Guidelines for the preparation of a Laboratory Contingency Plan (LCP)

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GUIDELINES FOR THE PREPARATION OF A LABORATORY CONTINGENCY PLAN (LCP)

Results from a workshop in Legnaro – Padova, 11-12 March 2010
CONTENTS

PREAMBEL 5
NOTE 5
ABBREVIATIONS 6
LABORATORY CONTIGENCY PLANNING 7
INTRODUCTION 7
MAIN PRINCIPLES TO BE CONSIDERED FOR THE PREPARATION OF A LCP 7
STRUCTURE OF THE LCP 8
A) GENERAL PART 8
   1) Identification 8
   2) Scope 8
   3) Organization and crisis management/
      Chain of command-decision making and definition of responsibilities 8
   4) Description of the interaction between the LCP and the National Contingency Plan 9
   5) Definition contingency situation-Activation of the LCP 10
   6) Levels of alert 10
   7) Personnel and recruitment of additional personnel 10
   8) Outsourcing of work 11
   9) Prioritization of work 11
  10) Prioritization of samples 11
  11) Communication 12
  12) Laboratory Information management System 12
  13) Logistic flow of samples 13
  14) Epidemiological context of the country/area-Epidemiology 13
  15) Transport and packaging of samples 13
  16) Financial issues and human resources 13
  17) Bio-Safety 13
  18) Quality management and quality assurance 13
  19) Laboratory contingency plan exercises/laboratory exercises 14
  20) Revision 14
  21) Databases and checklists 14
  22) Catering 14
  23) Disease cards 14
B) DISEASE SPECIFICATION / THEMATIC PART

1) Information on the laboratory/laboratories
2) Information on the disease
3) Disease cards
4) Epidemiology and risk assessment
5) Scenarios
6) Calculation of resources needed
7) Number of staff needed
8) Number of test kits, reagents and disposables/consumables needed
9) Number of equipment/machinery
10) Number of rooms/facilities needed
11) Description of activities during a crisis
12) Samples acceptance and dispatching unit
13) Prioritization of samples
14) Diagnostic assay
15) Sampling and epidemiological investigations
16) Bio-Safety

APPENDICES
REFERENCES
MEMBERSHIP OF THE WORKING GROUP
PREAMBEL

The prompt identification of an infectious disease and the rapid onset of control measures is a prerequisite for the appropriate management of an outbreak of any epizootic disease. In order to adequately and efficiently handle outbreaks such emergency situations, Competent Veterinary Authorities (CVA), including veterinary laboratories, need to be prepared by having contingency plans available.

Within the EPIZONE Network of Excellence (Contract No. Food-CT-2006-016236) a working group of scientists, who are involved in contingency planning, was established. The aim of this working group was to outline the relevant aspects having to be taken into consideration for the management of a crisis caused by an outbreak of “an exotic disease” at laboratory level. This document is the outcome of the workshop held in Legnaro, Padua, Italy on March 11-12th 2010 at the Istituto Zooprofilattico Sperimentale delle Venezie.

NOTE

It shall be pointed out, that there is no “generic” laboratory contingency plan (LCP), which could be used in any laboratory! Contingency planning always has to take into consideration the specificities of each laboratory and the diseases it is designed for as well as the structure of the veterinary services in the respective country! This document shall only provide a basis for developing an individual LCP and shall give advice on issues which need be taken into consideration. It shall assist veterinary laboratories in preparing for an exotic disease emergency, also aiming at the harmonization and facilitation of LCP.
ABBREVIATIONS

AI: Avian Influenza
CP: Contingency Plan
CVA: Competent Veterinary Authority
CSF: Classical swine fever
EI: Epidemiology Unit
FMD: Food and Mouth Disease
IATA International Air Transport Association
LCP: Laboratory Contingency Plan
LDCC Local disease control centre
LIMS: Laboratory Information Management System
MIS: Management Information System
ND: Newcastle Disease
OIE World Organisation for Animal Health [Office International des Epizooties]
PPE: Personal Protective Equipment
RVL Regional Veterinary Laboratory
SVD: Swine Vesicular Disease
LABORATORY CONTINGENCY PLANNING

INTRODUCTION

In order to be able to operate effectively and without excessive interruption or delay during the outbreak of a disease, it is essential that each laboratory involved in the diagnosis of epizootic diseases is in possession of a laboratory contingency plan. Laboratory contingency planning (LCP) is designed to mitigate the risk of system breakdown and unacceptable service unavailability in case of a crisis. 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.

This guideline for laboratory preparedness reviews the issues that each laboratory must address in preparing an appropriate contingency plan.

The issues and questions mentioned within this guideline are neither complete, nor do all of them fit for each laboratory. 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).

Main principles to be considered for the preparation of a LCP

- The preparation of a LCP needs to be performed well in advance of a contingency.
- It needs to be lined out how the LCP fits into the framework of national contingency plans and how interaction with veterinary services (and – if applicable - other laboratories) is foreseen.
- The LCP should be developed by a team representing all functional areas (e.g. sample acceptance staff, diagnosticians, bio-safety advisers, epidemiologists, administration and telecommunication/IT staff) and needs to be approved of by all groups.
- The LCP needs to be short, precise, comprehensive and up-to-date. It must be easily accessible to all staff members and must be secured from changes by unauthorised persons.
- It is strongly recommended not to change the organisation of the laboratory or its procedures in case of a contingency but to stick to the procedures that apply for normal laboratory operation.
- Before starting to draw up a LCP possible contingency scenarios must be identified. The number of samples to be expected should be known and agreed upon with the veterinary authorities.
- An assessment needs to be done on how many samples can be analysed with by how many people for each of the diagnostic tests available and how much material/ disposables/kits will be needed. Also it needs to address which and how many machines are necessary.
- Regular revision and up-dating of any existing LCP is an absolute necessity. Its functionality should be tested periodically.
- The LCP should be read in conjunction with other documents that outline the responsibilities of State governments and relevant bodies/authorities in the event of an exotic disease emergency.
STRUCTURE OF THE LCP

Depending on the structure of the laboratory/institute it is recommended to divide the LCP into two parts:

- **A general part** which covers general procedures which apply in any case of contingency (This document shall be valid for all laboratories and shall cover super-ordinate procedures and actions as well as administrative issues.)
- **A disease specific part** providing detailed information on measures to be applied and actions to be taken in case of an outbreak of a specific infectious disease.

This approach is especially advisable if several laboratories within one organization and with the same background need to draft their LCPs. Common features need not to be repeated, whereas the specificities can be considered within the disease specific /thematic part.

A) GENERAL PART

The general part shall contain information which is applicable to all laboratories within the same organisation / institution such as definitions, administrative and financial issues, and general logistical procedures and so on.

**If the LCP is not divided into different parts these issues nevertheless need to be addressed!**

1) **Identification**
   An LCP has to provide information on the name and address of the organisation / the departments / the laboratories it is designed for. If feasible, also the address of the website and the telephone number of the organisation’s telephone switchboard shall be shown. A short description of the technical competence and the expertise of the laboratory (as it is e.g. stated for quality management purposes) could be fitted in.

2) **Scope**
   Outline the scope of the LCP, what are the aims?

3) **Organization and crisis management / Chain of command – decision making and definition of responsibilities**
   The chain of command has to be clearly depicted in each LCP. The LCP must provide detailed information on who is in charge and takes the lead in handling the crisis. A crisis management team should be immediately installed in case of an alert or a contingency situation. This team deals with “internal” aspects (such as e.g. management of the diagnostic work performed in the laboratory) of the contingency as well as with “external” aspects (such as e.g. providing advice and expertise to veterinary authorities and to the public). Members of this steering group must not only come from the laboratory personnel itself, but should be selected from all areas involved in the handling of the crisis, such as amongst others: staff from the laboratory and dispatching, administrative personnel, personnel responsible for financial issues, lawyers, telecommunication and IT people.
The “external” crisis management team could for example be composed of a manager for “external contacts”, a legal affairs officer, a human resource officer, a financial controller, a communication officer, an epidemiologist, a quality assurance officer, a bio safety officer, a facility manager, a manager of diagnostics (who is also in charge of the internal crisis management team) and a disease expert (who should also be a member of the internal crisis management team) and a secretariat.

The “internal crisis management team” (= diagnostic team) could consist of the manager of diagnostics and a disease expert, the laboratory coordinators and team leaders and team members for different diagnostic assays, the head and team members of dispatching and the head and team members of the post-mortem inspections. In addition a quality assurance manager, a manager of the LIMS, and an officer responsible for reporting of results need to be included. For each team member a deputy should be appointed (several duties could be assigned to the same person). .. This was mentioned under disease specific... but it is a general comment.

Close communication between “internal” and “external” crisis management groups need to be assured.

A timetable of actions that should be taken immediately in case of an alert or the declaration of a (laboratory) crisis is very helpful in handling the situation. Template protocols with questions/topics that need to be discussed during the first meeting(s) of the management/steering group greatly facilitate the work.

4) Description of the interaction between the LCP and the National Contingency Plans

Most of European legislation regarding Community measures for the control of major OIE Listed diseases (e.g. FMD, CSF, SVD, AI, ND) require each Member State to draw up a contingency plan (CP) specifying the national measures to be implemented in the event of an outbreak. These plans shall assure 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 specific annexes of the respective legislation. It is stated that provision must be made for appropriate resources to be available to ensure a rapid and effective campaign, including laboratory staff, equipment and infrastructure; moreover an instruction manual must be provided. It must give a full practical description in detail of all the procedures, instructions and measures to be implemented in the case of an outbreak. Yet, within these directives no specific references are made to LCP. As the structure of veterinary authorities, veterinary services and veterinary diagnostic laboratories differs from country to country each laboratory has to depict where and how its LCP fits into the framework of the national CPs. It has to define where the national CP ends and the LCP begins. The role of the laboratory, its functions, tasks and responsibilities should be clearly outlined. Depending on the tasks attributed to and the competencies of the staff, procedures that must be integrated with those available in the CP for official veterinarians in the field should be prepared. Whereas in some countries laboratory staff will not be involved in sampling or epidemiological investigations in the field, this role may well also be assigned to laboratory veterinarians in other countries.

Within this context it is also important to clearly define the flow of information (within the laboratory itself, among all laboratories involved and between lab and relevant authorities involved in crisis management) and the contact points to the competent veterinary authorities as well as the interactions between laboratory and veterinary authorities. The chain of command needs to be outlined clearly.
It is recommended to liaise with the people responsible for preparing the national CP and to crosscheck the plans (CP and LCP) in order to identify errors in peacetime.

5) **Definition contingency situation - Activation of the LCP**

A clear definition of what is considered to be a contingency needs to be given. When and under which circumstances will the LCP be activated?

It is strongly recommended to define a contingency situation based on the number of samples arriving at the laboratory and not on the disease situation in the country, as a contingency situation for the laboratory does not necessarily mean a contingency situation for the country. For example an outbreak of an infectious “exotic” disease in a neighbouring country might already lead to a drastically increased number of samples arriving at the lab, causing a crisis in the lab, whereas the disease is not (yet) present in the country itself. A crisis might also still continue in the lab due to intensive testing for freedom of disease, whereas there is no longer a contingency situation existent in the country. Vice versa a well-defined small outbreak must not necessarily lead to a contingency situation in the laboratory if the amount of samples is only slightly above normal.

In any case it is crucial to describe how, when and by whom a LCP is activated. It is also important to define when a contingency situation is no longer encountered so that the laboratory can enter into recovery phase.

6) **Levels of alert**

It might be helpful to describe different levels of alert, which describe distinct scenarios that might be encountered. During **peacetime** with no specific level of alertness it is necessary to regularly check and to update all documents, to train personnel and to make agreements and 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 suspicion of a disease within the country or the introduction of a disease to a neighbouring country, an inventory of the consumables and reagents immediately available to the laboratory should be done, and stockpiles should be created. Checklists will help in addressing all important issues to be taken into consideration. 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. A checklist of immediate actions, that have to be taken, should be already available in the LCP. It might greatly facilitate the work during the first days of a contingency.

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.

7) **Personnel and recruitment of additional personnel**

In order to handle the workload encountered during a contingency situation changes of the routine have to be implemented. Working for extra hours or working in shifts may be sufficient to deal with the crisis, but it should be kept in mind, that a contingency might last for several months. It might therefore become a necessity to recruit additional personnel. Additional staff might either come from other laboratories within the same institution/organisation, from branch offices (e.g. regional laboratories) or even from other, non-related laboratories. It is necessary to provide and document training for all newly employed personnel and to ensure that quality management issues are not violated.
Templates for contracts with newly employed personnel should be available and the conditions should be clearly defined well in advance.

Also, if other laboratories are foreseen to be involved in the testing, contracts / agreements with these laboratories should be drafted during peacetime.

During a crisis additional tasks are attributed to the (leading) laboratory staff. They might be part of the “external” management team, can act as disease expert and be members of various expert groups. Depending on the structure and organization of the veterinary services and the interaction with the laboratory staff, laboratory personnel may also be involved in activities outside the laboratory (e.g. in the field or in a Local Disease Control Centre). These additional activities absorb time, a fact which has to be taken into consideration when drafting the LCP.

It has to be ensured, that the personnel can handle the enormous pressure which arises from the intensive workload. Sufficient time off work, which can be used for recovery, must be available!

It is essential to foresee a deputy for every position.

8) Outsourcing of work

In principle, outsourcing of work to other non-related laboratories would be possible. However it has to be eyed with great caution and is not recommended for several reasons. It has to be ensured that the quality of work is equal and that all relevant QM issues are strictly followed. Furthermore the flow of information and the reporting to veterinary authorities might be problematic. It also has to be ensured that bio safety is guaranteed.

If outsourcing is foreseen in the LCP very clear and detailed instructions should be given on that topic.

9) Prioritization of work

It is highly likely that in case of a crisis other activities such as surveillance programmes or research have to be scaled down. This also effects the management of facilities. As some areas will have to scaled up (most likely dispatching and the laboratory involved in the crisis) other rooms will have to be rededicated. It is important to describe the process on how priorities will be set and who will decide. This decision should be transparent and needs to be passed on and explained to all people involved.

10) Prioritization of samples

In case of a contingency prioritization of samples might become necessary. Procedures have to be included in the LCP on who decides and what the criteria for prioritization of samples are.

It has to be ensured that prioritization is only applied for the samples arriving at the same day. If not all of the samples can be subjected to diagnostic tests on the same day, then even lower ranking samples should be analysed the next day and should not be dropped down in the queue again.
11) Communication

The switchboard should be thoroughly advised or manned with a communication officer who will assure that the disturbances at the lab are reduced to what is needed. Opening hours for questions concerning samples is an option.

a) Internal communication within the laboratory and within the institution

It must be ensured that the flow of information is ensured at all times within the laboratory itself (e.g. change of personnel for shifts or weekends) and within the institution. It is advisable to clearly define and depict how, when, to whom and by whom information needs to be reported. It must be assured that a close contact does not only exist within the lab itself but also to other supporting areas such as dispatching and logistics. Administration must be involved as well as telecommunication and IT people.

In the description of tasks and duties of the staff as described above communication and reporting must also be addressed. Specific flow charts describing the internal flow of information involving the different laboratories/diseases may be helpful in visualizing the process. More disease specific information should be included in the “thematic plan”.

b) Flow of information to the veterinary authorities

LCP must describe how reporting to veterinary authorities is done. The lines of communication between the main bodies involved, with information and policy matters relevant to veterinary laboratories, should be included. Communication can be through formal and informal channels but should be agreed upon in advance.

c) Communication with clients

Veterinary laboratories also serve their local area and many have disease management and research programs that provide a wider state or national service component. Their clients can range from private or government veterinarians, district field officers, or individual farmers, to national animal industry bodies. During a crisis other activities of the lab also have to be maintained and lines of communication with the clients need to remain functional. Through these channels information can also be distributed to a wider community.

d) Press / Public

The main role of the laboratory is to perform diagnostic tests and provide results to the veterinary authorities. Communication with the press / public has to be regarded with great caution, as this is usually a task covered by veterinary authorities. It is recommended not to provide information to the press, but to refer questions to the respective authorities.

e) Leaflets / FAQs

Answers to frequently asked question could be prepared in advance and could be displayed e.g. on the website. Nevertheless it is useful to have information material available (e.g. leaflets) which could be handed over to the public in case of an emergency. Answers to frequently asked question could be prepared in advance and could be displayed e.g. on the website. This issue should also be addressed in the thematic part of the LCP for the specific diseases.

12) Laboratory Information Management System (LIMS)

During a crisis a fully functional LIMS is of utmost importance. The LIMS poses a crucial (and often error-prone) element for the diagnostic laboratory. Entering the samples into the LIMS might be a time-consuming process. Ways (e.g. bar codes and bar code readers or upgrading the number of people involved) should be sought to minimize the delay until the samples become available for the lab for diagnostic testing.

Depending on the specific situation of the laboratory the LIMS might be the gateway for reporting results to the veterinary authorities. It should be agreed upon in advance whether data electronically transferred to the authorities via the LIMS will be accepted.
13) Logistic flow of samples
The logistic flow of samples needs to be explained in detail in the LCP. Flow charts and decision trees are excellent tools to graphically depict the situation and to make the information available at one glance.

14) Epidemiological context of the country/area - Epidemiology
An up to date overview on the epidemiological situation regarding the major OIE listed diseases worldwide and in particular in neighbouring countries should be available. Risk factors associated with the possible introduction of these diseases in country could be mentioned as well. This overview should be helpful to identify animal diseases posing high risks (high probability and impact) to animal and/or public health.

Some laboratories might also be responsible for merging of laboratory results with epidemiological data in order to produce epidemiologic reports. Functions, duties and obligations during peacetime and during a crisis need to be thoroughly described.

15) Transport and packaging of samples
Usually transport of samples to the laboratory is not in the laboratory’s responsibility. However, if different laboratories (e.g. regional laboratories or a branch of the laboratory 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 laboratories. Current legislation and regulations (such as IATA) have to be taken into consideration. If necessary contracts with courier services could be agreed upon in advance.

16) Financial issues and human resources
As any contingency costs enormous amounts of money additional financial supplies are needed. Financial issues need to be discussed during peacetime already and administration has to be involved herein. Questions to be addressed are amongst others: Who pays for the additional expenses? How fast can additional money be assigned to the lab? Are there any legal provisions for this? How to employ new staff – extra hands – such as phd or master students. Will the QA system allow this?
It is strongly recommended to seek contracts with the veterinary authorities and to agree upon conditions applicable during a crisis.

17) Bio-safety
It has to be guaranteed that bio-safety can be maintained at a very high level also during a contingency situation. Provisions must be made to ensure that information on issues regarding bio-safety (e.g. rededication of rooms; increased level of bio-security due to work with pathogens causing epizootic diseases) is passed on to all personnel involved (including cleansing staff and other service personnel).

18) Quality management and quality assurance
It has to be guaranteed that all procedures during a contingency are in compliance with regulations on quality management and quality assurance (e.g. Isoguide 17025).
Some flexibility of the quality management during a crisis should be predicted or a prioritization of activities should be defined in advance (i.e. delay in the storage of documents or in updating papers connected with labs not involved in the crisis).
Questions which often arise concern for example how training of additional (external) staff can be done, if tests which are not (yet) accredited might be used and if samples not meeting the expected standards can be rejected.

19) **Laboratory contingency plan exercises / laboratory exercises**

After developing a LCP it is essential to thoroughly test it in order to find out whether it is “fit for purpose” and to check its functionality. One means to do so could be by performing a laboratory exercise. Training exercises could be carried out regularly for example at the time of revising the LCP. These exercises can either be “desk-top” exercises giving training on specific components of the plan or ‘full-scale’ exercises, involving all laboratory staff. For these real-time laboratory exercises also the LIMS and the communication to veterinary authorities could be included and their performance evaluated.

In any way, the testing process itself must be properly planned and should reproduce authentic conditions as far as possible.

Records need to be kept on the testing, and proper evaluation of the results is of utmost importance. During such exercises and revision of the plan deficiencies in the standard operating procedures can be identified and rectified.

According to the results the plan should be further refined or modified if necessary.

20) **Revision**

Each LCP has to be revised regularly in order to keep it up-to-date. It has to be defined who is responsible for updating the LCP and how often this shall be done. Critical points need to be identified and should be reviewed with special care. Any relevant changes, e.g. changes in the personnel or a change of methods should be included immediately.

Regular revision of the LCP during peacetime needs discipline and a devoted manager, but is an absolute necessity to ensure a fully functional LCP in case of a crisis.

Changes in the LCP of course also have to be communicated to the staff.

21) **Databases and checklists**

In order to assure a rapid availability of necessary information and to avoid delays, it is recommended to prepare databases and to have checklists available for e.g. the following:

- Personnel (Name, address, phone, qualification, experience, training, authorisation, description of duties)
- Disposables (Name, address, contact person of supplier, product number and description)
- Equipment
- Facilities/Room/Space
- Contracts with suppliers
- Supplements and annexes (e.g. maps of laboratories and other relevant buildings; relevant legislation; publications; list of contacts; contracts with the government, veterinary services and suppliers; templates of documents)

This information could also be integrated into the specific part of the LCP.

22) **Catering**

Provisions for catering should be foreseen, in order to keep the labour force of the personnel on a high level.

23) **Disease cards**
The use of “Disease cards” can help in getting a quick overview on the methods and procedures employed in case of a contingency. These cards should summarize the most important facts about the disease, should provide information on the diagnostic assays which will be run and also on where a more detailed description of the employed procedures can be found (e.g. a link to the valid SOPs in the quality management handbook). All laboratories which are involved in the diagnostic process need to be identified and staff members involved in the diagnostic work in the respective laboratories need to be identified. These cards could be used to gain an overview by the “external” steering group or other non-laboratory people in case of a crisis.
B) DISEASE SPECIFIC / THEMATIC PART

In this part specific and detailed planning should be laid down for each distinct animal disease and information on the disease and the management of the contingency situation must be provided. It will provide an *ad hoc* description and instruction for laboratory management. Each involved laboratory should adhere to the rules and guidelines depicted in the LCP.

1) **Information on the laboratory/laboratories**
   The LCP has to provide information on the name and address of the single laboratory/laboratories involved in crisis management. A description of responsibilities and tasks within peace time and in an emergency situation shall be included. All other departments or regional laboratories also involved in the management of a specific disease should be mentioned and it should be described how their work is integrated and fits into the LCP.
   Contact data (names, addresses, phone number) of the staff of the laboratories have to be provided as well.

2) **Information on the disease**
   The name and characteristics of the disease and the causative pathogen for which the thematic supplement is valid need to be mentioned. Not only must the name be mentioned and the agent described shortly, but also the most important information on aetiology, clinical signs, pathology, immunology, affected species, transmission of the disease, role of vectors (if applicable), epidemiology and suitable diagnostic tests must be included.

3) **Disease cards**
   The use of “Disease cards” can help in getting a quick overview on the methods and procedures employed in case of a contingency (see above). They could be integrated into the general part of the LCP or in the thematic part.

4) **Epidemiology and risk assessment**
   A disease specific and up-to-date overview on the epidemiological situation worldwide and in particular in the neighbouring countries should be included. A risk assessment indicating risk factors and the most likely routes of introduction of an “exotic” disease as well as areas thought to be at the highest risk in the country is helpful. The impact of introduction of the specific disease to animal and/or public health and to the economy should be depicted.
   If the disease had been encountered in the country in the past experiences with crisis management (major difficulties, critical points) and lessons learnt could be quoted.

5) **Scenarios**
   Based on all information available on the disease and the susceptible animals in the country (animal number, average herd size, densely populated livestock areas, etc.) a worst case scenario should be established. The number of samples arriving at the laboratory in a worst case scenario (outbreak of an OIE listed disease in the most densely populated livestock area in the country after a prolonged high risk period with spreading of the disease) should be calculated.
   Often the number of diagnostics tests in a worst case scenario will exceed the laboratory’s capabilities.
   Therefore the maximum number of tests which could be performed for each of the distinct diagnostic assays with the personnel available in peace-time and the additional personnel during a crisis should be thoroughly and realistically calculated. It has to be kept in mind that the increased number of tests might have to be performed for a long period of time.
Based on these figures agreements/contractual obligations with the veterinary services / the government should then be sought during peacetime.

6) Calculation of resources needed
Before starting to prepare the thematic supplement of the LCP detailed information has to be available on the time needed for examination of X samples by Y people in diagnostic assay Z. A list of reagents, test kits, consumables and disposables, equipment and machinery needed for each of the diagnostic assays has to be compiled. These data must be gathered during peacetime and shall form the backbone of the calculations for the contingency situation.

Based on the number of samples which are to be expected during a crisis (see above) calculations need to be done on:

7) Number of staff needed
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 (also for additional personnel helping in coping with the crisis). Responsibilities have to be outlined and the chain of command needs to be clearly depicted.

A database providing information on the and details on each employee’s qualifications should be available. Name, address, phone number and mobile phone number of the employees should be included 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 laboratory to laboratory, thoughts should be given to out of hour services and prolonged working times.

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) Number of test kits, reagents and disposables/consumables needed
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 of a contingency situation should be available to the lab at any time. The LCP should provide answers to the questions on 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 laboratory 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.

9) Number of equipment/machinery (also including non-laboratory related equipment such as additional computers, (mobile) phones, fax and photocopying machines) needed;
In order to deal with the increased number of samples, additional equipment such as laminar flow devices, centrifuges, PCR machines, incubators, fridges, grinders, mortars and pestils,
glassware and so on might be needed. Robots may help in preparation and testing of samples and might be a means to increase the throughput within the laboratory.

The number of additional equipment needed for analysing the maximum number of samples that was calculated should be written down. Arrangements should be made to ensure that the equipment will be readily available in case of a crisis. Equipment usually employed by other laboratories might have to be used and an agreement on that has to be made in advance, as this might influence other activities. Increasing the working hours and including night and weekend shifts is also a means to make the best use out of the equipment available.

10) Number of rooms/facilities needed
Additional space and rooms will often be necessary to deal with the increased number of samples in case of a crisis. Not only will additional space be needed in the diagnostic laboratory itself, but also for the arrival area of the samples, the dispatching unit and rooms for storage of sample. Furthermore rooms for meetings of the internal crisis management group and for regular briefings of the staff need to be available and adequately equipped (e.g. phone, computer with access to the www, fax, printer, copy machine, maps). A map could be a means to graphically illustrate the changes between peacetime and a contingency situation.

In general it can be said, that during the first weeks of a contingency situation 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 large amount of samples have to be tested to prove freedom of disease so that the laboratory crisis might continue.

Checklists on the different issues mentioned above will greatly help in checking the resources in case of a crisis.

11) Description of activities during a crisis
In order to efficiently organize laboratory activities during a crisis, it is useful to prepare in advance a check list of all possible activities to be implemented. Whereas general information is provided in the super-ordinate part of the LCP, laboratory specific details should be described here. A specific document that clearly defines procedures/operating instructions enables a more efficient and effective crisis management.

The whole process from the arrival of the samples including receipt, preparation for testing, handling of retain samples, testing and storage of the samples and entering of results into the LIMS to the release of results to the veterinary services must be outlined. Descriptions of procedures to be employed in case of e.g. samples not suitable for analyses/rejection of samples or inconclusive results shall be described.

Flow charts and decision trees are useful tools to illustrate an overview of the processes and can depict the roles/tasks/functions, relationship and responsibilities of the staff.

12) Samples acceptance and dispatching unit
During a crisis additional space will probably be needed for the arrival area of samples and for dispatching (see above).

It is suggested to label samples for investigations of a contingency situation differently (e.g. red label) from samples arriving for routine diagnostic procedures. This assures that samples from a crisis are treated with priority and delays are avoided. Clear guidelines and dedicated procedures for receiving samples, the registration of samples in the Laboratory Information Management System (LIMS) and for internal transport to laboratories should be given.
13) Prioritization of samples
In case of a contingency number of samples arriving per day might exceed the laboratory’s capacities, so that prioritization of samples might become an issue. In such a situation it might be useful to classify the samples in different categories (e.g. samples with low likelihood of an exotic disease versus samples with a high likelihood; samples from a suspicion with an existing restriction zone versus samples of a suspicion in an area not yet affected and outside restriction zones). Clear procedures must be laid down during peacetime already and it has to be described who takes the decision of prioritising samples.
It has to be ensured that prioritization is only applied for the samples arriving at the same day. If not all of the samples can be subjected to diagnostic tests on the same day, then even lower ranking samples should be analysed the next day. Otherwise the risk exists that these low-ranking samples will not be analysed at all or only several days later, so that positive case might be missed.

14) Diagnostic assays
A clear and detailed description of each of the diagnostic assays to be used in case of a contingency is to be provided. For each of the diagnostic tests used in the lab the maximum capacity per day/week shall be stated. It is recommended to stick to the routinely employed methods as much as possible in order to avoid mistakes. If new methods, which are not yet included in the accreditation, are to be employed, validation data have to be available to show that the method is fit for purpose. Regular training of the staff on the diagnostic assays they have to perform is mandatory and training has to be well documented.

Within the EC laboratories involved in the diagnosis of OIE listed diseases have to be accredited according to ISO/IEC 17025. Detailed descriptions on the diagnostic assays and methods employed for analysing samples (Standard operating procedures – SOPs) are laid down in the respective documents for quality management and reference can be made to that.

15) Sampling and epidemiological investigations
Depending on the structure and organisation of the veterinary services laboratory personnel might also be involved in sampling and in epidemiological investigations.
Technical support in the field or in the local disease control centre (LDCC) in order to help local veterinary authorities in performing sampling or epidemiological investigations and tracing exercises might be a task assigned to the staff. Special training for that should be given during peace-time. Standard operating procedures related to sampling, packaging, collection of epidemiological information, validation, data-entry and analysis should be established (e.g. templates for the letter accompanying samples, epidemiological enquiry forms; dedicated databases for data storage; guidelines for performing tracing exercises etc).
A Management Information System (MIS) related to data collection of outbreaks, monitoring activities, restriction areas should be provided and this MIS should be integrated with the LIMS. Templates for standard reports (epidemiological situation, ongoing surveillance programme, results of tracing etc) should be prepared in advance.
In addition checklists for sampling equipment/sampling kits (including personal protective clothing and disinfectants), transport of samples according to the international rules and a calculation of numbers of staff included in these issues need to be available.

16) Bio-safety
Appropriate bio-safety and bio-security must be provided at all times. Special information should be given to the sampling teams in the field to ensure adequate packaging of samples already at farm level. Moreover, procedures for quarantine and decontamination of the
laboratory after specimens from a suspected or confirmed exotic disease case have been handled should be available, together with those referring to handling of waste, sterilisation and disposal.

Control of access to and movements within the laboratory of staff and visitors need to be controlled and ad hoc procedures should be made available.

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 the specific disease
- OIE Manual
- Regulations and guidelines for the transport of samples (e.g. IATA and ADR), packaging instructions
- Maps of the laboratory complex
- List of approved disinfectants
- Relevant publications
- Contracts with suppliers
- List of consumables and reagents and their suppliers
- List of personnel with contact information, clearance and responsibilities
REFERENCES

ANONYMUS:

ANONYMUS:

ANONYMUS:
Commission Decision 2002/106/EC

Australian Veterinary Emergency Plan ausvetplan 1996.


William A. Geering, Peter L. Roeder; Timothy U.Obi,


Public Health Emergency Response Guide For State, Local, And Tribal Public Health Directors Version 1.0 Department Of Health And Human Services Centers For Disease Control And Prevention (CDC)


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