



Wilton Park



Report

Responding to deliberate biological release: the requirements for effective, coordinated international action

Wednesday 27 – Friday 29 September 2017 | WP1556

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Executive Summary

The dialogue held at Wilton Park gathered international experts from multiple perspectives to build on the outcomes of the previous year's meeting, "The 2014-2015 Ebola outbreak: lessons for response to a deliberate event". Through a series of plenary discussions and smaller group workshops, the participants were able to map the existing challenges and gaps in responding to deliberate biological events, propose a set of activities that leverage existing expertise, and agree upon a discrete list of tasks required for moving forward.

Key challenges identified

- Due to the high variability of infectious diseases, context and type of agents are highly influential on the characteristics of the outbreak, and thus the characteristics of response.
- At the International Organisation (IO) level, no agency has been designated as the lead authority on issues related to deliberate biological releases. The map of all stakeholders potentially involved in preparedness and response to a deliberate bio-event is extremely crowded, and roles and responsibilities are poorly defined.
- While the Biological and Toxins Weapons Convention (BWC) has a theoretical role in providing assistance (via Article VII) and investigating (via Article VI) during a deliberate biological event, in practice, it lacks the functional capacities to effectively coordinate a response with the pertinent agencies and IOs.
- When the BWC was negotiated, parties agreed that assistance would be provided when a State Party is 'exposed to danger as a result of a violation of the Convention'. This formulation is still subject to interpretation today, which raises further uncertainties on what type of event might fall under this determination, and what proof or data the requesting state party might have to put forward to request such assistance.
- The absence of clear procedures on how to trigger Article VII and the lack of understanding on what assistance would entail in practice, or how response would be operationalised, coordinated or managed, put into the question any additional benefits the provision might offer to the requesting

state.

- Deliberate biological events might lead to great confusion about the role of the military, especially under the assumption that international assistance may already be provided prior to the confirmation of a deliberate use of biological agents.
- The lack of Standard Operating Procedures (SOPs) depicting how best international humanitarian and law enforcement agencies may interact with each other, nor how and what type of information may be shared, creates further challenges for the smooth and conflict-free development of international response efforts.

Key recommendations

- A roster of experts, composed of responder agencies and other relevant actors, and involving the health, security, law enforcement and humanitarian sectors, ought to be created and meet regularly to address the issues identified above.
- This working group will aim to undertake a situational assessment and mapping of existing mandates, capabilities, resources and mechanisms already in place at the IO level. During this process, it is also incumbent on the Organisations in question to self-assess and report back to the working group. The roster would also be tasked with the creation of a glossary of terms to standardise vocabulary across organisations and facilitate coordination.
- It is crucial to clarify the separation of humanitarian and investigative aspects of the response. IOs should come together to design a mechanism of information sharing between the public health community and the law enforcement community in a way that respect their mandates.
- IOs harbour significant amount of knowledge, mechanisms and frameworks that could be used to validate next steps. Similarly, multiple member states have highly efficient national chemical, biological, radiological and nuclear (CBRN) response teams, which are well trained and have created SOPs for evidence collection that can be use jointly by responders and investigators. These SOPs and other key strategic documents could be used as a basis for the development international SOPs.
- Gold standard national forensic laboratories around the world should provide guidance and best practices to the IOs in the development of key guidance documents on the secure packaging and transport of sample and maintaining the chain of custody in the context of deliberate events.

Introduction

Background

The recent use of chemical weapons in Syria and Iraq, along with the growing threats of emerging and re-emerging infectious diseases, triggered the international community's renewed interest in strengthening its capacity to prepare and respond to the deliberate release of a biological agent. The 2014-1016 Ebola crisis in West Africa demonstrated the

complexity in collaborating effectively at the international community level, and unfortunately highlighted how poorly prepared that community is for a large scale pandemic. Many practical, legal, logistical and operational gaps and challenges need to be overcome before effective international collaboration can be achieved, particularly in the context of deliberate use of biological weapons.

Specific goals and objectives

This Wilton Park dialogue was held to support the Biological Weapons Convention (BWC), the Global Partnership (GP)'s Biological Security Working Group and the Global Health Security Agenda Response Action Packages. More specifically, this meeting aimed to identify how governments, international organisations (IOs) and non-governmental entities can effectively implement collaborative action in the event of the use of a biological weapon, whether by states or non-state actors, in order to ensure effective response that contains the outbreak promptly and promotes a quick recovery.

Against this background this Wilton Park meeting sought to:

- Identify existing challenges for response to deliberate biological events
- Review existing stakeholders, frameworks and mechanisms at the international and national level
- Map existing gaps
- And validate a collaborative work plan that describes discrete steps that could be taken by states and IOs to build and sustain a more effective operational capability against deliberate biological events.

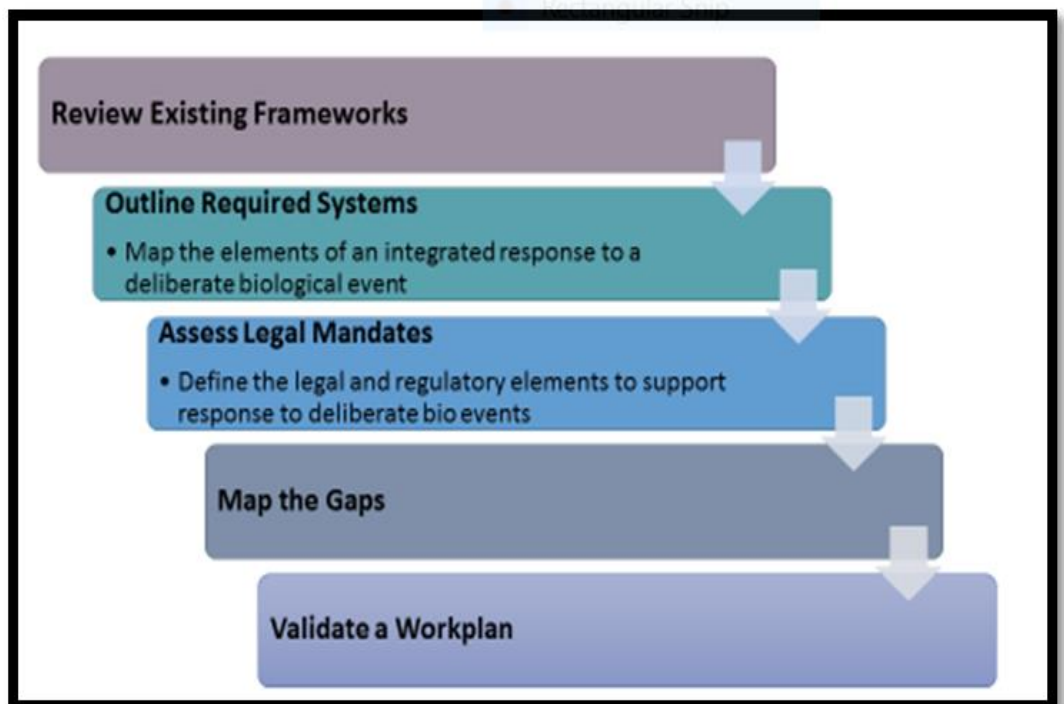


Figure 1 – Goals and objectives

The challenges

Through a series of plenary discussions and small group work, participants came together to identify the various gaps and challenges that exist when dealing with a deliberate biological event. While these gaps were discussed thematically, it is important to remember that these challenges are interrelated and impact on each other in complex and non-linear ways.

Outbreaks are highly variable by nature

1. New mathematical models have shown that there could be over 22 million possible outbreak scenarios, all of which are considerably diverse in nature and highly contingent on circumstances. There is little doubt that infectious diseases are indeed highly variable, and that even when dealing with a naturally occurring outbreak, no response and coordination efforts would ever be exactly replicated.
2. The weaponised biological agent itself may also impact the response efforts. Indeed, consider the comparison between the release of anthrax and a highly infectious and pathogenic influenza virus: an attack using the former would be highly localised and more similar to a chemical attack in its epidemiology, whereas the spread of latter would be highly mobile, with transmission occurring through droplets made when infected individuals cough, sneeze or talk. Context and type of agents, are, therefore, highly influential on the characteristics of the outbreak, and thus the characteristics of response.
3. When a deliberate act is suspected, response efforts are further complicated, especially as questions surrounding deliberate use may remain unanswered, and that the security environment may exhibit varying levels of permissiveness. For example, a deliberate release may create uncertainties regarding the appropriate use of sanctions or military response, as well as how best to balance humanitarian efforts with criminal investigation in a continuously changing environment, where the order of magnitude of the outbreak may be bigger than in a natural one. All of these factors shape the response and the necessity for different actors and capacities.

Challenges at the International Organisation level

4. At the IO level, no organisation or agency has been designated as the lead authority on issues related to deliberate biological releases. To further complicate the landscape, the map of all stakeholders potentially involved in preparedness and response to a deliberate bio-event is extremely crowded, and roles and responsibilities are poorly defined, not designated and also simply not widely known. Coordination amongst IOs could therefore be rendered very complex following a deliberate act, and the United Nations (UN) system would have very little capacity overall to responding to a natural outbreak in non-permissive environment or to a deliberate outbreak.
5. In retrospect, if Ebola had reached the ungoverned portions of Nigeria or Mali, it is unclear what assistance the UN system might have been able to provide, nor how effective that assistance might have been. It is clear, though that IOs have yet to effectively come together to define and map the frameworks for preparedness, detection, reporting, response, recovery, investigation and governance in the context of a deliberate event. IOs cooperation might benefit from the creation of a platform where information and/or recommendation for best practices is been integrated and can be shared.
6. While the Biological and Toxins Weapons Convention (BWC) has a theoretical role in providing assistance (via Article VII) and investigating (via Article VI) during a deliberate biological event, in practice, it lacks the functional capacities to effectively coordinate a response with the pertinent agencies and IOs.
7. When the BWC and Chemical Weapons Convention (CWC) were first negotiated, only state on state belligerent actions were considered. This may weaken the Convention's leadership position when dealing with contemporary threats, such as state vs. non state actor events. However, in Syria in 2013, an investigation was requested on alleged use of a chemical weapon by a non-state actor, which provides a precedent for the role of the CWC during an alleged attack by a non-state actor. It is unclear if this would be sufficient for the involvement of the BWC during an alleged biological attack by a non-state actor.

BWC Article VII specific challenges

8. When the BWC was negotiated between 1969 and 1971, negotiators agreed that assistance would be provided when a State Party is 'exposed to danger as a result of a violation of the Convention'. This formulation is still subject to interpretation today, which raises further uncertainties on what type of event might fall under this determination, and what proof or data the requesting state party might have to put forward to request such assistance. Considering the variable nature of infectious diseases, confirmation of the deliberate nature of an outbreak could be considerably delayed, even arriving after containment of the outbreak in some cases, which might render the value of the assistance provided through the invocation of article VII debatable.
9. The formulation "exposed to danger" is particularly ambiguous, yet its most common interpretation is that assistance means humanitarian and medical support, not military or security assistance – unless military personnel is providing humanitarian aid, such as those deployed in West Africa during the 2014-2016 Ebola crisis. In addition, the formulation "threat of use" may also be problematic as it is too broad and subject to a wide ranging set of interpretations. Depending on how threat of use is defined, it may risk draining out all the available, but finite, resources if response were to be required for all threats.
10. Lastly, the absence of clear procedures on how to trigger Article VII and the lack of understanding on what assistance would entail in practice, or how response would be operationalised, coordinated or managed, also put into question any additional benefits the provision might offer. The 2014-2016 Ebola outbreak in West Africa provides a clear example of how an uncontrolled outbreak may become a humanitarian, economic, political and societal crisis that requires prompt assistance from the international community. It is therefore possible that valuable time could be lost if IOs needed to wait for the slow and often politically complex determination of deliberate biological weapons use by the UN.

Challenges at the NGO level

11. In the event of a deliberate release of a biological agent, which may often manifest itself like natural outbreak at first, it is likely that assistance may already be provided by IOs, regional organisations as well as foreign governments and non-governmental organisations (NGOs) before deliberate use is suspected or confirmed. Once circumstances change, and a deliberate act is either suspected or confirmed, the core mandate of NGOs and IOs would not necessarily change, but in practical terms, some may lack the capacity to operate in such an environment. Indeed, medical personnel's safety would become a more important issue, while many NGOs may not be able to provide adequate life insurance to their worker in a conflict environment, and medical evacuation may become more logistically complicated.

Challenges at the Member State level

12. A significant and first line defence against natural, accidental and deliberate outbreaks is effective surveillance, detection, identification and mitigation capabilities. These capacities, however, are lacking in many parts of the world where implementation of the International Health Regulations still has a long road to go. Many states still have underdeveloped national surveillance capacities; requiring further national commitment and bilateral and regional coordination.
13. In addition, while humanitarian disaster response is well coordinated, it remains resource-intensive and must be better supported by national capacities. Many member states must further develop their regulatory capacity to provide and receive assistance during emergencies, including medical countermeasures, public health, medical, and veterinary personnel. Member states must ensure that their capabilities to logistically receive and redistribute the aid is sufficient, secure and follows core compliance requirements.

14. The absence of standard operating procedures (SOPs) and clear provisions for invoking Article VII create political and legal uncertainties for the requesting state, which may appear to outweigh the benefits it may get from requesting assistance through this process over other existing mechanisms.

Uncertainties regarding the role of the military

15. It is clear that the role of the military will differ during a deliberate event, versus a natural outbreak, versus a natural outbreak in a non-permissive environment. Deliberate biological events might lead to great confusion about the role of the military, especially under the assumption that international assistance may already be provided prior to the confirmation of a deliberate use of biological agents. Indeed, under such circumstances, it might become very hard for the affected population to distinguish between foreign military who are mandated to provide medical and humanitarian aid, like those deployed in West Africa during the 2014-2016 Ebola crisis, and those who would be deployed for security purposes and who would exhibit a more active role in a conflict situation. This confusion may exacerbate the local populations distrust, and lead to unrests and resistance which may hinder the response efforts.
16. Lastly, many unresolved questions remain on military-military cooperation and how foreign militaries might co-exist in the same space during a deliberate biological event. There is no existing best practice document or framework that provides the necessary guidance for them to effectively operate during this type of crisis.

Conflicting humanitarian and investigative missions

17. Cooperation and coordination between humanitarian or medical response actors and those involved in the criminal aspects of the investigations might pose serious practical challenges and trade-offs that require careful examination. Agencies and organisations with humanitarian mandates have access to medical, epidemiological, and other patient data that would undoubtedly be useful to a criminal investigation in the case of a deliberate event, however, such information sharing could jeopardise confidence and trust in those organisations' neutral mandate, as well as their confidentiality obligations. As such, if NGOs and other humanitarian aid oriented agencies, like the World Health Organization (WHO), appear to be working alongside law enforcement or security teams, their access to affected population may be impacted negatively, which would hinder the effectiveness of the response efforts.
18. It is particularly important that humanitarian organisations on the ground maintain the trust of the affected population, as this allows for better cooperation between responders and the community, and enables the proper functioning of coordination and control of the response by reducing the likelihood of public resistance. For communities to engage fully with the humanitarian responders, they must understand their role and the scope of their efforts, as well as trust that these agencies would stand by their reputation of neutrality and their humanitarian mandate. Moreover, in the event of a deliberate biological attack, fears concerning possible repeated attacks may be heightened, and certain humanitarian organisations may feel that sharing even non-confidential information and working alongside law enforcement agencies may put their personal at increased risk due to population, or even insurgent backlash.
19. Currently, there are no up-to-date SOPs depicting how best international humanitarian and law enforcement agencies may interact with each other, nor how and what type of information may be shared. Despite the challenges and the trade-offs posed by cooperation between the health and criminal sector, it is particularly important that such guidance documents be considered and eventually drafted in order to facilitate adequate and complimentary investigations by public health professionals and law enforcement. These procedures ought to take into account the challenges and suggest ways to overcome them.

Next steps: addressing the identified challenges

Through plenary discussions and small group workshops, the participants identified the numerous challenges described above, and came together from multiple perspectives to propose a holistic list of discrete activities to be tackled in the next several months to years.

Leadership and stakeholder mapping

20. A roster of experts, or a deliberate biological event working group, composed of responder agencies and other relevant actors, and involving the health, security, law enforcement and humanitarian sectors, ought to be created and meet regularly to address the issues identified above. This group would be tasked with a specific number of action items aimed at strengthening the IOs' capacity to prepare and respond to deliberate biological events.
21. This roster of expert would be specifically tasked with strategic and operational coordination efforts, to include planning, preparedness and exercises, and well as with the creation of a glossary of terms to standardise vocabulary across organisations and facilitate coordination. This working group would also aim to undertake a situational assessment and mapping of existing mandates, capabilities, resources and mechanisms already in place at the IO level. During this process, it is also incumbent to the organisations in question to self-assess and report back to the working group. Designing a visual representation of the all the stakeholder that would be involved in the response to deliberate biological events, their mandates and how they interrelate would be a particularly helpful tool to further clarify roles and responsibilities, and connect the existing capacities that are currently disjointed.
22. Lastly, leadership determinations may be highly uncertain and contingent on circumstances of the deliberate biological event. One solution to address this issue might be to create a coordinating group (including WHO, the UN Office for Disarmament Affairs (UNODA), and other international stakeholders, and to establish matching operating procedures and Memorandums of Understanding (MOUs) that clarify the roles between the Conventions, the state parties and the IOs. Each relevant entity would lead part of the response according to its area of responsibility and expertise.

Humanitarian response versus criminal investigation

23. Going forward it is also important to clarify the separation of humanitarian and investigative aspects of the response. International organisations should come together to design a mechanism of information sharing between the public health community and the law enforcement community in a way that respect their mandates. The first steps of this process include strengthening the relationship between the relevant health and security agencies ahead of time, identifying a core set of elements that can be shared and defining a set of agreed guidelines for investigations. Guidance might focus on ensuring effective information sharing and sustaining complementarity efforts without compromising either operation.
24. To further clarify the separation between public health investigation and law enforcement investigation, it is crucial to first agree on a standardised definition of "investigation" in particular circumstances. Importantly, it might be useful to define whether the objective of an investigation is to put blame on someone or if the investigation is solely carried out for epidemiological and clinical purposes. It could prove valuable to replicate the "no blame culture" that applies in the aviation field when investigating a plane crash. That way, the public face of any investigation should be "no blame", even if it happens in articulation with other investigative processes. In such instances, mandates for fact finding and putting blame could be different.

Leveraging existing expertise and resources

25. Member states and IOs independently harbour significant amount of knowledge, mechanisms and frameworks that could be used to inform and validate next steps. For example, 15 years ago, stakeholders were experiencing similar challenges with how to

address deliberate chemical events, yet today the OPCW has numerous SOPs, MOUs and a team of trained experts ready to deploy at all times. These frameworks and documents, which were used effectively during the recent fact-finding missions in Syria and Iraq, should be an inspiration for the future of deliberate biological event preparedness and response. While it is clear that the OPCW SOPs and guidelines are specific to chemical events, they could be used to inform biological events SOPs. The challenges and uncertainties outlined above make it difficult to identify a scenario where assistance under the BWC, as it stands today, may play an important role during a response to a deliberate biological event. Moreover, with the absence of an Office for the Prohibition of Biological Weapons (OPBW), it is unclear who would coordinate the assistance offered under Article VII. A number of options exist to address these issues, including 1) setting up a mechanism within a new OPBW or enlarge the BWC Implementation Support Unit (ISU) with experts that could perform an investigation of alleged use; or 2) duplicate the UN Secretary General Mechanism (UNSGM) and create a similar mechanism solely under the BWC; and 3) rely on the current UNSGM and strengthen its operational readiness. Option 3 may be the most viable option at the current stage, and a set of designated and specifically trained experts may be required to facilitate the drafting of SOPs and training exercises, which are crucial to ensure that expertise and experience are promptly available in the case of an investigation of alleged use.

26. Similarly, multiple member states have highly efficient national chemical, biological, radiological and nuclear (CBRN) response teams, which are well trained and have created SOPs for evidence collection that can be used jointly by responders and investigators. These member states also organise regular exercises and training programs based upon a whole government approach to promote inter-sectorial cooperation. These national level SOPs and other key strategic documents could be used as a basis for the development of international SOPs.
27. While SOPs and guidelines on secure sample packaging and transport exist, they are lacking in the context of deliberate events. Nations should be the driving force of the initiative to develop these much needed SOPs. Gold standard national forensic laboratories in particular should provide guidance and best practices to the IOs in the development of those key documents, while engaging in discussions and validation processes with a roster of international experts.
28. There is need for adequate mechanisms and standard protocols for the cross-checking of lab results in the event of deliberate biological event. Leveraging the expertise of some member states by creating a reference laboratory network for forensic investigations under the UNSGM could be a pertinent first step towards stronger forensic capacity at the international level. This reference laboratory network could also collaborate with the roster of expert in the development of gold standard protocols in the context of a deliberate event.

Medical Counter Measures (MCM) and genetic sequencing

29. In the context of deliberate events, discussions on the access to genetic sequence data and the utilisation of reference databases are plagued by many uncertainties. There are no existing procedures on the handling of genetic data during heightened security environments, and it is unclear if this data would be kept private during a forensic investigation or if, depending on the sequencing of events, it may be too late by the time deliberate use is determined. The legal implications and their impact on forensic investigations should be further explored by a circle of experts in the forensic laboratory sphere. The end result of this preliminary research could be a white paper on how these issues might impact forensics and what it might mean in the context of deliberate events.
30. There is a need to clarify Medical Countermeasure (MCM) stockpiling strategies and procurement mechanisms. MCM are a crucial part of the response to infectious diseases crises, natural or deliberate, and the international community should look

back on past epidemics to draw lessons on the difficulties of delivering MCMs to an affected country. To this day, challenges and uncertainties remain on who might be responsible for guaranteeing the expedited clearance through customs of a particular MCM, who might be in charge of providing security at the airport, during transit or storage, and how the MCM will be moved and distributed at the site of the outbreak. The Ebola crisis of 2014-2016 in particular highlighted how the lack of an approved drug or vaccine at the beginning of the outbreak made the discussions on the bioethics for clinical trials and compassionate use authorisation even more relevant in crises situations. These issues ought to be discussed and untangled prior to a crisis, in order to allow for the development of procedures and rules for the use unapproved countermeasures in time of emergencies; and contracts for equipment and assistance could be placed with potential suppliers ahead of time.

Conclusion

This Wilton Park meeting gathered experts from different fields, with different perspectives and experiences, to undertake a practical and thorough discussion on how IOs and member states can effectively come together to implement collaborative action in the event of the use of a biological weapon. Participants identified a large number of interconnected challenges, and recognised that this meeting would be the first of many more to come. Despite the difficulties ahead, the participants acknowledged that deep expertise already exist amongst the different international stakeholders, proposed a holistic set of activities that leverage such expertise, and agreed upon a discrete list of tasks required for moving forward.

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