GLOBAL HEALTH SECURITY AGENDA PILOT ASSESSMENT OF PORTUGAL

April 12 to 17, 2015





With sincere thanks and gratitude to the Portuguese host team and the international GHSA partnership experts for their contribution to a successful assessment mission

Prevent, Detect, Respond

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Preamble

The Global Health Security Agenda (GHSA) is an effort by nations, international organizations, and civil society to accelerate progress toward a world safe and secure from infectious disease threats; to promote global health security as an international priority; and to spur progress toward full implementation of the World Health Organization (WHO) International Health Regulations 2005 (IHR), the World Organization for Animal Health (OIE) Performance of Veterinary Services (PVS) pathway, and other relevant global health security frameworks. Assessments will be performed in order to determine the status of participating Global Health Security Agenda participating countries for the purpose of identifying the baseline situation and later measuring progress of work implemented in the 11 Action Packages of the GHSA.

Portugal was the fourth country to be assessed for the GHSA (following Georgia, Peru and Uganda), in order to pilot test the usefulness of a novel GHSA Assessment Tool.

Abbreviations:

ANPC - Autoridade Nacional de Proteção Civil - National Authority of Civil protection ARS Algarve - Administração Regional de Saúde do Algarve - Regional Health Administration of Algarve DGAV- Direção-Geral de Alimentação e Veterinária - National Directorate of Feeding and Veterinary DGS - Direção-Geral da Saúde - Directorate General of Health ENSP – Escola Nacional de Saúde Pública - National School of Public Health INEM – Instituto Nacional de Emergência Médica - National Institute of Medical Emergency INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. - National Authority of Medicines and Health Products INIAV – Instituto nacional de Investigação Agrária e Veterinária – National Institute of Agriculture and Veterinary Research INSA – Instituto Nacional de Saúde Doutor Ricardo Jorge - National Institute of Health LBDB - Laboratório de Bromatologia e Defesa Biológica - Portuguese Army Biological Defense Laboratory MNE – Ministério dos Negócios Estrangeiros - Ministry of Foreign Affairs SIS – Servico de Informações de Segurança - Security Intelligence Service

Links to some institutions:

http://www.portugal.gov.pt/pt.aspx www.dgs.pt www.insa.pt www.inem.pt www.infarmed.pt http://www.infarmed.pt/portal/page/portal/INFARMED/CONTACTOS/MAPA/MAPA_DETALHADO www.ensp.unl.pt http://www.dgv.min-agricultura.pt/portal/page/portal/DGV http://www.prociv.pt/Pages/default.aspx

Executive Summary on GHSA capabilities

The Portuguese system for infectious disease prevention and control is well developed and has most necessary components present. With some minor exceptions, Portugal reached the highest level of scoring for the capacities required by the GHSA Action Packages, as measured by the indicators in the assessment tool. In the context of the GHSA the Portuguese system can be considered as a fairly comprehensive system for health security.

GHSA assessment tool scoring summary			Portugal
Prevent 1	Antimicrobial resistance	Surveillance Plan Implementation	4
		Laboratory testing	4
Prevent 2	Zoonotic Disease	Surveillance systems in place for priority zoonotic diseases/pathogens	4
		Veterinarians	4
Prevent 3	Biosafety and Biosecurity	Whole-of-government biosafety and biosecurity system is in place	2
		Biosafety and biosecurity training and practices	2
Prevent 4	Immunization	Vaccine coverage (measles)	4
		National vaccine access	4
Detect 1	National Laboratory Systems	Laboratory testing capacity for 10 core tests for detection of 10 priority diseases	4
		Specimen referral and transport	4
		Effective modern point of care and laboratory based diagnostics	4
Detect 2 & 3	Real-Time Surveillance	Syndromic surveillance systems	3
		Inter-operable, interconnected, electronic real-time reporting system	3
Detect 4	Reporting	System for efficient reporting to WHO, FAO and OIE	3
		Reporting network and protocols in country	3
Detect 5	Workforce Development	Trained field epidemiologists - Human	3
		Field Epidemiology Training Program or other applied epidemiology training program in place	3
		Workforce strategy	2
Respond 1	Emergency Operations Centers	Status of EOC (space)	4
		Status of EOC (staff)	4
		Emergency Operations Program	4
Respond 2	Linking Public Health with Law and	Public Health and Law Enforcement are linked	4
	Multisectoral Rapid Response	during a suspect or confirmed biological event	
Respond 3	Medical Countermeasures and Personnel Deployment	System is in place for sending and receiving medical countermeasures during a public health emergency	4
		System is in place for sending and receiving health personnel during a public health emergency	4

GHSA assessment tool scoring summary

During the mission the team saw ample evidence of coordinated joint action covering multiple sectors and stakeholders. Evidence was seen for the necessary communication links form the local level to the top levels of the administration.

In terms of the GHSA action packages the following main findings can be highlighted.

Prevent 1, Antimicrobial resistance

Portugal has developed and implemented a national programme to promote sound antibiotic stewardship compliant with international guidance from WHO, EU and expert scientific opinion. The programme sustains education on optimum antibiotic prescribing for professionals in hospitals and community health settings; and the public in the appropriate indications for being prescribed antibiotics. The programme also reinforces the complementary necessity of sustaining and improving infection prevention and control.

The antibiotic resistance in animals and foodstuffs and the consumption of antimicrobials in animals is monitored in line with the EU requirements. Portugal has an equitable health system predominantly supported by government revenue and free at the point of use. Antibiotic prescribing is restricted to registered physicians and is amenable to initiatives to improve prescribing quality for the population who are not exposed to substantial volumes of antibiotics from unregulated access. A national – five years - plan of action (PANRUAA) for reducing the use of antibiotics in animals and the promotion of their prudent use was launched in 2014 by DGAV.

There is a a network of publically funded microbiology laboratories and a well-resourced national reference laboratory (at INSA) to which specimens are sent.

Portugal has the leadership, technical and organizational capacity to develop a world leading system of antibiotic resistance surveillance and antimicrobial pharmacy surveillance, if it invests in development of appropriate reporting and analysis information systems.

However, while linkages between human and animal sectors exist, these could be further strengthened, especially for the systematic monitoring and comparison of specific genetic determinants of AMR in zoonotic microbes collected from both sources.

Prevent 2, Zoonosis:

Portugal has a surveillance system in place for zoonotic diseases/ pathogens of greatest public health concern well above the measured target to express sustainable capability in this tool. The most important diseases in this context are eg. brucellosis, tuberculosis, BSE, salmonellosis, leishmaniasis, leptospirosis, avian influenza and rabies, of which not all exist in PT.

The effect of measures implemented to reduce the spillover into human population can already be seen as a decreasing number of human cases in several zoonosis. There are also laboratory services of high quality and with modern techniques available for the diagnostics of zoonotic diseases in humans, animals and foodstuffs.

Passive monitoring in animals is in place for over 80 notifiable diseases and in humans for 52 diseases (including zoonotic diseases). Further enhancement of co-operation between the health and veterinary services could be pursued through formalized procedures and designated responsibilities to support the sustainability, even if good informal exchange of information exists.

Prevent 3, Biosafety and Biosecurity

A coordination network mechanism (LabPt) has been established for Biosafety and Biosecurity capacity development by INSA and laboratories participate on voluntary basis.

Locations for especially dangerous pathogens and toxins are consolidated in 3 main laboratories owned by the Instituto Nacional de Saude that fulfill the requirements for BSL-3. A Military laboratory for biologic defense is able to conduct core tests identified by IHR.

A list of dangerous pathogens and toxins manipulated at BSL-3 laboratories can be found in the "Portuguese BSL 3 Facilities: Rules and Guidelines", 1st Edition, edited by the Lab PTBioNet network in January 2015. The country has molecular diagnostic tests in place both at human and animal health level as well as environmental (PCR and real time PCR for example).

Appropriate security measures are in place and followed in the most important laboratories like those of INSA to minimize potential inappropriate removal or release of biological agents (e.g. theft, earthquake, flood), nevertheless, no assessment has been carried out in the other public or private laboratories throughout the country.

Biosafety and biosecurity legislation and/or regulations are in place but assessments outside the INSA haven't been carried out. Legislation concerning Biosafety and biosecurity is linked to national and European legislation as for biosafety/biosecurity at workplace and protection against biological agents, but Portugal is developing a specific proposal for the implementation of an inter-ministerial biosafety-biosecurity authority. No third party has assessed biosafety and biosecurity at national laboratory facilities and there is a gap in terms of laboratory licensing monitoring, especially for the private sector even though a national accreditation system is in place.

The establishment of a national authority for the laboratory system as a whole, including both human and animal labs, would help to assure a better management of biosafety and biosecurity issues. Channels to facilitate a more comprehensive communication between human and animal laboratories could be useful to solve some specific issues involving both types of laboratories, part of this issue is addressed through the LabPt network activities.

Prevent 4, Immunization

The country started a national immunization activity at the 18th century, but an integrated nationwide program began in 1965. The National immunization programme (NIP) is operated by the Directorate General of Health (DGS). As of April 2015, the Portuguese immunization programme includes 12 vaccines/diseases (i.e. TB, HepB, Hib, DTP, IPV, MenC, MMR, and HPV), and PCV for children is going to be introduced in the programme soon. In the country, NIP vaccines are provided to all people who live in the country at free of charge, utilizing hospitals and local health centers, which are located in every municipality.

The country's goals of the NIP are to achieve the coverage level of over 95% of NIP vaccines for children (except for HPV vaccines, of which the target is over 85% of adolescent girls). Two-dose MMR vaccination coverage of children has exceeded 95% for more than 5 years.

Detect 1, National Laboratory Systems

The country has the capacity to test for all 52 diseases that are included in the EU level human disease surveillance and also the zoonotic diseases which are specified under EU level food safety regulations. Approximately 130 primary microbiological laboratories that perform tests exist in the country. These are categorized into primary diagnostic laboratories (private and public; hospital and local) and reference laboratories (located on the national level). Hospital and clinical microbiological laboratories have generally accredited their methods; point of care tests are used for applicable diseases.

Detect 2 & 3, Real-Time Surveillance

Several partially interconnected electronic systems for event and syndrome based real time surveillance exist in Portugal, many of which are maintained by the DGS. Notably, **SINAVE** (Sistema National Vigilancia Epidemiologia) is a real-time electronic web-based reporting tool that is integrated into and as part of the electronic patient record software used by the National Medical System by all clinicians at local, 5 regional and 2 Archipelago health centers and by national level health providers. It is used to monitor Nationally Notifiable Disease and the data is used to develop reports based on those identified cases and outbreak events.

Also, **Saude 24** (Health 24) — is a public citizen national call center phone line that allows triage, counseling, and public health evaluation of individuals that have health events (acute and chronic) of personal concern. The Saude 24 has 118 algorithms for clinical evaluation purposes that are followed of which approximately 40 are infectious disease related. These are set up in syndromic-like fashion. This system has the potential to provide early detection and surveillance of important health events

Detect 4, Reporting

The National IHR Focal Point (NFP) has been set up within the Ministry of Health and assigned under the Director General of Health. Then NFP consists of a team of 4 persons including 24/7 arrangements and a generic email address.

DGAV is the focal point for reporting to OIE-WAHIS in Portugal. The six-monthly reports have been sent to OIE regularly. There was evidence also of emergency reporting to OIE of a few diseases in the past with minor delays, but not necessarily of immediate public health importance.

Detect 5, Workforce Development

Specialization in Public Health (PH) is available for medical doctors and nurses, which does include some general epidemiology training. Post-graduate training courses ("advanced studies in epidemiology") exist, but there are no separate programs available for epidemiology.

Field Epidemiology Training Programs (FETP) trainings are included during the PH Residency program for MDs where one year out of the 4 year program is devoted to field epidemiology training.

The curriculum in the Veterinary Colleges in Portugal includes veterinary public health-related courses (e.g., epidemiology, food safety, post-mortem inspections, etc.). There are training courses organized by DGAV of emergency diseases and field investigations. Graduate-level courses in food safety and public health exist which include Masters and doctoral level programs.

Epidemiological training for professionals on the local level can be done on-the-job, but not systematically, since there is no national program, no strong incentives and no human-resource strategy for it.

Respond 1, Emergency Operations Centers

A public health Emergency Operations Centre (HEOC) was set up in 2005 under the authority of the National Public Health Officer and Public Health Emergencies Unit (UESP) under the DGS. The HEOC is a separate entity which functions independently but in a coordinated fashion with the Civil Protection EOC. The HEOC has roles in Early detection; Epidemic intelligence/event-based surveillance; Rapid communications; Risk Assessment; International collaboration (houses focal points for EWRS, IHR and EU HS Committee); and, DGS Website and social networks. In response its involvement is largely strategic rather than operational.

The Civil Protection Emergency Operations Centre (EOC) is professional and dedicated service run as a permanent 24/7 unit to ensure the operational command of relief operations and the integrated operational command of all fire brigades, under the Integrated Protection and Relief Operations System. The National Relief Operations Command (CNOS) is the operational structure of the National Civil Protection Authority (ANPC).

There is an organized, regular and sustained coordination between the two EOC structures on a routine (sharing of weekly bulletins and participation in joint meetings) and emergency (e.g. the 2013 heat wave when both EOCs were activated and communicated daily) basis. Taken together, these two national systems and EOC structures are complementary in their objectives, skills and competences

Respond 2, Linking Public Health with Law and Multisectoral Rapid Response

National Operational Guidelines for CBRN events (independent of whether they are natural, accidental or intentional) provide the operational framework for intersectoral collaboration at the national and local levels. Involved authorities include the Ministry of Interior, the Ministry of Health, the Ministry of Defense, the Ministry of Agriculture and Sea, the Ministry of Economy, the Ministry of Environment, Spatial Planning and Energy, the Ministry of Justice (Interpol) as well as the Intelligence Services. The Ministry of Foreign Affairs is involved in international events or if the perpetrator is a foreign citizen.

Under the National Guidelines, the ANPC (National Civil Protection Authority) is responsible for the overall coordination of a CBRN response and assumes the command role. Under the Civil Protection EOC structure, the Ministry of Health, the Ministry of Environment, and the Ministry of Agriculture

and Sea DGAV - Directorate General of Food and Veterinary are all involved to address health related issues.

At a national level, the Interpol national focal point is located within the Ministry of Justice, with the Judiciary (criminal) Police as a competent authority in the conduct of criminal investigations. If the Ministry of Health had to provide or request information from Interpol, it would do so through the Interpol national focal point.

Respond 3, Medical Countermeasures and Personnel Deployment

Portugal has well developed and exercised structures, staff, stockpiles of key medications, medicinals and materials to respond to major public health emergencies. No area of weakness in plans and probable capability could be identified by the visiting team. The systems observed appeared capable of urgent mobilisation and deployment to of public health and other appropriate personnel and resources to mitigate massive public health emergencies.

Practical demonstration of this capacity at the Health EOC - UESP was demonstrated within the last year in the prompt detection, investigation and protection of public health in a substantial outbreak of Legionnaire's Disease; and in responses to possible imported cases of Ebola (none confirmed). These events showed the ability of the health system to identify promptly severe infection posing risk to the population, assess it, and mobilise resources including staff with expertise in epidemiology, public health, human and environmental microbiology, clinicians in hospital.

Within the remit of this mission and national confidentiality, the visitors were assured of adequate consideration of stock piles and management of stockpiles of key biodefense antibiotics, medicinals antidotes and protective equipment.

Background

Mission place and time

Lisbon, Portugal; April 12 to 17, 2015

Mission team members

Mika Salminen	Finland	Team Colead
Kelly Vest	USA	Team Colead
Taina Aaltonen	Finland	Team member
Mark Reacher	UK	Team member
Paolo Parente	Italy	Team member
Roberto Falvo	Italy	Team member
Tae Un Yang	Republic of Korea	Team member
Thomas Hoffmann	WHO Euro office	Team observer member
Catherine Smallwood	WHO Geneva	Team observer member

Host team members

Alexandra Bordalo	DGS	Division of Epidemiology and Statistics
Alexandre Abrantes	ENSP	Deputy Director of the National School of Public Health
Ana Cristina Costa Fonseca	ARS Algarve	Member of the National Council of Medical Doctors Residency in Public Health Specialisation
André Sobral Cordeiro	MNE	Head of Disarmament and Non Proliferation Division Security and Defence Department Directorate-General of External Policy Ministry of Foreign Affairs of Portugal
Andreia Jorge Silva	DGS	Director of Department of Prevention of Disease and Health Promotion
António Lopes João	LBDB	Major Veterinary Doctor - Armed Forces Laboratorial Area
Carlota Vieira	DGS	Head of the Office of Strategic Planning and Evaluation
Cristina Abreu Santos	DGS	Team Coordinator for the Support Unit of the National Public Health Officer and Public Health Emergencies Management
Cátia Sousa Pinto	DGS	Head of the Division of Epidemiology and Surveillance
Eduardo Gomes Silva	CHLC	Clinical Director of Hospital Centrum Lisboa Central
Eva Falcão	DGS	Director of the Directorate of International Relations
Francisco George	DGS	Director-General of health - Chief Medical Officer
Inês Gomes	LBDB	Captain Veterinary at the Portuguese Army Biological Defense Laboratory
Isabel Castelão	DGS	Medical Officer at the Directorate of Disease Prevention and Health Promotion

Isabel Marinho Falcão	DGS	Medical Officer at the Support Unit of the National Public Health Officer and Public Health Emergencies Management
João Pires	DGS	Medical Doctor at Hospital of Amadora Sintra - Consultant for Ebola Preparedness
Jorge Machado	INSA	Team coordinator of the Infectious Diseases Department
José Maria Albuquerque	INSA	Deputy Director of the National Institute of Health Dr. Ricardo Jorge
José Artur Paiva	DGS	Director of the PPCIRA
José Pedro Marques Freitas	JPDPM	Capitan Veterinary Doctor - Armed Forces Laboratorial Area, Ministry of National Defense
Júlio Carvalho	LBDB	Head of the Portuguese Army Biological Defense Laboratory
Luis Meirinho Soares	INFARMED	Head of the Biology and Microbiology Laboratory
Madalena Almeida Santos	CHLC	Virologists at Hospital Curry Cabral
Manuela Caniça	INSA	Head of the National Reference Laboratory of Antibiotic Resistances and Healthcare Associated Infections at Department of Infectious Diseases
Marco Martins	ANPC	National Operations Assistant at the National Command for Relief Operations
Maria da Graça Freitas	DGS	Deputy Director General of Health
Maria João Martins	DGS	International Public Health Authority
Mariana Madureira	INFARMED	Adviser to the Executive Board
Mauro Martins	MNE	Officer at Division of Disarmament and Non Proliferation
Miguel Cruz	ANPC	National Operations Assistant at the National Command for Relief Operations
Miguel Fevereiro	INIAV	Senior Officer at National Institute of Agricultural and Veterinary Research
Natália Pereira	DGS	Senior Officer at the Directorate of Disease Prevention and Health Promotion
Patrícia Henriques	DGS	Communication officer at the Public Health Emergencies Unit
Paula Vasconcelos	DGS	Head of the Office of Preparedness and Public Health Support
Paulo Campos	INEM	Director of National Institute of Medical Emergency
Pedro Rosário	DGS	Physicist, Senior Officer, Division of Environmental and Occupational Health
Raquel Ramos	INEM	Lisbon Training Center Coordinator of National Institute of Medical Emergency
Ricardo Mexia	INSA	PH doctor at Departmnet of Epidemiology at National Institute of Health Dr. Ricardo Jorge

Rita Cordeiro		Laboratory Expert at INSA
Rui Carmo	MNE	Director for Security and Defense, Ministry of Foreign Affairs
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Sofia Ferreira	DGS	Nurse- Public Health adviser at DGS
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Sónia Rosa		
Susana Guedes Pombo		Head of Regional Services of Food and Veterinary of Lisbon and Tagus Valley
Yolanda Vaz	DGAV	Head of Department of Animal Protection at Directorate General of Feeding and Veterinary

Objectives

Primary objective

To assess the application of the GHSA Assessment Tool (version December 8, 2014) using information, data and observations on those structures and functions in Portugal, which are included in or relevant for the 11 Action Packages of the GHSA Action Packages document (version adopted September 26, 2014), in order to make proposals for improving the Assessment Tool.

Secondary objective

To describe structures and functions in Portugal essential in performing communicable disease surveillance and control, to the extent enabling application and evaluation of the GHSA Assessment Tool in the Portuguese context.

Additional objective

By request of the host country, the team reviewed the preparedness for Ebola cases for Portugal during the week. This was done through a series of presentations given by the relevant health and other authorities and a separate summary review has been provided in a separate section of this report.

Preparation and Implementation of the Mission

- Setting of the mission strategy and logistics was established by teleconference communication between all stakeholders including the pilot assessment team and host country partners.
- Information packets comprising note-taking tools and report templates were provided to the assessment team by the GHSA organization
- A thorough self-evaluation as well as supportive electronic documentation was provided to the assessment team from the host nation one week before the in-country assessment, precisely as agreed between the host nation and assessment team

- All Action packages were evaluated during the country assessment week based on presentations, additional material and specific written as well as numeral assessment and scoring, respectively, by the host country.
- The evaluation scoring was discussed with representatives of the host country before final scoring performed by the external assessment team.
- The WHO experts participated in the evaluation as all other assessment team members.
- The assessment document, as well as the scoring is based on mutual opinion of the assessment team and reflected the refined self-evaluation of the host country finalized during the specific assessment talks

Strengths, Limitations and Assumptions

- The lead time for preparing the mission, and acquiring the documents, data and other information prior to the mission was approximately 2 months. While longer than for some of the earlier pilot missions, optimal circumstances would probably require 3-4 months of efficient and interactive preparations with the country to be assessed, and a number of the conclusions would be more definite.
- The size of the piloting assessment team was nine persons, with expertise covering most of the range of issues in all 11 Action Packages. This was a clear advantage to some earlier missions with smaller teams, as it was possible to divide primary responsibility to assess specific tasks between experts, and also to divide the team into visiting different sites/authorities to acquire information.
- The team consisted of individuals representing 5 nations and 2 representatives of the WHO (Geneva office and the European regional office). This breath of experience on the national level and from the international coordinating multilateral organizations was very useful as it significantly increased the collective understanding of different operational models.
- The inclusion of additional expertise from the OIE would have been beneficial for the assessment; however, the team had two experts with considerable expertise in the veterinary public health and food safety sectors.
- Due to time constraints of the visit the team was not able to request visits to the regions or provinces to acquire information and consolidate or validate the local or regional information acquired on central level, which would have been useful for verification of the description of processes and workflows. The Portuguese governance system, as far as could be assessed, is fairly centrally and vertically managed. On the national level is based on Ministries, Departments and agencies. Under these 5 continental regional administration + 2 autonomous island regions administrations coordinate work of 300+ municipal authorities. Thus it is assumed that the description of the division of work and processes described are operational and functional as described by the host of the visit.
- The information acquired during the mission on described systems in the central level could be assessed more confidently if there would be an opportunity for visiting a limited random sample of regions and peripheral sites over 1-2 days in a country of Portugal's size. This would incorporate more objectivity in the assessment. However, this would require a longer duration of the assessment.
- Limited availability of official documents and regulations in English (which is not unexpected as English is not an official language of the country) set some constraints for in-depth analysis of some documents. However, one team member was fluent in Portuguese and others who spoke Spanish and Italian partially compensated for this.
- Contrary to some previous assessments, the team found the separate list containing all the questions for note-taking to be helpful in collecting the information. This may reflect the possibility to divide the responsibilities more clearly between team members.

- In the assessments that will take place after the GHSA pilot assessment phase, all terms of reference, including objectives and methodology used should be given to both the assessment team and the hosting country at least 3 months prior to the site visit in order to support effective interaction in advance preparations between the assessment team and the hosting country.
- It is noted that completeness of the GHSA self-assessment varied depending on the government organization/persons providing the information.

Structure of the Assessment

The assessment part of the report is organized by each of the 11 GHSA Action Packages, consisting of

- 1) key findings made in Portugal that are relevant for scoring the 'level of capability' according to the Assessment tool criteria;
- 2) areas of potential improvement for the consideration of the Health Security leadership on the national level;
- 3) comments on the Assessment tool (version December 8, 2014) regarding its applicability or difficulties in applying it in the context of Portugal; and
- 4) comments on whether the GHSA Action Packages main document approved in September, 2014, contains components which could be introduced into the Assessment tool, when revisions are made, or if there are areas of the Action Packages that might need some revision.

The assessment and scoring by Assessment tool was based on the state of the structure or function at the time of the mission, regardless of possible plans or prospects of establishing the structure or function in the near future. In some cases this led to some difficulty in objectively assessing the country situation, which in that case is reflected in the comments.

The scoring of the level of capabilities for each of the action packages is based on a 5-step Likert scale (0-4; 4 = highest level of capability; 0 = no capability). Criteria for achieving each score level are given for each action package using a set of fixed indicators. For each action package, there is 1-3 sub-criteria to be assessed and scored separately.

A list of documents and presentations acquired, are separately provided in an annex as a collection of supporting documents, covering in more detail the functions in Portugal relevant for the GHSA Action Packages.

GHSA Antimicrobial Resistance

(GHSA Action Package Prevent-1)

Introduction

Bacteria and other microbes evolve in response to their environment and inevitably develop mechanisms to resist being killed by antimicrobial agents. For many decades, the problem was manageable as the growth of resistance was slow and the pharmaceutical industry continued to create new antibiotics.

Over the past decade, however, this problem has become a crisis. The evolution of antimicrobial resistance (AMR) is occurring at an alarming rate and is outpacing the development of new countermeasures capable of thwarting infections in humans. This situation threatens patient care, economic growth, public health, agriculture, economic security, and national security.

Portugal Level of Capabilities

<u>Surveillance plan implementation capability level 4 criterion:</u> Plan is being fully implemented nationwide and monitoring is being conducted with steps for

continuous quality improvement

<u>Laboratory testing implementation capability level 4 criterion:</u> One or more reference laboratories capable of testing for four or more WHO priority AMR pathogens and results are used for policy decisions on AMR

- Portugal has developed and implemented a national programme to promote sound antibiotic stewardship compliant with international guidance from WHO, EU and expert scientific opinion. This promulgates key messages to prescribers and the public that antibiotics are a scarce resource threatened by antibiotic resistance selection pressures in bacteria, which compromises effective treatment of life threatening infection in individual patients; and that this situation can be mitigated by optimum prescribing of antibiotics in individual patients.
- The programme sustains education on optimum antibiotic prescribing for professionals in hospitals and community health settings; and the public in the appropriate indications for being prescribed antibiotics. The programme also reinforces the complementary necessity of sustaining and improving infection prevention and control.
- Portugal complies with current EC and WHO standards for antibiotic resistance surveillance by the return by sentinel diagnostic laboratories of aggregate reports of key Organism antibiotic resistance reports and appropriate denominators. Key high level WHO antibiotic resistance under surveillance include Meticillin Resistant Staphylococcus aureus (MRSA), Extended-Spectrum Beta-Lactamases (ESBL), like Escherichia coli and other Enterobacteriaceae-producer strains, as well as Carbapenemase producing-Enterobacteriaceae and other Gram negative (such as KPC, NDM, and other Carbapenemase families), and also Vancomycin Resistant Enterococci (VRE).
- The antibiotic resistance in animals and foodstuffs and the consumption of antimicrobials in animals is monitored in line with the EU requirements. The monitoring programme on AMR covers the following agents: *Salmonella* Spp, *Campylobacter jejuni* and *C.coli, E.coli, Enterococcus faecalis* and *E. faecium,* ESBL- or AmpC- or Carbapenemase-producing

Salmonella spp and *E.coli*. The results are reported to the European Food Safety Authority (EFSA) and European Medicines Agency (EMA).

- Portugal has an equitable health system predominantly supported by government revenue and free at the point of use. Antibiotic prescribing is restricted to registered physicians and is amenable to initiatives to improve prescribing quality for the population who are not exposed to substantial volumes of antibiotics from unregulated access.
- A national five years plan of action (PANRUAA) for reducing the use of antibiotics in animals and the promotion of their prudent use was launched in 2014 by DGAV.
- Portugal has a network of publically funded microbiology laboratories able to competently test for antibiotic resistance using current standard methods.
- There is a well-resourced national reference laboratory (at INSA) to which high importance specimens are sent by national diagnostic laboratories for high level characterization including definitive typing, antibiotic resistance testing and using up to date genotypic methods including detection of antibiotic resistance genes. This laboratory is correctly related to wider microbiology laboratory network.
- The Reference laboratory is well placed to evaluate and promote wider uptake of appropriate antibiotic resistance gene detection technologies as they become increasingly available in the future. This laboratory is also well placed and already works well with the veterinary reference laboratory and together will be able to make sense emerging trends in human and animal antibiotic resistance trends and mechanisms.
- In common with many countries, Portugal may have limited capacity for electronic reporting and analysis of individual laboratory antibiotic test results amenable to automated analyses and generation of time series and surveillance trends at high volume and frequency.
- However, developments are being done to improve electronic interoperability of systems to allow data analysis from individual labs
- Portugal has the leadership, technical and organizational capacity to develop a world leading system of antibiotic resistance surveillance and antimicrobial pharmacy surveillance, if it invests in development of appropriate reporting and analysis information systems. This requires an ambitious step change from existing ways of running these systems and goes well beyond the standard being sought in this present evaluation. This requires modest investment which would be very cost effective.

Scoring for Portugal Using the Assessment Tool

- Surveillance plan implementation: 4/4
- Laboratory testing: 4/4

Areas for consideration

- While linkages between human and animal sectors exist, these could be further strengthened, especially for the systematic monitoring and comparison of specific genetic determinants of AMR in zoonotic microbes collected from both sources.
- Discussion with experts brought up the issue that current re-imbursement models in hospital settings do not fully support the prudent use of antibiotics and would be worth a reassessment

Assessment Tool

- The two assessment tool indicators for this Action Package (AP) seem well applicable to reflect the level of capabilities in the country.
- The information and data to be collected interfaces closely with Action Packages D-1 and D-2/3 in several ways: it is thus useful to address at least the surveillance component in an 'integrated' manner with those Action Packages.
- Conceptually TB susceptibility monitoring belongs to the 'AMR issues'. As it is not presented elsewhere in the 11 APs as a program, it could it be incorporated somewhere in the assessment (tool).
- The monitoring of trends on the use of antimicrobials in animals could be included in the tool to acquire some information of the future risks in this field reflecting also the environmental contamination

GHSA Action Packages Main Document

• There may be possibilities to derive further indicators from examining the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) Pathway approaches and guidance as well as the OIE Animal Health Code, to include also the monitoring of AMR situation and the use of antimicrobials in animals, as well as the capability to regulate, control and promote the (prudent) use of veterinary medicines?

GHSA Zoonotic Disease

(GHSA Action Package Prevent-2)

Portugal Level of Capabilities

- There are surveillance, control and eradication plans for several prioritized zoonotic diseases that exist in Portugal i.e. Brucellosis, Tuberculosis, BSE, Salmonellosis, Leptospirosis (only on the Autonomous Region of Azores), Leishmaniosis, Trichinellosis and Echinococcosis hydatidosis.
- There are also active surveillance programmes for rabies and avian influenza which are currently not detected in the country. Rabies vaccination in dogs is compulsory.
- The DGS has the **SINAVE** (Sistema National Vigilancia Epidemiologia) which is a real-time electronic web-based reporting tool that is integrated into and as part of the electronic patient record software used by the National Medical System. This tool is used to monitor 52 Nationally Notifiable Diseases which includes 28 zoonotic diseases.
- Due to the successful implementation of the eradication programmes and other control measures, a reduction can be seen in the prevalence of certain important zoonoses in animals such as brucellosis, salmonellosis and BSE. There has also been a consistent decrease in the number of human cases of brucellosis and a reduction of food-borne outbreaks due to salmonella.
- Portugal has been approved by OIE as a country of negligible risk for BSE.
- The diagnostics for animal diseases and zoonoses in animals is carried out at the National Institute of Agriculture and Veterinary Research (INIAV), which is an accredited laboratory network comprised of four laboratories located in different regions in Portugal (including BSL-3 facilities). Several methods are accredited such as those for brucellosis, tuberculosis and antimicrobial resistance and there is an intention to proceed with the accreditation procedure with some other diseases. INIAV is participating in the proficiency testing at EU level (eg. rabies, avian influenza and AMR).
- Passive monitoring is based on a list of 57 notifiable terrestrial animal diseases (17 Zoonoses). All samples can be sent to INIAV from anywhere in Portugal within less than 24, if needed.
- One Health Approach:
 - There is a partnership between the Ministry of Health and the Ministry of Agriculture and Sea by means of having a representative of the Veterinary Services in the Executive Council implementing the National Health plan. Also the health officials participate in those simulation exercises dealing with zoonotic diseases such as avian influenza.
 - There is informal exchange of information between the health and veterinary officials at all administrational levels (ie. local, regional and national), but there is no legal requirement or official guidelines for reporting disease events in animals to human health services or vice versa.
 - In food-borne outbreaks, the lead of the investigation is in the Health Services, but the veterinary sector participates. Information can be collated into SINAVE, but the veterinary authorities don't have access to it. Samples from humans and products of animal origin are examined at INSA. INIAV and ASAE depending on the origin of the product- carry out examinations in foodstuffs as ordinary control of food chain.
 - Information of animal diseases and certain zoonoses is sent to OIE, the European Food Safety Authority (EFSA) and the European Disease Control Centre (ECDC). There

is no national published report of zoonoses. Data on zoonoses is sent to EFSA/ECDC from DGAV but lacks some national coordination, as for several pathogens no information on human cases could be provided.

- Co-operation between INSA and INIAV was limited for example in sharing and comparing strains of zoonotic agents including foodborne agents.
- There are 220 public health trained veterinarians in Portugal of which 90 PH veterinarians are assigned to the Central (Lisbon) region.
- The curriculum in the Veterinary Colleges in Portugal includes veterinary public health related courses (eg. epidemiology, food safety, by-products, post-mortem inspections, etc). Postgraduate courses in food safety and public health exist which include Masters and doctoral level programs. In addition, there are training courses organized by DGAV and EU Commission on emergency diseases and food safety.

Areas of consideration

- 1. Consider defining "official guidelines" or legal requirements on the notification criteria (eg. list of zoonoses and zoonotic agents) and procedures for communicating zoonotic events between the veterinary and human health officials at different administrational levels, in order to support sustainability
- 2. Consider pursuing cooperative activities to analyze trends of zoonoses (incl. food-borne agents) together with the health, veterinary and food safety authorities and laboratories

Scoring for Portugal Using the Assessment Tool

- Surveillance systems in place for priority zoonotic diseases/pathogens (in animals): Sustainable Capability 4/4
- Veterinarians: Sustainable Capability 4/4

Assessment Tool

- 1. Animal Units should be defined in the assessment tool as there is no international standard available.
- 2. A general glossary would be useful for the tool based on the definitions of WHO and OIE.
- 3. In the Note taking tool there was a question concerning the current animal population. Instead of the animal population, it should ask for the "number of animal units" to be able to calculate the number of public health trained veterinarians per 400 000 animal units.
- 4. It was not clear what is meant by a public health trained veterinarian in the tool in the context of the Zoonosis AP, but a reference was made to "a FETP" or equivalent postgraduate training described in the Workforce development AP.
- 5. There is some overlapping between Workforce development and Zoonosis Action Packages. The Workforce Development AP measures the capacity by a target of "one trained veterinarian per 400 000 animal units who can systematically cooperate to meet relevant IHR and PVS core competencies", but the Zoonoses AP uses the measure " one *public health* trained veterinarian per 400 000 animal units with planning for veterinary continuing education"
- 6. There is nothing on outbreak investigations in the assessment tool: questions should cover outbreak investigation collaboration between human and food safety/veterinary sectors, and the ways/processes how microbiological laboratories support it. Suggest adding in assessment tool a question on a list of outbreak investigations over the most recent two

years, particularly caused by enteric pathogens, the causative agents identified, how the animal or food safety laboratory functions contributed to the investigation, and in how many outbreak investigation an analytic epidemiologic investigation (cohort or case-control investigation) was implemented. This links intimately to the quality and impact of measuring workforce development (Action Package Detect-5).

7. Consider adding one more target with an indicator measuring the cooperation between the health and veterinary officials at different administrational levels in zoonoses events (incl. investigation of food-borne outbreaks) and also assessing the involvement of the health sector in the process of prioritizing the zoonoses of most concern and in analyzing the state of play and trends of zoonoses in the country

GHSA Action Packages Main Document

- 1. Assessment of the analytic capacity and compatibility of different animal and human data systems could be introduced in the tool in some way to confirm the basis for detection of emerging diseases and also reporting
- 2. Some of the actions included in the Zoonotic Disease Action Package of the main document are already addressed in some other Action Packages in the Assessment tool instead of the Zoonosis AP and that is a workable solution. Also, for example the action reinforcing veterinary supervision of the use of antibiotics in animals (and addressing guidelines for prudent use of antibiotics in animals, if not available) could be addressed, but preferably in AMR AP.

GHSA Biosafety and Biosecurity

(GHSA Action Package Prevent-3)

Introduction

Working with pathogens in the laboratory is vital to ensuring that the global community possesses a robust set of tools—such as drugs, diagnostics, and vaccines—to counter the ever evolving threat of infectious diseases.

Research with infectious agents is critical for the development and availability of public health and medical tools that are needed to detect, diagnose, recognize, and respond to outbreaks of infectious disease of both natural and deliberate origin. At the same time, the expansion of infrastructure and resources dedicated to work with infectious agents have raised concerns regarding the need to ensure proper biosafety and biosecurity to protect researchers and the community. Biosecurity is important in order to secure infectious agents against those who would deliberately misuse them to harm people, animals, plants, or the environment.

Portugal Level of Capabilities

- Before assessing Portugal level of capabilities it must be considered that the Portuguese term "Biossegurança" is referred to both biosecurity and biosafety, with major emphasis put on the aspects related to biosafety.
- Locations for especially dangerous pathogens and toxins are consolidated in 3 main laboratories owned by the Instituto Nacional de Saude that fulfill the requirements for BSL-3: one in Lisbon, one in Águas de Moura and one in Porto. Moreover a Military laboratory for Bromatology and biologic defense (namely food safety) is able to conduct core tests identified by IHR.
- A list of dangerous pathogens and toxins manipulated at BSL-3 laboratories can be found in the "Portuguese BSL 3 Facilities: Rules and Guidelines", 1st Edition, edited by the Lab PTBioNet network in January 2015 and includes, among others, *Bacillus anthracis*, Brucella species *Burkholderia mallei* and *pseudo mallei*, *Coxiella burnetii*, *Francisella tularensis*, *Mycobacterium tuberculosis complex* and *Leprae*, Mycobacterium spp. other than M. tuberculosis complex and *M. leprae*, Rickettsiaceae family, *Yersinia pestis*, Retroviruses, including Human and Simian Immunodeficiency Viruses (HIV and SIV), Influenza virus, Severe Acute Respiratory Syndrome Coronavirus. (*Coxiella burnetii* nevertheless, was not listed in the presentation for GHSA at INSA laboratory)
- The country has molecular diagnostic tests in place both at human and animal health level as well as environmental (PCR and real time PCR for example) so it is possible to eliminate the need for culturing especially dangerous pathogens
- As for Physical Security, appropriate security measures are in place and followed in the most important laboratories like those of INSA to minimize potential inappropriate removal or release of biological agents (e.g. theft, earthquake, flood), nevertheless, no assessment has been carried out in the other public or private laboratories throughout the country. It must be noted that the laboratory of INIAV and the Military Laboratory for bromatology collaborate to ensure security measures to be in place.
- The access to sensitive information (e.g. inventory of agents and toxins) is controlled by adequate policies and procedures and the access to pathogens of security concern is restricted to authorized personnel only; procedures for a safe and secure transport of

culture, specimens, samples and other contaminated materials are established in both the manual "Portuguese BSL 3 Facilities: Rules and Guidelines", 1st Edition. Lab PTBioNet. January 2015, and the "Manual de Segurança dos Laboratórios de Segurança Biológica de Nível 3 do Instituto Nacional de Saúde Doutor Ricardo Jorge de Águas de Moura, Lisboa e Porto".

- Biosafety and biosecurity legislation and/or regulations are in place but assessments outside the INSA haven't been carried out. Legislation concerning Biosafety and biosecurity is linked to national and European legislation as for biosafety/biosecurity at workplace and protection against biological agents, but Portugal is developing a specific proposal for the implementation of an inter-ministerial biosafety-biosecurity authority. A list of laws and directives can be found in the annexes and is available at the website: http://www.labptbionet.ibmc.up.pt/node/17.
- Biosafety and biosecurity monitoring activities are not fully implemented, anyway internationally validated checklists are used in some labs to this scope (at least the 13 BS-3 laboratories that belong to Lab Pt Bionet network, coordinated by INSA)
- Until now, no third party has ever assessed biosafety and biosecurity at national laboratory facilities
- There is a lack in terms of laboratory licensing monitoring, especially for the private sector even though a national accreditation system is in place
- There is no specific funding to support biosafety and biosecurity programs/initiatives and their oversight and enforcement at the ministry level. A need of a national authority for the laboratory system as a whole exists
- As for the biosafety and biosecurity risk management practices, they are available only in few laboratories in the contingency plans (in the LabPt network labs) as well as the responsibilities related to biosafety and biosecurity officers and managers are defined in the labs protocols. The absence of information refers mainly to BLS-2 laboratories that come within the scope of universities. Nevertheless, biosafety and biosecurity risks have been assessed during Ebola epidemic simulations and exercises and actions plans have been draft accordingly.
- As for the biosafety and biosecurity training and practices, Portugal has a training program in place and a common curriculum is in preparation in accordance to both INSA and INIAV and will soon be implemented.
- Staff is trained on biosecurity and biosafety procedures every year and workshops are planned throughout the year; moreover staff is tested or exercised every two years, at least at INSA laboratories. Monitoring and assessment of these exercises are carried out by the same institution that proposes them so to put in place correction plans when needed.
- A train the trainer program has not been implemented yet
- Portugal doesn't have yet a sustained academic training in institutions that train those who maintain or work with especially dangerous pathogens
- Training programs are available on the internet at INSA website but it was not possible to assess the biosafety and biosecurity training and practice measures in other laboratories

Scoring for Portugal Using the Assessment Tool

- Whole-of-government biosafety and biosecurity system is in place: **score 2** out of 4.
- Biosafety and biosecurity training and practices: **score 2** out of 4

Areas for consideration

- 1. The establishment of a national authority for the laboratory system as a whole, including both human and animal labs, would help to assure a better management of biosafety and biosecurity issues
- 2. Channels to facilitate a more comprehensive communication between human and animal laboratories could be useful to solve some specific issues involving both types of laboratories, part of this issue is addressed through the LabPt network activities.
- 3. Establish an adequate and sufficiently strong national mechanism to support biosafety and biosecurity programs and initiatives

Assessment Tool

- A separation between biosafety and biosecurity should be considered: these packages should be considered separately in order to allow a proper evaluation and a score definition
- Some indicators seem to be to some extent repetitive or redundant
- The indicator: "Is there a mechanism for biosecurity oversight of dual use research and responsible code of conduct for scientists?" should not be addressed to the laboratory chief

GHSA Action Packages Main Document

- A separation between biosafety and biosecurity should be considered: these packages should be considered separately in order to allow a proper evaluation and an appropriate score definition.
- There should be more biosafety and biosecurity questions addressed to agricultural, veterinary, food safety, research and clinical laboratories.

GHSA Immunization

(GHSA Action Package Prevent-4)

Introduction

Immunization is one of the most successful global health interventions and one of the most costeffective ways to save lives and prevent disease. Immunizations prevent greater than two-million deaths a year globally.

Portugal Level of Capabilities

- The country started a national immunization activity at the 18th century, but an integrated nationwide program began in 1965. The National immunization programme (NIP) is operated by the Directorate General of Health (DGS) in collaboration with the following organizations:
 - ARS (Administração Regional de Saúde): Regional administration in charge of vaccine distribution and vaccination
 - INFARMED (Autoridade Nacional do Medicamento e Produtos de Saúde): Marketing authorization, vaccine regulation, lot release and pharmacovigilance
 - SPMS (Serviços Partilhados do Ministério da Saúde): Procurement and information system
 - CTV (Vaccine Technical Committee): National immunization technical advisory group, i.e. a Group of experts/consultants of DGS
 - Industry: Supplier
- As of April 2015, the Portuguese immunization programme includes 12 vaccines/diseases (i.e. TB, HepB, Hib, DTP, IPV, MenC, MMR, and HPV), and PCV for children is going to be introduced in the prgramme soon
- In the country, NIP vaccines are provided to all people who live in the country at free of charge, utilizing hospitals and local health centers, which are located in every municipality.
- Vaccine-preventable diseases dramatically decreased in the country (98.5% decrease of pertussis, poliomyelitis, tetanus and diphtheria cases when comparing the data between 1956-65 and 2003-2012) as a result of population immunity, which was achieved by a high vaccination rate.
- The country's goals of the NIP are to provide vaccination for all people who live in the country including immigrants, and to achieve the coverage level of over 95% of NIP vaccines for children (except for HPV vaccines, of which the target is over 85% of adolescent girls). Two-dose MMR vaccination coverage of children has exceeded 95% for more than 5 years.
- Since 2000, information system has been used for registering individual vaccination records by local vaccination teams at every health center/unit, and data is stored in an electronic database. A new electronic immunization registry is going to be implemented soon.
 Vaccination coverage was calculated from national immunization registry, and defined as the proportion of vaccine recipients in a birth cohort among all children of the cohort registered in local health services. The coverage is estimated twice a year at the regional level, and sent to the central.
- The last vaccination campaign conducted in the country was HPV catch-up in 2009–2011 for adolescent girls. The DGS has conducted several "micro-campaigns" for rural or particular regions to reach the marginalized population.

- The country procures NIP vaccines at the national level, and pharmacy departments of the regional health administration (ARS) ensure local distribution of vaccines to all health centers/vaccination services. The cold chain is secured by each private distribution companies following their own delivery international standards.
- Influenza vaccination in the country is targeted for the elderly and at-risk populations. Adults aged 65 years or older can receive flu vaccines at local health centers (free of charge) or pharmacies (out-of-pocket expense). The flu vaccination coverage is estimated from a telephone survey, because vaccines consumed at pharmacies are not registered to the national immunization registry.
- There is legislation that requires the notification of adverse events following immunization (AEFI). AEFIs are monitored by pharmacovigilance surveillance of INFARMED without vaccine injury compensation system, and severe cases are dealt by ad-hoc meetings between the INFARMED and the DGS.

Scoring for Portugal Using the Assessment Tool

- Vaccine coverage (measles): Sustainable Capability (score 4 out of 4)
- National vaccine access: Sustainable Capability (score 4 out of 4)

Areas for consideration

- During the assessment, it remained uncertain how cold chain was monitored and assured at the national, regional and local level respectively, and how it would be integrated. Guidelines and protocols to ensure cold chain at the national level would help guarantee the good quality of distributed vaccines.
 - **NOTE:** In post-assessment draft report review, the Portuguese authorities gave the following information:
 - There are specific strong guidelines for cold-chain monitoring and assurance. Distribution to each local unit is ensured by delivery company. Coldchain at each local health unit is based on specific guidance and SOP that are mandatory. It includes twice a day check of the cold chain and reporting to local vaccination team coordinator. In case irregularities are detected (lack of energy or any other) report is mandatory on measures being taken
- Timely and comprehensive AEFI investigation in a regular joint committee including DGS and INFARMED would support keeping public confidence in vaccines.

Assessment Tool

- Portugal & assessment team comments:
 - One-dose measles-containing vaccine (MCV) is not enough to secure population from measles. Achievement of over 95% coverage of 2-dose MCV could be targeted aligning with global standard, and modifying the capacity levels with stratification of scores by number of dose and its coverage rate should be reasonable.
 - Current indicators for assessing capacity on immunization seems to be inadequate for ensuring national health security. For example, training programs for healthcare personnel and risk communication strategies with public regarding immunization would be important in countries where already reached a considerably high level. Targets and indicators should be reviewed thoroughly according to well-defined objectives.
- Portugal comments:

- Logically, countries with capacity level 0 may not include any plan to improve coverage, such as supplemental immunization activities.
- Significance of animal vaccination (e.g., rabies) could be in consideration.

GHSA Action Packages Main Document

- If the purpose of GHSA is to *spur* progress toward full implementation of the WHO IHR and OIE PVS pathway, it would be efficient to extract one or two core indicators from well-established global guidelines or initiatives, such as the *Global Vaccine Action Plan*. Of course, those indicators should be scalable, and align with the purpose of the agenda. Communication with the respective advisory groups in each area and identification of the worst gap that should be filled by making a concerted effort would be beneficial (e.g., SAGE for immunization). Current indicators don't reflect existing global objectives optimally.
- During the mission in Portugal, indicators and a long list of additional "Measures" in each action package were proved to be very good chance for the country to review its own health security level and also to find weak points in a comprehensive way. Yet, the benefit needs to be compared with the workload to collect and generate those data to fill all the blanks, especially in limited-resource countries. In this context, it seems to be necessary to modify some measures.

GHSA National Laboratory System

(GHSA Action Package Detect-1)

Introduction

Public health laboratories provide essential services including disease and outbreak detection, emergency response, environmental monitoring, and disease surveillance. State and local public health laboratories can serve as a focal point for a national system, through their core functions for human, veterinary and food safety including disease prevention, control, and surveillance; integrated data management; reference and specialized testing; laboratory oversight; emergency response; public health research; training and education; and partnerships and communication.

Portugal Level of Capabilities

- The country has the capacity to test for all 52 diseases that are included in the EU level human disease surveillance and also the zoonotic diseases which are specified under EU level food safety regulations.
- Approximately 130 primary microbiological laboratories that perform tests exist in the country. These are categorized into primary diagnostic laboratories (private and public; hospital and local) and reference laboratories (located on the national level).
- Hospital and clinical microbiological laboratories have generally accredited their methods; point of care tests are used for applicable diseases
- National reference laboratories for human infections are situated in three geographical locations at the National Institute of Health Doctor Ricardo Jorge (INSA) reporting to the Directorate General of Health (DGS) and for veterinary infections in the National Institute of Agriculture and Veterinary Research (INIAV) reporting to the National Directorate-General of Food and Veterinary Issues (DGAV). Both institutions perform testing on a number of zoonotic pathogens, and have accredited part of the methods they perform (ISO 15189).
- INSA reference laboratory functions are mainly intended for surveillance purposes and diagnostic testing for clinical purposes is not performed. They are organized under the following groups:
 - Gastrointestinal Infections
 - Respiratory Infections
 - Parasitic and Fungal Infections
 - STIs
 - Antimicrobial Resistance
 - Vaccination Preventable Infections
 - Vector-Borne infections
 - INSA reference laboratories perform AMR testing for a number of drugs and microbes.
 - The specimen referral networks are documented for each of the tests necessary to detect and confirm etiologies of priority diseases.
 - Standardized SOPs are in place for specimen collection, packaging, and transport. (North Labs to INSA –Porto and South Labs to INSA Lisbon).
 - The specimen transport, eg, courier contracts supported by partners or INSA.
 - Methodologies at National Reference Laboratories are accredited or in process by ISO 15189 (INSA).

- Guidelines and protocols for quality management system are enforced and in use by public human Health National Reference Laboratories.
- MoH/MoA have in-country production and/or procurement processes for acquiring necessary media and reagents for performance of core laboratory tests.
- INIAV reference laboratories perform diagnostics and reference level microbiological tests on animal diseases, including zoonotic diseases.
- A separate authority, the ASAE (operating under the Ministry of Economic Affairs)) performs official controls of the Food Chain and collect and analyses food products samples to identify health hazards including microbial contamination and has the power to intervene and take legal action if contaminated products are discovered.
 - ASAE has 120 tests accredited by ISO 17025
- Under the Ministry of Defense a separate laboratory for Biodefence detection exists (Portuguese Army Biological Defense Laboratory), which has capabilities for detecting a limited number of relevant pathogens in environmental samples.

Scoring for Portugal Using the Assessment Tool

- Laboratory testing capacity for 10 core tests for detection of 10 priority diseases: Sustainable capability (score 4 out of 4)
- Specimen referral and transport: Sustainable capability (score 4 out of 4)
- Effective modern point of care and laboratory based diagnostics: Sustainable capability (score 4 out of 4)

Areas for consideration

- During the mission, it remained unclear to what extent reference level data on zoonotic infections (typing and strain data) collected through the inspection, animal health and human health diagnostic and surveillance systems was routinely and systematically compared.
- Veterinary services are in charge of food and waterborne outbreak evaluations and information seemed to be formally transferred only through the chain of command upwards to the level of the respective human and veterinary/food sector safety Directorates where possibilities for recognition of regional and local potential outbreaks may be limited
- More active and systematic cooperation on local public health and veterinary level in the formation of joint outbreak investigation teams would benefit outbreak control in especially food and waterborne outbreaks
- While the INSA laboratories are examining human and food/environmental samples in cases where a suspicion of an outbreak has been recognized, it remained unclear if there exists a routinely operating mechanisms for recognition of a dispersed, low-level outbreak by direct comparison of typing/genetic data collected from zoonotic infections in humans, animals and foodstuffs among the various laboratories operating at INSA, INIAV and ASAE
- Data from laboratories (primary and reference level) are not currently routinely notified to the SINAVE system for linkage to cases, even if this could provide a cost-effective and rapid basic surveillance tool if electronically implemented

Assessment Tool

- There should be separate, specific series of relevant questions for human and veterinary/food safety sector laboratories, respectively.
- There should be more specific and separate focus on tests from the animal and food safety sector for public health purposes. The 10 core tests list in the footnote of the GHSA Action Packages main document for Detect-1 does not necessarily reflect the needs in middle income and high-income countries.
- The question on '10 priority diseases' is ambiguous: there should be a request for a more specific lists on microbes of any public health importance for which standard microbiologic diagnostics are available, at what level, list of microbe strains/isolates systematically referred to central reference laboratory, as well as the number of referred isolates for a recent year.
- Some of the 'Measures' in the tool contain anticipation of future events/developments: this should be deleted and assessment applied only on currently existing documents, systems and facts.

GHSA Action Packages Main Document

• The assessment tool would benefit from containing contain material from OIE/PVS-related assessment methodologies particularly in regard to animal and food safety laboratory functions.

GHSA Real-Time Surveillance

(GHSA Action Package Detect-2/3)

Introduction

The purpose of real-time surveillance to advance the safety, security, and resilience of the Nation by leading an integrated biosurveillance effort that facilitates early warning and situational awareness of biological events.

Portugal Level of Capabilities

Portugal has the following surveillance system capabilities that are used for multiple activities for public health and disease awareness and reporting purposes:

- Saude 24 (Health 24) -- is a public citizen national call center phone line that allows triage, counseling, and public health evaluation of individuals that have health events (acute and chronic) of personal concern. The Saude 24 has 118 algorithms for clinical evaluation purposes that are followed of which approximately 40 are infectious disease related. These are set up in syndromic-like fashion. This system has the potential to provide early detection and surveillance of important health events.
- **The UESP** (Public Health Emergency Unit) utilizes MEDISYS and other tools, i.e. ProMed etc. to screen media and other official and non-official sources of information for early detection, validation, information sharing and to develop risk assessments and monitor health event occurrences locally, regionally, nationally and internationally.
- Influenza Sentinel surveillance system contains 100 sentinel sites based on the WHO model. Uses 2 arms: Clinical diagnostic component (ILI definition) and a Laboratory component (Nasal pharyngeal swabs) where 2 swabs are sent to the lab each week. Further severe acute respiratory infection monitoring occurs at 29 sites.
- **SINAVE (Sistema National Vigilancia Epidemiologia)** –**SINAVE** is a real-time electronic web-based reporting tool that is integrated into and as part of the electronic patient record software used by the National Medical System by all clinicians at local, 5 regional and 2 Archipelago health centers and by national level health providers. It is used to monitor Nationally Notifiable Disease and the data is used to develop reports based on those identified cases and outbreak events.
- **SICO (Sistema de Informaticao de Obito)** a real-time electronic mortality registry system used by all physicians who register deaths and causes of death.
- National Authority of Civil Protection Event Tracking Tool a powerful real-time event tracking tool that tracks emergent events as they are reported in real time, followed, responded to and are resolved with outcome reports by all participating agencies to include health and mortality events.
- Director General of Food and Veterinary (DGAV) conducts zoonosis surveillance in animals using both passive and active notification systems. The passive system is based on syndrome detection and suspicions investigation (e.g. West Nile virus and rabies), and active surveillance uses sampling in slaughterhouses (e.g., trichinellosis and echinococcosis-hidatidosis) and on farms (e.g., brucellosis, tuberculosis). Some diseases are subjected to both types of surveillance (e.g., BSE and avian influenza). In some outbreak situations, zoonoses are detected through the reporting of human cases to the veterinary services.

Scoring for Portugal Using the Assessment Tool

- Syndromic surveillance systems: Demonstrated Capability (3 of 4)
- Inter-operable, interconnected, electronic real-time reporting system: **Demonstrated Capability** (3 of 4)

Areas for Consideration

- **Saude 24 (Health 24)** with its syndromic-like algorithms has the potential to provide early detection and surveillance of important health events as reported by the public.
- The National Authority of Civil Protection Event Tracking Tool is an unrecognized and unused resource for health surveillance and potentially could be utilized to address important public health questions about acute and chronic health problems. Even though in most cases infectious diseases are not reported within the system, algorithms could be developed where certain events, variables and factors may identify key infectious disease events, acute and chronic health and mortality associations, as well as follow outcomes associated with outbreaks.
- Portugal has a great vision and is off to a great start with the SINAVE. Future plans should include determining how best to link their surveillance tools across the public health sector to include diagnostic/laboratory, pharmacy, and particularly with and between the human and veterinary/animal sectors. This will improve communication between key government agencies.
- Portugal emphasizes that there is a need to clear define the chain of command in emergency situations, which can be adjusted according to the type of event
- An additional consideration should include incorporating a clear syndromic disease diagnostic/reporting within the SINAVE system. Adding syndromic elements into the system will make it a more sensitive system.

Assessment Tool

- The core disease syndromes are defined in the GHSA: Action Package Main Document, but needs to be added to the tool.
- The terms "real-time", "syndromic", and "event-based" surveillance systems need to be defined as to the expected qualities and attributes of the systems.

GHSA Action Packages Main Document

- Similarly for the Main Document, the terms "real-time", "syndromic", and "event-based" surveillance systems need to be defined as to the expected qualities and attributes of the systems.
- Portugal highlights that there should be established a link between GHSA, the BTWC and the resolution 1540, as the response to emergency may have to be international and include security issues

GHSA Reporting

(GHSA Action Package Detect-4)

Introduction

Health threats at the human–animal–ecosystem interface have increased over the past decades, as pathogens continue to evolve and adapt to new hosts and environments, imposing a burden on human and animal health systems. Collaborative multidisciplinary reporting on the health of humans, animals, and ecosystems reduces the risk of diseases at the interfaces between them.

Portugal's Level of Capabilities

- The National IHR Focal Point (NFP) has been set up within the Ministry of Health and assigned under the Director General of Health. Then NFP consists of a team of 4 persons including 24/7 arrangements and a generic email address.
- Simulation exercises are conducted for specific events (i.e., Ebola) which test reporting capability of national, regional and local public health authorities.
- Recent outbreaks have tested and exercised the reporting function of the country:
 - o Dengue outbreak on Madeira island (2012)
 - o Legionella outbreak (2014)
- The role of the Director-General as National Health Authority seems to be an opportunity for the country to set standards and to be able to intervene and respond with a top-down approach. As the Chief Medical Officer he can mobilize material and human resources (e.g., exports/consultants from outsourcing, create task forces, etc). Under his supervision and coordination, Portugal has a network of regional and local public health authorities. This network facilitates the exchange of information, alerts and coordination of response for any public health event of importance to the national and international level.
- Overall the surveillance and reporting systems used by different sectors are not yet linked. This is well recognized and methods are being considered to integrate information tools and sources. Some systems do exist where some linking has been demonstrated (e.g., linking ports and airports to public health authorities as a single-window concept for ports, and a line of communication established between the airport and the local public health authority).
- Portugal has legal regulations and laws that define the health authorities and expected competences in relation to the IHR. Additionally, laws exist and support the development and functioning of the http://www.sg.min-saude.pt/NR/rdonlyres/6BCFA75A-508B-4CFF-B3BB-726FF2CFC244/36829/0601206018.pdf national surveillance and reporting system as well as establishing a national committee for emergencies. http://www.portaldasaude.pt/NR/rdonlyres/3658FAF1-356B-4D97-868E-013175EB177C/0/0549105495.pdf
- DGAV is the focal point for reporting to OIE-WAHIS in Portugal. The six-monthly reports have been sent to OIE regularly. There was evidence also of emergency reporting to OIE of a few diseases in the past with minor delays, but not necessarily of immediate public health importance.

Areas for consideration

• Expand and broaden the number of national stakeholders for the IHR. Ideas and examples of this include establishing a multi-sectoral committee or working group. This could increase the whole-of-government ownership for the IHR and their daily use as all-hazard framework for surveillance and response.

• Because of the hierarchal and "stove-pipe" structures of the government offices it is difficult to include similar offices at all levels. Thus, it is keenly important to be transparent and work at developing defined roles and relationships at the lowest levels to share information and consolidate reports.

Scoring for Portugal using the Assessment Tool

- System for efficient reporting to WHO, FAO and OIE -- Demonstrated Capability (3 of 4)
- Reporting network and protocols in country -- **Demonstrated Capability** (3 of 4)

Assessment Tool

- In relation to the "IHR Focal Point", all the Measure questions that use this terminology should be written in the singular form. The WHO is clear that the focal point should reside solely under the Ministry of Health either as an individual or as a recognized team or office. Therefore it is one entity and not a number of different entities. This will bring terminology in line with the IHR that countries are already familiar with.
- If it is desired to learn about the roles of other Ministries may be involved as "supporting" focal points, then those questions should be reworded to and described not as "other focal points" but as supporting or subordinate focal points that report to the IHR or National Focal Point. This will eliminate confusion between focal points.

GHSA Action Packages Main Document

- In the "As Measured by" and "Desired Impact" sections, these need to be reworded because under the IHR the country only has one (1) IHR Focal Point, thus measuring the number of focal points is inaccurate. See Assessment Tool comments above. A suggested change would be "...(and/or) the number of nations connected to the learning package on reporting to WHO using the IHR focal point."
- It was not clear how reporting to OIE should be addressed here. In the Main document there is reference to even OIE listed diseases, but the tool focuses on the PHEIC events. Not all OIE listed diseases are PHEIC events. However, it would be useful to examine the reporting of "OIE listed zoonoses of public health importance" in this context independently from reporting to WHO as the focal points and processes are usually different.

GHSA Workforce Development

(GHSA Action Package Detect-5)

Introduction

Workforce development is important in order to develop a sustainable public health system over time by developing and maintaining the highly qualified public health workforce with appropriate technical training, scientific skill, and subject-matter expertise.

Portugal's Level of Capabilities

- Specialization in Public Health (PH) is available for medical doctors and nurses, which does
 include some general epidemiology training. Post-graduate training courses ("advanced
 studies in epidemiology") exist, but there are no separate programs available for
 epidemiology.
- Field Epidemiology Training Programs (FETP) trainings are included during the PH Residency program for MDs where one year out of the 4 year program is devoted to field epidemiology training.
- An additional program is run by the EU, i.e. the 2-years EPIET training, which is open also to other professional fields than the medical sector; The trainees do on-the-job training in another EU country, but most of alumni's return to the country.
- The curriculum in the Veterinary Colleges in Portugal includes veterinary public healthrelated courses (e.g., epidemiology, food safety, post-mortem inspections, etc.). There are training courses organized by DGAV of emergency diseases and field investigations. Graduate-level courses in food safety and public health exist which include Masters and doctoral level programs.
- Epidemiological training for professionals on the local level can be done on-the-job, but not systematically, since there is no national program, no strong incentives and no human-resource strategy for it.
- Field epidemiological expertise is mainly available on the national level, and only to some extent on the regional and local level. Harmonization and standardization of interventions seems to be a challenge.
- Data management and administration is done on all administrative level. At the local level, data is mainly collected manually.

Areas for consideration

• Given the fact that Portugal is a centralized country, a national human resource strategy for epidemiological expertise could strengthen the country's capability to detect and respond to public health threats.

Scoring for Portugal using the Assessment Tool

- Trained field epidemiologists Human **Demonstrated Capability** (3 of 4)
- Field Epidemiology Training program or other applied epidemiology training program in place **Demonstrated Capability** (3 of 4)
- Workforce strategy **Developed Capacity** (2 of 4)

Assessment Tool

- There is some overlapping between Workforce development and Zoonosis Action Packages. The Workforce Development AP measures the capacity by a target of "one trained veterinarian per 400 000 animal units who can systematically cooperate to meet relevant IHR and PVS core competencies", but the Zoonoses AP uses the measure "one public health trained veterinarian per 400 000 animal units with planning for veterinary continuing education".
- The "Target" and "As Measured by" sections focus on multiple professional areas included in public health to include human and animal professions, yet the Capability Metrics appear to be written to only the Human sector and do not include the animal and veterinary professions. This is inconsistent with each other.
- The term Field Epidemiology Training Programs (FETP) trainings is unclear as to the expected type or level of training and what must be included to be "basic", "intermediate" or "advanced" FETP trained.

GHSA Action Packages Main Document

- The main document draws in the One Health concept including and considering the animal and veterinary professional sector with the human sector. This is inconsistent with the capability metrics/measures in the tool. The tool ought to be brought into line with the Main Document to be consistent to include the Animal Sector.
- The tool focuses on the training of professionals, but in the Main Document also strengthening the international, regional and national networks in sharing of scientific data and best practices and other co-operation with international entities is addressed.

GHSA Emergency Operations Centers

(GHSA Action Package Respond-1)

Introduction

A public health emergency operations centers (EOC) is a central location for coordinating operational information and resources for strategic management of public health emergencies and events. EOCs provide communication and information tools and services and a management system during a response to an emergency or event. They also provide other essential functions to support decision-making and implementation, coordination, and collaboration.

Portugal Level of Capabilities

The assessment team was able to visit two Emergency Operations Centres that could or would be involved in the management of public health emergencies. Both would interact with the ambulance emergency services (INEM), to coordinate response operations.

A **public health Emergency Operations Centre (HEOC)** was set up in 2005 under the authority of the National Public Health Officer and Public Health Emergencies Unit (UESP) under the DGS. The HEOC is a separate entity which functions independently but in a coordinated fashion with the Civil Protection EOC. The HEOC has roles in Early detection; Epidemic intelligence/event-based surveillance; Rapid communications; Risk Assessment; International collaboration (houses focal points for EWRS, IHR and EU HS Committee); and, DGS Website and social networks. In response its involvement is largely strategic rather than operational.

The HEOC is set up around a small but flexible office and meeting room area, and is equipped with relevant ICT equipment, as well as standby power systems.

The six core staff within the emergency team is trained on the job on HEOC processes however no specific training is undertaken on incident management systems. Staff can be drawn from other departments to support the emergency team as necessary; an all-hazard approach is implemented to fill specific technical needs. During public health emergencies, a national Task Force is established within the EOC at the central level, and in some circumstances this is replicated at the local level to lead operations. Public Health Officers at the municipal level supplement the work of the EOC and local teams can be strengthened with national or regional staff as necessary (e.g. Dengue 2012).

The HEOC is connected to the SINAVE real-time surveillance systems, and the hotline for medical professionals (3 people minimum on roster). The HEOC operates an SMS service –to announce new guidance or public health measures. The HEOC has been evaluated by ECDC (2010 and 2014), and has taken part in a number of exercises organized by the Civil Protection EOC. The evaluatein were in 2010 – ECDC country visit; October/November 2014 - national exercise Melliandou - EOC and its functions related to Ebola were evaluated by ECDC experts. In the last years HEOC participated in several exercises organized by several institutions, including by the Civil Protection EOC. HEOC also organized national exercises in public health issues.

The **Civil Protection Emergency Operations Centre (EOC)** is professional and dedicated service run as a permanent 24/7 unit to ensure the operational command of relief operations and the integrated operational command of all fire brigades, under the Integrated Protection and Relief Operations System. The National Relief Operations Command (CNOS) is the operational structure of the National Civil Protection Authority (ANPC).

Events managed by the EOC structure range from minor accidents to national disasters. A phased system for scaling up response from the local to the central level is in place. Operational framework of a single command independent of chain of command in other authorities. Command role of the EOC will always be firefighters or civil protection, other functions or tasks are embedded within an established Coordination mechanism.

The national EOC is highly equipped with ICT, transport (including ambulances and a mobile EOC) and operated a system for scale-up equipment through the armed forces. Subnational EOCs exist in all 18 districts (and are linked to municipal commissions). Civil protection municipal, district and national commissions exist and multisectoral coordination structures are in place at all levels, with public health focal points in all 18 districts. Weekly coordination meetings take place at the National level, and are subsequently held at the district levels.

Terms of Reference have been detailed for each function of the EOC and these are applied across levels i.e. at the national and the district level EOCs. This includes roles and responsibilities for CBRN incidents. Internal and external education dedicated to the roles they play in EOC. Two courses specific to Telecommunications Operators Course and Command Post Course. There have also been language courses provided to EOC functions.

The EOC was recently involved the LIVEX (ORDOP03 / CNOS / 2014) exercise on Bioterrorism involving the following entities: National Civil Protection Authority (CNOS and CDOS Lisbon); National Guard; National Institute of Medical Emergency; Health General Directorate; PJ; National Institute of Health Dr. Ricardo Jorge, IP (INSA, IP); Loures Fire Department. Following the LIVEX, a report compiled by all entities involved in the exercise set out lessons learned and aspects to improve for a more efficient response. Functional or tabletop exercises take place at least once a year at national level, more at the district level. The last national TTX was conducted in 2014 – Functions of Coordination Structure and Networks available for communications.

There is an organized, regular and sustained coordination between the two EOC structures on a routine (sharing of weekly bulletins and participation in joint meetings) and emergency (e.g. the 2013 heat wave when both EOCs were activated and communicated daily) basis. In the context of EVD and under the EU Civil Protection Mechanism, the civil protection EOC has been appointed to participate in EU meetings, and participates in close cooperation with the HEOC. Taken together, these two national systems and EOC structures are complementary in their objectives, skills and competences.

Scoring for Portugal Using the Assessment Tool

The two structures are independent and have therefore been scored separately. However the team notes that the two systems present complementary capabilities and competences that are effectively coordinated. As such, Portugal's two EOC provide a sustainable capacity if assessed as a single multisectoral system.

• Status of EOC (space):

- o **EOC** = Sustainable Capability 4,
- **HEOC** = Demonstrated Capability 4
- Status of EOC (staff):
 - **EOC** = Sustainable Capability 4,
 - **HEOC**= Demonstrated Capability 3
- Emergency Operations Program:
 - **EOC** = Sustainable Capability 4,
 - **HEOC**= Sustainable Capability 4

Areas for consideration

- In the HEOC, procedures and roles and responsibilities are provided to Task Force staff but these are ad hoc and not codified or formalized into generic terms of reference for event management.
- The integration between EOC and HEOC is very good but can be implemented through formal operational protocols that provides specific roles in case of emergency
- It could be useful to formalize the identification in case of emergency of the spaces for the EOC district level

Assessment Tool

- Portugal comments:
 - Measure of space: The term "connectivity" is not clear it means electronic? Or that links/networks exists?
 - Measure of training in emergency operations: Not necessarily needed in public health. The training could be in managing tools and equipment, communication, training coordination skills, etc.
- Assessment team comments:
 - EOC measures focused significantly on infrastructure rather than systems. The tool should place a higher emphasis on scale-up procedures, on surge capacity, and on the linkages between strategic and operational decision making.
 - o RRTs may not be applicable to all assessed countries

GHSA Action Packages Main Document

• WHO's ERF document (an internal WHO procedure) is not an appropriate tool for EOC standards. The document should refer instead to WHO's EOC-NET's specific tools for EOCs.

GHSA Linking Public Health with Law and Multisectoral Rapid Response

(GHSA Action Package Respond-2)

Introduction

Public health emergencies pose special challenges for law enforcement, whether the threat is manmade (e.g., the anthrax terrorist attacks) or naturally occurring (e.g., flu pandemics). In a public health emergency, law enforcement will need to quickly coordinate its response with public health and medical officials.

Portugal Level of Capabilities

There are a number of legal instruments regulating the relations of public health and law enforcement entities at the national level. In addition to a legal framework for cooperation, National Operational Guidelines (October 2010) for CBRN events (independent of whether they are natural, accidental or intentional) provide the operational framework for intersectoral collaboration at the national and local levels. Involved authorities include the Ministry of Interior, the Ministry of Health, the Ministry of Defense, the Ministry of Agriculture and Sea, the Ministry of Economy, the Ministry of Environment, Spatial Planning and Energy, the Ministry of Justice (Interpol) as well as the Intelligence Services. The Ministry of Foreign Affairs is involved in international events or if the perpetrator is a foreign citizen.

Under the National Guidelines, the ANPC (National Civil Protection Authority) is responsible for the overall coordination of a CBRN response and assumes the command role. Under the Civil Protection EOC structure, the Ministry of Health, the Ministry of Environment, and the Ministry of Agriculture and Sea DGAV - Directorate General of Food and Veterinary are all involved to address health related issues. As a technical body, the Ministry of Health is involved in triage and transport of patients through INEM, in laboratory testing through INSA, and in epidemiological investigation and outbreak control measures (DGS). In the animal health field, DGAV conducts epidemiological investigation and control of outbreaks. The criminal investigation of intentional incidents in the food chain trade are managed through a formal criminal procedure under through ASAE.

The implementation of the Guidelines occurs through standard protocols defined by each relevant authority, and legislation requires the notification of relevant information (such as deliberate intent) to relevant authorities. Contact points across sectors are maintained and updated for this purpose.

The CBRN Directives are due to be reviewed and updated to improve its procedures, accommodate new changes within government structures, and to incorporate recommendations for exercises. The revision will also address the obligations set out in the EU Decision 1082/2013/EU on serious cross-border threats to health.¹

Health and law enforcement authorities have collaborated in the following recent public health events:

¹ http://ec.europa.eu/health/preparedness response/docs/decision serious crossborder threats 22102013 en.pdf

- Heat wave, 2013 both common messaging adopted by health and civil protection authorities;
- Legionella outbreak, 2014 involved the implementation of the chain of command;
- Ebola Virus Disease (EVD) preparedness, 2014-2015 development of EVD plans and procedures with civil protection, armed forces, Ministry of Environment and Ministry of Foreign Affairs.

There has been a number of joint law enforcement and public health training and exercises on CBRN. In the biological field:

- Training took place at the EU level with the participation of Portuguese experts from both health and law enforcement in 2008.
- Participation of a mobile sampling team to the Exercise and Training for the UNSGM's investigation of alleged use of biological weapons in Berlin in November 2014.
- Exercise PREVENT EBOLA 2014 Certification of patient transport capacity in biological containment cell using the C-130 or C-295 aircraft. This ability now created in the military, is a complementary to existing capacity in the National Health Service and is intended primarily to transport and evacuation to the country, national military in operations abroad.
- Other military exercises and training on CBRN.

At a national level, the Interpol national focal point is located within the Ministry of Justice, with the Judiciary (criminal) Police as a competent authority in the conduct of criminal investigations. If the Ministry of Health had to provide or request information from Interpol, it would do so through the Interpol national focal point.

Other relevant information:

- A Strategic medical stockpile exists for natural disasters, deliberate events and flu pandemics. The stockpile is under the control of the Public Health authority, and can only be released by INEM or DGS with an associated distribution plan. There is no clear link to law enforcement in terms of releasing the stockpile during a deliberate event.
- Law Enforcement authorities have access to the MOH mortality survey data.

Scoring for Portugal Using the Assessment Tool

• Public Health and Law Enforcement are linked during a suspect or confirmed biological event: **Sustainable Capability**, **4**

Areas for consideration

- In the revision of the national CBRN guidelines, further consideration may be given to the Ministry of Health's leading role in coordinating the public health response;
- In order to facilitate the mandate of the public health response to a possible deliberate event without undue impact on the forensic investigation, public health officials could receive appropriate training on implementing chain of custody mechanisms where necessary during outbreak investigations.

Assessment Tool

- This tool could provide further detail on the role of epidemiological investigations in identifying deliberate events.
- In addition it should seek to encourage the lead of public health authorities in managing events that have ongoing health implications.
- As previous pilot assessments have noted, an MOU is too rigid a measure and does not reflect the reality in a number of countries assessed.
- The terminology of Public Health and Law Enforcement are linked "during a suspect or confirmed biological event" is confusing. Does "suspect/confirmed" relate to a possible biological event? or to a "suspect/confirmed" case of disease?
- Portugal raised the question of the lack of a stronger connection with international legal instruments which should be included, at least the BTWC. This added item should be included in the future in the tool

GHSA Action Packages Main Document

• See comments above.

GHSA Medical Countermeasures and Personnel Deployment (GHSA Action Package Respond-3)

Introduction

Medical Countermeasures (MCM) are vital to national security and protect nations from potentially catastrophic infectious disease threats. Investments in the MCM create opportunities to improve overall public health. In addition, it is important to have trained personnel would can deploy in case of a public health emergency for response.

Portugal Level of Capabilities

- Portugal has well developed and exercised structures, staff, stockpiles of key medications, medicinals and materials to respond to major public health emergencies. No area of weakness in plans and probable capability could be identified by the visiting team.
- The systems observed appeared capable of urgent mobilisation and deployment to of public health and other appropriate personnel and resources to mitigate massive public health emergencies
- Portugal has several EOCs in different sectors of Portugal. Relevant to the GHSA are two principal Emergency Operation Centres (EOC), one in the Department of Health with competence in Health and the other the National EOC within the National Civil Protection Authority (ANPC).
- The Health EOC and National Civil Protection Authority EOC systems exhibit the capacity for integrated working and division appropriate division of responsibilities.
- Practical demonstration of this capacity at the Health EOC UESP was demonstrated within the last year in the prompt detection, investigation and protection of public health in a substantial outbreak of Legionnaire's Disease; and in responses to possible imported cases of Ebola (none confirmed). These events showed the ability of the health system to identify promptly severe infection posing risk to the population, assess it, and mobilise resources including staff with expertise in epidemiology, public health, human and environmental microbiology, clinicians in hospital.
- A key concept in Portuguese national resilience is the ability to set up an EOC at any location within any national jurisdiction including non-continental Portuguese territories and to ensure that EOCs at any site are fully operational and integrated into the hierarchy of command and control and response networks (at any public health unit, at local and regional level). Capacity to replace key staff is also assured.
- Substantial capacity in communications and secure communication was demonstrated across the National Civil protection Authority and Health system with appropriate consideration given to resilience in the event of loss of normal civilian communications including the internet and cellular phone networks, and failure of civilian electrical supply. It is probably that this sustained capacity would permit deployment of Public health and medical Personnel effectively end in the circumstance of massive disruption to infrastructure.
- Within the remit of this enquiry and national confidentiality, the visitors were assured of adequate consideration of stock piles and management of stockpiles of key biodefense antibiotics, medicinals antidotes and protective equipment. Communications with public health and other professional responsible for storage and deployment of these had clearly

been considered. It was not possible within the remit of its review to check logistic exercise of personnel and material deployment.

- The breadth and scope of EOC capacity for wider emergencies both natural and potential or proven deliberate release, was demonstrated at the National Civil Protection Authority EOC centre.
- The emergency services of the Fire and recuse and engineering response were also addresses with inventories of available key equipment identified as asset for requisitioning by government ids required such as large machinery such as cranes and excavators.
- Portugal has deployed health professionals to multilateral international missions using the ECDC/GOARN systems and on bilateral missions (Guinea-Bissau and other countries upon request)

Scoring for Portugal Using the Assessment Tool

- System is in place for sending and receiving medical countermeasures during a public health emergency: Score 4 out of 4
- System is in place for sending and receiving health personnel during a public health emergency: Score 4 out of 4

Areas for consideration

1. No area of weakness in plans or thinking could be identified by the visiting team and all support mobilizing of an appropriate mix of public health and health personnel as well as other appropriate classes or personnel.

Assessment Tool

• Instead of creating a separate plan for deployment, the information in Pandemic Preparedness Plans (PPP) could be used, possibly complemented by incorporating a few items not covered by the PPP in tabletop exercises of various preparedness scenarios

GHSA Action Packages Main Document

• No clear-cut further indicators identified in the Action Items list through the Portugal piloting experience that could be used in further development of the Assessment Tool

Special topic: Portugal Ebola Virus Disease (EVD) Preparedness

This section contains the rapid assessment requested by Portugal as an additional feature of the GHSA pilot assessment. It does not necessarily fully represent the countries full capacities and capabilities for EVD Preparedness and should therefore be interpreted with great care

Portugal has implemented EVD Preparedness activities since March 2014. Although the GHSA assessment team has not conducted any formal assessment of the country's level of preparedness, the team received a summary of the measures taken both in Portugal and in support of at-risk countries. The team notes the recent activities undertaken by ECDC which address a number of preparedness areas, and presents the following understanding of EVD preparedness in Portugal.

Coordination and Strategic Plans:

The main objective of Portugal's EVD preparation activities and plans includes the early detection of imported EVD cases and the prevention of secondary chains of transmission within the country. An Inter-Ministerial Commission for EVD exists under the leadership of the Ministry of Health and involves the Ministry of Foreign Affairs, Ministry of Interior and the Ministry of Defense. A National Preparednes/Contingency Plan is established for the health sector and includes 11key partners or sectors. The DGS has the coordination and leadership role according to the plan, as well as, the responsibility to produce technical guidelines for this matter. The plan was derived using guidance from ECDC, WHO standards and the Marburg virus disease guidance (2005) and provides the main strategic, tactical and operational planning for preparedness and response.

A national Task Force was established in March 2014 and after the WHO declaration of a PHEIC, the Task Force was strengthened (August 2014) with experts to address four key axes, including: risk assessment; infection prevention and control; communication (key messages, instructions); evaluation (internal and external). The national Task Force prioritized the elaboration and dissemination of procedures, protocols and algorithms to all relevant partners (health professionals, public health authorities, and other sectors). There are 9+3 technical guidelines established for the management of EVD cases. In addition the Armed forces and the National Republican Guard has established some additional guidelines. Areas for further work include the need to review internal procedures/adapting national references to local context; production of flowcharts for procedures; and an improvement of the dissemination of electronic information.

Public Awareness and Community Engagement:

As part of the National Contingency plan, a communication plan exists for Step 1 (no cases) and Step 2 (response). For each step the country has identified the need for seven measures and 15 actions. The plan targets the public, health professionals, and other sectors such as tourism, borders services, schools, specific groups (travelers, migrants, NGO) and others. Media products include a specific website; fliers and posters; and television and radio spots. Online information management includes website, social networks and ePORTUGUÊSE; banner on other agencies' websites; and usage of the PDS - Health Data Platform.

Health professionals liaison with the national task force to receive the latest information in articulation with the training programme. A centralized network of communicators is used to assure effective and coordinated messages to the public. Media management includes a network of experts to elaborate answers to media questions by subject (e.g., drugs; patient transportation; epidemiology); press conferences; informational workshops; for press release templates to use for the first confirmed case and for subsequent confirmed cases; and for workflow of information for media offices in main health services. An Interactive Voice Response (IVR) system with specific line options is established within the PNHS call centre. Monitoring includes press analysis, email analysis, focus groups among others. Finally, a public website is available at http://www.ebola.dgs.pt/ which contains information for the public, for healthcare workers and for laboratories.

Epidemiological Surveillance:

EVD is a notifiable disease in Portugal and is included in Portugal's real-time electronic surveillance system (SINAVE). The DGS/UESP will notify EWRS and WHO. The case definition used includes a person with fever and a travel history within past 21 days to an affected country (national guidance OT-12). Notification is conducted via SINAVE from the attending reference/designated healthcare facility. In addition, there is a national health telephone hotline (Health24) that is available 24/7 and is run with 400 registered nurses. This line as the first contact with health services is emphasized. Ideally this should avoid unnecessary ER burden. A separate hotline exists for the validation of suspect cases at the central level staffed by the DGS. Since 2014, nine suspect cases have been reported; all eventually found negative for Ebola virus. Of these, two were detected using the Health24 hotline, and seven were detected at public health facilities. All assessments were validated by the DGS Medical Support Line.

Laboratory:

National guidelines exist for sample collection and transportation which address personal protective equipment (PPE) and other important practices. All procedures have been used in enhanced training (e.g. Biosafety; Transport of Infectious substances; Good laboratory practices). The National Referral Laboratory (INSA) has been updated to manage EVD patient specimens (i.e., PPE, class 3 biosafety cabinet, and vaporized hydrogen peroxide equipment) and is the only National facility with this capability.

When suspect cases are identified and specimens are taken, samples are transported from the reference/designated hospitals to INSA and the RT-PCR result is communicated to DGS within 4-5 hours. Positive results/confirmed cases are reported to the IHR accordingly. INSA uses their BSL-3 laboratory to inactivate the virus and extract RNA (1h30m). Testing includes both Ebola and Marburg virus detection (2h30m). Further analysis is performed in parallel for detection of *Plasmodium* spp. and Lassa fever virus. If the patient is within the first three days of symptom onset and the first test is negative, repeat testing is performed after 48 hours. Confirmation of results and further sequencing is arranged with the Bernard Nocht Institute in Hamburg, Germany where transport procedures are in place for this purpose. An area of consideration includes better communication between the different partners involved in Ebola virus outbreak response.

Infection Prevention and Control

Portugal implements a written national infection prevention and control program which includes EVD. Guidance and procedures for IPC, PPE and waste management were developed by a consultative process and have been distributed to all health care facilities. PPE is bought by individual healthcare facilities according to technical specifications set out by the MOH.

A training plan is also implemented for the public and private sector and covers health facility administration to care providers. Focal points for each institution (IPC unit in each unit from the infection control commission) are responsible for implementing training. The private sector is invited to participate in training activities but their involvement is not mandated. Ebola preparedness is to be phased into the general preparedness plan for public health emergencies with pathogens requiring high biosafety levels. Improving collaboration among decontamination and waste management has been identified nationally as an area to strengthen.

Case management:

There are two designated hospitals under the same administration (an infectious disease hospital for adults and a different building, in the pediatric hospital for referral of pediatric EVD cases) identified for the management of EVD cases. These facilities are located in Lisbon (14 beds; with addition potential capacity) and one in Porto. Non-referral hospitals have established temporary isolation sites for patients under investigation and triage algorithms are used for wards receiving patients.

Only reference/designated hospitals are designated to perform invasive care to patents, including samples to send to national reference lab. Specimen collection and laboratory analysis at the national reference lab (INSA) is conducted once a suspect case is received at one of the reference hospitals. Dead body management (including disinfection and burial of confirmed cases) is under the joint responsibility of the Armed Forces (facility decontamination) and the National Republican Guard (dead body management). Procedures exist and the capability has been tested through simulation exercises.

The INEM (National Institute for Emergency Medicine) operates 3 specialist teams for transport of patients to the reference hospital. Six hours is the maximum time for transportation to a referral hospital on the Portuguese continent; air transport procedures are in place to transport patients from the Portuguese archipelagoes (the MedEv is ensured by Portuguese Air Force Força Aérea Portuguesa). For Madeira and the Azores, the patient is transported to the mainland once the case is laboratory confirmed. A medical hotline is routed to the national level where validation of diagnosed case is applied prior to transport. Procedures, protocols and algorithms for case management are periodically reviewed.

Contact tracing:

Contact identification and tracing guidelines and procedures have been distributed. In the event of a confirmed case, one public health officer in each municipality is responsible for contact tracing (supported by regional and national staff). DGS promotes contact tracing in articulation with regional/local public health officers and IPC local coordination groups. National exercises have tested the competency of trained staff.

Points of Entry:

The designated Points of Entry to Portugal are comprised of 10 ports and 5 airports. Written procedures exist for the port health and maritime authorities. Vessels must declare travel or crew with travel history to any affected country in last 21 days and must declare if there is a sick person on board. Procedures are in place and have been tested in the management of any declared persons with travel history to affected countries. At airports, designated rooms are identified for patient and crew interviews, respectively. If a suspect case is identified, information leaflets are distributed to the crew and travelers that sat in nearby seats or other exposures. Posters are present in ports and airports. Simulation Exercises have included all Port authorities.

Training and Simulation exercises:

A national Training Plan aims at the effective dissemination of scientific and technical information, in the shortest time, using a network model from the national to the local level. It also aims for a standardized response, particularly in the safety and protection of different professional groups involved. Over 14,000 public health staff have been trained from pre-hospital services, health services, and public health laboratories. Four major EVD exercises have been implemented in Portugal to test plans and procedures and a further three exercises are planned. The formats include Tabletop, Command post and field exercises. Regional level exercises test the coping ability of local levels. Evaluations of the EVD Preparedness has been undertaken internally and through an ECDC assessment in April 2015.

MEDEVAC

Portugal has established an evacuation plan using the military for infected Portuguese citizens in affected countries. This evacuation plan is based on a collaboration Protocol between DGS/MNE/FAP

International cooperation and assistance

Portugal has identified Guinea-Bissau as a natural partner for international assistance because of its historical links and particular risks in the context of the ongoing outbreak in West Africa. Portugal has provided Guinea Bissau with a mobile laboratory and 11 staff for a period of six months to run the lab and conduct training. Capacity will be left in-country at the end of the training period. Further support is planned in surveillance and epidemiology. This initiative is under the regular bilateral cooperation Agreement between the 2 countries but also under the umbrella of multilateral cooperation as UNMEER had contacted the Portuguese Authorities to collaborate on the preparedness support to GB under the current PHEIC. This specific bilateral support is conducted under an Inter ministerial Commission fro the coordination of Ebola Response and has been in place since March 2015 by INEM, DGS and INSA.

Annexes

Annex 1	Program for the GHSA Pilot assessment in Portugal 13-17.4.2015
Annex 2	Global Health Security Agenda Action Packages
Annex 3	Global Health Security Self-Assessment for Portugal
Annex 4	List of presentations and background documents received and collected during the mission
Annex 5	List of Portuguese Biosecurity and Biosafety legislation

Annex 1

Global Health Security Agenda (GHSA) Pilot Assessment visit to Portugal 13-17 Abril 2015



Day 1 - Dia 13 de abril 2015, 2ª-feira Time Main speaker /key Place Subject informer 09:15am -DGS Introductions and Health Systems Director-General of Health 10:45am Overview Mika Salminen Introductions • Eva Falcão **GHSA** Introductions • Overview of the organizational structure of the national health Cátia Sousa Pinto system, public health services General overview of surveillance system DGS Coffee/Tea Break 10:45am -11:00am 11:00am -DGS Andreia Jorge Silva Overview of Ebola Preparedness and • Cristina Abreu Santos 12:30pm Response national strategies Paula Vasconcelos Discussion 12:30pm -DGS Lunch 1:30pm 1:30pm -DGS Cátia Sousa Pinto Real time Surveillance • 3.45 pm Alexandra Bordalo Demonstration of tools: SINAVE; SICO • Sérgio Gomes • Reporting – National call center – hotline Saúde 24 Cristina Abreu Santos Reporting – EI; event monitoring; IHR Maria João Martins Discussion 3:45pm – Coffee/Tea Break DGS 4:00pm 4:00pm -DGS Teresa Fernandes Immunization • 4:30pm (PNV and Tool comments)

Direção-Geral da Saúde Alameda D. Afonso Henriques, 45 1049-005 Lisboa

Agenda

Day 2 - Dia 14 de abril 2015, 3ª-feira				
Time	Place	Subject	Main speaker /key informer	
9:15am – 10:30am	INSA	National Laboratory SystemDiscussion	Jorge Machado	
10:30am – 10:45am	INSA	Coffee/Tea Break		
10:45am – 12:00pm	INSA	Zoonotic DiseaseDiscussion	Miguel Fevereiro INIAV	
12:30pm – 1:30pm	INSA (cantina)	Lunch (self arrangement)		
2:00pm –	INSA	 Biosafety and biosecurity: Specific ppt on Influenza and others diseases Laboratory Visit (INSA Group) 	Sofia Núncio INSA	
2:30pm	LBDB	Laboratory Visit (LBDB Group)	LBDB	

INSA Avenida Padre Cruz 1649-016 Lisboa

LBDB

Avenida Doutor Alfredo Bensaúde 1800-172 Lisboa

Day 3 - Dia 15 de abril 2015, 4ª-feira				
Time	Place	Subject	Main speaker /key informer	
9:15am – 10:00am	DGS	 Work Force Development (Training) Discussion 	CNIM ENSP DGS	
10:00am – 10:30am	DGS	 Specificities of Ebola: points of entry; other operational approach Virology aspects Clinical aspects 	DGS (Plataforma Ébola) Madalena Almeida santos Eduardo Gomes Silva	
10:30am – 10:45am	DGS	Coffee/Tea Break		
10:45am – 11:15pm	DGS	 EOC – Emergency Operations Centers (articulation UESP and EOC's) 	Cristina Abreu Santos	
11:30am – 12:00pm	INEM	Visit to the Emergency Dispatch Center (CODU) at INEM	Raquel Ramos Paulo Campos	
12:30pm – 1:30pm	INEM (cantina)	Lunch (self arrangement)		
1:30pm – 2:00pm	ANPC	Travelling to ANPC		
2:00pm -	DGS	Specific package meeting on Immunization	Teresa Fernandes Visitors from Italy, Koreia and WHO Paula Vasconcelos	
2:00pm – 3:00pm	ANPC	 EOC – Emergency Operations Centers Misc issues Discussion 	Miguel Cruz Joaquim Almeida Sónia Rosa	
3:00pm - 3:20pm	ANPC	Coffee/Tea Break		
3:20pm 4:00pm	ANPC	Visit to ANPC (National Authority of Civil Protection)	ANPC	

INEM : Rua Almirante Barroso, 36, 1000-013 Lisboa

ANPC: Av do Forte em Carnaxide, 2794 - 112 Carnaxide

Day 4 - Dia 16 de abril 2015, 5ª-feira			
Time	Place	Subject	Main speaker /key informer
9:15am – 10:40am	INFARMED	Antimicrobial ResistanceDiscussion	Artur Paiva
10:40am – 11:00am	INFARMED	Coffee/Tea Break	
11:00am – 12:30pm	INFARMED	 Counter Measures International Deployment Discussion 	INFARMED INEM INSA DGS
12:30pm – 1:30pm	INFARMED (cantina)	Lunch (self arrangment)	
1:45pm		Departure to MNE	
2:15pm – 3:45pm	MNE	 Linking Public health and Law enforcement Discussion 	MNE SIS DGAV MD ANPC DGS
3:45pm – 4:00pm	MNE	Coffee/Tea Break	
4:00pm – 6:00pm	MNE	 Plenary session – discussion on several packages 	All partners
6:00pm 6:30pm	MNE	Porto de Honra	All partners

INFARMED

Parque de Saúde de Lisboa - Avenida do Brasil, 53 1749-004 Lisboa

MNE Largo do Rilvas 1399-030 Prazeres Lisboa

Day 5 - Dia 17 de abril 2015, 6ª-feira				
Time	Place	Subject	Main speaker /key informer	
9:15am – 10:30pm	DGS	Review of packagesReview of Ébola specificities	GHSA DGS	
10:30am– 10:45am	DGS	Coffee/Tea Break		
10:45am– 12:00pm	DGS	Drafting reportClosing remarks GHAS	GHSA Director-General of Health	
12:00pm– 1:30pm	DGS	Lunch		
		End of visit		



