	Immediately Notifiable	No	Yes	No	Mumps is a viral infection, affecting primarily the salivary glands. The virus is transmitted by direct contact, or airborne droplets from the upper respiratory tract of infected people. The virus usually causes mild disease in children, but can lead to complications, such as meningitis and orchitis, in adults. Mumps can be prevented by immunization. Although there have not been outbreaks of mumps reported in Ukraine recently, there are concerns that low vaccination rates could spark outbreaks.	186, 187, 188
Pertussis, including parakashyluk	Immediately Notifiable	No	No	No	Pertussis, spread by person-to-person contact, is characterized by a whooping cough. There were outbreaks of pertussis as recently as 2014 in Ukraine. However, there are concerns that low vaccination rates will result in more outbreaks of this vaccine-preventable disease.	189, 190, 191
Poliomyelitis acute	Immediately Notifiable	No	No	No	Polio is a highly infectious disease caused by a human enterovirus member of the family of <i>Picornaviridae</i> virus. It invades the nervous	192, 193, 194

Disease/ Pathogen	Priority	HHS/ USDA Select Agent List	Endemic	Trans- boundary	Description	Source
					system, and can cause total paralysis in a matter of hours. The virus is transmitted by person-to-person spread mainly through the fecal-oral route. Health officials in Ukraine were afraid of a major polio outbreak, after it was announced in September 2015 that the disease had paralyzed two children in the southwestern region of Trans-Carpathia.	
Rabies	Yes (Group II)	No	No	No	Rabies is an infectious viral disease that is almost always fatal once clinical symptoms appear. Rabies affects domestic and wild animals, and is spread to humans through bites or deep scratches. There have been outbreaks in Ukraine of human rabies as recently as 2015 with six fatalities.	195, 196, 197
Rickettsial, including epidemic typhus, a disease	Yes (group II) Rickettsia prowazekii Rickettsia rickettsii	Rickettsia prowazekii	Yes	No	The vectors for R. prowazekii are human body louse, flying squirrel ecto-parasites, and possibly some ticks. The vector for R. rickettsia are ticks, and rodents are the animal reservoir. Most symptomatic rickettsial diseases cause moderate illness, but some can be fatal. There have been no reports of rickettsial disease in Ukraine in recent years.	198, 199
Rubella	Immediately Notifiable	No	Yes	No	Rubella is an acute, contagious viral infection, which is generally mild in children, but has serious consequences in pregnant women (e.g., fetal death or congenital defects), especially if it occurs during the first trimester. Humans are the only known host and transmit the virus when infected people sneeze or cough. There was an outbreak of 18 cases of rubella in Lviv in 2011. Low vaccination rates in Ukraine may cause additional outbreaks.	200, 201, 202, 203
Salmonella	Immediately Notifiable	No	No	No	Salmonellosis, caused by the bacteria <i>salmonella</i> , is one of the most common and widely distributed foodborne diseases. There was an outbreak of salmonella in Ukraine in 2011 (14 cases) associated with contaminated poultry products.	204, 205, 206
Shigella	Immediately Notifiable	No	No	No	Shigellosis is a diarrheal disease caused by a group of bacteria called <i>Shigella</i> . There are sporadic outbreaks of shigellosis in Ukraine. There was one in 2011 and then again in 2015.	207, 208, 209
Tick-Borne Encephalitis (TBE)	Yes I(Group II)	Yes	Yes		Currently, the highest incidence of clinical cases of TBE are being reported in the Baltic States, the Russian Federation, and Slovenia. Other countries that have reported cases within their territories, or that are considered to be at risk because of focally high prevalence of the virus in ticks includes Ukraine.	210, 211
Tuberculosis of the respiratory system, including destructive	Immediately Notifiable	No	No	No	Tuberculosis (TB) is caused by the bacteria <i>Mycobacterium tuberculosis</i> , most often affecting the lungs. TB is spread from person to person through the air. It is curable and preventable. The TB epidemic has been costly in Ukraine because it has been characterized by	212, 213, 214, 215

Disease/ Pathogen	Priority	HHS/ USDA Select Agent List	Endemic	Trans- boundary	Description	Source
					widespread multi-drug resistant (MDR) and extensively drug-resistant (XDR) tuberculosis, relatively high mortality from inappropriately or untreated TB, and increasing TB/HIV co-infection. The chronic threat of TB infection persists throughout Ukraine. The United States Agency for International Development (USAID) has helped improve TB infection control practices by promoting implementation of up-to-date TB infection control measures, lobbying for national and regional infection control policies, and provided support to regional healthcare staff.	
Varicella	Immediately Notifiable	No	No	No	Chicken pox is caused by the varicella zoster virus. It is spread easily through the air when a person who has chicken pox coughs or sneezes. It can also spread by touching an infected person's blisters. Chicken pox is usually a mild uncomfortable ailment, but can be serious and even life-threatening, especially in babies and people with weakened immune systems. Ukraine has 100-120 thousand cases of varicella annually. Currently, many children are not vaccinated against varicella. This may cause a large-scale epidemic of chicken pox in Ukraine.	216, 217, 218
West Nile Fever	Yes (Group II)	No	Yes	No	West Nile virus (WNV) is a mosquito-borne virus of global importance. Initially a febrile illness in humans, it can progress to encephalitis, occasionally with fatal outcomes. In Ukraine, the earliest reports confirming the presence of WNV infections in humans dates back to the 1970s, with cases confirmed as recently as 2011 and 2012.	219, 220

APPENDIX VII: ENDEMIC, NOTIFIABLE, AND TRANSBOUNDARY ANIMAL DISEASES IN UKRAINE

Disease/ Pathogen	Priority	HHS /USDA Select Agent List	Endemic	Trans- boundary	Description	Source
African swine fever (ASF)	Yes Immediately Notifiable	Yes	Yes	Yes	Transboundary disease first reported in 2012. The most current case was reported in March 2016. ASF is an extremely contagious, viral disease of pigs with significant economic impact.	^{221, 222}
<i>Bacillus anthracis</i> (Anthrax)	Yes	Yes	Yes	Yes	Anthrax is endemic to the country. More than 23,000 animal outbreaks have been reported in more than 8,000 Ukrainian sites from years 1913 to 2012.	²²³
Blue Tongue virus	Yes	No	No	Yes	Blue tongue is a viral disease that is transmitted via insect bites from insects that have fed from infected animals. In 2011, Ukraine banned the import of infected cattle from Bulgaria to minimize the chances of the disease emerging in Ukraine. Other similar bans had been implemented in prior years.	²²⁴
Bovine Leukemia	Yes	No	Yes	No	Bovine leukemia virus has been reported to be consistently present in the country for the last 6 years. Infected cattle suffer loss of milk productivity. The European Union has a Bovine Leukemia control program.	²²⁵
Bovine Spongiform Encephalopathy	Yes	No	No	Yes	Bovine spongiform encephalopathy has not been reported in Ukraine for more than 5 years; however, because of its economic loss and potential of zoonotic risk, it has been regarded as a disease of high importance.	²²⁶
Bovine Tuberculosis	Yes	No	Yes	Yes	Bovine tuberculosis has been consistently detected in Ukraine for the past 6 years. Bovine tuberculosis is important because of its high prevalence and zoonotic potential.	²²⁷
Brucellosis	Yes	Yes	No	Yes	Brucellosis is important owing to its zoonotic potential. The country was declared brucellosis-free in 2008. However, the disease is highly prevalent in its neighboring country The Russian Federation.	²²⁸
Chlamidiosis	Yes	No	No	Yes	Chlamidiosis refers to a disease that causes spontaneous abortions in small ruminants. It is of zoonotic concern.	²²⁹
Classical swine fever virus	Yes	Yes	No	Yes	This transboundary, re-emergent disease was reported in January 2015. Previously, The Most recent time it was detected in the country was 2001. Classical swine fever is an extremely contagious and economically significant viral disease of pigs.	^{230, 231}
<i>Coxiella burnetii</i>	Yes	Yes	Yes	Yes	This zoonotic pathogen is present in livestock	^{232, 233}

Disease/ Pathogen	Priority	HHS /USDA Select Agent List	Endemic	Trans- boundary	Description	Source
(Q fever)					and wildlife; the most common infectious carriers are ticks. This pathogen is of importance owing to its zoonotic potential. No outbreaks have been reported in livestock in the last 6 years.	
<i>Congo-Crimean Hemorrhagic Fever virus</i>	Yes	Yes	Yes	Yes	This zoonotic pathogen has reemerged in Ukraine in the last 10 years. It is transmitted via ticks that feed on infected animals and subsequently infect humans.	²³⁴
Foot-and-mouth disease (FMD) virus	Yes	Yes	No	Yes	FMD is highly contagious disease of cattle, swine, small ruminants, and deer. This disease is of concern because it can spread quickly and cause significant economic losses. The last case was reported in 1988; however, cases have been reported in neighboring countries as recently as 2014.	^{235, 236}
Highly pathogenic avian influenza (HPAI) virus	Yes Immediately Notifiable	Yes	No	Yes	HPAI was reported in neighboring Russian Federation on June 2015, posing a significant transboundary risk and potential of great economic loss if reintroduced to the country.	²³⁷
Leptospirosis	Yes	No	Yes	Yes	Ukraine has recognized leptospirosis as a disease of great zoonotic concern. It has been reported in significant numbers for the last 5 years.	²³⁸
Newcastle disease virus	Yes	Yes	Yes	Yes	Newcastle virus is present in 21 oblasts of Ukraine and in the Crimean peninsula. This disease is important because it causes significant economic losses in poultry production.	²³⁹
Rabies virus	Yes	No	Yes	N/A	Rabies is endemic in Ukraine and of great importance to the State Veterinary and Phytosanitary Service. The main zoonotic risk for exposure is to wildlife and stray or unvaccinated companion animals.	²⁴⁰
Salmonellosis	Yes	No	Yes	Yes	Ukraine is focused in food security so it can export more products to other countries. Control of salmonella is vital to achieve this goal.	²⁴¹
Schmallenberg virus	Yes	No	No	Yes	Schmallenberg virus primarily affects the large and small ruminant populations and causes economic losses by lowering productivity of animals and causing congenital malformations of their offspring. Food security is of great importance, and therefore cattle and meat from countries where the virus is present have been banned from entering Ukraine.	^{242, 243}
Trichinellosis <i>Trichinella spiralis</i>	Yes	No	Yes	Yes	This parasite is contracted by eating undercooked meat (pork). Control of trichinella infections is of great importance because it is directly related to food security.	²⁴⁴

APPENDIX VIII: ACRONYMS

Acronym	Description
A&AS	Advisory and Assistance Support
AAIR	Agency for Animal Identification and Registration
AI	Avian influenza
AIDS	Acquired immune deficiency syndrome
ARS	Agricultural Research Service
ASF	African swine fever
BEP	Biological Engagement Program
BS&S	Biosafety and biosecurity
BSC	Biosafety cabinets
BSL	Biosafety level
BSV	Biosurveillance
BTRIC	Biological Threat Reduction Integration Contractor
CBEP	Cooperative Biological Engagement Program
CCHF	Crimean Congo hemorrhagic fever
CCTV	Closed-circuit television
CDC	Centers for Disease Control and Prevention
CE	Continuing education
CEN	Comité Européen de Normalisation
CONOPs	Concept of operations
CPA	Central public authority
CSES	Central Sanitary Epidemiological Station
DakKS	Deutsches Akkreditierungsstelle GmbH
DALY	Disability-adjusted life year
DOS	Department of State
DTRA	Defense Threat Reduction Agency
EBRD	European Bank for Reconstruction and Development
ECDC	European Centre for Disease Prevention and Control
EDP	Especially dangerous pathogens
EIDSS	Electronic Integrated Disease Surveillance System
EOC	Emergency operations center
EQAS	External quality assessment scheme
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FMD	Foot-and-mouth disease
FY	Fiscal year
GDP	Gross domestic product
GMO	Genetically modified organisms
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HIV	Human immunodeficiency virus
HPAI	Highly pathogenic avian influenza

Acronym	Description
ICT	Information and communication technology
IECVM	Institute of Experimental and Clinical Veterinary Medicine
IFRC	International Federation of Red Cross and Red Crescent Societies
IHR (2005)	International Health Regulations 2005
IMC	International Medical Corps
IMF	International Monetary Fund
ISO	International Organization for Standardization
IT	Information technology
IVM	Institute of Veterinary Medicine
LIMS	Laboratory information management system
LRIEH	Lviv Research Institute of Epidemiology and Hygiene
MFA	Ministry of Foreign Affairs
MoAPF	Ministry of Agrarian Policy and Food
MoD	Ministry of Defense
MoH	Ministry of Health
MSF	Medecins Sans Frontieres
NAAS	National Academy of Agrarian Sciences
NAAU	National Accreditation Agency of Ukraine
NFP	National focal point
NGO	Non-governmental organization
OIE	World Organisation of Animal Health
OLC	Oblast Laboratory Center
PACS	Pathogen Asset Control System
PCR	Polymerase chain reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Public Health Center
PPE	Personal protective equipment
PVS	Performance of Veterinary Services
RDVL	Regional Diagnostic Veterinary Laboratory
RTCADD	Research Training Center for Animal Disease Diagnostics
SDC	Swiss Agency for Development and Cooperation
SES	Sanitary Epidemiological Station
SESU	State Emergency Service of Ukraine
SME	Subject matter experts
SOP	Standard operating procedure
SSRILDVSE	State Research Institute for Laboratory Diagnostics and Veterinary-Sanitary Expertise
SSCIBSM	State Sanitary Control Institute of Biotechnology and Strains of Microorganisms
SSES	State Sanitary Epidemiological Service
SSFSCP	State Service on Food Safety and Consumer Protection
STCU	Science and Technology Center of Ukraine
SVPS	State Veterinary and Phytosanitary Service
TB	Tuberculosis

Acronym	Description
UCDC	Ukraine Center for Socially Dangerous Disease Control
UCDCM	Ukrainian Center for Disease Control and Monitoring
UMA	Ukraine Medical Association
UN	United Nations
UNHCR	United Nations High Commissioner for Refugees
URAPI	Ukrainian Research Anti-Plague Institute
US	United States
USAID	United States Agency for International Development
USD	United States dollars
USDA	United States Department of Agriculture
USG	United States Government
WAHIS	World Animal Health Information System
WHO	World Health Organization
WRAIR	Walter Reed Army Institute of Research
WTO	World Trade Organization

APPENDIX IX: GAPS

Human Health System

Gaps: Disease Detection

Gap	Explanation	Root Cause	Recommendations
Healthcare Worker Distribution	There is an uneven geographical distribution of healthcare workers with most practicing in the urban areas.	Funding	Form a multisectoral working group to discuss ways to mitigate the scarcity, misdistribution, and turnover of the healthcare workforce. Topics of discussion would include identification of where the needs are in the country, specific recruitment and retention efforts, budgeting/funding sources, and role of universities in preventing “brain drain.”
Primary Healthcare Structure	There have been ongoing efforts to improve access to care through the establishment of primary healthcare in Ukraine. The system, however, has not yet reached its goal, especially in the rural areas.	Governance	Work with MoH and the Primary Healthcare Working Group to implement strategies to further stated primary healthcare access priority.
Physician Continuing Education	Mandatory recertification for physicians does not require any courses in disease detection or reporting.	Legislation and Regulation, Education and Training, Funding	Form working group with government and medical education facility representation to create legislation for mandatory inclusion of disease detection and reporting in recertification classes and to discuss funding sources.
Infection Control Practices	Healthcare providers are unaware of national infection control guidelines and/or do not always follow them.	Education and Training, Funding	Convene working group with government, hospital, clinic, and medical education facility representation to determine whether there is a lack of guidelines and the quality of existing guidelines, and to develop a plan for distribution, education, and compliance with the use of infection control guidelines.
Clinical Guidelines	Clinical guidelines do not exist for diseases caused by pathogens of security concern. Hospitals develop local protocols for diagnosis and treatment of diseases, and it is reported that they are approved by local healthcare departments, but this process could lead to nonstandardized care. While physicians receive training in their basic education, there is no system to educate on new protocols and no systematic auditing for compliance.	Ideology, Education and Training	Collaborate with State Expert Center to develop clinical guidelines for diseases caused by pathogens of security concern. Collaborate with oblast and rayon healthcare departments toward standardization of local protocols. Discuss with universities and post-graduate facilities how the education of new protocols can be assured. Work with a group of hospitals to establish auditing to assure accurate use of clinical guidelines/protocols. Work with MoH to discuss/encourage possible needed legislation.

Gaps: Laboratory Diagnostics

Gap	Explanation	Root Cause	Recommendations
Laboratory Quality Management	With no national quality office, Ukraine has struggled with consistent oversight for compliance with quality standards. In	Governance	Support the new Quality Unit under the PHC, which should improve quality oversight for the laboratory network.

Gap	Explanation	Root Cause	Recommendations
System	addition, there is no national EQAS, and there is a lack of standardization of procedures and laboratory training, including training for sample collection and transport, working with EDPs, and laboratory quality management.		Support efforts to improve the laboratory quality management system, including developing a national EQAS, training, and standardization of national procedures.
Human Resources Development	There is no national training program or office to coordinate required trainings for laboratory staff.	Governance, Education and Training	Support PHC's efforts to fill this gap through its training center. The training program will include trainings for sample collection, packaging, and shipping; biosafety and biosecurity; and SOPs for diagnostic testing.
Equipment Maintenance Practices	The culture of equipment maintenance is generally absent, leaving equipment idle, unsafe to use, or potentially producing inaccurate test results.	Funding	Incorporate maintenance of equipment into regulations. Include preventive maintenance agreements in the annual budget. Encourage establishment of biomedical engineering departments within MoH to routinely maintain equipment.
Reagents and Consumables	Expenditures on diagnostic kits and consumables are limited.	Funding	Leverage scientific expertise and functionality of the Institute of Veterinary Medicine (IVM) and State Sanitary Control Institute of Biotechnology and Strains of Microorganisms (SSCIBSM) to manufacture diagnostic kits for PHC upon validation and approval.
Electronic Laboratory Reporting System	There is no system wide implementation of LIMSs.	Governance	Identify LIMS utility and install system in a select number of sites.

Gaps: Epidemiological Analysis and Investigation

Gap	Explanation	Root Cause	Recommendation
System Coordination and Integration	Functional units within the surveillance system do not coordinate efforts effectively. One unit collects data, but legislation prevents it from implementing control measures.	Funding, Governance	Improve the integration among the surveillance subsystems to eliminate duplication of functions and inappropriate use of resources.
Analysis of Disease Trends	Data analysis consists of descriptive statistics. There is minimal analysis of disease data to understand disease trends and risk factors.	Education and Training, Ideology	Develop advanced modern analytic capabilities that are capable of analyzing trends, determining risk factors, etc. Provide advanced training and apprenticeship of key analytical epidemiologists.
Data Quality	Data quality is poor, and there are no mechanisms to monitor the quality of data.	Education and Training, Ideology	Train epidemiologists on methods to monitor and evaluate data quality.
Baseline Disease Data	Baseline data exist only for influenza, TB, and HIV/AIDS. There is minimal baseline data for other diseases to inform alert or epidemic thresholds.	Education and Training, Ideology	Train epidemiologists to generate baseline data and calculate thresholds.
Human Resources	Reforms have significantly reduced personnel, and there is a low retention rate of trained graduates in the public health system, causing existing staff to	Funding, Education and Training	Redistribute and optimize staff functions, implement mechanisms for retaining qualified staff.

Gap	Explanation	Root Cause	Recommendation
	be overburdened. Current staff capabilities are limited to outdated Soviet techniques in surveillance and disinfection.		
SOPs for Outbreak Investigation and Response	The guidelines for responding to an outbreak are outdated and mired in legislation.	Governance	Train personnel on appropriate analytical and investigative epidemiological methods; develop SOPs for investigation of diseases of public health importance.

Gaps: Reporting and Communications

Gap	Explanation	Root Cause	Recommendation
Outdated Notifiable Disease List	The current list of notifiable diseases does not include emerging diseases or pathogens of international health concern. Daily reporting of more than 60 conditions is very costly and brings little benefit.	Legislation	Update normative/legislative base to prioritize notifiable diseases, include recently emerging priority diseases, and eliminate those of low national priority.
Timely and Complete Reporting	Underreporting is a persistent problem. Reporting of outbreaks is discouraged owing to fear of punishment for failing to prevent or control them. The reporting system is laborious and paper-based.	Ideology, Governance	Establish a web-based reporting system, preferably capable of conducting basic quality checks, analytic functions, and generating key alerts. Offer incentives for reporting; enforce penalties for not reporting.
Parallel Surveillance Systems	TB and HIV surveillance data are siloed; these data are collected and analyzed independently of national disease data.	Funding, Governance	Develop standards for incorporating data from other systems into the national surveillance system.
Integration of Case Definitions into Clinical Guidelines	Protocols exist for reporting diseases, but without uniform case definition, clinicians may use various criteria for case reporting.	Legislation, Governance, Ideology	Integrate case definitions into clinical protocols, particularly for disease of security concern.
Data Sharing Between Rayons and Oblasts	Flow of information is linear from the lowest administrative level to the central level. Oblasts do not know the epidemiological situation in neighboring oblasts, which could delay disease detection.	Governance	Develop communication protocols between rayons and oblasts, or provide access to data from other oblasts.
Data Exchange Standards	There are no data exchange standards.	Governance	Develop data exchange protocols and standards to improve interoperability of information systems.
ICT Infrastructure	There is a lack of consistent ITC infrastructure.	Funding	Upgrade healthcare facilities to support basic IT functionality. Provide computers, electricity, and Internet/network capabilities.

Gaps: National Legislative and Regulatory Framework

Gap	Explanation	Root Cause	Recommendation
Dangerous Pathogen Regulations	Biosecurity regulations do not exist for pathogens of security concern.	Ideology	Develop regulations for pathogens of security concern that are similar to the U.S. Select Agent Program or Comité Européen de Normalisation (CEN) Workshop Agreement 15793.

Gap	Explanation	Root Cause	Recommendation
Outdated National BS&S Regulations	BS&S regulations are outdated and do not align with international guidelines.	Ideology	Develop regulations that align with international BS&S guidelines.
Fragmented BS&S Regulations	BS&S regulations are fragmented between different ministries.	Legislation and Regulation	Consolidate BS&S regulations.
Biosafety Level (BSL) Guidelines	Risk groups and risk assessments are not used to determine biocontainment. Internationally accepted BSL guidelines are not used.	Legislation and Regulation	Develop regulations that identify pathogen risk groups and require risk assessments to determine biocontainment.

Gaps: Facility-Level Biorisk Management Systems and Culture

Gap	Explanation	Root Cause	Recommendation
Defined BS&S Roles	Roles and responsibilities of BS&S personnel are not clearly defined.	Funding, Legislation and Regulation	Support PHC to develop updated legislation that aligns with international guidelines. Assist with resources needed to support onsite biosafety officers.
Formally Assigned BS&S Personnel	Biosafety officer positions are not filled by dedicated BS&S personnel with formal biosafety training.	Funding, Training and Education	Recruit staff with experience in BS&S. Provide opportunities for personnel filling BS&S positions to attend trainings and conferences to further expertise.
Formal BS&S Training	Current legislation and governing entities do not provide clear training requirements, or clear legislation on which to focus training.	Training and Education, Legislation and Regulation	Provide advisory assistance to implement training programs that incorporate updated BS&S regulations.
Facility Infrastructure	Facilities are located in old buildings with numerous infrastructure and utility issues. Infrastructure improvements made during previous engagement have not been sustained.	Funding	Focus engagements on facilities at which the government is likely to support ongoing operations beyond CBEP engagement.
Equipment Maintenance	Facilities do not have resources to maintain, repair, or replace biosafety equipment.	Funding	Assist with resources to upgrade equipment and facilitate development of long-term maintenance plans.
Formal Risk Assessment Process	Policies and procedures are not based on formal risk assessment process	Training and Education, Legislation and Regulation	Implement national regulations that require the employment of best practices and international guidelines. Train BS&S staff and principal investigators to understand and conduct risk assessments.
Incident Reporting	There is no system in place to report and track laboratory incidents.	Legislation and Regulation	Provide advisory assistance to incorporate into updated BS&S legislation.
BS&S Signage	Not all facilities display proper signage indicating biohazard areas.	Legislation and Regulation	Provide advisory assistance to incorporate requirements into updated BS&S framework. Provide signage materials to facilitate alignment with WHO regulations.

Gaps: Pathogen Consolidation and Security

Gap	Explanation	Root Cause	Recommendations
Pathogen Consolidation	Several institutes have large collections of pathogens of security concern, and institutional leadership opposes consolidation for political reasons.	Ideology	As institutes merge under the PHC, identify target facilities to serve as repositories and initiate pathogen consolidation.

Gap	Explanation	Root Cause	Recommendations
Physical Security	Security features such as grilles on windows, electronic access control, CCTV, volumetric sensors, and integrated alarm systems are broken or not in use.	Funding, Legislation and Regulation	Identify mechanisms to support maintenance and sustainment of security features.
Material Control and Accountability	Paper logbooks are used to track samples of pathogens of security concern, creating difficulties in maintaining an accurate inventory and chain of custody. Wax seals, which are an outdated technique, are used to monitor access to pathogens.	Funding, Legislation and Regulation	Implement PACSs at select facilities, which will improve pathogen inventory and tracking.
Personnel Security	Personnel do not undergo background checks to ensure suitability prior to accessing pathogens of security concern.	Funding, Legislation and Regulation	Develop system for verifying academic and professional backgrounds of personnel and for performing criminal background investigations.
Transportation Security	Chain of custody records are not maintained during sample transport, which may lead to loss or theft of material.	Funding, Legislation and Regulation	Develop procedures for chain of custody during sample transport.

Animal Health System

Gaps: Disease Detection

Gap	Explanation	Root Cause	Recommendations
Continuing Education Requirements	CE is mandatory for veterinarians every 5 years.	Legislation and Regulation, Training and Education	CE is intended to further advance knowledge and keep veterinarians up to date on the latest advancements in the veterinary field. Require CE at least every 1 to 3 years, ideally yearly.
Professional Licensure	State veterinarians are not required to take a national licensing examination upon graduation, which results in variability in general veterinary knowledge among veterinary practitioners. Private veterinarians are required to obtain a license to practice; however, the only requirements to obtain a license are personal identification information and veterinary diploma. An examination is not required.	Governance, Training and Education	Assemble a working group to create a statutory body to establish a standardized national veterinary licensing exam. Licensing exam is intended measure student's competencies to be able to practice veterinary medicine. Ideally, license all veterinarians (state and private).
Private Veterinarians	Private veterinarians are only allowed to deliver preventive care.	Legislation and Regulation	Create a working group to revise private veterinarians' role in disease detection and revise current laws/regulations.
Clinical Guidelines	Clinical guidelines (orders) exist for a large number of diseases; however, these guidelines are not comprehensive and are not revised frequently.	Legislation and Regulation, Governance	Create a working group composed of higher and lower jurisdictional levels, academia, and researchers to standardize creation and revision of clinical guidelines.
Compensation	Farmers do not receive compensation in the event of a disease outbreak that	Funding, Legislation and Regulation	Create a working group to formulate compensation regulations for farmers

Gap	Explanation	Root Cause	Recommendations
	requires the elimination of a herd or flock; consequently, farmers delay contacting the veterinary services rather than reporting the earliest signs of a disease outbreak.		who lose livestock as a result of a public health emergency. Elevate to Cabinet of Ministers for consideration.
Standardized Veterinary Education	There is a lack of clinical or hands-on training by some veterinary schools.	Training and Education, Governance	Create a statutory body that has oversight for accreditation of veterinary schools in the country.

Gaps: Laboratory Diagnostics

Gap	Explanation	Root Cause	Recommendation
Laboratory Quality Management System	With no national quality office, Ukraine has struggled with consistent oversight for compliance with quality standards. In addition, there is a lack of standardization of procedures and laboratory training, including training for sample collection and transport, working with EDPs, and laboratory quality management.	Governance	Support efforts to improve the laboratory quality management system, including developing a national EQAS, training, and standardization of national procedures.
Human Resources Development	There is no national training program or office to coordinate required trainings for laboratory staff.	Governance, Training and Education	Develop a national training program for detection and identification of organisms that includes EDP training on diagnostic procedures and sample collection and transport.
Equipment Maintenance Practices	The culture of equipment maintenance is generally absent, leaving equipment idle, unsafe to use, or potentially producing inaccurate test results.	Legislation and Regulation, Funding,	Incorporate maintenance of equipment into regulations. Include preventive maintenance agreements in the annual budget.
Reagents and Consumables	Expenditures on diagnostic kits and consumables are limited.	Legislation and Regulation, Funding,	Leverage internal scientific expertise and functionality to manufacture diagnostic kits for SVPS upon validation and approval.

Gaps: Epidemiological Analysis and Investigation

Gap	Explanation	Root Cause	Recommendation
SOPs for Outbreak Response	The guidelines for responding to an outbreak are outdated, and not all disease-specific protocols are driven by timelines.	Legislation and Regulation, Governance	Establish protocols for mobilizing an outbreak response team.
Veterinary Epidemiologists	Epidemiologists are not part of the veterinary health system, and the existing epidemiology training received by veterinarians is not on par with international standards.	Ideology, Training and Education, Ideology	Train veterinarians in modern analytical and investigative methods in epidemiology. Integrate veterinary epidemiologists into the national surveillance system.
Analysis of Disease Trends	Analysis occurs only at the central level, and there is no analysis of disease data to understand disease trends and risk factors.	Ideology, Training and Education	Train veterinary epidemiologists in analytic and investigative epidemiology.
Baseline Disease Data	There are no baseline data to inform alert or epidemic thresholds.	Ideology, Training and Education	Train epidemiologists to generate baseline data and calculate thresholds.
Case Definitions	Standardized case definitions do not exist; clinicians may use various	Legislation and Regulation,	Develop standardized case definitions for priority diseases, reportable diseases, and

Gap	Explanation	Root Cause	Recommendation
	criteria for case reporting.	Governance, Ideology	diseases of security concern. Integrate case definitions into clinical protocols.
Human Resource Capacity	Training in epidemiological analysis is not robust in internationally accepted epidemiological methods.	Training and Education	Provide advanced training and apprenticeships for key analytical epidemiologists.

Gaps: Reporting and Communication

Gap	Explanation	Root Cause	Recommendations
Timely and Complete Reporting	Underreporting is a primary challenge; farmers fear that their herds will be culled, and veterinary health professionals fear that failing to control an outbreak would result in termination.	Ideology, Governance	Establish an electronic reporting system and incentives for reporting.
Data Sharing Between Rayons and Oblasts	Oblasts do not know the epidemiological situation in neighboring regions, oblasts could delay disease detection.	Governance	Develop communication protocols between rayons and oblasts, or provide access to data from other oblasts. Improve communication from the national level down to the local level.
Priority Disease List	Reporting all the OIE notifiable diseases is costly and time consuming.	Legislation, Regulation, Funding	Update legislation to prioritize a select number of emerging diseases of security concern.
Data Exchange Standards	There are no data exchange standards.	Governance	Develop data exchange protocols and standards to improve interoperability of information systems.
ICT Infrastructure	There is a lack of consistent ICT infrastructure.	Funding	Upgrade healthcare facilities to support basic IT functionality. Provide computers, electricity, and Internet/network capabilities.

Gaps: National and Regulatory Frameworks

Gap	Explanation	Root Cause	Recommendation
Pathogens of Security Concern Regulations	Biosecurity regulations do not exist for pathogens of security concern.	Legislation and Regulation	Develop regulations for pathogens of security concern that are similar to the US Select Agent Program or CEN Workshop Agreement 15793.
Outdated National BS&S Regulations	BS&S regulations are outdated and do not align with international guidelines.	Ideology, Legislation and Regulation	Develop regulations that align with international BS&S guidelines.
Fragmented BS&S Regulations	BS&S regulations are fragmented between different ministries.	Legislation and Regulation	Consolidate BS&S regulations.
BSL Guidelines	Risk groups and risk assessments are not used to determine biocontainment. Internationally accepted biosafety level guidelines are not used.	Legislation and Regulation	Develop regulations that identify pathogen risk groups and require risk assessments to determine biocontainment.

Gaps: Facility-Level Biorisk Management Systems and Culture

Gap	Explanation	Root Cause	Recommendation
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Gap	Explanation	Root Cause	Recommendation
BS&S Roles and Responsibilities	Facilities do not have full-time biosafety officers.	Legislation and Regulation, Funding	Provide advisory assistance to improve alignment with international guidelines. Assist with resources needed to hire or train biosafety officers.
Formal BS&S Training	Formal training is needed to consistently and properly instruct personnel on BS&S. In healthcare facilities, disease-specific training is burdensome and may lead to inconsistent BS&S practices.	Legislation and Regulation, Governance, Funding, Training and Education	Provide assistance to implement training programs that incorporate updated BS&S regulations.
Equipment Maintenance	Limited funding will limit the ability to properly maintain equipment.	Legislation and Regulation, Funding	Assist with resources to upgrade equipment and facilitate development of long-term maintenance plans.
Formal Risk Assessment Process	Policies and procedures are not based on formal risk assessment process	Legislation and Regulation, Training and Education	Implement national regulations that require the employment of best practices and international guidelines. Train BS&S staff and principal investigators to understand and conduct risk assessments.
BS&S Signage	Not all facilities display proper signage indicating biohazard areas.	Legislation and Regulation	Provide signage materials to facilitate alignment with WHO regulations.

Gaps: Pathogen Consolidation and Security

Gap	Explanation	Root Cause	Recommendations
Physical Security	Gaps in physical security, such as incomplete fencing and missing grilles on windows, lead to vulnerabilities at facilities. Maintenance for BS&S measures, such as access control and alarm systems, is limited because of inadequate funding, which increases the likelihood for failure.	Legislation and Regulation, Funding	Assess physical security measures to identify gaps and address gaps. Identify mechanisms to maintain existing physical security measures.
Material Control and Accountability	Paper logbooks are used to track samples of pathogens of security concern creating difficulties in maintaining an accurate inventory and chain of custody. Wax seals, which are an outdated technique, are used to monitor access to pathogens.	Legislation and Regulation, Funding	Implement PACS at select facilities to improve pathogen inventory and tracking.
Personnel Security	Personnel do not undergo background checks to ensure suitability prior to accessing pathogens of security concern.	Legislation and Regulation, Funding	Develop a system for verifying academic and professional backgrounds of personnel and for conducting criminal background investigations.
Transportation Security	Chain of custody records are not maintained during sample transport, which may lead to loss or theft of material.	Legislation and Regulation, Funding	Develop procedures for chain of custody during sample transport.

Gaps: One Health

Gap	Explanation	Root Cause	Recommendations
Multisectoral Communications	There is no formal protocol for inter-agency communication.	Legislation and Regulation	Form a multisectoral working group to create legislation that would

Gap	Explanation	Root Cause	Recommendations
	Communications are reactive and ad hoc during outbreaks.		clarify communication and disease reporting roles prior to and during an outbreak.
One Health in Training Curricula	The One Health educational approach does not exist between the human and animal sectors.	Funding, Training and Education	Form a working group with both human and veterinary medical universities to create joint educational efforts.
Trained Outbreak Response Teams	There is a shortage of trained interdisciplinary teams and staff to manage outbreaks and conduct investigations.	Funding, Training and Education	Create a roster of trained personnel from both sectors who can form a team that can respond to a zoonotic outbreak.
Zoonotic Pathogens/ Disease List	A list of common zoonotic pathogens or diseases does not exist.	Legislation and Regulation	Develop a list of priority zoonotic diseases and pathogens that require intersectoral notification.
Outbreak Exercises	Intersectoral outbreak exercises do not exist.	Training and Education	Develop workshops or exercises to assess response capacity to zoonotic disease threats.
One Health Legislation	One Health legislation does not exist.	Legislation and Regulation	Form a multisectoral working group to create One Health legislation.

¹ The team of interdisciplinary SMEs is composed of members of the DTRA/CBEP Assistance and Advisory Support (A&AS) contract team.

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