UNSGM Designated Laboratories Workshop Report

Spiez, Switzerland
20 – 22 June 2017

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Acknowledgements

The third UNSGM Designated Laboratories workshop took place from 20 – 22 June 2017 in Spiez, Switzerland.

The following Swiss Federal Departments made the workshop possible:

- Swiss Federal Department of Foreign Affairs
  - Directorate of Political Affairs, Division for Security Policy
- Swiss Federal Department of Defence, Civil Protection and Sports
  - Staff of the Armed Forces, International Relations Defence
  - Federal Office for Civil Protection, Spiez Laboratory

The organisers express particular thanks to Ralf Trapp (Disarmament consultant) and James Revill (University of Sussex) for their help in preparing this report.

Spiez Laboratory, the Swiss Federal Institute for NBC-Protection, is responsible for the content of the report. It does not reflect an official Swiss position.

Executive Summary

This was the third of a series of workshops organised by Switzerland with the objective to develop practical steps towards a functional network of trusted laboratories designated under the United Nations Secretary-General's Mechanism (UNSGM) to support investigations of alleged use of biological and toxin weapons. Building on previous workshop outcomes, participants discussed the value of a scoring system for laboratory methods and explored best practice approaches in a table-top exercise format. Three expert groups from the classical fields of virology, bacteriology, and toxinology started to develop a common understanding on adequate analysis and quality assurance criteria as well as defining a reasonable way forward in practical terms.

For any kind of UNSGM investigation that includes an analysis of samples by roster laboratories, the ultimate goal is the establishment of a clear sample provenance, a fully respected chain of custody, and a demonstrable technical competence for the analytical tasks required and performed, which would thereby reduce or eliminate the scope for political challenge. This is particularly relevant in the context of biological weapons investigations, given the absence of a dedicated and resourced international organisation. A collaborative network that provides confidence and trust in each laboratory's scientific competence and analytical skills as well as in its applied quality assurance systems is therefore of utmost importance.

In an investigation of alleged biological weapons use, isolation and cultivation of the causative agent may not always be achievable. To reach an acceptable level of confidence in laboratory results, analysis might therefore have to rely on the application of orthogonal complementary methods which, in turn, would necessitate the assignment of values. Although such a scoring system on its own would likely not be suitable as independent proof of biological weapons use, it could, when applied in a flexible manner, still serve as a guidance tool for the unambiguous identification and deeper characterisation of a causative agent. In the end, such scored results contribute to the overall evidence a UNSGM mission would have at its disposal to conclude whether an incident was the result of deliberate use or a natural event.

To develop a functional network of trusted laboratories designated under the UNSGM, practical steps that take into account the demonstration of laboratory competence and the conduct of inter-laboratory calibrations, as set out in the UNSGM Guidelines and Procedures, are required. The three expert groups identified several key factors for acceptance of laboratory results, particularly in the political context of a UNSGM investigation. High standards in quality assurance were considered of prime importance and should include accreditations, the use of quality-assured reference standards and library data as well as appropriate controls. Participants recognised that an unambiguous identification of a causative agent in the setting of a UNSGM mission will depend on both context and mandate. Depending on the scenario, there would be merit in a UNSGM Designated Laboratory acting as hub laboratory and thus providing reach-back capability for the field team, especially when inherently complex technical questions related to sampling, laboratory analysis, and any processes in-between need to be answered. In order to tackle several of these aspects practical work is required, such as the conduct of confidence building exercises which was deemed conducive by the participants. Piggy-backing on existing external quality assurance exercise schemes should also be encouraged. This approach would allow for the development of appropriate reporting standards that, at the same time, need to remain adaptable to a given context and mandate.

Several factors that would need to be taken into account, in order to successfully move towards a trusted network of UNSGM Designated Laboratories, were highlighted. Inclusiveness, both in terms of scientific scope

and geographical representation, was deemed key. The UNSGM roster of laboratories should include both generalist as well as specialised laboratories, in order to reflect a comprehensive mix of laboratory capabilities. Although a UNSGM investigation differs significantly from a public health / veterinary response to a disease outbreak, a close collaboration with other existing laboratory networks would still be desirable and add value. Not only would such a laboratory network act as a platform to share good practices, it would also function as a curator of generally accepted performance criteria based on validated and mutually accepted analytical methods, reference materials, and reference data. In the absence of adequate staffing and financial allocation in the regular budget of the UN Office of Disarmament Affairs, leadership and support for these technical aspects will eventually have to be provided by the laboratories themselves.

Workshop participants identified a number of initial practical steps of a 'not yet' fully developed roadmap. These steps included preparation of a checklist containing the minimum requirements that laboratories should meet, continuation of the discussion on the value of a scoring system for laboratory methods and increased confidence through the conduct of external quality assurance exercises. Further steps would be the development of sample guidelines taking into account existing sample acceptance criteria of laboratories, the elaboration of a reach-back concept that would involve a UNSGM Designated Laboratory as hub laboratory, further discussions on the curation of reference databases and materials, development of training packages, as well as assessment of the nomination status to the UNSGM laboratory roster. Finally, through bolstering the efforts of the Organisation for the Prohibition of Chemical Weapons (OPCW) more support for the UNSGM could be achieved.

As a consequence, a number of activities at working level were offered as immediate follow-up steps. In the autumn of 2017, a meeting will be held in Berlin in order to further the discussions on the value of a scoring system for laboratory methods. This will be followed promptly by a confidence building exercise with inactivated bacteria or isolated genetic material. A second effort is geared to the conduct of yet another confidence building exercise in the form of a dry lab test that would use artificial virus sequencing data. In the field of toxins, the preparation of an input paper on priority toxins is expected which could also serve as a basis for encouraging and empowering the OPCW to include other relevant toxins in future exercises. Finally, a web-based solution for sharing documents electronically amongst participants and serving as a repository of knowledge will be set up.

Switzerland will host a fourth workshop in the second week of September 2018 that will take stock of the progress made in the intersessional period at working level. It will discuss next steps towards a robust quality assurance system for UNSGM Designated Laboratories in order to further develop them into a global trusted network.

1. Introduction

This report presents the outcomes of the third Swiss workshop organised by Spiez Laboratory on steps towards establishing a network of trusted laboratories designated under the United Nations Secretary-General's Mechanism (UNSGM) to investigate allegations of the use of chemical, biological and toxin (CBT) weapons. The workshop was attended by 54 participants from 17 countries, the UN Office of Disarmament Affairs (UNODA) and several other international organisations.

The Swiss initiative complements activities to improve existing capabilities and to strengthen the operational capacity of this mechanism by the UNODA as well as by UN Member States. These activities are also supported by a number of competent international organisations, including the Organisation for the Prohibition of Chemical Weapons (OPCW), the World Health Organisation (WHO), the World Organisation for Animal Health (OIE), the International Police Organisation (INTERPOL), and others.

The overall objective is to strengthen the operational capacity available to the international community to investigate allegations of the use of CBT weapons. The efforts to invigorate the operational capacity of the UNSGM complement endeavours to strengthen both the Biological and Toxin Weapons Convention (BTWC) and the Chemical Weapons Convention (CWC). These efforts remain particularly pertinent given the dual use nature of the life sciences, the pace at which science and technology are advancing in this field, and the lack of a verification mechanism under the BTWC.

The UNSGM is a mechanism supported primarily by the UN Member States. It lacks an institutional support structure and therefore depends critically on what Member States make available to it, and on what partner organisations, such as the OPCW, the WHO, the OIE and INTERPOL, are able to contribute. The UNSGM faces particular challenges in the area of biological weapons where there is no dedicated and resourced international organisation, such as the OPCW, that bears responsibility and has the technical competence to conduct such investigations. Several Member States have supported the operationalisation of the UNSGM by providing training for roster experts as well as through financial contributions to the UNODA. Despite the absence of human and financial resources in its regular budget, the UNODA has been providing leadership, has made best use of national training offers, experts and expert consultants, and it coordinates closely with partner organisations.

One particular challenge is the ability of UNSGM missions to call upon roster laboratories to conduct analyses in support of their investigations. Previous workshops and discussions have helped to clarify the role that laboratories designated to the UNSGM would have to play in an investigation. These discussions have also underlined the importance of developing a collaboration network to provide confidence and trust in their scientific competence and analytical skills as well as in the quality assurance systems they apply. This is comprised of the validation of methods, standards and reference data, the use of robust quality assurance systems, and rigid adherence to the necessary administrative and reporting procedures which includes the maintenance of an unbroken chain of custody throughout their involvement in a UNSGM investigation.

Building on these previous discussions, the third UNSGM Workshop in Spiez focussed on practical aspects of launching a bottom-up approach towards developing such a network. The workshop pursued the following objectives:

1. Considering a proposed scoring system for laboratory analysis methods;
2. Exploring best practice approaches for laboratory analysis of specific samples in a table-top exercise;
3. Developing a common understanding of adequate identification and quality assurance criteria;

4. Establishing three expert groups in the fields of virology, bacteriology and toxinology which will continue their activities after the workshop.

Previous workshops elaborated on the differences between investigations of an alleged use of chemical weapons, for which the OPCW has set up its own networks of designated laboratories (one for environmental samples, a second one for biomedical samples), and UNSGM investigations pertaining to the alleged use of biological weapons. In biological investigations, identification of an agent by itself may not be sufficient to conclude whether or not a biological weapon has been used. The work of off-site laboratories will not only include the unambiguous identification of the causative agent but will have to go further into a detailed characterisation of the agent in order to discriminate between a natural occurrence and a deliberate use of a biological weapon.

2. Discussion of a Scoring System for Laboratory Methods

The gold standard for the identification and characterisation of a biological agent is isolation and cultivation, followed by characterisation of the agent with a range of suitable methods. In an investigation of alleged biological weapons use, isolation may no longer be possible, depending on the specific circumstances. In the case that a dissemination device were to be found, it may still be possible to collect conclusive evidence of a biological attack, even without a live agent being isolated. But there are also scenarios where neither a biological weapons device nor a live agent can be secured.

Discussions at the previous workshop suggested that in such situations, laboratory analysis might have to rely on the use of orthogonal complementary methods that, taken together, would allow the unambiguous identification and characterisation of a causative agent at an acceptable level of confidence. This, however, would require assigning scores (weighing factors) to the analytical methods used. The aim would therefore be an objective methodology that does not depend on subjective interpretations of individual experts. In other words, what would be needed is a scoring system that allows weighing and then aggregating analytical results from different methods, recognising that none of them would allow for an unambiguous agent identification on its own.

The methodological basis for the presented approach was described 15 years ago.[1] To assess whether a biological weapon has been used or a disease outbreak was more likely of natural origin, it combines political considerations, military analysis, regional factors, epidemiology, and the results of analytical tests by laboratories. But the methodology can also be adapted to weighing and combining laboratory results only. In this sense, a scoring system can be of use for the unambiguous identification and deeper characterisation of a causative agent – as part of the overall evidence a UNSGM mission would have at its disposal to conclude whether an incident was the result of a hostile release or a natural event.

Crucial for the acceptance of such an approach would be an agreement among experts about the scores to be used. A NATO standard already exists, but it is very ambitious and requires an aggregation of positive results from genetic, immunological, as well as functional tests in suitable animal models. Also, it relies on access to live agents. The approach presented in detail at this workshop is more practicable and relies on a scoring system that combines sample types with the results obtained from a range of laboratory methods (e.g. spectrometry, antigen detection, classical microbiology, serology, light or electron microscopy, PCR, DNA sequencing including next generation sequencing methods). The workshop briefly discussed some illustrative examples to assess the degree of confidence in agent identification by combining the findings of multiple analytical methods. This proposed scoring methodology would allow the distinction between unambiguous identification of an agent and an identification that could be considered as confirmed, or positive, or preliminarily positive, or doubtful.

Workshop participants stressed that whoever sets the scores, and how this was done, would be critical for the acceptance of the conclusions in a political context. The ultimate goal should aim for the establishment of a clear sample provenance, a fully respected chain of custody, and a demonstrable technical competence for the analytical tasks required and performed, that would thereby reduce or eliminate the scope for

[1] Grunow, R. and Finke, E.-J. (2002), A procedure for differentiating between the intentional release of biological warfare agents and natural outbreaks of disease: its use in analyzing the tularemia outbreak in Kosovo in 1999 and 2000. Clinical Microbiology and Infection, 8: 510–521

political challenge. With regard to the scores, these would therefore need to be agreed in a transparent manner based on actual data, for example from testing schemes or past outbreaks, and by agreement among qualified experts. The selection of these experts would have to be inclusive and within an internationally recognised framework.

Another concern was that a rigid methodology might in certain scenarios underrate particular findings that are in fact highly relevant with regard to demonstrating whether or not a biological or toxin weapon had been used. For example, methods that are of little relevance for one type of agent may be highly relevant for another, such as electron microscopy in the identification of certain viruses. Furthermore, the evidential weight of laboratory findings may change significantly when weapons remnants or dissemination devices have been found. Any scoring system, therefore, needs to be applied in a flexible manner.

There is also a potential problem that such a scoring system for clinical samples would be at odds with the internationally agreed case definitions developed by the WHO and the OIE for several diseases. These case definitions are based on clinical and epidemiological parameters combined with laboratory confirmation by a competent reference laboratory. These laboratory investigations are usually undertaken at a time when isolates can still be secured for culture and characterisation, whilst the scoring system proposed for UNSGM investigations would in most cases become relevant at a later point in time when isolation is probably no longer possible. An investigation under the UNSGM is not part of the outbreak response, nor is it a diagnostic tool in the public health / veterinary response, and the most likely scenario is that it would be activated after the public health / veterinary systems have already responded to an outbreak. Therefore, the relationship between laboratory analyses performed as part of the outbreak response and laboratory data from designated laboratories as part of a UNSGM investigation needs to be further clarified in the context of clinical samples.

The discussions also recalled that the scoring system could be a useful tool to aggregate laboratory data to allow the unambiguous identification of a causative agent, but that identification by itself usually did not suffice to answer the question of whether or not a biological weapon had been used. Laboratory data, even after unambiguous identification, still need to be interpreted in the given context of an investigation, together with other information such as clinical and epidemiological data, testimonies and interviews, and contextual information or weapons remnants.

On the other hand, a scoring system might be a useful tool for UNSGM Designated Laboratories to substantiate their own level of confidence in the conclusions they draw from their analytical tests. Particularly in situations when they can no longer isolate the causative agent and need to rely on a combination of data from several independent analytical methods, none of which would allow an unambiguous identification on its own. It might also serve as an internal guidance for designated laboratories when communicating the confidence they have in their findings and conclusions to the UNSGM. As a consequence, such an approach could make the results and conclusions obtained by different roster laboratories through various methods more comparable.

The participants noted that similar scoring methodologies are being used in a number of countries in the context of forensic investigations of crimes. In these scenarios, the weight of different types of evidence is established against agreed criteria and combined into a single score, which is then communicated as the overall probability of a culprit having committed the criminal act. But whilst the courts of these countries are expecting this approach of communicating the results of forensic investigations, evaluating the results of a UNSGM investigation is as much a political process as it is a judicial matter. Whilst a scoring system may help to put the evaluation and presentation of la-

boratory findings on a more objective basis, it is unlikely that Member States would simply accept the results of such a scoring methodology as independent proof of biological weapons use.

The discussion nevertheless concluded that it would be worthwhile to further the proposed scoring methodology, bearing in mind that there is a need for flexibility. The scoring system has to be developed based on expert consultations, peer review and exercises. And ultimately, it would be important to more clearly establish the purpose of the methodology in the broader context of a UNSGM investigation.

3. Exploring Best Practice Approaches in a Table-Top Exercise

The second segment of the workshop was intended to further clarify requirements and practical steps towards the development of a network of trusted laboratories under the UNSGM. The basic requirements, such as the conduct of inter-laboratory calibration tests and the demonstration of laboratory competence, are set out in the UNSGM Guidelines and Procedures. The workshop discussed the need to develop a roadmap towards such a trusted network, and it identified certain initial key steps towards that end. It is important to ensure that laboratory results used as evidence in a UNSGM investigation meet a certain standard of acceptability in what is essentially a political context.

The workshop approached this task in the form of a table-top exercise (TTX), split into the classical disciplines of bacteriology, virology, and toxinology. The TTX used a simplified scenario inspired by a previous UNSGM field exercise conducted in Germany in 2014, in collaboration with the UNODA. The TTX was not a fully-fledged exercise because it was not conducted with an evolving scenario and was not using role-playing techniques. Instead, the scenario served as a background for creating a realistic context within which participants were able to discuss, in a structured manner, requirements and possible solutions with regard to the role of designated laboratories in support of a UNSGM investigation, and to identify key elements of a roadmap towards a trusted laboratory network. The scenario did, however, fully respect the UNSGM Guidelines and Procedures.

The participants were asked to address a set of specific questions to bring out key factors for acceptance of laboratory results in the political context of a UNSGM investigation. This included questions such as assured sample provenance, chain of custody from sample acquisition to laboratory analysis and reporting, how to demonstrate the scientific competence of the laboratory for the analytical tasks given to it and its ability to comply with the administrative and quality assurance requirements.

The results of these discussions were briefly summarised and discussed in a hot-wash session immediately after the exercise. After overnight reflection, the subsequent workshop session allowed for deeper probing into the findings and recommendations that had emerged from the exercise.

Whilst the groups worked separately using different specific storylines of the TTX scenario that matched the three disciplines (bacteriology, virology, toxinology), a number of commonalities emerged. These included:

- The acceptability of laboratory findings and of the conclusions drawn from them depends on the confidence in the analytical methods used, as well as in the laboratories involved in the analysis. Acceptability is ultimately driven by several factors, such as the use of validated methods and standards, applied quality control systems, the reputation of the laboratory based on its scientific merits and standing, its record with regard to quality assurance and compliance with chain of custody requirements, its accreditation for the methods used in the investigation (ISO 17025, ISO 15189, or equivalent national standards), and its overall scientific competence relevant to the tasks it was given by the UNSGM mission.
- There is no “silver bullet” – no single analytical technique is likely to provide a fully accepted answer to the question of whether a biological or toxin weapon had been used. Unambiguous identification of the causative agent of a possible biolog-

ical weapons use will be both context and mandate dependent. In this regard, laboratory data need to be interpreted in the broader context of the investigation and in connection with other evidence gathered by the UNSGM mission.

- The cooperation between the UNSGM mission team and the designated laboratories that have been selected to conduct the analyses of samples collected by the field team(s) is crucial – and in a biological or toxin weapons investigation it will have to be different from the OPCW procedures developed for investigations of the alleged use of chemical weapons. The OPCW approach works with a firewall between the investigation team in the field and the designated laboratories tasked to undertake the off-site analysis. The laboratories do not interact with the field team, although they will receive some general information about the investigation context. In other words, they obtain very few details regarding sample provenance and collection, and receive sets of coded vials containing authentic and control samples without being able to tell which is which. This anonymised system was established to ensure high confidence in the independence and impartiality of the laboratories and the quality of the analytical results. The detection and unambiguous identification of several types of CW agents or their characteristic degradation products carries by itself a very high evidential weight with regard to demonstrating that a chemical weapon had been used.

- In a biological or toxin weapons investigation, this may not be the case, as a natural occurrence cannot always be ruled out. At the same time, for epidemiological reasons, sampling strategies and plans as well as applied techniques can be more complex than in a chemical weapons investigation. A UNSGM laboratory could therefore act as a hub by providing a reach-back capability for the field team. This way, it could give advice on the most appropriate types of samples, how to collect, process, pack and transport them, and on required steps to comply with any import / export regulations that may apply. The field team and the hub laboratory could also share contextual information that could be selectively provided to the analysing laboratories. The discussions during the workshop also highlighted the desirability of developing detailed sampling guidelines for field teams that should go hand in hand with sample acceptance criteria of laboratories.

- A further issue that still needs to be addressed was the screening of samples before or upon receipt by designated laboratories for threats other than CBT agents, such as radiological hazards or explosives. Whilst some laboratories nominated to the UNSGM roster may have appropriate screening facilities in place, others may not. Hence, acceptable safe pre-screening procedures would need to be set up.

- All three groups opted for a step-by-step approach, beginning with screening methods such as PCR, ELISA, functionality testing, or protein quantification in the case of toxins. This approach allows for preliminary results within short time frames and serves to guide subsequent, more detailed and deeper analyses. Preliminary screening results will help prioritise subsequent detailed analyses as well as select the most appropriate analytical method. This initial screening would also support decisions about whether cultivation and isolation are possible, or other methods

ought to be used. The discussions highlighted the timing of sample collection and, depending on agent load, the sample amount as potentially limiting factors.

- There is a need to use validated methods and benchmarking, as well as to have methods published and protocols shared among the designated laboratories. Similarly, the importance of quality-assured reference standards and library data was underscored. There was also broad agreement that quality needs to be assured by using positive (spiked) and negative (blank) controls as well as method controls. Accreditation of the methods used in accordance with ISO standard 17025 / 15189 or equivalent would be important.
- To make progress towards the development of a network of trusted UNSGM laboratories, the first practical steps should have the character of confidence building exercises. The focus should lie on learning and sharing experiences, exchanges of good practices, and details of the analytical methods and standards used. It was considered beneficial to piggy-back, as far as possible, on already existing external quality assurance exercise schemes.
- Information management is an important aspect of any UNSGM investigation. With regard to the involvement of designated laboratories, the management of quality assurance systems and chain of custody measures will be essential. Laboratories that have been designated by Member States to the UNSGM roster may need guidance and coaching to ensure that they are fully aware of these requirements and trained accordingly.
- Reporting by the designated laboratories is equally critical. Once an inter-laboratory testing system has been developed, it can be used as a tool to agree on and train the use of appropriate reporting standards and formats. The groups, at the same time, recognised that the actual content of laboratory reporting will heavily depend on the given mandate. Reporting templates may thus differ from OPCW standards. There should be a balance between templating reports in advance and ensuring flexibility to adapt laboratory reporting to the specific context of the mission and the tasks given to the laboratories.
- Finally, there was general agreement that it is important for the laboratories to aim for continuous improvement, and to make use of advances in science and technology, including improved analytical methods, instruments, standards, reference materials, and data analysis tools.

The selection of designated laboratories to support a particular UNSGM mission would be based on mission-relevant expertise and reputation. This includes factors such as regular activities of a laboratory in fields that are relevant to the particular investigation, its publication record, the level of transparency about its work, quality assurance systems in place and results obtained in respective exercises, its status of accreditation, training records of staff, and accessibility.

In addition to these commonly observed issues, the groups also identified certain aspects that were specific to their particular scientific discipline. These included:

- Constraints need to be taken into account in case the causative agent was suspected to be smallpox or, for that matter, another eradicated virus. In those cases, there may be restrictions on which laboratories would be allowed to store, culture, isolate, and investigate samples, and there may be special regulations regarding shipment and notifi-

cations. In the case of smallpox, for example, only two laboratories act as global repositories of live variola virus, and work with the variola virus and its DNA sequence is tightly regulated.[2, 3]

- The procedures for virus identification and characterisation need to be able to discriminate against hoaxes and synthetic items that pretend to be a virus. Whilst this can in principle be done through whole genome sequencing and comparisons with strain collections, the question would need to be further considered of how comprehensive these reference libraries are and whether the data have been properly validated.
- The time needed for the cultivation of unknown viruses can be significant. It may turn out that only after many weeks of laborious cultivation experiments the conclusion may emerge that the isolate was not viable or not relevant for the investigation. The reporting times used by the OPCW in investigations of alleged chemical weapons use may therefore not be achievable in such cases, and it would be imperative to manage expectations about how quickly the results of laboratory analyses can be provided.
- In the case of investigations of alleged toxin weapons use, toxins other than ricin and saxitoxin will be of relevance to UNSGM investigations. The efforts of the OPCW in the field of toxin analysis, important as they are for furthering the international capabilities of investigations in this field, have so far focussed solely on the two toxins listed in Schedule 1 of the Chemical Weapons Convention. The OPCW would be an obvious international lead organisation to further develop the toxin analysis capacity for weapons investigations. Competent laboratories that have experience in toxin analysis could provide support to the OPCW, encouraging and empowering it to include other relevant toxins in its future work. Finally, it was pointed out that there was a need to further consider criteria for unambiguous identification of toxins.

[2] http://www.who.int/csr/disease/smallpox/variola-virus-research/en/

[3] http://www.who.int/csr/disease/smallpox/handling-synthesis-variola-DNA.pdf?ua=1

4. Moving Towards a Trusted Network

The workshop underlined the importance of other factors that need to be taken into account when developing and agreeing on a roadmap towards a trusted UNSGM Designated Laboratory network.

First, it is important to ensure that the evolving network will be inclusive, both in terms of scientific scope by covering the broad range of possible agents and geographical representation. Whilst some of the laboratories that have been nominated by Member States to the UNSGM have already been sensitised for the need to create and develop the network, and all roster laboratories have been kept informed by the UNODA about the results of the previous UNSGM laboratory workshops, the number of laboratories that have actually participated in these discussions remains limited and their geographical distribution is as yet not fully representative.

Second, the discussions underlined that the UNSGM roster of laboratories should be composed of a mix of capabilities. There is a requirement for both generalist laboratories and specialised laboratories that are proficient in particular biological agents.

Third, the evolving UNSGM laboratory network would benefit from close collaboration with other relevant laboratory networks, including the OPCW's network of designated laboratories and the networks of collaborating centres and reference laboratories of the WHO and the OIE. To some degree, there is likely already an overlap between these networks in terms of capabilities but also participation. At the same time, it is important to recall that a UNSGM investigation is not part of, and distinct from, the public health / veterinary response to a disease outbreak. A UNSGM investigation will likely have to deal with environmental samples and not exclusively with samples of a clinical nature. It will therefore be important to further clarify the relationship between a UNSGM investigation and the outbreak response.

Fourth, there is a need for transparency and information sharing between the laboratories nominated to the UNSGM roster. The workshop welcomed that the UNODA had committed to approach Member States about whether they would be willing to share information about the laboratories they have nominated to the UNSGM roster.

Fifth, with regard to laboratory analysis, the overall goal would be to develop a UNSGM laboratory network that functions as a curator of generally accepted performance criteria based on validated and mutually accepted analytical methods, reference materials, and reference data. The network would also need to act as a platform to share good practices, to increase the knowledge in capabilities and capacities of the participating laboratories, and to share information among them.

Sixth, the setting up of such a network will require leadership by the UNODA, as well as leadership and support by the laboratories themselves. At the same time, there is a risk of setting the stakes too high given the limitations in resources available to UNODA, the still limited participation of laboratories nominated to the UNSGM roster, and the constraints that the laboratories themselves face. It will therefore be important to set achievable goals and agree on realistic time frames for actions to be taken.

Finally, with regards to lack of financial and human resources, several factors will contribute to overcome some of these constraints, through collaborative efforts and by using opportunities as they present themselves. Such factors include an as broad as possible geographical distribution of the UNSGM roster laboratories that participate in the network, links to relevant international laboratory networks (OPCW, WHO, OIE) and centres of excellence, coordination with the work of the OPCW to enhance investigation and laboratory capacities, and the efforts under the BTWC (for example with regard to the operationalisation of Article VII).

5. Way Forward

A roadmap towards a trusted UNSGM Designated Laboratory network would be important to help Member States to plan and align a common strategy to strengthen the operational capacity of the UNSGM. It would help to avoid fragmentation and create synergies between individual contributions of Member States, and would thus be useful for setting priorities and identifying opportunities and challenges.

The workshop noted the intention of UNODA to make more use of the expert consultants nominated by Member States to the UNSGM, and welcomed the meeting with expert consultants that the UNODA was planning to host in autumn. Participants suggested that this would be an opportunity to involve expert consultants in the discussions of a strategy for further developing the UNSGM laboratory network. This would include the development of sampling guidelines by taking into account laboratory acceptance criteria, the training of chain of custody procedures for designated laboratories, and the agreement of mutually accepted identification criteria.

The workshop also noted the desirability to set up an electronic platform for authorised UNSGM roster experts, expert consultants, and laboratories to allow them to share information and experiences, provide access to contact details and to support other functions in the network, including acting as a repository of relevant documents. The electronic platform developed by the CTBTO Preparatory Commission could serve as a point of reference.

It was apparent from all the considerations summarised above that the workshop was not in a position to actually adopt a fully developed roadmap. The participants of this core network did, however, identify a number of practical steps towards the formation of a trusted UNSGM Designated Laboratories network:

- Agree on a checklist of minimum requirements that laboratories nominated to the UNSGM roster should meet, including accreditation, and the use of validated methods and reference standards. These minimum requirements would not only be related to the specific tasks and types of analyses that the laboratories are expected to perform, but also to the biosafety and biosecurity requirements they ought to meet.
- Further the discussion on a possible scoring system for the identification of biological agents in circumstances when isolation and cultivation can no longer be accomplished. This would include the evaluation of the pros and cons of such a system, an iterative development of a scoring table by peer review, testing and validation in external quality assurance exercises, and discussion of the relationship to existing WHO / OIE case definitions with regard to clinical samples.
- Conduct confidence building and external quality assurance exercises by starting with isolated genetic material or inactivated biological agents.
- Assess the current nomination status to the UNSGM laboratory roster. This should include a capacity and gap analysis with regard to the coverage of different biological and toxin agents, and available laboratory capacity; the identification of needs to further expand the network; and opportunities of developing liaisons to other relevant laboratory networks including the OPCW, the WHO and the OIE.
- Reinvigorate the efforts of the OPCW in areas that can support the UNSGM, such as encouraging the inclusion of other priority toxins in future exercises to enhance toxin

analysis capabilities, avoiding duplication of efforts, expanding the UNODA-OPCW collaboration beyond a narrow limitation on investigations of the alleged use of chemical weapons, and making relevant OPCW experience available to biological weapons investigations.

- Make use of other relevant projects that could help develop the UNSGM laboratory capacity further. Examples include EuroBioTox[4] and EMERGE[5].
- Develop sample guidelines by taking into account sample acceptance criteria of laboratories. Guidelines should make reference to sample collection, processing, packaging, shipment, as well as chain of custody procedures.
- Elaborate on a reach-back concept that would involve a hub laboratory which adequately links a UNSGM mission with the UNSGM roster laboratories conducting the off-site analyses.
- Curate reference databases and materials / collections, in order to identify gaps as well as detect reference data of uncertain quality. This should also apply to exotic agents of low priority for public health / veterinary services but with relevance to UNSGM investigations.
- Develop a training package for designated laboratories in the fields of chain of custody and forensics awareness. This should include training on specific reporting requirements under the UNSGM.

The support and participation of interested laboratories to further this agenda will continue to be critical for making progress. The UNODA can promote this process and provide guidance, also by making use of the expertise of expert consultants nominated by Member States. A next opportunity in this regard will be the meeting that the UNODA will be hosting for UNSGM expert consultants in the autumn of 2017, and the responses to its Note Verbale concerning information sharing on laboratories nominated to the UNSGM roster.

It will be very important to secure longer-term funding to support the different efforts of enhancing the operational capacity of the UNSGM. Some short-term opportunities were identified (see below), but other funding sources and mechanisms are needed as well. Moving ahead with developing the laboratory network is an important aspect, as much is the promotion of other aspects of the mechanism, including training of roster experts, table-top and field exercises, and the adoption of agreed operating procedures. The workshop discussed some potential funding options, such as national offers, EU funding mechanisms (e.g. Horizon 2020, the Instrument contributing to Stability and Peace (IcSP), Council Decisions, partnerships with the EU project EMERGE on efficient response to highly dangerous and emerging pathogens at EU level), or synergism with the work on BTWC issues under the auspices of the Implementation Support Unit and supported by financial contributions from some BTWC Member States and the EU. But participants also noted that it was desirable to strengthen the resources available to the UNODA in support of the UNSGM. The current situation is characterised by the absence of adequate staffing and financial allocation in the regular budget, and UNODA's capacity to work on the UNSGM depends on the use of consultants and on offers coming from Member States. This creates unpredictability, and makes planning uncertain and short-term. A solution should be found that would create a more sustainable and predictable long-term capacity within UNODA.

As immediate steps following the workshop, a series of activities at working level were offered and welcomed by workshop participants, making use of existing funding opportunities and responding to a number of is-

[4] http://www.rki.de/DE/Content/Institut/OrgEinheiten/ZBS/ZBS3/EuroBioTox.html
[5] http://www.emerge.rki.eu/Emerge/EN/Home

sues that the workshop had identified as critical. These follow-up steps are open to all UNSGM roster laboratories, and the UNODA offered to inform them accordingly.

The offers included:

- Hold a meeting in Berlin in the autumn of 2017 to further discuss the scoring system, and conduct a confidence building exercise with inactivated bacteria or isolated genetic material (Point of contact: Mr Roland Grunow, RKI Berlin, Germany; funding offered by Germany);
- Conduct a confidence building exercise in the form of a dry lab test using artificial virus sequencing data (Point of contact: Ms Karin Hjalmarsson, FOI Umeå, Sweden; to be implemented in collaboration with the Global Microbial Identifier (GMI) – Technical University of Denmark, and with financial support by the United States of America);
- Set up a correspondence group on toxins regarding priority toxins, sampling guidelines and criteria for analytical methods; the group will attempt to prepare an input paper on priority toxins for consideration by the meeting of expert consultants nominated to the UNSGM in the autumn of 2017, as well as by the OPCW (Point of contact: Ms Cerys Rees, DSTL Porton Down, United Kingdom of Great Britain and Northern Ireland);
- Finally, Spiez Laboratory offered to establish a SharePoint solution for sharing documents electronically among the workshop participants and other interested experts (accessibility will be tested to ensure compatibility with cyber security measures).

During the second week of September 2018, Spiez Laboratory is planning to hold its fourth UNSGM Designated Laboratories Workshop. This workshop will take stock of the progress made at working level, and discuss further steps towards a trusted network of UNSGM Designated Laboratories. These steps should include actions leading to a robust quality assurance system for these laboratories.