WORKSHOP ON CONTINGENCY PLANNING FOR FOOT-AND-MOUTH DISEASE LABORATORY DIAGNOSTIC ACTIVITIES

Universidad de Córdoba

Organised by the European Commission for the Control of Foot-and-Mouth Disease (EUFMD), a constituent Commission of the Food and Agriculture Organization of the United Nations

Financially supported by DG-SANCO, EC
Summary
The subject of contingency planning for FMD laboratories arose from difficulties experienced in the crisis situation in 2001. The 35th General Session of the EUFMD Commission in April 2003 recommended that the National Laboratory of each EUFMD member state should develop a contingency plan for diagnostic and serological surveillance functions in an emergency and that the plan be regularly rehearsed and modified as necessary. The Session also recommended a workshop be conducted for laboratories of the member states, and following receipt of support from the EC (DG-SANCO), a workshop (WS) on contingency planning for FMD laboratory diagnostic activities was held in Cordoba, Spain, and attended by 40 participants from 32 European countries, of which 21 were EU members or acceding countries, and 11 others, from Iceland to Israel. The WS was opened by the CVO of Spain, Dr Arnaldo Cabello Navarro, who emphasised the importance of addressing laboratory issues when developing emergency plans.

The aims of the workshop were principally to engage laboratory managers in the process of developing, reviewing, and implementing technical guidelines relating to contingency planning for diagnostic services and the scaling up of laboratory services in emergency situations. The scale of the problem to be faced was illustrated by speakers from the four counties directly affected in 2001. The experience of Ireland is that even a single outbreak can result in hundreds of thousands of test being
required, and therefore it is essential that each laboratory and each country identify in advance the process for scaling up capacity, and the limiting factors. Of the limiting factors, workspace in high containment facilities is limiting in most countries and therefore options were considered for moving test performance to other facilities, and possibly using portable devices.

The workshop was a rare opportunity for managers of FMD reference laboratories to meet and to engage as stakeholders in the development of guidelines affecting their functions; many were also meeting for the first time. Fourteen of the 15 EC member states and 7 of the 10 countries acceding on 1 May 2004 were represented (exceptions being Portugal, Malta, Slovakia, and Poland), almost entirely through their national FMD reference laboratory. Other participants included several CVOs, and senior state officers for infectious disease control/epidemiology. The workshop was organised by the Secretariat of the European Commission for the Control of FMD, an FAO Commission, with technical inputs mainly from FMD laboratory experts who are elected members of the Standing Technical Committee of the EUFMD Commission, and financially supported by the EC (DG-SANCO) and the EUFMD Commission. Prior to the WS the Standing Technical Committee (also known as the Research Group) had developed through working groups several technical papers in areas relating to diagnostic reagent banks and biosecurity requirements for serology laboratories, two areas seen as important for rapid escalation of diagnostic activities to the levels that may be required under the new EC Directive.

The workshop was therefore organised in order to:

- Review the issues of rapid escalation of FMD diagnostic activities, and to
- identify potential solutions that require to be covered in contingency plans,
- To review the draft guidelines and to adapt their content following stakeholders comments.
- Provide an updating on scientific opinion on the selection and use of diagnostic tests, bearing in mind the changing policy and regulatory and diagnostic options relating to vaccination and post-vaccination surveillance.

The workshop was successful in most of these aims. The general conclusion and recommendations include within them a timetable for follow up actions by laboratory participants, by the EUFMD Commission, and by the experts of the working groups, with an important commitment of laboratories represented to complete LCP by the end of 2004.

Drafts of three guideline papers were reviewed, on structure of model LCPs, on minimum standards for biosecurity for laboratories undertaking FMD serology, and on the transport of specimens to FMD reference laboratories; several of these texts were already considered to be useful as reference documents in draft form. Further, the working groups considered issues and potential solutions for scaling up of virus diagnosis, of sero-diagnosis, and the potential use of portable diagnostic tests. One group (on biosecurity for FMD serology laboratories) developed a revised text during the meeting; each of the reports of the other working groups will be incorporated into revised texts for review by the research group before or during the October Closed Session. The guidelines on biosecurity for FMD serology laboratories may if agreed and accepted at European level greatly facilitate establishment of capacity for mass serology in laboratories operating to less stringent biosecurity levels, such as regional veterinary laboratories and specialised high throughput ELISA facilities, thereby assisting member states in planning for the level of surveillance that will be required during and following outbreaks in order to provide national and European confidence that serological screening and follow up surveillance will be completed in an acceptable period of time, and hence to more rapidly regain on regional or national basis a status of freedom from infection.

Acknowledgements

The EUFMD gratefully acknowledges the efforts of many individuals to bring the workshop to reality. The workshop would not have been possible without the efforts of the following: the Dean of the Faculty of Veterinary Medicine, University of Cordoba, Spain, and Prof J.M Sanchez-Vizcaino, member of the EUFMD Standing Technical Committee, for practical arrangements in Spain. The Chairman of the EUFMD Standing Technical Committee, Dr Kris de Clercq, and members of the working groups (Dr Haas, Dr Palfi, Dr Dekker, Dr Paton, Dr Brocchi, Dr de Simone and Dr Yadin) and Dr Donal Sammin, EUFMD Secretariat, Rome, are thanked for their inputs in the design of the
programme and in the technical content. The Clerk of the Commission, Egiziana Fragiotta, and Dr Simona Sangiovanni, FAO volunteer, are thanked for their exceptional efforts before, during and after the workshop to assist with travel and other arrangements.

Output 1: General conclusions and recommendations

EUFMD/EC Workshop on Contingency Planning for Foot-and-Mouth Disease Laboratory Diagnostic Activities

Universidad de Córdoba, 28-30 April 2004

Recognising that:

1. Even a single confirmed outbreak of FMD in a single European country will create a high and urgent demand for diagnostic tests to be performed in the country concerned and in other European countries, and may require hundreds of thousands of serological tests to be performed.

2. The scaling up of diagnostic activities following a confirmed outbreak will be constrained by factors including the limited size of available space in the high security containment laboratories, of biological resources required for the tests, of available competent technical staff, financial resources and other factors.

3. Other options need to be reviewed to reduce the cost of maintaining a high standing capacity for performance of FMDV diagnostic tests within days of first requirement.

The workshop reaches the following general conclusions and recommendations:

1. Each European country should before 2005 develop, evaluate, and update on a yearly basis a contingency plan, to elaborate the strategy, organisation and resources required to be maintained during non-outbreak periods and each phase of an FMD emergency in Europe.

2. The model laboratory contingency plan should be further developed by mid-June 2004, following the review of the WG5, and thereafter circulated and made available on-line to assist the NLs in developing their own plans.

3. The LCP should address the issue of rapid scaling up of virus diagnostic capacity. The report (of working group 1) provides a guide for major elements to be considered and addressed.

4. Countries should urgently put into place arrangements for transport of specimens for FMD diagnosis, and sera, to reference laboratories in the European region.

5. The guidelines being developed by the EUFMD working group on transport of specimens for FMD diagnosis should be developed further by October 2004 and updated on a yearly basis by the EUFMD Research Group.

6. The LCP should address the issue of rapid scaling up of serological diagnostic capacity. The report (of working group 3) provides a guide for major elements to be considered and addressed.

7. The guidelines developed by the EUFMD working group on biosecurity requirements for serodiagnostic laboratories, as modified by the working group during the workshop, were accepted in principle. The group is encouraged to complete the review by the EUFMD research group by October 2004 with a view to early acceptance at the European level.

8. Portable diagnostic devices have a potential to increase the speed of detection and confirmation of FMD virus infection, particularly in countries without national reference laboratories, and to reduce the scale of diagnostic activity required of reference laboratories. Guidelines are required to address issues relating to test performance, authorisation of personnel, indications for use, and on the subsequent submission to and use of reference laboratories. A WG should be established.

9. The creation of a European FMD diagnostic reagent bank is urgently required. The guidelines on the development of the bank should cover the arrangements for drawing rights, the necessity of laboratory contingency plans which address the provision of the resources required which are not provided by the bank. The technical specification of kits in the bank should be reviewed at least on an annual basis.
10. The subject of evaluation of LCPs should be addressed at the next meeting of the EUFMD RG.

**Structure of the workshop**

**Background**
The subject of contingency planning for FMD laboratories arose from difficulties experienced in the crisis situation in 2001. The subject was discussed by representatives of the 33 member states at the 35th General Session of the EUFMD Commission in April 2003. The Session recommended that the National Laboratory of each EUFMD member state should develop a contingency plan for diagnostic and serological surveillance functions in an emergency and that the plan be regularly rehearsed and modified as necessary. The Session also recommended a workshop be conducted for laboratories of the member states. Following these and other recommendations, the Standing Technical Committee (also known as the Research group) developed through working groups several technical papers in areas relating to diagnostic reagent banks and biosecurity requirements for serology laboratories, two areas seen as important for rapid escalation of diagnostic activities to the levels that may be required under the new EC Directive. The workshop was therefore organised in order to:

- Review the issues of rapid escalation of FMD diagnostic activities, and to
- identify potential solutions that require to be covered in contingency plans,
- To review the draft guidelines and to adapt their content following stakeholders comments.
- Provide an updating on scientific opinion on the selection and use of diagnostic tests, bearing in mind the changing policy and regulatory and diagnostic options relating to vaccination and post-vaccination surveillance.

**Aims of the workshop**

1. To review position papers relating to increasing capacity for FMD diagnostic activity in Europe (contingency planning for FMD outbreaks), laboratory prepared by Working Groups of the EUFMD research group. The workshop therefore enables stakeholders to interact with those preparing the papers to ensure the final guidelines address relevant concerns.
2. To identify ways by which laboratory capacity for virus diagnosis and for serology can be increased to meet requirements of emergency situations, issues to be addressed in implementation, and actions required in contingency plans.
3. To receive stakeholders feedback on the model Laboratory Contingency Plan (LCP).
4. To capture requirements of countries without facilities for FMD virus diagnosis for support from reference laboratories.
5. To identify options for conducting simulation exercises to test LCPs.
6. To increase awareness among national laboratories of member states of the EUFMD Commission of issues relating to FMD laboratory diagnosis, particularly the implications of the new EC Directive and the use of NSP antibody tests.

Activities addressing aims 1, 2, 3 were addressed first, as priorities; aims 4 and 5 were relegated to lower in the priority list and could not be covered in the time available. The format of the workshop and presentations supported increasing awareness of recent technical advances and regulatory changes (aim 6).

**Form of the Workshop**

- Presentation of experiences and main issues by resource persons (Wedns AM, additional presentations on Friday AM)
- Division into working groups (6 on Wedns)
- Working groups (Chair, resource person, rapporteur plus 3-6 participants)
- Presentation and discussions of findings/recommendations to plenary on Thursday
- Feedback recorded by an independent rapporteur (one who has not been a working member of the group) and incorporated into final report, presented on Friday.
Roles of participants in relation to working groups
1. All participants had a role – as Chairperson, resource person (e.g. presenter of a paper), rapporteur for working group, or rapporteur for the feedback of the main group on each item.
2. Chairpersons – their given role was to ensure that all points of view are heard, to ensure group discussion is held and that group completes task. Usually but not always presented the report to plenary.
3. Resource person: assists the group with their prepared position papers, information, experience relevant to task.
4. Rapporteur – records, summarises, revises with colleagues after feedback from plenary.
5. Feedback rapporteur – record discussion, questions and answers, summarise key points to be addressed in the final report, and passes these to WG rapporteurs.
6. Participants were expected to have no more than one significant role (rapporteur etc).

Timetable – as happened

Wednesday 28th April
AM Opening by CVO Spain, Dr Arnaldo Caballo Navarro.
Introductions: scope of the workshop

Presentations - Recent experience - Why the need for laboratory contingency plans?

1. Experience and Issues in scaling up laboratory virus diagnostic activity during and after an FMD outbreak (the UK experiences in 2001). Nigel Ferris, IAH Pirbright
2. Issues in scaling up laboratory sero-diagnostic activity in countries without a national FMD laboratory, during and after an FMD outbreak. Dianne Clery, Ireland (Annex 4)
   Update and issues - EUFMD working groups relating to contingency planning.
3. Update/ Issues relating to the delivery of specimens to the NRL and international transport of infectious materials (by air). Vilmos Pálfi, Hungary (Annex 3)

PM Participants divided into 6 working groups, prepare report of findings.
Working Group 1 - Scaling up of virus diagnostic capacity to level required in FMD emergencies.
Working Group 2 - Review of the guidelines on transportation of samples to and between FMD diagnostic laboratories.
Working Group 3 - Scaling up of sero-diagnostic capacity to a level required in and following foot-and-mouth disease outbreaks.
Working Group 4 - Review of paper on biosecurity levels for FMD sero-diagnostic laboratories – does it adequately address stakeholders needs and concerns?
Working Group 5 - Develop a model Laboratory Contingency Plan for European national laboratories
Working Group 6 - Develop draft guidelines on use of portable diagnostic tests for FMD virus.

Thursday 29th April

AM Working groups continued to 10.30 am. Thereafter between 11 am and 4.30 pm plenary debated the working group reports.
4.30-5.30 PM Update/Issues relating to the establishment and maintenance of a European FMD diagnostic reagents bank. Bernd Haas, Germany (Annex 10)

Friday 30th April
AM 9-11.30 am
Presentations

(i) Revision of the contingency plans for laboratory diagnosis in France following the FMD situation 2001; Eric Plateau, AFSSA
(ii) Virus detection methods - increasing the speed and reliability of detecting infection. Kris de Clercq (omitted for time reasons) (paper Annex 2)
(iii) Serological test methods – considerations for selection and use. Franco de Simone and Emiliana Brocchi (Annex 6)
(iv) Recent experience with NSP antibody detection tests in Israel. Hagai Yadin (Annex 8)

11.30-1 am Presentation and discussion of the draft report of the workshop.

The following working groups did not meet - for reason of time constraints:

1. The role of laboratory networks and/or reference laboratories in peace-time and crisis situations.
2. Testing the plans - Simulation exercises for laboratories.

Output- 2

Report of the Working Group 1

Task. Identify key components to be included in a Laboratory Contingency Plan (LCP) relating to scaling up of virus diagnostic capacity to level required in FMD emergencies

Chairperson: Kris de Clercq, other members Nigel Ferris (resource person), Dr Sedlak, Barbara Thuer, Lena Renstrom

Background and related papers: Annex 1 (Laboratory Contingency Plans), Annex 2 (Testing for FMDV)

Outputs = What needs to be put into lab preparedness/contingency plans to ensure preferred options can be implemented to planned timescale?

1. Sampling
   Optimisation of samples (number, quality, considering the species)
   Commission, lab people included, should decide in peace time
   Planning, training

2. Tests
   Scaling up
   Reduce tests
   Alter methods (ELISA, VI, PCR)
   Reduce serotypes (only predominant)
   Pooling
   Reduce duplicates
   Rationalise tests (automatisation)
   Reorganise (other labs involved and rearrange responsibilities)
   Simulation in peace time

3. Space
   Storage space (samples, materials)
   Cell culture (incubator, cooling place)
4. Staff

Training
Payment, time compensation
Teams (virology / serology / logistics, the whole institute involved, links between them)
Avoid exhausting shifts
Motivation

5. Support

Stock, consumables
IT, data management
Logistics
Waste
Support personal (accommodation, eating, clothes)
Containment (technical support)

Working group 2

Task: Review of the guidelines on transportation of samples to and between FMD diagnostic laboratories, and formulate recommendations on testing sample transport to reference laboratories

Members: Dr Palfi (resource person), Drs Must, Stylianas, Reboutzakou and Gunnarson

Outputs – a summary of discussions. Recommendations to author (Dr Palfi and others) of the draft guidelines.

Background and related papers: Annex 3 (Draft Guidelines on transportation of samples)

What are the main problems anticipated or experienced in sending samples, specimens and other biological materials to another national laboratory/WRL? For virus diagnosis? Including serum samples?

The FMD laboratory needs an agreement with either a courier or airlines before sending materials. Only some airlines admit dry ice in the shipment.
The transport takes several days in special during the weekend, so the courier can be too slow in crisis situation.
In spite of the international regulations there are differences among the airlines, couriers and countries.
Financial problems for the payment of the shipments of biological material.
The sending of serum samples collected in different epizootiological situations (crisis situation and peacetime) is not clearly regulated.

What are the potential solutions to these problems?

- Previous agreement and contract with the carriers and airlines companies.
- The use of wet ice as refrigerant in case of difficulties with the dry ice transport in crisis situation.
- Financial provisions for the shipment of FMD materials must be included in the Contingency Plan.
- A qualified person should be in charge in each laboratory to send infectious materials to other laboratories.
- Serum samples collected in crisis situation are considered infectious substance; therefore the transport of such samples is regulated by IATA Dangerous Goods Regulations.
- Samples collected in peacetime cannot be considered infectious substance, so the transport is out of the Dangerous Goods Regulations. In this case the consideration of the paper about
collection and transport of specimens prepared by the IAH Pirbright experts is recommended when sending serum samples for investigation.

Questions 3, 4 and 5. Does the document prepared cover all these problems/issues? If so what areas must be addressed?

It is necessary to have available in the laboratory templates of the necessary documents for the shipment of biological materials.
This prepared document has to be supplemented with the copy of the necessary templates for the shipment of biological materials.
The Group has revised the prepared document and the corrected version will be circulated in the near future.

6. Who/when/where/how often should it be updated?

EU-FMD research group should be responsible for updating the shipment document once a year or every time that transport regulations are changed.
Each National Laboratory has to review the quality assurance documents once a year. During this revising the changes in the transport regulations have to be considered in accordance with the laboratory quality assurance system.

7. What reference should be made to these guidelines in the laboratory contingency plans?

The shipment of FMD materials must be a part of the laboratory contingency plan.

8. What does the Group recommend on testing your preparedness for specimen transport between countries?

The shipment of FMD materials should be a part of the simulation exercises for the control of FMD.

Task 3. Identify key components to be included in a laboratory contingency plan relating scaling up of sero-diagnostic capacity to a level required in and following a foot-and-mouth disease outbreak.

Output = What needs to be put into lab preparedness/contingency plans to ensure preferred options are kept under review, are updated as required, and necessary resources are in place to enable implementation to planned timescale?

Background and related papers: Annex 4 (Experience of Ireland in scaling up sero-diagnosis), Annex 5 (Issues in post outbreak and post-vaccination surveillance), Annex 6 (Review of sero-diagnostic methods and test selection for FMD)

Lorena Jemeršic (chair), Dianne Clery (rapporteur), Emiliana Brocchi, Dita Krastina, Ivan Holko, Naci Bulut, Karl Johan Sørensen, Aldo Dekker.

Introduction

This document describes issues which have to be taken into account when writing a laboratory contingency plan for serological testing of foot-and-mouth disease.
In case of an outbreak other laboratories outside the national laboratory can be included if the number of samples per day exceeds its capacity or when distance requires an additional laboratory. Regional laboratories should be checked by the national reference laboratory and should also have a laboratory contingency plan.
The number of samples that a laboratory will have to be prepared for, depends on the veterinary organization, density of susceptible animals and the way animals are housed. The numbers used in the
A laboratory contingency plan should be in line with the numbers mentioned in the national contingency plan. The number of samples a laboratory will have to handle may depend on whether a “vaccination to live” policy is used, currently there are no approved protocols for surveillance after an emergency vaccination. The numbers considered in the text are independent whether vaccination is used or not. The numbers in the text are indicative, they may be different for various laboratory situations. The numbers mentioned in the text are based on one test per sample (a test for one serotype or a test for antibodies against non-structural proteins of foot-and-mouth disease).

A general epidemiological principle states that lower sensitivity of an assay can more easily compensated by a small increase in sample size than by increasing the analytical sensitivity of the assay (e.g. by testing in duplicate). Enhancement of the analytical sensitivity usually causes an increase of false positive samples.

Only an outbreak with a single serotype is considered, outbreaks with multiple serotypes might occur. In the latter case an assay using the non-structural protein of foot-and-mouth disease can be considered.

A ramping-up period within the foot-and-mouth disease outbreak should be defined in the laboratory contingency plan, depending on the expected number of samples. This will also depend on the density of the livestock in a country. The capacity to follow up serology during the outbreak should be reached within 2 - 4 weeks. A laboratory contingency plan should also consider the post-outbreak surveillance, which often requires very high number of samples to be tested to prove absence of disease. This capacity should be available within two months after the first case of foot-and-mouth disease.

A database system should be setup in which communication with the disease crisis center is possible.

**Items to be addressed in a laboratory contingency plan**

**Facilities**

- Reception area / recording and registration
- Testing rooms
  - Separation of serum
  - Testing the samples
- Storage facilities
  - + 4
  - – 20
  - Room temperature
- Reporting / IT database
- Waste disposal
- Catering facilities

**Personnel**

**Depending on LIMS system / Barcoding or manual labeling**

<table>
<thead>
<tr>
<th>Facilities</th>
<th>No of samples per day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>500</td>
</tr>
<tr>
<td>Reception / registration</td>
<td>0.5</td>
</tr>
<tr>
<td>Preparation / separation of serum</td>
<td>0.5</td>
</tr>
<tr>
<td>Testing (depending on equipment and test system)</td>
<td>1</td>
</tr>
<tr>
<td>- At least one experienced staff member</td>
<td></td>
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<tr>
<td>- Adequate training during non-outbreak period</td>
<td></td>
</tr>
<tr>
<td>Reporting</td>
<td></td>
</tr>
<tr>
<td>Waste disposal / cleaning</td>
<td>0.5</td>
</tr>
<tr>
<td>Catering</td>
<td></td>
</tr>
<tr>
<td>Management</td>
<td>2 x 0.15</td>
</tr>
<tr>
<td>- Head of laboratory / laboratory expert</td>
<td></td>
</tr>
<tr>
<td>- Manager for purchasing supplies and equipment</td>
<td></td>
</tr>
<tr>
<td>IT database</td>
<td>1</td>
</tr>
</tbody>
</table>
In the contingency plan it should be described how people are recruited from institutes that are involved in other diagnostic testing. Other personnel or laboratories that can supply technicians trained in similar methodologies should be identified in advance.

**Equipment and supplies**

**Biologicals**

Depending on test system the laboratory contingency plan should consider the source and a procedure to acquire these biologicals. The laboratory must ensure that stocks of biologicals are available to cover the time needed for the producers to replace them including scaling-up of the diagnostic capacity.

- Kits
- Control sera
  - Primary standards
  - Secondary standards
- In house reagents
  - Availability
  - Ramping up period
- Reagents produced in another laboratory
- Reagents bank

**Non-biologicals**

- Tips
- Chemicals and buffers
- Plates
- Tubes / glassware etc.

**Equipment**

Depending on the system used in the laboratory it may vary, the following items should be considered. In all cases a backup or spare parts should be considered. The number of various pieces of equipment may vary with the number of samples that have to be tested.

A list of suppliers should be kept to be able to purchase equipment in needed.

- Plate washer
- ELISA reader
- Several computers / printers / barcodescanners
- Pipets
- Pipetting robots
- Shakers
- Incubators

**Waste disposal**

Way of disposal is handled in another working group

- Liquid
- Solid

**Confirmation of positive results from ELISA**

In laboratories in which confirmation of positive ELISA results by virus neutralization test is not possible a contract with another laboratory that can perform the confirmatory test should be agreed in advance and this laboratory should have a contingency plan to ensure adequate capacity.

**Quality assurance**

- Test

A laboratory should use an OIE recognized test or can use an alternative test provided compliance with standard reference sera (if available) and diagnostic performance is documented.
Personnel
Training records of personnel should be kept, and a training plan for newly assigned personnel should be established.

Review
A laboratory contingency plan should be reviewed on a yearly basis (e.g. is assigned personnel still working in the institute?) Stocks of reagents should be checked at least on a yearly basis.

Public relations
Also activities relating serology should be handled by the official channels (Press office, a central phone area for queries).

Working group 4

Task: Review of paper on biosecurity levels for FMD sero-diagnostic laboratories – does it adequately address stakeholders needs and concerns?

Members: Dr Sanchez-Vizcaino (Chair), Dr Haas (Rapporteur), Dr Mehmadbasic, Schon, Cumpanasiou, Rikula, de Simone

Outputs: recommendations on adoption and/or changes to paper.

Background and related papers: Annex 7 (Biosecurity considerations)

The working group chose to revise the draft document prepared by EUFMD Secretariat. This is presented as Version 3, Cordoba, below.

Version 3.
Minimum standards for bio-security for laboratories undertaking serology with blood samples from areas not considered free from foot-and-mouth disease

[Note: Final version adopted on 11 October 2004 is available from the EUFMD Secretariat and will be published in the report of the Session of the Research Group held in Greece on 11-15 October 2004].

Report of working group 5

Task: Develop a model Laboratory Contingency Plan for European national laboratories
Members: Drs Yadin, Plateau, Georgiev, Malovrh, Jacevicius, Diaconu, Romero González (Rapporteur)

Outputs: recommendations on the content of a revised, “model LCP” for consideration by the main workshop.

Background and related papers: Annex 1 (Laboratory Contingency Plans)

The model of Garland, 2003 (35th general Session of the EUFMD, 2003) was provided as an example. However, since this was developed for an international reference laboratory, the model needs relevant to the needs of national laboratories of smaller countries including those who do not have high security facilities for FMD diagnosis.

Report

Contingency planning for FMD laboratories
1. The working group is composed of seven members representing average N.R.L for FMD with average size of 300m² except for one in Israel having facilities of 1000m² including area for animal experiments.
2. All members of the group mentioned that their staff is responsible also for other list A diseases and some of them are in charge of administrative management.
3. The Working Group (WG) agrees upon the four levels of alert described by the introduction.
   Level A – No outbreak in the region.
   Level B – Outbreak in the region.
   Level C – First outbreak in the country.
   Level D – secondary and tertiary outbreaks.
Nevertheless for some WG members the limit between C and D levels can be adapted to the epidemiological situation.
4. Consideration regarding the different levels:
   - **Level A**: at this stage the laboratory should fully comply with the following capacities:
     i. Having the know how with virus isolation and antigen identification different types of serological tests and molecular virology (PCR).
     ii. Can give accurate advices to the Veterinary Services regarding field investigations (sample collection, epidemiology of FMD and differential diagnosis).
     iii. Development of international contacts with other FMD centers and be involved in proficiency tests.
     iv. Should have adapted knowledge in vaccinology, strain selection, vaccine production, vaccine control and evaluation of safety and efficiency.
     v. Active implication in knowledge should be transfer to local official staff, laboratory and Veterinary Services. This knowledge transfer should include sample collection transport and diagnosis procedure.
     vi. Permanent maintenance and technical supervising of the high containment facilities according to official recommendations should be implicated.
     vii. Be in position to purchase all the necessary equipment.
     viii. Be regularly supplied with all the necessary reagents.
     ix. The laboratory facilities should comply with ISO norms.
     x. The laboratory should evaluate periodically its diagnostic capacities regarding different type of situations scenarios and report it to their authorities.
5. **Level B**: A higher degree of alert should be adapted. Checking the reagents stock, upgrade the alert of the staff. Collect and connect all data from different sources.
6. **Level C** & **Level D**: Complete mobilization of all laboratory capacities in order to be able to comply with the unclear developed situation.

**Summary of the plenary discussion on this item:**

Rapporteur: Prof. Edmond Panariti, with additional points from the Chairman

1. The Disease Security Officer should be considered an essential position, and with functions identified in the Contingency plan (CP hereinafter) structure. He/She should be in position to take responsibility for biosecurity measures, assure the legal basis for the enforcement of safety and security in all lab or in field procedures.
2. The position of crisis manager (external relations) should be included in the CP, to handle external relations in place of technical staff whose skill and time is in short supply.
3. The difference between the C and D action levels in the Contingency Planning is not well defined. It appears that the main difference lies in the virus typing which is normally not done in level C, but D.
4. It is important to start with the contingency plan and later on establish the level of action which can vary from A-C. The CP should be flexible enough by taking into account the different situations in various countries. Different parts of the CP can be activated in accordance with the situation needs.
5. Lab capacities and needs for the implementation of the CP should be made known well in advance to the authorities. The capacity should state the sample throughput INCLUSIVE of expected levels of re-testing—the latter may be significant. This statement of capacity should then be valuable in contract negotiation with Government.

6. CP should be based on local resources available at that point in time. If the CP indicates that resources will be exceeded, this should be made known to the competent authorities (CA).

7. Negotiation should be started with the CA on the alternative ways by which the required capacity can be gained during the crisis.

8. In case that the lab capacities lie beyond what is required, other alternatives should be investigated as a way out. Other labs might be eventually involved for carrying out supplementary work. The need for such supplementary capacity/work should be stated in the CP itself.

9. A periodical reassessment (yearly) of capacities is necessary in view of the ever changing situations.

10. Management of the crisis will require management styles that enable problems to be quickly identified and resolved, in advance of the crisis, and during the scaling up of activities. Team management approaches are encouraged, especially during the scaling up process. This should assist to improve problem identification and communication, to achieve a consensus on priorities and daily tasks to be undertaken, and to use the scarce personnel and skills to greatest effect.

**Working group 6**

**Task:** Develop draft guidelines on use of portable diagnostic tests for FMD virus

Members: Dr Mitrea (Chair), Drs Tharaldsen (Rapporteur), Sumption (resource person), Panariti, Cobanov, Separovic, Krnjaic, Sangiovanni

**Outputs: recommendations on coverage and draft content of guidelines**

| Background and related papers: Annex 9 (Outlook and issues relating to use of portable diagnostic tests), Annex 2 (Testing for FMDV) |

Definition: Portable devices are any rapid tests used outside the regular laboratory.

Such tests could be considered used in any situation when there is a special need for rapid results. As an example, the National Laboratories can be under great pressure in case of an outbreak of FMD, and rapid tests could be considered an additional tool.

Test requirements: Pen-side test can be used for detection of virus provided it has equal or better sensitivity than the ELISA, and ideally, both antigen and antibody tests should be available. A portable RT-PCR may also meet these criteria and provide a possible test system.

The quality of the tests should be validated by competent, independent reference laboratories in compliance with OIE test requirements. All relevant characteristics which may influence the test result, such as temperature and humidity, should be included in the validation.

The test performance will determine the use of these tests, and it will be up to the National Authorities to decide if they are going to use it and under which conditions.

Personnel performing these tests must be authorized and specially trained.

**Summary of the discussion:**

The pen-side tests must be fully validated in accordance with the OIE guidelines.
The guidelines for these tests should specify under which conditions they should be used. Which further actions to be taken will be depending on the outcome of the test.

The guidelines should reflect the difference between pen-side tests for antigen detection and those for antibody detection.

Recommendation: The guidelines should be further developed.
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