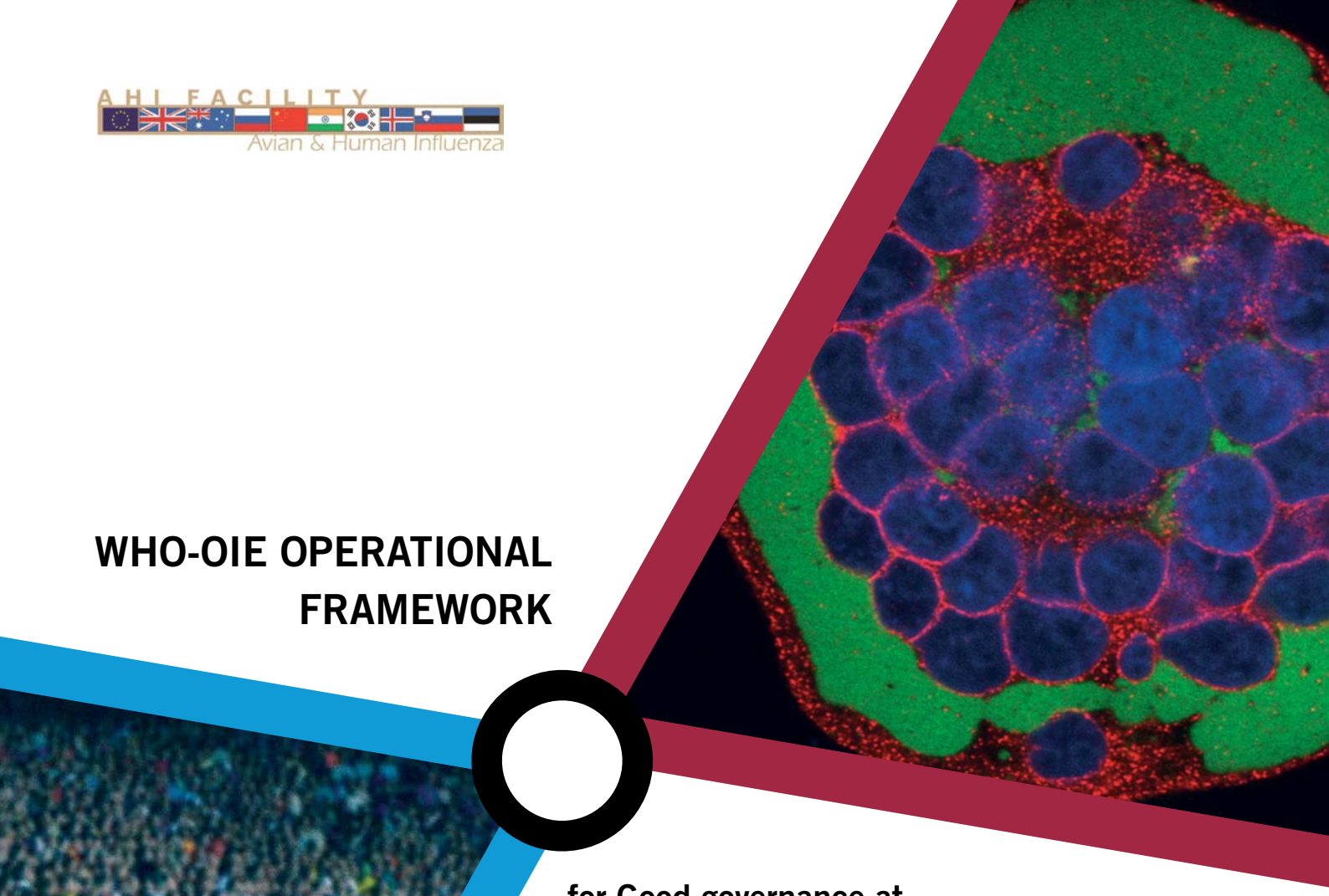
AHI FACILITY
Avian & Human Influenza



WHO-OIE OPERATIONAL FRAMEWORK

for Good governance at the human-animal interface:

Bridging WHO and OIE tools for the assessment of national capacities

World Health Organization

OIE WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

WORLD BANK GROUP

WHO-OIE OPERATIONAL FRAMEWORK
for Good governance at the human-animal interface:

Bridging WHO and OIE tools for the assessment
of national capacities

World Health Organization

OIE WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

WORLD BANK GROUP

ACKNOWLEDGMENTS

This Operational Framework was prepared by the World Health Organization (WHO) in collaboration with the World Organisation for Animal Health (OIE).

Assistance and expertise in writing the Operational Framework was provided throughout the development process by a team from WHO and the OIE consisting of Rajesh Sreedharan, Sebastian Cognat and Virginie Dolmazon of WHO, Stéphane de La Rocque of OIE–WHO, and Susan Corning, Jennifer Lasley and Emily Tagliaro of OIE. The final version of the Operational Framework was consolidated by Stéphane de La Rocque and Emily Tagliaro.

The organisation of the IHR/PVS Pathway National Bridging Workshops would not have been possible without the support from François Caya and his team in the OIE Regional Activities Department (HQ), staff from the OIE Regional and Sub-Regional Representations, staff from the EURO and SEARO WHO Regional Offices and staff from WHO country offices in Azerbaijan and Thailand.

Both organisations would like to express their sincere appreciation to Isabelle Nuttall, Stella Chungong, Florence Fuchs and Dominique Metais (WHO), Alain Dehove (OIE) and François Le Gall and Caroline Planté (World Bank) for their valuable comments, orientation and support.

Both WHO and the OIE are grateful for the financial support from the European Community, represented by the Commission of the European Communities under the European Commission Avian and Human Influenza Trust Fund and from the World Bank acting as administrator of the grant funds (Avian and Human Influenza Facility).

This project was supported by a World Bank grant to the OIE (Human and Animal Health Systems Assessment Tools and Bridges), through the OIE World Animal Health and Welfare Fund. A sub-grant was established between the OIE and WHO to implement scheduled WHO activities under the project.

TABLE OF CONTENTS

TABLES

FIGURES

ABBREVIATIONS AND ACRONYMS

AFRO	World Health Organization Regional Office for Africa
AHIF	Avian and Human Influenza Facility
Aquatic Code	OIE *Aquatic Animal Health Code*
AMR	Antimicrobial resistance
AMRO	World Health Organization Regional Office for the Americas
APSED	Asia Pacific Strategy for Emerging Diseases
CDC	US Centers for Disease Control and Prevention
DLD	Department of Livestock and Development of Thailand
EID	Emerging Infectious Diseases
EMRO	World Health Organization Regional Office for the Eastern Mediterranean
EURO	World Health Organization Regional Office for Europe
FAO	Food and Agriculture Organization of the United Nations
FP	Focal Point
G20	Group of Twenty Finance Ministers and Central Bank Governors
HPAI	highly pathogenic avian influenza
IDSR	Integrated Disease Surveillance
IHR	International Health Regulations
IHR MF	International Health Regulations Monitoring Framework
INFOSAN	International Food Safety Authorities Network
IPC	Infection, Prevention and Control
IPPC	International Plant Protection Convention
LAT	Laboratory Assessment Tool
MF	Monitoring Framework
MoA	Ministry of Agriculture
MoPH	Ministry of Public Health
NFP	National Focal Point
NGOs	Non-Governmental Organisations
OECD	Organisation for Economic Cooperation and Development
OIE	World Organisation for Animal Health
PHEIC	public health emergency of international concern
PoE	point of entry
PMAC	Prince Mahidol Award Conference
PVS	Performance of Veterinary Services
RA	risk assessment
RRT	rapid response teams
SARS	Severe Acute Respiratory Syndrome
SEARO	World Health Organization Regional Office for South East Asia
SOP	standard operating procedures
Terrestrial Code	OIE *Terrestrial Animal Health Code*
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
VA	Veterinary Authority
VS	Veterinary Services
WB	World Bank
WHA	World Health Assembly
WHO	World Health Organization
WPRO	World Health Organization Regional Office for the Western Pacific
WTO	World Trade Organization

PREFACE

'Improvements in governance, infrastructure and capacity building will prove valuable to secure the livelihoods of vulnerable populations'.

FAO, the OIE and WHO (2010):
Sharing responsibilities and coordinating global activities to address health risks at the animal–human–ecosystems interfaces. A tripartite concept note.

Both animal and human health authorities have a stake in, and responsibility for, the control of zoonoses, diseases of increasing importance to both human and animal public health over the last two decades (FAO, 2013). More than 60% of human infectious diseases worldwide are caused by pathogens of a zoonotic nature, mostly originating from wildlife and having serious consequences for livestock (Jones *et al.*, 2008; Morse, 2004).

Severe acute respiratory syndrome (SARS), highly pathogenic avian influenza (HPAI) H5N1 and pandemic influenza A(H1N1)2009 are examples of how disease events can develop into major outbreaks or pandemics, with significant impacts on public health, animal health and economies (World Bank, 2012; Jonas, 2013). Many other zoonotic diseases, including so-called neglected diseases, may be more limited in terms of rapid spread, but strongly affect human and animal health, production capacity, value chains and trade, and livelihoods (FAO, 2002; WHO, 2013).

The ability to stop the spread of pathogens relies on the capacity of countries to detect unusual events early and to rapidly implement control measures. Considering that the majority of emerging threats are zoonotic, a country's capacity to effectively respond is dependent on the coordinated involvement of multiple actors from a variety of sectors and at different levels of implementation.

Efforts to prevent and respond to the outbreak of HPAI H5N1, which remains entrenched in some countries, have demonstrated that many countries are not sufficiently prepared to deal with such events (World Bank, 2010; WHO, 2011). This has been further exacerbated by the fact that veterinary and public health services have been largely neglected in many low- and middle-income countries during previous decades.

Although substantial improvements have been made since these recent disease events, many countries still need significant long-term investments – such as those for the development of infrastructure and the strengthening of human resources – in order to tackle the challenges posed by emerging diseases.

Experience has shown that a weakness in one country's capacities to detect and respond to emerging disease events is a serious global threat. International organisations share a responsibility in supporting their Member Countries to strengthen their capabilities for early warning and rapid response by acting at both global and national levels (FAO, OIE & WHO, 2010).

Using a capacity-building approach, WHO and the OIE have developed frameworks and tools to support their Member Countries to assess the capacities of their human and animal health sectors respectively, enabling the identification of gaps and leading to the definition of appropriate strategies to improve compliance with international standards.

Both approaches, the WHO International Health Regulations (IHR) Monitoring Framework and the OIE Performance of Veterinary Services (PVS) Pathway, assist Member Countries in determining their organisational and operational strengths and weaknesses, and promote a prioritised and strategic approach to structuring their improvement. Furthermore, both approaches engage countries in routine monitoring and follow-up mechanisms to reassess the overall level of performance, recognise improvements and plan for the future.

This Operational Framework recognises the importance of acknowledging shared disease risks between animals and humans and explains the existing synergistic methods to accelerate integrative efforts towards compliance with IHR (2005) and OIE intergovernmental standards. •

EXECUTIVE SUMMARY

The health and well-being of the global population and its access to safe food is the responsibility of all countries. In order to fulfil this national and global responsibility, countries must be equipped with strong systems which operate under the tenets of good governance. Countries must be accountable, transparent and capable of monitoring their performance and enforcing legislation; they must be able to formulate and implement sound policies, manage resources efficiently and provide effective services.

Global health is a shared responsibility, a partnership and a priority that requires the cooperation of all countries and an intersectoral approach. Countries need to build robust and effective systems; furthermore, they must recognise the intersections of different sectors and their impact on global health. Appropriate measures must be put in place to facilitate and strengthen collaboration and coordination within and across sectors.

People and animals act as co-determinants of each other's health; accordingly, efforts must be taken to unite the sectors working to protect humans and animals. The concept of One Health epitomises and embodies this approach; it addresses public health events at the intersection of human, animal and environmental health. It brings together experts working in the areas of animal and human disease, as well as those in other relevant sectors, to address the prevention of, and response to, emerging zoonotic disease threats. One Health provides a new synthesis for public health and veterinary communities, and is a platform on which to build partnerships with a broader range of disciplines to develop solutions for preventing and responding to zoonotic disease threats.

It is estimated that the majority of all new, emerging and re-emerging diseases affecting humans at the beginning of the twenty-first century have originated from animals. Humans are at increased risk of contracting diseases of animal origin because of a wide range of interconnected variables, including mass urbanisation, large-scale livestock production, increased travel and so on.

In addition, new threats related to climate change, food safety and chemical hazards pose a complex set of challenges involving human, animal and environmental health. The One Health approach thus promotes cooperation and coordination for disease surveillance, outbreak investigation and response activities undertaken by professionals from various fields.

The World Health Organization (WHO) and the World Organisation for Animal Health (OIE) are longstanding promoters of the One Health approach and work together to promote its implementation in their respective Member Countries.

In 2010, WHO, the OIE and the Food and Agriculture Organization of the United Nations (FAO) issued a joint tripartite concept note entitled 'FAO, the OIE and WHO: Sharing responsibilities and coordinating global activities to address health risks at the human–animal–ecosystems interfaces'. This document outlined areas of common interest when 'address[ing] health risks at the animal–human–ecosystems interfaces' (FAO, OIE & WHO, 2010). In particular, the tripartite concept note recognised 'a need to strengthen animal and human health institutions' and suggested that 'protocols and standards … should be jointly developed' to achieve coherence of any related global standard-setting activities, and to address gaps in the capacities of countries to comply with tenets of good governance.

In addition to the normative frameworks of the International Health Regulations (IHR, 2005) and the international standards described in the OIE's *Terrestrial* and *Aquatic Animal Health Codes*, WHO and the OIE have taken this recommendation seriously and have each developed frameworks and tools to support their Member Countries to assess the capacities of their respective human and animal and health sectors.

The **objective** of this Operational Framework is to help Member Countries contribute to the development of a coherent system of global health governance at the human–animal interface.

The **purpose** of this Operational Framework is to inform WHO and OIE Member Countries of the processes and tools that have been developed and which are available to support them in operating under the principles of good governance.

The Operational Framework has been developed for **public health authorities, IHR National Focal Points** and **national Veterinary Services** to assist them in obtaining a comprehensive overview and understanding of all the available tools, how to access them and the outputs produced. The Operational Framework also provides detailed information on the synergies and complementarities of the tools developed for each sector, human and animal, and how these tools can be used to create bridges and meet One Health goals and objectives.

This Operational Framework is composed of **three main parts**:

- **Part 1** introduces the concept of good governance and then explains the foundations and key references for good governance at the human–animal interface. It provides detailed information on the global legal basis for human and animal disease notification and corresponding references to intergovernmental standards, as well as a thorough introduction to existing and relevant initiatives and experiences supporting the coordinated prevention of diseases that have a high impact on public and animal health.

- **Part 2** provides a detailed overview of the support processes and tools developed by WHO and the OIE to assist their Member Countries, as well as their overlapping complementarities. It aims to clarify and highlight the benefits that countries and users can obtain from using the tools, and the mutual and intersectoral by-products of their use. Finally, it highlights the cross-sectoral activities and areas of cooperation for human and animal health services to effectively address key diseases and issues causing negative impacts on public health. It is composed of the following two sections:

  – The first section introduces the Performance of Veterinary Services (PVS) Evaluation mission and corresponding PVS Tool. It then highlights the links between the PVS Tool and the WHO Monitoring Framework by summarising the analysis contained in a specific *WHO–OIE Handbook*.

  – The second section includes a presentation of the outcomes of two national workshops, which have united national human and animal health sectors and provided them with an opportunity to share country views and lessons learned from participation in the IHR Monitoring Framework and the PVS Pathway. The methodology, tried and tested through these two pilot workshops and described herein, will be deployed in other Member Countries, using assessment outcomes of the IHR Monitoring Framework and the PVS Pathway to jointly identify opportunities to enhance animal and human health intersectoral collaboration at the national level.

- **Part 3** describes in detail the various tools developed by WHO and the OIE; it also highlights and presents the outcomes of synergistic approaches and identifies similarities and differences as well as opportunities for synergies to achieve better efficiencies of animal and human health services at both national and global levels. It is composed of three sections:

  – The first section presents the OIE and WHO assessment and monitoring tools in detail, including what the tools do and how they can be linked.

  – The second section provides a comprehensive overview of the costing tools developed by the OIE and WHO. Information on the objectives, processes, methodologies, outputs and outcomes is provided for each tool.

  – The third section is dedicated to the complementary tools developed by WHO and the OIE with regard to helping Member Countries analyse the laboratory situation at country level and identify targeted and strategic improvements. This section is also supported by the outcomes of a review of the OIE and WHO laboratory tools, which aimed to identify points of convergence and synergies, as well as differences and gaps.

Countries complying with their national and international obligations and taking advantage of these tools will allow the benchmarking of human and animal health system performance and guide the development of appropriate strategies and programmes to address national cross-cutting human and animal health priorities.

PART 1

1. Governance and principles of good governance

The term 'governance' is not new; originating from the Greek city-state to the modern nation-state, governance – or the act of governing – is a complex and multifaceted concept that has numerous meanings and definitions which are used in a broad range of contexts, including political, economic and financial (Msellati *et al.*, 2012).

In this Operational Framework, the concept of 'good governance' is used to refer to human and animal health systems which comply with international regulations, standards and obligations to protect people and livestock against major health threats that have the potential to spread internationally. In order to operate in good governance, this Operational Framework considers that Member Countries must be accountable, transparent and able to monitor performance and enforce legislation; they must be able to formulate and implement sound policies, manage resources efficiently and provide effective services.

A coherent system of global health governance is the collective defence against transnational health threats and should embody the principles of accountability, transparency, monitoring and enforcement. It requires clear targets with sufficiently detailed, benchmarked, budgeted strategies to achieve them, with strong health information systems that can monitor progress in real time (Gostin *et al.*, 2010).

Moreover, recognising that around 60% of all human diseases and around 75% of emerging infectious diseases are zoonotic (transmissible from animals to humans), this Operational Framework considers that good governance corresponds to systematic intersectoral collaboration at the human–animal interface in order to address common challenges as effectively and efficiently as possible.

Box 1: Selected meanings of governance

Although there is no clear consensus on a single definition of 'governance', there is some broad agreement on the general principles that characterise 'good governance'.

- The United Nations Development Programme defines governance as the exercise of political, economic and administrative authority in the management of a country's affairs at all levels. It also recognises nine good governance principles: participation, consensus orientation, strategic vision, responsiveness, effectiveness and efficiency, accountability, transparency, equity and the rule of law.
- For the Organisation for Economic Co-operation and Development, governance denotes the use of political authority and the exercise of control in a society in relation to the management of its resources for social and economic development. This broad definition encompasses the role of public authorities in establishing the environment in which economic operators function and in determining the distribution of benefits as well as the relationship between the ruler and the ruled.
- For the World Bank, good governance is epitomised by predictable, open and enlightened policy-making (that is, transparent processes), a bureaucracy imbued with a professional ethos, an executive arm of government accountable for its actions, and a strong civil society participating in public affairs; and all behaving under the rule of law.

Global health is a shared responsibility, a partnership and a priority that requires the cooperation of all countries and needs to be intersectoral.

2. Foundations and key references for good governance at the human–animal interface

To facilitate users of this Operational Framework to better understand the World Health Organization (WHO) International Health Regulations (IHR) Monitoring Framework and the World Organisation for Animal Health (OIE) Performance of Veterinary Services (PVS) Pathway and their associated tools, a description of the context and the objectives guiding their development is presented.

This section includes useful background information to contextualize, legitimise and implement joint WHO and OIE activities to support their Member Countries and to operate under the tenets of good governance.

It provides clarifications on the scope and limitations of this Operational Framework. Relating to the human health sector, it focuses mainly on the key functions associated with the IHR (2005): early detection, proper management and early response to public health emergencies of international concern (PHEICs). Concerning the animal health sector, it also centres on early detection, response and control of pathogenic agents to animals and, in the case of zoonoses, to humans, as outlined in the intergovernmental standards contained in the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) and the *Aquatic Animal Health Code* (*Aquatic Code*).

2.1. Global legal basis for early warning and notification

One of the mainstays of early warning functions is reporting cases detected in countries to the global community. WHO and the OIE are responsible for the official dissemination of disease information to the international community for diseases of humans and for animal diseases, including zoonoses, respectively. Both WHO and the OIE work closely with the national competent authorities under legally binding frameworks, respectively the IHR for WHO and the *Terrestrial* and *Aquatic Codes* for the OIE.

Notification through the WHO International Health Regulations

> The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade
>
> ***The International Health Regulations*** **(IHR, 2005), Article 2**

When they were first adopted by the World Health Assembly in 1969, the IHR covered six diseases.

The regulations were first amended in 1973, when the number was reduced to four, then again in 1981, after the eradication of smallpox, when the regulations turned their focus to three diseases, namely cholera, yellow fever and plague.

In consideration of the increase in international travel and trade, the emergence, re-emergence and international spread of diseases and other health threats, and the recognised need for collective effort to address this spread, the World Health Assembly called for a substantial revision in 1995.

The revision extended the scope of diseases and related health events covered by the IHR to take into account almost all PHEICs, irrespective of their source and nature (biological, chemical, radiological or nuclear). The revised regulations were adopted in 2005 and entered into force on 15 June 2007 (WHO, 2008).

Article 6 of the IHR (2005) requires that States Parties[1] report to WHO within 24 h any incident that could be considered a PHEIC using the fastest available means of communication via their national IHR Focal Points. A decision instrument described in Annex 2 of the IHR (2005) is used by Member States to decide whether an acute public health event requires formal notification to WHO (Fig. 1).

1 As of December 2013, there are 194 WHO Members and 196 States Parties to the IHR (2005). Certain states that are not members of WHO may become a party to the IHR by notifying acceptance of the Regulations to the Director-General of WHO. The current 196 States Parties to the IHR (2005) include all WHO Member States as well as the Holy See and Liechtenstein

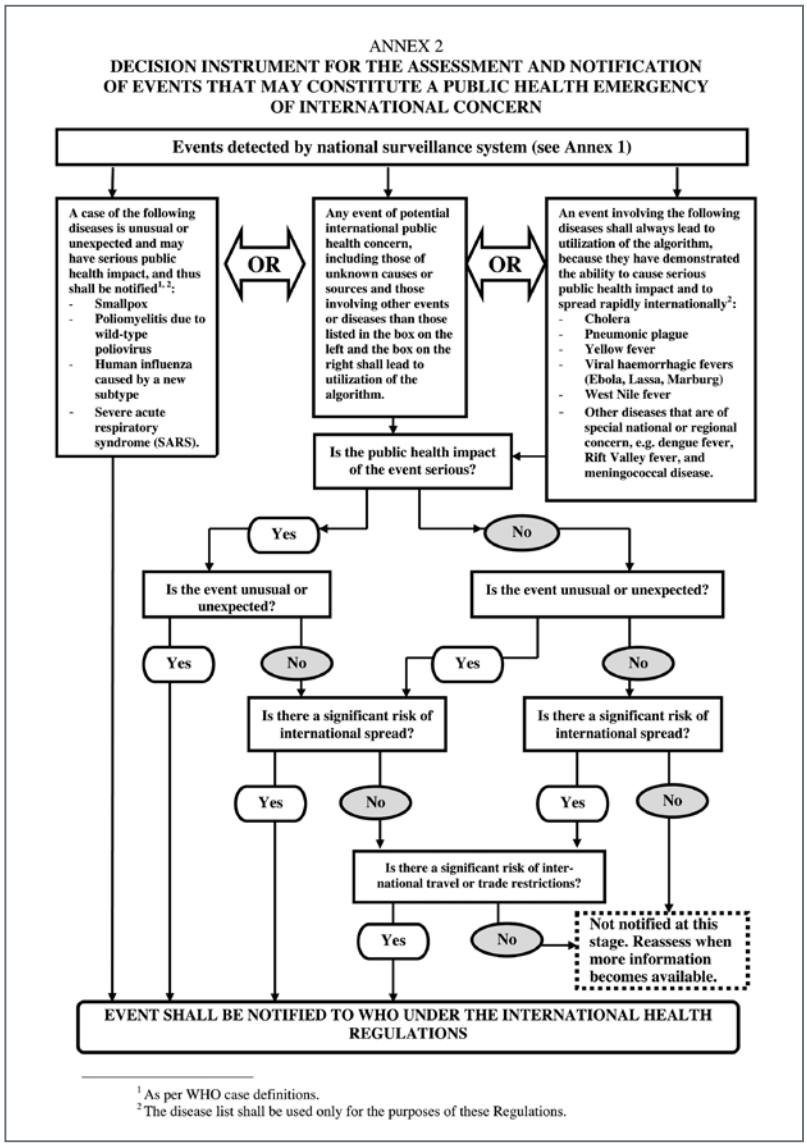


Fig. 1
Decision instrument for the identification of an event that may constitute a public health emergency of international concern

Reporting through the OIE World Animal Health Information System

> Member countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their aetiological agents, and to assist in achieving better worldwide control of these diseases
>
> **OIE *Terrestrial Animal Health Code*, Article 1.1.2, 1.**

The obligation to disclose all relevant information about animal diseases is set out in the OIE Organic Statutes, signed and ratified by the founding Member Countries. All OIE Member Countries must report the occurrence of animal diseases, the emergence of new diseases and significant epidemiological events within 24 h of the event (OIE, 2012). This also includes diseases transmissible to humans and the intentional introduction of pathogens.

General principles on epidemiological animal disease surveillance are described in the *Terrestrial* and *Aquatic Codes* and include an official list of notifiable diseases.

The list is reviewed on a regular basis and if modifications are adopted by the World Assembly of Delegates at its annual

general session, the new list comes into force on 1 January of the following year.

The procedure for disease listing is outlined in Articles 1.2.1 and 1.2.2 of the *Terrestrial* and *Aquatic Codes* (2013). This procedure identifies two channels for listing as an OIE-notifiable disease: in the first case, the international spread of the agent must be proven in order to be classified as an OIE-listed disease; in the second case, the infection or infestation must be classified as an emerging disease.

The decision trees outlining these two procedures are shown in Figures 2 and 3.

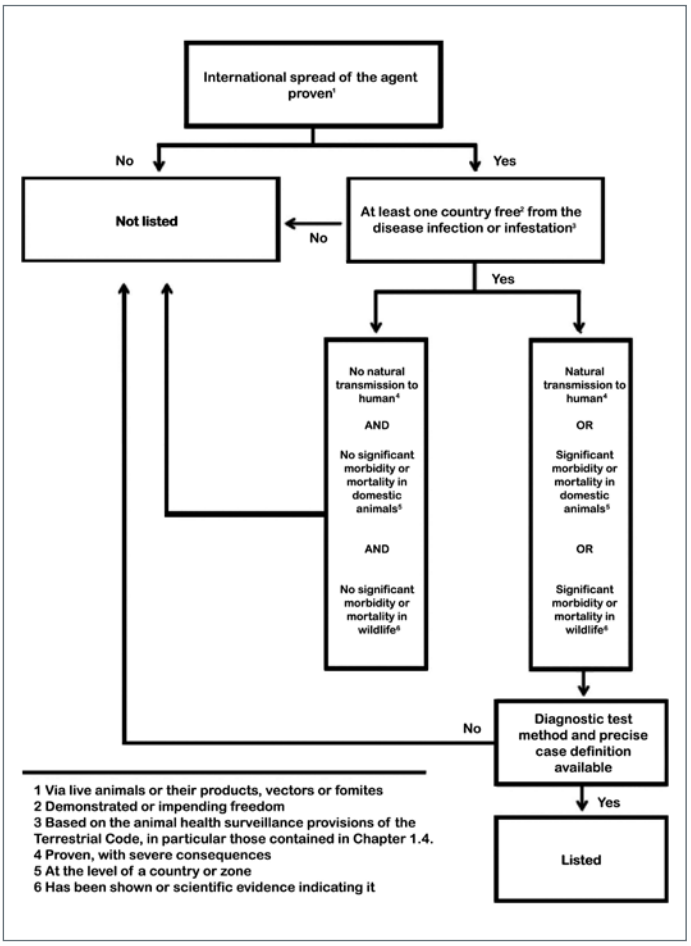


Fig. 2
Decision tree highlighting the criteria for the inclusion of a disease in the OIE list of notifiable diseases (2013)

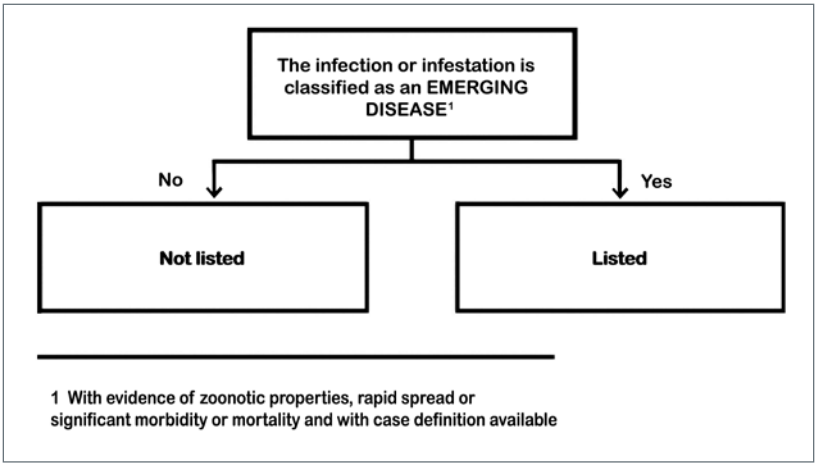


Fig. 3
Decision tree highlighting the criteria for the inclusion of an infection or infestation in the OIE list of notifiable diseases as an emerging disease (2013)

2.2. Global references and standards for the development of national capacities for early detection and response

> The best systems are only as strong as their weakest components and the timely notification of a disease is dependent on the ability of countries to detect diseases at an early stage.
>
> **OIE (2012), *Notification of animal and human diseases – Global legal basis***

Given that the both the WHO and OIE notification systems have the necessary instruments and legally binding obligations for a fast and efficient distribution of information globally on human and animal diseases, the priority is to focus efforts on strengthening operational forces, including governmental public health and Veterinary Services.

Requirements of the International Health Regulations

> Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations (...), the capacity to detect, assess, notify and report events in accordance with these Regulations... and . . . the capacity to respond promptly and effectively...'
>
> **The International Health Regulations (IHR, 2005), *Articles 5 and 13***

With the revised IHR (2005) coming into force, all States Parties were required to assess the ability of their national structure and resources to meet minimum national Core Capacities for surveillance and response, as specified in Annex 1 of the IHR (2005), and to develop a plan of action to ensure that these capacities would be present and functioning throughout their territories by 2012.

Annex 1 of the IHR (2005) provides a list of core functions – the capacity to detect, report, assess and respond to a PHEIC – expected at the three levels of implementation in countries – central, intermediate and community levels. All States Parties have committed to reporting their level of compliance with the IHR (2005) Annex 1 to the World Health Assembly on an annual basis.

States Parties may have obtained a two-year extension to the 2012 deadline for fulfilling their capacity obligations on the basis of a justified need and an implementation plan to be reported to WHO. In exceptional circumstances, a further two-year extension would be available in 2014 (Fig. 4).

Furthermore, WHO is mandated to provide appropriate tools, guidance and support to States Parties to achieve these goals. Various assessment and monitoring tools for IHR implementation have been developed worldwide, most addressing either regional specificities (i.e. upon initiative of regional economic communities) or technical areas (i.e. laboratory assessment tools, point of entry monitoring tools, etc.).

The IHR Monitoring Framework has been developed by WHO for self-assessment and a questionnaire with indicators of performance for predefined Core Capacities and specific hazards is proposed for reporting to WHO (WHO, 2012).

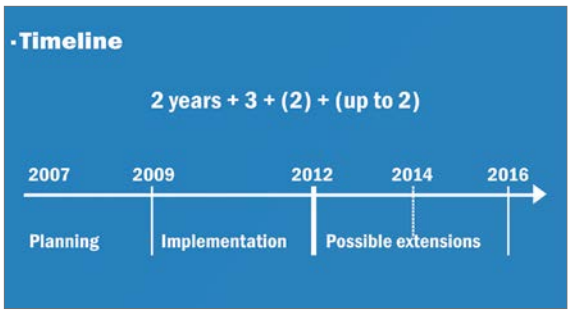


Fig. 4
The World Health Organization Monitoring Framework timeline

Intergovernmental standards of the OIE Animal Health *Codes*

> The OIE *Terrestrial Animal Health Code* sets out standards for the improvement of animal health and welfare and veterinary public health worldwide, including through standards for safe international trade in terrestrial animals (mammals, birds and bees) and their products.

The definition of standards for the improvement of animal health and welfare and veterinary public health worldwide,

including thorough references for safe international trade of animal and their products, are recorded in the OIE *Terrestrial* and *Aquatic Codes*. For the *Terrestrial Code*, the development of international standards, guidelines and recommendations is the result of continuous work since the establishment of the OIE in 1924.

The health measures are regularly revised and formally adopted by the World Assembly of Delegates from its Member Countries. The measures in the *Terrestrial Code* and the *Aquatic Code* are used by the veterinary authorities (and the Aquatic Animal Health Services) of importing and exporting countries for early detection, reporting and control of pathogenic agents to terrestrial animals and, in the case of zoonoses, to humans, and to prevent the transfer via international trade in terrestrial animals and terrestrial animal products, while avoiding unjustified sanitary barriers to trade.

To help ensure the effective performance of the Veterinary Services (and of the Aquatic Animal Health Services) of Member Countries, the OIE has dedicated two chapters of the *Terrestrial* and *Aquatic Codes* to the quality of Veterinary Services (and two chapters to the quality of Aquatic Animal Health Services). Using these references, the OIE developed the PVS Pathway, which allows countries to undertake a comprehensive evaluation of their Veterinary Services and identify gaps and areas requiring strengthening in order to meet the international standards they have democratically adopted.

Early in the process, the Food and Agriculture Organization of the United Nations (FAO) joined the OIE in this effort to strengthen national Veterinary Services of developing countries to comply with OIE standards, thereby ensuring good governance to address emerging and re-emerging animal and zoonotic disease threats, and to promote safe trade in livestock and livestock products (OIE & FAO, 2007).

3. Sharing responsibilities

3.1. Common references

To be effective against emerging infectious diseases, human health and animal health sector institutions need to operate effectively and efficiently but must also strongly synergise with other relevant services.

> ...we stress the importance of strengthening international and regional networks, international standard setting (...),
> good governance and official services, since they ensure an early detection and a rapid response to biological threats, (....) We encourage FAO, WHO, OIE, the Codex Alimentarius Commission, the IPPC and WTO to continue their efforts towards enhancing interagency cooperation.
>
> ***G20 Ministerial Declaration***
> **Agriculture Ministers, June 2011**

This translates into concrete actions that improve governance mechanisms, develop and promote policies, design and implement systems and processes, strengthen surveillance and response capacities, and target investments at the national, regional or international level.

Governance was one of the issues that prompted the World Health Assembly in 1995 to call for a revision of the IHR (WHO, 2008).

Good governance between health systems at the interface between humans and animals

Recent zoonosis crises have led to significant and unprecedented cross-sectoral partnerships and cooperation among technical agencies, international financial institutions and other international partners. In particular, the organisations in charge of setting standards for good governance and for providing institutional support to build capacities at the national level have worked hand in hand with donors and financial partners to support countries in developing and implementing strategies to strengthen capacities to detect and respond to major emerging health events .

One of the key principles guiding the development of a common strategic framework is to reaffirm the need to build more robust public and animal health systems that are based on good governance and are compliant with the IHR (2005) and OIE intergovernmental standards; this approach shifts away from externally driven, short-term, emergency response type 'vertical' approaches, and contributes to a more sustainable, 'horizontal approach' and long-term strengthening of systems.

Box 2: The global public good concept

The shared benefits of global human–animal health are in the realms of global public goods. As commonly defined, a public good has two characteristics (Kaul *et al.*, 2002):

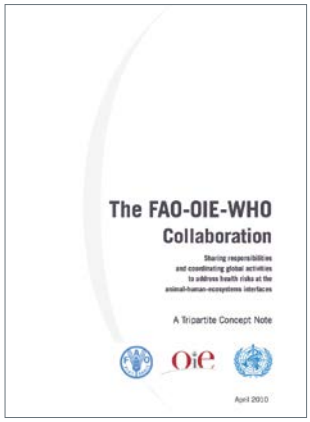
1. Once supplied to one person, the good can be supplied to all other people at no extra cost (**non-rivalry of consumption)**.
2. Once the good is supplied to one person, it is impossible to exclude other people from the benefits of the good (**non-exclusion**).

The positive outcomes of successfully managed global public goods or, conversely, the harmful consequences of poor management are easiest to observe over the medium to long term. The time lag between an event and its impact means that the management of global public goods should take into account the interests of not only the present generation, but also future generations (Bourguinat, 2003).

Some global public goods are interdependent and synergies between them may confer mutual benefits. Progress in one field may lead to improvements in others. Human and animal health are intrinsically linked. In a world of open borders, increased movements of individuals and escalating cross-border trade, there is a high risk that a local failure will have repercussions beyond the national territory. The success of infectious disease control and prevention in one country will impact the spread of disease to other countries, particularly in a globalised world, and success in addressing a health threat in one country can inform effective approaches in other countries.

Good governance must boost the capacity of public authorities to manage public goods effectively and fairly. For this reason, good governance mechanisms have now become a priority for most international organisations, whatever their mandate.

Preventing and controlling emerging infectious diseases is an international public good (Box 2), which requires strong commitments, political and financial, at national, regional and international levels (Eloit, 2012).



In 2010, the three main international organisations responsible for animal and human health, FAO, the OIE and WHO, defined strategic directions aimed at aligning their various efforts for better coordination of global activities.

A joint tripartite concept note 'FAO, the OIE and WHO: Sharing responsibilities and coordinating global activities to address health risks at the human–animal-ecosystems interfaces' (2010) described areas of common interest when 'address[ing] health risks at the animal–human–ecosystems interfaces' (FAO, OIE & WHO, 2010).

Although numerous coordination mechanisms had already been developed at the technical level, the tripartite concept note recognised 'a need to strengthen animal and human health institutions', and suggested that 'protocols and standards…should be jointly developed' to achieve coherence of any related global standard-setting activities, and to address gaps in the capacities of countries.

The three organisations, FAO, the OIE and WHO, agreed to search for alignment and coherence of related global standard setting activities, respecting existing structures, mandates and mechanisms. They furthermore recognised that the use of the existing regulatory frameworks is instrumental for developing good governance at the human–animal interface. Additional protocols and standards for managing emerging zoonotic diseases would be jointly developed, when appropriate.

3.2. Using the existing frameworks

> Improvements in governance, infrastructure and capacity building will also prove valuable to secure the livelihoods of vulnerable populations
>
> ***A Tripartite Concept Note*, 2010**

In order to more comprehensively develop national capacities for the control of zoonotic diseases, several initiatives have tried to extract or combine some of the criteria used in the IHR Monitoring Framework and/or the PVS Pathway to stimulate intersectoral collaboration and guide the development of shared approaches for the strengthening of capacities between national human and animal health authorities.

This Operational Framework has benefited from a number of initiatives, including those mentioned below.

In May 2010, a meeting was organised by FAO, the OIE and WHO, in collaboration with the United States Centers for Disease Control and Prevention, the World Bank and the United States Agency for International Development, in Stone Mountain (Georgia, USA) entitled 'One Health: A policy perspective – taking stock and shaping an implementation roadmap'. This meeting brought together experts from national ministries of health and agriculture, the European Commission, the United Nations and the World Bank, as well as from other institutions representing academic, policy and economic sectors, to contribute their expertise and experience to the discussion on One Health.

During the meeting, the participants reviewed the progress to date in terms of leading practices related to One Health and identified key policy and financial commitments necessary to support sustainability of the initiative. An output of this meeting was the development of *A Framework for Identifying Institutional Strengths and Needs for One Health Programmes*. This self-assessment process can be used by countries to identify programmatic areas for targeting improvements to meet One Health goals and objectives. The framework focuses on non-technical attributes such as leadership, governance and partnership development and provides a set of principle and guiding questions that can be adapted to address issues specific to the user to undertake a self-guided review. The framework includes a section on intersectoral collaboration and makes reference to the international standards and processes under the PVS Pathway and the IHR. The framework is intended to be used not for formal national assessments, but as a tool for reflection by interested parties on needs and opportunities to improve One Health programmes, policies and/or personnel.

Another example of a similar approach was the Central Asia One Health Project, supported by the World Bank, which carried out an economic assessment of the impact of zoonotic diseases in four countries in the medium and long term (10 years), and provided an evidence base for evaluation and development of additional programme interventions and investments to mitigate the risks posed.

The economic assessment tool aimed to determine a biologically and epidemiologically sound causal relationship of zoonosis transmission and, on this basis, develop a financial analysis of the cost of disease prevention. The tool was used in combination with 13 Critical Competencies of the PVS Tool given their direct relevance to detecting and controlling zoonotic diseases.

In an attempt to highlight the contribution of the Veterinary Services to global public health and to further highlight the areas requiring systematic collaboration and cooperation between human and animal health systems, the OIE explored the development of a specific One Health PVS Assessment Tool. This tool placed the emphasis on the intersectoral activities of Veterinary Services through a qualitative review of a subset of relevant Critical Competencies. Taking into account the experience of the three pilot One Health PVS missions conducted (in Costa Rica, Kenya and the Philippines), the OIE preferred to systematically incorporate a One Health approach into all PVS Pathway missions, rather than conduct isolated One Health PVS missions. In order to do so, significant additions concerning One Health collaboration and approaches have been included in the 2013 edition of the PVS Manual of the Assessor (Guide to conducting a PVS Evaluation), including issues relevant to the preparation and conduct of the mission and guidance on working with a country to identify its priority public health outcomes and undertaking the review process from a One Health perspective.

In 2013, prior to the Prince Mahidol Award Conference on One Health, conducted in Bangkok (Thailand) in January 2013, the World Bank organised a debate among country officials, international partners and World Bank managers. This debate provided a forum to discuss the role and actions undertaken by the World Bank to reduce risks at the

human–animal–environment interface and the future directions of this approach. Taking stock of the recent experiences relating to human–animal influenza, the participants exchanged ideas and thoughts on the main implementation challenges experienced by country policy-makers and World Bank senior managers.

During the conference, WHO, the OIE, FAO and the World Bank organised a parallel session entitled 'Unprecedented move toward a more coherent approach among sectors for the strengthening of national human–animal–ecosystem health capacities'. On this occasion, WHO and the OIE presented and introduced current efforts to harmonise the IHR Monitoring Framework and the PVS Pathway tools supported by concrete examples of countries' experiences and gaps between the human and animal health sectors. This session confirmed the value of referring to existing regulatory frameworks – considering that they are well acknowledged by users in their respective area of competence – to enhance dialogue between the sectors and to develop a common language for defining joint areas of strategic action.

An underlying conclusion of all relevant initiatives was that the identification of specific capabilities for zoonoses was not relevant. In fact, it was clear that zoonoses should not be considered in isolation of the overall performance of animal or public health systems; rather, a systems-wide approach, based on existing monitoring tools, was preferred.

Enhancing alignments

The joint use of outputs of the IHR Monitoring Framework and the PVS Pathway by Member Countries enables a detailed assessment of existing national forces and bridges and gaps in human and animal health coordination, and provides wide-ranging benefits for the development of national strategies targeting and enhancing capacities in the human and animal health sectors. This vision promotes the concomitant and facilitated use of existing frameworks, rather than the development of new processes and procedures.

The OIE and WHO have developed this Operational Framework to explain the linkages between the OIE and WHO frameworks and tools; the points of convergence are explained in specific documents available in Part 2. These documents highlight and outline bridges, complementarities and synergies and should be used to facilitate improved coordination and action between human and animal health services at the national level.

The objective of this Operational Framework is to provide a methodological reference for information on key human health and animal health requirements, standards, good governance principles and references as well as the frameworks and tools available to help countries assess their systems and address deficiencies.

This Operational Framework is also a key tool for countries and the international donor community to better understand existing frameworks and outputs available to prepare, at the national and/or regional level, targeted investment plans and strategies.

•

PART 2

The OIE and WHO promote a collaborative and all-encompassing approach when addressing animal and public health globally. The two organisations have identified numerous points of convergence and the critical need for constant and structured collaboration between human and animal health systems. However, it is not is sufficient to limit this cooperation to the international level; it must be translated into operational guidance material at the national level.

It is for this reason that the Operational Framework presents the IHR Monitoring Framework and the PVS Pathway together. Although the two frameworks have differences, they both aim to help their Member Countries have the capacities to ensure the coordinated prevention of high-impact public health and animal diseases globally. Indeed, there is a wide range of similarities and complementarities in structure and approach, but an in-depth analysis of the corresponding tools also highlighted possible junctures to help national human and animal health services better understand when and how they should work in collaboration.

Therefore, this part of the Operational Framework provides the reader with a detailed overview of the support processes and frameworks developed by WHO and the OIE to assist their Member Countries and their overlapping complementarities. It aims to clarify and highlight the benefits that countries and users can obtain from using the tools, and the mutual and intersectoral by-products of their use. Finally, it highlights the cross-sectoral activities and cooperation areas for human and animal health services to effectively address key diseases and issues causing negative impacts on public health.

This part is divided into two sections:

- The first section provides detailed information on the IHR Monitoring Framework and the PVS Pathway, and highlights synergies and complementarities between the two frameworks.
- The second section includes a presentation of the outcomes of two national workshops which united national human and animal health sectors and provided them with an opportunity to share country views and lessons learned from participation in the IHR Monitoring Framework and the PVS Pathway. The methodology tried and tested through these two pilot workshops and described herein will be deployed in other Member Countries, using assessment outcomes of the WHO IHR Monitoring Framework and the PVS Pathway to jointly identify opportunities to enhance animal and human health intersectoral collaboration at the national level.

1. Introduction to the International Health Regulations Monitoring Framework and the PVS Pathway and their synergies

1.1. The International Health Regulations Framework and Monitoring Tool

Context

With the revised IHR coming into force on 15 June 2007, all IHR States Parties have been required to assess the ability of their national structures and resources to meet minimum national Core Capacities for surveillance and response as specified in the IHR, and to develop a plan of action to ensure that these capacities will be present and functioning throughout their territories.

In accordance with Article 54 of the IHR, and related resolution of the World Health Assembly 61.2, States Parties

> Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.
>
> **IHR (2005), *Article 13***

and WHO are required to report annually to the World Health Assembly on the implementation of the Regulations. WHO is mandated to provide appropriate tools, guidance and support to States Parties to achieve these goals.

For this purpose, an IHR Monitoring Framework has been developed by WHO, representing a consensus of technical expert views drawn globally from Member States, technical institutions and partners, as well as from within the WHO Secretariat and subject-matter experts. The framework provides a set of 28 global indicators developed in order to reflect the required capability to detect, assess, notify and report events and to respond to public health risks and emergencies of national and international concern, as stipulated in Articles 5 and 13 and Annex 1 of IHR (2005).

From these 28 indicators, a subset of 20 is used for annual reporting to the World Health Assembly, but countries are encouraged to report on all 28 indicators (Table I).

Tools developed in the International Health Regulations Monitoring Framework

The tools developed for the IHR Monitoring Framework include a checklist and an associated questionnaire. For their development, existing regional and sub-regional tools and strategies worldwide were considered, such as the Asia-Pacific Strategy for Emerging Diseases (APSED) in the Western Pacific region and South-East Asia region; the Integrated Disease Surveillance and Response (IDSR) strategy in the African region; the Emerging Infectious Diseases (EID) strategies in the Americas including the MERCOSUR tool, and Eastern Mediterranean regions; and strategies in the European region. Countries are requested to complete the questionnaire and return it to WHO two months before the World Health Assembly. They were pilot tested in all WHO regions (AFRO, AMRO, EMRO, EURO, SEARO and WPRO).

Practically, the 28 indicators are divided into **eight Core Capacities**, plus specific capacities at points of entry (PoEs) and for IHR-related hazards, notably biological (zoonotic, food safety), chemical, radiological and nuclear hazards. The Core Capacities are listed in Table II.

It is important to understand that the Core Capacities refer to a country's capabilities in the context of the IHR (2005) and the expected functions defined in the regulation. As an example, the core capacity on national legislation, policy and financing is exploring these items in the perspective of the legal framework to support and enable implementation of the IHR, and does not explore other legal or regulatory areas covering the activities of public health authorities or other parties. The scope and limitations of the eight Core Capacities are described in Table III.

The core capacity may be depicted through components (from 1 to 4 for each core capacity), with relevant indicators associated. As mentioned above, the Monitoring Framework includes a total of 28 indicators. Table IV illustrates the structure of the checklist. The indicators are then further described using attributes. The checklist includes a total of 256 attributes. Attributes are classified into four distinct capability levels:

- **Capability level < 1** (the foundational level) includes attributes that are considered key to the development of the inputs and processes needed for the implementation of the IHR.
- **Capability level 1** is generally characterised as a 'moderate' level and attributes listed here include the 'inputs and processes' needed to build or maintain IHR Core Capacities.
- **Capability level 2** represents a 'strong' technical capacity and a high level of performance with defined public health outputs and outcomes.
- **Capability level 3** represents an advanced level of capabilities and achieving a 'reference model' of capability.

States Parties were expected to achieve attributes for levels 1 and 2 by the 2012 deadline.

Table I Selected indicators for reporting to the World Health Assembly

The 20 selected indicators for reporting to the World Health Assembly
1. Legislation, laws, regulations, administrative requirements, policies or other government instruments in place are sufficient for implementation of the International Health Regulations (IHR).
2. A functional mechanism is established for the coordination of relevant sectors in the implementation of the IHR.
3. IHR National Focal Point (NFP) functions and operations, as defined by the IHR (2005), are in place.
4. Indicator-based surveillance includes an early warning function for the early detection of a public health event.
5. Event-based surveillance is established and functioning.
6. Public health emergency response mechanisms are established and functioning.
7. Infection prevention and control is established and functioning at national and hospital levels.
8. A Multi-hazard National Public Health Emergency Preparedness and Response Plan is developed and implemented.
9. Priority public health risks and resources are mapped and utilised.
10. Mechanisms for effective risk communication during a public health emergency are established and functioning.
11. Human resources are available to implement IHR core capacity requirements.
12. Laboratory services are available to test for priority health threats.
13. Laboratory biosafety and laboratory biosecurity (biorisk management) practices are in place and implemented.
14. General obligations at point of entry (PoE) are fulfilled (including for coordination and communication).
15. Routine capacities and effective surveillance are established at PoE.
16. Effective response at PoE is established.
17. Mechanisms for detecting and responding to zoonoses and potential zoonoses are established and functional.
18. Mechanisms are established and functioning for detecting and responding to foodborne disease and food contamination.
19. Mechanisms are established and functioning for the detection, alert and response to chemical emergencies that may constitute a public health event of international concern.
20. Mechanisms are established and functioning for detecting and responding to radiological and nuclear emergencies that may constitute a public health event of international concern.
The eight additional indicators
1. Funding is available and accessible for implementing IHR NFP functions and IHR core capacity strengthening.
2. Case management procedures are implemented for IHR relevant hazards.
3. A programme for disinfection, decontamination and vector control is established and functioning.
4. A coordinating mechanism for laboratory services is established.
5. Influenza surveillance is established.
6. A system for collection, packaging and transport of clinical specimens is established.
7. Laboratory data management and reporting are established.
8. Coordination in the prevention, detection and response to public health emergencies at PoE is established.

Table II International Health Regulations Monitoring Framework Core Capacities and specific capacities

Eight Core Capacities	Specific capacities
1. National legislation, policy and financing	9. Points of entry
2. Coordination and National Focal Point communications	10. Hazards
3. Surveillance	_ 10.1. Zoonotic
4. Preparedness	_ 10.2. Food safety
5. Response	_ 10.3. Chemical emergencies
6. Risk communications	_ 10.4. Radiation emergencies
7. Human resource capacity	
8. Laboratory	

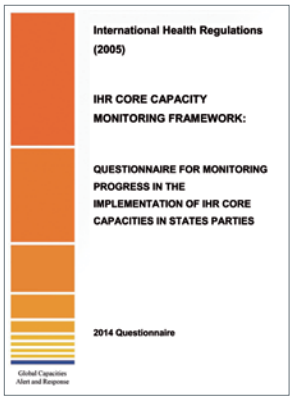
Table III Scope and limitations of the International Health Regulations (IHR) Monitoring Framework Core Capacities

Scope and limitations of the eight Core Capacities
1. National legislation, policy and financing States Parties need to have an adequate legal framework to support and enable implementation of the IHR. This may require that they adopt implementing or enabling legislation for some or all of their obligations and rights. New or modified legislation may also be needed by States to support the new technical capacities being developed in accordance with Annex 1. Even where new or revised legislation may not be specifically required, States may still choose to revise some regulations or other instruments in order to facilitate implementation in a more efficient, effective or beneficial manner. Implementing legislation could serve to institutionalise and strengthen the role of IHR (2005) and operations within the State Party. It can also facilitate coordination among the different entities involved in implementation. In addition, policies which identify national structures and responsibilities as well as the allocation of adequate financial resources are also important. Detailed guidance on IHR implementation in national legislation is available at: www.who.int/ihr/legal_issues/legislation/en/index.html
2. Coordination and NFP communications The effective implementation of the IHR requires multisectoral/multidisciplinary approaches through national partnerships for effective alert and response systems. Coordination of nation-wide resources, including the designation of an IHR National Focal Point (NFP) is a key requisite for IHR implementation. The IHR NFP should be accessible at all times to communicate with the World Health Organization (WHO) IHR contact points and with all relevant sectors and other stakeholders in the country.
3. Surveillance The IHR require the rapid detection of public health risks, as well as prompt risk assessment, notification and response to these risks. To this end, a sensitive and flexible surveillance system with an early warning function is necessary. The structure of the system and the roles and responsibilities of those involved in implementing the system need to be clear and preferably should be defined through public health policy and legislation. Chains of responsibility need to be clearly identified to ensure effective communications within the country, with WHO and with other countries as needed.
4. Preparedness Preparedness includes the development of national, intermediate and community/primary response level public health emergency response plans for relevant biological, chemical, radiological and nuclear hazards. Other components of preparedness include mapping of potential hazards and hazard sites, the identification of available resources, the development of appropriate national stockpiles of resources and the capacity to support operations at the intermediate and community/primary response levels during a public health emergency.
5. Response Command, communications and control operations mechanisms are required to facilitate the coordination and management of outbreak operations and other public health events. Multidisciplinary/multisectoral rapid response teams should be established and be available at any time. They should be able to rapidly respond to events that may constitute a public health emergency of national or international concern (PHEIC). Appropriate case management, infection control and decontamination are all critical components of this capacity that need to be considered.
6. Risk communications Risk communications should help stakeholders define risks, identify hazards, assess vulnerabilities and promote community resilience. An essential part of risk communication is the dissemination of information to the public about health risks and events, taking into account the social, religious, cultural, political and economic aspects associated with the event, as well as the voice of the affected population. Communication partners and stakeholders in the country need to be identified, and functional coordination and communication mechanisms established. In addition, it is important to establish communication policies and procedures on the timely release of information with transparency in decision-making that is essential for building trust between authorities, populations and partners. Emergency communications plans need to be developed, tested and updated as needed.
7. Human resource capacity Strengthening the skills and competencies of public health personnel is critical to the sustainment of public health surveillance and response at all levels of the health system and the effective implementation of the IHR.
8. Laboratory Laboratory services are part of every phase of alert and response, including detection, investigation and response, with laboratory analysis of samples performed either domestically or through collaborating centres. States Parties need to establish mechanisms that assure the reliable and timely laboratory identification of infectious agents and other hazards likely to cause PHEICs, including shipment of specimens to the appropriate laboratories if necessary.

Practical use of the Monitoring Framework
A self-assessment process

The Monitoring Framework is to be used by Member States to carry out self-assessments on the development and strengthening of their capacity. It is proposed that the countries use the IHR Monitoring Framework questionnaire developed by WHO to facilitate the reporting.

Completion of the questionnaire by national respondents could be carried out through a process led by the designated IHR National Focal Point (NFP), in consultation with the national subject-matter experts in the country and, if requested, with assistance from WHO regional offices and country offices. Inputs from professionals and representatives from various sectors such as animal health, food and water safety, environmental health, radiological, nuclear and chemical disciplines are needed for this review.



The questionnaire is available online[2] as a 'fillable' PDF form or as a printable PDF and can also be submitted to WHO as hard copy. Data are stored in a secure database at WHO, accessible only to the IHR NFPs and relevant WHO staff. The data collection tool assures confidentiality, as IHR NFPs can access data only for their own country.

Evaluation of the level of compliance

The answers to the questionnaires are used to develop country and regional profiles based on the proportion of attributes attained at levels 1 and 2. The tool also generates summary results, which facilitate planning and mobilisation of resources[3].

2 The 'fillable' PDF 2014 questionnaire file for online entry can be accessed from: https://extranet.who.int/ihrportal/Presentation/2014/2014DownLoads.htm

3 Annual results can be found at the WHO Global Health Observatory: www.who.int/gho/ihr/en/

Table IV Component and indicators associated with core capacity 1 (CC1) on national legislation, policy and financing. For this core capacity, two components are considered: one on the legal and regulatory framework, and one on financing. In this example, each of the components is further detailed with only one indicator

Core capacity 1: national legislation, policy and financing	
Component	**Indicator**
National legislation and policies	Legislation, laws, regulations, administrative requirements, policies or other government instruments in place are sufficient for implementation of International Health Regulations (IHR)
Financing	Funding is available and accessible for IHR National Focal Point functions and IHR core capacity strengthening

Table V Components, indicators and attributes defined in the International Health Regulations (IHR) Monitoring Framework for core capacity 2 on national legislation, policy and financing

Core capacity 2: national legislation, policy and financing					
Component	**Indicator**	**Attribute Level < 1 foundational**	**Attribute Level 1 Input and processes**	**Attribute Level 2 outputs and outcomes**	**Attribute Level 3 Additional achievements**
National legislation and policies	…	…	…	…	…
Financing	Funding is available …	Funding for IHR focal point function is available	Funding available for IHR Core Capacities, IHR relevant hazard and point of entry	IHR Core Capacities strengthened at the sub-national and community/ primary response level in the last 12 months	Resources committed to meet IHR requirement beyond country's borders

Specific questions at the human–animal interface

Of the four specific hazards, capabilities associated with (i) zoonotic events and (ii) food safety are more directly linked to actions at the human–animal interface. The attributes defined in the IHR Monitoring Framework checklist for these sections are described in Tables VI and VII, with reference to the associated level of capability.

From data received in 2011 on questionnaires completed by States Parties (representing 83% of the 194 Parties), Figure 5 illustrates the reported level of capability for the four hazards.

The score is the proportion of attributes that have been attained in levels 1 and 2 and is a measure of overall achievement in reaching the targets for 2012.

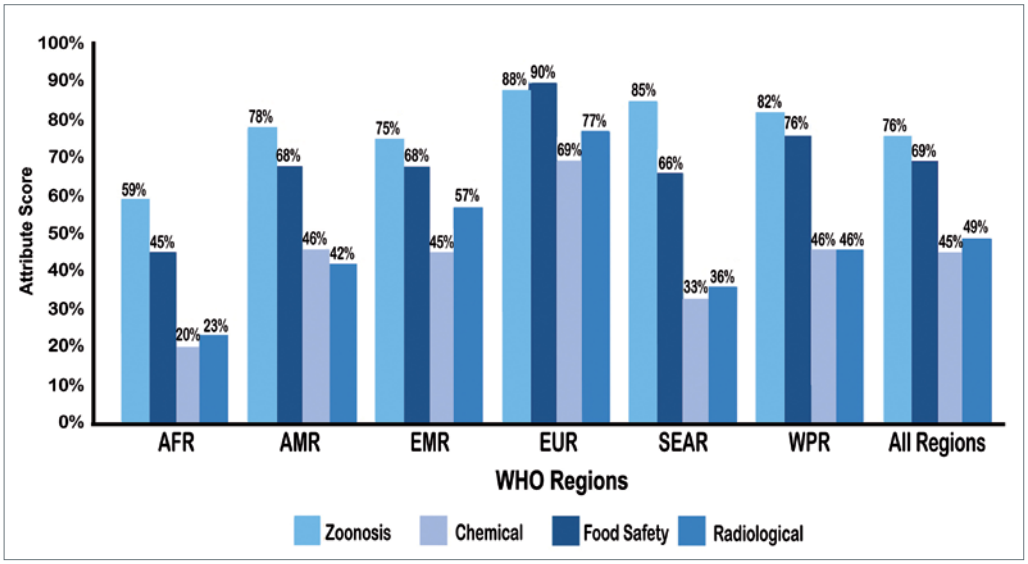
The responding countries achieved more required attributes for surveillance of and response to zoonotic and food safety events (76% and 69%, respectively) than for response to chemical and radio-nuclear events (45% and 49%). Meetings organised by WHO in late 2012 in each region have confirmed that the intersectoral work remained a challenge.

Table VI Specific capacity: zoonotic events

Core capability	10	Zoonotic events
Component	10.1	Capacity to detect and respond to zoonotic events of national or international concern
Indicator	10.1.1	Mechanisms for detecting and responding to zoonoses and potential zoonoses are established and functional
Capability level	**Attributes**	
<1	Coordination exists within the responsible government authority(ies) on the detection of and response to zoonotic events	
1	National policy, strategy or plan for the surveillance and response to zoonotic events is in place	
1	Focal point(s) responsible for animal health (including wildlife) designated for coordination with the ministry of health and/or International Health Regulations National Focal Points	
2	Functional mechanisms for intersectoral collaborations that include animal and human health surveillance units and laboratories are established	
3	Country experiences and findings related to zoonotic risks and events of potential national and international concern have been shared with the global community over the last 12 months	
<1	List of priority zoonotic diseases with case definitions available	
1	Systematic and timely collection and collation of zoonotic disease data is done.	
1	Access to laboratory capacity, nationally or internationally (through established procedures) to confirm that priority zoonotic events is available	
2	Zoonotic disease surveillance that includes a community component is implemented.	
2	Timely and systematic information exchange between animal surveillance units, human health surveillance units and other relevant sectors regarding potential zoonotic risks and urgent zoonotic events	
<1	A regularly updated roster (list) of experts that can respond to zoonotic events is available	
1	A mechanism for response to outbreaks of zoonotic diseases by human and animal health sectors is established	
2	Timely (as defined by national standards) response to more than 80% of zoonotic events of potential national and international concern	

Table VII Specific capacity: food safety

Core capability	11	Food safety
Component	11.1	Capacity to detect and respond to food safety events that may constitute a public health emergency of national or international concern
Indicator	11.1.1	Mechanisms are established and functioning for detecting and responding to foodborne disease and food contamination
Capability level	Attributes	
<1	National or international food safety standards are available	
1	National food laws, regulations or policy to facilitate food safety control are in place	
1	A coordination mechanism is established between the food safety authorities, e.g. the International Food Safety Authorities Network (INFOSAN) emergency contact point (if a member) and the International Health Regulations National Focal Point	
2	Functional mechanisms for multisectoral collaborations for food safety events are in place	
3	The country is an active member of the INFOSAN network	
<1	A list of priority food safety risks is available	
1	Risk-based food inspection services are in place	
1	Guidelines or manuals on the surveillance, assessment and management of priority food safety events are available	
1	Epidemiological data related to food contamination are systematically collected and analysed	
2	Access to laboratory capacity (through established procedures) to confirm priority food safety events of national or international concern including molecular techniques	
2	Timely and systematic information exchange between food safety authorities, surveillance units and other relevant sectors regarding food safety events	
<1	A roster of food safety experts is available for assessment and response to food safety events	
1	Communication mechanisms and materials are in place to deliver information, education and advice to stakeholders across the farm-to-fork continuum	
2	An operational plan for responding to food safety events is tested in actual emergency or simulation exercises and updated as needed	
2	Mechanisms are established to trace, recall and dispose of contaminated products	
2	Information from foodborne outbreaks and food contamination is used to strengthen food management systems, safety standards and regulations	
3	Published analysis of food safety events, foodborne illness trends or outbreaks	
3	Food safety control management systems (including for imported food) are implemented	



Capacity scores for the detection of and response to public health hazards, 2011, per WHO regions AFR: *Africa – AMR: Americas – EMR: Eastern Mediterranean – EUR: Europe – SEAR: South-East Asia – WPR: Western pacific. For more details, see www.who.int/about/regions/en/index.html.* Extract from Summary of 2011 states parties report on IHR core capacity implementation, www.who.int/ihr/publications/WHO_HSE_GCR_2012.10eng/en/index.html

Fig. 5

Capacity scores for the detection of and response to public health hazards, 2011, per World Health Organization (WHO) regions

1.2.
The OIE PVS Pathway

Context

The OIE is the intergovernmental organisation responsible for improving animal health worldwide. The OIE develops normative documents relating to rules that Member Countries can use to protect themselves from the introduction and the spread of diseases and pathogens, without setting up unjustified sanitary barriers. The main normative works produced by the OIE are the *Terrestrial Animal Health Code*, the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, the *Aquatic Animal Health Code* and the *Manual of Diagnostic Tests for Aquatic Animals*.

OIE intergovernmental standards are recognised by the World Trade Organization as reference international sanitary rules. They are prepared by elected specialist commissions and working groups that bring together internationally renowned scientists, most of whom are experts within the network of more than 280 OIE collaborating centres and reference laboratories that also contribute to the scientific objectives of the OIE. These standards are adopted by the World Assembly of Delegates annually in May during the OIE General Session.

The OIE provides assistance to its Member Countries to improve the governance of their national Veterinary Services, so that their capacity may be strengthened and better aligned with OIE intergovernmental standards. For that purpose, since 2006, the OIE has progressively developed a global programme, the PVS (Performance of Veterinary Services) Pathway.

Veterinary Services, as per the OIE definition, comprise both public and private sector veterinarians and veterinary para-professionals, working under the overall control and direction of the Veterinary Authority. Providing the foundation for the PVS Pathway is the dedicated chapter on the quality of Veterinary Services in the *Terrestrial Code* (Section 3, Chapter 3.1, 'Veterinary Services', and Chapter 3.2, 'Evaluation of Veterinary Services').

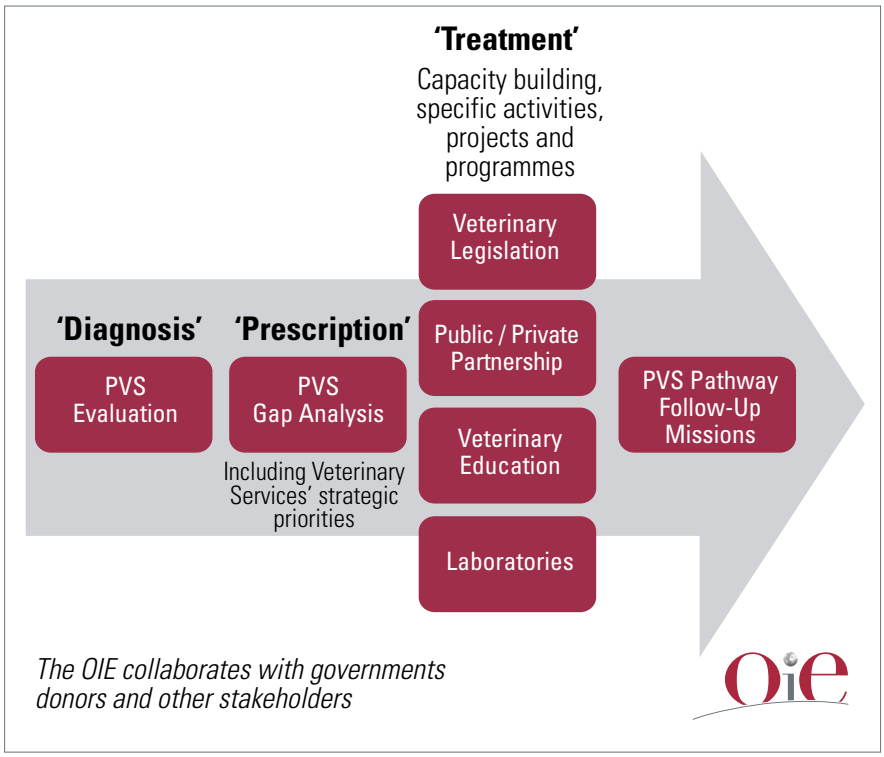


Fig. 6
Visual representation of the PVS Pathway

The PVS Pathway is a comprehensive, multi-staged continuous process which uses a set of complementary tools designed to assist Veterinary Services[4] to improve their governance mechanisms (Fig. 6). The PVS Pathway missions and corresponding tools strengthen the capacities of Veterinary Services by helping them understand and better align with the OIE intergovernmental standards that they have democratically adopted. This process focuses on building capacities of systems using a horizontal approach, giving national Veterinary Services tools to identify weaknesses and develop strategies to address these gaps.

The PVS Pathway encourages the constructive engagement and participation of all stakeholders, including the Veterinary Authority, the private sector, consumer groups and other competent authorities with shared interest in public and animal health. Through brainstorming, using combined skills and understanding, and building on gaps, the PVS Pathway strengthens animal health systems and contributes to ensuring human and animal health. Country engagement in the PVS Pathway is voluntary; a specific PVS Pathway mission will only be implemented further to the receipt of an official and formal request from the OIE Delegate to the Director General of the OIE.

Process

The sequence of support provided by the PVS Pathway includes the following steps (in chronological order):

- The **PVS Evaluation**, the first step in the PVS Pathway, is a qualitative assessment of the performance of a country's Veterinary Services and their compliance with OIE intergovernmental standards using the PVS Tool. It is an external evaluation conducted by a group of OIE-certified PVS experts which collects and analyses baseline information to assess the country's Veterinary Services' level of compliance against 47 Critical Competencies (2013 edition). The final output is a comprehensive assessment, providing a complete overview of its condition, evaluating its performance and identifying weaknesses.

- The **PVS Gap Analysis (PVS Costing Tool)** is the second step in the PVS Pathway. It is a brainstorming exercise with Veterinary Services to determine the goals, strategies, activities and investments required to improve national veterinary governance. During the mission, the country's Veterinary Services, supported by a team of OIE-certified PVS experts, refer to the level obtained during the PVS Evaluation for each of the 47 Critical Competencies and, using this information as a baseline, develop costed strategic actions to improve their performance and meet national targets. The final output identifies the country's Veterinary Services' objectives and priorities in terms of compliance with OIE quality standards and the estimated cost to reach the desired level of compliance within a five-year timeframe. In the report, this cost is illustrated by an indicative annual budget and one budget for exceptional investments developed during the mission; these are also consolidated into a provisional five-year budget for the national Veterinary Services.

Further to the implementation of a PVS Gap Analysis (PVS Costing Tool) mission ('prescription') and further to an official request to the OIE from the Delegate (or at ministerial level), additional specific technical expertise can be provided by the OIE to support the country's endeavours to bettering compliance ('treatment') with international standards. Some of the ('treatment') activities available to OIE Members under the PVS Pathway include:

- **PVS Veterinary Legislation Support Programme**: assists countries in developing a strong legislative framework in line with Chapter 3.4, 'Veterinary Legislation', of the *Terrestrial* and *Aquatic Codes*. It consists of two phases: the initial phase of the veterinary legislation identification mission is aimed at obtaining a detailed picture of the current state of veterinary legislation in the country. The second phase consists of the signature of an agreement between the country and the OIE; this agreement formalises the support provided by the OIE to countries when correcting deficiencies in their veterinary legislation. The review and modernisation of the national veterinary legislation is implemented by countries (*ad hoc* national taskforce) on the basis of their national priorities.

- **PVS Pathway Laboratory mission**: provides Veterinary Services' decision-makers with information to better allocate appropriate budgets to the national veterinary laboratory network and to better advocate for sufficient resources to support accurate and timely diagnosis. The methods used include a country-based mission with an in-depth focus on demand for laboratory services and new markets to make the national laboratory network a more efficient, coherent and better structured investment.

Finally, a **PVS Evaluation Follow-up mission** serves as a measuring and evaluation tool to monitor the progress made by countries. Cross-referencing to the initial PVS Evaluation

4 Similar tools have also been developed for the Aquatic Animal Health Services

and considering the goals established during the PVS Gap Analysis (PVS Costing Tool), when relevant, this mission assesses and monitors progress made (change in legislation, technical capacities, etc.), registers improvements and acknowledges actions to maintain existing performance levels, as well as noting new deficiencies. The output is an updated comprehensive diagnosis to guide and accordingly revise the Veterinary Services' strategic initiatives. Based on the performance of the Veterinary Services, this mission may also suggest the implementation of other PVS Pathway activities to remedy persistent problems.

Basis of the tools developed for the PVS Pathway

The aforementioned steps of the PVS Pathway are based on the PVS Tool.

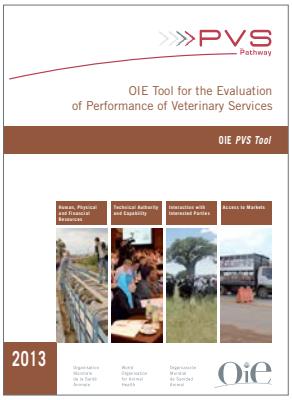
This tool is based on the intergovernmental standards outlined in the *Terrestrial Code*, and considers that effective Veterinary Services have the following fundamental components (Table VIII):

Table VIII Fundamental components of the PVS Tool

Fundamental component 1	The **human, physical and financial resources** to attract resources and retain professionals with technical and leadership skills
Fundamental component 2	The **technical authority and capability** to address current and new issues including prevention and control of biological disasters based on scientific principles
Fundamental component 3	The sustained **interaction with interested parties** in order to stay on course and carry out relevant joint programmes and services
Fundamental component 4	The ability to **access markets** through compliance with existing standards and the implementation of new disciplines such as the harmonisation of standards, equivalence and zoning

For these four fundamental components, there is a total of 47 Critical Competencies grouped according to the relevant fundamental components.

The list of the 47 Critical Competencies are provided below and are accordingly revised and/or added based on modifications to the OIE *Terrestrial Code*.



The sixth edition of the PVS Tool, released in 2013, contained a series of modifications to the previous version of the PVS Tool; these modifications were primarily concerned with Critical Competencies dealing with veterinary education, laboratory infrastructure, food safety and animal feed safety. The set of 47 Critical Competencies of the PVS Tool are provided in Table IX.

For each Critical Competency, five qualitative levels of advancement are described in a preformatted specific Critical Competency card (Fig. 7).

A higher level of advancement assumes that the Veterinary Services are complying with all preceding levels of compliance (e.g. level 3 assumes compliance with level 2 advancement). Relevant references from the *Terrestrial Code* are quoted under each critical competency.

Table X shows Critical Competency III-1, related to the capability of the Veterinary Services to inform partners of their activities and programmes.

As Table X demonstrates, level of advancement 1 corresponds to non-compliance with OIE intergovernmental standards; the higher the level of advancement, the more compliant the national Veterinary Services are for the corresponding critical competency.

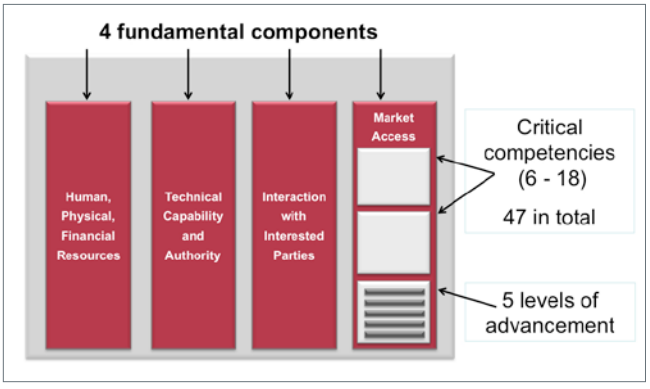


Fig. 7
Visual representation of the PVS Tool

Table IX The 47 Critical Competencies of the PVS Tool

47 Critical Competencies of the PVS Tool
Human, physical and financial resources
I-1.A. Professional and technical staffing of the Veterinary Services. Veterinarians and other professionals
I-1.B. Professional and technical staffing of the Veterinary Services. Veterinary paraprofessionals and other technical professionals
I-2.A. Professional competencies of veterinarians including the OIE Day 1 competencies
I-2.B. Competencies of veterinary para-professionals
I-3. Continuing education
I-4. Technical independence
I-5. Stability of structures and sustainability of policies
I-6.A. Coordination capability of the Veterinary Services. Internal coordination (chain of command)
I-6.B. Coordination capability of the Veterinary Services. External coordination
I-7. Physical resources
I-8. Operational funding
I-9. Emergency funding
I-10. Capital investment
I-11. Management of resources and operations
Technical authority and capability
II-1.A. Veterinary laboratory diagnosis. Access to veterinary laboratory diagnosis
II-1.B. Veterinary laboratory diagnosis. Suitability of national laboratory infrastructures
II-2. Laboratory quality assurance
II-3. Risk analysis
II-4. Quarantine and border security
II-5.A. Epidemiological surveillance and early detection. Passive epidemiological surveillance
II-5.B. Epidemiological surveillance and early detection. Active epidemiological surveillance
II-6. Emergency response
II-7. Disease prevention, control and eradication
II-8.A. Food safety. Regulation, authorisation and inspection of establishments for production, processing and distribution of food of animal origin
II-8.B. Food safety. Ante and post mortem inspection at abattoirs and associated premises
II-8.C. Food safety. Inspection of collection, processing and distribution of products of animal origin
II-9. Veterinary medicines and biologicals
II-10. Residue testing
II-11. Animal feed safety
II-12. A. Identification and traceability. Animal identification and movement control
II-12.B. Identification and traceability. Identification and traceability of animal products
II-13. Animal welfare
Interaction with interested parties
III-1. Communication
III-2. Consultation with interested parties
III-3. Official representation
III-4. Accreditation/authorisation/delegation
III-5.A. Veterinary Statutory Body (VSB). VSB Authority
III-5.B. Veterinary Statutory Body (VSB). VSB Capacity
III-6. Participation of producers and other interested parties in joint programmes
Access to markets
IV-1. Preparation of legislation and regulations
IV-2. Implementation of legislation and regulations and compliance thereof
IV-3. International harmonisation
IV-4. International certification
IV-5. Equivalence and other types of sanitary agreements
IV-6. Transparency
IV-7. Zoning
IV-8. Compartmentalisation

Table X PVS Critical Competency III-1: communication

III-1 Communication	Levels of advancement
The capability of the Veterinary Services (VS) to keep interested parties informed, in a transparent, effective and timely manner, of VS activities and programmes, and of developments in animal health and food safety. This competency includes collaboration with relevant authorities, including other ministries and competent authorities, national agencies and decentralised institutions that share authority or have mutual interest in relevant areas	1. The VS have no mechanism in place to inform interested parties of VS activities and programmes
	2. The VS have informal communication mechanisms
	3. The VS maintain an official contact point for communication but it is not always up to date in providing information
	4. The VS contact point for communication provides up-to-date information, accessible via the Internet and other appropriate channels, on activities and programmes
	5. The VS have a well-developed communication plan, and actively and regularly circulate information to interested parties

Terrestrial Code references:
Point 13 of Article 3.1.2 on Fundamental principles of quality: Communication. Sub-point (b) of Point 2 of Article 3.2.6 on Administrative resources: Communications. Point 4 of Article 3.2.14 on Administration details. Chapter 3.3 on Communication.

Practical use of the tools

All steps in the PVS Pathway are voluntary; the OIE implements a PVS Pathway mission solely further to an official request from the Member Countries to the Director General of the OIE. The PVS Tool is used during the implementation of a PVS Evaluation and PVS Evaluation Follow-up mission; although the Critical Competencies of the PVS Tool are used during a PVS Gap Analysis (PVS Costing Tool) mission, the order of the Critical Competencies is different and they are situated under pillars rather than fundamental components (further information on the PVS Gap Analysis (PVS Costing Tool) Methodology can be found under section 2.4.1).

During a PVS Evaluation mission (and PVS Evaluation Follow-up mission), a team of OIE-certified PVS experts conduct a thorough evaluation of a national Veterinary Services' performance against the 47 Critical Competencies.

The final output is a report which comprehensively and qualitatively assesses the country's Veterinary Services' compliance with OIE international standards, provides a complete overview of the Veterinary Services' performance and identifies its gaps and weaknesses. It also provides the country's Veterinary Services with detailed and constructive information on how to improve its animal health system to better meet national needs. In order to ensure harmonisation of country missions and reports, the OIE has developed a manual for assessors, which contains information and procedures relevant to the conduct of a PVS Evaluation and PVS Evaluation Follow-up mission.

If a country waives the confidentiality of its PVS Pathway reports, the OIE can share these reports with OIE partner organisations and international donors; PVS Pathway reports inform and shape future national and/or regional investment plans to strategically build country Veterinary Services, focusing on and targeting the gaps emerging from the PVS Pathway reports.

As of April 2014, a total of 117 PVS Evaluation missions had been implemented, of which 73% of PVS Evaluation reports are available to donors and partners of the OIE and 27% are confidential. Of those 73%, 16% of country PVS Evaluation reports are available on the OIE website.

With regard to PVS Gap Analysis (PVS Costing Tool) missions, as of April 2014, a total of 72 missions had been implemented; 43% of the corresponding country PVS Gap Analysis (PVS Costing Tool) reports are confidential while the remaining 57% are available to donors and partners of the OIE. Of those 57%, 15% of PVS Gap Analysis (PVS Costing Tool) reports are available on the OIE website.

Specific questions at the human–animal interface

The OIE considers that effective national Veterinary Services contribute to a country's ability to promote and protect human health. Through the PVS Pathway, the OIE assists national Veterinary Services to assess their competencies to better comply with international standards supporting public health outcomes.

The OIE has refined the PVS Tool to help countries improve the quality of their efforts to work on issues at the human–animal interface, and ultimately support a country's ability to report on its implementation of the IHR.

When implementing PVS Pathway missions, issues relating to how the activities of the Veterinary Services contribute to public health outcomes are systematically examined. This includes discussions on intersectoral collaboration and has the following two main objectives:

1) to review further the collaboration related to activities at the human–animal interface (how Veterinary Services activities contribute to public health outcomes); and

2) to undergo a capacity-building/brainstorming process of identifying where collaboration could improve the quality of the performance of the Veterinary Services in achieving these public health outcomes.

Table XI provides examples of Critical Competencies that may require the involvement of more than one competent authority (e.g. human health services) to achieve the maximum level of compliance with international standards.

Table XI PVS Critical Competencies requiring the involvement of more than one competent authority

List of PVS Critical Competencies requiring the involvement of more than one competent authority
I-3. Continuing education
I-6.B. External coordination
II-1. Veterinary laboratory diagnosis
II-4. Quarantine and border security
II-5 (A and B). Epidemiological surveillance and early detection
II-6. Emergency response
II-7. Disease prevention, control, and eradication
II-8. (B and C). Food safety
II-9. Veterinary medicines and biological
II-10. Residue testing
II.11. Animal feed safety
III-1. Communication
IV-1. Preparation of legislation and regulations

It is not a closed list of PVS Critical Competencies of interest in the One Health context. Rather, it provides examples of Critical Competencies for which coordination/cooperation mechanisms should exist between various competent authorities.

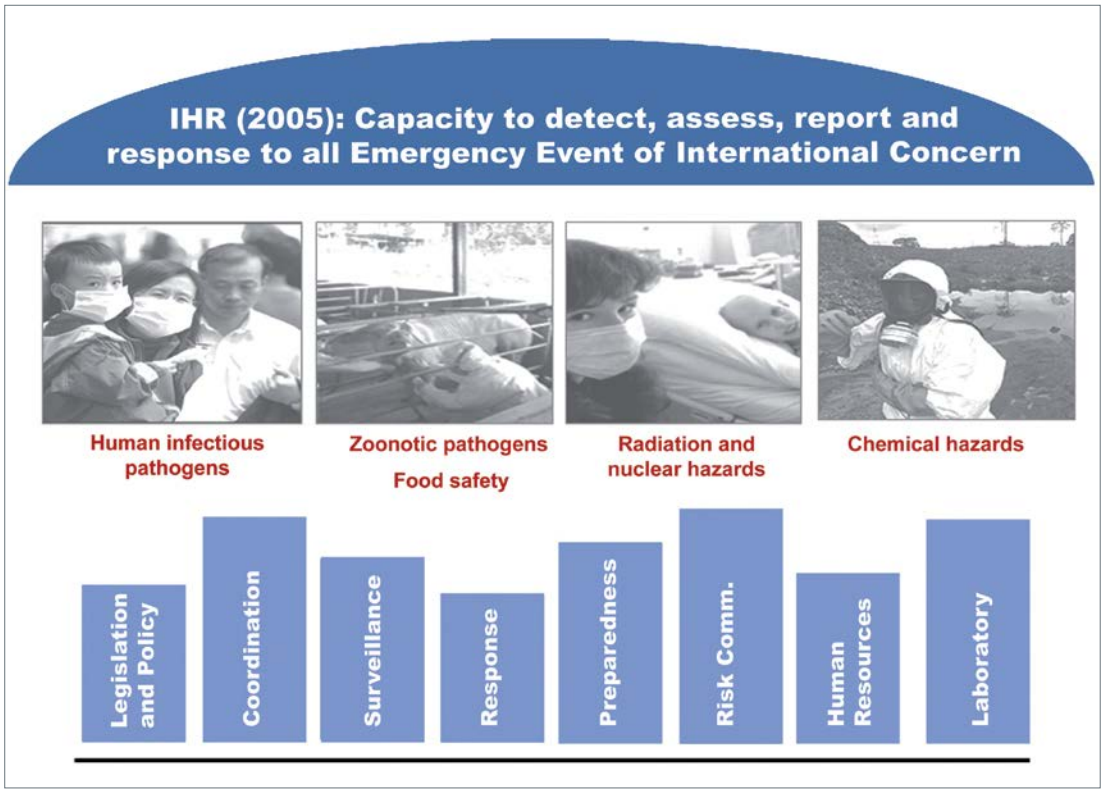
1.3 Synergies, differences and converging areas

When looking at the two frameworks and their underlying principles it is clear that both the OIE and WHO have numerous similarities and points of convergence. Firstly, both frameworks are based on key competencies that structure and improve the performance of their Member Countries using prioritised and strategic approaches. They both engage their Member Countries in routine monitoring and evaluation exercises but also support the development of capacities and skills to enhance performance and compliance with international standards and regulations.

From a methodological perspective, they are similarly structured: the IHR Monitoring Framework foresees the assessment of Core Capacities while the PVS Pathway evaluates Critical Competencies; capacities are classified through the use of levels of advancement and the outputs are the propriety of each country. Although both frameworks can be used for self-assessment at the country level, the OIE and WHO support their members with targeted technical support to facilitate the development and use of the outputs. Furthermore, both frameworks assess governmental and non-governmental bodies involved in public and animal health.

The first difference that emerges is the sectoral focus of the frameworks. The IHR Monitoring Framework addresses the overall capacity of countries; all sectors, whether institutional or non-institutional, are included. This signifies that the IHR Monitoring Framework does not simply review the capacities of those working in the public health sector, but rather involves all sectors that have an impact on public health, including veterinary public health. It focuses on capacities for early detection and rapid response to PHEICs.

The PVS Pathway focuses on and works with countries' Veterinary Services (both public and private components) and their improved compliance with the international standards contained in the *Terrestrial* and *Aquatic Codes*; this includes



areas and activities that are directly or indirectly related to animals, their products and by-products, and which help to protect, maintain and improve the health and welfare of humans, including through the protection of animal health and welfare and food safety.

Although the PVS Pathway addresses responsibilities and competencies that are shared among different competent authorities, it evaluates only the compliance of the Veterinary Services, as defined by the OIE in the *Terrestrial Code*. Furthermore, the first step in the Pathway, the PVS Evaluation, is in most cases an external assessment of a country's compliance with OIE international standards; however, self-evaluation is also foreseen and outlined in Chapter 3.2, 'Evaluation of Veterinary Services', of the *Terrestrial Code*.

Another difference corresponds to the reference base of the frameworks. The PVS Pathway is based on the international standards democratically adopted by its Member Countries and included in the *Terrestrial* and *Aquatic Codes*, including a specific chapter on the quality of Veterinary Services (Section 3, Chapter 3.1, 'Veterinary Services', and Chapter 3.2, 'Evaluation of Veterinary Services').

All PVS Pathway missions are implemented using a unified and harmonised approach based on the international standards voted annually by the World Assembly of Delegates to the OIE; any modifications to the *Terrestrial* and *Aquatic Codes* are taken on board and integrated into the PVS Pathway tools.

The IHR Monitoring Framework is based not on standards but on recommended practices for core functions as delineated in Annex 1 to the IHR (2005). The absence of standards provides countries with flexibility when undertaking their self-assessment as well as freedom of interpretation when assessing their level of performance.

Assessing the similarities and differences between the two frameworks is only the first step towards the identification of synergies. Recognising and highlighting the overlapping areas can provide numerous advantages for establishing areas for potential coordination or the implementation of joint activities for national strategic planning.

Table XII summarises the main similarities and differences between the IHR Monitoring Framework and the PVS Pathway.

Table XII Main similarities and differences between the International Health Regulations (IHR) Monitoring Framework and the PVS Pathway

	IHR Monitoring Framework and tools	PVS Pathway and tools
Objective	**Assesses the capacities of States Parties to promptly and effectively respond to public health risks and emergencies** according to international regulations	**Continuous process** to help Member Countries to sustainably improve **compliance of Veterinary Services** with OIE intergovernmental **standards** (OIE Codes)
Use of manual and tools	Mainly via **self-evaluation**	Mainly via **third party** (OIE-certified PVS experts)
Obligation	**Mandatory annual report to the World Health Assembly** (States Parties can choose their preferred monitoring process, including use of the IHR Monitoring Framework)	**Voluntary process** initiated solely further to a request from the country to the OIE (country-driven)
Time frame	**Specific deadlines** outlined in the IHR (2005)	Step-based and continuous **process**
Scope	**Countries' capability** to address international public health emergency of international concern	**Improve compliance and performance** of Veterinary Services
Outcome	Sustainable foundations for the integrated protection of human health and animal health at national, regional and international levels	
Confidentiality	The outputs are the property of the country and are kept confidential by the World Health Organization and the OIE[a]	

a The results of PVS Pathway reports are the property of the country concerned and are kept confidential by the OIE. A number of countries have waived the confidentiality of their PVS reports, authorising that their PVS report be shared with OIE partner organisations and international donors working jointly with the OIE to strengthen Veterinary Services. In addition, some countries have authorised the OIE to make their PVS Pathway reports fully public; these can be viewed on the OIE website at: www.oie.int

Mapping of synergies

Human and animal health systems communicating and collaborating together in synergy and complementarity has been largely advocated by the OIE and WHO. The two organisations have taken this principle on board and work together to advocate for their Member Countries to take advantage of existing frameworks and benefit from coordinated actions to prevent the spread of animal diseases of high impact for public health.

The development of different yet synergistic tools is a prime example of such effort.

Taking a closer look, it is also possible to identify areas in which the Core Capacities under the IHR Monitoring Framework match, overlap or synergize with the Critical Competencies under the PVS Pathway. There are a number of obvious overlapping or converging areas such as zoonoses, foodborne diseases and food contamination. However, further to the implementation of the mapping exercise, the OIE and WHO identified a series of convergence points (Table XIII). This matrix is a key tool for conducting workshops that bring together human and animal health services, and offer participants an opportunity to confirm points of convergence identified by the OIE and WHO and to revise the matrix and corresponding convergence points on the basis of the national context (see next section, 'IHR–PVS Pathway National Bridging Workshops').

The capacities for specific hazards on (i) chemical events and (ii) radiological emergencies were not included because they are less relevant in the context of analyses at the human–animal interface. In addition, because of the difference in perspectives between the related areas covered in the IHR (2005) and the specific sections on cross-border control depicted in the PVS Pathway, requiring an in-depth analysis, the specific capacity for point of entry has not been included in this version. Further work on this specific topic is currently in progress.

Table XIII Matrix – International Health Regulations (IHR) Monitoring Framework Core Capacities and PVS Pathway Critical Competencies

Indicators in the IHR Monitoring Framework		*I.1. A & B. Professional and technical staffing of the Veterinary Services*	*I.2. A & B. Competencies of veterinarians and veterinary para-professionals*	*I.3. Continuing education*	*I.4. Technical independence*	*I.5. Stability of structures and sustainability of policies*	*I.6. Coordination capability of the VS: A. internal – B external*	*I.7. Physical resources*	*I.8. Operational funding*	*I.9. Emergency funding*	*I.10. Capital investment*	*I.11. Management of resources and operations*	*II.1. A. Veterinary laboratory diagnosis. Access to diagnostic*	*II.1. B. Vet.. laboratory diagnosis.sustainability of nat. Lab. infrastructures*	*II.2. Laboratory quality assurance*
National legislation, policy and financing	Legislation, laws, regulations, administrative requirements, policies or other government instruments in place are sufficient for implementation of IHR						■								
	Funding is available and accessible for implementing IHR National Focal Point (NFP) functions and IHR core capacity strengthening								■	■	■				
Coordination and National Focal Point communications	A mechanism is established for the coordination of relevant sectors in the implementation of IHR						■								
	IHR NFP functions and operations are in place, as defined by the IHR (2005)						■								
Surveillance	Indicator-based surveillance includes an early warning function for the early detection of a public health event														
	Event-based surveillance is established												■	■	
Response	Public health emergency response mechanisms are established and functioning									■			■	■	■
	Case management procedures are implemented for IHR relevant hazards														
	Infection prevention and control is established at national and hospital levels														■
	A programme for disinfection, decontamination and vector control is established														

Please note that the following Core Capacities of the IHR Monitoring Framework have not been included in this matrix:
i) Point of Entry,
ii) Chemical events,
iii) Radiological emergencies

They were not included given that they are less relevant in the context of analyses at the human-animal interface.

				■						*II. 3. Risk analysis*
										II.4. Quarantine and border security
				■	■	■			■	*II.5. Epidemiological surveillance and early detection A. Passive – B. Active*
■		■	■	■						*II.6. Emergency response*
■				■					■	*II.7. Disease prevention, control and eradication*
				■						*II.8. Food safety – A. Authorisation; B. & C. Inspection*
										II.9. Veterinary medicines and biologicals
	■									*II.10. Residue testing*
										II.11. Animal feed safety
										II.12. Identification and traceability– A. animal; B. Products
										II.13. Animal welfare
						■	■			*III.1. Communications*
				■		■				*III.2. Consultation with interested parties*
										III.3. Official representation
										III.4. Accreditation/authorisation/delegation
										III.5. Veterinary Statutory Body– A. Authority; B. Capacity
						■				*III.6. Participation of producers and interested parties in joint programmes*
									■	*IV.1. Preparation of legislation and regulations*
						■			■	*IV.2.Implementation of legislation and regulations and compliance thereof*
										IV.3. International harmonisation
										IV.4. International certification
										IV.5. Equivalence and other types of sanitary agreements
				■						*IV.6. Transparency*
										IV.7. Zoning
										IV.8. Compartmentalisation

Indicators in the IHR Monitoring Framework		I.1. A & B. Professional and technical staffing of the Veterinary Services	I.2. A & B. Competencies of veterinarians and veterinary para-professionals	I.3. Continuing education	I.4.Technical independence	I.5. Stability of structures and sustainability of policies	I.6. Coordination capability of the VS: A. internal – B external	I.7. Physical resources	I.8. Operational funding	I.9. Emergency funding	I.10. Capital investment	I.11. Management of resources and operations	II.1. A. Veterinary laboratory diagnosis. Access to diagnostic	II.1. B. Vet. laboratory diagnosis.sustainability of nat. Lab. infrastructures	II.2. Laboratory quality assurance
Preparedness	**A Multi-hazard National Public Health Emergency Preparedness and Response Plan is developed and implemented**														
	Priority public health risks and resources are mapped and utilised						■	■				■	■	■	
Risk communication	**Mechanisms for effective risk communication during a public health emergency are established and functioning**														
Human resources capacity	**Human resources available to implement IHR core capacity requirements**	■	■	■											
Laboratory	*Coordinating mechanism for laboratory services is established*												■		
	Laboratory services are available to test for priority health threats												■	■	■
	Influenza surveillance is established														
	System for collection, packaging and transport of clinical specimens is established												■	■	■
	Laboratory biosafety and laboratory biosecurity (Biorisk management 1) practices are in place													■	■
	Laboratory data management and reporting is established												■		
Specific hazard: zoonosis	**Mechanisms for detecting and responding to zoonoses and potential zoonoses are established and functional**					■	■		■				■	■	■
Specific hazard: food safety	**Mechanisms are established and functioning for detecting and responding to foodborne diseases and food contamination**						■						■	■	■

■	■									■		*II. 3. Risk analysis*
■												*II.4. Quarantine and border security*
	■											*II.5. Epidemiological surveillance and early detection A. Passive – B. Active*
■	■								■	■	■	*II.6. Emergency response*
	■											*II.7. Disease prevention, control and eradication*
■	■											*II.8. Food safety – A Authorisation; B. & C. Inspection*
												II.9. Veterinary medicines and biologicals
												II.10. Residue testing
												II.11. Animal feed safety
												II.12. Identification and traceability– A. animal; B. Products
												II.13. Animal welfare
■	■								■			*III.1. Communications*
■	■											*III.2. Consultation with interested parties*
												III.3. Official representation
												III.4. Accreditation/authorisation/delegation
												III.5. Veterinary Statutory Body– A. Authority; B. Capacity
												III.6. Participation of producers and interested parties in joint programmes
												IV.1. Preparation of legislation and regulations
■												*IV.2.Implementation of legislation and regulations and compliance thereof*
												IV.3. International harmonisation
												IV.4. International certification
												IV.5. Equivalence and other types of sanitary agreements
												IV.6. Transparency
												IV.7. Zoning
												IV.8. Compartmentalisation

2. International Health Regulations–PVS Pathway National Bridging Workshops

2.1 Using assessment outcomes to jointly identify opportunities to enhance animal and human health intersectoral collaboration at the national level

The National Bridging Workshop which was held in Baku, Azerbaijan, from 13 to 14 March 2014 was attended by 46 national experts, representing mainly the Ministry of Agriculture and the Ministry of Public Health. At that date, **Azerbaijan** had completed the following assessment exercises: PVS Evaluation (2008), PVS Gap Analysis (2011) and IHR Assessment (2012).

Similarly, 59 national experts, representing mainly the Department of Livestock Development, Ministry of Agriculture and the Ministry of Public Health, participated in the National Bridging Workshop which took place in Bangkok, **Thailand**, from 26 to 27 March 2014. Thailand had undertaken a PVS Evaluation (2012), PVS Gap Analysis (2014) and IHR Assessment (2012).

Background and approach

National Bridging Workshops aim to facilitate the identification of synergies and gaps between the outputs and outcomes of the IHR Monitoring Framework and the PVS Pathway. The identified areas can then be used by countries in their own strategic consideration of feasible opportunities to improve collaboration at the human–animal interface.

With the support of the World Bank and the European Commission, WHO and the OIE organised two pilot IHR–PVS Pathway National Bridging Workshops to gain insight into country perspectives on the IHR (2005) and the PVS Pathway.

In order to ensure optimal feedback for these pilot workshops, two countries, Azerbaijan and Thailand, were selected as representatives because they were relatively well advanced in the implementation of the IHR assessments and/or PVS Pathway and they had expressed interest in activities conducted at the human–animal interface.

Objectives and approach used during the workshops

Methodology of the IHR–PVS Pathway pilot National Bridging Workshops

The IHR–PVS Pathway National Bridging Workshops have the following objectives:

Objective 1: Increase awareness and understanding of the IHR Monitoring Framework and the PVS Pathway.

Objective 2: Discuss how the results of the IHR Monitoring Framework and the PVS Pathway can be used to bring benefits to the endeavours of both sectors.

Objective 3: Identify practical next steps and activities for a joint national roadmap to strengthen collaboration and coordination.

The above-mentioned objectives of the IHR–PVS Pathway National Bridging Workshop have been used to develop and frame the workshop methodology.

Objective 1: To increase awareness and understanding of the IHR Monitoring Framework and PVS Pathway, WHO and OIE experts provided an introduction to each of their respective assessments and associated tools. Following this introduction, participants were asked to share some of their own ideas regarding possible benefits of the two frameworks in developing a strategy for the improvement of their intersectoral collaboration (Fig. 8).

Organogram exercises were then used to actively engage the two sectors in mapping the current and most frequent channels of communication and partnership between the ministries (Fig. 9).

Fig. 8
Participants' ideas for beneficial collaboration

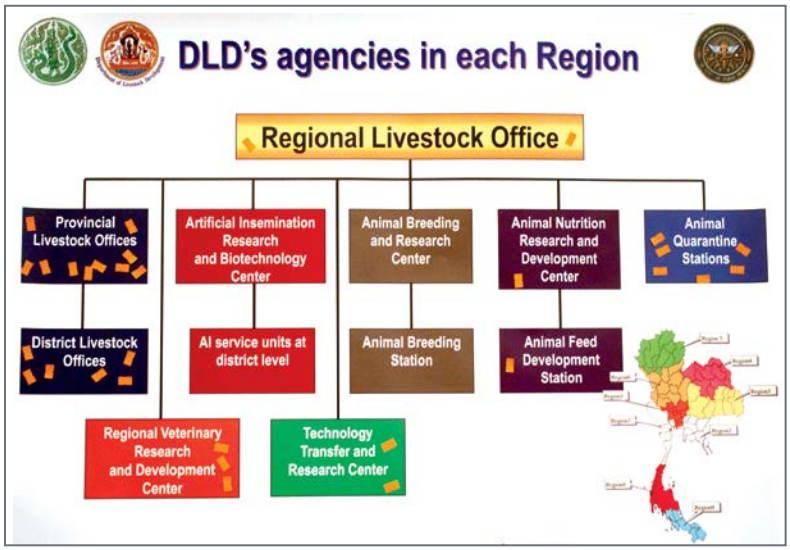


Fig. 9
Organogram of Department of Livestock and Development of Thailand (DLD) on which Ministry of Public Health participants indicated services with which they collaborate

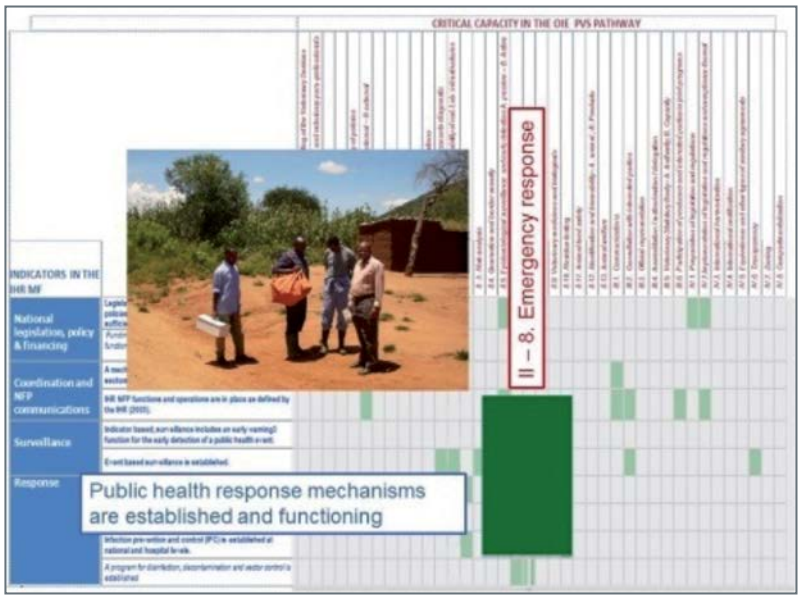


Fig. 10
Example of a matrix of the PVS Tool Critical Competencies and World Health Organization International Health Regulations Monitoring Framework indicators, and practical use for intersectoral collaboration during outbreaks

Following this introduction and general group discussion, a matrix of the indicators and Critical Competencies respectively used in the IHR Monitoring Framework and the PVS Tool was provided to offer a graphical representation of the relationships between these two assessments (Fig. 10). This mapping enabled participants from both sectors to better visualise how specific areas of common interest could form the basis of the development of mutually beneficial and joint approaches.

Objective 2: To facilitate a more focused group discussion regarding how the results of the PVS Pathway and IHR Monitoring Framework can bring benefits to the endeavours of both sectors, the main results of the assessments that had been conducted in the countries were then presented by the IHR Focal Point (or representative) and by the PVS Gap Analysis team leader alongside the representative of the National Animal Health Authority. This session helped participants to understand the nature of the previously identified gaps, and to gain knowledge of any current or planned corrective measures.

Day 2 of the National Bridging Workshops provided an opportunity for participants to practically consider together how **(Objective 3) to identify next steps and activities for a joint national plan of action to strengthen collaboration and coordination**. Working groups, composed of participants from both the human and animal health sectors, were each given a predefined scenario to use as a case study to envisage collaboration between the two sectors in the management of an event of zoonotic nature (Table XIV). Participants discussed the management of these cases in terms of:

- surveillance
- early detection
- stakeholder communication
- human resources
- infrastructure, and
- financial resources.

Table XIV Case studies:
examples of scenarios proposed to the working groups

1. A case of rabies, which has been confirmed in a dairy cow recently inseminated and regularly milked, generates panic in the population
2. H7N9 was confirmed in a veterinarian who returns from a conference in an endemic country and lives in a poultry production area
3. Nine people showed identical anthrax-like lesions reported in a district hospital close to a border post. One is working in a village slaughterhouse
4. A private veterinarian reports unusual mortality among piglets in a commercial farm. Workers on the farm also show illness
5. An exporting country suspects that a shipment of piglets to your country was contaminated with *Streptococcus suis* and entered into the market

During this working group session, the participants were also asked to answer generic questions related to these disease events (Table XV).

Based upon the groups' reports, WHO and OIE experts were able to map the matrix of the Core Capacities of the IHR Monitoring Framework (CC IHR) and the Critical Competencies of the PVS Pathway (CC PVS), and the gaps identified (Fig. 11).

Table XV Examples of working group guide questions

1. In general, how would you qualify the current capability of your country to conduct disease surveillance, early detection and rapid response to zoonotic and emerging diseases?
2. In general, how would you qualify the interaction between the different animal health and public actors of your country in addressing zoonotic and emerging disease?
3. How do you think the PVS Pathway and the International Health Regulations helped or could help your country in improving disease surveillance, early detection and rapid response to zoonotic and emerging diseases?
4. How would you qualify the capability of Veterinary Services and public health services in advocating and obtaining proper financial support to align national priorities with international standards? What opportunities exist (new sources, resources pooling, etc.)?

Fig. 11
Positioning identified gaps in a large poster of the matrix of Core Capacities of International Health Regulations and Critical Competencies from the PVS Tool

Fig. 12
Result: cluster of sticky notes where gaps (in yellow) are more frequently identified

As a result of this mapping exercise, particular intersections could be identified as frequently reported gaps in the operational collaborations between the two sectors (Fig. 12), including:

- risk communication (CC PVS III.1/CC IHR 6);
- joint epidemiological investigation between human and animal (CC PVS II.7/CC IHR 4);
- risk assessment (CC PVS II.3/CC IHR 4); and
- joint surveillance (CC PVS II.5/CC IHR 3).

The working groups were then requested to further explore these gaps from a wider perspective (i.e. focused not only on the proposed scenarios) and elaborate on possible corrective activities, keeping in mind the presentation of the IHR focal point and the results of the PVS missions the day before, in which strategic directions and possible actions had already been identified and described. An example of this is provided in Table XVI.

The results proved to be highly pertinent and aligned with the gaps identified during the IHR and the PVS assessment exercises. Furthermore, the participants realised the value of the assessment frameworks and were able to visualise the practical actions needed to address the gaps.

For WHO and the OIE, it was also an opportunity to validate the synergies already identified and mapped in the matrix, as presented in Part 2, Chapter I-3 of this Operational Framework. It also confirmed that the matrix is a good support for these discussions.

Table XVI Identification of gaps and joint activities by the participants of one of the National Bridging Workshops

Risk communication	Joint investigation	Risk assessment	Joint surveillance
Gap			
Lack of standard operating procedures (SOPs) for efficient crisis communication	Lack of operational joint SOPs	Lack of joint framework for risk assessment, lack of knowledge on risk assessment (RA)	Need to strengthen surveillance
Activities			
• Create an *ad hoc* working group • Define policy, guidelines, draft of SOPs • Co-training + field test • Finalisation of SOPs and guidelines, website • Training programme	• Conception of guidance: Working Groups, involvement of experts and laboratories • Definition of contingency plan, joint exercise, use and coordination of alert system • Harmonising investigation, report platform, sharing resources, equipment data	• Conception of the framework: event database, data information, pilot model • Test of the pilot model and update • Training of trainers, selection of experts (committee for RA) • Mechanism and use of RA results for risk management (decision-making), and for communication	• Meeting to develop a guidelines to define a relevant surveillance plan and strengthen knowledge of local officers • Pilot experience in some areas to validate the methodology • Meeting to improve and finalise the guidelines • Diffusion of the guidelines
Expected outputs			
• A finalised SOP on risk communication • Trained staff to apply these SOPs • Plan to define specific SOPs for some key diseases	• A guidance for joint investigation • Integrated contingency plan • Well-designed reporting system	• A clear and effective framework for RA • Relevant human resources	• Effective team and good guidelines to define and organise relevant surveillance

Key observations from pilot workshops

Participation

National Bridging Workshops are appropriate for countries which are relatively well advanced in the implementation of the PVS Pathway and/or IHR assessments, and which have expressed interest in activities conducted at the human–animal interface. In the case of the PVS Pathway, countries should have completed the PVS Evaluation (assessment component of the PVS Pathway) and PVS Gap Analysis (PVS Costing Tool) steps.

In order to ensure optimal facilitation of discussions and group activities, the number of participants is best kept to approximately 50, with equal representation from ministries governing human and animal health. It is important to encourage high-level decision-makers to participate, in order to gain both a true understanding of the potential benefits and endorsement of effective intersectoral collaboration.

The availability of detailed information regarding the results of the IHR Monitoring and the PVS Pathway assessment exercises is important to derive optimal value from these workshops. Although the recipients may wish to maintain confidentiality, these results are key for the achievement of Objectives 2 and 3 (see Box 1). The value lies not so much in the gaps identified, but more in relation to the strategies and corrective measures which were discussed during these assessments. Ensuring that the workshop delegation includes those who actually used these tools could facilitate the sharing of confidential data.

Methodology and structure

The level of awareness of the IHR (2005) and the PVS Pathway is considered low (except among IHR NFPs and National Veterinary Services' headquarters staff, respectively), and the related assessment tools are neither well known nor well understood; therefore, the explanation of these assessment frameworks is essential to any meaningful participation in this workshop.

Despite this, the WHO and OIE presentations relating to Objective 1 (see Box 1) should be kept to a minimum, as the participants perceived particular value in the working group sessions, and were highly interested in actively participating in discussions about future strategies and potential joint activities. In order to ensure sufficient time for the group activities and discussions, a minimum of two full days should be scheduled for National Bridging Workshops.

A well-structured approach and robust facilitation is required to achieve all the objectives of the workshop. The use of the matrix proved to be a good and consistent support throughout the pilot workshops. When presented with precise scenarios dealing with clear operational issues, the conceptualisation of joint activities was better facilitated and gaps more easily identified. This enabled intersectoral discussion about possible corrective measures, in the form of constructive and well-defined proposals.

Opportunities for the development of further IHR–PVS Pathway National Bridging Workshops

The pilot workshops have provided a viable structure on which to base further IHR–PVS Pathway National Bridging Workshops, and WHO and the OIE should explore the feasibility of, and financial resources for, the implementation of additional National Bridging Workshops (or Regional Seminars) to engage the human and animal health sectors in dialogue. When relevant, these sectors should share their assessment results, as this is a necessary prerequisite for motivating the further intersectoral collaboration necessary to establish sustainable national 'One Health' collaborative action plans and practices.

Future workshops (national or regional) could also be expanded to include additional facets that may assist countries in the formulation of their strategies. For example, operational issues could include scenarios relating not only to zoonosis management, but also to food safety issues and antimicrobial resistance. The workshop discussions pertaining to potential joint actions could also be expanded by considering how these activities might form a foundation to move forward the national One Health agenda as well as to improve compliance with international standards and regulations.

National Bridging Workshops could also end with a session on 'available external assistance', specifically presenting the guiding and capacity-building tools developed by both WHO and the OIE (PVS Pathway 'treatment' phase), focusing on the tools that could specifically address gaps identified in previous assessments (e.g. legislation, laboratory).

Future follow-up meetings may be an appropriate next step to review progress made in the implementation of specific plans of action proposed during the National Bridging Workshops.

Key points derived from the pilot National Bridging Workshops

1. All stakeholders require further explanation and comparison of the IHR Monitoring Framework and PVS Pathway objectives, tools and intended outcomes.
2. Stakeholders need to engage in scenario exercises to better conceptualise and more willingly embrace opportunities for joint activities.
3. Workshops to engage both sectors in dialogue and (as appropriate) share assessment results is a necessary prerequisite in order to motivate future intersectoral liaison in establishing a national 'One Health' collaborative plan of action.

PART 3

The WHO and the OIE have worked closely together to address the complementarities of the PVS Pathway and the IHR Monitoring Framework. This part of the Operational Framework provides the reader with an in-depth explanation of the various tools developed by WHO and the OIE; it also explores, highlights and presents the outcomes of synergistic approaches, identifying similarities and differences as well as opportunities for synergies to achieve better efficiencies of animal and human health services at both national and international levels.

- The **first section** introduces the PVS Evaluation mission and corresponding PVS Tool. It then highlights the linkages between the PVS Tool and the WHO Monitoring Framework by summarising the analysis contained in a specific *WHO–OIE Handbook*.

- The **second section** provides a comprehensive overview of the costing tools developed by the OIE and WHO; information on the objectives, process, methodology, outputs and outcomes is provided for each tool.

- The **third section** is dedicated to the complementary tools developed by WHO and the OIE with regard to helping Member Countries analyse the laboratory situation at country level and identify targeted and strategic improvements. This section is also supported by the outcomes of a review between the OIE and WHO laboratory tools in order to identify points of convergence or synergies, as well as differences and gaps.

Enhanced information-sharing and mutual contribution between the two sectors during and after assessment missions can lead to new opportunities to achieve greater benefits in the protection of national and global animal and public health, in line with One Health principles.

1. Assessment and monitoring tools

According to the IHR (2005), countries should have the capacity to detect, assess, notify and report and should be able to cover all sort of events which may constitute a PHEIC, including those originating or shared with animals (zoonosis) or animal products (food safety). WHO developed the IHR Monitoring Framework, a structured approach to (i) support countries in assessing their status in the development of IHR Core Capacities and (ii) facilitate the reporting of States Parties to the World Health Assembly as required under the IHR (2005). Using indicators developed for pre-identified Core Capacities, statistics are produced and reflect countries' self-assessment regarding compliance with the IHR (2005), including for events of a zoonotic or food safety nature[5]. The IHR Monitoring Framework was presented in detail in Part II, section 1.1.

The OIE Tool for the *Evaluation of Performance of Veterinary Services* (the PVS Tool) proposes a comprehensive and tried and tested approach for evaluating the performance of Veterinary Services against the intergovernmental standards published in the *Terrestrial Code*, including references for early detection of disease incursions, transparency and notification, and rapid response to animal disease outbreaks. The results of this exercise reflect the strengths and weaknesses identified by Veterinary Authorities, and should be used in IHR assessment and reporting national duties. The connection between the frameworks highlights the contribution of Veterinary Services to the implementation of the IHR (2005).

5 www.who.int/gho/ihr/en/

1.1. OIE PVS Evaluation, Manuals and Tool

Context

Veterinarians and national Veterinary Services (public and private components) play a major role in the prevention, control and eradication of animal diseases, including zoonoses; they contribute to ensuring the sustainability of livelihoods and protecting human health, and cannot fulfil their mission without the appropriate regulatory framework and the necessary means to enforce the corresponding legislation, including private and public partnerships. Good veterinary governance is a key to improving national productivity and income generation as well as contributing to human health. The OIE provides assistance to its Member Countries to improve the governance of their national Veterinary Services, so that their capacity may be strengthened and better aligned with OIE international quality standards. At the specific request of a Member Country, the OIE provides expertise through its PVS Pathway, a continuous process which helps countries to identify and address areas where there are gaps in the performance of its Veterinary Services.

The PVS Evaluation mission ('diagnosis') is the first step in the PVS Pathway; it is an external evaluation conducted by a group of OIE-certified PVS experts who collect and analyse baseline information to assess the country's Veterinary Services' level of compliance with OIE international standards on quality against the 47 Critical Competencies of the PVS Tool. By comprehensively assessing a country's Veterinary Services' compliance with OIE international standards, the PVS Evaluation provides a complete overview of the Veterinary Services, evaluating its performance and identifying weaknesses.

The objective of a PVS Evaluation mission is to undertake a qualitative assessment of a country's national Veterinary Services' performance and its compliance with OIE international standards on the quality of Veterinary Services using the PVS Tool. This Tool is based on the OIE intergovernmental standards democratically adopted by OIE Member Countries and contained in the *Terrestrial Code*.

The PVS Evaluation is more than just a diagnostic instrument; it helps countries to improve management of the interrelationship and responsibilities of all actors from both the public sector (including other ministries and departments) and the private sector, in order for the Veterinary Services to function effectively.

A PVS Evaluation mission is a constructive and advisory exercise and not an audit. Through this mission, performance is evaluated, gaps are identified, differences are explored and priorities are established. It also seeks to promote and stimulate national Veterinary Services to continually better their compliance with OIE intergovernmental standards.

Manuals and tools

PVS Tool

This Tool is based on the intergovernmental standards outlined in the *Terrestrial Code*, in particular Chapters 3.1 and 3.2 on the quality of Veterinary Services. Using the PVS Tool, a PVS Evaluation mission focuses on and assesses a country's Veterinary Services on the basis of the fundamental components listed in Table XVII.

The structure of the PVS Tool is based on these four fundamental components. For each fundamental component there is a total of 47 Critical Competencies grouped according to the relevant fundamental component. The 47 Critical Competencies are listed in Table XVIII and are accordingly revised and/or added to based on modifications to the *Terrestrial Code*.

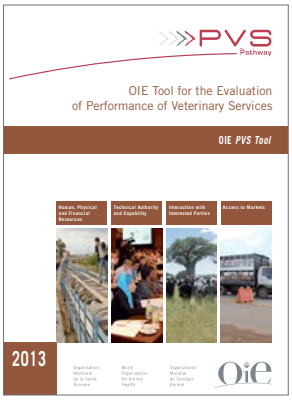


Table XVII Fundamental components of the PVS Tool

Fundamental component 1	The **human, physical and financial resources** to attract resources and retain professionals with technical and leadership skills
Fundamental component 2	The **technical authority and capability** to address current and new issues including prevention and control of biological disasters based on scientific principles
Fundamental component 3	The sustained **interaction with interested parties** in order to stay on course and carry out relevant joint programmes and services
Fundamental component 4	The ability to **access markets** through compliance with existing standards and the implementation of new disciplines such as the harmonisation of standards, equivalence and zoning

Table XVIII The 47 Critical Competencies of the PVS Tool

47 Critical Competencies of the PVS Tool
Human, physical and financial resources
I-1.A. Professional and technical staffing of the Veterinary Services. Veterinarians and other professionals
I-1.B. Professional and technical staffing of the Veterinary Services. Veterinary paraprofessionals and other technical professionals
I-2.A. Professional competencies of veterinarians including the OIE Day 1 competencies
I-2.B. Competencies of veterinary para-professionals
I-3. Continuing education
I-4. Technical independence
I-5. Stability of structures and sustainability of policies
I-6.A. Coordination capability of the Veterinary Services. Internal coordination (chain of command)
I-6.B. Coordination capability of the Veterinary Services. External coordination
I-7. Physical resources
I-8. Operational funding
I-9. Emergency funding
I-10. Capital investment
I-11. Management of resources and operations
Technical authority and capability
II-1.A. Veterinary laboratory diagnosis. Access to veterinary laboratory diagnosis
II-1.B. Veterinary laboratory diagnosis. Suitability of national laboratory infrastructures
II-2. Laboratory quality assurance
II-3. Risk analysis
II-4. Quarantine and border security
II-5.A. Epidemiological surveillance and early detection. Passive epidemiological surveillance
II-5.B. Epidemiological surveillance and early detection. Active epidemiological surveillance
II-6. Emergency response
II-7. Disease prevention, control and eradication
II-8.A. Food safety. Regulation, authorisation and inspection of establishments for production, processing and distribution of food of animal origin
II-8.B. Food safety. Ante and post mortem inspection at abattoirs and associated premises
II-8.C. Food safety. Inspection of collection, processing and distribution of products of animal origin
II-9. Veterinary medicines and biologicals
II-10. Residue testing
II-11. Animal feed safety
II-12. A. Identification and traceability. Animal identification and movement control
II-12.B. Identification and traceability. Identification and traceability of animal products
II-13. Animal welfare
Interaction with interested parties
III-1. Communication
III-2. Consultation with interested parties
III-3. Official representation
III-4. Accreditation/authorisation/delegation
III-5.A. Veterinary Statutory Body (VSB). VSB Authority
III-5.B. Veterinary Statutory Body (VSB). VSB Capacity
III-6. Participation of producers and other interested parties in joint programmes

47 Critical Competencies of the PVS Tool
Access to markets
IV-1. Preparation of legislation and regulations
IV-2. Implementation of legislation and regulations and compliance thereof
IV-3. International harmonisation
IV-4. International certification
IV-5. Equivalence and other types of sanitary agreements
IV-6. Transparency
IV-7. Zoning
IV-8. Compartmentalisation

The sixth edition of the PVS Tool, released in 2013, contained a series of modifications to the previous version of the PVS Tool; these modifications primarily concerned Critical Competencies dealing with veterinary education, laboratory infrastructure, food safety and animal feed safety. For each critical competency, five qualitative levels of advancement are described in a preformatted specific critical competency card.

A higher level of advancement assumes that the Veterinary Services comply with all preceding levels of compliance (e.g. level 3 assumes compliance with level 2 advancement). Level of advancement 1 corresponds to non-compliance with OIE intergovernmental standards; the higher the level of advancement, the more compliant the national Veterinary Services is for the corresponding critical competency.

The relevant references from the *Terrestrial Code* are quoted under each critical competency.

PVS Evaluation Manuals

The PVS Manual of the Assessors (Volume 1) serves not only as an instrument in the training of PVS experts and during the implementation of missions, but also as an instructional reference detailing the process, approach, methodology, outputs and expected outcomes of every PVS Evaluation mission. This manual provides additional information and guidance for experts in relation to conducting evaluations of a country's Veterinary Services and when implementing PVS Evaluation Follow-up missions, as well as highlighting key points and relevant Critical Competencies of the PVS Tool relating to One Health. The PVS Manual of the Assessors (Volume 2) provides guidance and guidelines for writing a PVS Evaluation report.

Using a template, the manual provides instructions and helpful tips to experts to ensure that PVS Evaluation reports are of high quality and drafted in a harmonised manner.

Process

Further to an official request from the country to the OIE, a PVS Evaluation mission is implemented. It is the first ('diagnosis') step of the PVS Pathway. The PVS Expert's Manual (Volume 1) describes in detail each step of the PVS Evaluation and its three phases of implementation:

(1) *pre-mission preparation* (3–5 months): confirmation of request, administration and data collection;

(2) *mission* (10–21 days); and

(3) *post mission* (3 months): report writing, peer review and validation by OIE Headquarters and the Member Country's OIE Delegate.

Approach and methodology

A PVS Evaluation mission collects and analyses baseline information to assess a country's Veterinary Services[6] level of compliance with OIE international standards on quality against the 47 Critical Competencies of the PVS Tool. In order to obtain a comprehensive diagnosis of a country's Veterinary Services, the OIE assesses all interested parties involved in the veterinary domain. Figure 13 represents the veterinary domain and defines all the activities that are directly or indirectly related to animals, their products and by-products, and which help to protect, maintain and improve the health and welfare of humans, including through the protection of animal health and welfare and food safety.

It also summarises the responsibilities and competencies described in the *Terrestrial Code* that can be shared among different competent authorities, including that of the Veterinary Authority.

6 The terms 'Veterinary Authorities' and 'Veterinary Services' refer to the definitions outlined in the OIE *Terrestrial* and *Aquatic Codes*:
– 'Veterinary Authority' means the governmental authority, comprising veterinarian, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Terrestrial Animal Health Code* in the whole territory
– Veterinary Services' means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the *Code* in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians and veterinary paraprofessionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions

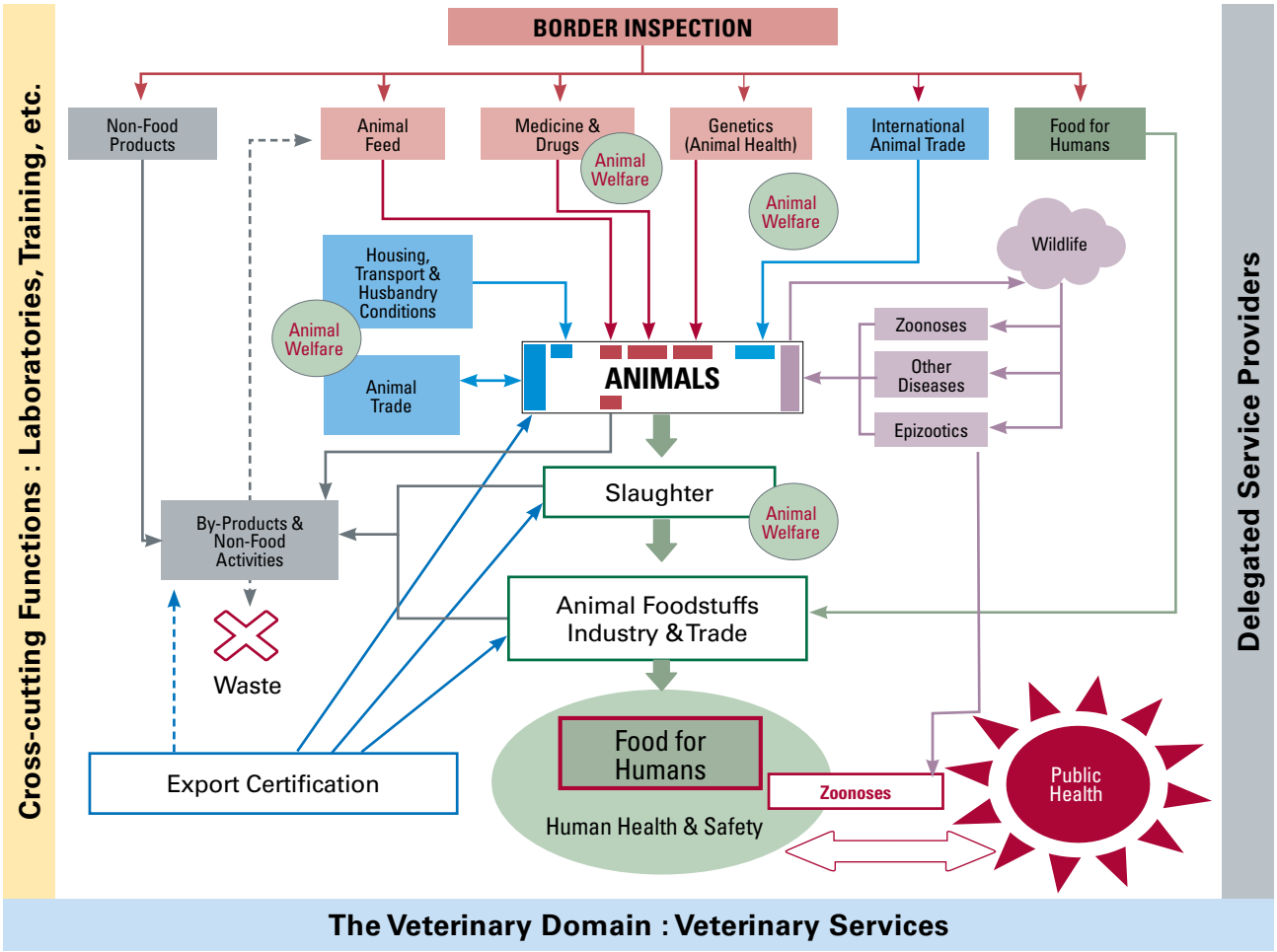


Fig. 13
Responsibilities and competencies as described in the *Terrestrial Code*

A representative sample of actors involved in implementing activities pertaining to the veterinary domain is visited during a PVS Evaluation; actors at both national and local level are visited and subject to evaluation during the mission.

Based on these visits and using the PVS Tool, the expert team assesses and evaluates the country's Veterinary Services' capacity and corresponding level of advancement for all 47 Critical Competencies. It is an impartial and external comprehensive assessment. Although the PVS Evaluation mission addresses responsibilities and competencies that are shared among different competent authorities involved in the veterinary domain, it only evaluates the compliance of Veterinary Services.

Outputs

The experts' final mission report to the country's Veterinary Services contains:

- an executive summary highlighting the key findings of the mission as well as key recommendations for each of the four fundamental components of the country's Veterinary Services assessed during the mission;
- information on the country, including geographical features, national economy and impact of the livestock sector on national gross domestic product, the structure of the country's Veterinary Services, and animal disease occurrence;
- a list of categories of sites and sampling during the PVS Evaluation;
- the findings of the mission for each of the 47 Critical Competencies. For each critical competency the report provides:
  - the level of advancement assessed
  - evidence and reference data to support the mission findings
  - strengths and weaknesses of the country's Veterinary Services for the specific critical competency, and
  - possible recommendations to steer future actions and to guide improvements in compliance with OIE intergovernmental standards.

Outcomes

The PVS Evaluation mission report ultimately enables Veterinary Services' strategic planners to have a well-informed understanding of the current level of compliance with OIE intergovernmental standards, and of its structure, performance and viability in the national context.

Key decision-makers benefit from the receipt of quantitative and qualitative information about the functioning of the Veterinary Services, both public and private components, allowing them to identify strengths and weaknesses and areas for improvement. The report also proposes ways in which the Veterinary Services can improve their compliance with OIE intergovernmental standards as well as their overall performance.

With the support provided by trained PVS Evaluation mission experts, national Veterinary Services are well equipped to decide upon an appropriate strategy to further their compliance of Veterinary Services to international standards. Such improvement better ensures the rapid detection and control of animal diseases, including those critical to the control of major emerging issues at the human–animal interface.

1.2. WHO–OIE Handbook for the assessment of capacities at the human–animal interface

Context

In order to assist the States Parties[7] in their responsibility to report to the World Health Assembly, WHO has developed a data collection tool which enables each State Party to provide standardised information on the progress of its core capacity development in the implementation of IHR (2005). The data collection tool is interfaced with an online questionnaire derived from the checklist and indicators document[8] developed through the IHR Monitoring Framework. This questionnaire is designed primarily for use by IHR NFPs in collaboration with public health professionals, managers and other sectors and stakeholders responsible

7 Certain states that are not members of WHO may become a party to the IHR by notifying acceptance of the Regulations to the Director-General of WHO. The current 196 States Parties to the IHR (2005) include all WHO Member States as well as the Holy See and Liechtenstein

8 www.who.int/ihr/checklist/en

for implementing the IHR. This process aims to capture the contribution of the specific sectoral authorities, in reaching the objectives of the IHR (2005).

When it comes to the specific contribution of the Veterinary Authorities, the PVS Pathway assesses the performance of a country's Veterinary Services and their compliance with the OIE intergovernmental standards on the quality of Veterinary Services. All aspects relevant to the *Terrestrial Code* and the quality of Veterinary Services, as per the OIE's definition[9], are reviewed using the PVS Tool. A team of OIE-certified experts collects and analyses baseline information against 47 Critical Competencies, each of which is described in a specific card. The data contained in PVS Evaluation reports can greatly facilitate the IHR NFPs when completing the IHR Monitoring Framework questionnaire, given that PVS Evaluation reports provide concrete elements on the contribution of a country's Veterinary Services to some of the Core Capacities defined in the IHR (2005).

The contribution of a country's Veterinary Services may be obvious for some specific hazards (zoonosis, food safety); however, there are also other key areas that are useful for providing information on other Core Capacities in the questionnaire. The *WHO–OIE Handbook for the assessment of capacities at the human–animal interface in the IHR Monitoring Framework: Taking advantage of OIE PVS Pathway outcomes* contains detailed information on the connection between the two processes and how the data contained in PVS Evaluation reports can assist and aid countries in better answering the IHR Monitoring Framework questionnaire.

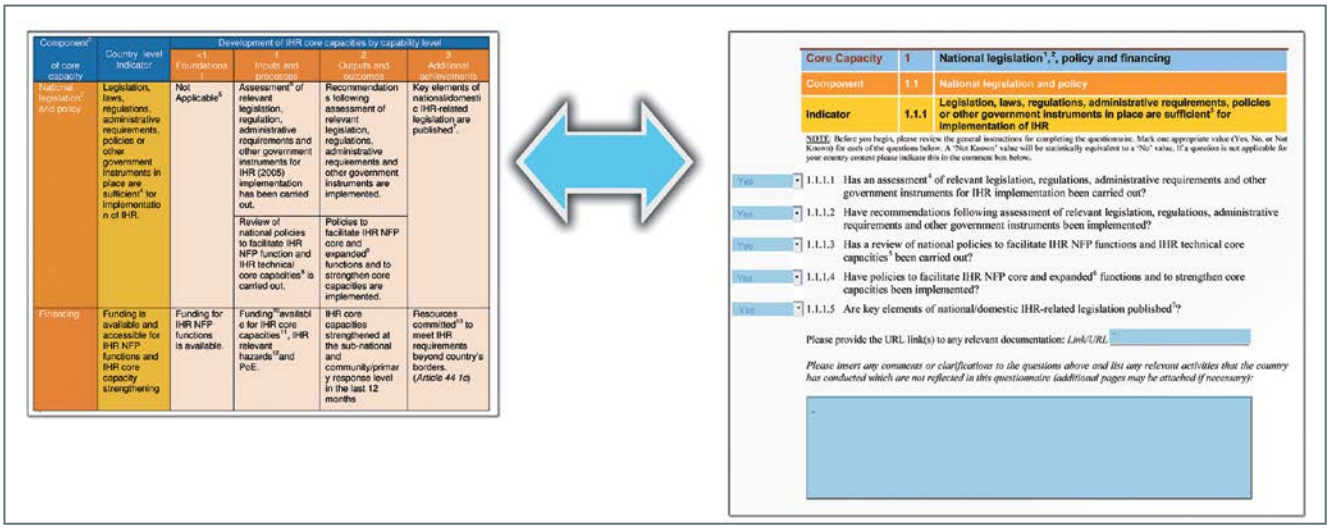
9 See definition provided in reference 6

Objective

The objective of the *WHO–OIE Handbook for the assessment of capacities at the human–animal interface in the IHR Monitoring Framework: Taking advantage of OIE PVS Pathway outcomes* is to facilitate the assessment of existing capacities in areas where a country's Veterinary Services contribute to the objectives of the IHR (2005). More particularly, it aims to facilitate the annual IHR assessment by using the results of the PVS Pathway missions and, through this process, increase the visibility of the contribution of the Veterinary Services in the implementation of the IHR (2005).

Approach and methodology

In order to achieve this objective, parallels between the IHR Monitoring Framework questionnaire and the PVS Tool have been established. The questions from the IHR Monitoring



The indicators are specified by several attributes reflecting a 'capability level', (four capability levels: Level < 1: prerequisites (foundational level); Level 1: inputs and processes; Level 2: outputs and outcomes; Level 3: additional).

Attributes are translated in questions in the Questionnaire ('Yes', 'No', or 'Not Known' questions). If a question is not applicable for the country context, this is indicated in the comment box.

Fig. 14

An example of the translation of the International Health Regulations (IHR) checklist and indicators to the online questionnaire

Framework questionnaire that require a contribution from a country's Veterinary Services have been identified and associated with the relevant critical competency(ies) of the PVS Tool.

Content of the handbook

The IHR Monitoring Framework questionnaire is derived from the IHR 'Checklist and indicators' document. Figure 14 illustrates the translation from the IHR 'Checklist and indicators' to the online questionnaire, with the example of the first indicator of core capacity 1: national legislation, policy and financing.

The first indicator is **legislation, laws, regulations, administrative requirements, policies or other government instruments in place are sufficient for implementation of IHR.**

This handbook will help users of the IHR online questionnaire explore the possible contribution of the country's Veterinary Services by guiding them, for each question, to the relevant PVS critical competency(ies).

Table XIX illustrates this link for the first question of the previously presented indicator of core capacity 1: national legislation, policy and financing.

Table XIX Link between the questions in the International Health Regulations (IHR) questionnaire and PVS Critical Competencies

Questions in the IHR questionnaire	PVS Critical Competencies
1.1.1.1. Has an **assessment of relevant legislation, regulations**, administrative requirements and other government instruments for IHR implementation **been carried out**?	IV-1. Preparation of legislation and regulations
	II-7. Disease prevention, control and eradication
	II-6. Emergency response

Table XX International Health Regulations Monitoring Framework Core Capacities and specific capacities

Eight Core Capacities	Specific capacities
1. National legislation, policy and financing	9. Points of entry
2. Coordination and National Focal Point communications	10. Hazards _ 10.1. Zoonotic _ 10.2. Food safety _ 10.3. Chemical emergencies _ 10.4. Radiation emergencies
3 Surveillance	
4. Preparedness	
5. Response	
6. Risk communications	
7. Human resource capacity	
8. Laboratory	

Table XXI Representation of the two pillars of the International Health Regulations (IHR) Monitoring Framework

Section 1: Enabling environment	Section 2: Operational capacity
Legal and regulatory framework ▪ Review of the legal landscape ▪ Regulation and policies enabling the National Focal Point and strengthening the Core Capacities, as defined in the IHR (2005) ▪ Definition of roles and duties in the IHR framework ▪ Existing references **Review of structures and resources available** ▪ Mapping of existing structures and operational resources ▪ Financial resources ▪ Human resources **Coordination between sectors** ▪ Facilitating mechanisms between responsible authorities ▪ Coordination with stakeholders ▪ Operational frameworks ▪ Procedures ▪ Operations	**Capacity to detect an unusual event and identify its aetiology** ▪ Global review of the network of collaboration and shared references ▪ Interactions during routine surveillance programmes and assessment of potential risks ▪ Existing capacities to obtain a diagnosis ▪ Ensuring quality in the laboratories ▪ Information on risk factors ▪ Shared protocols for events management ▪ Actions for rapid confirmation ▪ Specific surveillance of AMR **Capacity to ensure a coordinated response** ▪ Rapid response teams ▪ Mechanisms for rapid action ▪ Evaluation of the interventions and quality review ▪ Development of a communication plan

Structure of the handbook

The *online questionnaire* follows the same structure as the IHR 'Checklist and indicators': the questions are organised along the eight Core Capacities, plus point of entry (PoE), and four sections on specific hazards – zoonoses, food safety, chemical and radio-nuclear (Table XX).

As mentioned above, it is apparent that a country's Veterinary Services not only contribute to specific hazards on zoonosis[10] and food safety but also play a fundamental role in protecting human health; therefore, their activities and actions are also relevant to many other components of the eight Core Capacities[11].

As a result, a linear review along the structure of the questionnaire has been found tedious and resulting in redundancies and confusion.

It has therefore been proposed to organise the selected questions around two pillars[12] (as illustrated in Table XXI):

i) The first pillar includes questions referring to the **environment enabling the implementation of IHR (2005)** and includes sections on the legal and regulatory framework, the resources and the coordination mechanisms between the two sectors.

ii) The second pillar includes questions exploring the **operational capacities** to detect an unusual event, identify its aetiology and ensure a coordinated response.

How to use the handbook

There are 256 questions in the IHR Monitoring Framework questionnaire. These questions are identified by numbers, the first character(s) being the number of the core capacity they refer to (e.g. 7.x.x.x for a question associated with core capacity 7), the second character referring to the component and the third character to the indicator (Fig. 15).

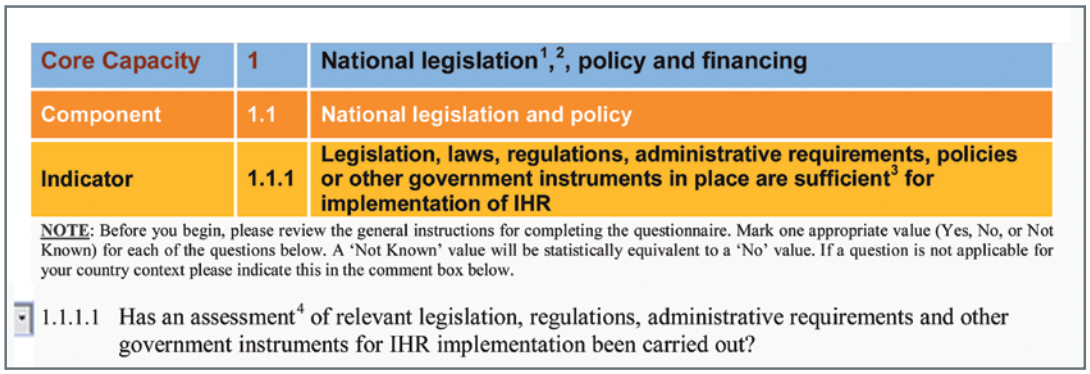
All the questions selected from the IHR Monitoring Framework questionnaire are organised thematically following the structure described above. The user can explore the possible contribution of a country's Veterinary Services by consulting the selected corresponding PVS critical competency proposed.

The definition and the area covered by the PVS critical competency(ies) are provided in the last column, with special references to areas of interest for the specific question of the IHR Monitoring Framework questionnaire.

10 The term 'zoonosis' here refers to the definition given in WHO's checklist and indicator document: 'Any infection or infectious diseases that is naturally transmissible from vertebrate animal to human'. In this document, it should then be considered as limited to infectious diseases.

11 In this version, the specific capacities for PoE, chemical and radiation emergencies have not been considered, as the contribution of the Veterinary Services is more difficult to objectify.

12 The delimitations of these sections have been defined using the experience of previously or currently developed strategies and roadmaps for improved intersectoral coordination for zoonosis and the PVS One Health pilot missions conducted by the OIE.



Core Capacity	1	National legislation[1],[2], policy and financing
Component	1.1	National legislation and policy
Indicator	1.1.1	Legislation, laws, regulations, administrative requirements, policies or other government instruments in place are sufficient[3] for implementation of IHR

NOTE: Before you begin, please review the general instructions for completing the questionnaire. Mark one appropriate value (Yes, No, or Not Known) for each of the questions below. A 'Not Known' value will be statistically equivalent to a 'No' value. If a question is not applicable for your country context please indicate this in the comment box below.

1.1.1.1 Has an assessment[4] of relevant legislation, regulations, administrative requirements and other government instruments for IHR implementation been carried out?

Example:
The first question (1.1.1.1) is identified by:

1.-.-.-.: Core capacity 1
1.1.-.-.: Component 1
1.1.1.-.: Indicator 1
1.1.1.1.: Question 1

Fig. 15
An example of a question in the International Health Regulations (IHR) Monitoring Framework questionnaire

Where appropriate, a short paragraph has been added below to the question to describe or make explicit the contribution of the country's Veterinary Services to achieving the core capacity.

Table XXII illustrates the structure of the tables presented in the handbook, using the first question of indicator 1, core capacity 1 and the first PVS critical competency (VI-1: Preparation of legislation and regulations).

In total, the *WHO–OIE Handbook for the assessment of capacities at the human–animal interface in the IHR Monitoring Framework: Taking advantage of OIE PVS Pathway outcomes* identifies the contribution of a country's Veterinary Services to 98 questions of the IHR Monitoring Framework questionnaire, with additional information extracted from 36 PVS Critical Competencies.

Table XXIII shows the table of correspondence and summarises the association between the selected questions from the IHR Monitoring Framework questionnaire and the PVS Critical Competencies. This table facilitates rapid review of the specific actions provided by national Veterinary Services and described in the PVS Critical Competencies that contribute to the global objectives of the IHR (2005).

Table XXII Structure of the tables presented in the handbook highlighting linkages between the International Health Regulations (IHR) Monitoring Framework (MF) and PVS Critical Competencies

Questions in the IHR MF questionnaire	PVS Critical competency	Description
1.1.1.1. Has an assessment of relevant legislation, regulations, administrative requirements and other government instruments for IHR implementation been carried out? *The Veterinary Services (VS) have an active role in the development of the legal and regulatory framework for the prevention and control of animal diseases including zoonosis, food safety, medicines and several other areas under their mandate*[a]*. The main issues to consider here are (i) the involvement of the VS in the review of the existing legal, regulatory and administrative instruments covering the core functions defined in the IHR (2005); and (ii) the description of the synergistic, overlapping or possible conflicting areas between the legal, regulatory and administrative frameworks developed in the human and animal sectors for the core functions defined in the IHR (2005)*	**IV-1. Preparation of legislation and regulations**	This critical competency reviews the authority and capability of the VS to actively participate in the preparation of national legislation and regulations in domains that are under their mandate, in order to guarantee its quality with respect to principles of legal drafting and legal issues and its accessibility, acceptability and technical, social and economic applicability. This competency includes collaboration with relevant authorities, including other ministries and competent authorities, national agencies and decentralised institutions that share authority or have mutual interest in relevant areas. The critical competency reviews, *inter alia*: – the legislative and regulatory framework of the veterinary domain and the mandate of the veterinary authority; – the coordination of VS with relevant authorities on developing legislation and regulations regarding areas of joint or shared responsibility; – the evidence that national legislation identifies VS roles and responsibilities related to activities where there is shared authority with other competent authorities.

a. *Terrestrial Code*: Article 3.2.8 on Animal Health controls and Article 3.2.9 on Veterinary Public Health controls

Table XXIII Table of correspondence between questions in the International Health Regulations (IHR) Monitoring Framework questionnaire and the critical competency cards in the PVS Tool

Questions in the IHR Monitoring Framework	PVS Critical Competencies																																				
	I-1-A	I-1-B	I-2-A	I-2-B	I-3	I-5	I-6-B	I-7	I-8	I-9	I-10	I-11	II-1-A	II-1-B	II-2	II-3	II-4	II-5-A	II-5-B	II-6	II-7	II-8-A	II-8-B	II-8-C	II-9	II-10	II-12-B	III-1	III-2	III-3	III-4	III-6	IV-1	IV-2	IV-3	IV-6
Core capacity 1: National legislation, policy and financing																																					
1.1.1.1.																				X	X												X				
1.1.1.3.							X											X	X									X						X			
1.1.1.4.							X											X	X									X						X			
Add Q, CC1									X	X	X																										
Core capacity 2: Coordination and National Focal Point communication																																					
2.1.1.1.							X																					X									
2.1.1.2.							X					X																									
2.1.1.3.							X													X								X									
2.1.1.4. A							X					X																									
2.1.1.4. B							X					X																									
2.1.1.5.							X																					X									
2.1.2.5.							X																					X	X			X					
2.1.1.6.																												X	X			X					
2.1.2.6.							X											X	X									X						X			
2.1.2.7. A							X																					X	X			X					
2.1.2.7. B							X																					X	X			X					
2.1.2.8.																												X	X			X					
Core capacity 3: Surveillance																																					
3.1.1.1.																		X	X	X																	
3.2.1.3.													X			X				X			X														
3.2.1.4.																X		X	X																		
3.2.1.5.																X		X	X																		
3.1.1.7.																		X	X		X								X								
3.2.1.9																		X												X						X
Core capacity 4: Response																																					
4.1.1.1.										X										X																	
4.1.1.10.												X								X																	
4.1.1.2.																				X																	
4.2.1.11.															X										X	X											
4.2.1.12. A															X										X	X											
4.2.1.12. B															X										X	X											
4.1.1.4.																				X																	
4.1.1.5. A												X								X																	

Questions in the IHR Monitoring Framework		PVS Critical Competencies																																					
		I-1-A	I-1-B	I-2-A	I-2-B	I-3	I-5	I-6-B	I-7	I-8	I-9	I-10	I-11	II-1-A	II-1-B	II-2	II-3	II-4	II-5-A	II-5-B	II-6	II-7	II-8-A	II-8-B	II-8-C	II-9	II-10	II-12-B	III-1	III-2	III-3	III-4	III-6	IV-1	IV-2	IV-3	IV-6
	4.1.1.5. B												X								X																	
	4.1.1.6.																				X																	
	4.1.1.7.																				X																	
	4.1.1.8.					X								X		X																						
	Core capacity 5: Preparedness																																					
	5.1.1.1.							X	X				X																									
	5.1.1.2.							X	X				X								X																	
	5.2.1.1.																				X																	
	5.1.1.3.							X	X				X								X																	
	5.2.1.2.																X		X	X																		
	5.2.1.3.							X	X				X								X																	
	5.1.1.4. A																				X																	
	5.1.1.4. B																				X																	
	5.1.1.5.										X										X																	
	5.1.1.6.										X										X																	
	5.2.1.7.										X										X																	
	Core capacity 6: Risk communication																																					
	6.1.1.1.																X				X								X									
	6.1.1.2.																X				X								X									
	6.1.1.3.																X				X								X									
	6.1.1.4.																X				X								X									
	6.1.1.5.																												X									
	6.1.1.6.																												X									
	Core capacity 7: Human resource capacities																																					
	7.1.1.2.	X	X	X	X	X																																
	7.1.1.3.	X	X	X	X	X																																
	7.1.1.7.	X	X	X	X	X																																
	Core capacity 8: Laboratory																																					
	8.1.1.1.															X																						
	8.1.1.3.													X	X	X																						
	8.1.1.10.					X								X		X																						
	8.1.1.11.					X								X		X																						
	8.1.1.12.					X								X		X																						
	8.1.1.14.													X																								
	8.1.1.15.													X																								
	8.1.1.2.															X																						
	8.2.1.1.															X																						

Questions in the IHR Monitoring Framework		PVS Critical Competencies																																							
		I-1-A	I-1-B	I-2-A	I-2-B	I-3	I-5	I-6-B	I-7	I-8	I-9	I-10	I-11	II-1-A	II-1-B	II-2	II-3	II-4	II-5-A	II-5-B	II-6	II-7	II-8-A	II-8-B	II-8-C	II-9	II-10	II-12-B	III-1	III-2	III-3	III-4	III-6	IV-1	IV-2	IV-3	IV-6
	8.1.1.4.													X	X	X																							
	8.1.1.5. A													X	X	X																							
	8.2.1.4.															X																							
	8.1.1.6.															X																							
	8.1.1.7.													X																									
	8.2.1.6.															X																							
	Core capacity 10: Zoonotic events																																							
	10.1.1.1.							X													X								X										
	10.1.1.10.																				X																		
	10.1.1.11.																				X																		
	10.1.1.2.						X												X	X	X	X																	
	10.1.1.3.							X													X								X										
	10.1.1.4.												X						X	X																			
	10.1.1.5.																		X	X	X																		
	10.1.1.6																		X	X		X								X									
	10.1.1.7												X	X			X				X			X															
	10.1.1.8.													X	X	X																							
	10.1.1.9.																		X	X		X								X									
	Core capacity 11: Food safety																																							
	11.1.1.1																						X	X	X						X						X		
	11.1.1.13.													X	X	X																							
	11.1.1.14.													X			X				X			X															
	11.1.1.15.																				X																		
	11.1.1.17. A																				X																		
	11.1.1.17. B																				X																		
	11.1.1.18.																	X					X		X			X											
	11.1.1.19.																												X										
	11.1.1.2.																						X	X	X										X	X			
	11.1.1.20.																																		X				
	11.1.1.21.																						X												X				
	11.1.1.3. A																																		X	X			
	11.1.1.3. B																																			X			
	11.1.1.4.							X													X								X									
	11.1.1.5																							X	X														
	11.1.1.6.							X													X								X									
	11.1.1.6.																				X																		
	11.1.1.7.																		X	X	X																		
	11.1.1.8.													X			X				X			X															
	11.1.1.9.													X			X				X			X															

2. Costing tools

Further to assessing the level of capability and identifying gaps in capacities required to fully implement the IHR (2005) and comply with the OIE intergovernmental standards, countries are encouraged to identify strategic directions and corrective measures for inclusion into a national action plan and detailed roadmap. Action plans are a prerequisite for countries to obtain an extension to IHR implementation deadlines and must be submitted to WHO and the IHR review committee. In the tools developed under the PVS Pathway, operational roadmaps with associated timelines are also discussed to structure improvements to a country's performance against PVS Critical Competencies.

To help national decision-makers identify and quantify the inputs needed to address gaps and include them in national budget planning, countries require standardised approaches to estimate the costs associated with the implementation of these action plans and roadmaps. The PVS Gap Analysis (PVS Costing Tool) is a quantitative evaluation of a country's needs and priorities based on the outcomes of the independent external evaluation of the country's Veterinary Services using the PVS Evaluation report. More recently, WHO initiated the development of the IHR Costing Tool to help countries quantify the inputs needed to achieve and maintain the minimum core capacity requirements as described in the IHR, across all areas of work and levels of implementation in the country. While the scopes and scales of the two Costing tools are different, complementarity between them was an objective guiding the development of the IHR Costing Tool.

2.1. OIE PVS Gap Analysis (PVS Costing Tool) mission, manuals and tools

Context

The OIE provides assistance to its Member Countries to improve the governance of their national Veterinary Services, so that their capacity can be strengthened and better aligned with OIE international quality standards.

At the specific request of a Member Country, the OIE provides expertise through its PVS Pathway, a continuous process which helps countries to identify and address areas where there are gaps in the performance of its Veterinary Services.

Although Veterinary Services play a key role in protecting human health and livelihoods, in many countries they have long been subjected to unfavourable government policies and underfunding. Insufficient funding and inadequate provisions for the coordination of the control of animal diseases can generate gaps and weaknesses. It is important that Veterinary Services know and understand their gaps so they can develop a strategic plan which enables them not only to meet national priorities and comply with international standards, but also to control major emerging issues at the human–animal interface.

Based on the findings of the initial PVS Evaluation mission and through the use of a participatory, strategic and proactive approach, a PVS Gap Analysis (PVS Costing Tool) mission provides national Veterinary Services with an opportunity to undertake a strategic planning process to identify the necessary investments required to reach their national goals and improve their compliance with OIE international standards over a five-year timeframe.

Objective

The objective of a PVS Gap Analysis (PVS Costing Tool) mission is to facilitate the development of a country's Veterinary Services five-year strategic plan to appropriately and sustainably respond to current and future needs in line with overarching national goals.

It encourages the constructive engagement and participation of all stakeholders, including, for example, the private sector, consumer groups and other competent authorities with shared interests in animal health and veterinary public health.

Through brainstorming, utilising combined skills, and understanding and building upon gaps, a PVS Gap Analysis (PVS Costing Tool) mission offers a country's Veterinary Services an opportunity to undertake a strategic planning process to identify the necessary investments required to reach their national goals and to improve their compliance with international standards over a five-year timeframe.

Process

A PVS Gap Analysis (PVS Costing Tool) mission is implemented after an official request from a Member Country to the OIE and should, in chronological order, follow the implementation of a PVS Evaluation mission ('diagnosis'), as the 'prescription' step of the PVS Pathway.

The PVS Gap Analysis (PVS Costing Tool) Expert's Manual describes in detail each step of its three phases of implementation:

(1) *Pre-mission preparation* (3–5 months): confirmation of request, administration and data collection.

(2) *Mission* (1–2 weeks, depending mainly upon the complexity of the national veterinary laboratory network).

(3) *Post mission* (3 months): report writing, peer review and validation by OIE headquarters and Member Country's OIE Delegate.

Manuals, tools and cards

A series of manuals, tools and cards has been specifically developed by the OIE for the implementation of a PVS Gap Analysis (PVS Costing Tool) mission.

PVS Gap Analysis (PVS Costing Tool) manuals

The PVS Gap Analysis (PVS Costing Tool) Expert's Manual (Volume 1) serves both as an instrument in the training of PVS Gap Analysis experts in the implementation of missions and as an instructional reference detailing the process, approach, methodology, outputs and expected outcomes of each PVS Gap Analysis (PVS Costing Tool) mission.

The PVS Gap Analysis (PVS Costing Tool) Expert's Manual (Volume 2) provides guidance and guidelines for the writing of a PVS Gap Analysis report.

Using the template format of a PVS Gap Analysis (PVS Costing Tool) report, the manual provides instructions and helpful tips to experts to ensure that PVS Gap Analysis reports are of high quality and drafted in a harmonised manner.

PVS Gap Analysis cards

The two cornerstones of the PVS Gap Analysis (PVS Costing Tool) are the critical competency cards and the cost estimation cards, regrouped under the five pillars of the PVS Gap Analysis.

During a PVS Gap Analysis (PVS Costing Tool) mission, the critical competency cards are used to organise and facilitate discussion with Veterinary Services about the development of strategies and cost estimates (through the use of the cost estimation cards), as well as to identify activities based on the outcomes and/or recommendations of the initial PVS Evaluation (final report).

Associated cost estimation cards have been developed and are used to facilitate the formulation of an interim costing of the human and physical resources required by the Veterinary Services to reach their desired level of advancement towards improved compliance with international standards. The costing conducted for each cost estimation card provides an interim costing for the activities outlined in the corresponding critical competency card. The interim costings conducted in each cost estimation card are then summed in the 'Total Costing' spreadsheet of the PVS Gap Analysis (PVS Costing Tool), providing the final output of the analysis.

PVS Gap Analysis Tool Box

To prepare the indicative costing of the Veterinary Services, a Tool Box, which contains a set of tools, has been designed to assist the OIE-certified experts in assessing the workload of the Veterinary Services. This workload should be determined on the basis of the activities identified to help the Veterinary Services reach their desired level of advancement towards improved compliance for each critical competency.

Table XXIV lists the documents and tools provided to the experts in order to conduct a PVS Gap Analysis (PVS Costing Tool) mission.

Approach and methodology

Approach

The PVS Tool is composed of 47 Critical Competencies grouped into fundamental components. In the PVS Gap Analysis (PVS Costing Tool), 41 Critical Competencies of

Table XXIV List of documents and tools provided to PVS Gap Analysis experts

PVS Gap Analysis Tool (PVS Costing Tool)	**Expert's manual**	Volume I – Guidelines for conducting a mission
		Volume II – Guidelines for writing a country PVS Gap Analysis Report
	Templates	Template letter (in Word format)
		Template Report including Critical Competency Cards (in Word format)
		Presentations for opening and closing meetings (in PowerPoint format)
	Costing Tool	Excel file containing the following spreadsheets: Unit Cost, Cost Estimation Cards, Sub-Total for each PVS Gap Analysis Pillar, Total Cost, and Analysis of the Resources
	Tool Box	Trade Tool Veterinary Public Health Tool Animal Health Tool Compensation Funds Tool Veterinary Laboratory Tool

the PVS Tool[13] have been repartitioned into the following five pillars: Trade; Veterinary Public Health; Animal Health; Veterinary Laboratories; and Management of Veterinary Services including Regulatory Services (Fig. 16).

13 The six Critical Competencies of the PVS Tool which are not included in the PVS Gap Analysis (PVS Costing Tool) are the required human (CC I-1A&B), physical (CC I-7) and financial (CC I-8, 9, 10) resources of the Veterinary Services. These Critical Competencies have been excluded because they correspond to and represent one of the outputs of the PVS Gap Analysis Report, namely the indicative costing of the human and physical resources required to improve the Veterinary Services' priorities and objectives

There is one critical competency card for each of the 41 Critical Competencies used during the PVS Gap Analysis (PVS Costing Tool) mission; they represent the link between the PVS Tool and the PVS Gap Analysis (PVS Costing Tool).

The cost estimation cards correspond to the translation of each critical competency card into cost lines. They form part of the Excel document entitled 'Costing Tool'.

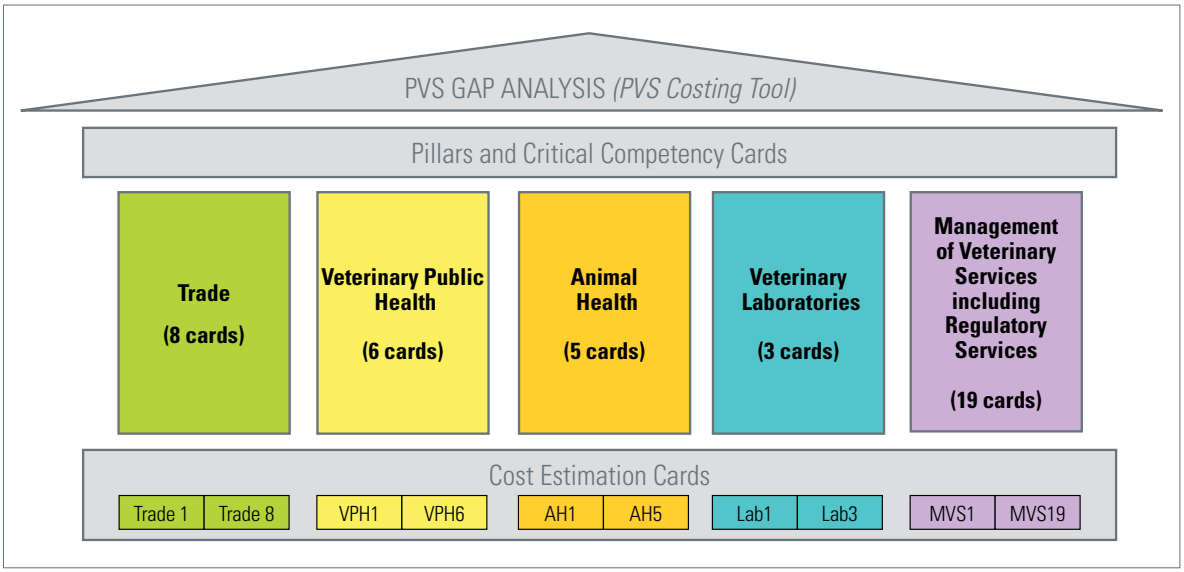


Fig. 16
Visual representation of the PVS Gap Analysis (PVS Costing Tool)

Methodology

Further to the receipt of preliminary data from the country, and using as a basis the outcomes of the PVS Evaluation, a PVS Gap Analysis (PVS Costing Tool) mission foresees the implementation of the following steps:

a. **Define the Veterinary Services' priorities** for each of the following categories: Livestock Development and Trade; Veterinary Public Health; Animal Health; and Organisation and Management of Veterinary Services including Regulatory Services. The Veterinary Services priorities are the foundation of the PVS Gap Analysis (PVS Costing Tool); they frame and orientate the strategies, the activities and the indicative costing developed during the mission. These priorities are synergistic and complement broader country priorities, strategies or programmes advocated at the national level (e.g. ministry, government and parliament).

b. **Identify a strategy for each of the five PVS Gap Analysis (PVS Costing Tool) pillars**: (i) Trade; (ii) Veterinary Public Health; (iii) Animal Health; (iv) Veterinary Laboratories; and (v) Management of Veterinary Services including Regulatory Services. These strategies constitute the Veterinary Services' five-year plan towards meeting its priorities based on improved compliance with international standards.

c. **Determine desired level of advancement** towards improved compliance with international standards for each of the Critical Competencies. Based on the outcomes of the initial PVS Evaluation and for each of the 41 Critical Competencies redistributed among the five PVS Gap Analysis pillars, the Veterinary Services' decision-makers will establish the country's Veterinary Services' desired level of advancement towards improved compliance with international standards to be reached over a period of five years.

d. **Define the activities (workload)** to be implemented by the Veterinary Services over the next five years in order to reach their desired level of advancement for each of the 41 Critical Competencies of the PVS Gap Analysis (PVS Costing Tool). Improving compliance with international standards, meeting priorities and implementing strategies requires the definition of activities to be undertaken by the Veterinary Services over a five-year timeframe.

e. **Estimate the cost** of human and physical resources required to implement the identified activities (workload). Strategically rationalising activities to accomplish goals and reach priorities enables the Veterinary Services to quantify and assess the required human, physical and financial resources and to identify the cost of the Veterinary Services' activities defined during the PVS Gap Analysis (PVS Costing Tool) to improve compliance over a five-year timeframe. The results of this costing should be used by the Veterinary Services to demonstrate the resources required and advocate for its effective and efficient functioning in line with national priorities.

The PVS Gap Analysis (PVS Costing Tool) mission report ultimately presents a series of costed strategic plans to strengthen a country's Veterinary Services' performance and compliance with OIE international standards.

Outputs

The expert's final mission report to the OIE Delegate includes:

- a summary of the Veterinary Services' priorities, which are complementary with overarching national objectives, goals and targets;
- an indicative strategy to strengthen the Veterinary Services;
- an overview of the desired level of advancement established for each of the 41 Critical Competencies used for the PVS Gap Analysis (PVS Costing Tool);
- an indicative costing of the human and physical resources required for the effective and efficient implementation of the activities defined:
  1. an annual costing of the official Veterinary Services programmes and activities delineated in the PVS Gap Analysis (PVS Costing Tool);
  2. a costing of the exceptional investments to be made, if appropriate; and
  3. a consolidated five-year costing.
- completed critical competency cards and corresponding cost estimation cards.

Outcomes

An immediate result of this exercise is the hands-on capacity-building gained by the Veterinary Authority in structuring a strategic plan, which translates national development objectives into concrete actions that comply with international standards. The final report should be used as a first step towards the definition of a strategic and operational plan of action for the Veterinary Services. The translation of this report into future steps is subject to its endorsement by national political authorities; the Veterinary

Services should use the outputs of the PVS Gap Analysis (PVS Costing Tool) to advocate and negotiate for the required investments (human, physical and financial resources) to strengthen the national Veterinary Services. Key decision-makers benefit from the receipt of detailed information explaining what is required in terms of investment in order to enable the Veterinary Services to meet national objectives, priorities and targets.

The broader, long-term goal is shifting the mindset towards a horizontal strengthening of institutions and systems capable of defining, implementing and enforcing national policy. Acknowledging that 'prevention is better than cure', this step of the PVS Pathway provides an opportunity for national decision-makers to consider their system as a complete organism and to prescribe costed solutions to meet targets.

2.2. IHR Costing Tool

Context

> In developing the Monitoring Framework, consideration has been given to the IHR mandate that:
> States Parties shall utilise existing national structures and resources to meet their core capacity requirements under these Regulations, including with regard to:
> (a) their surveillance, reporting, notification, verification, response and collaboration activities; and
> (b) their activities concerning designated airports, ports and ground crossings.
>
> ***(IHR 2005; Annex 1)***

The IHR (2005) is a global legal framework that obligates all States Parties to establish, strengthen and maintain national minimum public health surveillance and response capacities that are critical for the early response to PHEICs. The Core Capacities necessary to be in place by the IHR deadlines are described in Annex 1 of the IHR (2005) and certain other articles, including Articles 5 and 13. When the IHR (2005) came into force on 15 June 2007, WHO was mandated to provide appropriate tools, guidance and support to States Parties to achieve these goals. This support materialised in a series of technical elements and guidance covering the different areas of work for implementation of Annex 1 of the IHR[14]. In particular, WHO developed the IHR Monitoring Framework to support countries in reporting annually on the implementation of the Regulations to the World Health Assembly[15] through a set of global indicators.

The framework can facilitate measurement of levels of attainment of the IHR Core Capacities and allows the analysis of country data with a high level of detail for each of the eight Core Capacities and PoEs and the four hazards. The main purpose is to enable countries to measure their status at any point in time, and to assess their progress over time. This facilitates the identification of strengths and weaknesses as well as incremental achievements from year to year. The IHR specify a timeline for the establishment of national Core Capacities based on the entry into force of the IHR for a State Party, and must be 'as soon as possible but no later than five years from the entry into force' (Articles 5 and 13); therefore, June 2012.

Time extensions could be requested, provided that the country formally submitted the request to WHO with a justified need and an implementation plan[16]. This extension plan described the areas of work and activities that States Parties commit themselves to implement in order to fulfil their obligations. To help national decision-makers identify and quantify the inputs needed to address the remaining gaps and include them in national budget planning, WHO developed a standardised approach for estimating costs associated with achieving and maintaining the minimum Core Capacities requirements as described in the IHR, across all areas of works and level of implementation in the country.

Objective

The IHR Costing Tool aims to be used by countries in estimating realistic start-up[17] and operating[18] costs for core actions needed to develop, strengthen and maintain IHR Core Capacities. It is applicable at the country level, adaptable to specific country contexts and takes into consideration already existing capacities and resources.

14 www.who.int/ihr/area_of_work/en/

15 In accordance with Article 54 of the IHR, and related resolution World Health Assembly 61.2

16 www.who.int/ihr/publications/ihr_core_capacity_2012/en/

17 Start-up costs typically occur once, at the onset of a programme, with related outputs used for many years

18 Operating costs occur on an ongoing basis year by year and fall into two categories: variable costs, which generally increase with each additional input or output, and fixed costs, which generally remain constant, regardless of additional outputs

The end users of the Costing Tool are WHO Member States, and the primary target audience of the tool includes public health agencies and policy-makers responsible for IHR implementation estimates and health economics. Through an interactive process with the IHR NFPs and associated national and international experts, it helps establish costs for the current national and sub-national functional capacity for surveillance and response as defined in the IHR (2005), and identify possible corrective actions and inputs needed.

Countries are expected to use the Costing Tool for effective planning, budgeting and advocacy needs. This will help ensure the inclusion of the identified costs within the regular funding framework of the countries, especially for recurrent costs needed to maintain IHR capacities, and facilitate the consideration of IHR-associated requirements within the routine activities of the authorities in charge of public health. This would ultimately strengthen the national health system, of which IHR core capacity development is an integral part.

Process

The IHR Costing Tool is structured along the following conceptual frame (Fig. 17):

- The primary data originate from the last annual report sent by the NFP to the WHO through the IHR Monitoring Framework. These data are used to assess the level of compliance for each of the Core Capacities and identify areas where gaps remain.
- Corrective measures proposed by the country can be found in the national action plans and/or the extension plans or any other strategic action plans.
- The Tool proposes to further describe the practical activities to be conducted in order to increase capability for the various areas where gaps have been identified.
- Once the activities are clearly defined, the identification of the associated operational inputs allows for their costing, using actual local costs.

Approach and methodology

Capacities described in the IHR Monitoring Framework

The IHR Monitoring Framework architecture provides the scaffold for the IHR Costing Tool's machinery. The Framework and the associated questionnaire use a checklist of indicators, categorised through eight Core Capacities, capacities at PoEs and specific hazards.

The indicators are described through attributes reflecting the levels of capability. For the purpose of the Costing Tool, the attributes have been divided into discrete sets of corrective actions that countries might undertake to close any gaps in current Core Capacities.

The comprehensive IHR monitoring questionnaire has been utilised since 2010. The current database has information from approximately 181 countries, and it is presumed that the majority of countries are familiar with the structure used for the annual monitoring. The costing of the IHR implementation through the attributes is therefore a logical approach for countries familiar with the Monitoring Framework.

Functions required to be in place by the IHR (2005)

At an early stage in the development of the Costing Tool, consultations with potential users from countries revealed that a more functional approach, with a review of critical capabilities for the critical core functions[19] described in

19 References for the Core Functions can be found in Annex 1 and paragraph 1 of Article 5, paragraph 1 of Article 13 and Articles, 19, 20, 21 of the IHR (2005)

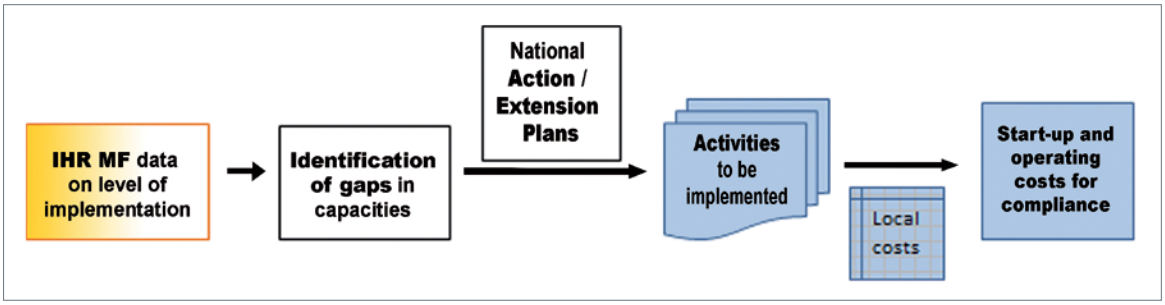


Fig. 17

Process of using International Health Regulations (IHR) Monitoring Framework (MF) data and national plans to cost the activities in the IHR Costing Tool

Annex 1 (page 87) of the IHR and at the different levels of implementation (community level and/or primary public health response level, intermediate level(s) and national level) was also desired. Table XXV depicts how these functions are related to the following capabilities:

1. **Detect** events involving disease or death above the expected levels for the particular time and place in all areas within the territory of the State Party.

2. **Assess** immediately events that are reported to the intermediate public health response levels; and, at the national level, assess within 48 h all domestic reports of urgent events for potential notification to WHO.

3. **Report** all available essential information immediately to the appropriate level of healthcare response and, at the national level, notify WHO through the IHR NFP of any event that may constitute a PHEIC, within 24 h.

4. **Respond** promptly and effectively to public health risks and emergencies of international concern.

5. **Implement measures at points of entry**[20].

20 As described in Annex 1B of the IHR (2005)

A dual-entry interface

Early in the development of the Costing Tool it was understood that users would primarily be the IHR NFPs. The familiarity of the NFPs with the IHR monitoring indicators and attributes meant that using the same attributes for costing would be ideal. On the other hand, it was seen to be very useful to also allow users to access the basics of the IHR and allow decision-makers and planners to cost the functions required to be in place by the IHR (2005). This prompted the decision to build the Costing Tool with a dual data-entry user interface, via Core Capacities or core functions (Fig. 18).

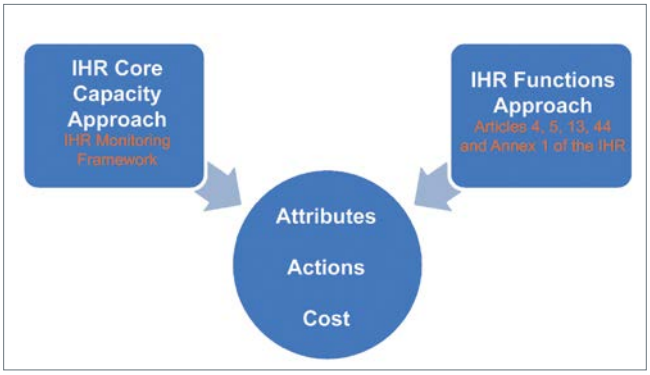


Fig. 18
Dual-entry approach for the International Health Regulations Costing Tool

Table XXV Capacities required by the International Health Regulations (IHR) (2005)

Level of implementation	To detect	To assess	To report	To respond
National	Events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party	All reports of urgent events within 48 h	To notify the World Health Organization (WHO) through the IHR National Focal Point of all qualifying events within 24 h of such an assessment (Article 6/Annex 2) and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9	To support or implement additional control measures
Intermediate		Reported events immediately and, if found to be urgent, to report all essential information to the next (intermediate/ national) level	To confirm the status of reported events	
Local community			To report all available essential information immediately to the appropriate level of healthcare response	To implement preliminary control measures immediately

Each of the IHR Monitoring attributes has a number of actions linked to it that can be costed. These actions define specific work tasks that should take place in order to fulfil an IHR indicator or to enable a core function at the appropriate level of implementation (local, intermediate or national).

Actions were developed using subject matter expertise input from Member States and technical experts as well as existing domain specific technical guidance and available public health surveillance literature.

The core capacity and core function approaches differ only in componential organisation and result in similar outcomes.

The practical activities proposed to fill identified gaps are the nucleus of the Costing Tool and also the connection points for the two entries.

The *core capacity* approach uses the IHR Monitoring Framework breakdown of capacities, i.e. the eight Core Capacities, capacities at PoEs and the four hazards needed by countries to meet the obligations of the IHR (Fig. 19).

This means the user can enter the tool and cost an attribute directly e.g. that of core capacity 3 (Surveillance). The *core function* approach is slightly different, whereby the entry point of the user is via one of the core functions, it aligns closer to the PVS Tool and costs actions at each level of implementation.

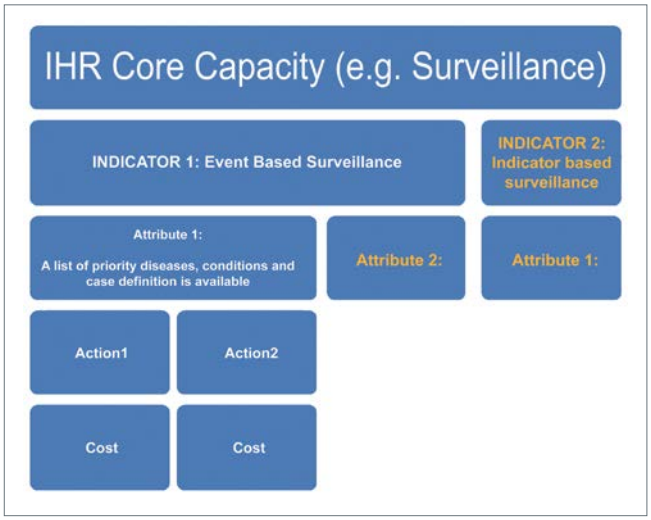


Fig. 19
Diagram of the core capacity approach: from indicators to actions

Core capacity 3: Surveillance

Component	Indicator	Attribute	Actions	Inputs needed
Indicator-based surveillance	Indicator-based surveillance includes an early-warning function for the early detection of a public health event	A list of priority diseases, conditions and case definition is available	Meetings with experts (national or international) to review the list Development of educational material for the diseases listed Dissemination of the material Training at the community level	~~*Infrastructure*~~ *Human resources* *Training* *Equipment* *Material and reagents* ~~*Systems*~~ ~~*tools and processes*~~ ~~*SOPs*~~
…	…	…		

Level of implementation	To detect	To assess	To report	To respond
National	To detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party.	To assess all reports of urgent events within 48 hours	To notify WHO through the National IHR Focal Point of all qualifying events within 24 hours of such an assessment (Article 6/Annex 2) and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9	To support or implement additional control measures
Intermediate		To assess reported events immediately and , if found urgent, to report all essential information to the next (intermediate/national) level	To confirm the status of reported events	
Local community			To report all available essential information immediately to the appropriate level of healthcare response	To implement preliminary control measures immediately

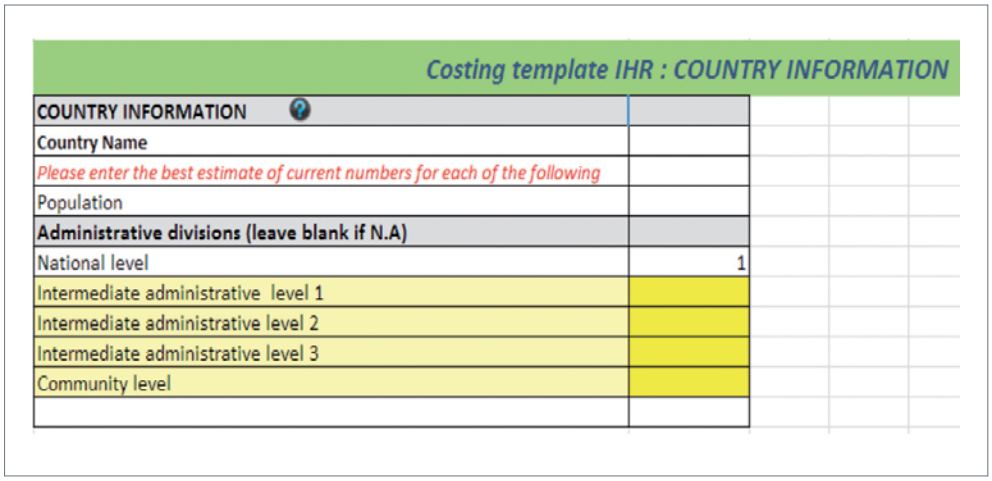
Fig. 20
Articulation between the Core Capacities and core functions approaches

Associated with each action, a set of inputs is proposed in the Costing Tool to explore the need for specific infrastructure, human resources, skills, tools or processes to complete that action. The national structures and resources needed to meet the capabilities are specific to each country, and the suggested inputs are merely proposed for consideration; the user has the opportunity to add additional categories of inputs. An example of the structure with the first attribute of Core Capacity 3, Surveillance, is given below in Figure 20, describing also the point of articulation between the Core Capacities or core functions approaches.

Practical use of the Costing Tool

Using the IHR Monitoring Framework questionnaire, WHO has self-reported data available from over 93% of Member States. This therefore allows the option to prepopulate the IHR Costing Tool with country-specific information. Though all attributes will be visible to the end-user, the attributes that have been reported (via the annual IHR Monitoring Framework questionnaire) as less than 100% will be highlighted, along with the self-reported top three priorities. This will allow the end-user the option of focusing on a core capacity, national priorities or self-identified areas that need strengthening. The end-user is given the choice of starting the Costing Tool via the eight Core Capacities or via the core functions. A rendering of the framework using the core capacity method is provided in Annex 1.

At the beginning of the process, the user is asked to provide country-specific information – 'Initial Inputs' (a one-off exercise) – through a set of start-up screens, such as information on the administrative structure of the country or financial information such as salaries for the various categories of staff (Fig. 21). These data will be used as multipliers for results in the latter stages.



Costing template IHR : COUNTRY INFORMATION

COUNTRY INFORMATION	
Country Name	
Please enter the best estimate of current numbers for each of the following	
Population	
Administrative divisions (leave blank if N.A)	
National level	1
Intermediate administrative level 1	
Intermediate administrative level 2	
Intermediate administrative level 3	
Community level	

Fig. 21
Screenshot of the input screen of the Core Capacity approach

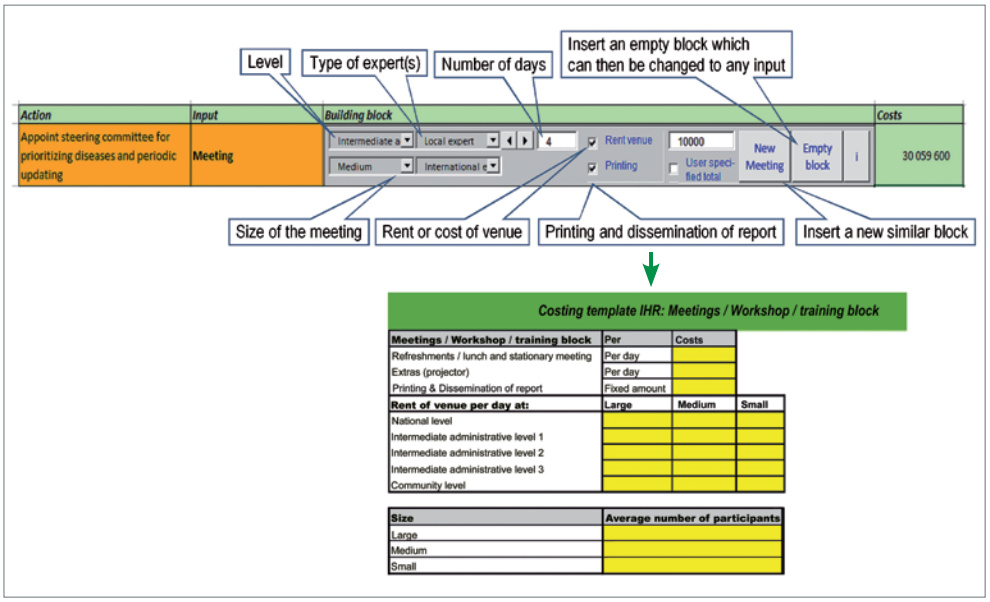


Fig. 22
Screenshot of a 'building block' in the core capacity approach

Actions and inputs that represent routine activities, such as meetings or training workshops, are organised into 'building blocks' that prompt the user to select from a few key variables (such as the size and length of the meeting) to simplify use of the tool in calculating costs (Fig. 22). Sixteen building blocks have been defined, including:

- Equipment
- Level of effort
- Consultant
- Advocacy/outreach
- Supervisory visit
- Field visit
- Transport
- Meetings/workshop
- Website
- Printing
- Translation
- Information and communication
- Software purchasing/licensing
- Inspection/certification services
- Annual fees
- Materials and flash consumables.

Users can then step through each attribute screen by screen and are provided with a number of suggested actions. The user can then walk through each action and decide what needs to be implemented in the context of his or her country. When an action is selected, the proposed inputs appear with, when appropriate, the associated building box(es). The Costing Tool then translates these choices into financial estimates and adjusts and aggregates accordingly using inputs obtained at earlier stages.

Outputs

The outputs of the IHR Costing Tool are essentially a breakdown of costs to fulfil IHR capacity development and maintenance. The initial output will allow users to verify and validate individual form fields and overall inputs to adjust the actions based on the amount of time and money available to carry out activities in strengthening and maintaining capacities for one year. Essentially, the reports can produce costs by capacity, activity and function.

Intuitive forms are used to perform standard calculations, providing a range of costs based on the values entered. There is also the option to generate broad estimates for end-users who are interested in quick cost estimates.

Some countries have organised their national capacity-building plans around a functional approach; the outputs of the core function approach are more defined, focus on functional outcomes, integrate planning for each administrative level (local, intermediate and national levels) and help prioritise capacity-building to step up IHR implementation level. Costs are identified by category (e.g. start-up costs or operating costs) for additional advanced economic analysis.

Outcomes

The outcome is easily comprehensible but detailed enough to be used in the preparation of projects and investments at the country level. The costing of the implementation and the maintenance of IHR capacities will help in prioritising activities based on (national/regional) priorities and advocating for funding both within countries and with partners.

The outputs of the tool can be used for planning and budgeting purposes. At the international level, the cost analysis should enable regional or global comparisons of costs and contribute to more accurate international estimates of the resources needed for IHR implementation.

3. Laboratory tools

Laboratory services are an essential and fundamental part of all health systems. Prevention and management of infectious and non-communicable diseases often require diagnostic information provided by the laboratory. Many therapeutic and public health decisions rely heavily upon laboratory data, notably during outbreak investigation and response.

An effective and credible laboratory service is also an essential component of any early detection system. It is needed by countries to fulfil their reporting obligations to the OIE regarding listed animal diseases, unusual epidemiological events and emerging diseases, and for the investigation of events of potential international public health concern, which are reported to WHO as required by the IHR.

Owing to the commonality of techniques and comparable standards, laboratory competence has always been a shared area of interest for the public health and animal health sectors. Furthermore, it is essential to develop strong links between animal health and public health laboratories in order to ensure early detection of zoonotic pathogens emerging in

wild and domestic animal populations before they become a threat to human health.

The OIE and WHO are the two main global institutions responsible for international standards affecting animal and human health. Each has developed tools to help define the laboratory situation at country level, assisting countries which need to determine sustainable strategies to improve compliance with international standards and regulations, ultimately ensuring more timely and accurate diagnosis of known and emerging pathogens.

Although both human and veterinary laboratories have benefited from significant capacity-building efforts, there is still a need for deeper intersectoral cooperation in order to achieve more robust and sustainable diagnostic capacity, particularly with respect to the early detection of zoonotic diseases.

The following sections provide a comparison of the approaches taken by the OIE and WHO to assess laboratory services, identifying similarities and differences as well as opportunities for synergies to achieve better efficiencies of animal and human health laboratories at both national and global levels.

3.1. OIE PVS Pathway Laboratory Mission, Manual and Tools

Context

The OIE provides assistance to its Member Countries to improve the governance of their national Veterinary Services so that their capacity can be strengthened and better aligned with OIE international quality standards.

At the specific request of a Member Country, the OIE provides expertise through the PVS Pathway, a continuous process which helps countries to identify and address areas where there are gaps in the performance of its Veterinary Services.

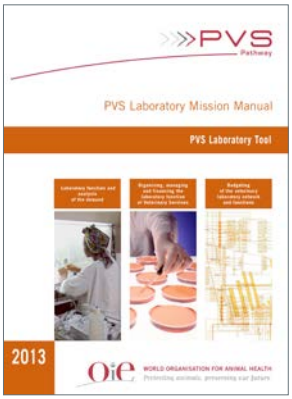
The national veterinary laboratory network plays a particularly important role in providing services to support the needs of a country's Veterinary Services. Addressing issues to improve the capacity of the national veterinary laboratory network is not only important for meeting national priorities and complying with international standards, but also critical to the control of major emerging issues at the human–animal interface.

In order to meet the Veterinary Services' priorities, the national veterinary laboratory network must be able to provide timely and accurate results regarding:

- disease surveillance and early detection;
- food inspection and residue surveillance;
- border inspection;
- veterinary medicines and biologicals quality control; and
- post-vaccination serological controls.

Therefore, in response to findings of initial PVS Evaluation and PVS Gap Analysis (PVS Costing Tool) missions, a PVS Pathway Laboratory mission ('PVS Laboratory mission') may be undertaken by OIE-certified PVS Laboratory experts to address specific gaps that have been identified. A PVS Laboratory mission may thus be recommended if, for example, the national veterinary laboratory network has been judged unsuitable to meet the Veterinary Services' needs or if it needs to expand upon or focus one or more activities to meet the Veterinary Services' priorities.

Objective



The objective of a PVS Laboratory mission is to determine the *resources required* by a national veterinary laboratory network to appropriately and sustainably respond to the current and future laboratory needs/goals of its Veterinary Services. It also evaluates its structure and viability in the context of national priorities, and presents information and options to assist key decision-makers in their strategic planning. It should be noted that a PVS Laboratory mission *does not evaluate technical capacity* or efficiency, nor does it suggest technical improvements. The PVS Laboratory Mission Manual serves both as an instrument in the training of PVS Laboratory mission experts and as an instructional reference detailing the process, approach, methodology, outputs and anticipated outcomes of every PVS Laboratory mission.

Process

When a PVS Laboratory mission is deemed appropriate and has been requested by a Member Country, it should follow, in chronological order, the PVS Evaluation ('diagnosis') and PVS Gap Analysis (PVS Costing Tool – 'prescription'). The mission forms part of the subsequent technical expertise that the OIE can provide to support compliance ('treatment') of the quality of Veterinary Services with international standards as defined in the *Terrestrial Code*.

The PVS Laboratory Mission Manual, used by OIE-certified PVS Laboratory mission experts, describes in detail each implementation phase of the PVS Laboratory mission:

(1) Pre-mission preparation (3–5 months): confirmation of request, administration and data collection.

(2) Mission (1–2 weeks, depending mainly upon the complexity of the national veterinary laboratory network).

(3) Post mission (3 months): report writing, peer review and validation by OIE Headquarters and Member Country's OIE Delegate.

Approach and methodology

Following the collection of preliminary data, a PVS Laboratory mission will analyse the need (**demand**) for veterinary laboratory analyses in relation to the existing availability (**supply**) of veterinary laboratory analyses. The mission report will ultimately present a range of costed, sustainable **options** for management, organisational, budgetary and financial solutions for key decision-makers for use in their strategic planning. The OIE and its laboratory experts have developed specific quantitative mechanisms, or 'Tools', which are described in the PVS Laboratory Manual and used by experts to conduct these analyses (Fig. 23).

The 'Demand Tool' determines the current and prospective demand for laboratory analyses by reviewing information from a variety of sources, including the PVS Gap Analysis (PVS Costing Tool) report and data requested from the country during the pre-mission preparation phase. The current and prospective demands are compared with data generated by the 'Supply Tool', which provides information about laboratory services and tests currently offered by the national veterinary laboratory network (or via an affiliated international laboratory network). The 'Supply Tool' then establishes ratios for human, physical and financial resources and assists the expert in assessing whether the laboratory analyses offered are able to meet the demands. Finally, the 'Analytical Line Tool' and 'Calculation Tool' are used to establish the total costs of analyses including the human, physical and financial resources needed, possible profits or losses and any required subsidisation. The Calculation Tool further simulates different demand scenarios, and proposes advantages and disadvantages of strategic options for consideration in planning an appropriate strategy to meet the goals of Veterinary Services.

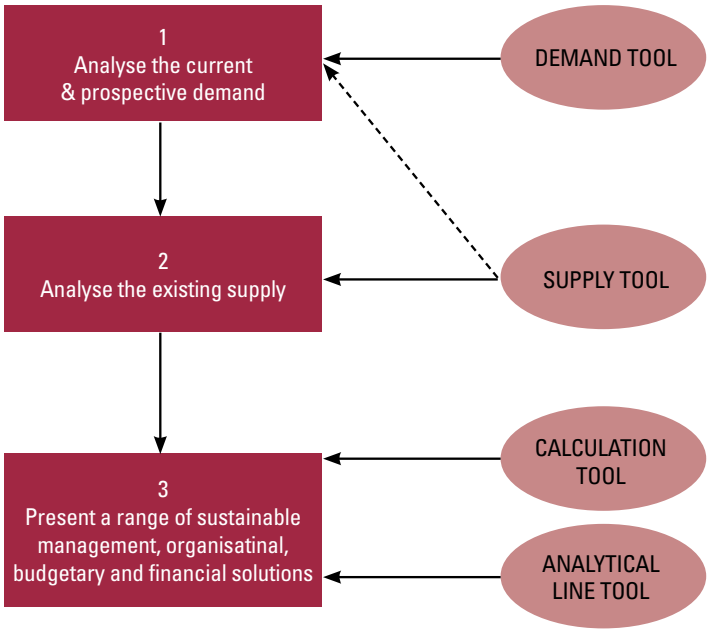


Fig. 23
PVS Pathway Laboratory mission approach and tools

Outputs

The expert's final mission report to the Member Country's OIE Delegate will specify:

- an estimate of the demand and the total cost of veterinary laboratory analyses for the next five years;
- an estimate of the current laboratory functions supplied and potential new markets;
- options for the development of a strategy for the organisation and management of a sustainable national veterinary laboratory network;
- estimates of human, physical and financial resources related to these options; and
- an evaluation of the total cost of the national veterinary laboratory network (as it compares with known resources and budget allocations).

Outcomes

The PVS Laboratory mission report will ultimately enable Veterinary Services to have a well-informed understanding of the resources needed by the national veterinary laboratory network, and of its structure and viability in the national context.

Key decision-makers will benefit from quantitative information about both the current and prospective demand for veterinary laboratory analyses, as well as the total cost of the laboratory network and analyses. The report will also propose ways in which the laboratory network can function as a sustainable investment, and describe how to allocate and/or advocate for sufficient resources.

With this support provided by OIE-certified PVS Laboratory Experts, Member Countries will be well equipped to decide upon an appropriate strategy to further the compliance of Veterinary Services to OIE intergovernmental standards. Such improvement will better ensure the accurate and timely diagnosis of priority animal diseases, including those critical to the control of major emerging issues at the human–animal interface.

3.2.
WHO Laboratory Assessment Tool

Context

The IHR, adopted by the World Health Assembly in 2005, have placed specific responsibilities on WHO Member States for building and strengthening national Core Capacities for the surveillance of and response to disease outbreaks and other events that may constitute a PHEIC. Laboratories play a critical role in this surveillance and response process.

They offer their services to many clients, including patients, physicians and public health programmes. Many medical hospital, public health and academic laboratories – be they public or private – contribute through their diagnostic activities to health care and public health improvement. In addition, animal health, food safety and environmental health laboratory services contribute to public health security. Therefore, many health programmes conduct laboratory assessments for different purposes and objectives. Some assessments focus on technical capacities of a restricted number of laboratories, such as polio or measles reference laboratories in the scope of WHO eradication programmes. Other initiatives are aimed at assessing laboratory services widely across a country either for specific diseases (e.g. HIV or tuberculosis control programmes) or in a cross-cutting manner.

Laboratory services are functional only if a combination of the following elements is adequate and in place:

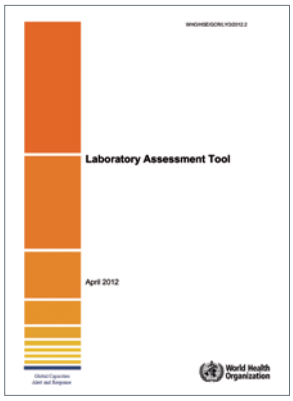
- well-identified national laboratory leadership structure;
- functional organisational structure;
- national policy;
- national regulations;
- appropriate testing services;
- referral and networking activities (data and specimen sharing);
- infrastructures;
- human resources;
- reagents and equipment procurement systems;
- information management;
- financing system;
- quality management system;
- biorisk management.

All these interconnected elements constitute the national laboratory system. The WHO Laboratory Assessment Tool (LAT) addresses key components of this system, including key components at the individual laboratory level.

Objective

The WHO LAT is composed of a manual, describing the scope and methodology of assessment, and two accompanying questionnaires:

- the LAT/System Questionnaire (LAT Annex 1) to help assess a national laboratory system; and
- the LAT/Facility Questionnaire (LAT Annex 2) to help assess an individual laboratory.



Its cross-cutting and holistic approach makes the tool appropriate for the assessment and monitoring of laboratory capacities for the benefit of various stakeholders or programmes relying on the laboratory services (e.g. healthcare programmes and disease surveillance and control programmes).

It is based on the internationally recognised standards and good practices governing laboratory services but does not take into account specific national norms or regulations.

It can be used as a basis for either self-assessment or external assessment to:

- provide information in a standardised way on the health laboratory administrative organisation and environment;
- provide a snapshot of a representative sample of laboratories at various levels;
- identify strengths and weaknesses of the health laboratory system;
- raise awareness of the laboratories' performance at country level;
- provide objective data to national decision-makers for planning and implementing laboratory capacity-strengthening activities.

Application

The target audience of the WHO LAT is any stakeholder performing laboratory assessments, such as national health authorities, multilateral agencies, non-governmental organisations and laboratory managers. The tool can be used for a mission that is not led by WHO.

Assessors can use the generic Tool or customise the available materials to meet local requirements or specificities and better fit the assessment context.

The Tool is available on the internet at www.who.int/ihr/publications/laboratory_tool/en/. The questionnaires are provided in PDF format, which can be easily printed, and as Excel files, which enable automatic calculations of module indicators and data analysis.

The tool is available in four languages: English, French, Spanish and Russian. The questionnaires are multilingual and the language can be easily changed during use.

Approach and methodology

To fully assess the laboratory system, two areas need to be addressed: strategic organisation and support at the national level from the government (e.g. policies and regulatory framework), and specific technical capacities at the laboratory level. Therefore, the Tool comprises two complementary phases.

Assessment of the structure, organisation and regulations of the national laboratory system

This phase is composed of collection of data at central level (and intermediate/peripheral level if time and resources allow and/or if health authorities are decentralised) using interviews or meetings. The assessment team can be guided by the WHO LAT/system questionnaire.

This checklist is mainly intended for the health authorities in charge of diagnostic and public health laboratory management. However, this checklist could be adapted to assess other health-related laboratory systems (e.g. food safety, environmental health laboratories).

The LAT/system questionnaire is designed to:

- describe and evaluate the essential elements of national laboratory systems (e.g. existing national health laboratory policies, resources and activities);

- automatically generate numerical indicators related to the structure and organisation of laboratory services in different parts called 'modules'; and
- follow up over time.

It comprises eight specific modules covering the following areas:

1. Coordination and management
2. Structure and organisation
3. Regulations
4. Quality of laboratory system
5. Laboratory information management
6. Infrastructure
7. Human resources
8. Biorisk management.

Assessment of an individual laboratory

Assessment of a limited number of laboratories that are representative of the national laboratory system and its organisational structure is recommended. The assessment team can use any existing checklists or assessment tools provided by disease control programmes, inspection, licensing or accreditation bodies.

If a checklist is not available or does not suit the laboratory under assessment, the assessment team can use the WHO LAT/facility questionnaire. It is recommended that the laboratories that are assessed are from different entities or networks, operate under different status and funding mechanisms (public and private sector, hospital and academic sector, faith-based facilities, military facilities) and are from each level of the healthcare delivery system (primary, secondary and tertiary, if any) and administrative organisation:

- At least three central-level laboratories: national reference laboratories, national public health laboratories, university teaching hospital laboratories, animal health or environmental laboratories, poison centre laboratories.
- At least three intermediate-level laboratories (regional or provincial level): hospital-based or public health laboratories.
- At least three peripheral laboratories (district or health centre level): diagnostic laboratories (public or private).

The LAT/facility questionnaire is designed to:

- assess any individual laboratory;
- automatically generate numerical indicators related to the laboratory capacities and quality in different parts called 'modules';
- follow the improvement of the same laboratory over time; and
- perform an evaluation based on the technical and management requirements expected according to the level of the laboratory (reference, intermediate, peripheral).

It comprises 11 specific modules covering the following areas:

1. Organisation and management
2. Documents
3. Specimen collection, handling and transport
4. Data and information management
5. Consumables and reagents
6. Equipment
7. Laboratory testing performance
8. Facilities
9. Human resources
10. Biorisk management
11. Public health functions.

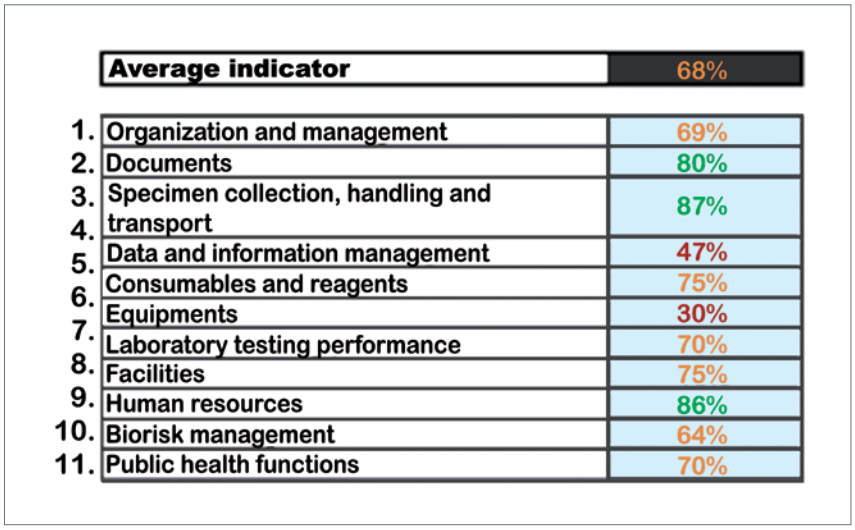
Outputs

Completion of each questionnaire results in a representation of indicators with background colour ranging from red to green (Fig. 24). The assessors can therefore easily assess the condition of each indicator.

In this example:

- **Red:** below 50%; the area requires significant improvement.
- **Yellow:** between 50% and 80%; some improvement is necessary.
- **Green:** above 80%; the laboratory is in good standing.

Combining the results of two questionnaires allows users to cross-check the information given at the central level by the health authorities and the functionality of the laboratory services and networks in the field. However, each part of the assessment may also be used independently.



	Average indicator	68%
1.	Organization and management	69%
2.	Documents	80%
3.	Specimen collection, handling and transport	87%
4.		
5.	Data and information management	47%
6.	Consumables and reagents	75%
7.	Equipments	30%
8.	Laboratory testing performance	70%
9.	Facilities	75%
10.	Human resources	86%
11.	Biorisk management	64%
	Public health functions	70%

Fig. 24
Screenshot of completed questionnaire

The analysis of the results of the questionnaire(s) and the recommendations should be discussed with the health authorities. At the laboratory level, results of the assessment should also be discussed with the laboratory director or manager and possibly with all other interviewees who collaborated in the assessment. This ensures a common understanding of the laboratory services situation in the country and best buy-in of the recommendations.

Outcomes

A complete assessment should result in an objective picture of the laboratory landscape in the country, with qualitative and quantitative data from the detailed questionnaires. The national decision-makers will benefit from the assessment results and the mission experts' recommendations for planning and implementing rational laboratory capacity-strengthening activities in priority areas such as zoonosis diagnosis.

3.3. Synergies and complementarities of the laboratory tools

A basic parallel can be established between the PVS Laboratory Tool and the WHO LAT:

- The PVS Laboratory Tool gives guidance on a PVS Laboratory mission methodology and components via its manual and four accompanying tools.
- The WHO LAT gives guidance on assessment of national laboratory systems and laboratories via its manual and two corresponding questionnaires.

These tools have been reviewed and compared to determine their respective coverage, overlaps, points of convergence or synergies, differences and gaps. The comparisons are detailed in the following tables. Table XXVI delineates and cross-references topics addressed in the OIE and WHO tools. Tables XXVII, XXVIII and XXIX further describe and compare the tools' components. Tables XXX and XXXI then review the approaches, designs and uses of the OIE and WHO laboratory tools in order to identify similarities and differences.

It should be noted that, in some instances, the terminology or vocabulary in one tool is different from that of the other Tool. However, the meanings or definitions are largely very similar; they are briefly reviewed in Annex 2.

Comparison of topics

The topics below are a non-exhaustive list of topics to be addressed during review of laboratory networks or individual laboratories. Use of the tools and questionnaires provided in the PVS Laboratory Tool and the WHO LAT helps to breach these topics. In both cases, however, the tools and questionnaires are indicative and there is some flexibility in their use by experts conducting a laboratory mission.

In Table XXVI, grey shading represents topics covered in both Tools. On the contrary, topics in orange under one tool are not, or minimally, covered in the other tool.

Table XXVI Comparison of topics

Topics in World Health Organization Laboratory Assessment Tool	Topics in PVS Pathway Laboratory Tool: Management and organisation of laboratory network/service	National/International regulations	Political commitment	Laboratory financing	Laboratory budget	Cost and price of analysis	Market demand	Data and information management	Quality assurance	Premises	Human resources	Laboratory safety and security	Documentation	Field activities	Equipment	Activities-Demand for laboratory analysis	Activities-Samples	Activities-Tests	Prospective activities
Management and organisation of laboratory network/ service	■																		
Management of individual laboratory																			
National regulations		■																	
Political commitment			■																
Laboratory financing				■															
Data and information management								■											
Quality management system									■										
Infrastructure/facilities										■									
Human resources											■								
Laboratory safety and security												■							
Biorisk management																			
Documentation													■						
Public health functions														■					
Specimen collection, handling and referral																			
Results reporting																			
Consumables and reagents																			
Equipment																■			
Procurement																			
Laboratory testing performance																	■	■	

Comparison of the Tools

Tables XXVII, XXVIII and XXIX describe and link the WHO LAT components and the Critical Competencies of the PVS Pathway.

- Tables XXVII and XXVIII compare (i) the modules of the WHO LAT/system questionnaire with the components of the PVS Pathway in general, and (ii) the modules of the WHO LAT/facility questionnaire with the modules of the PVS Laboratory Tool. Each module of the LAT questionnaires is explained on the left-hand side of the tables, and is aligned, on the right-hand side of the tables, with component(s) of the PVS Pathway and PVS Laboratory Tools that address the same topic. It is possible for one component of the WHO LAT to overlap with one or several components of the PVS Laboratory Tool (or PVS Pathway), or with none in a few instances.

- Table XXIX inversely compares the modules of the PVS Pathway Laboratory Tool and Mission Manual with the modules of the WHO LAT. Each module and sub-module of the PVS Pathway Laboratory Tool and Mission Manual on the left-hand side of the table is aligned with

Table XXVII Comparison of World Health Organization (WHO) Laboratory Assessment Tool (LAT)/system questionnaire with the PVS Pathway

WHO LAT/System Questionnaire (LAT Annex 1)		OIE PVS Pathway
General information	This module gathers information concerning the country being assessed and the respondent	To some extent, these areas are addressed during PVS Evaluation and PVS Gap Analysis (PVS Costing Tool) missions, specifically in relation to the PVS Critical Competencies II-1.A & B and II-2 (cited below), and more generally related to VS official programmes and need for laboratory services. *Reference to PVS Critical Competencies:* *II-1 Veterinary laboratory diagnosis* *A. Access to veterinary laboratory diagnosis: The authority and capability of the VS to have access to laboratory diagnosis in order to identify and record pathogenic agents, including those relevant for public health, that can adversely affect animals and animal products.* *B. Suitability of national laboratory infrastructures: The sustainability, effectiveness and efficiency of the national (public and private) laboratory infrastructures to service the needs of the VS.* *II-2 Laboratory quality assurance (QA)* *The quality of laboratories (that conduct diagnostic testing or analysis for chemical residues, antimicrobial residues, toxins, or tests for, biological efficacy, etc.) as measured by the use of formal QA systems including, but not limited to, participation in relevant proficiency testing programmes.* As described in Part I of the PVS Laboratory Mission Manual, the reports of these missions are reviewed and detailed during the PVS Laboratory mission. Part III, 'The Technical Components of the PVS Pathway Laboratory mission', presents the approach for gathering information related to the general structure of the laboratory system at ministerial level, laboratory network organisation, infrastructure, staffing, continuing education and resources, through the use of the PVS Laboratory tools during the PVS Laboratory mission.
1. Coordination and management	This module reviews how the relevant ministry coordinates health laboratory services, how those are funded and procurement systems for equipment and supplies	
2. Structure and organisation	This module summarises the general structure of the laboratory system including networking organisation of laboratories and reporting mechanisms	
3. Regulations	This module focuses on how the health laboratories are regulated (registration or licensing mechanisms, etc.)	
4. Quality of laboratory system	This module reviews the operations and quality requirements (external quality assessment, standards), as well as the supervision, certification and accreditation capacities in the country	
5. Laboratory information management	This module examines which data are collected from laboratories, and how they are collected, analysed and communicated	
6. Infrastructure	This module assesses the infrastructure conditions at country level	
7. Human resources	This module includes questions related to staff number and education in the country	
8. Biorisk management	This module assesses the implementation of biorisk management measures at country level	

module(s) of the WHO LAT that address the same topic. It is possible for one component of the PVS Laboratory Tool and Mission Manual to overlap with one or several components of the WHO LAT, or with none in a few instances.

The two assessment systems are not organised in the same way, and thus their components may not completely correspond.

Where the components are similar or different is detailed in the tables. Gaps in one questionnaire/tool compared with the corresponding questionnaire/tool are represented by diagonal lines on the right-hand side of the tables.

The topics below are a non-exhaustive list of topics to be addressed during review of laboratory networks or individual laboratories. Use of the tools and questionnaires provided in the PVS Laboratory Tool and the WHO LAT help to breach these topics. In both cases, however, the tools and questionnaires are indicative and there is some flexibility in their use by experts conducting a laboratory mission.

Table XXVII compares the LAT/system questionnaire with the PVS Pathway. Indeed, areas covered in the phase of the LAT assessing the organisation of the national laboratory system are addressed early in the PVS Pathway, and not only during the PVS Laboratory mission. Structure, organisation and regulations of the laboratory system are first discussed during the PVS Evaluation mission. Moreover, discussions on the laboratory topic at that stage and during the subsequent PVS Gap Analysis (PVS Costing Tool) mission may result in recommendations for a PVS Laboratory mission (as a 'treatment' of the PVS Pathway).

Table XXVIII compares the LAT/facility questionnaire with the PVS Laboratory Tools. The LAT/facility assists in assessing individual laboratories, which corresponds to the PVS Pathway Laboratory Supply Tool. The LAT/facility questionnaire is designed to be used by assessment teams or for self-assessment. The PVS Pathway Laboratory Supply Tool is the first to be completed by the laboratories prior to a PVS Laboratory mission, and is then complemented and finalised by the PVS experts during the mission itself.

Table XXVIII Comparison of the World Health Organization (WHO) Laboratory Assessment Tool (LAT)/facility questionnaire with the PVS Laboratory Tools

WHO LAT/Facility Questionnaire (LAT Annex 2)		OIE PVS Laboratory Tools	
Laboratory identification	This module gathers information concerning the laboratory being assessed and the respondent	**Supply Tool – 1. General information**	This sheet gathers information on the laboratory being assessed, the focal point of the mission, other key laboratories in the country, and key laboratory management documentation to be supplied to the PVS team
1. Organisation and management	This module summarises the general organisation, financing and supervision of the laboratory	**PVS Laboratory Mission Manual – Part III**	This portion of the mission addresses through discussion the general organisation, financing, chain of command and status of the national laboratory network, evoking information from previous PVS Evaluation and Gap Analysis missions
		Supply Tool – 1. General Information	This sheet gathers information on the documents to be supplied to the PVS team related to statutes, floor plans, organisational charts, job descriptions, quality management systems, reporting, invoices, etc.
		Supply Tool – 3d. Premises	This sheet gathers information about technical, telecommunication and administrative capabilities and infrastructure
		Supply Tool – 6. Budget Information	This sheet gathers detailed budget information, revenue and remuneration of staff over 3 years

WHO LAT/Facility Questionnaire (LAT Annex 2)		OIE PVS Laboratory Tools	
2. Documents	This module deals with the management of all documents handled in the laboratory: procedures, forms, reports, etc.	**Supply Tool – 1. General information**	This sheet gathers information on the documents to be supplied to the PVS team related to quality management systems, job descriptions, reporting, etc.
		Supply Tool – 4. Quality assurance	This sheet gathers information on proficiency testing and a list of necessary documentation related to quality management systems. Documentation management is not specifically addressed
3. Specimen collection, handling and transport	This module gathers information on the pre-examination procedures related to the sample collection (in or outside the laboratory), its transport to the laboratory or referral to other laboratories		
4. Data and information management	This module examines the laboratory procedures during the post-examination phase (laboratory results management and reporting systems)	**Supply Tool – 3d. Premises**	This sheet gathers information about technical, telecommunication and administrative capabilities and infrastructure.
			The reporting process is not enquired about specifically
		Supply Tool – 5a. Activities – demand	This sheet gathers information on the numbers of clients, requests, samples and tests performed per year, by source of demand (export, import, etc.), based on the sample and results registration systems as well as reporting processes in order to establish the current demand for laboratory analyses
		Demand tool	This Tool first examines through discussion sample and results registration and management systems (clients, requests, samples and tests) as well as reporting processes in order to establish the current and prospective demand for laboratory analyses
5. Consumables and reagents	This module assesses the way consumables and reagents are managed (storage, inventory, shortage, etc.)		
6. Equipment	This module assesses and lists the laboratory equipment and its maintenance. It is possible to adapt the equipment list according to the targeted laboratories	**PVS Laboratory Mission Manual – Part III**	This portion of the mission addresses through discussion the laboratory function and its general organisation and geographical distribution, evoking information from previous PVS Evaluation and Gap Analysis missions. The distribution of the network dramatically impacts the analytical lines that are available in each laboratory of the network
		Supply Tool – 3a. Equipment inventory	This sheet is a pre-entered list of equipment: model, maintenance, etc., in addition to acquisition year and acquisition value for calculation purposes. It is possible to adapt the equipment list. It automatically calculates the value of equipment by functionality, category and field of use
		Supply Tool – 3b. Equipment management	This sheet gathers information on maintenance and calibration generally, as well as documents maintenance service providers and temperature monitoring
		Analytical Line Tool	This Tool proposes a checklist of equipment by analytical line, including predetermined sets of minimum equipment and international reference prices. It is possible to adapt the equipment list to the specific needs of each laboratory

WHO LAT/Facility Questionnaire (LAT Annex 2)		OIE PVS Laboratory Tools	
7. Laboratory testing performance	This module makes it possible to manually list the relevant diagnostic tests performed in the laboratory and, for each and overall, to assess the diagnostic capacities taking into account staff training, procedures, equipment, reagents and internal and external quality controls. Sample type and number of tests performed per month are also to be entered for each test	**Supply Tool – 5b. Activities-Samples**	This sheet gathers information about the number of samples received per year, by type (milk, blood, urine, etc.) and by species (cattle, sheep, etc.)
		Supply Tool – 5c. Activities-Tests	This sheet gathers information about all the diagnostic tests performed in the laboratory, the number of tests performed per year, the tests' prices (tariff) and costs
		Demand Tool	This Tool presents the OIE-listed animal diseases and the corresponding existing diagnostic tests, including the OIE-prescribed and alternative tests
		Calculation Tool – 3. Estimated Staff & Finances	This sheet calculates, based on data entered in the other sheets of the Calculation Tool, the volume of activity that each major laboratory analysis represents for the laboratory network
		Calculation Tool – 4. Estimated Staff & Finances	This sheet calculates, based on data entered in the other sheets of the Calculation Tool, the estimated annual human and financial resources needed to perform desired laboratory analyses
8. Facilities	This module assesses the infrastructure and work conditions	**Supply Tool – 3d. Premises**	This sheet details the surface area and value of new construction costs by biosafety level, and gathers information on infrastructure related to water, electricity, telecommunications, waste management, refrigeration and administration
9. Human resources	This module includes questions related to staff management and qualifications	**Supply Tool – 2. Human resources**	This sheet gathers information on all staff members in the laboratory (name, age, position, education, training, etc.) and automatically calculates gender equality, surface area per staff member, age, status, education, position and field distribution, as well as average continuing education per staff member and specialised training
		Calculation Tool – 4. Estimated Staff & Finances	This sheet calculates, based on data entered in the other sheets of the Calculation Tool, the estimated annual human and financial resources needed to perform desired laboratory analyses
10. Biorisk management	This module deals with the implementation of biorisk control measures		
11. Public health functions	This module reviews how the laboratory possibly contributes to any public health programmes, such as the participation in surveillance networks, investigation of public health events (e.g. outbreaks) and/or the monitoring of trends for endemic diseases. This module is particularly adequate for public health laboratories, but also for any laboratory (academic, hospital, private, etc.) whose results can be used for any public health purpose	**PVS Laboratory Mission Manual, Part III**	Topic addressed through discussions during the PVS Laboratory mission and information from previous PVS Evaluation and Gap Analysis missions
		Supply Tool – 3c. Transport	This sheet gathers information on field work and vehicles

While the PVS Pathway Laboratory methodology contains four main tools (Supply Tool, Demand Tool, Calculation Tool and Analytical Line Tool) in addition to its Mission Manual, the LAT/Facility questionnaire overlaps mostly with the PVS Pathway Laboratory Supply Tool. However, their respective modules do not approach or cover the topics exactly the same way, and some modules have no equivalent.

A reverse comparison (PVS Laboratory Tools and Mission Manual versus LAT questionnaires and Manual) has been conducted to identify the gaps and opportunities between the two approaches.

Table XXIX Comparison of the PVS Laboratory Tools and Mission Manual (I, II, III, IV, & V) with the World Health Organization (WHO) Laboratory Assessment Tool (LAT)

I. OIE PVS Laboratory Supply Tool		WHO LAT	
1. General information	This sheet gathers information on the laboratory being assessed, the focal point of the mission, other key laboratories in the country, and key laboratory management documentation to be supplied to the PVS team related to statutes, floor plans, organisational charts, job descriptions, quality management systems, reporting, invoices, etc. This information assists the PVS experts to conduct a situation analysis in preparation of and during the mission	**LAT/Facility – Laboratory identification**	This module gathers information concerning the laboratory being assessed and the respondent
		LAT/System – 2. Structure and organisation	This module summarises the general structure of the laboratory system including networking organisation of laboratories and reporting mechanisms. The names of other laboratories in the country are not requested
		LAT Manual	The manual lists key documents/information to be requested ahead of time for the assessors to prepare the mission
2. Human resources	This sheet gathers information on all staff members in the laboratory (name, age, position, education, training, etc.) and automatically calculates gender equality, surface area per staff member, age, status, education, position and field distribution, as well as average continuing education per staff member and specialised training. This information allows the PVS experts provide expertise on an appropriately sized laboratory network according to its current supply of services and current and prospective demand. This information is then used in the Calculation Tool. Specific remuneration details are not requested. Only average monthly remuneration for a laboratory technician is requested as a parameter for the costing exercise	**LAT/Facility – 9. Human resources**	This module includes questions related to staff management and qualifications. Demographic and remuneration details are not requested
3a. Equipment inventory	This sheet is a pre-entered list of equipment: model, maintenance, etc., in addition to acquisition year and acquisition value for cost calculation purposes. It is possible to adapt the equipment list. It automatically calculates the value of equipment by functionality, by category and by field of use. This information helps the PVS experts to determine the costs of equipment to purchase, renewal costs and necessary capital investments and to rationalise the distribution of the laboratory function and analytical lines in response to market demand. This information is then used in the Calculation and Analytical Line Tools	**LAT/Facility – 6. Equipment**	This module assesses and lists the laboratory equipment and its maintenance. It is possible to adapt the equipment list according to the targeted laboratories. The equipment value is not registered in the LAT questionnaire

I. OIE PVS Laboratory Supply Tool		WHO LAT	
3b. Equipment management	This sheet gathers information on maintenance and calibration generally, and documents maintenance service providers and temperature monitoring. This information assists the PVS experts to more accurately calculate the laboratory network budget and compare the current and proposed budgets. This information is then used in the Calculation Tool	**LAT/Facility – 6. Equipment**	This module assesses and lists the laboratory equipment and its maintenance. It is possible to adapt the equipment list according to the targeted laboratories. The maintenance and calibration service providers working for the laboratory are not listed in the LAT questionnaire
3c. Transport	This sheet comprises questions on field work and vehicles. This information aids the PVS experts to more accurately calculate the laboratory network budget and compare the current and proposed budgets. This information is then used in the Calculation Tool if needed.	**LAT/Facility – 11. Public health functions**	This module reviews how the laboratory possibly contributes to any public health programmes, such as the participation in surveillance networks, investigation of public health events (e.g. outbreaks) and/or the monitoring of trends for endemic diseases. There is no question on vehicles
3d. Premises	This sheet gathers information about technical infrastructure by biosafety level. It further details the surface area and value of new construction costs, as well as gathers information on infrastructure related to water, electricity, telecommunications, waste management, refrigeration and administration. This information helps the PVS experts to determine the necessary capital investments, to rationalise the distribution of the laboratory function and analytical lines in response to market demand, and to more accurately calculate the laboratory network budget and compare the current and proposed budgets. This information is then used in the Calculation Tool	**LAT/Facility – 8. Facilities**	This module assesses the infrastructure and work conditions. It does not cost the premises
		LAT/Facility – 1. Organisation and management	This module summarises the general organisation of the laboratory, including external and internal communication means
		LAT/Facility – 4. Data and information management	This module examines the laboratory reporting system and IT capacities
4. Quality assurance	This sheet gathers information on proficiency testing and a list of necessary documentation related to quality management systems.	**LAT/Facility – 2. Documents**	This module deals with the management of all documents handled in the laboratory: procedures, forms, reports, etc.
	This information helps the PVS experts to more accurately calculate the laboratory network budget and compare the current and proposed budgets. This information is then used in the Calculation Tool	**LAT/Facility – 7. Laboratory testing performance**	For each diagnostic test listed, availability of procedures and participation in external quality assessment programmes are requested
		LAT/System – 4. Quality of laboratory system	This module reviews the national quality requirements (national external quality assessment, standards)
5a. Activities –demand	This sheet gathers information on the numbers of clients, requests, samples and tests performed per year, by source of demand (export, import, etc.), and annual billings based on the sample and results registration systems as well as reporting processes in order to establish the current demand for laboratory analyses. This information aims to assist the PVS experts to better understand the current demand for laboratory analyses and current and potential sources of revenue. This information is then used in the Demand Tool		

I. OIE PVS Laboratory Supply Tool		WHO LAT	
5b. Activities – samples	This sheet gathers information about the number of samples received per year, by type (milk, blood, urine, etc.) and by species (cattle, sheep, etc.). This information helps the PVS experts to better understand the current volume of activity of the laboratory network by type and by species and new potential activities to develop. This information is then used in the Demand Tool	**LAT/Facility – 7. Laboratory testing performance**	This module makes it possible to manually list the relevant diagnostic tests performed in the laboratory and, for each and overall, to assess the diagnostic capacities, taking into account staff training, procedures, equipment, reagents, internal and external quality controls. Sample type and number of tests performed per month are also to be entered for each test
5c. Activities – tests	This sheet gathers information about all the diagnostic tests performed in the laboratory, the number of tests performed per year, the tests' prices (tariff) and costs. This information helps the PVS experts to better understand the breadth of laboratory analyses conducted compared with OIE international standards, their prices and costs and to learn how the cost of tests is determined. This information is then used in the Demand and Calculation Tools	**LAT/Facility – 7. Laboratory testing performance**	This module makes it possible to manually list the relevant diagnostic tests performed in the laboratory and, for each and overall, to assess the diagnostic capacities taking into account staff training, procedures, equipment, reagents, internal and external quality controls. Sample type and number of tests performed per month are also to be entered for each test. The prices and costs of tests are not addressed in the LAT questionnaire
5d. Activities – prospects	This sheet gathers information about the geographical distribution of human and animal populations, local industry and competing laboratories, test(s) not performed but with the possibility to implement, and potential client(s) for these additional activities. This information helps the PVS experts to understand the activities that could be implemented based on current capability and market demand. This information is then used in the Demand Tool	**LAT/Facility – Laboratory identification**	This module gathers information concerning the laboratory being assessed and the respondent, and comprises one question on the population covered by the laboratory
6. Budget information	This sheet gathers detailed budget information, revenue, and remuneration of staff over 3 years. This information is broken down by internal (subsidies, revenue) and external (donor projects) funding. This information allows the PVS experts to better understand current budgeting, costing practices and streams of funding, while assisting the experts to develop more sustainable business plans and strategies for long-term growth. This information is then used in the Calculation Tool	**LAT/Facility – 1. Organisation and management**	This module summarises the general organisation, financing and supervision of the laboratory. Adequacy of the laboratory budget for different areas is inquired but no budget figure is requested

II. OIE PVS Laboratory Demand Tool		WHO LAT	
Demand Tool	This Tool first examines through discussion sample and results registration and management systems (clients, requests, samples and tests) as well as reporting processes in order to establish the current and prospective demand for laboratory analyses. This Tool gathers information about the current and prospective demand based on the official programmes outlined in the PVS Gap Analysis (*PVS Costing Tool*) Report, information gathered in the Supply Tool and during the mission. It calculates the total number of tests, the total cost and cost by test for consumables for the laboratory network and for international laboratory analyses. It also presents the OIE-listed animal diseases and the corresponding existing diagnostic tests, including the OIE prescribed and alternative tests. This information allows the PVS experts to provide an initial idea of cost of performing analyses in country or delegating laboratory analyses to other laboratories (private or external). This information is then used in the Calculation Tool.		

III. OIE PVS Laboratory Calculation Tool		WHO LAT	
1. Current and proposed budget	This sheet synthesises information about the current laboratory network budget and assists the expert to build proposed budgets based on strategic options chosen by the country. This information helps PVS experts to provide complete budget information to laboratory decision-makers who may not have procedures for determining tariffs or calculating costs based on market demand and volume of activity. This information is then used to present the proposed scenarios and strategic options in the Mission Report for the national laboratory network for the next five years		
2. Tariff estimation	This sheet uses parameters such as international reference prices for laboratory analysis and reagents, as well as the share of cost of staff, equipment and reagents and relative value in points to calculate optimal tariffs for laboratory analysis in country. This information allows the PVS experts to demonstrate to the country the overall cost of analysis, taking into account all direct and indirect costs. This can provide a starting point for the laboratory leadership to develop a costing procedure for its services, thus creating revenue. This information is then used in Sheets 3 and 4 of the Calculation Tool to refine scenarios and strategic options		

III. OIE PVS Laboratory Calculation Tool		WHO LAT	
3. Estimated cost of analysis	This sheet calculates, based on the number of tests conducted in the laboratory network, the cost of analysis and the volume of activity that each major laboratory analysis represents for the laboratory network and allows leadership to see where current and future efforts can be focused to best respond to market demand. This information is then used in Sheets 1 and 4 of the Calculation Tool to refine scenarios and strategic options		
4. Estimated staff and finances	This sheet calculates the estimated annual human and financial resources needed, based on relative value points of laboratory analyses, to perform desired laboratory analyses. This information is then used in Sheet 1 of the Calculation Tool to refine scenarios and strategic options	**LAT/System – 7. Human resources** **LAT/Facility – 9. Human resources**	In these two modules, number and distribution of laboratory workers per type (e.g. manager, technician, assistant) are questioned

IV. OIE PVS Laboratory Analytical Line Tool		WHO Laboratory Assessment Tool	
Analytical line Tool	This Tool proposes a checklist of equipment by analytical line, including predetermined sets of minimum equipment and international reference prices. It is possible to adapt the equipment list to the specific needs of each laboratory. This information allows the PVS experts to quickly calculate the value of equipment for budget development. This information is then used in Sheet 1 of the Calculation Tool to refine scenarios and strategic options	**LAT/Facility – 6. Equipment**	In this module, a basic equipment list is proposed that is customable to the laboratory or laboratory network before or during the mission

V. OIE PVS Laboratory Mission Manual	WHO Laboratory Assessment Tool Manual
The Mission Manual contains information about the approach and methodology of the PVS Laboratory mission. The Manual proposes that the PVS expert address through discussion the general organisation, financing, chain of command and status of the national laboratory network, evoking information from previous PVS Evaluation and Gap Analysis missions. Additionally, the laboratory function and its general organisation and geographic distribution are discussed at length in order to assist the experts to develop scenarios and strategic options for a sustainable laboratory function. This information allows the PVS experts to conduct the PVS Laboratory mission.	The LAT Manual offers guidance to assess laboratories and the national laboratory system. It details assessment method, planning and implementation, and the areas to look at when visiting a laboratory. It encourages discussion with relevant staff at national level for a deeper understanding of the laboratory situation and a more receptive consideration of the recommendations

Comparison of the approaches and methodologies

A deeper insight into the similarities and differences of the PVS and WHO Laboratory Tools can be gained by understanding how the Tools have been designed and are used (from mission request to mission report). Both the PVS Laboratory Tool and the WHO LAT describe an approach and process for reviewing national laboratory services and networks (and individual laboratories for the WHO LAT). The tools and questionnaires provided are meant to guide the mission, which depends largely upon the expertise of the mission team.

Table XXX explains the similarities of the OIE and WHO Tools and missions.

Table XXXI presents, for areas in which they differ, the characteristics of the PVS Laboratory Tool and mission in the left column, and the characteristics of the WHO LAT and mission in the right column. It should be noted that differences may not necessarily represent opportunities for harmonisation; rather, they may otherwise inherently reflect 'complementarities' or areas in which the existing differences may confer a mutually positive impact.

Where relevant, observations are proposed in italics in Table XXXI. Differences and complementarities are opportunities for greater efficiency and synergy of the laboratory area at the country level.

Table XXX Similarities between the PVS Pathway Laboratory Tools and the World Health Organization (WHO) Laboratory Assessment Tool (LAT)

	OIE PVS Laboratory Tool and Mission	WHO LAT and Mission
Similarities		
Purpose	Missions' outcomes will deepen the understanding of the national laboratory situation. The national decision-makers will then be well equipped to decide upon appropriate laboratory strategy or strengthening activities	
Agreement of the national authorities for conduct of a laboratory mission and use of the Tools	Request for a PVS Laboratory mission comes from the OIE Member Country. Request for a WHO Laboratory mission can come from the Member State or from another stakeholder at national, regional or international levels. The WHO LAT can be also be used by any stakeholder performing laboratory assessments for a mission not led by WHO. In both OIE and WHO missions, the agreement and deep involvement of the national authorities is needed to conduct a successful mission	
Confidentiality rules	For missions led by the OIE or WHO, assessment results remain the property of the country and are kept confidential until the country decides to share the data or reports. For PVS Evaluation and Gap Analysis missions, a number of countries have authorised the OIE to share reports with OIE partners or to make the reports fully public on the OIE website	
Reference to standards	Both Tools are inspired by and are meant to explain, encourage and further the compliance to international standards: • the *Terrestrial Animal Health Code;* • the ISO 15189 standard for medical laboratories (LAT/Facility Questionnaire).	
Involvement of other sectors/partners in mission	Involvement of other sectors or partners at country level is strongly encouraged for sharing of information and better understanding of the laboratory situation. The mission organisers at country level are requested to contact and invite other sectors and partners.	
Continuing education	Expert missions can serve as continuing education opportunities for national authorities and individual laboratories. At these occasions, the mandates and actions of the OIE or WHO can also be explained. Laboratory visits are, furthermore, a good opportunity to discuss technical points if time allows. The mission allows for a transfer of knowledge and capacity building about good laboratory management.	

	OIE PVS Laboratory Tool and Mission	WHO LAT and Mission
Similarities		
Preparatory work at country level (e.g. gathering data, filling in questionnaires)	The PVS Laboratory mission Manual and the LAT Manual recommend gathering data prior to the country missions. The laboratories serving the Veterinary Services are requested to complete the Supply Tool, as well as a list of documents to be prepared and supplied to the PVS Expert Team. Similarly, a list of key documents that can be requested in advance is provided in the LAT Manual. In both cases, this preparatory work is advised but not mandatory and is not a *sine qua non* condition for the laboratory mission to be conducted. Interestingly, the lack of information provided in advance can be a preliminary indication of the laboratory situation at country level.	
Tools format	Both Tools comprise a Manual describing the mission process, and Excel files that should be filled in. The Excel tools/questionnaires are divided into several modules, with pre-entered fields to help data collection	

Table XXXI Differences and complementarities between the PVS Pathway Laboratory Tools and the World Health Organization (WHO) Laboratory Assessment Tool (LAT)

	OIE PVS Laboratory Tool and Mission	WHO LAT and Mission
Differences and complementarities		
Process	The PVS Laboratory mission is integrated into the PVS Pathway in the 'treatment' phase. The mission implementation process is standardised	National laboratory services and laboratory assessments can be organised for different purposes by diverse stakeholders: use of LAT/System and/or LAT/Facility is possible. The mission process is to be adapted to the request and to the organiser and conductor of the mission
Main objective	The main objective of a PVS Laboratory Mission is to determine the resources needed by the national laboratory network and to evaluate its structure and viability in the national context. The mission presents strategic proposals for human, physical and financial resources, with associated indicative budgets (quantitative data) for the national laboratory network (to be ranked and validated by relevant staff during the final meeting). Depending on the scope of the mission, expertise on individual laboratories can be provided, but most expertise relates to the network as a whole	A Laboratory Assessment Mission, as advised by WHO, assesses the organisation of the national laboratory services and the quality and technical capacities of individual laboratories. Advising individual laboratories is a main component of a mission. Data collected at all levels are to be interpreted and discussed with decision-makers. Mission debriefing and report includes recommendations for the national laboratory services and network, and the individual laboratories assessed
	The Tools and Missions do not gather all of the same type of information and do not necessarily target the same type of laboratory. Sharing of Missions' outcomes at a national level could be very valuable for a concerted strengthening of the laboratory function, or to achieve greater technical efficiencies leading to the improvement of early detection outbreak response and disease surveillance	

	OIE PVS Laboratory Tool and Mission	WHO LAT and Mission
Differences and complementarities		
Scope: type and number of laboratories in consideration to analyse or create a national laboratory network	A PVS Laboratory mission first targets veterinary laboratories and the national laboratory network. It is the responsibility of the country to encourage laboratories to participate and provide data on these laboratories, and the responsibility of the PVS Experts to define, given the availability of sufficient data, which laboratories can be included in the scope of the mission. To date, PVS Laboratory pilot missions have included between 1 and 19 laboratories. Representativeness of the laboratory network is not a goal *per se* of the PVS Laboratory Mission	A WHO Laboratory Assessment mission first targets public health laboratories or laboratories with a public health role. A mission led by another stakeholder may target other laboratories: the targeted laboratories will depend on the mission purpose and organisers. A national Public Health laboratory network could be composed of several hundred laboratories. It is recommended that a representative sample of laboratories is selected from each level of the healthcare delivery system
	Laboratory network size will vary from country to country. In OIE or WHO missions, it would be virtually impossible to assess/visit all laboratories in a country: some have to be selected where relevant	
Approach	Quantitative and standardised (method and structure imposed)	Qualitative mainly. Quantitative information, such as number of tests performed or number of staff, is also collected at individual laboratory level. The approach can be considered standardised if the questionnaires are used entirely and without modification. The questionnaires are generic and meant to be modifiable. How the LAT is actually used is user, mission- and objective-dependent.
	The LAT Manual and questionnaires, designed for qualitative assessment of national laboratory services and individual laboratories, can serve as reference documents for PVS experts at the PVS Evaluation and Gap Analysis stages.	
Availability	Currently, the tools and manual are restricted to PVS Experts' use in preparation of and during missions. The tools are not currently downloadable from the internet and are password protected.	The questionnaires and manual are freely downloadable from the internet, and are modifiable for adaptation to the country context. Exactly how widely the LAT is used and adapted is not known
	Manuals, tools/questionnaires and processes are shared and discussed between the OIE and WHO. Where confidentiality rules allow, lists of countries in which the organisations have conducted laboratory missions and mission results can also be shared between the partner organisations. The country is encouraged to share the relevant reports internally and across and between sectors in order to increase national awareness about the joint activities and the importance of compliance with international standards	
Tools' target audience	The PVS Laboratory Tool is intended for use by OIE-certified PVS-trained experts only	The LAT intended audience is any stakeholder performing national laboratory services and/or laboratory assessments: national health authorities, multilateral agencies, non-governmental organisations, laboratory managers for self-assessment, etc.
Independent use of the tools (e.g. self-assessment)	The Supply Tool is first completed by the laboratories before a PVS Laboratory mission, and then completed and finalised by PVS experts during the actual mission. After the mission, the Supply Tool could be used as a laboratory management tool. Independent use of the tools is not recommended before a mission as it may be difficult to interpret results and conduct next steps without additional expertise provided during a mission. The Tools can be used for self-assessment once a mission has been completed	The LAT has been designed to be used by laboratories as self-assessment
Tool adaptability	Limited. Its structure is standardised but the calculation parameters could be modified in certain circumstances	The two Excel questionnaires are modifiable and meant to be adapted to the national context

	OIE PVS Laboratory Tool and Mission	WHO LAT and Mission
Differences and complementarities		
Scoring	During the PVS Laboratory Mission, there is no scoring of the quality or the performance of the laboratory or the national network. The tools enable automatic calculation only of some budget, price and cost figures	The questionnaires enable an automatic scoring indicative of the laboratory situation: results are presented as percentages for each module and overall. No calculation of budget figures is possible
Pre-mission(s)	The mandatory mission before a PVS Laboratory mission is the first step of the PVS Pathway: the PVS Evaluation mission. Furthermore, the Veterinary Services should have defined Veterinary Services' strategies (as captured in a PVS Gap Analysis (PVS Costing Tool) Report or other document) less than 5 years beforehand	In general, no pre-mission is mandatory. For a specific purpose, it may happen that a preliminary step (e.g. mission, survey) might be conducted
	Results from previous laboratory missions, including missions from other sectors or partners, can help in planning and preparing a laboratory mission (better understanding of the laboratory landscape, the national analytical capacities and the roles and responsibilities of public laboratories, duplication of assessment avoided, follow-up on previous assessments possible, etc.)	
Mission request	Official request for a PVS Laboratory mission comes from the OIE Member Country, most likely from the OIE Delegate	Request for a WHO Laboratory mission can come from the Member State or from another stakeholder at national, regional or international level. However, Laboratory missions can also be led by stakeholders other than WHO: mission request is dependent on the mission organisers and objectives
Mission organisation	At country level, all PVS missions are organised by the Veterinary Services and the OIE Delegate	Mission organisation is dependent on the mission lead and the mission objectives. A WHO mission is always organised with the Ministry of Health
	It is the responsibility of the national organisers to inform and invite other sectors and partners, and OIE and WHO strongly encourage an inclusive approach. Participation of partners and information sharing are always valuable as this often paves the way for future collaboration	
Mission length	The PVS Laboratory Manual provides an indicative agenda for a maximum of ten working days	The LAT Manual also provides an indicative agenda: a full mission (assessment of national laboratory services and individual laboratories) would be ten working days at the minimum. Mission length depends on its objectives
Training of experts/ assessors	Formal training is organised by the OIE for PVS Laboratory experts. All PVS team members must be trained before conducting a mission	The LAT Manual provides guidance on how to conduct an assessment mission, and explains how to adapt and use the questionnaires. WHO provides no formal training for the LAT. Training of the assessment team by the mission organisers (or team leader) and field test of the assessment questionnaires are advised in the LAT Manual
	Training is instrumental to ensure that a mission is appropriately conducted in a standardised manner. For the LAT, field testing allows refinement of the questionnaires according to local specificities	
Mission team composition	The mission team is composed of one team leader (experienced OIE expert) and two or three technical experts trained in the PVS Laboratory Tool. Roles and responsibilities of each team member should be determined prior to conducting the mission	The assessment team should be built according to the Terms of Reference of the assessment mission and the number of individual laboratories to visit. Roles and responsibilities of each team member should be clearly stated in the Terms of Reference
	Due to commonality of techniques and organisation and comparable applicable standards, laboratory experts from one sector can be an asset for the other sector	

	OIE PVS Laboratory Tool and Mission	WHO LAT and Mission
Differences and complementarities		
Mission location and level, and on-site laboratory visits	The mission is conducted at central level (Veterinary Services) or at the national veterinary laboratory if possible. A short visit to the national veterinary laboratory is recommended, but visits to secondary or tertiary laboratories lasting more than half a day are not included in the mission duration and must therefore be requested and planned in advanced for logistic reasons. On-site visits may be necessary for the experts to better understand the context but are not intended to assess technical aptitude of a laboratory and in some cases may risk confusion about the objectives and quantitative nature of the PVS Laboratory mission. Other laboratory visits may have occurred during the PVS Evaluation and PVS Gap Analysis (PVS Costing Tool) missions and this information can inform the PVS Laboratory mission. The final meeting, where the outputs and outcomes of the Mission are presented, can occur at the Ministry of Agriculture level	A full laboratory mission as described in the LAT Manual should visit all levels of the healthcare delivery system. It also depends on the mission organisers and objectives. The LAT/System is to be filled in at the Ministry of Health level (at the Laboratory unit, if applicable). The LAT/Facility questionnaire is mainly designed for central-level laboratories and can easily be simplified for other levels. On-site visits are mandatory for the qualitative nature of this assessment. They are a core component for a full LAT mission and require at least five working days. The LAT Manual recommends at least a day for a reference laboratory, and half a day for a peripheral laboratory. The visits must be carried out during opening hours, in order to observe staff at work. The final meeting and discussions on the recommendations for a full LAT mission will happen at the Ministry of Health level
Mission report	A defined template exists to respect the mission structure and ensure that all essential points are addressed in the mission report. PVS mission reports are important sources of information for other PVS Pathway activities, notable 'treatment' capacity-building activities	The report will be mission dependent
	Although both the WHO LAT and PVS Laboratory missions are confidential, sharing this information, and related strategic planning, may facilitate opportunities for improved technical efficiencies, and lead to greater political commitment to intersectoral collaboration.	
Budget, price and cost calculations	These concepts are the core components of the PVS Pathway Laboratory Mission approach. Based on their own expertise and analysis facilitated by the PVS Laboratory tools, PVS experts propose scenarios and strategic options to assist decision-makers	No such figures are requested and analysed in the LAT/System and the LAT/Facility. There are questions on adequacy of budget for national laboratory services and testing prices in the LAT/System and on the source of laboratory funding in the LAT/Facility
	Both the LAT and PVS Tools request information about the source(s) of laboratory funding at the individual laboratory and network levels. Funding opportunities and priorities can provide important information to be shared at country level, and may flag opportunities for cost efficiencies in either sector	
Prospective activities	Prospective activities that respond to market demand are addressed in the Supply and Demand Tools. This information is also collated from previous PVS mission reports (e.g. PVS Gap Analysis (*PVS Costing Tool*) mission). The 5-year Veterinary Services strategy (e.g. official surveillance and control programmes) is essential for establishing strategic proposals and budgets	Prospective activities are not inquired as such. They are, however, discussed in the country context in order to understand which laboratory capacities are needed and, if relevant, to help build national laboratory strategy and policy

Bridging opportunities

The PVS Pathway Laboratory and the WHO Laboratory Assessment Manuals and Tools each contain information that not only is useful cross-sectorally, but also may provide opportunities to add value to their individual processes and outcomes. Some areas of opportunity which have been generally observed in this review may be particularly relevant to countries that wish to consider their own strategies for enhanced collaboration between the human and animal health sectors.

For example, the sharing of missions' materials, outcomes and reports, and the participation (and thereby sensitisation) of experts in the other sector's missions will add value for these institutions in terms of improved understanding and strategic planning. At the national level, cross-sectoral participation in missions and sharing of information concerning future strategic plans may enhance political commitment and improve the management of laboratory networks and their services, and ultimately improve evaluation of compliance with international standards.

Greater efficiencies may also be identified through sharing ideas about information management and quality assurance.

Laboratory biosafety and biosecurity may also be optimised by involving other sectors or partners, as might their involvement in initiatives to harmonise various technical aspects of specimen collection, transport and handling.

Such multi-sectoral collaboration might also result in opportunities for cost rationalisation, as might sharing information about laboratory financing and procurement.

Importantly, disease response and compliance with international standards may be greatly enhanced by an all-risk and multi-sectoral approach. Such a joint effort could benefit, for example, from a review of LAT laboratory testing performance information alongside information derived from the PVS Laboratory Tool regarding the types of samples and tests that are used for zoonotic disease diagnosis. Identifying common goals and objectives for the laboratory function of both sectors through mid- to long-term strategic planning could lead to the improvement of early detection, outbreak response and disease surveillance. If appropriate, the OIE and WHO would be well placed to facilitate joint national workshops to share laboratory missions outcomes and options for future collaboration.

Bridging opportunities

1. Enhance mission preparation/understanding
2. Flag opportunities for greater efficiencies
3. Flag opportunities for cost rationalisation in each sector
4. Improve priority disease response and international standards compliance
5. Facilitate strategic planning

This comparison of WHO and OIE laboratory assessment tools has flagged some differences in their use and technical content, as well as many synergies and complementarities between the two sectors.

Enhanced information-sharing and mutual contribution between the two sectors during and after assessment missions can lead to new opportunities to achieve greater benefits in the protection of national and global animal and public health, in line with One Health principles.

CONCLUSION

The WHO and the OIE are committed to supporting their Member Countries in playing an active role in the development of a coherent system of global health governance at the human–animal interface. The two organisations recognise that building robust and effective health systems, which operate under the tenets of good governance, is key to ensuring the health and well-being of the global population and its access to safe food.

The approach and tools that have been developed and presented in this Operational Framework represent a way forward to meet the goal of global health safety and security. The partnership between WHO and the OIE and their acknowledgement of the benefits of the One Health approach are embodied in the IHR Monitoring Framework and PVS Pathway; through this Operational Framework, WHO and the OIE invite their Member Countries to take action and work together using an intersectoral approach.

Rather than developing new processes and procedures, the Operational Framework provides Member Countries with clarity on how to access and use existing, tried-and-tested processes and tools.

In particular, the Operational Framework:

- explains the foundations and key references for good governance at the human–animal interface, drawing attention to the relevant global regulations and standards;
- presents and describes the various processes and tools;
- identifies the synergies, complementarities and differences of the WHO and OIE processes and tools;
- highlights how the joint use of WHO IHR Monitoring Framework and OIE PVS Pathway outputs enables Member Countries to undertake a detailed assessment of the existing national strengths and gaps in the human and animal health sectors;
- underlines the importance of building bridges between the human and animal health sectors and provides concrete examples of how Member Countries can achieve national One Health roadmaps; and
- delineates the wide-ranging benefits that can be achieved from developing national strategies targeting joint capacity-building for the human and animal health sectors.

The WHO and the OIE propose that their Member Countries use the Operational Framework as a reference document to progress towards improved collaboration and coordination at the human–animal interface and develop an effective national One Health approach.

The implementation of the approach and tools described herein requires not only the active participation of national public health authorities and Veterinary Services, but also their commitment to take ownership of the actions required.

REFERENCES

Bourguinat H. (2003). – Quand les biens 'publics' deviennent 'globaux'. *Sociétal*, **39**, 47-50.

Eloit M. (2012). – The global public good concept: a means of promoting good veterinary governance. *In* Good governance and financing of efficient Veterinary Services (L. Msellati, ed.). *Rev. sci. tech. Off. int. Epiz.,* **31** (2), 577–590.

Food and Agriculture Organization (FAO) (2002). – Improved animal health for poverty reduction and sustainable livelihoods. Animal production and health paper No. 153. Food and Agriculture Organization of the United Nations, Rome, 45pp.

Food and Agriculture Organization (FAO) (2013). – World livestock 2013 – Changing disease landscape. Food and Agriculture Organization of the United Nations, Rome, 111pp.

Food and Agriculture Organization (FAO), World Organisation for Animal Health (OIE) & World Health Organization (WHO) (2010). – Sharing responsibilities and coordinating global activities to address health risks at the animal–human–ecosystems interfaces. A tripartite concept note. Available at: www.oie.int/fileadmin/Home/eng/Current_Scientific_Issues/docs/pdf/FINAL_CONCEPT_NOTE_Hanoi.pdf (accessed on 18 April 2014)

Gostin L., Ooms G., Heywood M., Haffeld J., Mosgedal S., Røttingen J-A., Friedman E.A. & Siem H. (2010). – The joint action and learning initiative on national and global responsibilities for health. World Health Report, Background Paper No. 53. World Health Organization, Geneva, 43pp.

Jonas O. (2013). – Pandemic risk. Background paper to the World Development Report 2014 on Risk and Opportunity: Managing Risk for Development. Available at: http://un-influenza.org/?q=content/pandemic-risk-paper-wdr-2014 (accessed on 5 April 2014)

Jones K.E., Patel N.G., Levy M.A., Storeygard A., Balk D., Gittleman J.L. & Daszak P. (2008) Global trends in emerging infectious diseases. *Nature*, **451**, 990–994.

Kaul I., Conceição P., Le Goulven K. & Mendoza R.U. (2002). – Why do global public goods matter today?, 2-20, *In* Providing global public goods. Oxford University Press, Oxford. Overview available at: http://web.undp.org/globalpublicgoods/globalization/pdfs/Overviews.pdf (accessed on 5 April 2014)

Msellati, L., Commault, J. & Dehove, A. (2012). – Good Veterinary Governance: definition, measurement and challenges. *In* Good governance and financing of efficient Veterinary Services (L. Msellati, ed.). *Rev. sci. tech. Off. int. Epiz.* **31** (2), 413–430.

Morse S.S. (2004). – Factors and determinants of disease emergence. *In* Emerging zoonoses and pathogens of public health concern (L.J. King, ed.). *Rev. sci. tech. Off. int. Epiz.* **23** (2), 443–451.

World Bank (2010). – People, pathogens, and our planet. Volume 1: Towards a One Health approach for controlling zoonotic diseases. World Bank, Washington, DC, 56pp.

World Bank (2012). – People, pathogens, and our planet. Volume 2: The economics of One Health. World Bank, Washington, DC, 50pp.

World Health Organization (WHO) (2008). – The International Health Regulations (2005), 2nd Ed. World Health Organization, Geneva, 74pp.

World Health Organization (WHO) (2011). – Strengthening response to pandemics and other public-health emergencies: report of the review committee on the functioning of the International Health Regulations (2005) and on pandemic influenza (H1N1) 2009. World Health Organization, Geneva, 166pp.

World Health Organization (WHO) (2012). – Checklist and indicators for monitoring progress in the development of IHR Core Capacities in States Parties. World Health Organization, Geneva, 71pp. Available at: www.who.int/ihr/checklist/en/ (accessed on 8 March 2014)

World Health Organization (WHO) (2013). – Sustaining the drive to overcome the global impact of neglected tropical diseases; second WHO report on neglected tropical diseases. World Health Organization, Geneva, 153pp.

World Organisation for Animal Health (OIE) (2013). – Aquatic Animal Health Code. Available at: www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/(accessed on 8 March 2014)

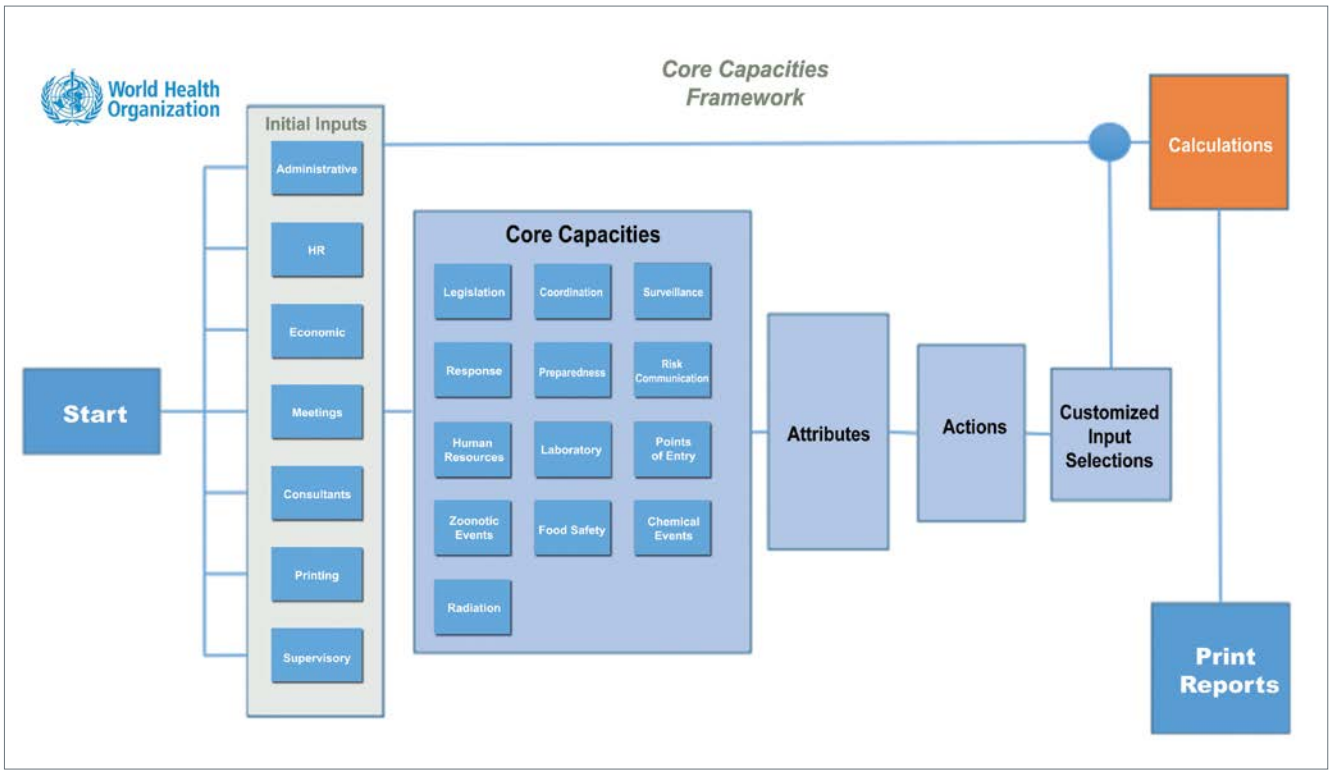
World Organisation for Animal Health (OIE) (2012). – Notification of animal and human diseases: the global legal basis. World Organisation for Animal Health, Paris, France, 29pp.

World Organisation for Animal Health (OIE) (2013). Terrestrial Animal Health Code. Available at: www.oie.int/en/international-standard-setting/terrestrial-code/access-online/ (accessed on 8 March 2014)

World Organisation for Animal Health (OIE) & Food and Agriculture Organization (FAO) (2007). – Ensuring good governance to address emerging and re-emerging animal disease threats. World Organisation for Animal Health, Paris, 29pp. Available at: www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/Good_vet_governance.pdf (accessed on 8 March 2014)

ANNEXES

Annex 1
Framework using the core capacity approach
Logic model of the core capacity approach



Annex 2
Terminology and parameters

Overall, the terminology in the WHO LAT is quite general and applicable to the veterinary laboratory area.

The PVS Laboratory Tool details financial and budgetary concepts that are not addressed in the WHO LAT, and thus uses the appropriate related terminology.

The **budget/financial concepts and definitions** in the PVS Laboratory Tool (e.g. cost, price, tariff) are compatible with concepts and definitions that could be used for laboratories in the public health sector, even though these concepts are not developed in the WHO LAT.

The **calculation references and parameters/figures** used in the PVS Laboratory Tool would have to be reviewed for use in the public health sector. The price and cost references may vary between countries (e.g. because reagents and equipment prices are different) and with time as prices evolve quickly. The calculation parameters and the 'relative value in points' were defined to minimise the impact of these variations on calculations. They are meant to be modified by the experts during a mission if needed. The 'relative value in points' approach would also be applicable to the public health sector.

In both Tools, the **laboratory** definition is similar.

The PVS Laboratory Mission Manual defines a 'laboratory' through its 'laboratory function'. A laboratory is therefore 'a physical entity that carries out all or part of the laboratory function' with the laboratory function being the 'service rendered'.

In the WHO LAT Manual, a health laboratory is defined as the 'basic unit […] which operates applying scientific analytical methods to provide relevant results for a defined health-related purpose(s), such as medical research, medical diagnostics, disease surveillance, food testing, etc.'. The 'service rendered' is here detailed as 'provide relevant results for a defined health-related purpose'.

Some technical vocabulary differs in the two tools, even though the definitions of the words are identical, for example 'premises' in the PVS Laboratory Supply Tool versus 'facilities' in the WHO LAT/Facility Tool.

•

World Health Organization

OIE WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

WORLD BANK GROUP