Public Health England

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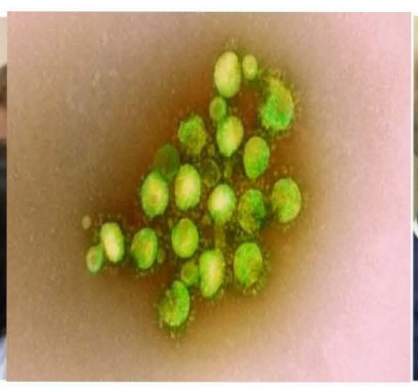
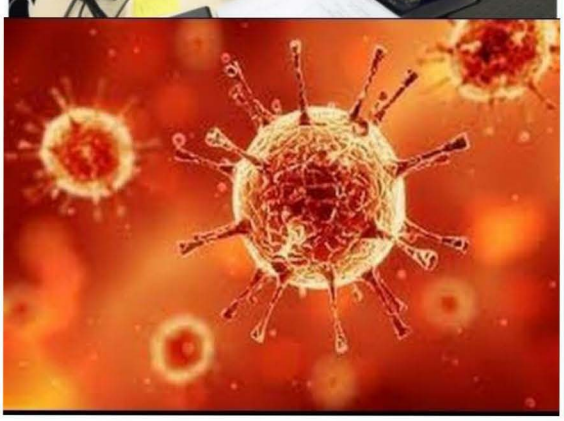
Exercise Valverde
21 May 2015
Report

The report on Exercise Valverde

Exercise Valverde was delivered on 21 May 2015, supported by member countries and organisations of the Global Health Security Initiative. This exercise was commissioned by the Global Health Security Initiative's Sample Sharing Task Group under the Risk Management and Communications Working Group to test the current draft arrangements of member countries for the rapid sharing of laboratory samples of non-influenza pathogens and related specimens during a public health emergency.

This report was prepared by Public Health England's Exercises Team within the Emergency Response Department.

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Executive summary

On 21 May 2015, member countries of the Global Health Security Initiative's Sample Sharing Task Group took part in a command post exercise to test the current draft arrangements in place for urgent sample sharing.

The Pandemic Influenza Preparedness Framework already exists to improve and strengthen the sharing of influenza viruses with pandemic potential and implements a global approach to pandemic influenza preparedness and response. The purpose of this exercise was to identify and aid in addressing the major policy, regulatory and logistical challenges associated with the rapid sharing of laboratory samples and critical biological materials of non-influenza pathogens in the context of a public health emergency.

Participants in the exercise included representation from the member countries and organisations of the Global Health Security Initiative's Sample Sharing Task Group; Ministries of Health; national level designated laboratories; and other relevant stakeholders and government departments that are involved in the process of sample sharing across international borders. The European Commission also participated in the exercise in a supporting role.

The exercise was considered to be a valuable opportunity for participants to walk through the process required for the requesting, sending and receipt of samples using the Operational Framework and Material Transfer Agreement that has been developed by the Sample Sharing Task Group for the purpose of facilitating sample sharing during a public health emergency. The exercise also helped demonstrate the complexity of the current arrangements in place and the broad network of stakeholders who need to be involved. It also clearly showed that not all of these stakeholders lie within the health sector (e.g. Customs and Border Force Agencies, legal and business departments) and that the process requires wider engagement across many government departments and agencies.

Comments from participants demonstrated a clear willingness and positive intent to enter into this short notice exercise and they should be commended on their positive, proactive engagement. This attitude serves to maintain the spirit of learning, sharing and cooperation and to strengthen the collective ability of Global Health Security Initiative countries to prepare for and respond to threats to global health security.

The key findings from this exercise included:

- The sample sharing process is very complex with many ad hoc mechanisms. In general, these mechanisms work, but the lack of shared knowledge of the process can potentially cause delays. There needs to be a toolkit or resources to support

these processes and mechanisms, and to facilitate identification of the relevant point of contacts in a timely fashion. Global Health Security Initiative members should bring together their international sample sharing stakeholders from across all relevant sectors to develop toolkits and/or formalised written coordination processes to ensure the rapid transport of samples during public health emergencies.

- Further work is required to finalise the Operational Framework for the Sharing of Biological Materials Relating to Non-influenza Pathogens with the Potential to Cause a Public Health Emergency of International Concern, including discussion and agreement on the Material Transfer Agreement.

- Further development of the language in the DRAFT Material Transfer Agreement is required to ensure that samples can be transported rapidly when a public health emergency occurs. There are several issues that countries still need to discuss with stakeholders, including legal experts. For example, one major issue with the current DRAFT is that the current language limits the transfer of samples for testing of already-existing medical countermeasures. It does not allow the use of samples for the development of new medical countermeasures. This and other issues need to be discussed internally in each country to agree to a common document.

- Both international and national terminology, processes and procedures could be better aligned and communicated to prevent or address any delays in sample transport.

- A set of outline scenarios with pre-prepared legal opinions could be included in a sample sharing toolkit as an optional guide.

- Deeper considerations need to be made with respect to legal counsel and broader consultations required from regulatory bodies within and outside of the public health sector.

- A mechanism is required for sharing the learning from exercises and actual events with partner Global Health Security Initiative member countries/organisations.

- Greater collaboration between public health and border security counterparts in order to expedite the sample sharing process, and to include them in any future exercises.

- The Nagoya Protocol is coming into effect with potentially unknown consequences and not all Global Health Security Initiative members are signatories of this

Protocol. The Pandemic Influenza Working Group is leading on this issue and the Sample Sharing Task Group will work closely with them to address the impact of the Nagoya Protocol on sample sharing during public health emergencies.

A summary list of the key areas for improvement is included at Appendix A.

1. Introduction

This report describes the design, delivery and outcomes of a functional exercise that was held on 21 May 2015. Exercise Valverde was designed test the current draft arrangements of the Global Health Security Initiative (GHSI) member countries for the rapid sharing of samples in order to identify and aid in addressing the major policy, regulatory and logistical challenges associated with the sharing of laboratory samples and critical biological materials of non-influenza pathogens.

This short-notice exercise provided participants with the opportunity to assess and review current capabilities, protocols and resources and to consider options for the development of future work plans. Participants also considered the interdependencies and requirements for coordination with other stakeholders relevant to the cross-border sharing of biological samples. The exercise was designed by Public Health England (PHE) with support from the Global Health Security Initiative Sample Sharing Task Group and Laboratory Network.

1.1 Background

The GHSI Sample Sharing Task Group (SSTG), under the Risk Management and Communications Working Group, formed by representatives from Canada, the European Commission, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States, was established in February 2014 as a direct result of difficulties experienced in acquiring and sharing Middle East Respiratory Syndrome Coronavirus (MERS-CoV) samples and the appreciation that on previous occasions a number of challenges and issues have been experienced. (The GHSI organisational structure is shown at Appendix B.)

The SSTG was charged with developing mechanisms for sharing biological materials of non-influenza pathogens with pandemic potential among GHSI members during public health emergencies. Since then, the SSTG has developed a draft Operational Framework, which includes guiding principles and a draft standard Material Transfer Agreement (MTA) that seek to address concerns over viral sovereignty and intellectual property (IP) among other issues. The SSTG has also identified a variety of regulatory and logistical challenges to the transfer of novel pathogens, which require additional considerations. Based on this existing research, a short-notice command post or 'functional' exercise was conducted on 21 May 2015 to test current draft agreements and to identify and address the major policy, regulatory and logistical barriers associated with the rapid sharing of laboratory samples. This exercise was followed by a presentation of initial findings to a meeting of GHSI Senior Officials in Ottawa on 11-12 June 2015.

Prior to the exercise, an Excel spreadsheet was shared among the GHSI members to assist them in identifying the key issues in the sample sharing process. This spreadsheet comprised twenty seven steps in the process from sample request through to sample receipt and sample use (see below).

Figure 1: Sample sharing issues for consideration by GHSI member countries:

Shipment ready					
1.Sample Acquired	2.Decision made to share sample	3.Export Permit completed	4.Packaging requirements	5.Temperature requirements	6.Provision for ice/dry ice top up, etc.

Shipping arrangements			
7.Chain of Custody requirements	8.Biosafety and Biosecurity	9.Material Transfer Agreements	10.Transfer Requests Documentation

Shipment collection					
11.Qualified TDG shippers on staff	12.Pilot refusals	13.Options for shipping on evenings and weekends	14.Documentation from foreign governments	15.Border Security Agency	16.Other Courier or Transport Challenges

Shipment receipt		
17.Import Permits	18.Agreements in place [Late night/weekend pickup]	19.Restriction of samples or personnel delivering samples

Sample use							
20.Restrictions due to prior MTAs	21.Use of sample (e.g diagnostics)	22.Retention / Destruction	23.Sample/ isolate ownership	24.Compliance with current MTA	25.Options for domestic distribution	26.Options for international distribution	27.Nagoya Signatory

2. Aim and objectives

2.1 Aim

The aim of the exercise was to test the arrangements in place for the rapid sharing of laboratory samples of non-influenza pathogens and related specimens during a public health emergency.

2.2 Objectives

The objectives of the exercise were:

- To familiarise participants with the Operational Framework of the SSTG

- To evaluate GHSI Members' ability to accept the terms of the SSTG Material Transfer Agreement in the context of a simulated public health emergency
- To evaluate current policy, regulatory and logistical protocols and procedures for sending/receiving human laboratory samples of non-influenza pathogens and related specimens during a public health emergency in GHSI countries
- To inform the development of the Task Group's future work plan

3. Scenario

A detailed scenario is provided at Appendix C. This scenario was based on an outbreak of a novel coronavirus causing severe respiratory failure in a fictional country (Valverde) in South America and a public health emergency of international concern (PHEIC) that required the sharing of biological samples. The government of Valverde refused to share patient samples and claimed viral sovereignty and cited intellectual property concerns. However, Public Health England had access to sample material and was willing to send this to appropriate research institutions. This required:

- Activation of the Operational Framework and use of the Material Transfer Agreement
- Communication and coordination with internal and external stakeholders
- Implementation and evaluation of current policies, protocols and procedures for sending/receiving human laboratory samples.

Participants were required to respond in accordance with existing plans, policies and procedures. In the absence of existing processes, participants were able to use the exercise as an opportunity to develop appropriate procedures as required. If participants were unable to agree the terms of the Operational Framework and MTA of the GHSI SSTG, they were permitted to either use existing MTAs in order to progress in the exercise, or proceed with the exercise under the assumption that the two countries had successfully negotiated a MTA. However, they were required to record and describe the reasons for this.

4. Exercise format

4.1 Exercise Style

Exercise Valverde was conducted as a command post exercise[1] (CPX) for around four hours on 21 May 2015 and was delivered from a central Exercise Control at the offices of

[1] A command post exercise (or functional exercise) strives to create a situation as close as possible to an actual event; therefore during the exercise, participants will operate from their own designated location (e.g. national laboratory, or command and control centre).

the Emergency Response Department, Public Health England Porton. Timings for delivery were arranged to facilitate participation from across different time zones. The exercise was run on Universal Coordinated Time (UTC)[2].

This one-day Command Post Exercise (CPX) was designed for participation by GHSI members: Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States of America and the European Commission. WHO were aware of the exercise and were party to all the exercise material.

Italy and Mexico did not respond to the invitation to participate in the exercise, and although France did not actively participate in the exercise, they engaged in the teleconferences and received all the exercise material.

In advance of the exercise, participants were given access to a secure, bespoke Sharepoint website in order to provide them with detailed exercise material and full instructions to assist them in their preparations for the exercise. This material was available to be shared with wider stakeholders (e.g. Other Government Departments, Border Force agencies, legal and business departments, etc.) to enable coordination and cooperation with external partner agencies. The exercise material was based on current arrangements for sharing laboratory samples and extant protocols and procedures in place to support the rapid sending/receiving of samples during a public health emergency. All exercise material provided was in English.

During the exercise, participants received injects based on the scenario by email, containing probing questions and instruction for action they should take in response. Participants were provided with a template report for completion by each country to demonstrate their workings through the process of requesting samples, permits and authorisations; receiving samples; coordinating with other national parties and detailing the procedures and complexities of the process. Participants were also able to highlight areas of good practice and areas where further work is required to facilitate the process. The exercise demonstrated the complexity of current procedures in place and the issues arising from requests for samples during a public health emergency. This also included the multi-layers of coordination with other stakeholders and partner organisations who need to be informed and involved in the process.

The lessons identified from the exercise will seek to improve procedures and protocols as well as to inform the development of the Task Group's future work plan.

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[2] Coordinated Universal Time (abbreviated as UTC) is the standard time common to every place in the world. Formerly and still widely called Greenwich Mean Time (GMT) and also World Time, UTC nominally reflects the mean solar time along the Earth's prime meridian.

4.2 Outline of the day

The exercise was delivered over a four-hour period (12:00 – 16:00 UTC) from Exercise Control based at PHE Porton, UK and was conducted by teleconferences, emails and the provision of material prepared by PHE's ERD Exercises Team.

In the exercise scenario a designated laboratory in the United Kingdom was willing to send a shipment ("virtual") of human serum from patients infected with a novel coronavirus, as well as isolates of the virus to designated laboratories in each of the participating GHSI member countries. Members were asked by the UK to accept samples based on the draft Material Transfer Agreement contained in the current version of the SSTG's Operational Framework (Version 3.0 dated May 2014). Participants also engaged with wider partner organisations, such as their Ministry of Health, Border Force agency, legal advisors, regulators and business departments to demonstrate the multi-layers and complex issues around sample sharing during a public health emergency.

Participants were required to dial in to two teleconferences during the exercise. These focussed on two specific issues and enabled participants to have a forum in which to raise common issues. Each country was encouraged to provide up to two informed spokespersons for these teleconferences; other participants were permitted to dial-in as silent observers in order to maximise on this learning opportunity.

At the end of the exercise, participants were requested to complete an online survey based on their observations and experience during the exercise. Exercise Controllers were also encouraged to conduct local hot debriefs in order to capture information for local use.

4.3 Participants

All GHSI member countries and organisations were invited to participate in Exercise Valverde. Participants in the exercise included representation from the following GHSI member countries and organisations:

Canada
Germany
Japan
United Kingdom
United States of America
European Commission

France participated as an observer. Mexico and Italy did not participate.

Each country engaged with its own network of stakeholders and partners. A list of participants and organisations is provided at Appendix D.

4.4 Exercise planning

A planning team for the exercise was established from PHE's Emergency Response Department.

4.5 Exercise assumptions and artificialities

- Valverde was a fictional country in South America
- Participants were asked by the UK to share materials using the MTA contained in the current version of the Operational Framework. Members were able to negotiate the terms of the MTA as part of the exercise
- All exercise communications during the exercise was via standard business networks (i.e. not security encrypted) and in English
- There was no 'time jump' during the exercise, but consideration was given to the whole sample sharing process (requesting through to receiving samples)

4.6 Out of scope

- Non-health issues relating to the transfer of samples (but not excluding communication and coordination discussions and requirements with non-health partners)
- Public messaging was not included in the exercise

5. Exercise evaluation and outcomes

Exercises help provide experience and practice to those who may be involved in response activities. They also provide an opportunity to share knowledge, identify and correct knowledge gaps and inconsistencies. An important tool for improving preparedness and planning is the evaluation of events and exercises, not only in identifying areas for improvement, but also identifying areas that are working well.

In Exercise Valverde, the scenario was designed to test existing arrangements and to draw out some of the challenges and pressures to be faced in response to a public health emergency of international concern (PHEIC). The exercise highlighted a number of issues, in terms of strengths and good practice as well as areas where gaps were identified and where further work is needed.

The evaluation of the exercise was based on the assessment and observations of the evaluators, controllers and the participants. Evaluators were nominated by each country to record and comment on their observations during the exercise, and an evaluation report template was provided to ensure consistency of evaluation across all participating

countries. Instructions for controllers and evaluators were provided in advance of the exercise to enable them to fully engage in their roles.

In addition to comments and observations from the Evaluators, participants were invited to complete an online survey at the end of the exercise. The questions mirrored those contained in the Evaluators' report template so that a holistic view on the exercise, including the challenges and obstacles, could be drawn.

As already mentioned, all the exercise material was made available to the participants in advance of this short-notice exercise. This enabled them to read in and prepare for their participation and to consider the potential issues and develop a more fully considered response for the exercise. Due to the nature of this type of public health emergency, it was acknowledged that in a real event those involved would already have acquired some information regarding the situation and would possibly already be engaging in discussions and information sharing. Exercise Valverde also provided participants with the opportunity to highlight areas for improvement for their own organisations.

This evaluation is therefore based on the observations of all those participating in the exercise. Observations on strengths and opportunities for improvement in the sample sharing process as well as issues relating to interdependencies with cross-government and international workings have been identified and included in this report.

However, as not all GHSI members participated in the exercise, the overall evaluation must consider that other issues, challenges and potential solutions may not have been explored.

5.1 Observations on Strengths and Opportunities for Improvement

5.1.1 Arrangements in place for the rapid sharing of laboratory samples of non-influenza pathogens and related specimens during a public health emergency

The International Health Regulations (2005)[3] provide a legal framework for international cooperation which supports the sharing of biological materials; however, the International Health Regulations' main focus is the sharing of information. Considerable international effort and negotiation assisted in the development of the World Health Organization (WHO) 'Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits'[4] ("PIP Framework") to facilitate the

[3] World Health Organization (WHO). International Health Regulations (2005) Second Edition http://www.who.int/topics/international_health_regulations/en/

[4] WHO Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits http://www.who.int/influenza/pip/en/

sharing of new influenza viruses with the global public health system (and eventually with the global pharmaceutical system). However, there is no agreement that covers non-influenza pathogens with the potential to cause a public health emergency of international concern (PHEIC), such as those causing new and emerging disease.

As a result, an 'Operational Framework for the Rapid Sharing of Biological Materials Relating to Non-Influenza Pathogens with the Potential to Cause a PHEIC' ("Operational Framework") was developed for GHSI countries by the GHSI Risk Management and Communication Working Group's Task Group on the Sharing of Biological Materials, in close cooperation with the sectors relevant to the sharing of biological materials within and between countries.

This Operational Framework consists of: definitions; guiding principles for the framework; a section on the process for sharing Biological Materials under this Operational Framework; and a template MTA. The template MTA is a document that GHSI Members would use to share biological materials between GHSI Members during public health emergencies when the Operational Framework is activated.

The Operational Framework represents an arrangement between GHSI countries to facilitate the rapid sharing of biological materials between these countries, expediting the development of international preparedness and response strategies. It is intended to support collaboration and the principles applied in this Framework may be used to develop future arrangements involving wider groups of stakeholders. Once the Operational Framework has been fully developed and implemented, the intention is to make it available in support of continued global efforts to strengthen collective preparedness for public health threats with pandemic potential.

Observations on Strengths

Responses to injects in the exercise confirmed participants' confidence in their preparation, notification and alerting procedures. On call and rotation systems are in place for events that may occur outside of normal working hours, and there are well-established pathways for alerting and notification across all relevant stakeholders. It was acknowledged in feedback from evaluators that the exercise offered an opportunity to build on cross government relationships.

Both formal and ad hoc arrangements exist to facilitate the transport of samples, and contingencies are in place to expedite the rapid transportation of samples should the need arise.

Communications regarding new and emerging pathogens are monitored through a variety of established mechanisms and pathways. In addition, existing intra country relationships with public health laboratories and ministries of health support the sharing

of information and of laboratory samples. It is clear that well established relationships exist at the strategic and policy level as well as at the technical and research levels.

During the exercise, the European Commission (EC) offered the support of the European Union (EU) reference laboratory networks, the European Food Standards Agency (EFSA) and the European Centre for Disease prevention and Control (ECDC) in preparing a joint risk assessment covering human health in respect of this novel coronavirus. This would be shared with the members of the Global Health Security Action Group (GHSAG). This Group of senior officials was established by Ministers in 2001 to develop and implement concrete actions to improve global health security. It also serves as a network of rapid communication/ reaction in the event of a crisis.[5]

The Commission also referred participants to the resource of the Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens (QUANDHIP)[6] which is a project that links the work of two networks: The "European Network for Highly Pathogenic Bacteria"(ENHPB) and "European Network of P4 Laboratories (ENP4Lab). The primary aim of these combined two networks, dealing with high threat bacteria (Risk Group 3) and with highly infectious viruses (Risk Group 4) is to create a stabilised permanent consortium that links and unites 38 highly specialised and advanced laboratories from 23 European countries. This aims to ensure a universal exchange of best diagnostic strategies to support a joint European response to outbreaks of highly pathogenic infectious agents, including the generation of a biodiverse repository of reference materials.

Observations on Opportunities for improvement

The impact of the Nagoya Protocol, which entered into force in October 2014, and how it may affect sample sharing between signatories and non-signatories of the protocol is an issue that needs further discussion and clarification within the SSTG. For example, the United States of America (US) is not a signatory of the Nagoya Protocol, nor does it recognise or define patient ownership rights related to pathogens or biological samples or "viral sovereignty" in its domestic law. These differences between GHSI members could potentially impede access to sample material and create legal risks.

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[5] GHSAG
http://www.ghsi.ca/english/background.asp

[6] QUANDHIP
http://www.quandhip.info/Quandhip/EN/Content/AboutUs/aboutus_node.html;jsessionid=D10A4BF2DEF45FE5A0DBAC398D579125.2_cid290

[7] A definition of 'rapidly' is not made here, in terms of time, but it is considered that countries and other actors should always endeavour to respond at a timescale that is proportionate to the degree of public health risk posed.

Participant feedback suggested that the Operational Framework and MTA required further discussion within the SSTG. The issues identified with the Operational Framework and MTA are detailed in 5.1.3 below.

5.1.2 To familiarise participants with the draft Operational Framework of the Sample Sharing Task Group

The Operational Framework for the Rapid Sharing of Biological Materials Relating to Non-influenza Pathogens with the Potential to Cause a Public Health Emergency of International Concern used in the exercise was a draft version dated May 2014.

The Operational Framework states that the "Transference of such biological material and information relating to non-influenza pathogens with the potential to cause a public health emergency of international concern (PHEIC) should occur rapidly[7] to facilitate:

- the identification of novel non-influenza pathogens with the potential to cause a PHEIC
- the sequencing of novel non-influenza pathogens with the potential to cause a PHEIC
- the development of a primary diagnostic test for novel non-influenza pathogens with the potential to cause a PHEIC
- serologic testing to confirm the infection and seroconversion testing of already-existing medical countermeasures (but not the development of new medical countermeasures)
- Sharing of biological material and information relating to non-influenza pathogens with the potential to cause a public health emergency of international concern (PHEIC) should occur openly and transparently among GHSI Members.

Observations on Strengths

Results from the participant survey confirmed that the majority of participants had some awareness of this document, and that they found the Operational Framework useful or very useful. The majority agreed that a GHSAG Material Transfer Agreement would be of future benefit.

Observations on Opportunities for Improvement

Feedback from participants and evaluator reports noted that further development of the language in the Operational Framework and Material Transfer Agreement is required in

[7] A definition of 'rapidly' is not made here, in terms of time, but it is considered that countries and other actors should always endeavour to respond at a timescale that is proportionate to the degree of public health risk posed.

advance of a public health emergency to ensure samples can be transported rapidly when that emergency occurs. The current language limits the transfer of samples only for testing of existing medical countermeasures and not for the development of new medical countermeasures.

Some member countries also commented on the use of terminology which can cause confusion. For example, in Germany the Point of Contact is not necessarily the Designated Laboratory. Further consultative discussion and work is required to address these issues.

Deeper considerations also need to be made with respect to legal counsel and broader consultations with regulatory bodies that sit outside the health sector. For example, Japan noted that if the pathogen was designated a select agent, this would result in significant delays caused by additional administrative requirements under the Infectious Disease Law of Japan[8].

5.1.3 To evaluate GHSI Members' ability to accept the terms of the SSTG Material Transfer Agreement in the context of a simulated public health emergency

The Operational Framework establishes that a standard MTA to facilitate the rapid exchange and use of non-influenza pathogens with the potential to cause a PHEIC (and related materials) and information should be developed in a way that recognises and protects the intellectual property rights of the providers whilst also addressing public health needs in emergency situations.

During the exercise, both the US and Canada stated that the DRAFT MTA, as written, would pose significant legal issues for their countries and in reality these issues could take considerable negotiation and time to resolve. However, for the purpose of the exercise, both countries assumed that the issues were successfully negotiated and a revised MTA was accepted in order to continue exploring the sample sharing process and issues.

Observations on Strengths

Participants commented that the exercise was a valuable opportunity to walk through the processes of sample sharing in the context of a public health emergency as they identified issues with the Operational Framework and MTA which they may not have considered otherwise.

If issues with the DRAFT MTA are resolved, it was noted that the Operational Framework could be of great value in facilitating the international sharing of samples. It could also

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[8] Infectious Disease Law of Japan
http://www.ifrc.org/docs/idrl/1003EN.pdf

potentially serve as a model in other international fora in which sample sharing is being discussed; for example, the Global Health Security Agenda.

Observations on Opportunities for Improvement

The GHSI Task Group should continue to work towards finalising the Operational Framework for the Rapid Sharing of Biological Materials Relating to Non-influenza Pathogens with the Potential to Cause a Public Health Emergency of International Concern, including discussion and agreement on the MTA. GHSI members should convene their international sample sharing stakeholders from across all relevant sectors to develop toolkits and/or coordination processes to ensure the rapid transport of samples during public health emergencies.

In the US, Canada, and Germany, several issues were highlighted that would require further discussion before approval of the SSTG MTA could be granted by their own legal counsels, which could potentially cause significant delays in the sample sharing process.

The GHSI SSTG Operational Framework and MTA are designed for the rapid sharing of sample material between GHSAG Laboratory Network Designated Laboratories. The Point of Contact, however, refers to the national representative at the GHSAG Laboratory Network. This designated Point of Contact then acts as a conduit to an authoritative person at a Designated Laboratory with authority to sign this MTA. Any further transfer within country would then be done by the designated laboratory and requiring a new MTA based on the same conditions as those originally imposed. It was suggested in responses to injects that the Designated Laboratories receiving the samples should be listed on the initial MTA or verbal agreement of the initial providing laboratory must be given in case of unexpected onward sharing. Since a prior agreement with all the Designated Labs might be difficult to accomplish, an option would be that the Point of Contact signs a modified version of the MTA

Participants noted that this MTA is an agreement between the Providing Laboratory and the Point of Contact but it also constitutes rights and obligations of the Designated Laboratories. In general, the Point of Contact is not entitled to act on behalf of the Designated Laboratories. Therefore the Point of Contact should not sign this MTA without prior agreement with each of the Designated Laboratories, including the obligation of the Designated Laboratory to act according to the regulations of this MTA and an authorisation of the Contact Point to sign on behalf of the Laboratory. Since a prior agreement with all the Designated Laboratories might be difficult to accomplish, one option would be for the Point of Contact to sign a modified version of the MTA.

In general, all countries acknowledged that further discussion is required within GHSI to resolve issues with the MTA. In particular, some Members believe that the MTA should not restrict the development of new MCMs for public use, as doing so may not be in the

interest of global public health depending on the severity of a novel disease event. Language in the MTA that limits the sharing of samples only for the testing of already-existing medical countermeasures and not for the development of new medical countermeasures was highlighted as an issue that needs further definition and discussion within GHSI. Explicit definition of Biological Materials and other terms and provisions used in the MTA is also supported by the participating countries in order for it to be used successfully in the context of preparing for and responding rapidly to public health emergencies.

In the exercise, PHE was the supplier of sample material and UK participants suggested that the language in the MTA could be improved around the limitation of liability ownership of derived Intellectual Property (IP) and commercial exploitation. It was also highlighted in evaluator reports that the language in the SSTG Operational Framework and MTA should be strengthened to ensure that sample sharing is not compromised by questions concerning benefit sharing and intellectual property.

The issue of sample sharing also raises ethical questions for consideration which require further clarification. It was noted that there is no 'single solution' for ethical questions; each situation may require a new ethical review which could cause significant delays in the sample sharing process.

However, for the purposes of the exercise, all participating countries assumed that these issues were successfully negotiated and a revised MTA was approved and signed and returned to PHE for countersignature.

5.1.4 To evaluate current policy, regulatory and logistical protocols and procedures for sending/receiving human laboratory samples of non-influenza pathogens and related specimens during a public health emergency

During the exercise, participants were required to consider shipping arrangements, including sample type, packaging requirements, import/export permits, shipment category, courier and customs arrangements, and to evaluate how effective protocols and procedures actually were. Participants considered these arrangements in respect of a virtual shipment; no actual shipment was made during the exercise. Participants therefore made an informed estimate of certain actions undertaken in the process, such as contingencies in place to support out of hours deliveries, delays in shipping, delays in arrival, etc.

As part of the exercise, two teleconferences were held to engage all participants in the exercise and to encourage cooperation and communication. One was held to consider possible logistical issues caused by shipping delays at London Heathrow airport. The second teleconference considered the request for sample material to be made available

for testing against a candidate vaccine which allowed participants to explore ethical and policy issues.

In Exercise Valverde, PHE, UK was the supplier of sample material to the other participating GHSI member countries. PHE confirmed that the patient samples in its possession were isolated from consenting patients in the UK and they therefore had the right to share this material. These isolated samples did not constitute human tissue and were therefore not subject to the provisions of the UK Human Tissue Act 2004[9] which regulates the removal, storage and use of human tissue in the UK.

Observations on Strengths

All countries used procedures that complied with national guidelines that were harmonised to international guidelines for the shipping and receipt of infectious substances. Participants commented that the exercise helped to reinforce confidence in established processes, agreements, networks, relationships and expertise. It also helped demonstrate strong linkages with and between various intra-agency offices as well as with wider stakeholders and cross government departments such as public health, biosecurity, animal health, border services, legal and business departments.

All countries confirmed that relevant departments and agencies have procedures in place to expedite permits during public health emergencies. Participants also expressed confidence in a number of contingency options to address any logistical issues for receiving the samples, such as alternative couriers and airports, and the use of private sector and the military. A public health agency like the CDC has in place standing permits to bring in pathogens in order to avoid delays in the process.

In the US, Customs and Border Protection (CBP) maintains specific "diversion plans" for aircraft that arrive in the U.S. unexpectedly. In this case, transport permits, separate from an import permit, are required to move the material to different facilities within the U.S depending on the mode of transit. However, if the material was kept in an airport quarantine area or was not unloaded, it could continue to its final destination when possible with no additional permit required.

Furthermore, ITAR (International Traffic in Arms Regulations)[10] and the EAR (Export Administration Regulations)[11] are export control regulations run by different departments

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[9] UK Human Tissue Act
https://www.hta.gov.uk/human-tissue-act-2004
[10] International Traffic in Arms Regulations (ITAR)
https://gov-relations.com/itar/

of the US Government. ITAR and EAR controlled items relate to a variety of "dual use" applications where the US Government considers authorising permission to transport or sell potentially dangerous items to foreign countries or parties (including biological or chemical items).

With regard to shipping arrangements, all countries confirmed that the packaging of samples would be in accordance with international guidelines for safe shipping and that the classification of the samples would be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or based on the professional judgment of the competent health authority. Existing permits facilitate the sample sharing process and within the EU there are no Customs restrictions or import permits required for human samples.

In the UK, the benefit of having joint leadership from individuals with medical knowledge and operational, logistical experience, able to cover issues from ethics to logistics was noted as a strength and may be considered as best practice for future response events.

The European Commission has an important role in the coordination of information sharing and in providing advice and guidance to its EU Member States. If difficulties in the process were experienced, some participants commented that they would expect the Commission and WHO to provide assistance in advice on the negotiation of contracts.

Observations on Areas for Improvement

Participants and evaluators noted that much of the current expertise and knowledge of the sample sharing process is based on ad hoc processes, institutional knowledge, and professional networks rather than being established in a formal, documented manner. Institutional memory could be lost when key individuals with sample sharing knowledge and experience are absent or leave the organisation. Some participants felt that establishing a checklist of issues and options might be useful, particularly to ensure this legacy knowledge is handed down when individuals move out of their current positions. In addition, a directory could be created to ensure individuals new in their positions would readily have the information required to respond to urgent sample sharing requirements.

Whilst most countries have well-established arrangements in place with pre-arranged framework contracts with couriers and other involved organisations, a couple of countries acknowledged that the availability of contact lists (for internal and external stakeholders) would improve the response to requests to urgent sample sharing. Better communication

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[11]Export Administration Regulations
https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear

and alignment both at domestic and international levels regarding terminology, processes and procedures would also help to prevent any delays in sample transport.

The sample sharing process is very complex with many ad hoc mechanisms. In general, these mechanisms work, but the lack of shared knowledge of the process can potentially cause delays. There needs to be a toolkit or resources to support these processes and mechanisms, and to facilitate identification of the relevant point of contacts in a timely fashion. Global Health Security Initiative members should bring together their international sample sharing stakeholders from across all relevant sectors to develop toolkits and/or coordination processes to ensure the rapid transport of samples during public health emergencies.

In response to injects, participants acknowledged that one of the greatest barriers to the rapid movement of samples exists around the lack of understanding of roles and communication between public health and border security counterparts. It was noted that enhanced collaboration between these entities, including joint participation in future meetings and exercises, would significantly improve the ability to overcome these barriers. A clear articulation of the roles of Border Agency, Airlines, Airport Authorities would also be beneficial.

Current legislation regarding public health emergencies relates to procedures aligned to the response to pandemic influenza and those emerging diseases requiring vaccination, isolation and social exclusion. Global sample sharing or the development of medical countermeasures is currently not within the scope of current legislation.

5.1.5 To inform the development of the Task Group's future work plan

In addition to all the above mentioned areas for improvement, other issues were also raised by participants and evaluators in feedback on the exercise.

Participants suggested there is a need to improve the general understanding of the role of the GHSI and the GHSI Laboratory Network within Member countries, especially among stakeholders whose remit lies outside the health sector.

The original intent of the Operational Framework and MTA was strictly for the rapid sharing of biological materials and information for public health emergency response. The future work plan of the SSTG should seek to resolve the point of discussion among GHSI Members around shared understanding of the purpose of the Operational Framework and MTA.

While not all GHSI Members are signatories of the Nagoya Protocol, that agreement creates an international framework for managing the world's genetic resources and ensuring that developing countries receive some of the financial benefits from the utilisation. Japan would try to trigger the Special Consideration (Article 8 of the Nagoya

Protocol) for expeditious procedure for sample sharing. Article 8 of the Nagoya Protocol on Access and Benefit Sharing raises the issue of Special Considerations where countries should "pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.

In the case of a public health emergency of international concern, countries could agree to waive their rights to material sovereignty in order to be "*mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes*"[12].

Some GHSI Members believe that there may be a need for GHSI to establish a fair and equitable benefit sharing mechanism for global access to genetic resources related to non-influenza pathogens with the potential to cause a PHEIC.

During a teleconference in the exercise, GHSI members were asked to consider a request for sample material from the US Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) to test against a novel candidate vaccine. It was recognised that this situation would also trigger communication within GHSI member countries to explore what research projects were being undertaken and where collaboration could be applied (see also reference to QUANDHIP on Page 15). A better awareness of the various research projects could enhance collaborative working and response activities during a public health emergency

Future work of the SSTG should include consideration and confirmation of the changes required to agree a GHSI MTA for use during a PHEIC. Further discussion is required around in country onward sharing which may differ between GHSI Member countries.

It was recommended in feedback that GHSI members should convene their respective internal stakeholders relevant to international sample sharing to develop toolkits and/or coordination processes to ensure rapid transport of samples during public health emergencies.

A mechanism is required for sharing the learning from exercises and actual events with partner GHSI member countries/organisations.

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[12] Nagoya Protocol
https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

6. Conclusion

Exercise Valverde provided an opportunity for the GHSI member countries and organisations to test and evaluate their policy, regulatory and logistical protocols and arrangements in place to respond to requests for the rapid sharing of non-influenza human samples during a public health emergency. The exercise also familiarised participants with the current draft Operational Framework of the SSTG and enabled them to evaluate GHSI Members' ability to negotiate and accept the terms of the SSTG MTA. A number of key issues with the Operational Framework and MTA were highlighted and will be taken forward for further discussion, and these will inform the development of the Task Group's future work plan. Participants in the exercise commented that the exercise was well organised and generated valuable discussions.

Material Transfer Agreement Issues

A number of participating countries expressed reservations about the DRAFT MTA in its current form and communicated that they would be unable to sign it or quickly resolve the issues:

- Germany pointed out that the MTA is an agreement between the laboratory providing the sample from one GHSI Member country and a GHSI Point of Contact in another country. In general the Point of Contact for a sample within a country may not be entitled to act on behalf its designated laboratories. This needs clarification.
- The US noted that the language limits the transference of samples to testing of already-existing medical countermeasures and **not** for the development of new medical countermeasures. The US believes that development of new medical countermeasures may be crucial to responding to a public health emergency. Critical early stage activities such as diagnostic development, animal model testing or human clinical testing, and/or production of experimental lots may all require some form of "commercialisation." The US looks forward to further discussion on the research restriction and commercialisation language of the MTA through the GHSI SSTG.
- Deeper considerations need to be made with respect to legal counsel and lessons learned in this exercise; broader consultations will still be required with legal regulatory bodies that are inside and outside of the public health sector.

Policy Issues

- International Health Regulations (2005) of the World Health Organization stipulate the importance of ensuring access to human pathogens for public health preparedness and response purposes.

- Neither the US or Canada are signatories of the Nagoya Protocol which took effect in October 2014. Nagoya may have a direct impact on the ability of signatories (EU Member States) and indirectly, the ability of non-signatories (the US for example) to share samples, and requires further discussion and clarification of legal implications as well as additional costs which may be incurred.
    - Article 8 - Special Considerations under the Nagoya Protocol: "*Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits*"
    - PIWG is currently leading on the Nagoya discussions and it is very important that any finalised MTA will address Nagoya commitments
- There is no 'single solution' for ethical questions. Each situation will require a new ethical review which could cause delays.
- The language in the MTA could be strengthened to ensure that sample sharing is not compromised by questions concerning benefit sharing and intellectual property.

Regulatory issues

- The Exercise clearly highlighted that the regulations/permits allowing for the movement of samples between countries is not simply a public health issue. In most Member States, it would involve border safety agencies, foreign ministries, and agricultural agencies. Moving forward, broader consultations will be required from regulatory bodies that are outside of the public health sector.
- GHSI countries may face challenges in sharing samples if the pathogen is on select agent/control lists and/or regulatory lists. For example, Japan's Infectious Disease Law would result in additional administrative delays if pathogen was deemed a select agent.

Logistical issues

- There are procedures and contingency options in place to address logistical challenges and ensuring sample integrity. However, some logistical arrangements are based on ad hoc processes, institutional knowledge, and professional networks rather than established in a formal, documented manner. This could be improved by:
    - A checklist / manual of issues and options, particularly to ensure knowledge is handed down when individuals move out of their current positions
    - A directory that ensures the appropriate people can be contacted to respond to urgent sample sharing requests

Further exercises might be beneficial to ensure that collaboration, agreements and processes are in place and are tested before an emergency situation occurs.

Next steps

- Consult and finalise the Operational Framework and MTA. A work plan is being developed with timeframes for both in-country and GHSI member discussion.
- Review language in the Material Transfer Agreement to ensure that GHSI members can agree to the terms and samples can be transported rapidly when an emergency occurs.
- Consider the development of a mechanism to share lessons learned from exercises and real events with all GHSI members.
- Enhance inter-country and intra-country collaboration between public health and other sectors such as border security, foreign affairs, agriculture and commerce counterparts in order to improve sample sharing. These sectors should also be included in future exercises.
- Consider the impact of the Nagoya Protocol (working with PIWG).
- GHSI members should convene their international sample sharing stakeholders from across all relevant sectors to develop toolkits and/or co-ordination processes to ensure the rapid transport of samples during public health emergencies

Appendix A: Summary of areas for improvement

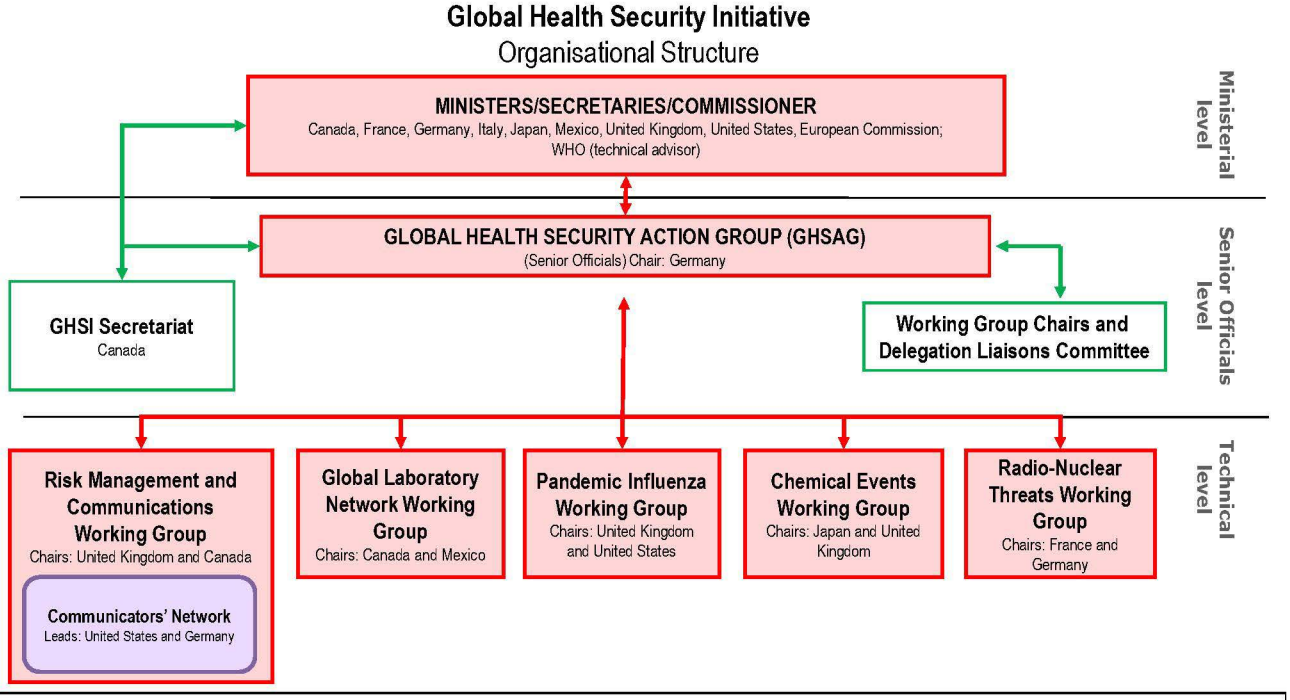
Serial	Sample Sharing Exercise – summary of areas for improvement
1	**Nagoya Protocol**: **1.1** GHSI may need to discuss the meaning of "establishing a fair and equitable benefit sharing mechanism for global access to genetic resources" (see Article 8 of the Nagoya Protocol) **1.2** Not all GHSI Member countries are signatories of the Nagoya Protocol so liaising with EU Member States on sample sharing could result in delays and legal issues. Further clarification and discussion is required on this issue. **1.3** Discuss the implication of the Nagoya Protocol to identify impact on the Operational Framework
2	**Operational Framework and MTA Clarifications:** **2.1** **Parties to the agreement**: The MTA is an agreement between the Providing Laboratory and the receiving Point of Contact, but it also constitutes rights and obligations of the Designated Laboratories. In general the Point of Contact is not entitled to act on behalf of the Designated Laboratories. This issue needs further discussion. **2.2** **Sample research limitations**: The MTA limits transfer of samples to testing of existing medical countermeasures. It does not allow the development of new medical countermeasures that could be crucial for public health response. **2.3** **Commercialisation**: In the future, products developed as a result of sample sharing may require partnership with commercial entities to scale up the response to a public health emergency. **2.4** Consider and confirm the changes required in order to agree a GHSI MTA for use during a PHEIC. Further discussion may be required around in-country onward sharing which may differ between GHSI Member countries.
3	**Policy, Logistics and Regulatory issues**: **3.1** Discuss the MTA with legal and regulatory entities that sit outside the health sector to minimise impact of delays on the sample transfer process **3.2** Enhance collaboration with public health and other sector counterparts such as border security in order to improve understanding of roles and responsibilities in the sample sharing process, and include them in future exercises. This would include clear articulation of the roles of border agencies, airlines and airport authorities **3.3** Improve communication and alignment both at domestic and international levels regarding MTA terminology, processes and procedures in order to help prevent delays in sample transport **3.4** Consider the development of a GHSI template for a toolkit or similar resource to facilitate identification of the appropriate points of contact, and sample sharing processes and mechanisms. This should include the identification of Point of Contacts and a directory of key contacts and stakeholders as an annex to the Framework
4	**Communications:** Some logistical arrangements are based on ad hoc processes, institutional knowledge, and professional networks rather than established in a formal, documented manner to support these processes and mechanisms. Knowledge and experience may be held with a few key individuals, which could represent a risk if that person is absent or leaves the organisation. This situation could be improved by: **4.1** A checklist of issues and options, particularly to ensure knowledge is handed down when individuals move out of their current positions

Serial	Sample Sharing Exercise – summary of areas for improvement
	4.2 A directory should be created to ensure individuals new in post would readily have the information required to respond to urgent sample sharing requirements
5	**Training and Lessons Identified:** 5.1 Continue to conduct exercises to ensure that collaboration, agreements and processes are in place and tested before an emergency situation occurs 5.2 Clarification of the role of the GHSI Laboratory Network as part of the Operational Framework implementation. 5.3 Build on the established process for sharing lessons learned from exercises and real events with GHSI members
6	Better awareness among GHSI Members of the various research projects being undertaken that could enhance the aim of collaborative working and activities during a public health response

Appendix B – GHSI Organisational Structure

The Global Health Security Initiative (GHSI) is a ministerial-level international partnership among Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States, the European Commission, and the World Health Organization (WHO) which works to strengthen global health preparedness and response to biological, chemical, radio-nuclear (CBRN) threats and pandemic influenza crises, and provides leadership and guidance for the development of international policies and processes to improve public health emergency preparedness.

The Global Health Security Action Group (GHSAG) is a committee composed of high level representatives of the national health authorities for the G-8 block of countries. The GHSAG was formed to develop and implement concrete actions to improve global health security and serve as a network for rapid response to biological, chemical, radio-nuclear terrorism (CBRN).
The Global Health Security Action Group Laboratory Network (GHSAGLN) is part of the GHSI action groups. The GHSAG comprises high-ranking officials from GHSI countries. It is tasked with developing and implementing activities to increase global public health security. It acts as a network, with a rapid-response communication system for emergency situations. The GHSAG-LN network's goals are to coordinate the diagnostic capabilities of all participants and contribute to disease surveillance around the world.



NOTES

Ministers/Secretaries/Commissioner: Lead GHSI; Set directions; Discuss key issues; Meet once a year

Global Health Security Action Group (GHSAG): Define objectives and directions for GHSI; Develop opportunities for policy discussions on key issues; Meet approx. four times per year (face to face or by videoconference and by teleconference as needed)

GHSI Secretariat: Assist GHSAG in coordinating discussions and meetings and in developing strategic directions and objectives for the organisation; Work with Working Gorup Chairs to ensure workplans are up-to-date and that linkages are made between Working Groups; Maintain secure website and circulate information among GHSAG

Working Groups: Develop technical and policy activities; Meetings, workshops and activities as required; Each Working Group has a chair or co-chairs; workplans approved by GHSAG on an annual basis

Communicators' Network: Develop activities that enable information exchange and cooperation on a topic; Answers to Risk Management and Communications Working Group

Appendix C – Scenario

[This scenario was developed for the sole purpose of validating the SSTG Operational Framework and to test a GHSI Member's ability to receive a potentially dangerous sample from a trusted institution within the GHSI laboratory network during a public health emergency.]

In early January 2015, Dr Ramon Macias noticed a number of individuals being admitted with severe respiratory infections and renal failure to the Cuscona District Hospital in the tourist area of Cuscona, Valverde. Unable to identify the etiologic agent, Dr Macias sent nucleic acid of a sputum sample from a 63-year old male patient with acute pneumonia and renal failure to a colleague at the Robert Koch Institute (RKI) in Germany. RKI obtained positive results in a pan-coronavirus PCR assay. Sequencing of the amplicon revealed that the etiologic agent appears to be a novel Betacoronavirus. By the time the Betacoronavirus was identified, the material was exhausted so that no full genomic sequence is available.

Twenty additional cases have since been identified in the countries of Valverde (17) and the UK (3). The three cases in the UK involved a family returning after vacationing in Valverde, showing evidence of limited sustained person-to-person transmission. This cluster of cases was immediately reported to the WHO by the UK National Focal Point (NFP) as required by the International Health Regulations (IHR). Of the 21 known cases, 15 have died (70% fatality).

Based on available data, the novel South American coronavirus is most closely related to unclassified viruses obtained from bats in Valverde, Brazil and Chile. While bats may be the natural host, it is more likely that patients were exposed to an intermediate animal host species (presumably llamas or alpacas) where a single variant from related betacoronaviruses in bats successfully crossed over and has rapidly established itself. The international news media has begun referring to the virus as Valverde Respiratory Syndrome Coronavirus, or VRS-CoV.

Several hospitals in Valverde have VRS-CoV samples from suspected cases; however, the government of Valverde is refusing to share patient samples with the global research community claiming viral sovereignty and citing intellectual property concerns.
RKI has agreed to send its remaining VRS-CoV material to Public Health England (PHE) so that PHE can complete and validate sequencing results. With RKI's material exhausted, PHE is now the only institution with access to clinical samples. PHE has also now isolated and propagated VRS-CoV. It is willing to send the material to research institutions that have the capability to work with highly pathogenic influenza.

The US Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) has developed a MERS-CoV candidate vaccine that may work against VRS-CoV given the similarity of the novel South American respiratory virus to MERS-CoV. Serum samples from patients who have recovered from this novel coronavirus would be needed in order for BARDA to test the antigenicity and cross-reactivity of the candidate MERS-CoV virus.

All GHSI Members, and many other countries and academic institutions request serum samples and viral isolates.

As at 21 May 2015 there are no reports of any symptomatic cases in any other country.

Appendix D – List of participants and participating organisations

This list is as provided to Exercise Control. It may not include all the participants in the exercise but serves to demonstrate the wide engagement in the exercise.

First Name	Last Name	Organisation	Role in the Exercise
Canada			
Allen	Lau		Logistics
Dionne	Drolet		Evaluator
Heidi	Wood		OCD
Kirsten	Duke		
Kristina	Gordon	National Microbiology Laboratory, Public Health Agency, Canada	Evaluator
Luc	Audette		Logistics
Matt	LeBrun		Evaluator
Ted	Kuschak		Controller
France			
Francois-Xavier	Chauviac		Observer
Germany			
Andreas	Nitsche	Robert Koch Institute	
Livia	Schuenadel	Robert Koch Institute	Controller/Evaluator
Bettina	Hanke	Robert Koch Institute	
Lars	Schaade	Robert Koch Institute	
United Kingdom			
Adrian	Collins	Public Health England	
Amanda	Walsh	Public Health England	Scientist
David	Conway	Public Health England	Evaluator
David	Baghurst	Public Health England	Logistics Manager
Name Redacted		Home Office/Border Agency	

Dawn	Clarke	Public Health England	Despatch
Emma	Hobbs	Public Health England	Logistics
Gwyn	Morris	Public Health England	Controller
Heather	Sheeley	Public Health England	Safety Advisor
Hilary	Kirkbride	Public Health England	
Name Redacted		Department of Health	
Lynne	Foster	Public Health England	Tasking/Logging
Meera	Chand	Public Health England	Lead/Medical
Nick	Gent	Public Health England	Control Player/ Teleconference Chair
Richard	ACourt	Public Health England	Business Development
Richard	Allen	Public Health England	Safety Advisor
Sian	Reece-Loram	Public Health England	Tasking
Simon	Warne	Health & Safety Executive	
Stephen	Clegg	Top Speed Couriers	
Thomas	Bjorn	Public Health England	Legal Counsel
Japan			
Makino	Tomohiki		Controller
Masayuki	Shimoji	National Institute of Infectious Diseases	
Shuetsu	Fukushi	National Institute of Infectious Diseases	
United States of America			
Adam	Tewell		
Brent	Davidson		
Lauren	Barna		
Lewis	Dodds		

Maria Julia	Marinissen		
Ruvani	Chandrasekera		
European Commission			
Vasilis	Zaharopoulos	DG SANTE	Player
Paolo	Guglielmetti	DG SANTE	Controller/Evaluator

Participating Organisations

Canada Public Health Authority, Canada
Germany Ministry of Health Robert Koch Institut
Japan National Institute for Infectious Diseases Ministry of Health, Labour and Welfare Biorisk/Safety Committees Ministry of Agriculture, Forestry & Fishing
United Kingdom Public Health England Department of Health Home Office/Border Agency Health & Safety Executive Top Speed Couriers
United States of America U.S. Department of Health and Human Services (HHS): • **Office of the Assistant Secretary from Preparedness and Response (ASPR)**– responsible for coordinating HHS' relationship with the GHSI • **Centers for Disease Control and Prevention (CDC)** – contains the USG GHSI designated receiving laboratory • **Food and Drug Administration** – represented with regard to MCM and related regulations • **National Institutes of Health** – represented scientific study of new pathogens, has significant global public health connections • **Office of Global Affairs (OGA)** – represented HHS international interests

U.S. Department of Homeland Security (DHS), Customs and Border Protection (CBP) – addressed issues of handling pathogens at the U.S. border U.S. Department of Commerce (DOC) – addressed permit and commercial issues U.S. Department of State (DOS) – broadly looked at USG international relations U.S. Department of Transportation (DOT), Federal Aviation Administration (FAA) – addressed regulations regarding flights and rights of refusal to handle the package U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) – addressed issues related to pathogens and animal health
European Commission DG SANTE – C3 Health Threats Unit

References

WHO Guidance on regulations for transportation of infectious substances
http://www.who.int/ihr/publications/who_hse_ihr_2012.12/en/

WHO Interim Recommendations on Laboratory biorisk management for laboratories handling human specimens suspected or confirmed to contain novel coronavirus
http://www.who.int/csr/disease/coronavirus_infections/Biosafety_InterimRecommendations_NovelCoronavirus_19Feb13.pdf

The Nagoya Protocol
https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

WMA Declaration of Helsinki – Ethical principles for medical research involving human samples
http://www.wma.net/en/30publications/10policies/b3/

WHO information on coronavirus infections
http://www.who.int/csr/disease/coronavirus_infections/en/

WHO International Health Regulations
http://www.who.int/ihr/en/

List of useful acronyms

BARDA	Biomedical Advanced Research and Development Authority
BST	British Summer Time (i.e. GMT+1)
CBP	Customs and Border Protection
CPX	Command Post Exercise
EC	European Commission
EAR	Export Administration Regulations
ENHPB	European Network for Highly Pathogenic Bacteria
ENP4Lab	European Network of P4 Laboratories
EU	European Union
GHSAG	Global Health Security Action Group
GHSI	Global Health Security Initiative
ITAR	International Traffic in Arms Regulations
LEC	Local Exercise Controller
MEL	Master Events List
MERS-CoV	Middle East Respiratory Syndrome – Coronavirus
MTA	Material Transfer Agreement
NFP	National Focal Point
PHE	Public Health England
PHEIC	Public Health Emergency of International Concern
PIP	Pandemic Influenza Preparedness
PIWG	Pandemic Influenza Working Group
QUANDHIP	Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens
RKI	Robert Koch Institute
SSTG	Sample Sharing Task Group
VRS-CoV*	Valverde Respiratory Syndrome – Coronavirus
UTC	Universal Coordinated Time
WHO	World Health Organization

**Valverde Respiratory Syndrome-Coronavirus was a virus based on a fictional country (Valverde) and was used entirely for exercise purposes only*

Acknowledgements

Planning Team	Organisation
John Simpson	Emergency Response Department, PHE
Veronica Nelson	Emergency Response Department, PHE
Angeline Walker	Emergency Response Department, PHE
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Pat Cane	High Containment Microbiology, PHE

Many people contributed to the planning, delivery and evaluation of this exercise. The exercise planning group would like to thank them for their time and efforts, with particular thanks to the participants.

Disclaimer

This report has been compiled from the comments made by the participants during the exercise and the observations of evaluators. The report's author has tried to assimilate this information in an impartial and unbiased manner to draw out the key themes and lessons: the report is not a verbatim account of the exercise. The report is then quality checked by the senior management within PHE's Emergency Response Department before it is released to the commissioning organisation.

The recommendations made in the report are not therefore PHE's corporate position; they are evidenced on the information gathered at the exercise and interpreted in the context of ERD's experience and judgement. It is suggested that the recommendations are reviewed by the appropriate organisations to assess if any further action is required.