WP4 - EPISOUTH PLUS STRATEGIC DOCUMENT

THE EPISOUTH PLUS PROJECT

RECOMMENDATIONS FOR THE INSTITUTION AND CONSOLIDATION OF A LABORATORY NETWORK

January 2014
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THE EPISOUTH NETWORK

EPISOUTH PROJECT (2006-10)

In occasion of the Year of the Mediterranean (2005), a number of countries that share the Mediterranean ecosystem and that have potentially common public health problems, agreed to develop the project “EpiSouth”, whose aim was to create a framework of collaboration on epidemiological issues in order to improve communicable diseases surveillance, communication and training in the Mediterranean region and South-East Europe.

EpiSouth started in October 2006 with the financial support of the EU DG-SANCO together with the Italian Ministry of Health (MoH). When it terminated in June 2010, it had established a network of 27 countries (9 EU and 17 non-EU countries plus 1 candidate to enlargement country). It was therefore the biggest inter-country collaborative effort in the Mediterranean region.

EPISOUTH PLUS PROJECT (2010-13)

This initial project was followed by a second project called “Episouth Plus”, from 15 October, 2010 to 14 January, 2014. Episouth Plus implied a shift of the network’s activities to a wider approach.

Building on the knowledge of regional gaps and needs identified during the EpiSouth Project, the goal of the EpiSouth Plus Project was to contribute to the control of public health threats and other bio-security risks in the Mediterranean region and South-East Europe. The project aimed at enhancing and strengthening the preparedness to common health threats and bio-security risks at national and regional levels, in the countries of the EpiSouth Network, in the framework of the International Health Regulations (2005) (IHR) implementation.

The reinforcement of relations of trust in the region was an instrument in the scope of Project’s implementation, as the achievement of the objective required a solid framework of collaboration and information exchange among the 27 participating countries. To this purpose, Focal Points from each participating country were appointed and asked for active involvement and collaboration in the project’s activities.

The project was organized in seven Work Packages (WP), jointly co-led by EU and non-EU countries. In each WP, two WP co-leaders were guided by a WP Steering Team.

The Steering Committee constituted by all WP co-leaders, and the Project General Assembly constituted by all participants, were responsible for the general strategic decisions. Finally, an Advisory Board, constituted by representatives of the collaborating institutions and external experts, provided support for the revision of relevant documents and recommendations.

Apart from three transversal WPs (i.e., WP1-Coordination; WP2-Dissemination; WP3- Evaluation) the project’s activities were articulated in four WPs:
1) Establishment of a Mediterranean Regional Laboratories Network to facilitate common threats detection in the countries involved (WP4).

2) Promotion of common procedures in Generic Preparedness and Risk Management Plans among the countries involved (WP5).

3) Enhancement of Mediterranean Early Warning Systems (EWS) and cross-border Epidemic Intelligence allowing alerts and Epidemic Intelligence information sharing among EpiSouth countries and, development of interoperability with other European early warning platforms, especially EWRS, as forecasted by the current EU legislation (WP6).

4) Facilitation of IHR implementation through the production of a strategic document, with guidelines, based on specific assessments describing how national plans/legislations can interact with IHR requirements (WP7).
1. Work Package 4 – setting up a laboratory Network

- **GOAL**
  The goal of the work package 4 is to contribute to the control of public health threats in the Mediterranean region and South-East Europe by establishing a Regional Laboratories Network.

- **OBJECTIVE**
  The main objective of the work package is to facilitate common threats detection by the establishment of a Regional Laboratories Network based on available resources in Mediterranean and South East Europe by mapping them, assessing their diagnostic and confirmation capacity, facilitating rapid access to laboratory facilities, strengthening the human and technical capacity of participating countries interacting with their public health institutions and officials based at the national reference laboratories.

- **RESULTS**
  The EpiSouth plus project, through its WP4, has succeeded in creating the Mediterranean Regional Laboratory Network (MRLN). This project has enabled the heads of laboratory from all over the Mediterranean rim to meet, collaborate and exchange information, for the first time. Thanks to this project, the heads of laboratory had the opportunity to train one of the staff of their laboratory to the laboratory diagnosis of Dengue and West Nile virus and to develop and strengthen their biosafety skills and practices. Trust and collaboration have been built throughout these two last years and the laboratories have expressed a great interest in continuing to further collaborate and develop the activities of the MRLN in the upcoming years. EpiSouth is the only network enabling all the Mediterranean area to get together and to work in partnership. The role of the EpiSouth plus project is central in the establishment and maintenance of multisectoral collaboration (i.e. veterinary and entomology) on the filed around the Mediterranean rim.

2. Process and tools needed to set up a Laboratory Network

2.1 IDENTIFICATION AND SELECTION OF THE LABORATORIES

- Description of profile of the needed laboratories included in a first questionnaire (annex I)

  The WP4 prepared a short questionnaire to assess the “basic” laboratory capacities and to support the selection of the labs to involve in the MRLN. This questionnaire was sent to the EpiSouth national focal points (FPs) who forwarded it to the concerned Laboratory(ies) (human fields) of their countries. The laboratories should have been national references for Dengue and/or West Nile, or a Virology unit which has the best possible expertise on diagnosis and identification of these pathogens or related viruses if no specific reference laboratory exists in the country.

  Points addressed were:

  - treatment of human and/or animal samples
  - reference level of the laboratory (regional, national, district,...)
  - number of samples treated
  - information on the infrastructure (Biosafety level, PCR facilities, waste management, ...)
  - main scope of activity (virology, bacteriology, immunology, molecular biology,...)
- frequency and way of reporting to authorities, international bodies
- existence of laboratory SOPs
- database management
- technologies available for pathogen detection and identification
- organisation of the laboratory
- quality management
- training level of the personnel

- Procedure of constitution of an expert comity

An expert meeting (international experts of the field of interest, WHO, ECDC, OIE and Countries representatives) was organised to identify selection criteria of the different laboratories and make links with the existing networks of laboratories to avoid overlapping and duplications. An inventory of the existing diagnosis or reference laboratories/disease/country was possible for each selected country partially by internet survey, WHO available information and complementary questionnaires. Minimal requirements amongst the above mentioned points were set by an expert committee. This expert committee was constituted of specialists of the different identified diseases and corresponding pathogens in terms of laboratory diagnosis and pathogen identification, clinicians, and quality control and public health specialists.

In the case of EpiSouth plus the following experts were called to take part in the expert comity for selection of laboratories for the network:

Representative of ENIVD (European Network for emerging viruses), representative of ECDC, representative of EBSA biosafety, representative for WHO biosafety, representative(s) of national reference laboratories from Spain, Turkey and Greece.

2.2 IDENTIFICATION OF NEEDS
- Assessment document of laboratories

Two questionnaires have been used for the assessment of the selected laboratories. The selection questionnaire and a follow up questionnaire have been filled by the heads of laboratory.

The second questionnaire concentrated on the following topics:

- Organisation of lab staff
- Laboratory instruments and equipment
- Tests and diagnostic capacity
- Equipment maintenance
- Specific SOPs on QC, handling of samples (including labelling and storage)
- Specific questions on the use of databases and
- IHR compliance
- Decontamination procedures and use of safety equipment

- Inventory to identify transport bottlenecks for transport of material for identified Laboratories

Transport of samples and reagents is very often a problem within and with the EU. Therefore a questionnaire has been distributed to identify some specific bottlenecks such as:

- Existence of an expedition service
• Use of a customs clearance agent
• SOPs for export and import of goods and samples
• Availability of packaging material
• Contact person at major airline companies
• Which courier companies are available

It has to be explored if some regional services can be mutualised (use of courier companies, sharing of SOPs, ...)

- Meeting with heads of laboratories

One meeting/year of the heads of laboratories is recommended to update on pathogen situation, identification of needs, feedback on organised activities, network building.

3. Points to take into consideration when organising a training/course

3.1 AVAILABLE COURSE FACILITIES

3.1.1. Infrastructure
The minimal infrastructure needed to organize a course/training is:

a) to have a laboratory sufficiently big to host all participants

b) to have at least one or two safety cabinets for biosafety applications

c) to have a computer room available for participants

3.1.2. Authorisation for the course
Check before if the country legislation allows to perform the course in the country, what are the legal restrictions to train on the chosen subjects and pathogens.

3.4. IDENTIFICATION OF PARTICIPANTS: OUTLINE OF PROFILE
The trainee profile should be set with the heads of laboratory.

For the EpiSouth plus courses it was determined in the following way:

- permanent staff
- actively working at the bench in the laboratory
- speaking English and at best French
- person who could provide training when coming back to his/her lab.

3.5 COURSE MATERIALS AND TIMING

3.5.1. General format of the course

The general format of the course was a five-day course.
The approach was to give a general scientific background of the pathogen including, clinical symptoms, the animal and vector general information. The aim is that participants understand all factors of the context of the disease while practical and theoretical courses are outbalanced in the best possible way (60/40).
On the last day case studies were planned in order to have a general overview on situation analysis and consequently tests to be performed.
Experts of the addressed fields were invited to give lectures. Pre-and Post-tests were performed to evaluate the effectiveness of the performed sessions. For specific certificates, specific questions and a corresponding test were set up. Indeed, a certificate is essential for the participants since this is a confirmation and valorization of their training.

3.5.2. Material to share

After the course all used protocols and presentations were available for the participants.

Course reagents were distributed amongst participants if relevant for the set up of the learned methods in their home laboratory.

The programs used for sequence analysis are freely available programs and sites where they could have been found were communicated.

3.5.3. Hands on sessions and Distribution of pairs

The target group was very heterogeneous. Therefore a more experienced trainee was always paired with a less experienced one. Attention was paid to the fact of the geographical proximity of the countries of origin while making the different pairs.

3.5.4. Preparation and format of round tables

Round table discussions were gradually built around a country situation, going from the set up of a surveillance system when a first case is detected, to an outbreak to an endemic situation. Discussed is the organization of the lab and the identification methods, which should be set up according to the different situations, and stages of development of the laboratory. Different examples highlighted the difficulties and key points to be addressed during these different stages.

3.5.5. Design of case studies

Case studies allowed to put the results obtained by the tests learned during the practical sessions in a realistic context.

They can be approached in different ways; the format that has been used during the project is the following: the clinical background (clinical symptoms, age, travel history, ...) of the samples analysed during the practical sessions were discussed and identification techniques were analysed according to the data provided. Additional testing was discussed when necessary.

This is an important part of the training as it considers most of the aspects addressed during the sessions of the course.

3.5.6. Course follow up

An important aspect of the a course is its follow up.

Actions of follow up are important to consolidate the learned material and could be under different formats:

- make the course material available.
- e-learning follow up (not implemented with EpiSouth Plus Project)
- follow up courses (the WN-biosafetyII course was a follow up course of the Dengue-Biosafety I course)
- organise External Quality Assessments, which give the opportunity to the trainees to apply the techniques learned and assess their own "home-made" detection methods.
- give participants the opportunity to exchange between each other and experts
- create the possibility of experts to go to sites with specific questions, which can only be solved by “on the spot” training, which is complementary to residential training.

4. Tools to keep the Network active

4.1. Internet site and common email addresses

An internet site remains, even after the end of a project, an important communication and dissemination portal.

A moderator and animator remains a key point to maintain communication among partners.

4.2. Exchange of material

What makes a Network active is also the possibility to exchange samples, positive controls, consumables etc.

Networks should make such exchanges possible, in the context of the international regulations, therefore common transport procedures, experience about carrier companies, packaging rules and procedures should be shared and common documents elaborated.

5. Lessons learned and recommendations

The support of the EpiSouth focal points for the setup of the MRLN was an essential asset which helped to identify the different possible laboratories in the targeted countries.

A Network “animator” is key for the set up and day to day life of a Network. It is important that partners feel they belong and participate. Therefore regular interaction with the coordination of the network on their advances, problems, information exchange is very important. As important is the identification of some regional “champions” to which members can easily turn to in case of questions or problems.

Meetings with the head of laboratories for face to face discussions are as valuable than shared tools, since they create an important regional dynamics which, if strong enough, will remain.

SOPs are important elements for the good functioning of laboratories, they are more and more used but in some countries they still need to be introduced and harmonised. However, it are easy and useful documents to share which can have a direct impact on the efficiency of the laboratory.

The setup of a network is a challenging but rewarding investment an important part of the investment however is the sustainability and therefore it is important that follow up activities are made possible.
### Acronyms and Abbreviations

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<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>ECDC</td>
<td>European Center for Disease prevention and Control</td>
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<td>EU</td>
<td>European Union</td>
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<td>EWS</td>
<td>Early Warning System</td>
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<td>EQA</td>
<td>External Quality Assessment</td>
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<td>IHR</td>
<td>International Health Regulations</td>
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<td>IP</td>
<td>Institut Pasteur</td>
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<td>MRLN</td>
<td>Mediterranean Regional Laboratories Network</td>
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<td>MS</td>
<td>Member State</td>
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<td>OIE</td>
<td>World Organization for Animal Health</td>
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<td>IPIN</td>
<td>Institut Pasteur International Network</td>
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<td>ST</td>
<td>Steering Team</td>
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<td>WHO</td>
<td>World Health Organization</td>
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