

# Decision support in a fieldable laboratory management during an epidemic outbreak of disease

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## Abstract

**Purpose** – The purpose of this paper is to analyze the decision-making process and provide a decision support framework for deployment of an on-site analytical capacity (a fieldable laboratory (FL)) to contain an expanding outbreak and protect public health.

**Design/methodology/approach** – The FL mission cycle consists of five successive interlinked phases with a set of operational functions (OFs) performed during the mission. The list of phases, OFs and their contents were iteratively developed during and after FL missions and validated with operational partners.

**Findings** – The well-defined structure of the FL domain appears as the best functional basis for tracking the decision-making process across the whole mission cycle. Description of all the FL elements and information flows addresses the major issue of interoperability of resources used by similar international capacities (inter-)acting as operational partners in global response to the crisis.

**Originality/value** – The work presents the first attempt in this field to systematically describe and chronologically organize the decisions taken by a FL manager and staff during all phases of the FL mission cycle. Definition of OFs with all the related information flows allows for comparison of procedures, their better planning and refining, validation of protocols, mutual training and operational improvement between FLs from different geographical, organizational and cultural origins.

**Keywords** Decision support, Knowledge management, Biological crisis response, Fieldable laboratory, Operational functions

**Paper type** Research paper

## 1. Introduction

In complex strategic situations, decision making is often based on a finite set of feasible alternatives, following multiple, at times conflicting objectives, in conditions of high uncertainty, imprecision or lack of information (Comes *et al.*, 2011). Such a challenging set-up, so typical for crisis response and management, requires a decision support mechanism that is robust and reliable, while at the same time flexible enough to help decision makers navigate through an enormous amount of information received from heterogeneous sources. Decision support should enable them to analyze, interpret and assess the value of a decision, and hence to reap the benefits of such a knowledge-based decision process for crisis management.

In the present work, we illustrate this decision support mechanism by providing a framework of the decision-making process which has been developed for and applied to the rapid deployment of a fieldable laboratory (FL) in response to a public health crisis caused by a biological agent (B-agent). The role of on-site analytical laboratory stations as part of healthcare, civil protection and/or humanitarian aid mechanisms is steadily increasing as also experienced internally by the Center for Applied Molecular Technologies (CTMA) staff. Our first FL capacity was deployed in 2009 in Kasai-Occidental, Democratic Republic of the Congo (Dumont *et al.*, 2014), in the context of



recurrent but limited Ebola outbreaks and changing monkeypox endemicity (Table I). Following this very first operational deployment, the FL concept was progressively adapted to a spectrum of mission specificities and biosafety constraints. This led to the progressive transformation of the FL capacity into a lightweight, flexible, largely autonomous, analytical capacity which can now be rapidly deployed near a field hospital or an improvised treatment center in case of any public health crisis (Vybornova *et al.*, 2016). In its current form, the CTMA-FL provides a consistent operational structure at the disposal of national, European and international stakeholders when there is a need to locally reinforce insufficient medical infrastructures or to overcome the lack thereof. This applies especially when the scale, intensity and complexity of the crisis require locally urgent and drastic countermeasures. The turnaround time for transporting and deploying the FL is very short since the current concept employs a series of compactly packaged, properly labeled and listed equipment placed in dedicated carrying cases which

Location and date	Mission type (operational framework)	Purpose	Means of verification
Kananga, West Kasai, Republic Democratic of Congo, April 2009	Military (Belgian Ministry of Defense)	Response to natural and intentional outbreak – identification of the orthopox (monkeypox, smallpox) and <i>Varicella zoster</i> virus in patients with skin rash illness	FL results were validated by the laboratory operators and military stakeholders
Pionki, Poland, April 2014	Civil/military (EC-FP7- PRACTICE)	CBRN scenario – PIONEX was a large scale CBRN exercise testing the FL integration in a CBRN crisis toolbox. The analytical process focused on the <i>Bacillus anthracis</i> detection and identification	External international observers and CBRN experts assessed and validated the FL quality performance
N'Zerekore, Guinea, December 2014- March 2015	Civil/military (WHO, DG ECHO, ESA, and France)	Contribution of B-LiFE to the international response to the Ebola outbreak in West Africa	FL results were validated by the international, European and local mission stakeholders and on-site operational partners
Munich, Germany, February 2016	Civil/military (ESA-IAP/ ARTES20/ B-LiFE)	Training mission – joint bilateral exercise of B-LiFE CTMA-FL and Bundeswehr Institute of Microbiology (EU Mob Lab); comparison of both Belgian and German laboratories laboratory functionalities; subsequent validation of the setting and contents of the OFs	External observers of the exercise validated the FL quality performance. An expert in risk prevention and protection at work was deployed with the CTMA-FL to carefully assess safety and security measures. The OFs and SOPs of each deployed laboratory were compared
Bologna, Italy, April 2016	Civil (EC-FP7- EDEN)	Large scale CBRN exercise focusing on food security; the aim was a rapid detection and identification of intentional food contamination and the on-site assessment of new bio-detections tools	External observers of the exercise validated the FL quality performance. FL certification was performed by Forsvarets forskningsinstitutt (FFI, Norway)

**Table I.**  
B-LiFE CTMA-FL deployment

can be easily moved together, deployed and used by a limited staff of trained experts. The main advantage of deploying an FL in close vicinity to the patients is its ability to provide quick diagnosis and health monitoring for evidence-based laboratory-guided medical decisions. This aspect was particularly well illustrated during the last Ebola outbreak where the Biological Light Fieldable Laboratory for Emergencies (B-LiFE) team deployed an FL from December 2014 to March 2015 to support the medical staff of the Ebola treatment unit of N'Zerekore run by the NGO Alliance for International Medical Action (ALIMA) in the forest area of Guinea (Sissoko *et al.*, 2016; Palich *et al.*, 2016a, b; Irengue *et al.*, 2016).

Each successive phase (i.e. initiation, planning, preparation and execution) is a complex process requiring to collect, interpret and share all the information needed while coordinating its exploitation. Consequently, decisions related to the FL mission are extremely diverse and may be particularly challenging when biological crises with epidemic or pandemic potentials result in irrational or dangerous behaviors (e.g. social unrest due to fear, panic, insecurity, despair, anger or animosity among the population), with a total disruption of already weak medical resources and the economic collapse in affected regions. For the head of the FL who is in charge of the mission, every decision making will always be a trade-off between the necessity to execute and complete the mission successfully, the creative scientific curiosity and drive for innovation and excellence, the wish to save patients' lives and, meanwhile, the heavy responsibility of protecting lives and health of the FL staff and healthy citizens. Furthermore, the head of the FL needs to maintain the quality and efficiency of the FL performance and to preserve the reputation of the laboratory. It is a combination of these factors, constraints and risks that influence the decision-making process while making it extremely difficult.

Consequently, cognitive and human factors play an essential role in the FL decision making. Experience, reliance on effective solutions from the past and current good and best practices are all taken into account. Besides, the highly stressful conditions in which decisions are made on a daily basis when deploying an FL impact the decisions. The following factors are crucial in the FL deployment:

- The physical load during the FL deployment is heavy due to everyday intense operations in difficult conditions like heat, humidity, and in some circumstances, the necessity to wear personal protective equipment that limits vision and movement and increases physical discomfort.
- The cognitive load is extremely high due to the amount of heterogeneous information to handle everyday. This information includes clinical, analytical, and epidemiological data, up-to-date information sent by various stakeholders and operational partners on the evolution of the crisis. To this is added the political, economic and security situation with its local impacts. Meanwhile, the information is often lacking, insufficient, imprecise, ambiguous or contradictory.
- The psychological load is huge due to the overwhelming feeling of responsibility, fear for one's own life and health and for the population in case of an uncontrolled and expanding biological threat, the necessity of working everyday under a tent in a confined space and performing repetitive testing on life-threatening samples which requires strict biosafety measures to prevent accidental infection or cross-contamination. Intellectual and psychological compatibility between the FL staff members is also a very sensitive issue which deserves promotion of team-building and team-spirit prior to the mission and their maintenance throughout.

Flexibility is another key component of any public emergency response. FL has been designed to have a highly flexible configuration which is therefore permanently adaptable to make it suitable for an expanding wide range of missions. Given the uncertainty inherent in every crisis situation, the FL staff has to be prepared for any unforeseen situation, even though the basis for preparedness remains a strong qualification of the staff and a solid experience in using cutting edge technologies, FL materials and equipment. The FL performance is largely regulated by the availability and use of laboratory standard operational procedures (SOPs), guidelines and best practices in the field, and the respect of national and international laws and ethics regarding the control and management of biological threats and patients care. Even though the staff benefits from a regular and specific training and has excellent knowledge and practical skills of this “static” part of the job, every mission situation is special and unique giving a generous space for creativity and paving the way for spontaneous actions and decisions impacting people and processes. In a real global crisis situation, every decision is based on a multi-factor analysis taking into account all available information and not-yet-available-but-needed information gaps. Missing information is analyzed in terms of why it is not available and how to obtain it. Evolution of the biological crisis situation needs to be predicted as the crisis response unfolds, and factors influencing directly and indirectly the FL operation need to be known, etc.

Every decision is unavoidably embedded into the current situational context, is interlinked with other decisions and can therefore have a very local or more global impact. Moreover, the decision makers often consider several alternatives for every decision, taking into account the current context and newly received information, or they iteratively revise previous decisions leading, modifying them partially or totally to adapt with changing circumstances in a rapidly evolving situational context.

The current work presents the first attempt to systematically unravel, chronologically organize and describe the decisions taken by an FL manager and staff during all phases of the FL mission cycle. The analysis of past FL missions allows us to elaborate and present the whole set of operational functions (OFs) performed in each mission irrespective of the mission type.

The methodology used to generate the mission cycle, OFs and decision support is detailed in Section 2, where a short review of the most relevant stakeholders and their interactions during a health crisis with infectious and communicable diseases is presented. The structure of the FL mission cycle and the contents of its phases are described in Section 3. Section 4 provides detailed insight into the decision-making process in each phase of the FL mission cycle.

## 2. Methodology

The methodology of OFs’ collection and validation is based on the comparison with the procedures of other FL capacities. FL is part of the global mechanism of biological emergency preparedness and response. Whereas FL missions and the decision-making process depend on the end users requesting the mission, conditions for the deployment depend on many possible stakeholders who may each influence the proper conduct of the FL missions.

### *2.1 Identification of relevant stakeholders and their interactions during a health crisis with infectious and communicable diseases*

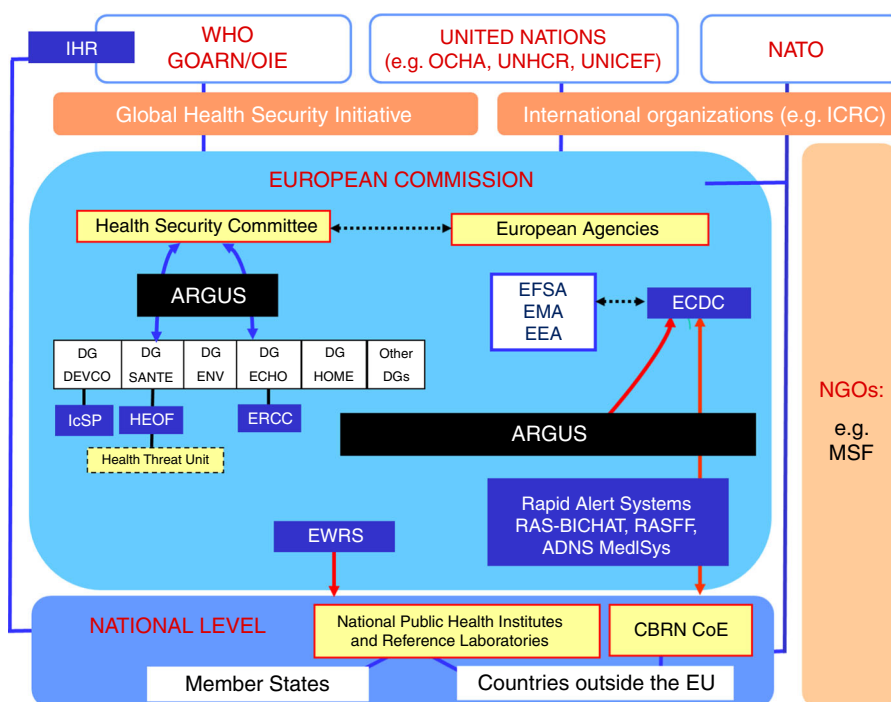
OFs are considered the structural backbone of the FL operational domain and the basis for modeling the decision-making process. In order to better understand the complexity

and interlinks between various components of the FL OFs, much attention was paid to identifying main relevant actors so as to understand how they interact with decision-making processes regarding FL deployment, and to define the parameters (e.g. needs and potential constraints) interacting with an FL capacity building to maximize the chance of transforming this capacity in a successful operational capability (Gala, 2008; Varvasovszky and Brugha, 2000; Potter and Brough, 2004; Mahy *et al.*, 2016).

There are multiple international, European and national (Member States') stakeholders and coordination mechanisms involved in a health crisis such as epidemic or pandemic outbreak ([www.pandem.eu.com/](http://www.pandem.eu.com/)), taking into consideration their natural or intentional origin (Figure 1). The overview is given using a top-down approach, starting from the international level to European and national levels.

*2.1.1 At the international level.* The World Health Organization (WHO) and the international community are rapidly notified by the surveillance network GOARN working at the regional or national level (Figure 1). The International Health Regulations (IHR) constitutes the legal framework in which the operations of alert and rapid actions that the WHO leads with the concerned countries. Depending on the type and scale of the crisis and its impact on the population, UN agencies can also be involved (e.g. United Nations Children's Fund, United Nations High Commissioner for Refugees, Office for the Coordination of Humanitarian Affairs and World Food Program (PAM/WFP)). Beside these international bodies, several non-governmental (e.g. Médecins Sans Frontières (MSF)) and international organizations (e.g. International Committee of the Red Cross, International Red Cross and Red Crescent Movement) can also bring their local support where and when needed. World Organization for Animal Health (OIE) has the specific mission to control the pandemic emergent diseases of animal origin.

*2.1.2 At the European level.* Each Member State is responsible for the safety of its citizens and the management of emergency situations (in case of human and natural caused disasters which may impact public health safety). But as communicable diseases and chemical, biological, radiological and nuclear (CBRN) events do not respect national borders, common mechanisms, which are part of the health security program, are needed to ensure a coordinated approach between EU countries for the public health management in emergency situations (Figure 1). The Directorate General for Health and Food Safety of the European Commission (DG SANTE) is the contact point for the public health at the EU level. Coordination of the management of public health emergency in Europe is done by the Health Emergency Operations Facility (HEOF). The DG for Humanitarian Aid and Civil Protection Department (DG ECHO) and its Emergency Response Coordination Centre (ERCC) play key operational roles in a major crisis inside and outside the EU. ERCC contributes, for instance, to rapid deployment through the voluntary pool mechanism and the European Medical Corps. In case of major crisis, it can bring medical support where needed as well as medical evacuation systems for cases and suspected cases of EU health workers or citizens from affected areas as illustrated during the 2014 Ebola outbreak. The European Centre for Disease Prevention and Control (ECDC) ensures epidemiological surveillance of communicable diseases and of related special health issues through the channel of national public health institutes and reference laboratories. The Health Security Committee (HSC) plays a central role in reinforcing health-security measures in the EU, i.e., the coordination and sharing of best practice and information on preparedness activities. Following a serious cross-border threat to health, European Member States



**Notes:** ADNS, Animal Disease Notification System; ARGUS, Alerte Rapide, Globale et Sûre; DG, Directorate General – Humanitarian Aid and Civil Protection (DEVCO); Health and Food Safety (SANTE), Environment (ENV), Humanitarian Aid and Civil Protection (ECHO), Migration and Home Affairs (HOME); CBRN CoE, Chemical Biological Radiological and Nuclear Risk Mitigation Centres of Excellence; ECDC, European Centre for Disease Prevention and Control; EEA, European Environment Agency; EFSA, European Food Safety Authority; EMA, European Medicines Agency; ERCC, Emergency Response Coordination Centre; EWRS, Early Warning and Response System; GOARN, Global Outbreak Alert and Response Network; HEOF, Health Emergency Operation Facility which coordinates the management of public health emergency at EU level; ICRC, International Committee of the Red Cross; IsSP, Instrument contributing to Stability and Peace; OCHA, Office for the Coordination of Humanitarian Affairs; OIE, World Organization of Animal Health; MediSys, Medical information system; MSF, Médecins Sans Frontières (doctors without borders); RAS-BICHAT, Rapid Alert System for bio or chemical terrorist attack; NATO, North Atlantic Treaty Organization; RASFF, Rapid Alert System for Food and Feed; UNHCR, United Nations High Commissioner for Refugees; UNICEF, United Nations Children’s Fund; WHO, World Health Organization

**Figure 1.** Overview of the health crisis stakeholders’ interaction and alert mechanisms

have to consult each other through the HSC in order to coordinate their national response and communicate to healthcare professionals and the public (Official Journal of the European Union, 2013). The goal is to provide consistent and coherent information adapted to Member States’ needs and circumstances. Several rapid alert systems (e.g. EWRS, RAS-BICHAT, RASFF, ADNS, MediSys) are part of the network for surveillance of communicable disease; they are run by the Health Threat Unit of DG SANTE. ARGUS,

a secure general rapid alert system, links all specialized systems for emergencies and interconnect all Member States to enable coordination in case of major emergencies. Practically, the HEOF coordinates the management of public health emergency at the EU level. The same process is activated in case of declaration of public health emergency of international concern by WHO in accordance with IHR. The Directorate General for International Cooperation and Development (DG DEVCO) and its Instrument contributing to Stability and Peace are responsible for implementing the EU's aid instruments in case of major external crises or emergencies which require ad-hoc decision making. As a good example related to serious threats with cross-border impact, the initiative developing an "EU mobile laboratory capacity" was taken and financially supported by DG DEVCO.

*2.1.3 At the national level.* Several institutions, bodies or organizations from EU Members States ensure preparedness and emergency response plans, and implementation of the EU CBRN Action Plan (2009), e.g., national ministries of health, ministries of home/internal affairs, civil protection agencies, ministries of defense, national emergency/crisis committees and crisis centers (Figure 1). In accordance with the IHR (WHO, 2005) and the EU CBRN Action Plan, local governments are advised to provide and maintain diagnostic capacity (i.e. resources, equipment, infrastructures). The diagnostic capacity consists of public health laboratories and networks (European Centre for Disease Prevention and Control, 2016a), including, whenever possible, at least one reference laboratory for each specific disease, a sentinel laboratory network and mobile detection, identification and sampling capabilities such as FLs. Outside the European Union, the European Union Chemical Biological Radiological and Nuclear Risk Mitigation Centres of Excellence Initiative has been launched in response to the need to strengthen the institutional capacity of countries outside the European Union to mitigate CBRN risks.

## *2.2 Activation of the Belgian B-LiFE analytical capacity*

Deployment of an analytical capacity in disaster situations is part of a global emergency response mechanism which involves international, European and national bodies and institutions (Figure 1).

Each of the possible FL mission stakeholders has their chain of decision making (Global Outbreak Alert and Response Network, 2005; WHO, 2005, 2013; European Centre for Disease Prevention and Control, 2016b; EC, 2015a, b, NATO, 2009; Calain, 2007; Guglielmetti, 2013), and reasons to involve various diagnostic capacities in response to a health crisis depend on the type, nature, location and scale of the crisis, and its potential cross-border threat to health. The rationale for deploying FLs on-site is to provide evidence for decision makers, facilitating the crisis response measures, such as the US Emergency Support Functions (US Department of Health and Human Services, 2016; World Health Organization/Pan-American Health Organization (WHO/PAHO), 2003).

In this chain of alert and response, the B-LiFE laboratory of the CTMA (Belgium) is part of the European emergency response capacity of DG ECHO voluntary pool of resources. This voluntary pool can be used to respond to emergencies and pre-committed by the countries participating in the EU Civil Protection Mechanism. The general scheme of FL mission launch on the example of the mission in Guinea is shown in Figure 2.

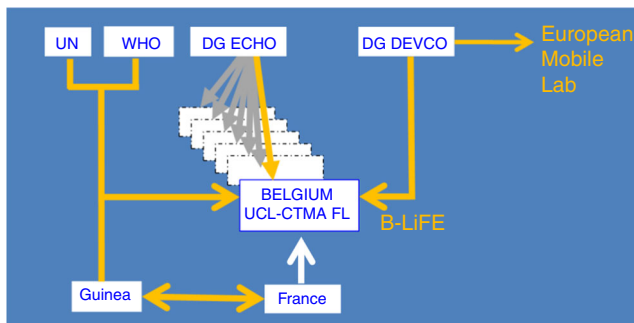
WHO and UN were involved in launching and coordinating the international response. DG ECHO coordinated the response at the EU level interacting directly with the EU Member States, including Belgium. DG DEVCO deployed the European Mobile

Laboratory (EU Mobile Lab) and asked Belgium to deploy B-LiFE FL. France, which was the WHO-mandated pilot country for coordinating the response to the Ebola crisis in Guinea, contacted Belgium to deploy the B-LiFE FL in N'Zerekore, Guinea as a support to the Ebola Center Unit (field hospital to contain and treat Ebola patients) deployed by the French NGO ALIMA.

### 2.3 Iterative generation of the mission cycle, OFs and decision support

When comparing the deployment of civil mobile laboratories (Sealy *et al.*, 2016), mobile hospitals (Naor and Bernardes, 2016; Von Schreeb *et al.*, 2007; WHO/PAHO, 2003) and mobile diagnostic CBRN military laboratories, launched by various international, European and national civilian and military stakeholders (Merin *et al.*, 2014) and the context, conditions and prerequisites justifying this request for the deployment, a few important observations can be made that sustain the usefulness of the current work:

- (1) It is practically impossible to compare the deployment of civil and military mobile capacities due the major differences regarding mechanisms of mission launch and parameters determining the conditions of deployment. Military mobile capacities like a CBRN diagnostic capacity or a field hospital benefit from a dedicated planning and preparedness coupled with efficient military logistics, all part of the operational planning and mission execution. This was illustrated by a first military mission where a prototype of rapidly deployable laboratory was deployed in a military camp (Table I). The first goal was to provide rapid DNA-based identification of infectious agents, namely, monkeypox. The CTMA-FL staff focused only on the tent laboratory OFs, while the military staff was in charge of all other OFs including transportation, accommodation, provisions of food, water and electricity and communication, medical evacuation and physical security of the deployed staff. But this emphasized the complexity and specificity of a mission using a deployable laboratory for identification of biological threats.
- (2) When considering a major international non-governmental organizations like Doctors Without Borders (MSF), their centralized organizations and financial power confer a total autonomy of decision regarding deployments and support to missions. Their working processes and organization are really similar to these used by militaries and enable them to deploy their capacities at any time and any location in the world. Nonetheless, it is striking that MSF field hospitals deployed during the last Ebola outbreak in West Africa were all supported by external MSF-independent laboratories. Here again, OFs and decisions support as initiated for B-LiFE would help define the best conditions of the laboratory deployment.



**Figure 2.** CTMA-FL (B-LiFE) mission launch mechanism

This work focuses on fully autonomous deployment when the mobile capacity operators themselves need to make decisions and implement all the OFs, from basic needs like provision of equipment, power supply, food and accommodation for the staff, to complicated procedures like logistics of transportation and supply chain. In these challenging circumstances, OFs and requirements for their implementation have to be defined by the FL operators, and depend on them for the communication and negotiation with the end user requesting the mission. The work of collecting and describing OFs started with the military deployment in the Democratic Republic of the Congo and the European Commission – 7th Framework Programme (FP7)-PRACTICE project (Preparedness and Resilience against CBRN Terrorism using Integrated Concepts and Equipment) ([www.practice-fp7-security.eu/](http://www.practice-fp7-security.eu/)), was pursued during EC-FP7-MIRACLE project (Mobile Laboratory for the Rapid Assessment of CBRN threats located within and outside the EU) (Vybornova *et al.*, 2015) and completed in the ongoing ESA IAP-ARTES 20 B-LiFE project (European Space Agency, Integrated Applications Promotion – Advanced Research in Telecommunications Systems, B-LiFE) (Vybornova *et al.*, 2016) (Table I). The FL training mission in Munich (B-LiFE exercise) and FP7-EDEN project (End-user Driven demo for CBRNE) enabled us to further assess and validate the OFs and decision-making mechanism (Table I).

*2.3.1 Contribution of the FP7-PRACTICE European project.* The initial work on systematization of the FL mission cycle and description of the OFs was initiated in the framework of FP7-Security project PRACTICE. Deciphering and comparing OFs which are essential for a laboratory tent deployment was then based on our experience with the military mission in Kananga, West Kasai, the Democratic Republic of the Congo. The PRACTICE project involved an FL deployment for which this work of decision support to FL deployment was requested. OFs and mission cycle described for this purpose were then tested during the FL deployment in Pionki, Poland in April 2014 as part of this large scale CBRN demonstration exercise and then updated at the end of the mission. An iterative process of OFs edition and update took place during the FP7-MIRACLE project.

*2.3.2 Contribution of the FP7-MIRACLE European project.* The aim of the MIRACLE research project, which we coordinated, was to compare, assess and validate CBRN mobile capacities' OFs in Europe based on the expertise and practical experience of project partners in an effort to strive to better European harmonization. The full mobile laboratory mission cycle and all the OFs, as first generated during the PRACTICE project were reassessed. Semi-structured questionnaires were used to interview mobile laboratories decision makers, operators and technology suppliers involved in deployments to support rapid assessment of threats caused by CBRN agents (CBRN-related events), with a cross-border or international impact. The purpose of the questionnaire was to gather information of mobile capacities from stakeholders in different European countries and related nations, e.g. their type, specificity, structure, type of equipment, functions and operational capacity, transportability, level of autonomy, organizational responsibility, management, decision-making process, average costs per mission, challenges and capability gaps. The information was analyzed and used to define a generalized CBRN mobile laboratory architecture and a first list of OFs which was presented to the MIRACLE project partners-operators of CBRN civilian and/or military mobile capacities (e.g. Bundeswehr Institute of Microbiology (Germany), the chemical and radiologic mobile capacity of the National Institute of Public Health and the Environment (RIVM, the Netherlands), Forsvarets forskningsinstitutt (Norway) and Totalforsvarets forskningsinstitut (Sweden)).

None of the partners had any experience in such systematization so that this first description of the whole mission cycle was totally new for them. The list of OFs was iteratively edited and updated by every partner individually according to their own expertise and practical experience with mobile capacities. Whereas the majority of the OFs (96 percent) appeared to be similar irrespective of the partner, hence independent of the type of mobile capacity, major differences were primarily related to the mission approval and launch mechanism which largely varies between institutions and countries. At the end of the MIRACLE project, a consensus version of the OFs list was produced and reviewed by external stakeholders for the final conference meeting.

*2.3.3 Lessons learned and OFs updates based on B-LiFE deployment in a real health crisis.* Following this encouraging result, the phases of the mission cycle and all the OFs were further validated and iteratively improved during the lifetime of B-LiFE project. Meanwhile, a practical application, validation and fine tuning of the OFs and decision-making process took place during the FL deployment for Ebola outbreak in 2014-2015 in N'Zerekore, a very remote location in the forest part in the south-east of Guinea. A major update was based on successive debriefings with the team and other experts present on-site and from lessons learned from this mission. This fully operational setting led to the first assessment and validation of the whole mission cycle in real conditions and to useful iterative updates following debriefings and lessons learned from this challenging mission.

*2.3.4 Iterative improvement of OFs and decision support based on the B-LiFE deployment in joint civilian and/or military exercises.* The complete final list of OFs and the related decision-making process were applied in two successive deployments: the first one occurred in February 2016 in the framework of the ESA/IAP-ARTES20/B-LiFE project where a joint bilateral training exercise was carried out in Munich, Germany, with two different deployable capacities (i.e. the BE/B-LiFE lab and the DE/EU Mobile Laboratory from Bundeswehr) working side by side, testing the same samples, using identical or comparable technologies, and acting in a military environment according to a common outbreak scenario as close as possible to real conditions. Validation of the final version of the list of OFs and the decision-making process related to each OF was performed in the preparation and execution of this joint exercise. The described OFs were used by the FL decision makers and operators as the reference basis in the different phases of the mission (i.e. mission assignment and confirmation, preparation and specification, execution and end of mission) to confirm that no essential OF had been overlooked and that each identified OF was relevant. All OFs and related decisions were used as a checklist for the mission's successful planning and execution. A thorough debriefing was carried out after the exercise, during the intermission phase, which enabled us to consolidate and validate the list of OFs and all related decisions. The latter were tested once again during the civilian exercise in Bologna in the framework of the FP7-EDEN project.

Except for the three-week mission in Kasai and three-month deployment in Guinea, all other exercises lasted for at least five days. Consequently, the current paper presents the last and most recent vision of the optimal OFs. They are derived from on-site experiences accumulated with the CTMA-FL over these years, and from successive iterative improvement of decision support mechanisms. The phases of the FL mission cycle, the OFs and decision-making process at each phase are described in detail in Section 3.

### 3. Results

#### 3.1 FL domain structuring

In the FL, different tools, i.e., materials, technologies and processes, are associated with different OFs. OFs are defined as activities (tasks) that need to be performed to identify and actively counter threats, to be prepared for, to respond to and to recover from crises/incidents/attacks ([www.practice-fp7-security.eu/](http://www.practice-fp7-security.eu/)). There are several conditions determining OFs implementation:

- When executing an OF, a particular goal/effect should be achieved, the decisions related to each OF are all directed to optimize the path to the goal.
- Particular resources will be needed to successfully perform a specific OF.
- Each OF is linked to other OFs serving as pre-conditions or triggers, being part of, being used in and linked to, as well as influencing, informing or referring to the given function. These links facilitate the clear decision path.
- Thus advanced input/information is needed to start and successfully perform each particular OF. The more detailed is the information, the more efficient is the decision-making process.

The FL components do not act separately but are unavoidably linked together by means of corresponding OFs to be executed within a single information space in order to achieve the desired result of FL work – to provide evidence-based decision support for decision-making authorities.

All OFs are grouped to perform a FL mission cycle as depicted in Figure 1. Every OF is linked to other OFs by its properties, and is associated with the list of tools used to execute this OF. Such a system creates a single information space where all the components, OFs and tools must be described in a consistent way excluding redundancies and overlapping in order to be easily manageable.

The current research focuses on the following four types of missions' deployment (Vybornova *et al.*, 2016) implying a crisis situation and requiring a rapid FL:

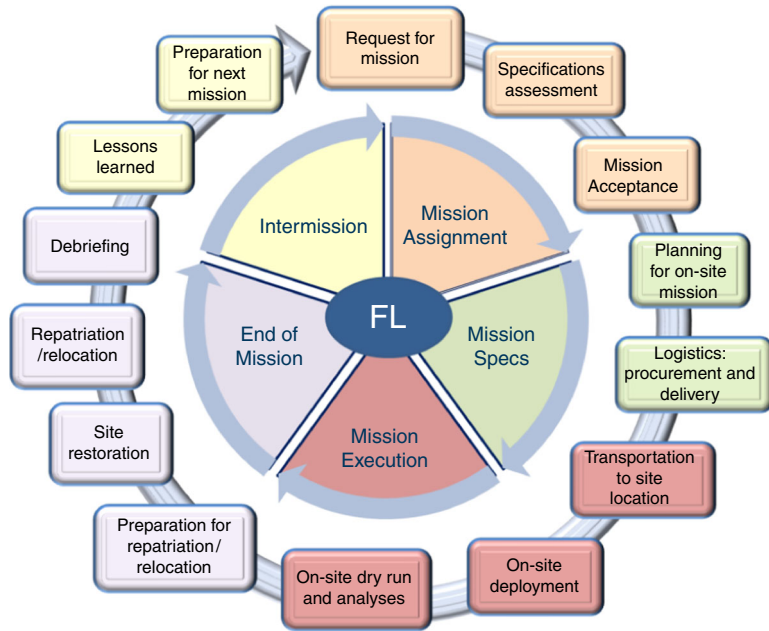
- (1) CBRN scenarios: the FL mission consists of field assessment of the spread of environmental and human contamination resulting from a deliberate or accidental CBRN environmental contamination. The FL mission is to provide evidence for accurate mapping of the indoor and/or outdoor contaminated area and persons at risk. This type of scenario is mainly considered within Europe. Main constraints are identified as rapidity of deployment, involvement of trained experienced staff, rapid analysis and identification of the threats, possibility of a mixed CBRN threat and biosafety issues for the staff and the population.
- (2) Response to outbreak scenario: a typical example is an outbreak caused by a life-threatening and highly contagious agent in a remote area with insufficient local laboratory capacity; this type of crisis often affects low resources African countries. As illustrated for Ebola, an FL is requested to provide quick and reliable diagnostic results for a longer period of time. The main constraints are the same as for CBRN scenario but remoteness, mission duration and harsh operational conditions imply extra-limitation of weight and volume, small size, robustness and easy handling of equipment, longer duration of the mission, and sustained maintenance and logistic support.

- (3) Validation and use of new technologies on-site: this implies the selection and on-site testing of the most appropriate point-of-care testing (POCT) devices vs conventional laboratory methods. The FL mission is to validate new technologies in field conditions using the same type of samples. The main constraint is identified as the quality management of analytical procedures and results, a clear definition of the most appropriate biosafety procedures according to the type of B-agent, and the need for POCT devices to withstand thorough stringent and regular decontamination procedures.
- (4) Training of local staffs and/or quality control of local capacities. The typical FL mission is to contribute to the capacity rebuilding in a post-disaster situation where local laboratory infrastructure and local experimented staff are lacking. The main constraint is to adapt the work to the specificities of multicultural audiences, to take into account the lack of appropriate knowledge and training, and to rapidly evaluate local technological and analytical gaps.

Each category of FL mission implies the selection of one FL configuration among those which are available and the choice depends on well-defined mission parameters (i.e. type of threat, nature of the crisis, activation mechanisms, location, duration, type of samples, number of samples to be analyzed per day) and is based on the execution of a range of OFs aimed at fulfilling the mission goals through the use of a particular set of OFs associated tools. For example, the location of deployment (i.e. areas easily accessible vs poorly accessible by road, like in very remote areas with no passable road), duration (short term vs long term) and frequency of the mission (occasional vs regular) should determine the most suitable features (weight/volume) of the laboratory. In a biological crisis situation outside the EU where remoteness and accessibility to the site of deployment is often a main issue, urgent interventions ideally require a specific light fieldable version of existing biological capacities. For biological incidents inside the EU, heavy national biological laboratories are suitable for rapid intervention and preservation of forensic evidence when necessary. Except for military capacities expected to intervene abroad, such mobile laboratories are usually conceived for short-term intervention on the homeland. Mixed solution combining light and heavier deployment is typically considered in a prolonged crisis situation. Until today, a prolonged intervention outside the EU has rather been an infrequent situation which therefore represents the biggest challenge for light fieldable biological capacities. Frequent crises in remote countries should rather favor stable structural solutions such as creation of new fixed-site stationary labs or reinforcement of existing laboratories in the host country. A valuable alternative consists in planning a rapid intervention of light fieldable capacities at a very early phase of response, with a progressive take over by heavier structures (truck; container) at a later step. This will depend on mission duration (weeks, months or years), intensity of the crisis and accessibility of the location.

Each category of the FL missions presumes the execution of a range of OFs and particular set of tools associated to these functions. Most OFs are activated irrespective of the type of mission and FL configuration, while the set of tools corresponding to very specific OFs are only applicable to particular missions. For example in the function Power Supply, the tool Generator 6.5 kVa may not be required if the mission customer provides electricity, which is often the case for crisis in Europe.

The generalized FL mission is represented as a cycle with five phases in 14 steps, which has been adapted from Vybornova *et al.* (2016), is described and illustrated hereafter (Figure 3).



**Figure 3.**  
FL Mission Cycle

The generalized contents of OFs in each phase of the FL mission cycles can be described as follows.

Phase 1: mission assignment starts with a request for mission addressed to the FL service manager. The FL manager needs to evaluate this request, to check for mission feasibility and to assess mission parameters and specifications. The mission is confirmed as soon as mission specifications are thought to be in line with FL capacity and available resources.

Phase 2: mission planning starts as soon as the mission is confirmed. The FL manager and staff prepare the mission for deployment according to the specifications of the mission. At the planning phase, the characteristics of on-site location where FL will be deployed are defined and the FL capacity is built according to the requirements of the mission; the plan for on-site access and installation are established, all authorizations and clearance required for staff and materials are collected, it is ensured that the host nation authorities are correctly informed about the mission, and provide their agreement to support it. The evaluation focuses on which services and tools can be supplied locally and which of them must be brought along. The costs of the mission are estimated and a tentative budget is established; the list of volunteers to participate in the mission is confirmed, the staff is comprehensively informed about the mission specifications. In addition to routine training during the intermission phase, complementary training is organized or specific extra-staff support is requested according uncovered needs (e.g. operating communication equipment, ensuring field safety and security recommendations, providing physical and technological training). All medical formalities, including health, eye and dental examination, vaccination and other preventive measures are fulfilled; on-site medical support and medical evacuation are planned with the stakeholders. In case clinical samples need to be collected during the mission, the required forms and approvals are proactively prepared in order to comply with and solve all ethical issues and guarantee personal data protection. The best suited FL

configuration is estimated and the list of tools to be transported is established; if necessary, useful complementary tools are purchased. All the tools are then packed and prepared for deployment. The duration of the planning phase mainly depends on the administrative and logistic constraints associated with acquisition of clearances and arranging transportation of staff, tools and logistics to the site of deployment according to international safety transportation rules (e.g. from the International Air Transport Association if the FL is transported by plane).

Phase 3: mission execution is the core of the FL mission cycle and therefore deserves a more detailed description. The mission execution starts when FL staff and tools are transported to the deployment site. Accommodation is provided to FL staff, the laboratory tent and tools are installed according to required operational conditions; healthcare and medical evacuation procedures are tested in case of necessity; on-site security is ensured. After having deployed the laboratory capacity, a dry run is carried out to test whether the capacity is fully operational. This includes ensuring that no power failure is observed when all equipment of the lab is running simultaneously and at full capacity; a checklist enables FL operators to verify the performances of each critical tool and procedure individually. Before starting to collect environmental or clinical samples, the pre-analytical phase is scrutinized to define the best and safest sampling strategy according to risk assessment, sample tracking (i.e. which sample collected where and, for biological samples, from whom), sample delivery by FL sampling team or by third party, and sample reception by the FL staff.

Reception of a sample requires a thorough recording of tracking data and assessment of sample packaging according to biosafety guidelines. Samples are then prepared and analyzed according to biosafety procedures; results are validated and interpreted.

Conventional support (printed or written results) and/or satellite communication tools are used for real time transmission to pre-defined beneficiaries. Irrespective of the support, results are delivered in an unambiguous format that is fully informative while respecting European standards for data confidentiality, security and privacy. Follow up is ensured including availability of the staff for further information upon request and preparation of the FL for the next analytical round. Waste is discarded and destroyed according to pre-defined safety guidelines and on-site capacity.

Phase 4: the end of mission comprises the set of OFs dedicated to site restoration and preparation to FL repatriation (return to the basis) or relocation (redeployment elsewhere). All equipment and materials used during the mission are cleaned and decontaminated before packaging; all temperature sensitive products are packed in appropriate cool boxes/containers for maintaining the cold chain unbroken; tools are prepared for transportation according to procedure (e.g. protection against shocks, removal or fixation of mobile parts, fuel is removed from power supply, etc.); tools are secured and safely loaded for transportation; repatriation takes place. Once back home or redeployed in another location, there is a debriefing step with immediate feedback on the successive phases of the mission just past. Return on experience is collected, lessons learnt are drawn and strengths, weaknesses, opportunities and threats analyses are made. If required a final report is prepared according for internal use and for specified stakeholders. A global listing of all analyses carried out during the mission is established and the in-depth inventory of all tools, samples and reagents used during the mission takes place. Tools that are not in good working order need to be repaired or replaced; waste not previously disposed on-site during past mission is discarded immediately according to biosafety rules. The total costs of the past mission are documented and updated. All tools are properly listed, repacked and stored for the next mission.

Phase 5: the mission cycle ends with the “Intermission” phase in which FL capacity is continuously improved and prepared for a next mission. Survey of existing and emerging technologies, identification of future needs, identification of list of actions for improvement, acquisitions of new technologies and materials, development and implementation of new processes are all ongoing tasks. Lab processes, functions and materials are being continuously improved; staff undergoes regular training for optimally using new technologies, equipment and applying new processes. Competency of the staff is maintained and improved by regular exercises. All stocks of reagents are refilled and stored according to the shelf life. New sources of funding are identified for launching research and development projects according to the gap analysis during the debriefing step (see above End of mission phase) and for preparing for next missions.

The present work focuses on the decision-making process in the FL.

### 3.2 Principles of reasoning within the FL domain

The FL staff fulfills three very distinct but interrelated roles (Vybornova *et al.*, 2016). They are:

- (1) developers of bio-detection and bio-identification technology, where technology is usually developed and validated in the national fixed-based laboratory, and exported during on-site FL operations;
- (2) operators (users) of FL tools and equipment after development or taken off-the-shelf; and
- (3) decision makers, where the FL manager individually or collectively with all the FL staff involved in the mission has to take quick but highly critical decisions at each step of the FL mission cycle.

Such interrelated roles are often shared at the same time by the FL staff and manager and presume their ability to handle a wide spectrum of heterogeneous information which is collected from different sources and processed according to mission specifications. The knowledge-based operational process, OFs list and interlinks make it possible to track the decision-making process and identify its inner logic.

According to D4H Technologies (2016), problem solving should be distinguished from decision making, and the inter-relation between them is the following: problem solving is a set of activities designed to analyze a situation systematically and to generate, implement, and evaluate solutions, whereas decision making is a mechanism for making choices at each step of the problem-solving process. Decision making is therefore a part of problem solving, and decision making occurs at every step of the problem-solving process.

The following main steps of the decision-making process are adapted from D4H Technologies (2016) and applied to the FL operational domain:

- Step 1: identification of the purpose of the decision.  
The first step is to recognize any problem and identify options that may be available.
- Step 2: information needs and situation awareness.  
What information is relevant or not to make the decision? What do FL staff members need to know before a decision can be taken, or that will help them make the optimal choice when taking it?

- Step 3: judging the alternatives.  
What alternative courses of action may be available? What different interpretations of the data may be possible?
- Step 4: select the best alternative. Risk assessment.  
To explore the alternatives which have provisionally been preferred in the light of future possible adverse consequences: what problems might be derived or created? What are the risks of taking this decision? What are the risks caused by any alternative decision or of taking no decision and no action at all?
- Step 5: execute the decision.  
To commit to making decisions which are implementable, practical and appropriate, to allocate and provide resources accordingly, and to put an action plan into place for implementing the decision.
- Step 6: evaluate the results.  
Capture the lessons learnt from past successes and failures, with the goal of improving future performance. It is an opportunity to reflect on an event so that you can do better next time.

For emergency response professionals, the ability to identify current and potential problems and to make sound and timely decisions before and during a biological crisis can literally affect the lives and health of the laboratory staff and of the population affected. The decisions taken by the FL personnel can impact the ability of response agencies to fulfill adequately their own mission and tasks, can have a strong impact on the resilience of the community and hence on its ability to quickly recover from an event.

Every OF in the FL consists of a set of complex activities requiring acquisition, continuous update and consolidation of heterogeneous information (i.e. multiple sources and formats) regarding the current crisis situation, SOPs, best practices in addressing crisis preparation management and in problem solving, specific operational knowledge about technologies and processes, knowledge of regulations, guidelines, legal and ethical issues to be adhered to. Within the single operational domain of FL functionality, some OFs are seen as decision-making nodes that have impact on other OFs execution, while others are action nodes requiring compliance with the SOPs with no variable decisions inside.

Since it is practically impossible for anyone to keep in mind all information and details about FL missions in general, and specifications of the currently planned one, the information management concepts and tools play a major role in the quality and thoroughness of mission preparation. To unify the communication process within the FL and consolidate the information necessary for optimal decision making at the document management level, a laboratory information management system (LIMS) is under development (Vybornova *et al.*, 2016). One of the advantages of LIMS is that it is compatible with the information systems of other stakeholders, e.g., other laboratories and field hospitals, and can be integrated in such a way that information sharing process is harmonized and transmission of relevant data facilitated.

The FL-LIMS includes integrated databases where each FL tool is linked with specific information among which the class and description, date of acquisition, price per tool (€), dimension (length × width × height (cm)), volume (m<sup>3</sup>) and weight (kg), electrical power (kW, kVA), SOP, related biosafety procedures, precise location in the storage room and dedicated carrying case. For each mission, information can be immediately retrieved with

respect to the number of available items, total volume, weight, electric energy consumption and value of the equipment selected. Within the LIMS, the databases will be connected with the FL-specific ontology described in Vybornova *et al.* (2016), Comes *et al.* (2015) and Piette *et al.* (2014). The ontology here is understood as a formal, explicit specification of a shared conceptualization describing the FL as operational domain. The FL ontology serves as a knowledge base combining tools, modeling patterns and a priori background knowledge about mission's parameters. The ontological approach to FL description and mission preparation serves a multifold purpose:

- to formalize and structure the domain of biological deployable laboratory operation in a crisis preparedness and response, therefore ensuring a continuous improvement of the performance;
- to provide an easy access to all the information, and to make the information reusable for different missions;
- to align the terminology, definitions between the tools and to provide a shared vocabulary of concepts to comply with the commonly recognized standards, best practices and procedures to facilitate common ground establishment between internal FL operators and external decision-makers and other stakeholders; and
- to provide technical and conceptual compatibility of sharable information between the heterogeneous tools.

The FL ontology models the information available a priori, provides the links between all the OFs, as well as parameters, attributes and tools used in every OF. Such a comprehensive approach largely facilitates the process of FL mission preparation and informed decision making.

Decisions taken at different phases belong to different categories, require various information needs to be taken, vary in scope, frequency, confidence and criticality. According to the logic presented in Gralla *et al.* (2013), the current research distinguishes between the following aspects attributed to the decisions:

- (1) Scope possible values are:
  - 3 – decision of global international scope, wide national, intercluster (involving the whole emergency response community);
  - 2 – medium scope for national, regional decisions that impacts FL and some stakeholders; and
  - 1 – local, these decisions impact FL only.
- (2) Criticality possible values are:
  - 3 – high, impact on mission go/no-go, stop/continue, life-saving/not life-saving;
  - 2 – medium, impacting FL service, service restriction, replacement or delay;
  - 1 – low, presuming minor inconvenience or requiring minor improvement, having impact on a beneficiary; and
  - 0 – having no impact.
- (3) Frequency decisions can be taken only once, or daily, weekly, monthly, yearly, or irregularly upon occurrence of certain conditions specified below.

(4) Confidence possible values are:

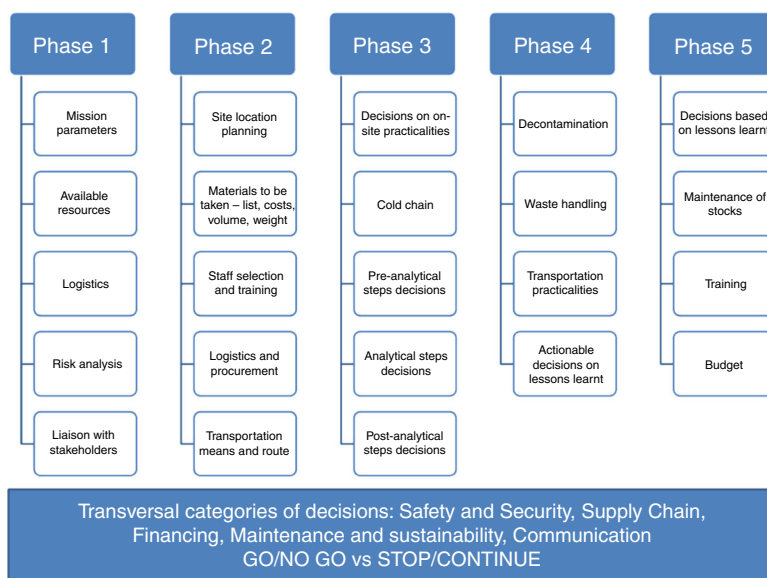
- 3 – high confidence when all the necessary information for taking the decision is available;
- 2 – medium, meaning that there are some information gaps, but it is possible to fill them and find out the necessary info or to guess;
- 1 – means uncertainty, lack of information on the problem at hand; and
- 0 – means the absence of information and impossibility to acquire it.

In the FL operational domain there are three major pillars underlying all the processes and related decisions:

- (1) Legal issues: any mission, OF or OF steps must be in line with international, national, regional or local laws and regulations. Lack of compliance with any legal provision can be a showstopper making impossible implementation of the mission.
- (2) Procedures: an appropriate knowledge of SOPs, protocols and guidelines for OFs execution is an absolute prerequisite for a successful operation.
- (3) Training of the staff: training is a key factor for any FL activity and type of mission. Availability of FL staff volunteers trained to correctly perform all the OFs in the mission is a crucial prerequisite for the success of the mission. And vice versa, a lack of training or a lack of relevant knowledge and skills can be dangerous when operating in difficult and dangerous environments. Untrained or insufficiently trained personnel can indeed put at risk themselves, their colleagues and people external to the laboratory.

The general categories of decisions taken in all the five phases of the FL mission cycle are presented in Figure 4.

It should be noted that we do not consider any decisions in terms of “right” or “wrong” ones. Presuming that the decisions are taken by experienced competent staff,



**Figure 4.** Categories of decisions in the FL mission cycle phases

based on multiple mission parameters and factors, we rather speak about decisions in terms of their impact on other decisions and on the mission as a whole.

Looking into the peculiarities of the decision-making process in FL operational domain, we have to understand in detail how and when decision are taken at every step, and on which factors they are based.

*3.2.1 Decision making in Phase 1.* The most important phase in terms of critical decisions is certainly Phase 1 corresponding to mission assignment. All OFs in Phase 1 are decision nodes, and all the decisions taken during Phase 1 are the major decisions regarding the feasibility of the FL mission and, in case of positive answer, decisions on the definition of the FL required role, configuration and interaction with other parties, logistics issues and response planning.

The main go/no-go decision associated with the last OF in Phase 1 confirmation of mission is composed of multiple factors; it is a consequence of Phase 5 – intermission assessment of the overall level of preparedness of FL to the next mission, on the human and material resources which are a priori available. It is triggered by all previous decisions taken during Phase 1 according to prior OFs which focus on goals and needs of this requested mission. This type of decision therefore requires handling and considering a wide range of information, and its main characteristic is that it is never final nor definitive. Even if the main decision is taken positively, the situation may change at some later stage. If, for example, it turns out during Phase 2 that resources initially thought to be available for the mission execution appear insufficient, or that security of the FL staff cannot be guaranteed, the main decision can be altered. On the contrary, if it was initially decided that the mission cannot take place, but some new circumstances emerge that allow taking the positive decision, the main go/no-go decision taken in the confirmation of mission OF can be amended and become a positive decision. In principle, this main go/no-go decision can be adapted at any step of the mission preparation phases. Likewise its counterpart “continue/stop decision” can always be altered at any time during the mission execution phase (this process will be described in Phase 3).

At first sight, the “no-go” decision might be considered as the 0 value, i.e. “no loss – no gain,” but this would be a too simplified approach. Both the “go” and “no-go” decisions at every step are associated with benefits and drawbacks in terms of resources, impact on operational activities and even on the laboratory reputation. In certain situation the mission might go ahead with a slightly negative expected value, if the value of no action (stopping or “no-go”) is deemed to be even more negative. Alternatively, the stop or no-go decision can sometimes have benefits, e.g. saving time and money, sparing expensive materials or allocating these resources, efforts, and attention to other more urgent tasks. Thus, a simplified and normalized “zero” situation actually contains some positive and negative aspects.

Timely reception of information giving a comprehensive situation awareness, as well as detailed and regularly updated information about the possible evolution of the crisis and situation around it are most important information needs for the critical decisions in Phase 1.

The decisions related to each OF in Phase 1 specifying the scope, criticality, frequency and confidence values, and the information needs for taking every decision are described in the LIMS as in the following example:

Phase 1 – mission assignment  
Step: specifications assessment  
OF: needs and constraints

OF description: FL service manager checks for availability of resources (staff, equipment, reagents, etc.), checks feasibility (security, safety, location, duration, costs, etc.) and prepares first evaluation of the service offer. Team members confirm their availability for the mission.

Decisions to be taken: can the safety and security of the staff and materials be guaranteed on-site? What are the risks? How to ensure security of the staff? How to ensure MEDEVAC – possibility of transportation to the home country of any personnel member in case of a disease?

Scope: 2

Criticality: 3

Frequency: daily

Confidence: 2

Information needs: the state of security in the area of planned deployment, information about the major threats and the situation evolution. Support of the local authorities, and other stakeholders.

The following decisions with the highest criticality are the most important ones to be taken during Phase 1 of the FL mission cycle implementation:

- (1) Is LFL involvement relevant and possible in the particular crisis response?
- (2) Are there enough resources available?
- (3) Is the staff security and safety guaranteed?
- (4) Is MEDEVAC guaranteed if needed?
- (5) Is permanent support from local authorities guaranteed?
- (6) Will supply chain be secured?
- (7) Is the volunteer staff trained adequately?
- (8) Is there an official contact and agreement with all relevant stakeholders?
- (9) Go/no-go, is the mission confirmed and will take place?

*3.2.2 Decision making in Phase 2.* After the most crucial decisions have been made in Phase 1 – mission assignment, and if the existential “go” decision was taken, the decisions of Phase 2 – mission specifications are all related to the practical aspects of the mission preparation and detailed planning. Useful information includes details contributing to a sound understanding of feasibility and practicalities related to this mission, i.e., the exact location of the mission, where and how FL will be deployed, how to reach the place, what kind of transportation means are available, what regulations must be observed to transport the FL materials (including hazardous materials) according to selected transportation means, what type and amount of material to take depending on mission specificity, objectives and duration, what location-specific formalities the staff must go through when preparing for the mission. The more detailed is the mission specification phase, the less unexpected problems the FL staff will face on-site.

The decisions related to each OF in Phase 2 specifying the scope, criticality, frequency and confidence values, and the information needs for taking every decision are described in the LIMS as in the following example:

Phase 2 – mission planning

Step: planning on-site deployment

OF: characteristics of on-site location

OF description: site selection and monitoring. FL service manager details the plan for transportation of staff and material and for access and installation on the site. Decisions to be taken: given the on-site characteristics information, what shall be the exact place for FL installation? What shall be specific requirement for FL deployment in this particular place?

Scope: 1

Criticality: 3

Frequency: once

Confidence: 3

Information needs: the exact location of the mission (including data from satellite communication and earth observation tools) and the on-site practicalities.

The following decisions with the highest criticality are the most important ones to be taken during Phase 2 of the FL mission cycle implementation:

- (1) What are on-site location specificities and practicalities for the deployment?
- (2) Is host nation support guaranteed and agreements with stakeholders provided?
- (3) Who and how many staff members shall participate in the mission?
- (4) What specific staff training is needed?
- (5) What materials shall be taken? Checklist, volume, weight, costs.
- (6) What transportation means shall be used according to the available resources, number of people, weight and volume of the materials?

*3.2.3 Decision making in Phase 3.* After the preparation for the mission has been completed, Phase 3 – mission execution starts with transportation and installation of the FL on-site along with solving different practical issues related to the deployment itself and to the preparation for samples reception and analysis. Many OFs in Phase 3 are action nodes, subjected to the established SOPs, guidelines and best practices. The decisions are mainly related to the particular FL organization and setting at the given location, and to security and safety check, risk analysis, as well as final appreciation of the FL operational readiness to carry out the first laboratory investigations. A substantial part of the decisions refers to security and safety of staff and materials, and to the practicalities of operations, e.g. decisions to repair or replace the equipment running out of order during transportation or during use in field conditions, related budget and supply chain issues, decisions associated to the precise modus operandi of pre-analytical, analytical and post-analytical steps according to mission specificities. An important part of the decisions is related to the communication and information sharing/exchange/transmission issues, e.g. the choice of communication channel(s), format and content of the information that shall be/can be conveyed and who will be considered as authorized operational partners (i.e. local, regional, national and international beneficiaries, health authorities and other stakeholders, media, and general public).

Even though most of the decisions are usually collectively discussed locally by all the FL staff members, and sometimes also with the staff of the reach-back laboratory in the home country, the essential burden of responsibility for the success of the mission, for the security and safety of the FL staff and for all the FL operations

on-site lies on the shoulders of the head of the mission. His/her responsibilities include but are not limited to:

- taking the final decision to initiate, end, continue or stop the mission;
- organizing the roles and duties inside the FL;
- making sure that all OFs are implemented correctly and solving issues on the way;
- daily decisions about the capacity of FL (number of samples to be analyzed per day) according to the current emergency needs, sampling mode, samples handling and interpretation of results;
- communication with operational partners, beneficiaries (e.g. physicians requesting medical analyses for urgent diagnosis or for biological follow up; epidemiologists, crisis managers at loco-regional, national or international level) and all other stakeholders exploiting the results;
- requesting assistance from the authorities; and
- notification to stakeholders of any problems or irregularities that could require immediate corrective measures or lead to other emergencies.

The categories of information needed for taking decisions in Phase 3 include mainly the situational awareness, continuously updated information about the status of operations, availability of supply chain, SOPs, guidelines, methods of FL analytical operations, safety, security and all the associated legal and ethical provisions.

The decisions related to each OF in Phase 3 specifying the scope, criticality, frequency and confidence values, and the information needs for taking every decision are described in the LIMS as in the following example:

Phase 3: mission execution

Step: on-site deployment

OF: healthcare and MEDEVAC (medical evacuation)

OF description: from the first day of the deployment, healthcare has to be accessible to the staff for the whole duration of the mission. This implies practicalities on medical evacuation or treatment in case of a disease before, during and after mission.

Decisions to be taken: in case of a disease – will healthcare provided locally be sufficient or will MEDEVAC be necessary?

Scope: 2

Criticality: 3

Frequency: when needed

Confidence: 2

Information needs: precise diagnosis of the disease and the cause of it. Information about the local healthcare capacity. Information about the infrastructure and availability of transport for MEDEVAC.

The following decisions with the highest criticality are the most important ones to be taken during Phase 3 of the FL mission cycle implementation:

- (1) Healthcare and MEDEVAC.
- (2) What materials and how many of them shall be delivered? How? From where? By whom?

- (3) Can cold chain be maintained for certain items?
- (4) Biosafety and biosecurity aspects throughout all the OFs.
- (5) Pre-analytical steps decisions (sampling strategy, acceptance/rejection of samples).
- (6) Analytical steps decisions (impact of external factors on the analysis, waste handling).
- (7) Post-analytical steps decisions (results interpretation).

*3.2.4 Decision making in Phase 4.* After the mission has been fulfilled at a given location, the evolution or worsening of the crisis may require its continuation, e.g. when the disease outbreak is not yet over with new clinical cases being recorded locally in the vicinity of the FL. It may then be justified to extend the FL service beyond the initially planned mission duration. However, the decision to continue or to stop the mission depends not only on decisions taken at national or international level, but also largely on local factors like willingness (it is of note that this type of humanitarian work depends on volunteers) and availability of the FL staff to continue the mission, in particular the possibility of staff rotation (all or part of the FL staff return home and mission is overtaken by new staff members), related transportation and budget issues, guarantee of security for the staff and materials, availability and condition of FL equipment and laboratory resources. There is also a possibility that mission continuation needs to be considered at a different location. Such a request for mission continuation after relocation occurred during the FL mission to Guinea in 2015 when the end of the very successful FL service deployed in N'Zerekore (Guinea), coincided with the Guinean authorities request to continue the mission in Conakry where new cases were suddenly recorded in the capital city. In that situation, due to the lack of guarantee of secure transportation and storage of the FL materials to Conakry, and with insufficient support of the authorities to solve this issue, it was decided to end the mission and return to the home country while refurbishing the FL material and staying prepared for a possible new request. In this case a new request would have corresponded to Phase 3 of the mission cycle.

The purpose of continue/stop decisions is figuring out the optimal scale and duration of operations if the mission should go forward, and to what extent it has been useful or beneficial.

Irrespective of the decision to end or continue the mission after relocation, the site of deployment must be restored to the state before deployment through site cleaning, decontamination and rehabilitation. This is carried out according to good practice defining the rules for decontaminating the site and equipment and the procedures for a waste management that is harmless to people, animals or to the environment. This also implies a thorough assessment for site cleanliness. The OFs on dismantling/packaging the FL and associated materials for transportation are considered as mirror actions to those undertaken in Phase 2, thus implying identical methods and regulations, unless a different mean of transport is chosen. In the latter case, the decisions on new appropriate regulations and requirements for tools packaging will be taken.

Right at the end of the mission, the first feedback from all the staff members is collected. This focus on first impressions and comments about what was good, difficult or impossible and what should be improved in the future. While this on-the-spot evaluation

will be complemented later during the Phase 5 – intermission by a thorough assessment of lessons learnt, such as a hot first return on experience is a highly valuable step in the process of continuous improvement of the FL capacity and its operators.

The decisions related to each OF in Phase 4 specifying the scope, criticality, frequency and confidence values, and the information needs for taking every decision are described in the LIMS as in the following example:

Phase 4: end of mission

Step: preparation for FL repatriation or relocation

OF: decontamination and cleaning

OF description: all equipment and materials used during the mission are cleaned and decontaminated before packaging. Attention is paid to electronic components and devices which do not withstand harsh decontamination. Equipment exposed to hazards are identified and decontaminated according to standard procedure. Depending on the type of samples processed, specific decontamination procedures are conducted.

Decisions to be taken: what methods of decontamination can be used for different kinds of equipment? “How clean is clean?” – is the decontaminated surface cleaned sufficiently and does not present any threat to people, animals or environment?

Scope: 1

Criticality: 3

Frequency: once

Confidence: 2

Information needs: SOPs on decontamination procedures for different kinds of equipment and surfaces. Biosafety guidelines.

The following decisions with the highest criticality are the most important ones to be taken during Phase 4 of the FL mission cycle implementation:

- (1) Shall the mission continue or stop?
- (2) If the mission continues – shall the FL stay at the same location or will have to relocate?
- (3) In case of repatriation or relocation – when? By what transportation means?
- (4) Safe packaging of hazardous samples and materials for transportation according to legal provisions?
- (5) Decision on the type of method for decontaminating the FL site.
- (6) Decisions on the site rehabilitation and waste disposal.
- (7) Actionable decisions on past-mission debriefing.

*3.2.5 Decision making in Phase 5.* The Phase 5 – intermission is an important part of the mission cycle. It starts with a detailed analysis of the lessons learnt during FL deployment and their translation into practical measures. Decisions are taken regarding what and why must be improved, when, at what costs, and by what means. The practical use of the lessons learnt through implementation of related decisions marks the beginning of the preparation for a next mission. Decisions on the feasibility of future mission(s) are taken and their conditions are foreseen. This planning is associated to multiple decisions concerning acquisition of new materials, acquiring and validating emerging technologies that would usefully complement the existing capacity, a financial

strategy enabling the acquisition of new materials, and, very importantly, a permanent training of the staff. All these OFs are being implemented as quickly as possible keeping in mind that FL can be requested on a very short notice and must be kept ready to deploy for any type of new mission at any time. The level of FL preparedness to the next missions is regularly evaluated and this evaluation influences the critical “go/no-go” decision in Phase 1 of the next mission.

Apart from purely objective reasons, there are cognitive, psychological, human factors that may influence the decisions: e.g. some possible negative experiences at Phases 3 and 4 of previous mission(s) can undermine the confidence and spirit of the team and prompt a “no-go” decision for the next mission at least for those who had this had experience. On the other hand, positive experiences reconfirm the confidence level and the “go” for a next mission becomes more likely. Careful analysis of lessons learnt and their translation into concrete actions to solve previous issues increase substantially this probability.

Useful activities taking place in Phase 5 – intermission are as follows:

- Revision of the overall information flow, of the decision-making process and the results of the decisions taken during the mission.
- Surveillance of current and emerging technologies beneficial for FL as complements or effective substitutes for tools currently used.
- Marketing analysis for selecting materials and manufacturers which optimally meet FL needs.
- Continuous research on current and potential needs in the field of biological crisis preparedness and response, monitoring of the past an ongoing crisis response and management activities, assessment of best practices, refining the concept of rapid on-site deployment and improving the operational capacity of the FL in order to offer a better and quicker response to urgent needs and enhance the support to the emergency community.
- Joint national and international exercises with other deployable laboratories to strive for better harmonization and scaling up of European capacities.
- Demonstration activities at thematic events (exhibitions, fairs, workshops, etc.) requested by the stakeholders for the purpose of raising awareness of the FL capacity and potential in the public health emergency response.

The decisions related to each OF in Phase 5 specifying the scope, criticality, frequency and confidence values, and the information needs for taking every decision are described in the LIMS as in the following example:

Phase 5: intermission

Step: preparation for next mission

OF: training and exercise

OF description: staff is regularly trained for using new technologies, equipment and applying new processes. Competency is maintained by regular exercises.

Decisions to be taken: who of the staff needs training? What new knowledge and/or skills have to be mastered? How long shall the training last? Who shall provide the training? If certification is needed – who will provide the certification?

Scope: 1

Criticality: 3

Frequency: monthly

Confidence: 3

Information needs: up-to-date knowledge and skills, understanding future and potential needs.

The following decisions with the highest criticality are the most important ones to be taken during Phase 5 of the FL mission cycle implementation:

- (1) Actionable decisions on thorough analysis of lessons learnt.
- (2) Will future mission(s) be possible? If yes – under which conditions?
- (3) What knowledge and skills must be mastered and improved by specific training?
- (4) What budget shall be made available for future mission(s)?
- (5) If the staff ready to volunteer for a future mission?

*3.2.6 Transversal decisions.* There are several transversal OFs which are present in all phases of the FL mission cycle and underlie all the decisions related to them. It is noteworthy that the decisions associated to transversal decisions are all of the highest criticality as they have high impact on other decisions in the mission cycle.

The decisions related to each transversal OF specifying the scope, criticality, frequency and confidence values, and the information needs for taking every decision are described in the LIMS as in the following example:

Steps: transversal

OF: maintenance and sustainability

OF description: ensure that stocks of materials are kept sufficient, equipment is still operational and ready to be deployed; shelf life of reagents and equipment calibration are essential parameters. Basic needs have to be kept available at all time inside the reach-back laboratory.

Decisions to be taken: what materials shall be kept in stocks? For how long? What materials and reagents will be obtained right before the mission? What materials shall be kept only for FL and what shall be shared with the reach-back laboratory?

Scope: 1

Criticality: 3

Frequency: multiple times at all phases

Confidence: 3

Information needs: shelf life of reagents, materials storage conditions, equipment calibration info.

The following decisions with the highest criticality are the most important ones to be taken within the transversal OFs of the FL mission cycle implementation:

- (1) What are the resources and conditions for ensuring FL sustainability and financing missions?
- (2) How to provide the supply chain and balance between quality, fit for needs, costs, and fit for transportation?
- (3) What materials are needed and how long can they be kept in stocks (shelf life)?

- (4) What are the requirements for a data transfer and communication which meet the goals of the mission? What information, with whom and in what format shall be shared?
- (5) Is the safety, biosafety, security and biosecurity for the staff and materials ensured?

#### 4. Conclusions

The current work presents key results of ongoing research on the analysis of decision-making process regarding the deployment and on-site use of a FL in the setting of a biological incident or outbreak. The phases, steps and OFs characterizing the FL mission cycle are described. The decisions are reported in terms of contents, context, information needs, related function, scope, criticality, frequency and degree of confidence.

Deploying a FL capacity as an emergency response to a crisis situation is characterized by a huge uncertainty. Consequently, creating a well-defined structure with clearly distinct phases of the mission cycle and a fixed set of OFs applicable irrespective of the mission type appears as the best structural and functional basis for tracking more efficiently the optimal decision-making process. This model has been built up from observations that were progressively collected, generalized and iteratively improved both during real crisis responses outside Europe, and training missions or exercises within Europe. The salient principles of this well-defined structure are derived from knowledge where various categories of information are put together and where the way information is tracked reflects the amount of decisions to be made at different phases of the FL mission cycle. We focused on actionable information (i.e. information which is trusted, accurate, timely relevant, comprehensive, and predictive, as well as analytical information that can be used for decision making) that is relevant to adapt the actions to the current context (e.g. urgent priorities, needs, available human and logistics resources, security situation and other factors at any time). The FL information flows were tracked across the entire FL mission cycle.

Furthermore, a well-defined structure of the FL operational domain and the description of all its elements and information flows address the major issue of interoperability of resources that are used by operational capacities (inter-)acting during an international crisis response. OFs and related information flows contribute to scalability and interoperability of operational capacities through the comparison and validation of procedures, a better planning, a mutual training and operational improvement between FLs from different geographical, organizational and cultural origins.

Multi-factor decisions are treated as logical entities inherently linked to each other and to the whole situation context. Once a decision is taken, it influences and changes the context representation by impacting various parameters and subsequent decisions. The process of consistent accommodation of every new decision in the local, temporary, potential alternative and global situational context has been explored. This approach is considered promising for an efficient modeling of the multi-factor decision-making process. It will therefore be further developed and coupled with the implementation of an ontology-based LIMS that we described previously (Vybornova *et al.*, 2016). By improving the FL information flow, exchange and support to the decision-making process, we aim to significantly enhance the ability of FL managers and relevant stakeholders to collect, record, transmit and exploit all relevant information. This can be achieved through a cooperative work process interlinking FL multi-functional and

multi-dimensional aspects. The resulting innovative solutions will optimize the FL operational work while reducing uncertainty and the quality of decision making in terms of resource estimation, planning and logistics for FL missions.

The thorough analysis and systematization of the decisions related to each FL OF should have a positive impact on decision makers and end-users when they consider to deploying a FL in the field in case of a major health crisis. FLs deployment should no more be a mysterious black box where no one else than laboratory operators understand the needs, procedures and requirements. A proper description of each fieldable capacity and a clear definition of all OFs should make the requirements and conditions for the deployment more transparent and easier to predict. Such transparency should lead to better preparedness and more efficient timely response to both local and cross-border biological crises and contribute to better harmonization, hence interoperability and scalability of this type of capacities.

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