



FMD and CSF Coordination Action



Manual for Laboratory Contingency Planning against CSF

FMD and CSF Coordination Action - Workpackage 6,
Laboratory Preparedness
Danish Technical University
Lindholm
Denmark



The production of a manual for laboratory contingency planning against CSF (Mnth 28)

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Abstract

One of the main objectives of Workpackage 6 “Laboratory preparedness” of the Coordination Action (CA) for Foot-and Mouth-Disease (FMD) and Classical swine fever (CSF) was to prepare a laboratory contingency planning manual for CSF for reference laboratories and national laboratories. In comparison to the work in the FMDV group where several previous workshops have focussed on this, the experience in the CSFV area was sparse. To this end a working group of laboratory experts on CSF was established. A workshop on "Laboratory contingency planning and laboratory exercises" was conducted at the premises of the Community Reference Laboratory (CRL) for CSF in Hannover, Germany on February 19th – 20th February 2008 in close cooperation of the NVI, Denmark, the CODA-CERVA, Belgium and the CRL, Germany. Twelve invited participants from eleven countries participated in this workshop. Participants were chosen as they came from countries with existing laboratory contingency plans.

As results of this workshop guidelines for a) laboratory contingency planning and b) for performing a laboratory real-time exercise on classical swine fever were produced (see Annexes).

Introduction

In order to adequately and efficiently handle outbreaks of contagious diseases such as CSF, FMD or highly pathogenic Avian Influenza (HPAI) competent authorities as well as laboratories involved have to be well prepared. For countries belonging to the European Union Article 22 of Council Directive 2001/89/EC on Community measures for the control of CSF requests, that each Member State shall draw up a contingency plan specifying the national measures to be implemented in the event of an outbreak of CSF. Whereas no explicit reference is made in this article to laboratories, Annex VII of the document, providing information on criteria and requirements relating to contingency plans, states that provisions must be made for appropriate resources to be available to ensure a rapid and effective campaign, including laboratory staff, equipment and infrastructure. In order to be able to fulfil these requirements laboratories need to be in possession of a functioning contingency plan.

A laboratory contingency plan (LCP) shall therefore include a practical description of all the procedures, instructions and measures to be employed in case of an outbreak of CSF. Furthermore, it should depict the chain of command and make sure that the necessary

facilities, financial and material resources as well as well trained personnel are available and guaranteed. It is essential that such a plan is established already during “peace-time” and is reviewed periodically to assure its practicability. A means to test the functionality and practicability of the LCP is to perform a (real-time) laboratory exercise.

The large epidemics of FMD and CSF that have occurred in Europe in the last decade have illustrated the need for better contingency plans including also laboratory preparedness. Increased trade in animals and animal products has considerably enhanced the risk of (re-) introduction of infectious diseases such as FMD and CSF into countries declared free of these diseases. Due to the complete ban of vaccination against CSF in Europe and in many other countries (e.g. Australia, Canada, U.S.A.) viruses will encounter a totally naive population, so that the danger of rapid spreading of the disease is enhanced. Densely populated livestock areas pose an additional risk. Rapid and reliable diagnosis of CSF is therefore of utmost importance in order to detect an outbreak fast and efficiently and to eradicate the disease effectively. Recent outbreaks of CSF (Germany, 2006) and experiences from the past (e.g. Germany and The Netherlands, 1997/1998 ; Spain, 2001) show that laboratories have to be prepared to test several thousands of samples per week. In addition, many of these tests will have to be performed under enormous time pressure. However, during peace-time routine testing for CSF is limited and the diagnostic and logistic capacities of the laboratories are (most) often not adapted to handling vast numbers of samples. To meet the sudden demand for rapid mass testing in a contingency, laboratories have to be well prepared in advance. By now, many laboratories have a quality management system put in place and are accredited (or in the process of being so) according to ISO/IEC 17025. However, still some laboratories have not yet established a LCP, others are currently revising and updating their plans.

The manual on laboratory contingency planning and the guidelines on how to perform a (real-time) laboratory exercise, which were established within this workpackage are intended to be of help to national (and regional) CSF laboratories.

Material and Methods

In order to establish guidelines on LCP and on performing laboratory exercises a working group was established. To this means first the results of D-WP6a "A global report on the current status of laboratory contingency planning for Classical swine fever (CSF)" were analysed and experts in these fields were identified. 15 persons were invited to attend to a workshop on LCP and laboratory exercises and 12 experts followed the invitation and participated in the workshop (see Annex I).

During the meeting, which took place in Hannover, Germany on February 19th to 20th 2008, experiences on LCP and lab exercises were exchanged and the participants agreed on guidelines for both topics.

Results / Summary

The conclusions and recommendations of the workshop in Hannover were afterwards compiled in two documents. These documents have also been forwarded upon request to other EU partners and they have been presented at the Annual Meeting of the National Reference Laboratories for CSF in May 2008.

The documents are included here as Annexes II and III.

In addition, a publication on “Real-time laboratory exercises to test contingency plans for classical swine fever: experiences from two national laboratories” was published (Koenen et al., 2007). This publication describes the experiences of two national reference laboratories for CSF with such exercises. Pitfalls and shortcomings that were encountered during the laboratory drills are depicted and lessons learnt are analyzed.

Outlook

It was suggested that laboratories conducting a laboratory exercise should invite external observers. Thus, an additional view from the "outside" would be generated, which might be helpful in identifying constraints and pitfalls. On the other hand the observers would also benefit and could take home improvements and new ideas for their labs. To this means a network of experts could be established. The idea shall be further pursued within the Network of Excellence "Epizone".

References

Koenen, F., Uttenthal, A., Meindl-Boehmer, A. (2007): Real-time laboratory exercises to test contingency plans for classical swine fever: experiences from two national laboratories. Rev. Sci. Tech. **26(3)**, 629-38.

ANNEXES

- Annex I:** Programme of the Workshop on “Laboratory contingency planning and laboratory exercises”
- Annex II:** Guidelines for laboratory contingency planning (LCP)
- Annex III:** Guidelines for performing a Laboratory Real-time exercise on classical swine fever

ANNEX I

**Workshop on
“Laboratory contingency planning and laboratory exercises”**

**19th – 20th February 2008
Hannover, Germany**

Location:

**Library, 3rd floor
Institute of Parasitology
University of Veterinary Medicine
Buenteweg 17
D-30559 Hannover**

Organizers:

**Community Reference
Laboratory
for CSF (CRL)**
University of Veterinary
Medicine
Institute for Virology
Buenteweg 17
D-30559 Hannover
Germany

**National Veterinary Institute
(NVI)**
Technical University of
Denmark

Department of Virology
Lindholm
DK-4771 Kalvehave
Denmark

**Veterinary and Agri-cultural
Research Centre (VAR-CODA-
CERVA)**

Groeselenberg 99
B-1180 Brussels
Belgium

within the framework of the Coordination Action on FMD and CSF

The aim of the workshop is to prepare the template for a LCP for CSFV. Invited participants are either in the possession of a LCP or in an advanced state of preparing one.

According to Council directive 2001/89/EC a LCP is required for each laboratory. Furthermore, all staff at any reference laboratory must participate in alarm drills twice a year. The optimal alarm drill at the laboratory level is to perform a real time exercise, but even an update of the changes in the quality system may be registered as an alarm drill.

During the meeting these issues will be discussed and after the workshop the organising group, mainly Åse Uttenthal, Alexandra Meindl-Böhmer and Frank Koenen will concentrate the results in a report for the CA-FMD-CSF. This report will be presented at the NSFL meeting in May 2008 in Hannover,

The invitation covers flight or train expenses up to 500 €, the hotel expenses for two nights for each invited participant. Also lunch, coffee breaks and a dinner at the second night will be covered. Travel expenses amounting to more than 500 € and the costs of the dinner the night before the workshop starts need to be covered by the participants. The participants are asked to make their own reservations and fill in forms for reimbursement during their stay in Hannover.

Invited Participants

Name	Country	Attendance
Frank Koenen	Belgium	Yes
Åse Uttenthal	Denmark	Yes
Kylli Must	Estonia	Yes
Marie-Frederique LePotier	France	No
Martin Beer / Bernd Hoffmann	Germany	No
Gian Mario De Mia	Italy	Yes
Pat Lenihan	Ireland	Yes
Eugenijus Jacevicius	Lithuania	Yes
Willie Loeffen	The Netherlands	Yes
Jorun Tharaldsen	Norway	Yes
Andrzej Lipowski	Poland	Yes
Mihai Ion / Eugen Olaru	Romania	No
Trevor Drew	United Kingdom	Yes
Alexandra Meindl-Böhmer	CRL, Germany	Yes
Sabine Kühne	CRL, Germany	Yes

Workshop Programme

Tuesday, February 19th 2008

- 8.10** **Leaving from the hotel reception for the tram station**
- 8.30 – 9.00** **Reception Buenteweg, Library, Institute of Parasitology**

Session 1: Laboratory contingency planning

- 9:00 - 9:45 Laboratory contingency planning – General aspects
Alexandra Meindl-Böhmer
- 9.45 - 10.00 Belgium: LCP
Frank Koenen
- 10.00 – 10.15 Denmark: LCP and the role of quality management in it Åse Uttenthal
- 10.15 – 11.00 Short (!) introduction to the LCPs of the participating laboratories (characteristic features, particularities, maintenance, problems)
-Ireland (Pat Lenihan)
-Norway (Jorun Tharaldsen)
-UK (Trevor Drew)
-Estonia (Kylli Must)
-Lithuania (Eugenijus Jacevicius)
- 11:00 - 11:30** **Coffee break**
- 11:30 - 12:00 Short introduction to the LCPs of the participating laboratories (characteristic features, particularities, maintenance, problems)
-Poland (Andrzej Lipowski)
-Italy (Gian Mario De Mia)
-The Netherlands (Willie Loeffen)
- 12:00 – 13.30 Discussion in working groups
- 13.30 – 14.30** **Lunch**
- 14.30 – 15.00 Discussion in working groups
- 15.00 – 15.45 Presentation of results; Template for LCP
- 15.45 – 16.00** **Coffee break**

Session 2: (Real-time) Laboratory exercises

- 16.00 – 16:30 Introduction to Laboratory real time exercises and experiences from the Belgian
Real time exercise
Frank Koenen
- 16.30 – 17.00 Experiences from the Danish Laboratory Real-time exercise
Åse Uttenthal

17.00 – 18.00 Short (!) presentations on the experiences with laboratory exercises of the participating laboratories (outline, duration, pitfalls, problems, shortcomings, suggestions for improvements in the future)

18.00 End of day 1

20.00 Dinner

Wednesday, February 20th 2008

Session 2: (Real-time) Laboratory exercises (continued)

9.00 – 9.30 Introduction to the practical exercise
Åse Uttenthal

9:00 - 10:30 Practical exercise in working groups: Planning a laboratory exercise for PCR

10:30 - 11:00 Coffee break

11:00 – 12.00 Practical exercise in working groups: Planning a laboratory exercise for PCR
(continued)

12.00 – 12.30 Presentation of results

12.30 – 13.30 Lunch

13.30 – 15.00 Final discussion

15.00 End of the workshop

ANNEX II

Guidelines for laboratory contingency planning (LCP)

Results from a workshop in Hannover, 19-20 February 2008

Compiled by Alexandra Meindl-Böhmer, CRL-CSFV, Hannover, Germany, Åse Uttenthal, Vet-DTU, Lindholm, Denmark and Frank Koenen, CODA, Brussels, Belgium.

Laboratory contingency planning (LCP) is designed to mitigate the risk of system breakdown and unacceptable service unavailability in case of a crisis. It is a means to ensure that the laboratory is able to operate effectively and without excessive interruption or delay during the outbreak of a disease such as Classical swine fever (CSF). Furthermore, it allows a laboratory to guarantee that the necessary quality standards will also be met during a crisis and it serves as a reference manual to all (laboratory) personnel in case of a contingency.

In addition, a LCP may be a valuable tool to present and proof a laboratory's preparedness and capability to external visitors and auditors (such as e.g. missions from the FVO or the European Commission).

Therefore, it is essential that a LCP is written in a short, simple, yet precise manner and is also comprehensible to people not belonging to the lab themselves. It must be easily accessible to all staff members, but must be secured, so that it can not be changed by any unauthorised person.

Thorough planning of all procedures and technical measures is needed well in advance of a contingency. It is vital that the organization takes the development and maintenance of the LCP seriously. A contingency can affect the laboratory at any time and this includes the next 24 hours!

The LCP should be developed by a team representing all functional areas (e.g. dispatching, diagnosticians, biosafety advisers, but also administration and telecommunication/IT staff). The aim is to have a plan at hand which allows handling of a contingency within a minimum of time, with minimum disruption and at minimum costs, and to this means all disciplines have to cooperate on a close basis.

To design different situations and also different level of alertness might help in preparing for a contingency.

During **peacetime** with no raised level of alertness it is necessary to regularly check and to update all documents, to train personnel and to negotiate with suppliers of reagents and test kits on conditions of delivery in case of a contingency.

In case of an **alert**, e.g. the introduction of the disease to a neighbouring country, an inventory of the consumables and reagents immediately available to the lab should be done, and if deemed necessary stockpiles should be created. Staff should be informed on the alert situation and service level agreements with the veterinary services and the government should be sought.

In a **crisis situation** immediately a crisis manager, who is responsible for handling of the crisis and the coordination of all activities, has to be installed. To have a checklist of immediate actions, that have to be taken, available might greatly facilitate the work during the first days of a contingency.

The formation of teams with a team leader and a clear description of tasks for each of the team members assures that no time is lost unnecessarily.

During the **phase of recovery** care has to be taken of the archives. It is most important to perform a thorough evaluation of the management of the crisis. Afterwards the LCP should be updated and amended according to the suggestions of this evaluation.

The issues and questions mentioned within the guidelines presented here are neither complete, nor do all of them fit for each laboratory, nor is the order in which they are presented here mandatory in any way. They cover the main necessary considerations in a comprised version and are intended to be of help to those in the process of preparing or revising their laboratory contingency plan(s).

Within a LCP the following key issues should be addressed:

1. Information on the disease background

A passage containing relevant information on Classical swine fever might prove to be helpful. Give details on e.g. the virus and its properties, on routes of transmission, on different courses of disease including clinical and patho-morphological symptoms, on differential diagnosis and so on. This passage should also contain recommendations on which materials to be sent in for CSFV suspicions; if such schemes are present elsewhere (like on the homepage of the institution) it is sufficient to establish a link to the recommendations.

2. Frame of the LCP in the context of the National CP

Article 22 of Council Directive 2001/89/EC on Community measures for the control of classical swine fever requires each Member State to draw up a contingency plan specifying the national measures to be implemented in the event of an outbreak of classical swine fever. "This plan shall allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak." Criteria and requirements relating to contingency plans are laid down in Annex VII of the above mentioned Council Directive. Amongst others it is stated that:

" [...] d) provision must be made for appropriate resources to be available to ensure a rapid and effective campaign, including laboratory staff, equipment and infrastructure;
e) an instruction manual must be provided. It must give a full practical description in detail of all the procedures, instructions and measures to be employed in the event of an outbreak of classical swine fever;"

Within this directive no specific reference is made to a LCP.

Each laboratory has to depict where and how its LCP fits into the framework of the national CP. It has to define where the CP ends and the LCP begins. Within this context it is important to clearly define the chain of command, to define the contact persons within the veterinary services and to depict the flow of information.

It might be useful to present the LCP to those persons responsible for setting up the superordinate CP in order to harmonize the plans.

3. Information and details on the laboratory

An LCP has to provide information on the name and address of the organisation / the department / the laboratory it is designed for. If feasible, also present the address of the website and the telephone number of the organisation`s telephone switchboard.

If there are any other departments or branch offices, their addresses have to be provided as well and it should be described how they fit into the LCP.

In this chapter information should also be given on the laboratory's functions, duties and obligations during peacetime and in a crisis scenario. A short description of the technical competence and the expertise of the lab (as it is e.g. stated for quality management purposes) could be fitted in.

4. Definitions

Each LCP has to clearly define the situation when it comes into action and for how long it will be used. A definition of what is considered to be a contingency and of the situation when the contingency ends and the laboratory returns to "routine" status is to be laid down.

Furthermore it is crucial to describe how a LCP is activated. Who takes the lead in the crisis management? Who decides on the activation of the plan?

The tasks and duties of a crisis manager shall be explained. If a crisis management group is put in place, the names and functions of the members shall be stated as well as their role in handling of the crisis.

To have timetable of actions that have to be taken immediately after a crisis has been announced, helps in handling the situation. Here, also template protocols with questions that have to be discussed during the first meeting(s) of the management/steering group facilitates the work.

It is highly likely that in case of a crisis other activities such as surveillance programmes or research have to be scaled down. It is important to describe the process on how priorities are set and who decides. This decision has to be passed on and explained to all people involved.

5. Scenario

In order to have a functionable LCP it is important to define a possible worst case scenario, that should and could be handled with the help of the LCP. There are two possible ways of doing so:

- a) Define the worst case scenario (outbreak of CSF in the most densely populated livestock area in your country with a prolonged high risk period with spreading of the disease) and calculate the number of diagnostics tests that would have to be run according to this situation.
- b) Calculate the number of diagnostics tests according to your laboratory's agreements / contractual obligations with the veterinary services / the government.

Based on these figures you should calculate the manpower, consumables, reagents, test kits, equipment and additional space that will be needed in a worst case scenario and design your LCP accordingly.

6. Space

An increased amounts of samples will have to be examined in case of a contingency. During the first weeks the amount of samples will probably be considerably higher than during peacetime, but the highest peak is to be expected somewhat later. After eradication of the disease also a large amount of samples has to be tested to prove freedom of disease.

Therefore, in most laboratories additional space will be needed. This will not only affect the diagnostic laboratory itself, but also the arrival area of the samples and the dispatching unit.

Additional space will also be required for storage of samples after examination. Rooms shall be available and adequately equipped (e.g. phone, computer with access to the www and emails, fax, printer, copy machine, maps) for meetings of the crisis management group and also for regular briefings of the staff.

Within the LCP the laboratory should clearly outline, how additional space will be gained. What will be the rooms, that will be used additionally? Which equipment is necessary and will be needed in which room? How will compliance with biosafety issues be met?

A map could be a means to graphically illustrate the changes between peacetime and a contingency situation.

7. Personnel

To ensure that the increased amount of samples can be handled, the LCP must provide clear information on how personnel will be mobilised and/or recruited.

It is most important that staff members take over only those tasks they are well acquainted with and for which they have the clearance to do so. That means that they must be trained on the job and records must be available, which prove their competence and qualification. It has to be described, how adequate training of personnel is ensured. Responsibilities have to be outlined and the chain of command needs to be clearly depicted.

A database providing information on the personnel and each employee's qualifications should be available. Name, address, phone number and mobile phone number of the employees should be included here as well as a short CV, the person's authorisation and responsibilities and information on the level of training.

In order to deal with the workload, it might be helpful to assign teams consisting of a scientist as the leader and sufficient technical staff.

As contracts of employees may vary from lab to lab, thoughts should be given to out of hour services and prolonged working times. Are they included in the contracts and are they thus obligatory? If not, how will this issue be handled?

If the contingency continues for a prolonged period of time keeping up the required number of staff might become more and more difficult. Further training of staff already working in the laboratory but usually dealing with other matters may be obtained during real-time exercises (see guidelines for conducting real-time laboratory exercises).

8. Methods and Procedures

Although the diagnostic tests suitable for the diagnosis of CSF are described in Commission Decision 2002/106/EC and the Technical Annex accompanying it, each laboratory has to define which diagnostic tests it will use in case of a contingency.

A thorough description of all diagnostic tests has to be included in the LCP. For each of the diagnostic tests used in the lab the maximum capacity per day/week shall be stated. Therefore, it is necessary to calculate how much time is needed to test a sample (or e.g. ten samples) in each of the distinct assays used.

However, not only need the diagnostic tests themselves to be described in detail, but the whole process from the arrival of the samples (including receipt, preparation, testing and storage of the samples) until submission of the diagnosis to the veterinary services should be outlined. Furthermore questions such as: "What happens in case of an inconclusive result" have to be answered. Flow charts and decision trees are an excellent tool to present an overview of the processes.

As by now most laboratories are accredited (or are in the process of doing so) according to ISO / IEC 17025 the documents used for accreditation and quality management can be quoted and greatly simplify this issue.

9. Supplies: Equipment, Reagents, Consumables

In order to deal with the increased number of samples, additional equipment such as laminar flow devices, centrifuges, PCR machines, incubators, fridges, grinders, glassware and so on might be needed. Furthermore an increased amount of reagents, test kits and other consumables will be needed. A sufficient amount of all materials necessary to perform the number of diagnostic tests expected for the first weeks after an outbreak should be available to the lab at any times. The LCP should provide answers to the questions of how much reagents/test kits would be needed in a worst case scenario and how the stock of reagents and test kits could be enlarged quickly. Contracts with supplies of e.g. test kits could be agreed upon, so that the suppliers guarantee to supply the lab with a certain number of test kits within a certain time.

Lists of all materials, reagents, supplies and consumables and of their suppliers are an integral part of the databases that should be included in any LCP if not present in the QA system.

Make sure that the databases are up to date, otherwise they are of no use. Be aware that they are a key feature of each LCP.

10. Transport

Usually transport of samples to the laboratory is not in the lab`s responsibility. However, if different laboratories (e.g. regional laboratories or a branch of the lab in a different location) will be involved in the testing, provisions have to be made to allow for a safe transport of samples between the labs. Current legislation and regulations (such as IATA and ADR) have to be taken into consideration. If necessary contracts with courier services could be agreed upon in advance.

11. Financial issues

Any contingency costs an enormous amount of money. Additional supplies are needed, overtime premium will have to be paid for and so on. It is helpful to already consider financial issues during peacetime and to contact and involve the lab`s administration into the planning. If e.g. additional personnel will have to be recruited, how will that be paid for? Are there template contracts available in such a case?

12. Revision

Each LCP has to be revised regularly in order to keep it up-to-date. Any relevant changes, e.g. a change in the personnel or a change of methods shall be included immediately. It has to be defined who is responsible for updating the LCP and how often this shall be done. Regular revision of the LCP during peacetime needs discipline and a devoted manager! Further more it has to be adressed, how changes in the LCP are communicated to the staff.

13. Appendices

In order to avoid having to search for information, relevant documents should be included as an appendix in the LCP. Useful documents could be amongst others:

- National and EU legislation on CSF (amongst others Council Directive 2001/89/EC and Commission Decision 2002/106/EC with the Technical Annex accompanying it)
- OIE Manual
- Guidelines for the transport of samples (e.g. IATA and ADR)
- Maps of the laboratory complex
- List of approved disinfectants

14. Further information

If deemed necessary additional information can be included. Information could be on e.g.: the laboratory's experience, its participation and results in proficiency testing and laboratory exercises; publications.

After developing the LCP it is essential to subject it to thorough testing in order to find out whether it is "fit for purpose" and to test its functionality, or to define its flaws and shortcomings. One means to do so could be performing a laboratory exercise. In any way, the testing process itself must be properly planned and should reproduce authentic conditions as far as possible.

Records should be kept on the testing, and proper evaluation of the results is of utmost importance. According to the results the plan should be further refined or modified.

It shall be pointed out that there is no "generic template" LCP, which could be used in every laboratory, but each lab has to take into consideration e.g. its special situation (personnel, space, quality assurance system, methods, branch offices), functions, duties and obligations!

Acknowledgements to the workshop participants:

Kylli Must, Gian Mario De Mia, Pat Lenihan, Eugenijus Jacevicius, Jorun Tharaldsen, Andrzej Lipowski, Trevor Drew, Willie Loeffen, Frank Koenen, Alexandra Meindl-Böhmer, Åse Uttenthal.

The workshop was funded by CA FMD/CSF (FP6-513755)

References:

ANONYMUS:
Council Directive 2001/89/EC

ANONYMUS:
Commission Decision 2002/106/EC

ANNEX III

Guidelines for performing a Laboratory Real-time exercise on classical swine fever

Results from a workshop in Hannover, 19-20 February 2008

Compiled by Åse Uttenthal, Vet-DTU, Lindholm, Denmark; Alexandra Meindl-Böhmer, CRL-CSFV, Hannover, Germany and Frank Koenen, CODA, Brussels, Belgium.

These guidelines cover the planning and conduction of a laboratory exercise in peacetime, in order to test the organisation and/or capacity that a laboratory may need during a crisis. According to Council Directive 2001/89/EC, Annex VII, g, ii “the staff must take part in alarm drills organised at least twice a year”. The drill could be an oral examination of the staff or a more authentic exercise. This type of exercise is especially useful for countries which have not had outbreaks of exotic diseases recently. Many laboratories have the agreement that an exercise is only conducted if no epidemics have occurred during the last year. A laboratory exercise can be carried out completely under the responsibility and supervision of the laboratory itself, although for certain parts the veterinary authorities may be asked to be involved.

Real-time exercise can also be carried out on a larger scale, involving the veterinary authorities including training in crisis management, handling suspicions, collecting samples, drawing protection and surveillance zones, identifying herds, etc. Usually these exercises will be under the responsibility and supervision of the veterinary authorities and may or may not involve the laboratory. Combined exercises like this are even more fulfilling and challenging.

These guidelines cover in short the main necessary considerations; they are intended to be an inspiration to countries which have never performed a real-time exercise before.

The planning and conduction of the exercise itself is divided into 4 stages:

1. Determine the goal of the exercise
2. Scenario the exercise
3. Carry out the exercise
4. Evaluate and report the exercise

1. Determination of the goal of the exercise

During a crisis situation, several key issues may arise, that a lab needs to be prepared for. This may concern e.g. high throughput for different tests (ELISA, VNT, VI, PCR) within the framework of screening (around infected herds or final screening for lifting of prohibitions, etc.). It could, however, also concern the handling of multiple suspicions received during the day. Analysis have to be carried out with a high time-pressure in order to report results as soon as possible. Responsibilities of the lab do not only concern carrying out the diagnostics tests itself, but may also include issues like receiving of the samples (day and night), administration and dispatching of samples, tracking and tracing of samples, sample preparation, validating and reporting of results. In addition other topics such as availability of supporting personnel to keep everything in and around the lab running (security of the lab,

catering after working hours, technical support (building, lab equipment, ventilation, communication and IT-systems etc.)), providing expertise to veterinary authorities, etc. have to be attended to. These issues may be left out of an exercise, may be part of it, or may even be the major focus of the exercise.

Therefore, it is necessary to clearly determine the goals of any exercise as the very first step during the planning process. For each laboratory and country it has to be taken into consideration how the responsibilities between the involved parties (laboratory, veterinary authorities) are divided nationally.

2. Planning of and general conditions for the Laboratory Real-time exercise:

A real-time exercise may include several diagnostic methods or might focus on one assay. As example, an example could be a high throughput exercise for the PCR test.

Planning:

- a. Plan for the regular daily work at the lab during the exercise, as this will have to be continued without too much interference.
- b. Duration of the exercise, how many days? Will there be prolonged working hours? Weekends?
- c. Economy: Which are the economic borders (In the DK exercise the estimated expenses for a one-week drill including planning was 85,000€).
- d. Supplies: Calculate the need of reagents, pipette tips and other consumables you will need, and take this opportunity to consider if your present storage of utensils will cover the first week of an outbreak.
- e. Consider your method of choice: Do you plan a high throughput exercise, 100 suspicions or a mix of both?
- f. Determine, where the exercise will start: If the samples are received in a realistic way and registered in the LIMS system, use original submission papers for identification. Does it include pre-treatment and correct storage of part of the samples?
- g. Will more than one geographical site of the lab be included? If so, the safe and legal transport of samples and accompanying information must be planned.
- h. Determine, where the exercise will end: Will it include reporting of the results? If so, to whom (who receives results in your country during a crisis)? Will it include an electronic transfer to the Veterinary Authorities? If so, will the Veterinary Authorities confirm the receipt on a daily basis? Reporting time is an issue when the Veterinary Authorities are involved. And when they are involved they can also ask to change the priority for some samples to test.
- i. Is it possible to hire an external bureau to supervise the exercise? Will this be an option?

Samples:

- a. A high number of samples are needed for an exercise. The number used could be based on the capacity that the laboratory claims to the authorities.
- b. As an alternative, the number could be determined based on the national pig population density. Imagine the worst case scenario: How many herds are present within a 3 km zone? How many samples would be submitted to fulfil requirements of Council directive 2001/89/EC and Commission decision 2002/106/EC.
- c. Preferably fresh, documented samples should be used. Assure, that your lab is allowed to use diagnostic samples for exercise purposes in advance. Availability of a sufficient amount of samples may also be an issue. Consider using "old" samples,

samples from experimental animals, wildboar or samples from other species if this makes it easier and does not negatively affect the goals of the exercise. Another possibility is to use dummy samples such as water. This will reduce the costs but again, see if it interferes with the goals you set for the exercise (pre-treatment for example).

- d. Will there be inclusion of spiked samples? 20 000 negative samples are not encouraging and will tell you nothing on the quality of the results (Are all positive samples detected? Do you have a potential problem with cross-contamination under these circumstances?). Inclusion of a number of positive and doubtful samples may therefore increase the value of the exercise with hardly any additional costs or effort.
- e. The drill may be used as part of the required training for quality assurance.

Information:

- a. In principle, it is possible to conduct an exercise without prior information of the laboratory staff to be involved to make it even more realistic. However, this might cause serious problems and confusion.
- b. Do you want to announce the exercise to the general public? If so, advertise for instance, that the exercise will take place, using veterinary periodicals. Consider the pro's and con's of announcing an exercise outside the lab!
- c. Make sure information is provided to visitors and craftsmen of the lab, that due to an exercise increased biosecurity is set temporarily in force.
- d. Information to those not participating in the exercise (e.g. other departments) to inform them on the importance of the exercise.
- e. Communication during the exercise: Consider also using fictive communication about things, the lab can be involved in during a crisis (insufficient capacity, wrong priority, wrong results are reported, confusion of samples, etc.) in addition.

3. How to conduct the exercise

- a. Who is in charge? Somebody at the spot must be responsible and able to reply to questions. Make sure that all involved know their responsibilities.
- b. Personnel must be at hand! This is a training which may be used in the Quality Assurance system and added to the CV of the personnel. Consider how to acquire additional personnel, if the crisis continues. How is new staff recruited and trained. Think of legal issues that might arise in such a case (new contracts).
- c. Add something new into the exercise, which has not been tested before (e.g. training for extraction robots).

4. Evaluation and reporting is of very high importance for immediate and later use

- a. The evaluation has to be done as soon as possible after the exercise, while everything is still fresh in everyone's mind.
- b. Focus on your pre-determined goals, but take all other issues that come about into consideration as well.
- c. The contribution of all participants involved in the exercise (lab staff, dispatching, etc.) is important. The original report may be rather "raw" with comments and contributions included (may be complicated to compile; should be in the national language to allow everybody to contribute), and a summary could be used to present the results to others.
- d. Consider seriously what is written by the daily users.

- e. Bottlenecks must be taken seriously! If the main problem is shortage of lab ware, something must be done, otherwise the enthusiasm will disappear
- f. After the report a meeting is conducted, including all involved locations, technicians, leaders and the director.
- g. A condensed version, stating mainly the conclusions, submitted to the authorities and the stakeholders is useful.
- h. Check after some time has elapsed whether bottlenecks and pitfalls have been removed.
- i. It may be useful to have an auditing team from another NSFL laboratory to review the exercise. Both sides can learn from this.

Acknowledgements to the workshop participants: Kylli Must, Gian Mario De Mia, Pat Lenihan, Eugenijus Jacevicius, Jorun Tharaldsen, Andrzej Lipowski, Trevor Drew, Willie Loeffen, Frank Koenen, Alexandra Meindl-Böhmer, Åse Uttenthal. The workshop was funded by CA FMD/CSF (FP6-513755)

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