Chapter 4

Operations Management and Decision Making in Deployment of an On-Site Biological Analytical Capacity

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Additional information is available at the end of the chapter

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Abstract

Deployment of an on-site laboratory to contain an expanding outbreak and protect public health through rapid diagnosis of infected patients and identification of their contacts is a challenging and complex response, further complicated by time limitation and dramatic consequences of failure. Effective operations management and decision-making are critical for a successful Fieldable Laboratory (FL) mission at each phase of the mission. To analyze the principles and challenges of the operations management and associated decision-making process, the FL mission has been broken down into five successive interlinked phases defined as the "FL mission cycle" (FL-MC). Each phase comprises a set of operational functions (OFs) corresponding to the mission activities. Some decisions are associated with a single OF, whereas others are taken across different OFs and FL-MC phases. All decisions are treated as logical entities inherently linked to each other and to the whole situational context within the FL operational domain. Being part of the laboratory information management system (LIMS), the FL domain ontology is developed as the main knowledge management tool supporting the decision-making process. This is an essential way to promote interoperability and scalability between different FL modules and health care capacities during cross-border biological crises.

Keywords: biological analytical capacity, operational functions, decision support, knowledge management, health crisis response

1. Introduction

Deployment of a biological analytical capacity—a Fieldable Laboratory (FL)—in response to a health crisis caused by a biological agent (B-agent), such as an outbreak of a disease, or a deliberate or accidental release of a B-agent, is a complex strategic enterprise undertaking requiring neat operations management based on efficient decision making. To be ready for a rapid FL deployment as soon as a disaster strikes implies a thorough preparedness complemented by detailed planning phases. The trained FL operators must be available for the mission and confident in the quality and objectivity of the decision-making process; the laboratory equipment and materials for B-agent identification and diseases diagnosis have to be in place and ready to use; the means of transportation, as well as security, safety and funding mechanisms of the mission have to be agreed in advance with the mission customers and secured.

Flexibility is another key component of any public emergency response. FL has a highly flexible configuration, which makes it suitable for a wide range of missions. Given the uncertainty inherent to every crisis response, 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 operating 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.

In its current form, the FL structure and specific requirements for a generic deployment of laboratory capacities have been identified taking as a model the B-LiFE (Biological Light Fieldable Laboratory for Emergencies) capacity developed by the Center for Applied Molecular Technologies (CTMA) of the Université catholique de Louvain (UCL) and supported by the Defense Laboratory Department (DLD) of the Belgian Armed Forces. The FL provides a consistent operational structure at the disposal of national, European and international stakeholders when domestic health care capacities are lacking or devastated by the disaster (e.g. shortages or absence of skilled local health care staff combined with a high fatality rate due to the outbreak). This applies especially when the scale, intensity and complexity of the crisis require 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 pre-listed equipment placed in dedicated carrying cases, which can easily be moved together, deployed and used by a limited staff of trained personnel. The main advantage of deploying a 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 [52] where the B-LiFE (Biological Light Fieldable Laboratory for Emergencies) team deployed a FL from December 2014 to March 2015 to support the medical staff of the Ebola Treatment Unit of N'Zerekore run by the NGO ALIMA (Alliance for International Medical Action) in the forest area of Guinea [35, 38, 41, 42, 53] see **Figures 1** and **2**.

The FL operations management serves as a bridge between the field operators deployed for the mission, headquarters in the reach-back laboratory and external stakeholders. In the present work, the problems of decision making, information sharing and coordination at FL are

Figure 1. B-LiFE deployable analytical capacity and inflatable antenna, Ebola mission, Guinea, December 2014 to March 2015.

Figure 2. Inside the FL tent: glovebox and analytical tools.

studied taking into account the needs, procedures and requirements of field operators. The present work summarizes the practical findings on structuring the FL operational domain, the heterogeneous information that the FL staff have to deal with in the crisis response and management situations. This work presents the most recent development in terms of tools, methods and mechanisms of the FL operations management and decision-making support. The result was consolidated by integrating the assessment of certifiers appointed by the European Commission during the certification procedure of B-LIFE/B-FAST as a self-sufficient module of the EU Medical Corps, namely the EU medical and laboratory modules exercise “MODEX” in Sweden in April 2017, and subsequent “ModTTX 4” Table-top exercise in Belgium in May 2017.

2. Structuring the FL domain

To facilitate the FL operations management, it is necessary to structure the FL domain in such a way that all its components and interlinks between them become visible, enabling laboratory operators to track the path of the informed decision-making processes. The basis for structuring the FL domain is FL operational functions (OFs), which need to be carried out by the FL at different phases of the mission cycle in order to identify and actively counter threats, to be prepared for, to respond to and to recover from crises of both incidental nature or deliberate attacks (http://www.practice-fp7-security.eu/).

The lessons learnt from past FL deployments (**Table 1**, Section 4) proved that even if every mission is unique in terms of goals and context, the FL mission cycle (FL-MC) consisting of OFs divided into five chronological phases and transversal functions is valid for any type of mission. The process described here is being used as support of operations management for decision makers regarding FL staff training, contacts and discussions with stakeholders, and preparation for next FL missions.

The generalized FL mission is represented as a cycle with five phases, shown in **Figure 3**.

Each phase of the FL-MC consists of several steps, which are in turn comprised of OFs to be implemented at each step. The whole FL-MC contains 92 OFs, and they are as follows:

Phase 1. **Mission assignment**

STEP 1-1. **Request for mission**. OF 1-1-1. Request for lab mission.

STEP 1-2. **Specifications assessment**. OF 1-2-1. Launch mission cycle. OF 1-2-2. Needs and constraints. OF 1-2-3. Logistics. OF 1-2-4. Adjustment of capacity to requirements. OF 1-2-5. Final feasibility check.

STEP 1-3. **Mission acceptance**. OF 1-3-1.Governmental and employer's approval. OF 1-3-2. Confirmation of mission.

Phase 2. **Mission specification**

STEP 2-1. **Planning on-site deployment**. OF 2-1-1. Characteristics of on-site location. OF 2-1-2. Mission clearance. OF 2-1-3. Ensure host nation support. OF 2-1-4. Establish contact with local authorities and services. OF 2-1-5. Finalize convention and contracts with third parties whenever needed. OF 2-1-6. Selection of mission staff and PersPack. OF 2-1-7. Specific staff training. OF 2-1-8. Medical check-up. OF 2-1-9. On-site medical support. OF 2-1-10. Operational ethical and legal requirements. OF 2-1-11. Selection and checklist of tools.

STEP 2-2. **Logistics: procurement and delivery**. OF 2-2-1. Procurement of tools and equipment.

Phase 3. **Mission execution**

STEP 3-1. **On-site transportation**. OF 3-1-1. PHS&T (safe packaging, handling, storage and transportation) and loading tools. OF 3-1-2. Hazardous materials and items specifications for transportation. OF 3-1-3. Transportation of cold products.

STEP 3-2. **On-site deployment**. OF 3-2-1. Accommodation, water and food. OF 3-2-2. Healthcare and MEDEVAC (medical evacuation). OF 3-2-3. Installation of platform/vehicle/existing infrastructure. OF 3-2-4. Cold chain. OF 3-2-5. Ensuring and securing power and water supply. OF 3-2-6. Ensure on-site security. OF 3-2-7. Biosafety aspects. OF 3-2-8. Lab organization.

Location and date	Exercise	Deployment type	Communication tool	Focus on mission cycle: Specific component or comprehensive cycle	Aim of mission (specific mission-related OF)
Kananga, West Kasai, Republic Democratic of Congo, 14 April–4 May, 2009	KAYA KUMPALA	***OPERATION*** (Mil)	Military parabolic antenna	Mission assignment Mission execution	OF related to a first deployment in a military environment threatened by a local outbreak (transportation, logistics of the laboratory, quality of tests, data transmission) [26] Aim: rapid identification of monkeypox virus [17]
Brussels, 29 November 202	First B-LIFE Exercise	***EXERCISE*** (Civ-Mil)	SES—EMERGENCY. Lu GATR antenna	Mission specification	OFs related to: site selection, geolocation and traceability of sample, biological detection, First integration of Civilian SatCom for data transmission
Rienne, Belgium 10–12 May 2012	MAYDAY	***EXERCISE*** (Civ-Mil)	Parabolic antenna ASTRA2CONNECT	Mission execution	OFs related to: rapid biological identification, testing access on-site using road transportation, data transmission using SES Broadband
Pionki, Poland, 22–25 April, 2014	PIONEX	***DEMO*** FP7-PRACTICE (Civ/Mil)	Local WiFi provider AIRBUS DEFENSE	Whole mission cycle	OFs related to each part of the mission cycle. Aim: large-scale CBRN exercise PIONEX; integration of B-LiFE capacity in the first multiuser response system to a CBRN incident.
N'Zerekore, Guinea, Dec 2014–Mar 2015	EBOLA OUTBREAK	***OPERATION*** *B-LiFE/B-FAST*	SES- EMERGENCY. Lu GATR antenna	Whole mission cycle	All previous OFs and additional ones appearing mandatory to deploy in a real life situation: rapid response to an Ebola outbreak—support to an Ebola treatment Center unit in a very remote location in guinea, with no communication.
Munich, Germany, 7–13 Feb, 2016	CLUELESS SNOWMAN	***EXERCISE*** *B-LiFE* (Civ/mil)	SES- EMERGENCY. Lu GATR antenna	Whole mission cycle	All OFs defined in the Ebola mission revised, improved or added after a thorough mission debriefing, and based on lessons learned and return on experience (e.g. a specific assessment of biosafety measures and procedures by a biosafety officer). Aim: training mission—joint exercise with the Bundeswehr Institute of Microbiology

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Location and date	Exercise	Deployment type	Communication tool	Focus on mission cycle: Specific component or comprehensive cycle	Aim of mission (specific mission-related OF)
Bologna, Italy, 12–15 Apr 2016	FOOD DEFENSE	***DEMO*** FP7-EDEN B-LiFE (Civ)	Not done	Whole mission cycle	All OFs as defined above, integrating new, specific biosafety procedures. Aim: validation and use of new technologies usable on-site for the new application of "Food Defense" as part of a large-scale CBRN exercise
Revinge, Sweden, 20–24 Apr 2017	MODEX EU AMPs modules	***EXERCISE*** B-LiFE/B-FAST *CERTIFICATION*	SES- EMERGENCY. Lu GATR antenna & Astra Connect parabolic antenna	Whole mission cycle	All OFs as defined above and implemented for the certification of B-LiFE as rapidly deployable, self-sufficient capacity within the framework of the EUCPM and the ERCC (Voluntary Pool) as developed by the EUCPM (DG ECHO) [24, 25, 29]. Aim: testing the interoperability between AMP/AMP-S, deployable analytical laboratories, EUCPT/TAST, and LEMA
Bruges, Belgium, 24–27 May 2017	Mod4TTX Table-top	***EXERCISE*** B-LiFE/B-FAST *CERTIFICATION*	Not done	Mission execution	OFs focusing on laboratory procedures Aim of the table top: testing the procedures used by B-LiFE; the aim was to look at these procedures while considering the need for interoperability with other medical modules (AMP/AMP-S) as well as USAR teams, other deployable analytical laboratories, EUCPT/TAST, and LEMA

Table 1. Contribution to B-LiFE deployment to the identification of mission-related operational functions (OFs).

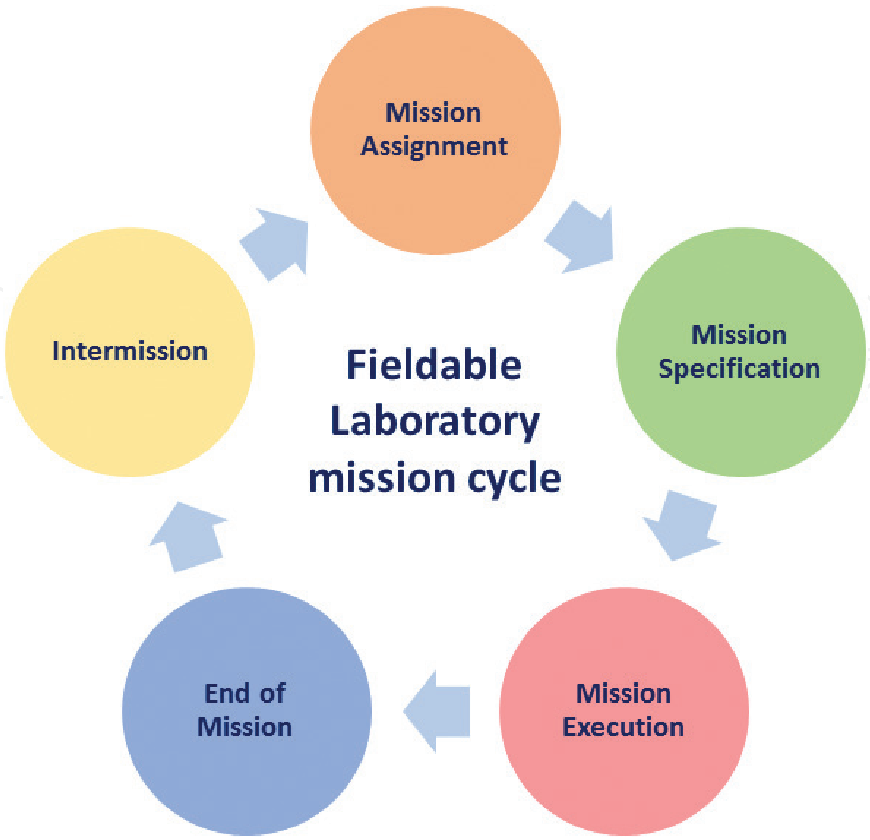

Figure 3. Five chronological phases of the FL mission cycle.

OF 3-2-9. Installation of sanitation area and toilets. OF 3-2-10. Set up of lab procedures and protocols. OF 3-2-11. Deploy tools according to required operational conditions. OF 3-2-12. Final security and safety check.

STEP 3-3. **On-site dry run**. OF 3-3-1. Power supply crash test. OF 3-3-2. Dry run of deployed lab.

STEP 3-4. **Briefing and communication**. OF 3-4-1. Briefing for all participants on the objectives and procedures of the mission. OF 3-4-2. Handover when new staff arrives to mission. OF 3-4-3. Communication with headquarter and recording actions.

STEP 3-5. **Pre-analytical phase**. OF 3-5-1. Decision on sampling. OF 3-5-2. Field security analysis. OF 3-5-3. Sampling strategy. OF 3-5-4. Move inside the site. OF 3-5-5. Sampling by lab team. OF 3-5-6. Sampling by third parties. OF 3-5-7. Tracking of samples. OF 3-5-8. Transmission of sample data to lab/communication. OF 3-5-9. Transportation of samples. OF 3-5-10. Decontamination of samples. OF 3-5-11. Preparing staff and materials. OF 3-5-12. Samples reception and validation of packaging. OF 3-5-13. Updating recorded data. OF 3-5-14. Inactivation of biological samples. OF 3-5-15. Preparation of aliquots for reach-back analysis. OF 3-5-16. Sample preparation.

STEP 3-6. **Analytical phase**. OF 3-6-1. Sample analysis. OF 3-6-2. Maintenance of laboratory. OF 3-6-3. Waste management. OF 3-6-4. Analytical impact of climate conditions.

STEP 3-7. **Post-analytical phase**. OF 3-7-1. Validate analytical results. OF 3-7-2. Interpretation of analytical results. OF 3-7-3. Reporting. OF 3-7-4. Follow up on report. OF 3-7-5. Storage of residual samples after analysis.

Phase 4. **End of mission**

STEP 4-1. **Preparation for FL repatriation or relocation**. OF 4-1-1. Decontamination and cleaning. OF 4-1-2. Condition hazardous samples and reagents for transportation. OF 4-1-3. Pack cold products for transportation. OF 4-1-4. Condition materials for transportation. OF 4-1-5. Dismantle tents, prepare vehicle for transport.

STEP 4-2. **Site restoration**. OF 4-2-1. Decontaminate site. OF 4-2-2. Rehabilitate site.

STEP 4-3. **Repatriation or relocation**. OF 4-3-1. Evacuate non-disposed waste. OF 4-3-2. Transportation practicalities.

STEP 4-4. **Debriefing**. OF 4-4-1. Immediate feedback on the past mission. OF 4-4-2. Final report. OF 4-4-3. Inventory. OF 4-4-4. Lab storage. OF 4-4-5. Medical and psychological follow-up. OF 4-4-6. Final budget.

Phase 5. **Intermission**

STEP 5-1. **Lessons learned**. OF 5-1-1. SWOT analysis and continuous improvement process (CIP). OF 5-1-2. Coordination of preparation.

STEP 5-2. **Preparation for next mission**. OF 5-2-1. Maintaining stocks. OF 5-2-2. Metrology. OF 5-2-3. Training and exercise. OF 5-2-4. Occupational health annual check-up. OF 5-2-5. Ensuring financial and human resources.

Transversal operational functions: OF 0-1. Financing. OF 0-2. Supply chain. OF 0-3. Maintenance and sustainability. OF 0-4. Communication and information management. OF 0-5. Safety/security.

3. Operations management and its support tools

Operations management is defined as the management of systems or processes directly involved with the provision of goods and services to customers [37, 50, 51]. The present work demonstrates consolidation of all the heterogeneous components of the operational system in the FL domain, i.e. planning, coordination, control of the human, financial and material resources, management of FL staff, equipment, including technology and information needed by FL to provide the service as defined by the FL service requesters and according to the specificity of the mission.

FL operations are based on the clear understanding of the needs of the service providers, where these needs have been iteratively collected and analyzed in multiple previous deployments listed in Section 4, **Table 1** and detailed in [59]. The whole FL structure (i.e., its mission-dependent configuration depending on the type of mission, the contents and amount if materials, equipment, staff members, logistics, supply chain) is all defined with the purpose to deliver the most appropriate FL service in relation to the parameters and specificities of the mission.

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In order to develop the FL as an operational system integrating all the materials, technologies, processes, information needs and the decisions associated with every activity, the following components have been developed:

- The mechanism allowing continuous improvement of the FL structure and configuration has been identified. The FL-MC has been described as consisting of five successive phases with 14 steps and 92 operational functions [57, 58]. The OFs required for carrying out the mission have been identified and described in detail; the decisions to be made at each OF have been defined and information needs for taking every decision have been identified.
- The FL technologies and processes (tools, such as lab equipment, materials, reagents, communication tools) required for executing OFs have been listed, described and associated with every OF.
- The ontology has been developed [57] as a component of the Laboratory Information Management System (LIMS), to serve as the knowledge base and the tool for existing FL domain information structuring, modeling, grounding and accommodation of new information. The ontology is applied to prepare the FL mission, to describe the relationships between OFs and tools and to provide the decision support for the FL operators and decision makers.

3.1. LIMS and ontology

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 mission in particular, the information management concepts and tools play a major role in the quality and precision of mission preparation. To unify the communication process within the FL and to consolidate the information necessary for optimal operations management and decision making at the document management level, a laboratory information management system (LIMS) targeted for FL is under development [57]. One of the advantages of LIMS is that it is compatible with the information systems of other stakeholders and health care modules, 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. A LIMS is therefore a crucial component of an operational laboratory as it gathers the key information which will be produced by the laboratory operators, used by them internally, and transmitted to the laboratory stakeholders for exploitation after proper formatting. The best illustration is, for instance, the collection of patients' data, which need to be used by the medical team for guiding patients' local care and treatment, and by local, national, regional and international health authorities implicated in the operational management of the crisis.

The FL-targeted 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 x width x height; cm*), volume (m^3) 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 are connected with the FL-specific ontology described in [11, 44, 57]. The *ontology* here is understood as a formal, explicit specification of a shared conceptualization describing the FL as operational domain [30, 31]. The FL ontology serves as a knowledge base for FL missions preparation, planning and execution. The ontology is used to formalize and structure the FL domain operation in the situation of a biological crisis preparedness and response to ensure a continuous improvement of the laboratory service. Being computer-modeled and flexible in its configuration, the ontology aims to provide an easy access to all the information stored in LIMS before and during the mission. Moreover, all the generic information is formatted in such a way that it is reusable for different missions. Ontology enables therefore the laboratory operators to compare easily the FL structure and functionalities to other similar capacities, be they civilian or military, fully autonomous or acting as part of larger organizations, such as NGOs or military authorities. The ontology facilitates the use of a common terminology while providing a shared vocabulary of concepts to comply with recognized standards, best practices and procedures, establishing in this way a common ground between internal FL operators and external decision makers and stakeholders.

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, standard operating procedures (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 adhere 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.

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. The ontology-based approach to the definition of FL domain framework provides the computer-readable domain representation, allows for updating the context and makes the computational support to human sense-making possible.

In fact, both LIMS and ontology cover and control all the aspects vital for the FL operations management, by defining and describing the laboratory OFs, financial and human resources to implement them, technologies, materials, equipment, processes and guidelines used for every OF execution, patterns and a priori background knowledge about FL mission parameters, records of information related to biological sampling, samples tracing and tracking, results of samples analysis, all biosafety and biosecurity aspects and reporting to external stakeholders. In that respect, the LIMS is the heart of an optimal, robust and efficient global operational crisis management.

The FL ontology is developed in the open-source Protégé environment release 5.0.0 beta-17 (http://protege.stanford.edu/) [47]. Protégé employs OWL formal language to express the semantics of constructs, enabling operators and developers to reason over the FL domain constraints and properties, and to infer new facts from existing definitions. All the information in the ontology can be both asserted (i.e. explicitly stated) and entailed by means of automatic reasoning. The logical consistency of the entire model of the FL operation domain is ensured by 3251 logical axioms (rules) and filters delimiting the restrictions for all the relationships between all kinds of ontology entries.

The major ontology classes describe the types of FL missions, the FL OFs that are performed during the different mission phases (**Figure 1**), and the transversal OFs which are present in all phases of FL missions, as well as the tools used in OFs. The current version of the FL ontology comprises 92 OFs (listed above in Section 2) and 117 categories of the following types of tools: lab equipment, lab consumables, polymerase chain reaction (PCR) equipment, personal protective equipment (PPE), storage devices, waste management tools, devices to record data, logistic tools, communication tools and generic tools.

The current version of the ontology is the result of iterative tests and validations during multiple FL missions. It was last validated in the B-LiFE project during the MODEX exercise in April 2017. The details of the validation process are presented below in Section 4.

3.2. Decision making for efficient operations management

When analyzing and modeling the decision-making process in the domain of a FL deployment in response to a biological crisis, we assume that all decisions during the FL-MC [39, 58] (with reference to numerous works in humanitarian and defense operations decision making, such as [1, 2, 4, 9, 10, 14, 18, 19–21, 27, 32, 34, 36, 43, 45, 48, 54–56, 61, 62] are taken considering all the knowledge accumulated by the time of the mission, the background context and the new information received in the course of the mission.

The possibility of a mission and its further implementation is based on the presupposition that a mobile capacity exists, is available and is ready for deployment. This starting point serves as the main prerequisite for the possibility for the mission launch. Then, all the decisions made during the mission assignment, specification, preparation and confirmation are made to specify the details, the mission parameters (such as the mission location, duration, number of tests to be performed daily, materials needed for this particular mission, trained FL staff members needed), conditions and requirements for the guarantee of security, staff safety and costs of the mission. With the said presupposition in mind, and from the point of definition of the mission goal in Phase 1 *Mission Assignment*, the overall behavior of the FL staff and their decision making are goal-oriented. All decisions are made with the view of the goal of the FL mission and the necessity to reach this goal. The FL mission goal is clear, and it is multi-fold. In general terms, the goal of any FL mission consists of the following elements:

- To be deployed in a defined location for a certain period of time, agreed with the mission stakeholders;
- To perform diagnostic tests and biological (biochemical) assessment of patients according to the biological threat agent and known clinical land biological consequences;
- To provide health care support to the population in the affected area and contain a spread of biological threats, hence containing or limiting the health crisis;
- To keep FL staff healthy and safe;

- To test novel technologies for biological threat detection and diagnostics, to follow-up patients included in therapeutic trials (e.g. new drugs, new vaccines) according to the mission scenario and specifications;
- To return to the base safely at the end of the mission and with all equipment and materials properly decontaminated and, if possible, in usable condition.

All these elements of the FL mission goal strongly determine the success of the mission. Thus, every phase, step, and OF performed by the FL as well as every decision taken at each critical moment of the mission, contribute globally to the final success of the mission. As in any real-life situation, every decision brings opportunities to reach the ultimate goal, and at the same time, can be associated with risks that, if neglected or too high, might prevent the team from reaching the goal. Thus, decisions are never binary, never strictly positive or strictly negative; the decision-making process is always about balance, choice, estimating what prevails and trying to anticipate opportunities or risks. Decision-making process is not linear; there can be regrets, comebacks to previous steps, e.g. taking another path that would bring a different outcome. In the domain of FL deployment for biological crisis response, the decision makers often consider several alternatives for every decision, taking into account the current context and looking for continuously updated information. Therefore, they may look back and consider previous decisions as no more appropriate to the evolving context and change them partially or totally to adapt them better to this new, sometimes elusive reality. However, following the methods of contextual inference in computational semantics [5, 46, 60], we consider every next decision in the FL-MC as increment of the context which satisfies all the logical requirements and therefore consistently fits in the whole picture like a puzzle. Every next decision, be it a new one, or an updated previous one, has to be accommodated in the context. The process of accommodation of every next decision is an active dynamic process requiring fusion and interpretation of all the available information, balancing the parameters, and using this information for finding an acceptable solution enabling advancement to the next step of the cycle.

A decision-making process consisting of various interrelated components (i.e. identification of the problem, assessment of the available information, evaluation and selection of alternatives, evaluation of the result) requires a general scheme where logically transparent representations of single decisions are first created, and then these representations are subjected to further semantic operations which relate them to the context where the decision is made. If a decision is a part of a decision belonging to a wider scope, the named semantic operations should integrate the new decision into the obtained interpretation of the previous context including all the decisions, which have been processed up to this moment of time.

Formally, the evolution of the decision-making process is of cumulative character, consisting of a sequence of decisions $<\varphi_1,\ldots,\varphi_n>$. These decisions can be thought of as simple choices from a set of possibilities, or more complex choices that include both a choice of action and various parameters associated with that action. In a simple case where parameters are not involved, the decisions can be defined as sets of possibilities, with possible continuous or discrete values. So for instance, the "go/no-go" decision is binary (and it clearly constrains what can happen in the future). But other decisions, such as how many items from a variety of materials shall be

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deployed for a particular mission, will be represented both by a choice and associated parameters, such as deciding whether to bring a certain type of reagents, and then how much of these to bring. In these cases a decision φ_i can be expressed as a vector $\varphi_i = (\delta_i, \pi_i)$, where δ_i is the categorical decision (which tools shall be brought to the mission, for instance) and π_i is a set of parameters that describe the decision in more details (such as the amount, volume, weight of the tool items) and $\varphi_i = 0$ would mean that this tool shall not be brought at all.

After decision φ_i has been made, we call a representation of the state of the world at that point in time R_i, which encapsulates the aggregate impact of all previous decisions φ_i through φ_i. Thus, there is a representation R_1 of the decision φ_1; we then use this representation as a context to adapt and interpret φ_2, which, when matched with R_1, will give the representation R_2 for $<\varphi_1, \varphi_2>$; and so on.

Thus, we have a series of decisions φ_i, which collectively define the current situation R_i at time *i*. These prior decisions jointly constrain the next decision, φ_{i+1}. That is, the set φ_{i+1} from which the next decision is drawn is itself a function of $<\varphi_1, \varphi_2, \ldots, \varphi_i>$. These decisions are made in a dynamic environment, so the information considered for taking the next decision may be different from the information on hand when taking prior decisions. Assume a sequential nature to the decisions, so that decision $k > 0$ may constrain decisions $k + 1, k + 2, \ldots, k + n$, but not decisions $1, 2, \ldots, k\text{-}2, k\text{-}1$. Then at any time *t*, due to new information, we can go back and change any given decision φ_i, where $i < t$ (i.e. the decision taken before the time *t*), changing the former state of the world from R_i to R'_i. But then we have to make sure that decision φ_{i+1} is in the permissible set given R'_i, φ_{i+2} is in the permissible set given R'_{i+1}, and so on up to time *t*. That is, changing past decisions may have a ripple effect on other past decisions, and could further constrain/reduce the constraints on the current decision.

In the process of a decision accommodation, then, the following main problem has to be resolved: given the fact that the evolution of the FL-MC context includes not only the entire preceding context, but also all the set of contexts corresponding to different alternatives at previous steps—in which context exactly shall the accommodation take place? In other words, which path of incrementing the context with new decisions shall be considered optimal and provide the best result? To answer this question, let us look into the decision accommodation process in more detail. We consider two types of situational contexts. The first type of context is *global* that covers the situation R_i at the given moment of time with all the events evolved, information received and decisions taken up to this moment, i.e. covering times *1* through time *t-1*. The second type of contexts are *local contexts* where individual decisions φ_i, parts or fragments of them are considered. The advantage of the notion of *local contexts* is that it gives maximum flexibility when "playing" with alternative decisions and alternative paths, sometimes considering them only temporarily, to estimate the possibility for the optimal decision path without breaking the logic and consistency of the global situation.

Thus, updating the situational context *C* with a decision of the form $\varphi \rightarrow \psi$, requires consideration of local contexts such as $C + \varphi$ and $C + \varphi + \psi$, and these local contexts will be considered during the process of the situational context update. Let ψ contain a decision that did not fit well enough in the context $C + \varphi$, then *C* does not accommodate this decision and needs its alteration as a whole or change of some its parameters. In this case the accommodated decision should update one of the considered contexts in such a way that ψ can be accommodated locally. It can take the form of direct update of the local situational context where the situation ψ must be computed, with some variable parameter α, so that the resulting update of the context will not be just $C\backslash(C + \varphi\backslash(C + \varphi + \psi)$, but $C\backslash(C + \varphi\backslash(C + \varphi + \alpha + \psi))$: this leads to *local accommodation*. Another variant of situational context update with a new decision is possible: the decision maker can come back not to the initial context, but to where the parameter(s) of the intermediate decisions can be changed, i.e. φ_j, where $j < t$ and then to add some information or new parameters, say, γ, to the context where the decision is computed. The result will be the following: $C\backslash(C + \gamma + \varphi)\backslash(C + \gamma + \varphi + \psi))$.

On the other hand, the decision maker might go back to the initial context, add a variable parameter β in the global situational context and start the update of the situational context again. This leads to the global accommodation of the decision, and the resulting update will take the form: $(C + \beta)\backslash(C + \beta + \varphi)\backslash(C + \beta + \varphi + \psi))$.

This process of accommodation of new decisions in the global situational context reflects the dynamic procedural approach to the decision-making process with its iterations and possibilities of changing previous decisions or parts of them. Such flexibility allows handling the complexity of the domain, heterogeneity of the information, parameters and factors of the decisions to be taken.

The developed ontology models the FL domain, and provides all the background context for further operations. Containing all the necessary entries—the OFs, tools, actors involved in the mission, and all links between them—the ontology thus contains the antecedents, i.e. reference points. New information received by FL during the mission preparation or mission execution can be either bound to the existing referents in the ontology, or new ontology entities (objects, tools, or events) can otherwise be created to accommodate new information if it did not exist before. In this way, new information is smoothly fused in the mission context, inheriting some of the existing links and creating new ones. That is why the ontology is the core tool for the context increment, update, data and information fusion for further use.

The knowledge-based operations management process, the list of OFs modeled in the ontology and interlinks between all the pieces of knowledge in the FL domain make it possible to track the decision-making process and identify its inner logic. OFs are interconnected with one another in such a way that OFs actually serve as the basis for tracking the path of decision-making process across the different phases of the FL-MC. In the FL domain all the information coming to the decision makers is considered relevant for decision making. Redundancy might complicate the computational modeling, but it appears practically that all the information are handy and can be used at some point, sometimes not immediately, but later at another phase. Redundancy sometimes helps to confirm hypotheses in case of uncertainty.

Information processing in operating complex systems such as FL can be seen as alternating between data-driven (bottom-up) and goal-driven (top-down) processing. In goal-driven processing, attention is directed across the environment in accordance with active goals [6, 7]. The decision makers actively seek information needed for achieving the mission goals, which, in turn, simultaneously act as a filter in interpreting the new information that is perceived. In data-driven (or stimulus-driven) reactive processing, perceived environmental cues are processed to create or enhance situational awareness with, as a consequence, the identification of new goals that need to be set [22]. The term *situation awareness* has emerged as an important concept in dynamic human decision making. According to Endsley [22], situation awareness is "the perception of the elements in the environment within a volume of time and space, the comprehension of their meaning and the projection of their status in the near future". Situation awareness is described as the decision maker's internal model of the state of the environment. Based on that representation, the decision maker can decide what to do about the situation and carry out any necessary actions.

The most critical component of the effective decision-making process is the correspondence of the real situation in the real environment and the situation model obtained in the decision maker's mind based on the situational awareness and analysis [49]. Human factors such as cognitive bias, stress, emotions [12], relationships within the team and with external stakeholders, and personal features of the decision maker naturally influence the decision-making process. While the existence of these factors is presumed, the practical lessons learnt and objective success of the FL multiple deployments have proven that the responsible FL manager and all FL staff members are excellent professionals. Their behavior during the mission and decisions they make are, in the first mission, goal-oriented. Driven by the motivation for the mission success, they are able to cope with human factors and make decisions objectively and impartially. That is why we do not consider any decisions in terms of "right" or "wrong". Presuming that the decisions are taken by experienced competent staff, 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.

The decision-making analysis is made with the help of structural-functional approach to studying the mechanism of balancing the compliance with the fixed procedures and decisions taken in a dynamically changing context. Prevailing of opportunities increases the chance for success. Prevailing of risks is not necessarily a mission-stopper. Actual or potential risks are present in every situation and arise from almost every decision. However, the presence of risks does not necessarily put the mission at stake. What matters here is the significance of the risks, their impact on the FL OFs, possibility or absence of possibility to minimize or neutralize the risks. Only if the risks are too high, presenting a threat that the FL mission goal will not be achieved, and if any subsequent measures and decisions aimed at decreasing the risk do not lead to opportunities, then the decision to stop the mission might be taken.

FL missions at their every step and as a whole are associated with three major types of risks:

- Risks related to security of the FL mission staff and materials;
- Risks related to health—here the staff safety, biosafety and medical issues such as then need for medical evacuation in case of a disease or an accident requiring urgent repatriation are included in health risks;
- Risks related to costs—costs of materials, reagents, transportation of FL staff and equipment, maintenance costs during the mission—all are included in this category.

The objective of every decision made during the FL mission is to ensure opportunities for the mission success, or find opportunities, or create them, and in parallel to minimize risks. Efficient decision-making process, prospective and retrospective risk analysis at every point of the FL mission and timely risk management are the integer part of FL operations management [16] and concurrently secure the FL service to the best needs of stakeholders.

The FL-MC has been defined as the result of multiple iterations and lessons learnt from previous FL deployments. The composition of the FL-MC presented in Section 2 and the list of OFs to be implemented at every phase and step of the mission have been iteratively developed and agreed between all the actors involved in the missions. This FL-MC and the associated set of OFs are common for any type of FL mission. Thus, it is highly unlikely that any new information received by the FL staff could disturb the MC and OFs. New information will be unavoidably bound to one or more existing OFs and will be processed accordingly. New information can impact only parameters of the mission, e.g. exact location of deployment, mission duration, the number of trained FL staff needed for the mission, the number of samples that need to be processed by FL per day, the 24/7 type of service or not, the equipment and other materials that can be used to fulfill certain tasks.

As mentioned above, the decision-making process is never linear, it is not always sequential, and it is based not only on internal FL operations but also on numerous external factors. New information or new data that influence the FL operations can occur at any time, at any phase, during any OF implementation. Every time the FL staff receives new information, its following properties are of most interest for decision-making process:

1. Timing—at what phase of the FL-MC the information is received, to which OF it is related;
2. If this new information can be bound to the existing ontology entities (processes, tools, actors), or new entities shall be created;
3. When the new information is embedded/integrated/fused to the current context, then the impact can be estimated in terms of what opportunities this new information brings and to what risks it is associated. This point is relevant for information bound to "decision nodes" in OFs. Information related to "action nodes" is neutral, just actionable.

The categories of new information that the FL staff usually needs to receive and interpret according to the current situation and integrate in the current context, are as follows:

- Epidemiological information about the current disease spread, the number and location of cases and their positioning on a local map.

Epidemiological data significantly influence the FL operations requiring the following decisions:

- The dynamics of the outbreak, e.g. the number of new cases and contacts per day or per week and the speed of spreading.
- Depending on the number and distribution of cases, it is important to decide the perimeter of the area considered for samples collection, i.e. the accessibility of the patients, or the

accessibility of patients to existing treatment centers or deployed health care facilities which function as sample collection points.

- If the currently deployed FL capacity can handle all the cases, or if extra mobile capacity must be envisaged in the area to investigate very remote patients and collect their samples. For instance, this can be done by using the Extra-Light Fieldable Laboratory (ELFL) that is a part of FL. ELFL is a vehicle-based capacity which can be deployed for 2 days as far as at 50 km distance from the FL. Deployment of ELFL in itself would require careful assessment of the available trained staff, division of effort, costs, safety and security risks, as well as the possibility of a permanent stable communication between the ELFL and FL.
- If and how many of additional FL staff members, how much of resources, assets, equipment, materials will be required for handling the new cases and if the work can be done within normal working hours or daily work, or if the workload requires a 24/7 work schedule and, in the latter case, for how many days.
- If the costs for additional assets, materials, and equipment are acceptable for the FL manager.
- Daily updated health status of every patient: close follow up of biological and clinical data knowing that critically ill patients and long hospitalizations require more laboratory human and material resources.
- Should the FL deployment be extended beyond what was initially planned? This type of decision will be taken according to the answers provided to some of the questions cited here above, hence to the sufficiency/insufficiency of resources, materials, supply chain possibility to provide more materials if needed and volunteers availability if the mission is prolonged;
- New information can appear internally in the FL and can be related to the condition of equipment in case such equipment, e.g. a glovebox necessary for samples analysis, breaks down and needs urgent repair or replacement. The problem can be solved by replacing the broken parts with spare parts, which presumes careful mission preparation, planning, and spare parts logistics of critical equipment deployed. Alternatively, a rapid supply chain solution must be in place in case spare parts or whole piece of equipment must be outsourced.
- Similarly, internal problems related to the physical health and mental condition of the FL staff members. Sometimes medical evacuation (MEDEVAC) of one or more persons can be necessary, and/or team member replacement. Here decisions about the necessity of MEDEVAC are made according to availability of transportation, availability of trained personnel to replace the evacuated staff member, associated costs, timing—all these factors would influence the decision-making process.
- Potential security issues, such as an attack on the FL in case of deployment in a politically unstable area and civil or military unrests with possible harm for the staff members and/or equipment, might force decisions to definitively stop or transiently interrupt the mission.
- Potential safety issues, such as other contemporary natural disaster, e.g. an out-of-control fire with toxic fumes, or an extensive environmental contamination with dangerous chemical products, might also require to stop or interrupt the mission, evacuate and/or repatriate the FL.

- An external stakeholder might request the FL deployment for the purpose of a new therapeutic trial (new vaccine, new drug therapy) for which standards of ethical and legal conduct impose a regular follow up of patients condition, i.e. a thorough evaluation of the therapeutic response and early identification of potentially related side effects. Likewise, testing a new diagnostic method (point-of-care testing [POCT] or Rapid Diagnostic Test [RDT]) by first responders may also be part of the request for deployment. Such a request can cause decisions on the feasibility of the tests, costs, availability of materials, reagents and trained staff to perform the tests, estimation of the workload for these additional tests and their compatibility with the main mission goals.
- Depending on the evolution of the epidemiological situation, or on the request for additional tests, the decisions might be taken to increase the work capacity in terms of staff or working hours, as discussed above.

It is important to underline that we do not associate risks to information itself. Any information, any fact is neutral. It can be interpreted in a positive or negative way, bringing opportunities or risks only when it is consistently integrated in the existing picture of the FL realm, when it becomes part of the context. Only then, it can be interpreted, analyzed, and actionable decisions can be taken accordingly. To illustrate the neutral character of new information, irrespective of its contextual interpretation, let us consider the following example: suppose that the FL manager receives information about new cases of the disease outbreak in a certain area. Globally, it is very negative news for health authorities and the population of the affected area. On the one hand, this information can fully justify the launch of the FL mission, and provides a real opportunity to start the mission. On the other hand, further feedback that no new cases are detected is a very good news for public health authorities while, for the FL deployment perspective, it may interrupt the preparation of the mission and even lead to the decision to cancel it. However, if this information about the absence of new cases is received when the FL is already deployed on-site, which means during the "mission execution", it can imply that the FL mission has a positive impact of the containment of the outbreak, according to the primary objectives of the mission.

4. Validation

The present work is the result of the practical experience accumulated by the FL staff through the multiple missions detailed in **Table 1**. The military mission in 2009 deployed the first fieldable laboratory prototype. This mission was a pioneer deployment without yet any specific supporting tools such as LIMS or ontology. The FL was not yet shaped into an autonomous capacity and a single structured information space but benefited from the military logistics and facilities at the military camp at Kananga where it was deployed. Following each new deployment, a careful planning and thorough preparedness appeared crucial to anticipate on all possible human resources and materials needed on-site to ensure a successful mission. Consequently, the work carried out to systematize the experience of laboratory operators, to structure the FL domain and to develop tools supporting the mission preparation and execution, started already before the second mission. Every new mission brought a new operational context with new parameters and new conditions of deployment for which the LIMS and ontology were iteratively developed and tested during the deployment. Lessons learned and return on experience from participants were systematically collected at the end of each mission in order to improve all the aspects related to the mission cycle and its OFs and to be prepared to implement them in the following deployment. This recently led to the MODEX exercise in Sweden and a final validation by the European Space Agency of all aspects related to terrestrial and SatCom integrated in B-LiFE, and to a European certification as autonomous module in the voluntary pool of assets set for activation by DG ECHO in the framework of the EUCPM.

Naturally, the process of ontology development faced many challenges, due to the intrinsic nature of the ontology concept. The ontology, as discussed and applied in the current work, is a model of a niche of interest, i.e. the FL domain of a deployable laboratory, and its design and configuration largely depend on the representation of the domain by the developers specifically addressing this niche [28]. In order to make the resulting ontology usable on the most possible generic way, and therefore not restricted to the FL staff, but also acceptable for external stakeholders, frequent consultations using formulation and clarification of competency questions were organized with experts inside and outside the laboratory, individually and in groups, to reach an agreement on the most appropriate organization of information in the ontology. A few variants of data representation were implemented in parallel, challenged by various case studies, and the variant performing best was chosen for the new version. Every new version of the ontology was iteratively tested by developers and assessed by B-LiFE users during the new mission planning and preparation phase, and the resulting version was further improved after each mission execution. With a substantial number of approaches, methodologies and metrics elaborated in previous research [3, 8], [13, 33, 40], the evaluation and validation technique appearing as the most relevant for the FL application ontology was chosen in order to cover both the domain conceptual and technical scope. The main functionalities of the ontology subject to the conformity assessment by users were:

- The ontology completeness, i.e. if it appropriately covers all the concepts (lexicon/vocabulary, hierarchy, taxonomy) of the FL domains without any gaps in knowledge;
- The overall usability and acceptability both by the users and the developers, e.g. consistent use of the terminology, precise description of concepts and correct definition of their properties and links between them;
- The ontology explanatory power, i.e. ability to support users in the decision-making process. An example of test case could include the questions: "Given the known mission location and duration, how many gloveboxes will be necessary to take along? Are they already available or do they need to be purchased additionally? Is there available personnel trained to use the necessary equipment? Do they need a specific maintenance during the mission?"
- The ontology logical consistency, i.e. the absence of contradictions in the definition of classes, subclasses, semantic relations, axioms and other entries;
- The ontology computational efficiency, i.e. the size and the speed with which the LIMS can work with the ontology;

- The ontology expandability to account for new missions, i.e. in the technical terms this criterion refers to the ontology structure/architecture design allowing further development.

Such in-depth analysis and iterative improvement process helped to achieve a result that was globally helpful for all the B-LiFE users, and was therefore considered final. It is noteworthy that the terms "final result" should be understood as an appropriate way of information representation of the ontology as validated by users. However, this does not exclude further development in case of a new mission characterized by new, not yet encountered or experienced requirements. In such case, it is possible to add a new module or new tools to the ontology without modifying or altering the global structure.

5. Conclusions

The current work presents key results of the research on operations management and decision-making process regarding the deployment and on-site use of a FL. This work is particularly applicable to the context of a health crisis caused by either a natural infectious outbreak, an accidental biological incident, or a deliberate release of life-threatening biological agents. Considering the lack of standards concerning the structure and use of deployable analytical capacities, the current research is a contribution to harmonization of the procedures, where harmonization is key in case of a cross-border crisis response requiring the use of deployable capacities from different countries and different actors, and where interoperability and scalability of the response is a must. With the aim of making the FL operations transparent and comparable to similar capacities, a unique effort of structuring the FL domain has been made. The phases, steps and OFs characterizing the FL-MC are described.

The tools and mechanisms supporting the FL decision-making process are discussed. It is of note that all the decisions made by the FL manager and staff during the mission are subject to the actual goals of the mission, being defined at the Mission Assignment phase. While there are no "right" or "wrong" decisions, each of them pushes the mission forward by bringing opportunities to reach the goals and make the mission successful, even though this path is often non-linear. Every decision is indeed associated with risks, subject to alternations [15], comebacks, regrets and updates depending on a dynamically changing context. The approach to modeling of the decision-making process, as presented here, is based on the method of contextual inference in computational semantics. The contextual inference supports the decision-making process, itself linked to the FL domain information space, which is modeled in the ontology. Every time new information is received from the internal FL operations or from external sources, it can be linked (bound) to the existing entity (process, tool, person, and event) in the ontology. In this way, it will be integrated in the FL domain mission context by means of the ontology reasoner ensuring logical consistency between the existing and new entries. Otherwise, if no entity in the ontology can bind the new information, the latter can be embedded in the context by creating a new one. In case the new information is confirmed, it must be integrated in the global context of the mission for further use. In case the new information is not confirmed, remains uncertain, or whose validity has not been firmly established, it can be accommodated only locally, temporarily, without changing the global context.

This work focuses on fully autonomous deployment when the mobile capacity operators themselves have to make decisions and implement the OFs, ranging from basic (e.g. provision of equipment, power supply, food and accommodation for the staff) to complicated procedures (e.g. logistics of transportation and supply chain), that are needed to fulfill the operational requirements. It is their responsibility to choose OFs and requirements to implement and to communicate and negotiate with the stakeholders requesting the mission and the downstream users. This work does not take into account military mobile laboratories or field hospitals [23] that both benefit, in principle, from a dedicated planning and preparedness coupled with efficient military or humanitarian logistics capacity. Neither do we consider deployments by major international non-governmental organizations like Doctors Without Borders (MSF, Médecins Sans Frontières) or United Nations humanitarian organizations like World Food Program, since their centralized organization and financial power provide them a total autonomy in decision making regarding the modalities of deployment and support to missions. In many ways, their working processes and internal organization appear, however, quite similar to those used by militaries, which enable them to deploy their capacities at any time and any location in the world.

A thorough analysis and systematization of the decisions related to each OF bound to a FL capacity should have a positive impact on decision makers and end-users when they consider a field deployment of this type of capacity during a major health crisis or biological incident. A field deployment of a FL capacity should no more be a mysterious black box where no one else than laboratory operators understand the needs, procedures and requirements. A proper characterization of each fieldable capacity with a clear definition of all related OFs should make the requirements and conditions of deployment more transparent and easier to carry out. Such transparency should lead to better preparedness, leading to a more timely and efficient response as well as a better harmonization of procedures. The latter requirement is essential if we want to promote interoperability and scalability between different FL modules and health care capacities during cross-border biological crises, as is the goal of the EUCPM.

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Abbreviations

AMP	advanced medical post
AMP-S	advanced medical post with surgery
ARTES	advanced research in telecommunications systems
B-FAST	Belgian first aid and support team
B-LiFE	biological light fieldable laboratory for emergencies
BoO	base of operations
CBRNE	chemical, biological, radiological, nuclear, and explosive materials
CTMA	Center for Applied Molecular Technologies
DG ECHO	Directorate General for European Civil Protection and Humanitarian Aid Operations
EDEN	end-user driven demo for CBRNE
EMC	European medical corps
ERCC	Emergency Response Coordination Centre
ESA	European Space Agency
ESTEC	European Space Research and Technology Centre
ETU	Ebola treatment unit

EU	European Union
EUCPM	European Union civil protection mechanism
EUCPT	European Union civil protection team
FL	Fieldable laboratory
FL-MC	Fieldable laboratory mission cycle
IAP	integrated applications promotion
LEMA	local emergency management authority
LIMS	laboratory information management system
MIRACLE	mobile laboratory capacity for the rapid assessment of CBRN threats located within and outside the EU
ModTTX	Modex table top exercise
OF	operational function
OSOCC	On Site Operations Coordination Centre
PRACTICE	preparedness and resilience against CBRN terrorism using integrated concepts and equipment
RDC	Reception and Departure Centre
TAST	technical assistance support team
UCL	Université catholique de Louvain

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