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Structured decision-making for the management of a biological fieldable laboratory during outbreaks: a case for European Union Civil Protection Mechanism (EUCPM)

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Abstract

Fast on-scene deployment of an analytical laboratory capacity to help contain an outbreak of infectious disease requires setting up an appropriate policy framework and a range of operating procedures to ensure efficient support to decision-making, as well as the optimal engagement and use of dedicated resources. This work focuses on fully autonomous deployment when the mobile capacity operators themselves need to make decisions and implement all the operational functions (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. A model of the identity and structure of specific decision-making requirements for a generic deployment of laboratory capacities was built from the real experience during specific deployments of the operators and managers of the Belgian capacity Biological Light Fieldable Laboratory for Emergencies (B-LiFE). Self- and external assessments were conducted and lessons learned successively reviewed after each deployment by B-LiFE laboratory operators and managers and observers in the framework of European demonstration projects and joint exercises. The result was consolidated by integrating the assessment of European Commission-appointed certifiers during the certification procedure of B-LIFE as a self-sufficient module of the European Medical Corps, namely the European modules exercise "Modex" in April 2017 (Revinge, Sweden) followed by the "ModTTX 4" Table-top in May 2017 (Bruges, Belgium). A complete and updated set of Fieldable Laboratory operational functions is presented, including their contents, cross-links, inter-dependencies, information needs for implementation, and related decisions.

Keywords Decision support · Knowledge management · Operational functions · Fieldable laboratory · Ebola · Biological crisis response · EUCPM · EERC · Voluntary pools · Certification

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
EC	European Commission
EDEN	End-user Driven Demo for CBRNE
EMC	European Medical Corps
EERC	European Emergency Response Capacity
ESA	European Space Agency
ESTEC	European Space Research and Technology Centre
ETU	Ebola Treatment Unit
EU	European Union

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EUCPM	European Union Civil Protection Mechanism
EUCPT	European Union Civil Protection Team
FL	Fieldable Laboratory
IAP	Integrated Applications Promotion
LEMA	Local Emergency Management Authority
MIRACLE	Mobile Laboratory Capacity for the Rapid Assessment of CBRN Threats Located within and outside the EU
ModTTX	Modex Table-Top Exercise
MUSAR	Medium Urban Search and Rescue
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
UNDAC	United Nations Disaster Assessment and Coordination
USAR	Urban Search and Rescue
WHO	World Health Organisation

1 Introduction

One of the major lessons from the Ebola outbreak that affected West Africa in 2014 and 2015 (Frieden et al. 2014) was the need to rapidly deploy capacities able to provide direct medical care to the population. Accordingly, the European Union has set up the EU Medical Corps (EMC) under the EU Civil Protection Mechanism to coordinate the medical response of EU Member States to emergencies with health consequences both inside and outside Europe (ECHO 2016a). The EU Medical Corps is part of the existing European Emergency Response Capacity (EERC), also named as "voluntary pool of assets" (ECHO 2015, 2016b). It consists of different modules and teams (i.e., emergency medical and public health teams, mobile biosafety laboratories, medical evacuation capacities, medical assessment and coordination experts, logistical support and coordination teams) (Naor and Bernardes 2016, US Department of Health and Human Services 2016; Pettit et al. 2009; Akhtar et al. 2012; Balcik et al. 2010; Bartsch et al. 2014; GOARN 2005) which can be mobilized quickly whenever needed. These modules and teams that are pre-committed by their national authorities in the EERC have to meet the high standards set up at WHO level for international deployments (Calain 2007; EC 2015a, b; European Centre for Disease Prevention and Control 2016a, b; Guglielmetti 2013; IFRC 2013; WHO/PAHO 2003) whenever requested during major crises inside or outside the EU.

In that respect, the current objective of the Member States and the European Commission is to work closely together to develop quality criteria and a certification process ensuring that all teams meet minimum quality and interoperability criteria and can effectively work together in the field in a flexible and scalable way. The certification and compliance with defined standards are supervised by certifiers appointed by the Directorate General for European Civil Protection and Humanitarian Aid Operations (DG ECHO) and assessed during EU-funded international table-top and field exercises (ECHO Factsheet 2015, 2016a, b).

The Belgian analytical and logistic capacity B-LiFE/B-FAST was integrated in this EERC/voluntary pool shortly before its 2014–2015 deployment in Guinea during the Ebola outbreak. The B-LiFE/B-FAST mission was to support the Ebola treatment unit of N'Zerekore, opened by the French non-governmental organization ALIMA (*Alliance for International Medical Action*) (Mahy 2017).

Structuring of the decision-making process was started before and pursued during the deployment in the framework of the MIRACLE project (*Mobile Laboratory Capacity for the Rapid Assessment of CBRN Threats Located within and outside the EU*) supported by the EU seventh framework research program (http://cordis.europa.eu/project/rcn/111244_en.html) (Vybornova et al. 2015). It was further consolidated by a joint exercise between two deployable capacities (B-LIFE/B-FAST and the German EU mobile laboratory) in Munich in February 2016. The latter inputs allow for an in-depth review of all available data on the B-LiFE information management (Vybornova et al. 2016) and the decision support of deployable capacities (Vybornova and Gala 2016).

In the course of European Emergency Response Capacity certification process, the B-LiFE/B-FAST capacity participated in the "EU Modex 2017" exercise in Revinge, Sweden, 24–27 April, 2017 (http://www.falck.nl/nl/modexfalck/fieldexercises/2016-2017/exercise-4-msb-revinge), and deployed jointly with EU Advanced Medical Posts and the EU mobile laboratory. The assessment was carried out by international observers and finalized during the B-LiFE participation in the EU Table-Top "Mod4TTX" in Bruges, Belgium, 20–24 May 2017, involving also the EU mobile lab and other EU modules of Medium and Heavy Urban Search and Rescue.

The aim of the current work is to aggregate all previous observations regarding the management of a deployable analytical capacity (Vybornova and Gala 2016), consolidate, and strengthen them to a generic decision-support tool. Advantage was taken from the latter certification process where interoperability criteria and own capacity to organize self-sufficiency and autonomy of the deployed module/technical asset was externally evaluated, i.e., by DG ECHO-appointed EU certifiers.

The current work details the requirements and impact of operational functions (OFs) on the decision-making process

in a fieldable laboratory (FL) regarding the management of deployment through the EU Civil Protection Mechanism at an operational, tactical, and strategic level, hence providing a comprehensive list of FL OFs which positions them in the corresponding phase and step of the mission (see Tables 1–5 in Supplementary material). This list also provides the OF nomenclature as used in the FL laboratory information management system (Vybornova et al. 2016), a description of each OF, their cross-links and inter-dependencies, the decisions to be taken by FL manager and staff related to every OF, and the information needs that are mandatory for making each decision.

2 Method

Identifying and structuring the specific requirements for generic deployment of laboratory capacities, the B-LiFE deployable capacity belonging to the Center for Applied Molecular Technologies of Université Catholique de Louvain (CTMA/UCL https://uclouvain.be/fr/instituts-recherche/irec/ctma) was taken as a model of application. The CTMA laboratory has all the expertise as an academic, clinical, and military laboratory, enriched by several EU projects targeting best laboratory practices, and by several missions where a tent laboratory was deployed to carry out sample analysis on the field. A snapshot of selected "laboratory practice"-related EU projects and CTMA missions with the deployable laboratory is presented hereafter in Table 1. It also includes the field and table-top EU exercises carried out in the course of the certification of EERC modules.

3 Results

The decision-making process regarding the FL management previously described in Vybornova and Gala (2016) and Piette et al. (2014) can be summarized as follows: the generalized FL mission is represented as a cycle consisting of 5 successive phases—Mission Assignment, Mission Planning, Mission Execution, End of Mission, and Intermission, in 14 steps, which has been adapted from (Vybornova et al. 2016). The FL mission cycle is illustrated hereafter in Fig. 1.

Each phase covers a set of OFs corresponding to the performed FL activities (Tables 1–5 in Supplementary material). Some decisions are associated with a single OF, whereas others involve several distinct OFs through different mission cycle phases. Every OF 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 and management, problem-solving, and specific actions. They also require a specific operational knowledge regarding technologies and processes, and a specific knowledge of regulations, guidelines, legal and ethical issues to which to adhere. Within the single operational domain of FL functionality, there are OFs considered as decision-making nodes that have impact on other OF executions, while others are action nodes requiring compliance with the SOPs but no inherent variable decisions. In line with the logic presented in Gralla et al. (2013), the current research distinguishes between the following aspects attributed to the decisions:

- **Scope** with possible values assigned as follows:
  - 3—decision of global international scope, wide national, inter-cluster (involving the whole emergency response community),
  - 2—medium scope for national, regional decisions that impact FL and some stakeholders,
  - 1—local—these decisions impact only FL.
- **Criticality** with possible values assigned as follows:
  - 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,
  - 0—no impact.

The decisions with the highest criticality value are the most important decisions taken in all phases of the FL mission cycle.

- **Frequency** decisions can either be taken daily, weekly, monthly, yearly; they can also be taken on a one-off basis according to the occurrence of certain conditions specified below. Numbers are not associated to the Frequency factor, because, no matter if the decision is taken regularly or only once, it can have serious or low impact on the global FL mission context, depending mostly on the Criticality value.

It is worth noting that the FL staff and materials can be ready for deployment within a few days from reception of the initial request for the mission. These few days are associated to selection of mission staff and tools, specific staff training, medical check-up, and vaccination. However, various questions related to the mission funding, guarantee of security, guarantee of emergency medical evacuation in case of illness during the mission, support of the home government and of the host nation, etc.—all these factors and decisions to be taken can sometimes delay

Table 1 Biological fieldable laboratory deployments

Location and date	Exercise	Deployment type	Purpose	Means of verification
Kananga, West Kasai, Republic Democratic of Congo, 14 April–4 May, 2009	KAYA KUMPALA	***OPERATION*** (Mil)	Response to outbreak—identification of the monkeypox virus versus varicella in patients with skin rash illness	FL results were validated by the mission stakeholders (Dumont et al. 2014)
Rienne, Belgium, 10–12 May 2012	MAYDAY	***EXERCISE*** (Civ–Mil)	To extend the spectrum of tests usable in a deployed laboratory, to assess the feasibility of rapid road transportation of material, and to test data transmission using SES Broadband (former ASTR2connect)	External military and European Space Agency observers
Pionki, Poland, 22–25 April, 2014	PIONEX	***DEMO*** FP7-PRACTICE biological (Civ/Mil)	CBRN scenario—a large-scale CBRN exercise PIONEX of FP7-PRACTICE project, integration of FL capability of *Bacillus anthracis* detection and identification in the CBRN scenario and integration in the first response system	External observers of the exercise validated the FL quality performance
N'Zerekore, Guinea, Dec 2014–Mar 2015	EBOLA OUTBREAK	***OPERATION*** B-LiFE/B-FAST	Response to outbreak—Ebola crisis response	FL results were validated by the international, European and local mission stakeholders and on-site operational partners (Irenge et al. 2016; Sissoko et al. 2016; Sealy et al. 2016; Palich et al. 2016a, b)
Munich, Germany, 7–13 Feb, 2016	CLUELESS SNOWMAN	***EXERCISE*** B-LiFE (Civ/mil)	Training mission—joint international exercise of UCL–CTMA and Bundeswehr Institute of Microbiology in European Space Agency IAP–ARTES 20 B-LiFE project	External observers of the exercise validated the FL quality performance. The OFs and SOPs were compared between two FLs
Bologna, Italy, 12–15 Apr 2016	FOOD DEFENSE	***DEMO*** FP7-EDEN B-LiFE (Civ)	Validation and use of new technologies on site—in the new application of "Food Defense" as part of a large-scale CBRN exercise of FP7-EDEN project	External observers of the exercise validated the FL quality performance FL certification was performed by Forsvarets forskningsinstitutt (FFI, Norway)
Revinge, Sweden, 20–24 Apr 2017	MODEX[1] EU AMPs modules	***EXERCISE CERTIFICATION*** B-LiFE/B-FAST	Four-day exercise for the certification of B-LiFE as rapidly deployable, self-sufficient capacity within the framework of the EUCPM and the EERC (Voluntary Pool) as developed by the EUCPM (DG ECHO). Interoperability between AMP/AMP-S, deployable analytical laboratories, EUCPT/TAST, and LEMA	Three official international certifiers nominated by the EC (DG ECHO) assessed for self-sufficiency, interoperability, procedures [Reception and Departure Centre (RDC), Base of Operations (BoO); On-Site Operations Coordination Centre (OSOCC); Handover procedures; safety and security procedures], coordination, learning opportunity

Table 1 (continued)

Location and date	Exercise	Deployment type	Purpose	Means of verification
Bruges, Belgium, 24–27 May 2017	Mod4TTX[2] Table-top	***EXERCISE CERTIFICATION*** B-LiFE/B-FAST	Scenario testing the interoperability between medical (AMP/AMP-S), USAR teams, deployable analytical laboratories, EUCPT/TAST, and LEMA	As above for MODEX

AMPs Advance Medical post with (AMP-S with/AMP without surgery), *EUCPT* European Union Civil Protection Team, *USAR* Urban Search and Rescue, *TAST* Technical Assistance Support Team, *LEMA* Local Emergency Management Authority

the deployment, because the negotiations can last a few weeks. That is why, even if FL is a fast deployable laboratory, some missions require longer mission acceptance and planning phase; hence, frequency labels "weekly" mark certain OFs in Phase 1 and Phase 2.

- **Confidence** with possible values assigned as follows:
- 3—high confidence: all the necessary information for taking the decision is available,
- 2—medium: there are some information gaps, but it is possible to fill them and find out the necessary info or to guess,
- 1—uncertainty, lack of information on the problem at hand,
- 0—absence of information and impossibility to acquire it.

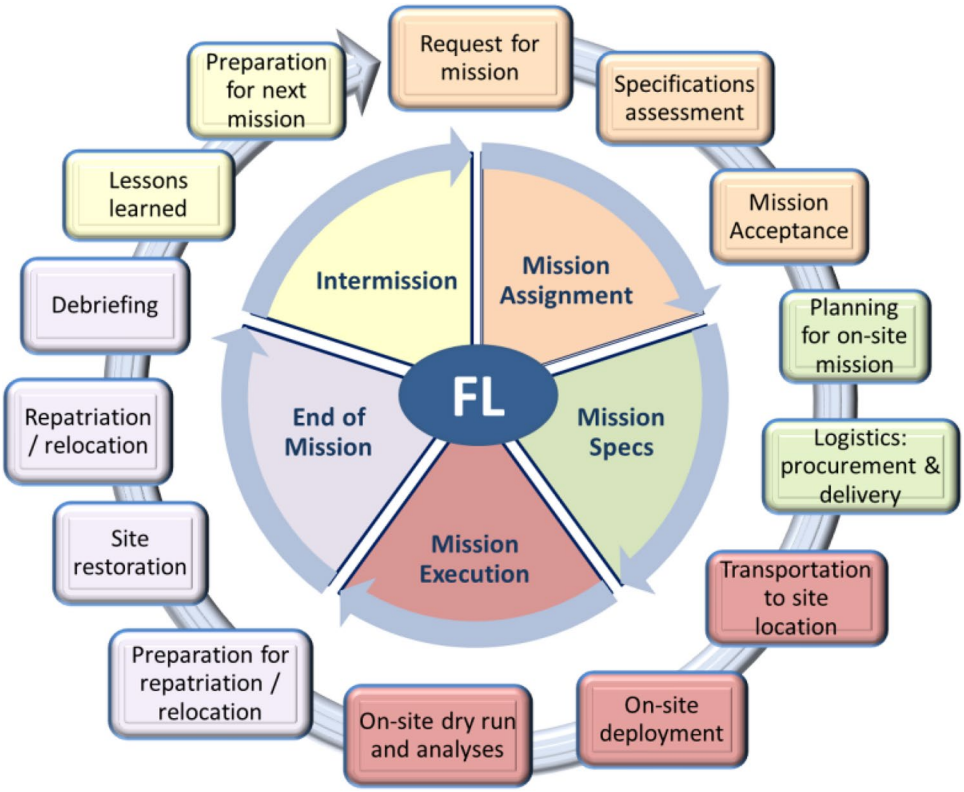
The confidence labels associated to every decision presented in Tables 1–6 in Supplementary material are a "typical" experience for the type of information required for each OF decision, collected from the previous FL missions. However, the confidence of decisions depends on the availability of information and thus can change from one deployment to another. If some information required for taking a decision during an OF implementation is not available at some point of time, but is obtained later, such situations can cause overlaps in OF implementation. Sometimes it is necessary to come back to previous decisions, correct, or update them according to new acquired information, which causes further impact on decisions taken afterwards (Comes et al. 2015). Parallel implementation, iterations, loops, comebacks, and corrections of the strategy take place frequently during missions.

It should be noted that we do not consider any decision in terms of being "right" or "wrong." Presuming that the decisions are taken by experienced competent staff based on multiple mission parameters and factors, all decisions are rather considered in terms of their impact on other decisions and on the mission as a whole.

This brings us to the representation of the FL mission cycle where the sequential phases are not strictly discrete, but to some extent overlap, because some OFs from neighbor phases are implemented in parallel (Fig. 2).

Looking into the peculiarities of the decision-making process in FL operational domain, we have to understand in detail how and when decisions are taken at every step, and on which factors they are based and what information is needed to take every decision. Tables 1–6 in Supplementary material present the full detailed description of every OF implemented by FL at each step and phase of the mission cycle, the decisions to be made in every OF and characteristics of every decision, and the information required for the correct decision-making.

Fig. 1 FL mission cycle



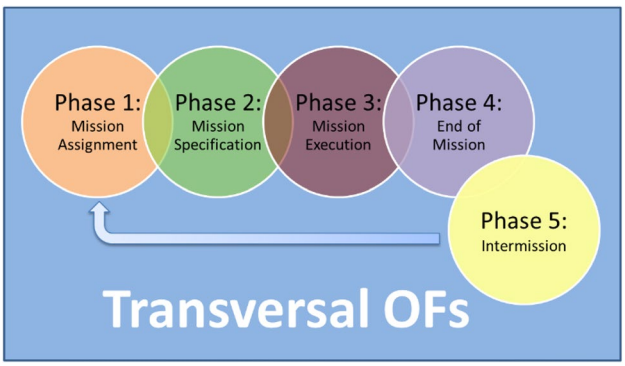


Fig. 2 Inter-connection between the phases and transversal operational functions within a FL mission cycle

Let us look in more detail at the processes taking place in every phase of the FL mission cycle.

Phase 1—Mission Assignment is the most important phase in terms of critical decisions. It starts with a request for mission addressed to the FL service manager, followed by the assessment of mission feasibility, mission parameters and specifications, especially the need for self-sufficiency and autonomy if no host nation support can be provided. The decisions about feasibility of the mission are taken based on thorough analysis of the information obtained from the stakeholders requesting the mission. This includes full detailed information about the current state of the situation and its potential evolution, such as the type of biological agent causing the health crisis, the geographic area affected, availability of preventive and/or curative strategies, type and number of population affected, the global and local political status in the region of question, the aim of the request, and the expected response of the authorities, possible host nation support.

The OFs corresponding to **Phase 1: MISSION ASSIGNMENT** are the following (see Table 1 in Supplementary material for detailed description of every OF):

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.

The mission is confirmed as soon as mission specifications are in line with FL capacity and available resources. All OFs in Phase 1 are decision nodes, and all the decisions taken during Phase 1 are highly critical decisions regarding the feasibility of the FL mission and, in case of positive answer, regarding the definition of the expected

FL activities and role, configuration, and interaction with other parties, logistics issues, and response planning.

The main go/no-go decision associated to the last OF in Phase 1 *Confirmation of Mission* is influenced by multiple factors; it is a consequence of *Phase 5—Intermission* assessment of the overall level of preparedness of FL to the next mission and the human and material resources which are a priori available. The go/no-go decision certainly has the highest criticality value, the largest scope influencing the whole process and involving all actors. This type of decision is taken once, being therefore a top-level decision. Such discrete variable depends, however, on many factors that may directly impact the process of decision-making and lead to a complete stop of the mission preparation at any step. This is why the value 2 is attributed to the degree of confidence of this decision. The "go" decision for the mission can be taken only when all the following requirements, needs, and constraints are fulfilled, i.e., the support of stakeholders is guaranteed, the budget is sufficient, and none of the sides has any obstacles or objections against the mission.

Phase 2—Mission Specifications usually starts even before the mission is confirmed. Some OFs from *Phase 2—Mission Specifications* are already implemented in parallel with *Phase 1—Mission Assignment* even though the main decision whether to embark on the mission or not has not yet been taken, i.e., there is a certain overlap in the implementation of Phase 1 and Phase 2.

The OFs corresponding to **Phase 2: MISSION SPECIFICATION** are the following (see Table 2 in Supplementary material for detailed description of every OF):

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.

The OFs of Phase 2 launched in parallel to Phase 1 are related to the checklist of tools, availability of tests and kits for analysis of specific biological agents as required by the new mission, because such estimations take time and a period of preparation. They are therefore started ahead of the deployment in order to ensure that the FL will be ready as soon as the main "go" decision is taken. After the most crucial decisions have been made in *Phase 1—Mission Assignment*, and if the existential "go" decision is taken, the decisions of *Phase 2—Mission Specifications* are all related to the practical and specific aspects of the mission preparation and detailed planning. The information for taking decisions at this phase includes a thorough analysis of the feasibility and practicalities of the mission, i.e., the geographical coordinates of the location on site, where exactly and how FL could 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 the list of hazardous materials) according to selected transportation means, what type and amount of material to take depending on mission specificity, objectives, duration, and intensity, and what location-specific formalities the staff must go through when preparing for the mission. The more detailed is the *Phase 2—Mission Specification*, the less unexpected problems the FL staff will face on site. Depending on these mission specifications, a specific training of members of the laboratory staff may be required at this phase. Let us illustrate the decision-making process for this *OF 2-1-7. Specific staff training* in *Step 2-1. Planning on-site deployment*. In this OF, the FL team members are briefed about the mission specifications and specific training is organized. Volunteers receive cultural and situational briefings and psychological support regarding the specificities of the mission. Based on the detailed information about the goals and parameters of the planned mission, defined in the preceding OFs of Phase 2 and in Phase 1, the following are determined: what knowledge and skills are required for the mission; if volunteer experts possessing the knowledge and skills are available; what kind of additional training the staff needs, e.g., training for certain equipment use, for biosafety level 3 or 4, etc.; who should provide such training; how long this training will take and how much it will cost. These decisions will have the following values: Scope—1, Criticality—2, Frequency—once, Confidence—3.

Phase 3—Mission Execution is the core of the FL mission cycle. 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. Except otherwise requested by the authorities, it is of note that the laboratory staff is not in charge of on-site sample collections, nor of transportation. If the deployment takes place according to the EU Civil Protection Mechanism, a registration to the local "Reception and Departure Centre" (RDC) opened by the EU Civil Protection Team, or the first capacity arriving on site, is made upon arrival.

The OFs corresponding to **Phase 3: MISSION EXECUTION** are the following (see Table 3 in Supplementary material for detailed description of every OF):

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. OF 3-2-9. Installation of sanitation area and toilets. OF 3-2-10. Setup 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.

Many OFs in Phase 3 are action nodes, subjected to the established SOPs, guidelines and best practices and site location for the deployment. The latter is decided in agreement with the EUCPT or its UN-counterpart United Nations Disaster Assessment and Coordination (UNDAC) in the On-Site Operation Coordination Center (OSOCC). 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. As soon as the laboratory is deployed, a briefing will be organized by the head of laboratory with the local beneficiaries of the laboratory activities (e.g., the medical staff of the field hospital, the local red cross, the local authorities, the EUCPT/UNDAC) in order to develop a common understanding of the mission, of the available analytical capability and of the best procedures regarding sample collection, transportation and reception in the laboratory, and traceability thereof. A substantial part of the decisions refers to security and safety of staff (security and safety plan) and materials, and to the practicalities of operations, e.g., turnover frequency and handover, 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 (Heckmann et al. 2015; Van Wassenhove et al. 2012), decisions associated to the precise *modus operandi* of pre-analytical, analytical and post-analytical steps according to mission specificities. This will be daily recorded and updated in a "Plan of Action" whereas contacts and meetings will be recorded in a Log Book. 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).

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.

Phase 4—End of Mission. The mission parameters, such as the mission objectives, complexity, and corresponding planned mission duration defined yet in Phase 1, can be reassessed and adjusted given the evolving situation in the field. After the planned mission duration at a given location is expired, it is possible to draw conclusions on the mission goals achieved so far. The evolution or worsening of the crisis may require the mission 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. In any case, Phase 4 often starts in parallel with OFs of Phase 3 related to the analytical and post-analytical steps where the everyday FL duty on the laboratory analysis is still ongoing, which stipulates overlap between Phase 3 and Phase 4.

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, and availability and condition of FL equipment and laboratory resources. There is also a possibility that mission needs to be continued at a different location. 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, according to good practices 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. In some cases, the handover of material to third parties (e.g., non-governmental organizations, health institutions from the host nation) may simplify this part of the mission.

The OFs corresponding to **Phase 4: END OF MISSION** are the following (see Table 4 in Supplementary material for detailed description of every OF):

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 is an important part of the mission cycle. It starts with a hot-wash debriefing carried out as quickly as possible to collect the first impressions on the achievement of pursued objectives. This is later followed by a more detailed analysis of all lessons learnt during the FL deployment. In order to translate the latter into practical measures for improvement, decisions are taken to identify what should be improved, why, when, at what costs, and by what means.

The OFs corresponding to **Phase 5: INTERMISSION** are the following (see Table 5 in Supplementary material for detailed description of every OF):

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.

The practical use of 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 most 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 for new deployment 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 Phase 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 experienced stressful or very difficult conditions. This highlights the importance of a clear and continuously updated "safety and security plan" during each mission to mitigate this risk and a post-deployment psychological assistance in case of stressful missions with traumatic consequences. 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.

3.1 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: *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* (see Table 6 in Supplementary material).

It is noteworthy that the decisions associated to transversal OFs are all of the highest criticality as they have a high impact on other decisions in the mission cycle. For example, *OF 0-2. Supply chain* presumes regular contact with technological, tool, and reagent providers to ensure access to reagents, specific spare parts, or backup equipment. Based on the characteristics of the material to be provided and deployed (e.g., volume, weight, speed, electricity consumption, biosafety, maintenance) and characteristics of reagents to be used on the field (e.g., costs/purchase, storage/shelf-life, and conditions; generic requirement in terms of easiness and speed of resupply considering also the bottleneck of customs clearance), the decisions must be taken in terms of choice of reagents and materials' manufacturers, and the right balance has to be found between FL needs versus purchase conditions, maintenance and operating costs, shelf-life and conditions of storage, and use of specific reagents.

4 Discussion

The lessons learnt from past FL deployments proved that, even if every mission is unique regarding goals and context, the mission cycle consisting of OFs divided in five chronological phases and transversal functions appears to remain valid irrespective of the type of mission. While focusing on the decision support to the management of a deployable analytical capacity, OFs and their chronological phases could be indeed, for a large part, generic, hence applicable to many pre-committed modules in the EERC. The current work presents the first attempt to systematically describe, chronologically organize, identify, and structure the information needs, decisions, and their properties processed by a FL manager and staff during the successive (though partially overlapping) phases of the FL mission cycle. The process described here is being used as support of decision makers regarding FL staff training, contacts and discussions with stakeholders, and preparation for next FL missions. Looking into the peculiarities of the decision-making process in FL operational domain, we have to understand in detail how and when decisions are taken, on which factors they are based and what may interfere with them and request a prompt adaptation.

Considering that the blatant lack of deployable laboratory capacity during the last Ebola outbreak was not due to the lack of laboratory operators but to the complexity of such deployment and the very specific nature of this type of mission, this work focuses specifically on a fully autonomous deployment. In this case, 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. 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. In contrast, military mobile laboratories or field hospitals (Elsharkawi et al. 2010) benefit from a dedicated planning and preparedness coupled with efficient military logistics. The same applies to the deployments carried out by major international non-governmental organizations like Doctors Without Borders (MSF, Médecins Sans Frontières), since their centralized organizations and financial power confer a total autonomy of decision regarding deployments and support to missions. In that respect, their working processes and organization are similar to these used by militaries which enable them to deploy their capacities at any time and any location in the world with an appropriate logistic support.

Anyhow, regardless of the type of mission, preparedness is crucial for the successful execution of any mission implying to deploy a laboratory capacity inside or outside the EU. For each mission, situational awareness implies a detailed, strict, and structured process of data collection, analysis, and systematization requiring iterative efforts to refine the results before, during, and after every mission.

5 Conclusions and perspectives

The current process, as described here, is now considered robust and validated through a series of FL missions and exercises of different types. Accordingly, it has been used as such since early 2016 with only minor adaptations. The certification procedure that was carried out by B-LiFE/B-FAST in April (MODEX) and May (Table-Top ModTTX) 2017 according to the EERC standards has enabled us for the first time to confront this process to an external assessment of DG ECHO-appointed international certifiers. Based on this certification, we believe that the current results aggregate and consolidate the expertise and knowledge progressively acquired by the FL staff, its external operational partners, and mission's stakeholders. It should therefore be useful for other laboratory operators wishing to develop a deployable version of a fixed laboratory, as well as for anyone confronted to an acute crisis and confronted with the need of a quick deployment.

This work presents the first publication of the full range of the operational functions of a deployable laboratory with detailed description of every function performed by the FL staff at every step in each phase of the laboratory mission cycle. The described categories of information needed for efficient decision-making in every OF allow for better preparedness for every next FL mission. Precise knowledge of the needs help to easily identify missing information and to look for the ways to obtain it. The

structured approach to description of the procedures and the information flow facilitate information exchange and comparison of capacity with other similar deployable capacities, including laboratories and field hospitals.

Ongoing research is now dedicated to the next step, which is computational modeling of the decision-making process based on the identified information flow, decisions of various scopes, criticality and confidence taken at every step, tracking the decision-making paths, the impact of every new decision on the current situation, and modeling the possible alternatives when taking decisions. The process of accommodation of new decisions in the global situational context should account for the complexity of the FL domain, heterogeneity of the information, parameters and factors of the decisions to be taken, reflecting flexibility, iterations, and possibilities of changing previous decisions or parts of them.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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