



Newsletter

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Editorial

Roland Grunow, Centre for Biological Threats and Special Pathogens, Robert Koch Institute, Germany

The human population is confronted with emerging and re-emerging infectious pathogens with the potential to cause serious cross-border outbreaks. A recent example is the Ebola outbreak requiring strong diagnostic, clinical, and public health measures in Europe and abroad in order to get this incident under control. The Joint Action EMERGE comprises a European network with about 40 diagnostic laboratories focused on risk group 3 bacteria and risk groups 3 and 4 viruses. EMERGE aims to provide a common, coordinated and effective response to infectious disease outbreaks at EU level and abroad. State of the art and new diagnostic methods for high threat pathogens are evaluated. External quality assurance exercises and training schemes are performed to ensure best approaches for laboratory responsiveness in outbreak situations.

News from the EMERGE Coordination

The Joint Action (JA) is coordinated by the Robert Koch Institute (RKI), Berlin, Germany with Roland Grunow as the person of contact and Daniela Jacob as deputy. The RKI is also mainly coordinating the activities of the laboratories working with risk group 3 bacteria (Network of Highly Infectious Bacteria (NIB)). A project manager was employed for administrative coordination and organizational questions. The RKI is also responsible for the financial administrative work. Furthermore, the JA is co-coordinated by the L. Spallanzani National Institute for Infectious Diseases (INMI), Rome, Italy with Giuseppe Ippolito as person of contact and Antonino Di Caro as deputy. In addition, INMI is coordinating the BSL 4 laboratory activities in the framework of the Joint Action (Network of Highly Infectious Viruses (NIV)).

Recent meetings

Kick-Off Meeting in Berlin / 11th & 12th of January 2016



The first EMERGE meeting was held on the 11th and 12th of January 2016 in Berlin, at the Robert Koch-Institute

(RKI). Representatives of all partner institutes were present (66 participants from 27 Member States) as well as two representatives from the European Commission's (EC) Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) and one representative from the European Centre for Disease Prevention and Control (ECDC).

This meeting was a good opportunity to exchange on a number of subjects, in particular the EMERGE objectives, the project timeline, the communication strategy, the launch of the new website, the EMERGE approach for selection of (re-)emerging risk group 4 viruses and risk group 3 bacteria with the potential for cross-border outbreaks and the capacities set up.

For new members of the consortium, it was also a great opportunity to meet for the first time in person, and to experience the full potential of EMERGE.

The first EMERGE meeting objective was also to present the role to be played by each partner during the course of the project.

In this view:

- Each Work Package has been described.
- Each task has been identified with a group of partners in charge of it.
- Deliverables and their specific deadlines have been listed.

Recent developments

Coordination of the Joint Action (Work Package 1 (WP1))

The coordination ensures the implementation of the JA as planned and budgeted. The main objective is to guarantee an efficient response to serious cross-border events by reinforcing the existing EU network of BSL 3 and BSL 4 laboratories which are already active in the field of identification of dangerous bacterial and viral human pathogens. EMERGE will act in a so-called inter-epidemic mode (IEM) which can be activated and switched into an outbreak response mode (ORM) on request by the Health Security Committee (HSC) in order to direct all activities to the outbreak management. The implementation of the WPs considers specific tasks for both IEM and ORM.

In standard operation, all WPs will be run in an “inter-epidemic mode” (IEM) to facilitate the best possible preparedness and interoperability of all partners in the JA and other relevant networks. Specific tasks are defined for this mode for each WP.

In response to the request by the EC, the Steering Committee (SC) will decide that all WPs are run in an “outbreak response mode” (ORM), activities of the JA will be directed to the laboratory management of cross-border outbreaks of highly pathogenic agents to facilitate the necessary activities for the outbreak management taking into account the

established rules and agreements developed in IEM.

Specific tasks are also defined for this mode for each WP.

An ORM-Working Group (WG) will be activated and comprises members of the SC operating in close contact with representatives of the EC and the ECDC. The coordinator takes the lead of the ORM-WG or designates one member of the SC to take the lead for the period of the ORM mode unless otherwise agreed by the ORM-WG.

The ORM-WG shall give recommendations on specific tasks required for the outbreak management, modifications of the work plan, and budget changes; the SC will take the decision.

In the framework of WP 1 coordination, several goals have been achieved so far:

The Kick-off meeting has taken place in Berlin. The next meeting will take place in Thessaloniki from 10-12 October 2016.

Website (www.emerge.rki.eu) and internal workspace, provided by the BSCW (Basic Support for Cooperative Work) Shared Workspace Server, have been installed.

The SC and Advisory Board (AB) have been established. Monthly telephone conferences allow a frequent exchange of information.

The Consortium Agreement has recently been finalized as a draft and has been

circulated among all partners.

Dissemination of the Joint Action activities (Work Package 2 (WP2))

This WP is coordinated by Institut National de la Santé et de la Recherche Médicale, Inserm, France.

It aims at achieving efficient and effective visibility, awareness and acceptance of the EMERGE project to external stakeholders and to broader general public.

Its objective is also to ensure coherent internal and external communication of EMERGE activities, progress and achievements.

A dissemination strategy has been developed, distributed and discussed with all EMERGE partners. This document lays out the strategy for communication and dissemination of the EMERGE project. It constitutes the roadmap for the action of WP2: “Dissemination of the JA activities”;

Inserm will develop in partnership with all the consortium members an up to date contact database of key organizations and contact persons to be informed regularly by JA EMERGE on its activities, its results and the added value will be created.

These stakeholders will include all EMERGE partners, EC, ECDC and the whole AB, the National Focal Points (NFP) and the Health Security Committee (HSC), as well as routine

clinical and public health laboratories, clinicians, epidemiologists, and policy makers in Europe and beyond.

The contribution of all EMERGE partners for fulfilling this database is essential to have an updated document and to communicate to the relevant stakeholders about EMERGE.

Evaluation of the Joint Action (Work Package 3 (WP3))

WP leader; Department of Health - Public Health England (PHE).

This WP evaluates and monitors the progress of the JA by providing quarterly evaluation of the WP progress and reporting of the findings, evaluation of meetings and oversight by an external AB.

PHE has established the SC, organized the external AB, established an evaluation strategy and provided reporting templates. We have also performed the first evaluation of the JA objectives which showed that 97 % of Milestones and Deliverables were on target or had been met. The evaluation of the kick-off meeting which was held in Berlin showed excellent support for this JA with 93 % of responses rated as very good or good. Further evaluation of this JA will be carried out during the project.

Networking of networks for laboratory response (Work Package 4 (WP4))

This WP is coordinated by EMC and co-led by INMI.

The deployment of laboratories by the international community has been one of the pillars in the emergency response to the Ebola virus disease (EVD) epidemic in the region.

During the heights of the epidemic, laboratories from eight European organizations/initiatives were deployed in West-Africa. The EC has asked for an evaluation of the European Ebolavirus laboratory response in West-Africa through WP4.

This evaluation will focus on the 17 laboratories deployed by the eight different European organizations. The evaluation has started and consists of interviews and electronic questionnaires targeting different stakeholders in the laboratory response. At this point 6 out of 8 deploying organizations were interviewed at the organisational/policy level and at laboratory, scientific, technical level.

Volunteers who were deployed in the laboratories of these organizations have been invited to fill in an on-line questionnaire. The questionnaires have been developed and address various topics relevant for the target group, aimed at gaining insight in decisions and compromises made in the deployment process, the identification of potential areas for improvement and of priority

topics for further “peace-time” preparedness planning. In addition, a similar questionnaire has been developed for retrospective assessment of the Ebola response in European laboratories.

Rapid capabilities for diagnoses (Work Package 5 (WP5))

This WP is coordinated by INMI and co-led by FoHM.

The WP5 objectives are:

- Improving capabilities for rapid laboratory diagnosis of new or emerging pathogens
- Identification of relevant target pathogens (together with WP4)
- Identification and evaluation of best diagnostic approaches and methods, including in-house and commercial diagnostic test kits: improvement and implementation of new diagnostic approaches by topical working groups

A list of pathogens with cross-border potential has been done as result of a questionnaire circulated among SC members (Milestone 18).

To update the existing diagnostic capabilities for the agents as potential cross-border pathogens two different questionnaires have been sent to all partners to have an inventory of the present situation in the different labs (viruses and bacteria) and define the contacts.

Working Group (WG): the list of participants at each WG has been decided during the kick-off meeting in Berlin. In order to define the activities a specific telephone conference has been organized (16 March 2016) (Milestone 19 has been achieved).

In details:

WG1

The Antimicrobial Susceptibility Testing (AST) Working Group will meet in Munich where partner Bundeswehr Institute of Microbiology, BwIM, will provide the "plates" to perform AST test.

WG2

Inserm will question all partners to collect information concerning metagenomics approaches used (i.e. sample preparation, bioinformatic pipelines, NGS platform used....). It was also suggested the possibility to use the EQAE for performing a metagenomic assay (voluntary based).

WG3:

Neutralisation and sample inactivation of risk group 4 viruses are the main topics. It was proposed to create a questionnaire to collect information on inactivation procedures available among partners and try to organize a neutralisation test (again voluntary based).

Quality assurance of laboratory diagnostics (Work Package 6 (WP6))

The WP6 is led by RKI and co-led by Philipps University of Marburg (UMR).

Several External Quality Assurance Exercises (EQAEs) on highly infectious agents (BLS3 and 4) will be carried out by the WP aiming to prepare, to maintain and to improve laboratory diagnostic activities for real outbreak situations. Relevant, (re-)emergent pathogens for the exercises were already identified and selected according to the assessment of health threats in WP4 and WP5 such as *Bacillus anthracis*, *Yersinia pestis* and the Lassa virus causing hemorrhagic fever. A statistical company was engaged to support the data analysis. Thus, the individual laboratories' performances will be assessed via z-scores and the robust means, standard deviations and the probabilities to fulfil certain tasks, depending on the laboratory competences and the difficulty of the task will be calculated.

With respect to the selected targets, two separate exercises are planned per year: one for bacteria and one for viruses. For the last round of EQAE the bacterial and viral part will be performed simultaneously in a single trial. In preparation of the first EQAEs planned for the beginning of May, all partners were invited to complete the 'Integrated European Checklist for Laboratory Biorisk Management (ECL-Biorisk)' generated during the Joint Action QUANDHIP and free available on

www.emerge.rki.eu.

For the bacterial part, living and inactivated samples mimicking clinical specimens will be provided, as for the viral part, inactivated material will be sent out. Further, for the bacteria, additional ASTs are planned using Standard Operation Procedures (SOPs) that were developed by the AST-Working Group (WP5) for further evaluations. The EQAE reports will identify the diagnostic gaps and accordingly, specific recommendation for improvement of methods, training for laboratory personnel, etc. will be made. During the IEM also consolidation and evaluation of bio-diverse repositories of risk group 3 bacteria and risk group 4 viruses will take place. During the ORM, the WP will provide ad-hoc proficiency tests for the causative highly pathogenic agent and reference material for further investigations and quality control. Also the EQAEs will be adapted to the individual outbreak situation according to the requirements evaluated in WP4, WP5 and WP7.

Training on diagnostics and biorisk management (Work Package 7 (WP7))

WP leader PHE and FoHM

This WP supports practical and theoretical training for partners of the JA in order to develop a standard capability in: diagnostic algorithms, laboratory methods, biorisk management and establishment of field

diagnostics with mobile laboratory infrastructure. Special focus is on relevant risk group 3 and 4 emerging and re-emerging pathogens within the scope of the JA.

Since the start of the JA, surveys have been sent out to the partners, assessing the training needs as well as the partner's possibilities to host training courses within the specified four areas. Together with the assessment of each partner's diagnostic capability carried out under WP5, a first version of the training program will be developed. The level of response in the surveys has been high and although the training program is not yet finalized it is clear that the program will contain a variety of relevant courses, predominately focusing on laboratory methodology, that meet the needs specified by the partners. The training program will be modified continuously during the Joint Action and each training course will be evaluated by the individual participants.

Recent publications

- "EU Joint Action EMERGE - Efficient response to highly dangerous and emerging pathogens at EU level", RKI-News, 1st February 2016 (internal)
- "Joint Action EMERGE – Efficient response to highly dangerous and emerging pathogens at EU level", Poster, High Level Conference on Global Health Security, Lyon, France, 22-23

March 2016

- “Joint Action EMERGE – Efficient response to highly dangerous and emerging pathogens at EU level”, Poster, 15th Medical Biodefense Conference, Munich, Germany, 26-29 April 2016
- “The European Network on Highly Pathogenic Infectious Agents”, Poster, 15th Medical Biodefense Conference, Munich, Germany, 26-29 April 2016
- “Joint Action EMERGE – Efficient response to highly dangerous and emerging pathogens at EU level”, Poster, ECCMID, Amsterdam, 9-12 2016

Coming soon

The next consortium meeting will take place in Thessaloniki, in Greece, 10-12 October 2016. It will be a technical meeting dedicated to the progress made concerning different WP and tasks of the EMERGE project.

The next issue of the newsletter is planned for November 2016