MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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EUROPEAN WIDE EXTERNAL QUALITY ASSURANCE EXERCISES FOR DETECTION OF HIGH THREAT BACTERIA

Submitted by Germany

1. The causative agents of diseases like plague, anthrax, tularemia and others being suspected for deliberate release require BSL3 laboratory containment and are mainly diagnosed by in-house assays. Reference materials and quality assurance exercises for diagnostics are rarely available or difficult to arrange.

2. Internal and external quality assurance of laboratory diagnostics requires wet labs and ring trials, the provision of appropriate reference materials, training assistance, and procedural improvements. The readiness to take over the responsibility for preparing and conducting an external quality assurance project is limited.

3. The situation of laboratory preparedness to diagnose agents of potential bioterrorism risk across the European Union is not well known. For this reason, DG SANCO, the Directorate of the European Commission responsible for Health and Consumers, launched a tender on „Setting up quality assurance schemes for diagnosis of very high threat pathogens“. In 2006, the Robert Koch Institut laboratory unit in Wernigerode was chosen as executing agency. Fourteen laboratories in 13 European countries participated in this project that finally ended with a strong requirement for improvement of the diagnostic capabilities for high threat pathogens.

4. To continue quality assurance work, another project “Establishment of Quality Assurances for Detection of Highly Pathogenic Bacteria of Potential Bioterrorism Risk” was

granted by the Executive Agency for Health and Consumers (EAHC) to the Robert Koch Institut in Berlin in May 2008. In this project 24 laboratories from 20 EU Member States and Norway collaborate.

5. The overall aims and challenges of this project are:

(i) broad participation,

(ii) analysing laboratory capabilities and their optimisation,

(iii) sustained effect by setting up a network, including exchange of information,

(iv) training of and visits to laboratories,

(v) gaining experience for national attempts to improve diagnostics.

6. The specific challenges include:

(i) an agreement between the collaborating laboratories for providing reference materials,

(ii) aspects of biosafety and biosecurity,

(iii) transportation of samples/reference materials, including export/import/transfer controls.

7. The project foresees three rounds of external quality assured exercises for the detection of the following high threat bacteria: B. anthracis veg. and spores, Y. pestis, F. tularensis ssp. holarctica and ssp. tularensis, B. mallei, B. pseudomallei, B. melitensis, B. abortus, C. burnetii as well as closely related bacteria. Each of the rounds includes approx. 30 samples for each laboratory. The first round comprised of inactivated samples and DNA. The second and third round will include native samples with pure and mixed cultures as well as samples in more complex matrices (e.g. clinical and environmental surrogates).

8. The first round in March 2009 was based on 15 DNA samples from 9 target pathogens and 6 closely related bacteria and on 15 samples of thermally or chemical inactivated bacteria in 3 different matrices.

9. This round aimed to

(i) identification by molecular and/or immunological and/or other methods,

(ii) gathering data on the time needed for identification of the 15 DNA samples,

(iii) gathering data on the detection limit by titration of DNA samples,

(iv) analytical specificity, and

(v) additional characterisation or approaches like genotyping.

10. The average time for distribution of the samples to the laboratories was approx. 20 hours. Eleven of the laboratories needed up to 6 hours for transmitting the first results of DNA samples, five labs needed up to 12 hours and 5 labs more than 12 hours. The sensitivity (detection limit by end-point titration) mean deviation was about +/- 100 copies, but with some labs with much higher deviation. Regarding DNA samples, the first round ended with 10 out of 21 laboratories with 100% correct results. Eleven out of 19 laboratories provided 100% correct results regarding bacteria samples. If combining DNA and bacteria samples 8 out of 19 laboratories provided 100% correct results. Major problems were linked with analysing bacteria in complex matrices.

11. The following conclusions can be drawn from the first exercise round of the project:

(i) laboratory preparedness for the detection varies at national and international levels,

(ii) correct identification of samples with more complex matrices should be improved,

(iii) no problems in terms of transportation occurred,

(iv) most labs provided time crucial results in hours,

(v) comparable evaluation of existing in-house and commercial assays and equipment is needed,

(vi) the evaluation process requires native agents as well as clinical and environmental samples as reference materials.

12. Lessons learned and recommendations from the first exercise round as well as subsequent training are expected improving results that will be obtained in the second and third round. Within the project also experience on biosafety, biosecurity and transportation issues will be collected and exchanged. The final aim will be to determine a minimum detection standard (Gold Standard) that will be reported to ECDC and may be shared with GHSAG and WHO.

13. Internal and external quality assurance exercises need to be implemented as an ongoing process as a prerequisite for all biological laboratories for demonstrating in-house experience and reliability of their diagnostic results.

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