European Modular Field Hospital 2017-2018

Electronic Patient Record & Technology Concepts

This project is co-funded by the European Union

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1 Introductory remarks

The European Modular Field Hospital (EUMFH) project aims to explore the possibilities of establishing a European Level 3 Emergency Medical Team (EMT) (referral hospital under the new WHO classification) by using a joint effort from different European Member States and to improve the medical capacity of the Union Civil Protection Mechanism (UCPM). A special Consortium has been set up by the European Commission to answer this challenge and to design this referral hospital on a multinational base, deployable on behalf of the Union Mechanism (UCPM) in case of events that require full medical capacity.

This Consortium is consisting of: the Italian Civil Protection Department, the Belgian Ministry of Health, the Danish Emergency Management Agency, the Estonian Health Board, the French General Directorate for Civil Protection and Crisis Management, the Romanian Ministry of Internal Affairs, the Johanniter, the University of Leipzig, the Association of Slovak Samaritans; and has the permanent support of: the Greek National Centre of Emergency Care, the World Health Organisation and Handicap International.

2 Crossreferences to other pillars

This document contains all EUMFH concepts related to information and communication or biomedical technologies. Crossreferences exist to the other pillars:

Chapter	Pillar
EUMFH Electronic Patient Record System	Healthcare
EUMFH Information and communication technology (ICT) concept	Logistics
EUMFH Biomedical technology (BMT) concept	Healthcare
EUMFH ICT-platform for education and training	Training
Teaching schedules	Training

3 EUMFH Electronic Patient Record (EPR) System concept

VERSION 9th February 2018

The electronic patient record system will be distributed under the name ***EOS – Emergency Medical Team Operating System.***

FIGURE 1: EOS LOGO

This project is co-funded by the European Union

Acknowledgements

Parts of the EPR concept are based on the IDF field hospital system, the work “Disaster and Humanitarian Emergency Response” by Gerlant van Berlaer, and the WHO Minimum Data Set specification.

3.1 Electronic Patient Record System – overview

In this section, the Electronic Patient Record (EPR) system is briefly described, including its objectives and major use cases, an analysis of the various user groups, the design philosophy, and the related legal considerations.

3.1.1 Objectives of the EPR system

The Electronic Patient Record system serves as the central component for the clinical information management of the EUMFH. Its objectives are the handling of patient data and the management of clinical pathways. Thus, it controls orders, patient transportation, and assists the documentation of examinations, diagnostic and therapeutic procedures, and patient care. It is the major point of access to patient data for the medical users. In summary, the EPR fulfills three tasks for clinicians:

- Management of patient data
- Documentation of work steps
- Management of orders and patient flow

At the same time, the EPR is an important data repository that will contain valuable information of clinical pathways and utilization of resources. From the perspective of the EUMFH field command, the EPR system serves as a data repository and thus is a key factor for disaster intelligence. Strategic decisions might be based on a statistical analysis of these recorded data. Access to these data will be included in the EPR system. As a management back end, the EPR system will fulfill the following objectives:

- Provision of a live overview of resources, allocation, and patient flows
- Generation of reports to the EUMFH headquarter and external stakeholders

The EUMFH concept supports a continuous improvement of the field hospital by adaptation of existing modules and the development of further modules. To that end, the electronically acquired data could be used as a basis for Research and Development. Thus, an export of the repositories may be facilitated. For these purposes, however, anonymization of the patients and staff individuals is required to ensure a proper privacy protection.

3.1.2 User groups and stakeholders

The involvement of system users, patients, hospital management and other relevant stakeholders is an essential part of the development and successful implementation of an EPR for EMTs. Thereby, the identification, analysis, definition and communication of system requirements and the context of use, in which the EPR will operate, define the goals and capabilities of the EPR system.

The main user group will be the **medical staff** of an EMT. These are health professionals, including physicians, nurses, radiology and laboratory technicians, paramedics, etc., who provide any kind of health care to patients in the field hospital. The medical staff will document diagnosis and treatment procedures. Based on this information a patient-individual treatment report will be generated.

As a result, the **patient** will receive a well-documented diagnostic and therapeutic treatment report, which includes an officially signed and printed discharge summery as well as their diagnostic imaging and laboratory results.

Another user group of the EPR system will be the particular **department management** units. The responsible staff will use the information stored in the EPR to manage the department and make informed decisions regarding organisational processes and resource management. In addition, the cooperation and communication with other **field hospital departments** is a key requirement. The EPR system interfaces should enable the exchange of patient data, resources and supplies as well as personnel information.

The **hospital command** will use the gathered information for analysis and informed decision-making in order to manage to whole hospital and made an efficient utilisation of medical resources based on real-time data. In addition, the Field **hospital home command** is a major user group of the EPR system. The command receives patient treatment statistics and other information that report the impact and usage of the field hospital to the financing bodies.

Other stakeholders will be the **patient family**, who will utilise a part of the EPR data to find missing family members in the field hospital. Also, the local **government** is a potential user group of the EPR system. Local authorities may use the stored patient data and treatment statistics as well as patient individual treatment records for disaster analysis or long-term storage in the local health system. The WHO is also interested in the analysis of anonymised patient treatment statistics for disaster statistics and management. The transfer of patient data is liable to strict data privacy and security terms.

Furthermore, **third party responder**, e.g. another field hospital, could receive patient record information of transferred patients and patient demographic information, e.g. to support family search activities.

3.1.3 Design Philosophy

The EPR system will manage diagnostic and treatment information for each patient. Most of the acquired data will be linked to a case instead of directly linking the information to the patient. This ensures a clear distinction of patient care procedures that root in different clinical indications. The EPR system design should emphasize a software-based assistance of clinical workflows by means of automated electronic data acquisition and tailored user interfaces. Across cases, the EPR should be designed to steer clinical pathways and to effectively manage the available resources.

A comprehensive user and rights management is essential to the EPR system. Critical functions, for instance patient data, order management, or reporting need to be protected from unauthorized access. Privacy protected, access control, and data protection must be anchored deeply in the design of the software. The EPR system will rely on a common role concept, in which each user is assigned one or more roles. And these roles are associated with certain access rights. For data protection to be effective, a user authentication concept is required that ensures a reliable identification of the individual user with a reasonable overhead for the user.

We expect multinational teams, which may be reinforced by local assistant staff, to operate the EUMFH. Thus, the localization of the EPR user interface – the selection of an appropriate language for the displayed texts and controls - needs to be flexible and include at least English. For a concrete implementation of the EUMFH, a user interface language that is consistent with those of the medical devices, may be chosen at deployment.

The user interface of the EPR system needs to be accessible from various client devices, such as stationary computers, laptops, tables, and other handheld devices. The usability of the EPR system is essential for a safe and effective operation of the software by the EUMFH staff members. The usability shall be considered early in the design and development of the software. Finally, user tests and usability tests that include the various client devices need to be performed.

3.1.4 Legal considerations

The management of patient data and patient treatment workflows is the major objective of the EPR system. In this context, it stores and displays patient data that is relevant for clinical decisions. The system needs to be classified, developed, and accessed according to the risk classification of the European Medical Device Directive (MDD). Furthermore, the software must have a CE mark to be applicable.

For the software system, a comprehensive risk analysis must be performed according to the MDD. The risks shall be minimized through risk control measures, which are implemented in the EPR system. To ensure a safe and reliable operation, a set of tests, including component tests, integration tests, system tests, and user tests must be implemented.

Besides the MDD and the associated regulations, privacy protection, access control, data protection and data integrity must be explicitly considered during the whole software life-cycle.

Depending on the national regulations of the country, in which the EUMFH is deployed, additional requirements and legal issues may arise.

3.2 EPR System Design

The following subsections summarize the design of the EPR system for the EUMFH.

3.2.1 System Architecture

The system should be based on a client-server architecture. The EPR system will be a web-based application, which is accessed through a standard web browser installed on a client device. The web-based approach enables a distributed server backend that can be managed across medical modules using the ICT infrastructure of the EUMFH.

The backend software will be implemented on redundant servers and will manage the orchestration and synchronization across units and departments. Data repositories provide persistent storage capabilities and fast access. There, the data of various types is represented in a syntactically and semantically structured manner. The data repositories are as well implemented redundant and may have capabilities for external backups through an uplink provided by the ICT network.

To facilitate the automation of data acquisition, various data interfaces to medical devices and IT systems need to be implemented. These data interfaces will gather relevant information and automatically store them to the appropriate data repository.

Finally, a browser-based user interface is provided. The main advantages of the web-based application are the ability to realize data access independent from the client device and a strict separation of data representation in storage and data presentation in the user interface.

3.2.2 Data interfaces

The EPR is designed as a digital system to reduce the manual data input and documentation workload that must be handled by the medical staff during the operation of the EUMFH. These input tasks shall be automated wherever possible for efficient, digitally assisted workflows in daily routine. However, the system must allow manual input for any relevant data as a fallback in case of a failure of the required networking, especially the network within the medical module (tertiary network, see ICT concept for details).

There are three types of input modalities that need to be considered: electronic interfaces to medical devices and IT systems and input modalities related to physical objects, and patient identity verification.

3.2.2.1 Medical device data

Following the concept of a comprehensive information and communication technology infrastructure for the EUMFH, medical devices and IT systems will share their data via network, if applicable. The EPR system and its comprehensive data repository is the primary consumer of the provided data. An automated documentation of measurements, data streams, parameters, and notifications will be realized based on established standards, such as IEEE Point-of-Care (PoC), IEEE Service-oriented Device Connectivity (SDC), HL7v2, and HL7 FHIR. The integration of the biomedical technology with the EPR system will significantly reduce the manual workload for the medical staff.

3.2.2.2 Input related to physical objects

Different types of data must be gathered that are related to physical objects, for instance blood samples, consumables, or printed third-party reports of previously performed patient care. Samples and virtually any resource circulating in the EUMFH should be marked with a machine-readable tag. For that purpose, bar codes and RFID tags seem to be suitable and the corresponding reader hardware can be attached to the system, which allows to quickly identify the objects and electronically track them. By means of that, acquired data can automatically be interlinked, for instance the results of a blood sample analysis can be related to a case without manual data entry.

Any printed third-party document should be available in the EPR system and the digital data repositories. Thus, document scanners need to be considered as another input modality attached to the EPR system. To further assist the documentation tasks, cameras and microphones are considered additional data interfaces that the EPR should support.

To compensate possible network failures, paper-based forms for any relevant data allow manual entry. When the network is operational again, scanner and importing tools based on Optical Character Recognition (OCR) can be used to easily digitize the previously filled paper-based forms. An example of such a paper-based form is illustrated in Figure 3.

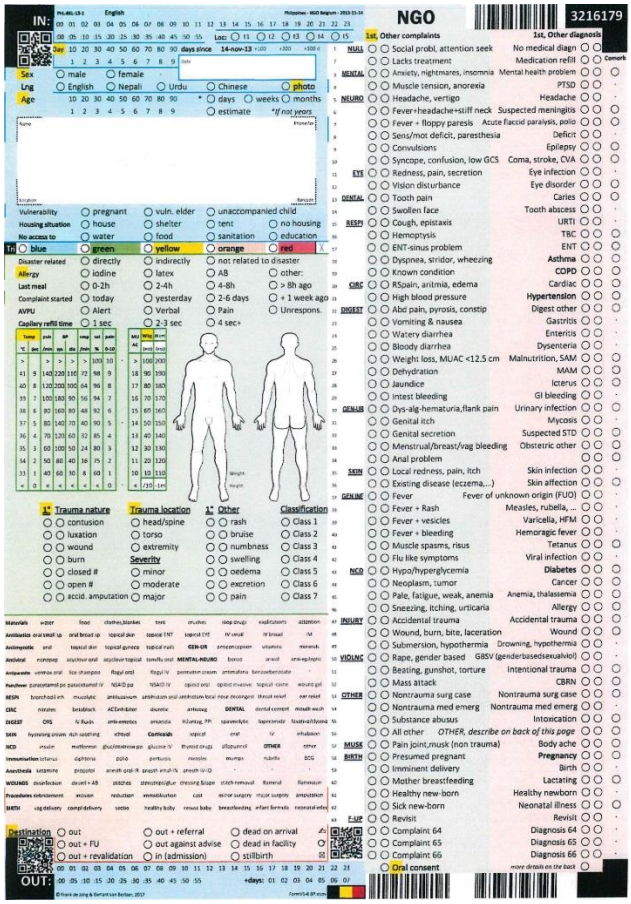


FIGURE 2: EXAMPLE OF A PAPER-BASED ENTRY FORM[1].

3.2.2.3 Patient identity verification

The patient's identity needs to be verified multiple times during the hospital stay. The verification process must be reliable and fast. Hence, a bracelet with a machine-readable tag (RFID or similar) and a printed human-readable code is proposed. The bracelet is attached to the patient at the initial admission and electronically assigned to an individual case id. And a case is always associated with exactly one patient. At the discharge, the bracelet is removed and destroyed to avoid unintended reuse of the codes.

At each medical module, the identity of the patient can then be quickly verified with a reader hardware data interface. The EPR system will use the machine-readable code to automatically display the patient data summary, including at least the patient name, gender, date of birth and the photograph to enable

[1] Berlaer, Gerlant van. "DISASTER AND HUMANITARIAN EMERGENCY RESPONSE." PhD Thesis, Vrije Universiteit Brussel, 2017.

a fast and reliable identification by the user. Additionally, the information can be used to automatically track patients and reconstruct clinical pathways. By means of that, patients can be electronically recognized, and resource allocation, responsibilities, and orders can be managed. The human-readable code on the bracelet is used as a fallback in case of interface device failures or defect bracelets. The EPR must provide such a fallback data interface with manual code entry.

3.2.2.4 Personnel Identity verification

To protect critical patient and treatment data, a user authentication concept needs to be implemented that supports distinct roles (physician, nurse, technician, etc.) and perspectives (administration, surgery, etc.). Besides these conventional authentication concepts, the EPR facilitates a quick but safe data entry in emergency situations when there is no time for logging in. For that, personal identification keys and hand crease scanners can be utilized. Instead of entering a login and password, data can be entered without logging in. Instead, a short but unambiguous key is required after data input that is linked to a registered user and will validate the data input. Alternatively, a hand crease scanner can be used to identify a user and validate the data input.

3.2.3 Data Repositories

The electronic storage of data in repositories is an essential part of the EPR system design. The system's architecture contains four repositories, where each repository handles a specific type of data.

3.2.3.1 Document repository

The document repository is dedicated to third-party and inhouse documents. The documents will be related to a case, if applicable. A machine-readable format, for instance OASIS Open Document Format for Office Applications (ODF, ISO/IEC 26300) or PDF, is preferred to enable text-based searches. However, the storage of scanned documents as images must be supported. Optionally, an annotation based on Optical Character Recognition (OCR) can be attached for text-based searches. For an efficient storage and responsive performance, specialized database software, for instance IBM Notes or CouchDB, can be used at the back end.

3.2.3.2 Media repository

The media repository stores all media files that may be generated or managed by the EPR system. This includes photographs, recorded audio streams, and videos. Images and streams from medical imaging

modalities, especially X-ray images and ultrasound recordings, are only referenced. The actual management of the medical image data is performed by a dedicated Picture Archiving and Communication System (PACS) according to the DICOM standard (see BMT and ICT concepts for details). For an efficient implementation, the system might use the same back end as for the document repository, despite the logical separation.

3.2.3.3 Core data repository

However, most of the data related to the EPR will be managed by the core data repository. The implementation will be based on a relational database that supports the well-established Structured Query Language (SQL) database language. The internal data structuring is implemented in the main database schema. Database entries must be related to a case if applicable. The EPR system must support multiple cases per patient. This applies if a patient returns to the EUMFH due to another clinical indication than the one that caused the initial admission.

For the clinical functions of the EPR system, core data repository must support at least the following data types:

- Textual data, e.g. patient name
- Categorial data, e.g. patient sex
- Dates, e.g. patient birthdate
- Measurement (including unit, timestamp, providing device)
- References to tags of physical objects
- References to other repositories (Document repository, media repository, PACS)

The repository should provide a traceability for most of the database entries. Thus, a protocol of changes, including at least the requesting individual or system, a time stamp and the changed entry (date), will be generated automatically. This is sometimes referred to as an audit log and allows to retrace the history of relevant repository entries.

3.2.3.4 Backend data repository

The backend data repository will also store the configuration and management data that are required for the administration, maintenance, and operation of the EPR backend. This includes for instance the identification of individuals, their assigned roles and access rights, or component configuration data.

3.2.4 User interface concept

The EPR is the main access point to patient data for the medical staff of the EUMFH. The core functions, the user authentication concept, and the core design principle of configurable views onto the managed data are described in the following subsections.

3.2.4.1 Core functions and user AUTHENTICATION

The user interface of the EPR system will provide a concise set of core functions. These mainly relate to essential navigation within the EPR system, including a home button, quick access to core information, and forward-backward navigation. To enable department-wide and hospital-wide notifications in case of emergencies, such as fire, acute natural disaster situations, or security threats, the EPR system offers a message and alert service.

The EPR user interface will support a common login feature based on a password or a numerical pin code. The passwords will be encrypted using for instance a client-side TwoFish - a symmetric key block cipher - to protect the system and the data from unauthorized access. The access to each view, function, and service of the EPR system is controlled through the rights management of the user role concept. It must be ensured that the individual and the associated permissions are checked by the system for each of the potentially restricted accesses. This is especially relevant for patient data access, order management, and reporting. The client devices, mainly docked laptops and mobile devices, are often physically accessible for and used by different individuals. In the current state of the concept, an authentication of the user will be required for each step. Always requesting a password or pin entry will not be suitable in those cases. Hence, an authentication by possession is preferred. To that end, each member of the EUMFH staff will have a personalized, digitally recognizable bracelet (RFID or similar) analogously to the patient identification tags. In combination with the password entry at login, usually at the start of shift, each user's identity is confirmed with a two-factor authentication (knowledge and possession), while the manual overhead is reasonable.

3.2.4.2 Configurable views

The optimal user interface in terms of data access and data modification highly depends on the disaster case, the available medical modules, and on the intended workflows during the operation of the EUMFH. Hence, the adaptability of the user interface, including the views onto the patient data, is a

crucial pre-requisite for the successful implementation of an EPR for a multi-purpose, modular field hospital.

The EPR system will account for the required adaptability by means of configurable views. The user interface mainly consists of tabs (views), which can be configured to provide data representations and input capabilities suitable for specified clinical functions. The concept of configurable views is schematically illustrated in Figure 3.

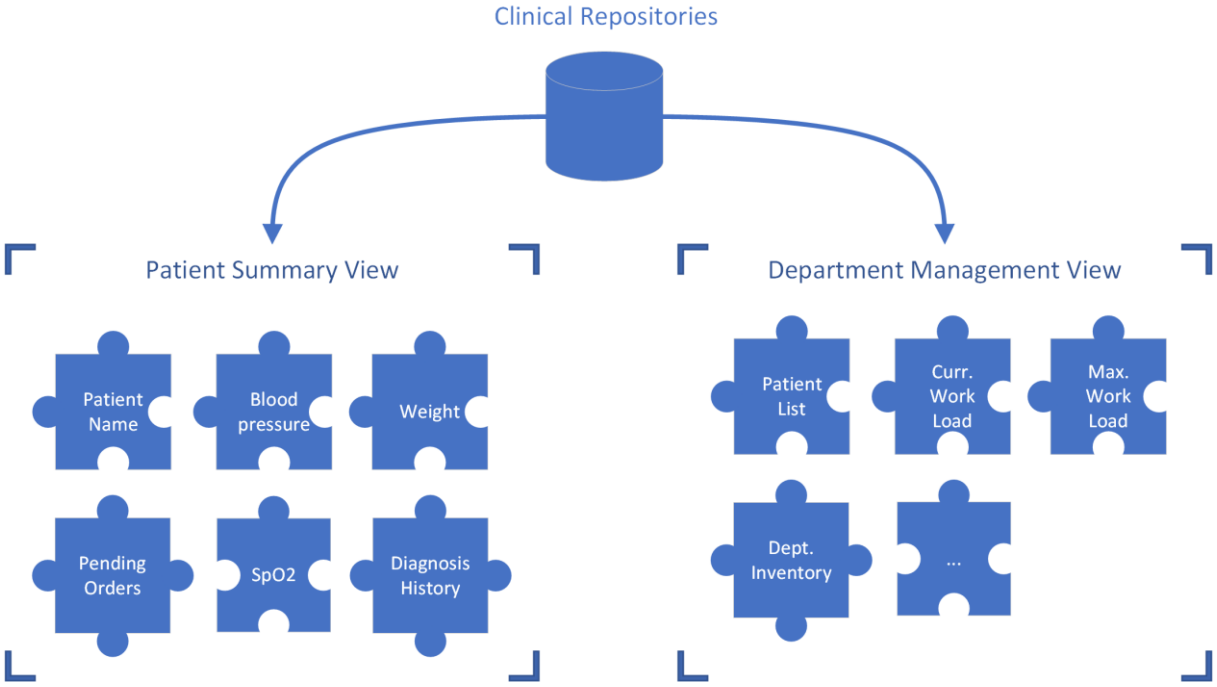


FIGURE 3: SIMPLIFIED EXAMPLES FOR THE CONFIGURATION OF DIFFERENT VIEWS BY ASSEMBLING DATA FIELDS FROM THE REPOSITORIES

While the user interfaces may differ across multiple implementations of the EUMFH, the underlying data representation and structuring within the repository remains identical. By means of that, the EPR system gains great flexibility in the user access to the data with little to no changes in the back-end software.

It is recommended to align the views along clinical functions, which are either represented by medical modules and departments, for instance a radiology department and view, or tasks, such as physical examination or nursing.

3.2.5 Paper-based backup system

In case of complete camp blackout or energy restrictions a paper-based patient record system will support the data acquisition task. The system allows a continuity of documentation during the blackout

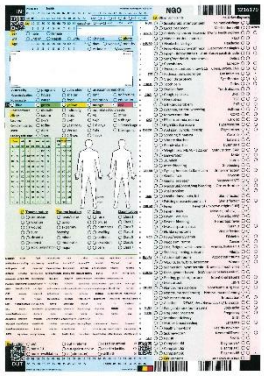


FIGURE 4: PAPER-BASED BACKUP RECORD [VAN BERLAER 2017]

time and a fast digitizing of the paper records after reestablished power supply.

This project is co-funded by the European Union

3.3 User interaction and data views

In this section, an incarnation of the configurable views of the EPR system is proposed. An example of an overall structure and selected views are described to illustrate a potential user interface for the EPR system. **The concrete specifications depend on the disaster case and the configuration of the EUMFH instance and must be continuously refined in close cooperation with the medical and technical users.**

The following subsections provide descriptions of views to structure the user interface of the EPR system. The views are divided into three major categories, according to the layered organizational structure of the EUMFH.

3.3.1 Case-related Views for medical modules

Admission vieW – Every new patient entering the field hospital will be added to the EPR. During the admission procedure, the information listed in the table below should be acquired. In the case of non-responding patients, some fields may be omitted. To allow identification even in case of communication problems or unconsciousness, non-verbal information about the patient should also be acquired (photograph of patient and/or identification documents or recognizable belongings). This information is also relevant for the Patient Search Station.

Entry	Description	Necessity Acquisition type
Patient id	Unique patient identification, generated by the system, associated with an RFID tag as bracelet on patient	Mandatory, Automatic
Case id	Unique identification of the case, generated by the system and associated with a patient id	Mandatory, Automatic
Patient name	Patient name may be omitted if unknown, may be added later for unconscious patients	Optional, Manual Text
Date of birth / age	Date of birth, age, and an estimation should be supported	Mandatory, Manual Text
Gender	Male, Female, and Unknown shall be supported	Mandatory, Manual Dropdown

Pregnancy	For female patients, this should be recorded. Supported values are Yes, No, and Unknown	Optional, Manual Dropdown
Patient photo	Photograph taken with the camera of the client device, used for Patient Search Station	Mandatory, Manual Camera
Voice recording of patient name	Recorded via microphone of the client device, used for patient identification and Patient Search Station	Optional, Manual Microphone
Accompanying persons	Name, and contact information should be documented	Optional, Manual Text areas
Relation to disaster	Directly, Indirectly, and Not-related shall be supported	Mandatory, Manual Dropdown
Protection	Vulnerable child, vulnerable adult, Sexual and Gender Based Violence (SGBV), Violence (non-SGBV), and Other shall be supported	Mandatory, Manual Dropdown
Evacuation readiness	Initial classification into three groups (Ready, Limited, Not ready)	Mandatory, Manual Dropdown
Evacuation priority level	Priority levels to be specified yet	Mandatory, Manual Dropdown

Physical examination view – The view should represent the results of a physical examination, which is usually performed after the admission. An illustrative representation of the human body is displayed, where the traumata can be marked at the various parts of the body. Every marking of an injury opens a text input to comment or provide further information. Instead of providing a complete – and thus very complex – list of ICD-10 diagnoses, a reduced list with most common diagnoses is provided. The complete list can be toggled on demand by the user. Alternatively, a search field with autocomplete functionality for ICD-10 diagnoses may be used for diagnosis input. For each ICD-10 diagnosis a standard operating procedure (SOP) can be associated, to give medical personnel advice on how to react to specific cases. In addition, photographs can be taken and linked to the trauma to support the documentation. Besides traumas, infectious diseases are frequent. Injuries and diseases may be classified according to the following example scheme. Multiple selections must be supported.

Classification of trauma	Classification of infectious disease
Major head injury Major spine injury Major torso injury Major extremity injury Moderate injury Minor injury	Acute respiratory infection Acute watery diarrhea Acute bloody diarrhea Measles suspected Meningitis suspected Tetanus suspected Acute flaccid paralysis Acute haemorrhagig fewer Fewer of unknown origin

The view will also include anamnesis information, which are acquired by questions to the patient or to the accompanying persons. These data must be optional in case of unconscious non-accompanied patients.

Entry	Description	Necessity Acquisition type
Known allergies	Especially allergies to drugs, to food ingrediencies, and materials, e.g. latex should be documented, a concise list of allergies can be provided for checking	Optional, Manual Checkboxes and text
Current medication	Regularly applied drugs should be documented including the (daily) dose	Optional, Manual Text
Known infectious diseases	Potentially infectious diseases should be documented, a concise list of probable diseases can be provided for fast, structured checking	Optional, Manual Checkboxes and text
Known pre-existing conditions	Any relevant known conditions of the patient should be documented	Optional, Manual Text

The view should also provide quick access to a function that allows to attach documents to the patient record, such as medical reports from other clinics or general practitioners.

Patient summary view – The patient summary will provide a brief overview of the currently selected patient. For a reliable verification of the patient's identity, patient name, gender, date of birth and a photograph shall be displayed. Additionally, relevant information is the current status, the current location, yet unserved orders.

The view may serve as a starting point to explore the available patient data. Thus, it will provide links to more specific views on the patient-related and case-related data. These may include the following specific views.

A summary of the care history with

- Diagnoses and performed procedures on a time line
- Previous cases associated with the patient
- Links to existing reports
- Documents from external care providers

A vital sign view with

- Diagrams over time of
    - Body temperature (fever chart)
    - Basic vital signs (Blood pressure, Heart rate, O_2 saturation)
- Trend information and limit alarms
- Automated classification of risk of infectious disease
- Mask for manual input of measurements

An imaging and media view with

- Sortable list of available medical images with modality and date of acquisition
- Links to the datasets in the PACS system
- Sortable list of radiological reports
- Thumbnail gallery of further images and videos
- Links to additional media files

A laboratory summary view with

- Basis classifications and major analysis results
- A summary of the latest laboratory report

A comprehensive set of such sub-views is designed to ease the structured exploration of patient data and might be especially useful for first patient-physician contact, telemedicine consultations, local medical meetings, and medical rounds.

3.3.2 Procedure-related views for medical modules

Emergency view – The emergency view is designed to document any emergency procedures that have been performed for a case. Due to the nature of emergency cases, we expect the relevant information to be documented afterwards. Thus, the patient identification might be performed when a stabilization of the patient was achieved. The following information entities are proposed:

Entry	Description	Necessity Acquisition type
Type of emergency	Classification of the type of emergency, a brief set needs to be specified	Mandatory, Manual Dropdown
Case id	Unique identification of the case	Mandatory, Semiauto. Patient bracelet
Reanimation	Information on type of reanimation measure and time span in seconds	Optional, Manual Dropdown and clock
Artificial respiration	Information on type of reanimation measure and time span	Optional, Manual Dropdown and clock
Estimated blood loss	Estimated blood loss in millilitres	Optional, Manual Numeric
Blood substitution	Information on type of substitution and volume in millilitres	Optional, Manual Dropdown, numeric
Haemostasis	Information on type of haemostasis measures	Optional, Manual Dropdown
Drainage	Placed drainages	Optional, Manual Checkboxes
Wound care	Type of wound care	Optional, Manual Dropdown/Checkboxes
Applied drugs	Any applied drugs should be documented with a dose	Optional, Manual, Text
Other measures	Any other emergency measures should be documented	Optional, Manual, Text
Follow-up instructions	Any additional follow-up instructions should be documented	Optional, Manual Text

Laboratory view – The view presents a summary of the data from the laboratory information system (LIS) and the associated reports. The examinations should be sorted according to the date and the type

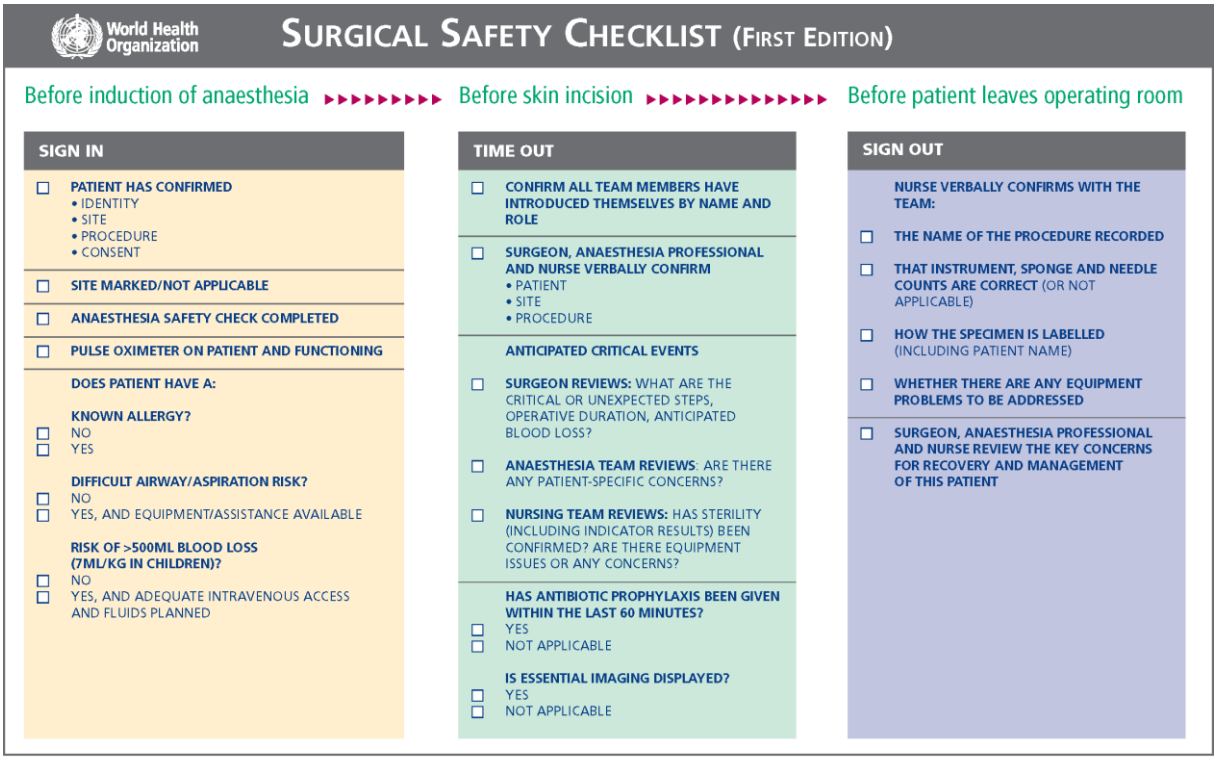
of examination. If the network is available, the data and reports should be automatically imported from the LIS. As a fallback a manual input function should also be provided. For manual input, special templates for diagnosis or laboratory examination based on the current region and the incident should be provided.

Department-specific views – A set of views tailored to the requirements of medical modules and departments, for instance Intensive Care Unit, Radiology, Gynecology, Pediatric, and Orthopedics can be specified. These mainly focus on the documentation of performed examinations and procedures. But they may include the implementation of views for an ICU Record, or a Birth record. The specialization of these views may simplify the user interaction by means of department-specific pre-selections and subsets for dropdowns.

OR reporting view – The reporting view for an operating room will list the relevant patient-related and case-related data in a concise visualization. This will include at least:

- Patient identification
- Planned procedure (ICPM codes and human readable labels)
- Planned team members (Lead surgeon, anesthesiologist, Assistant, Scrub nurse, circulator)
- Known allergies, and potential risk factors

The view will also include the WHO Surgical Safety Checklist, which should be completed prior to the intervention. Additionally, buttons and manual entry elements for cut-suture times will be provided for dynamic OR scheduling and documentation.



World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

☐ **PATIENT HAS CONFIRMED**
- IDENTITY
- SITE
- PROCEDURE
- CONSENT

☐ **SITE MARKED/NOT APPLICABLE**

☐ **ANAESTHESIA SAFETY CHECK COMPLETED**

☐ **PULSE OXIMETER ON PATIENT AND FUNCTIONING**

DOES PATIENT HAVE A:

KNOWN ALLERGY?
☐ NO
☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
☐ NO
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
☐ NO
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

☐ **CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE**

☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM**
- PATIENT
- SITE
- PROCEDURE

ANTICIPATED CRITICAL EVENTS

☐ **SURGEON REVIEWS:** WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?

☐ **ANAESTHESIA TEAM REVIEWS**: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?

☐ **NURSING TEAM REVIEWS:** HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
☐ YES
☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
☐ YES
☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

☐ **THE NAME OF THE PROCEDURE RECORDED**

☐ **THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT** (OR NOT APPLICABLE)

☐ **HOW THE SPECIMEN IS LABELLED** (INCLUDING PATIENT NAME)

☐ **WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED**

☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT**

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

FIGURE 5: WHO PROPOSAL FOR A SURGICAL SAFETY CHECKLIST[2]

Postoperatively, the OR report can be entered in a semi-structured template, which also includes conducted procedures as ICPM codes relevant for billing. With a digital signature of the lead surgeon, it is stored together with automatically recorded device data in the EPR data repository. Eventually generated intraoperative images from X-ray and ultrasound as well as optional captures of other video sources are displayed and will be stored to the PACS system after manual selection in the OR reporting view. Furthermore, automatically recorded anesthesia data and manually documented applications of medications are stored in a concise anesthesia report. Depending on the complexity of the OR reporting view, this may be subdivided into several views.

Nursing view – Nursing activities for inpatient cases must be documented. The view should be designed primarily to fasten the nursing documentation. The view provides a set of buttons, which describe frequently performed tasks, such as patient repositioning, change of bandages, or application of medication. The nursing staff documents the completion of a task by clicking the corresponding button. The performing individual, the related patient, the type of task, and the completion time are

[2] http://www.who.int/patientsafety/safesurgery/ss_checklist/en/

documented in the data repository. Additionally, the view may provide care instructions and a list of recently completed nursing tasks.

Some of the nursing activities will include the acquisition of measurements, for instance of the blood pressure or the body temperature. If such a task is selected the corresponding values are automatically documented if the measuring devices provides those data via network interface. Otherwise, an input form for manual data entry is provided by the nursing view.

3.3.3 Department-wide views

Order management view – An efficient management of orders is crucial for a structured management of clinical pathways. For the admission until the discharge, at any given time, there shall be exactly one department/medical module that is responsible for the patient. If a patient needs to be moved from one module to another, for instance from admission to radiology for X-ray imaging, a corresponding order shall be created. When the radiology starts to handle the order, the patient is transported and a handing over is performed.

The order workflow will be technically assisted by the EPR system. The order management view will display a list of yet unserved orders for the department, including patient identification, type of order, and a priority level. A patient can be chosen and will be marked as "requested" by the system. This state avoids concurrency in cases where there is more than one unserved order per patient. Usually, the patient will be fetched by assistant staff, which performs the handing over. The handing over is semi-automatically documented by reading in the patient bracelet, the bracelet of the current responsible, and the future responsible individual. The view presents the patient as "under way" until the patient' bracelet is read in at the requesting department.

During the procedure, new orders may be queued for the patient in the corresponding procedure view or in the order management view. As soon as the requested procedures have been performed, the queued orders can be approved in the order management view. This results in displaying the new orders as unserved for the other departments. Simultaneously, the patient is marked as "waiting" in the EPR system. All orders and patient state changes will be immediately documented in the EPR core data repository.

Department management view – The department management view is designed to present information and statistics that are relevant to the management of a department. Additionally, functions for the planning of staff and supply management can be included. The view may include:

- Inventory overview and supply requests
- Roster and staff member allocation
- Medical device statuses and planned maintenance offline times
- Statistics
    - Workload related

- Statistics about current workload (how many patients)
- Statistics about number of new Patients (admissions, total, daily, hourly)
- Patient distribution by department
- Occupancy percentages by department

- Injury related
  - Statistics about classification of patients
  - Statistics about main injuries
  - Warnings on infectious diseases
  - Distribution of injuries by body system
- Patient related
  - Number of pregnant patients
  - Number of premature infants
- General statistics
  - Birth
  - Death
  - Mortality
  - Admissions
  - Discharges

3.3.4 Hospital-wide views

Resource allocation view – The resource allocation view is designed to provide live data on the status of the available resources and the current patient flows. The representation will be based on complex analyses of the various data related to patient locations, order management, and roster among others. Additional software modules may be integrated to provide graphical representations of the different medical modules and resources, to generate predictions, or to identify potential bottleneck situations.

IT Configuration and management viewS – A set of views will be required for the monitoring and maintenance of the medical devices, networking and server hardware, and the IT systems. Furthermore, user and rights management as well as data quality management will be addressed by the technical staff via IT configuration and management views. The orchestration of the backend

software will also be handled in such views. Their concrete implementations will be specified alongside with the specification of the EPR components and the ICT concept.

Field Command view – The field command view provides information on relevant statistics and trends. It should support the hospital management, strategic decisions, and reporting to external partners. The major aim is to ensure an efficient and effective operation of the hospital. Possible statistics that can be automatically generated from the collected data are:

- Workload related
    - Statistics about current workload (how many patients)
    - Statistics about number of new Patients (admissions, total, daily, hourly)
    - Patient distribution by department
    - Occupancy percentages by department
- Injury related
    - Statistics about classification of patients
    - Statistics about main injuries
    - Warnings on infectious diseases
    - Distribution of injuries by body system
- Patient related
    - Number of pregnant patients
    - Number of premature infants
- General statistics
    - Birth
    - Death
    - Mortality
    - Admissions
    - Discharges
- Technology related
    - Number of imaging examinations
    - Number of ordered laboratory examinations
- Predictive evacuation statistics based on patient localization of evacuation classification

Dedicated software modules may be integrated to provide the required statistics. The view may also include software for an interactive, explorative information visualization.

Patient Search Station - The Patient Search Station is a view for relatives of patients and represents a separate view with lower security requirements. It is intended to enable people outside the field hospital to find their relatives. The pictures, names and audio recordings of their names are displayed in the form of a slide show.

3.4 Reporting functions

All reports should use templates that are filled from the various tabs, depending on the type of the report. To simplify document printing and viewing, all reports should be exportable as PDF. Any reporting except from reporting to the patient adheres strictly to the Helsinki declaration.

FIGURE 6: DEPICTION OF THE FIELD HOSPITAL REPORTING CONCEPT INCLUDING DATA SOURCES AND DATA DESTINATIONS

3.4.1 Reporting to the patient

On patient discharge, the patient receives a discharge report, documenting the course of treatment and the applied medication. The patient receives the report either printed out or as a QR code that allows the download of the full personal record from the hospital server. Eventually captured images and lab reports can also be included. The report is intended to allow other physicians the continuation of the treatment and to initiate further action (rehabilitation, medication). The report is written in English by default. During creation, the discharging physician should be able to select from all available data via checkboxes the data to be included in the report. For a digital distribution of the resulting PDF, the document should be digitally signed. The report is stored in the document repository and printed as patient handout. The discharge report can for instance be structured as follows:

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Entry	Description	Necessity Acquisition type
Patient demographic data	Generated based on the available data in the EPR	Mandatory, Automatic
Treatment summary	Generated from the Summary View	Mandatory, Automatic
Selection of relevant data from the EPR	The physician selects the relevant parts of the available data from a list, e.g. Radiology report and surgical report. These documents will be added to the document.	Optional, semi-automatically
Discharge report	If applicable divided into several sub-areas, such as current status, further therapy and medication.	Mandatory, Manual

3.4.2 Reporting to third party responder

In disaster scenarios all available resources must be bundled and focused to improve the general situation as quick and efficient as possible. Therefore, the EPR includes designated report functionalities to third-party institutions for collaboration and integration in the global helper network. Available third-party institutions are for instance other field hospitals in the early disaster phase as well as local hospitals and independent physicians in the later disaster phase.

On patient referral to a third-party institution, a referral report is generated. During creation, the discharging physician should be able to select from all available data via checkboxes the data to be included in the report. Thus, the report can consist of data from the Admission view, Examination view or any other view available.

The report is written in English by default and stored as PDF. Subsequently, the patient receives a printed version to be handed to the third-party institution. If applicable, the referral report is also sent digitally to the target institution. For this an intact communication link to the target destination is required. Also, the target institution must support adequate communication standards as HL7 v2.x, DICOM or EDIFact.

3.4.3 Reporting to Field hospital Headquarter

To keep the field hospital headquarter updated on a regular basis, an according report that contains different types of statistics and key performance indicators of the hospital can be issued. Among others, the report could contain:

- Statistics about current workload (how many patients)
- Statistics about number of new Patients
- Statistics about classification of patients
- Statistics about main injury categories
- Statistics about used/available materials, taken images
- Optional Warnings about shortage of medical supplies
- Anonymized data for scientific purposes

The report is written in English by default and is sent digitally over any communication uplink available. Additionally, a PDF document is generated and stored locally. If no communication uplink is available, the pending report is kept back until a suitable uplink is established.

3.4.4 Reporting to WHO and local GOVERNMENT

For each patient admitted to the field hospital, a report for the WHO is created. This report consists of the minimum data set for health workforce registry and does not contain any details about the patient's status, diagnosis, etc. If compatible with ethical considerations, the local government will receive the same reports as the WHO. The report is written in English by default and is sent digitally over any communication uplink available. Additionally, a PDF document is generated and stored locally. If no communication uplink is available, the pending report is kept back until a suitable uplink is established.

3.5 Supporting functions

The EPR concept comprises various functionalities to support the field hospital staff in their daily clinical routine, help to prevent errors and facilitate a safe and efficient treatment. These functionalities are described in detail below.

3.5.1 Dictionary

In advance of field hospital missions, the staff is undergoing various preparatory courses. These courses include language classes to familiarize the personnel with the local language of the deployment region. However, the relative short training time allows only the imparting of the most common vocabulary. When handling local resources, supply materials or interviewing local patients, additional vocabulary might be required.

For this, a dictionary (English – Local, Local – English) for offline lookup of vocabularies is included in the preinstalled browser. The goal is to prevent language barrier caused errors, ease communication to local patient and the proper handling of local supply materials, medicine, etc. Additionally, the dictionary can be a very useful tool for the field hospital's continuation, when the initial staff is being replaced by local physicians. In this phase, the new personnel might not be very familiar with the English language, so that the offline dictionary can be an important supporting tool.

3.5.2 Telemedicine Application

During its operation in disaster areas, the field hospital's personnel can be confronted with unexpected or very complicated clinical cases or patient with very special clinical needs. In such cases, the consulting of a specialist might be required, to facilitate an appropriate medical treatment. An integrated, preconfigured telemedicine application will enable users to initiate a video call to registered experts from different specialties for exchange of knowledge and clinical advice. A GSM or satellite uplink is required for consultation of external experts. However, if neither is provided, the application can still be used for quick inhouse communication.

3.5.3 SOP and Checklist integration

Based on procedural features such as the ICD10 code, it is planned to include checklists and Standard Operating procedures (SOPs) in the EPR system. Whenever for instance a specific ICD10 code is

indicated and a checklist should be filled for that code this should be presented to the user of the EPR system automatically.

3.5.4 Integrated DICOM Viewer

In order to provide an overview of the course of treatment, radiological image data should be available within the EPR. It should be possible to display images marked as relevant by the radiologist. Since the normal work computers / tablets are not approved for radiological diagnostics, it is possible to work with other data formats (jpg, png), so that no complete DICOM viewer has to be integrated into the EPR.

3.5.5 Document Viewer and Editor

The EPR should be able to display existing textual documents (e.g., PDF, ODF). This will enable the user to read previous medical reports or similar directly in the EPR environment. If applicable It should also be possible to edit existing ODF documents directly in the browser. Alternatively, the computers must be equipped with appropriate processing software.

3.5.6 Education Database

The education database is a local database that includes all teaching materials from all staff training courses. It is offline accessible by any staff member for a quick and uncomplicated way to close memory gaps, further education of current personnel or training of new local personnel for field hospital continuation.

3.6 Dissemination approach

It is planned to provide the EPR as open source software for non-commercial use under the name EOS – Emergency Medical Team Operating System. Therefore most of the field hospitals have the chance to implement the software in their operations and to work with a state-of-the-art tool for patient record management. Additionally, the software will be developed according to European medical device regulations and will be provided with a CE mark for clinical use.

The support and maintenance concept will be implemented in two strategies:

1. Accompanying to the development of the EPR software different technical online tutorials will be set up. These online tutorials have the objective to train ICT staff of EMTs to provide support and maintenance for their own EMT EPR implementations.
2. If no ICT staff is available for an EMT the provision of a centralized service an dsupprot from the EUMFH headquarter for this EMT is an option.

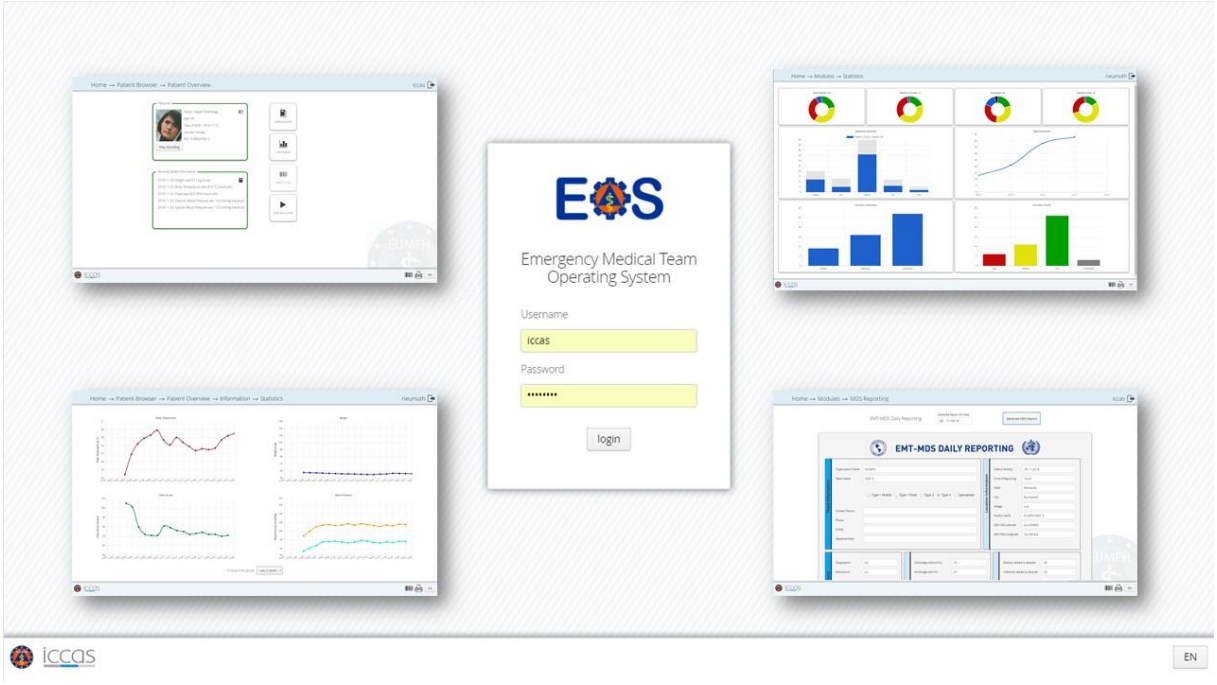

FIGURE 7: THE EMT OPERATING SYSTEM (EOS)

3.7 EPR Evaluation report

3.7.1 Management Summary

3.7.1.1 Introduction

The observation was performed during the MODEX exercise from Oct 14-18 2018 in Bucharest. Main objective of the observation was the verification and evaluation of the planned EUMFH EPR. This contained the the particular questions:

(I) Are all information entities available for medical diagnosis and treatment

(II) Are EPR functions missing in the EUMFH EPR system, and

(III) Is the planned system appropriate for medical treatment support from a qualitative perspective

Three different approaches have been used to answer the particular questions:

(1) Technical verification of EUMFH EPR for answering (I) and (II)

(2) Evaluation of EUMFH EPR by user assessment for answering (II) and (III)

(3) Observation of joint IDFFH/EUMFH-Team for identification of general findings

3.7.1.2 General setting for the exercise

The joint IDFFH/EUMFH EMT operated the IDF EPR system. The alpha version of the EUMFH EPR system was temporarily operated in parallel. This setting was chosen to avoid interruptions of the joint medical team work in case of errors in the EUMFH EPR Alpha Version and the full support of the IDF IT staff for the IDF EPR network infrastructure.

3.7.1.3 Summary and conclusions

We generally experienced a very high compliance when we started to evaluate the EUMFH EPR system, the blue people were keen to support us. The EUMFH EPR system is generally received as a valuable and supportive software tool for facilitating the medical documentation and the intra hospital information flow. No major missing information entities or implementations of process shortcomings have been identified. The software usability is appropriate for the current state. The tested Alpha-

stage version is complete and usable, the next stage is to optimize user friendly data input and field testing in exercises.

3.7.2 Technical verification of EUMFH EPR

3.7.2.1 Method

The EUMFH EPR was demonstrated by the developers to EUMFH staff and used to perform the several clinically use cases as given in Table 1.

3.7.2.2 Results

All use cases could be performed successfully.No major shortcomings appeared. In one demonstration we experienced a temporary interruption of the server connection. Reasons for this was the use of improvised server uplink equipment for the evaluation without backup connections.

TABLE 1: TEST CASES FOR TECHNICAL VERIFICATION OF THE EPR

Test case	Procedure	Result
Test case 1: EPR Login & Browsing	• Open browser and navigate to EPR address • Login the EPR with the provided login data • Optional: set personal preferences • Browse patient list	Passed
Test case 2: Perform a visit and capture vital data	• Pick an existing example patient from the list • Start a visit • Enter vital data: weight, pulse, blood pressure, respiration rate, etc.	Passed
Test case 3: Diagnosis	• Add a primary diagnosis: start typing and use suggestions from ICD-10 diagnosis list • Add a secondary diagnosis • End the visit	Passed
Test case 4: Open patient record and review charts	• Open the patient record of the previous patient • Explore the record, view demographic and vital data • Open and view charts (temperature, weight, etc.)	Passed
Test case 5: Merge unidentified patient with existing one	• Create a new unidentified patient • Merge this patient with an existing record (e.g. by barcode scan)	Passed
Test case 6: Admission, Transfer, Discharge	• Admit a new patient • Transfer the patient to a ward • Discharge a different patient and create a discharge report	Passed
Test case 7: Trillium II-Interface	• Use the Trillium II FHIR interface to import predisaster data for a specific patient (medication list, previous surgeries, etc.) electronically as well as paper-based	Passed

	• Use the Trillium II interface to export data for a specific patient (Discharge Report) electronically as well as paper-based	
Test case 8: Hospital Command View	• Open the command view of a ward and hospital command views • Explore statistics and possible warnings	Passed
Test case 9: Patient Search Station	• Start the Patient Search Station • View presented patients	Passed

3.7.3 Evaluation of EUMFH EPR by user assessment questionnaire

3.7.3.1 Methods

After the demonstration of the EUMFH EPR system and the performance of the use cases clothe EUMFH staff was asked to answer a questionnaire and to give their feedback for the system. Additional information about supportive, missing or bothering functions were requested from the interviewees. The interviewees had the chance to ask individual questions in case of unclear answers.

The interviewees have been EUMFH exercise participants and observers and were selected quasi randomly according to their current involvement during exercise/observations.

21 team members have been interviewed. 14 of them with medical roles (physicians and nurse) and 7 of them with supportive roles (Management, Logistics, or Training). Under the 14 medical interview partners have been 3 medical team leaders and all participants came from 9 European countries (see figure 1).

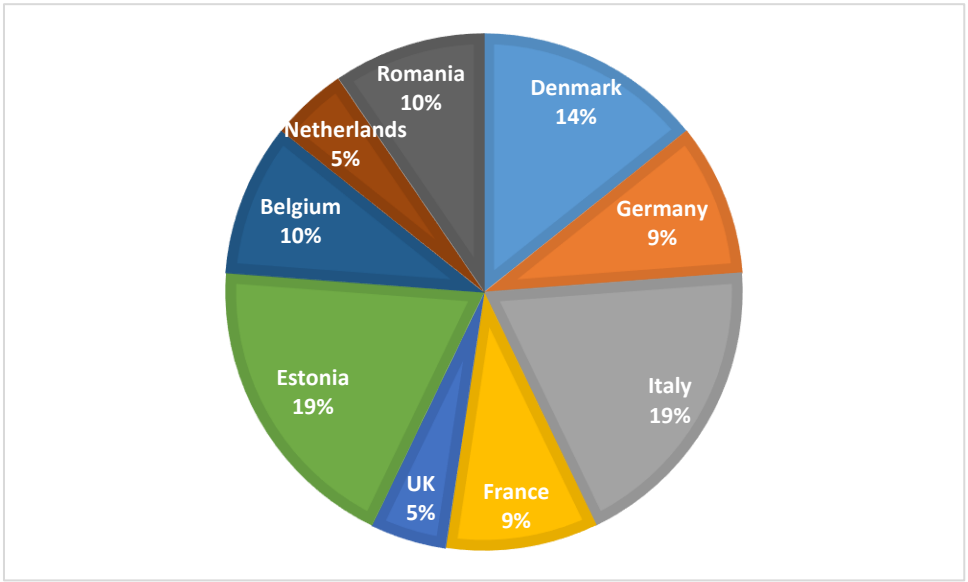

FIGURE 8: NATIONALITY OF THE INTERVIEWEES

3.7.3.2 Results

Table 2 shows the results of the survey as Likert scale answers.

TABLE 2: RESULTS OF THE INTERVIEWS (1 – STRONGLY AGREE, 2 – AGREE, 3 – NEUTRAL, 4 – DISAGREE, 5 – STRONGLY DISAGREE)

		All participants		Medical staff		Management/Logistics/Training staff	
		Mean ±Sdev	Median	Mean ±Sdev	Median	Mean ±Sdev	Median
The system is ...	useful	1,3±0,6	1	1,3±0,5	1	1,3±0,8	1
	comfortable	1,7±0,9	1	1,8±0,9	2	1,3±0,8	1
	necessary	1±0	1	1±0	1	1±0	1
	facilitating	1,4±0,6	1	1,5±0,7	1	1,3±0,5	1
	effective	1,6±0,7	2	1,8±0,6	2	1,3±0,8	1
	supportive	1,5±0,7	1	1,5±0,7	1	1,3±0,8	1
	advantageous	1,2±0,4	1	1,3±0,5	1	1,2±0,4	1
	desirable	1,2±0,4	1	1,2±0,4	1	1,1±0,4	1
	motivating	1,5±0,6	1	1,6±0,7	1,5	1,3±0,5	1
	sub challenging	2,7±1	3	2,9±0,5	3	2,3±1,6	2

The freetext answeres contained mainly improvement suggestions for minimizing the number of clicks for entering values, e.g. vital signs, the option of linking patients together, e.g. mother and child, and batch orders for ward activities..

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3.7.4 General findings from observation of joint IDFFH/EUMFH-Team

3.7.4.1 EPR specific findings

- generally, we didn't experience major (and unplanned) technical incidents
- the blue staff members quickly adapted to the use of the IDF EPR system
- The IDF laboratory had to correct the IDF EPR lab orders of the clinicians manually. The clinicians misrequested lab profiles, because the lab profiles were not chosen according to efficiency but according to displayed order
- The IDF EPR system showed temporary very long response time. The medical staff was waiting in particular several minutes to upload small size images.
- The green colleagues documented the measures and parameters in the EPR sometimes in Hebrew. In these cases the blue staff would not have been able to read the patient data.
- The documentation was nearly exclusively performed by the green colleagues
- The FH operated a heterogeneous documentation approach. While all other modules performed electronic documentation, the ICU practiced paper-based documentation

3.7.4.2 Other findings

- there was an open and inspiring communication between the staff members and between the members of both hospitals
- generally, it was a very positive working athmosphere
- many people were standing in the hallways, especially in the ER it was sometimes impossible to pass by some of the stretchers. It might be an approach to mark an area on the floor that needs to be kept empty so that staff can pass quickly.
- when patients arrived, they had their diagnosis already on their patient cards. This compromised the study where the medical staff needs to select an appropriate diagnosis by themselves instead of getting it that way "delivered". This has a negative impact on the training experience, because the staff members are not trained in this aspect.
- The evaluators should know the times of the injects in order to avoid missing the patients

4 EUMFH Information and Communication Technology (ICT) Concept

VERSION 09th February 2018

4.1 Introduction

4.1.1 Objective of this document

This document describes the concept of the information and communication technology of the EUMFH.

4.1.2 Information and communication technology - overview

The ICT concept for the EUMFH covers electronic data, voice, and video communication within the hospital and to external communication partners. It also describes the required network infrastructure, security mechanisms, access control as well as services and software.

The ICT will handle patient data that need to be protected from unauthorized access. Thus, a comprehensive data security concept is required. Additionally, the ICT concept must explicitly reflect the modular structure of the EUMFH. In this context, the communication infrastructure must address reliability, stand-alone operation, and synchronization and backup functionalities.

The operation of the EUMFH should avoid media breaks and manual paper work, which are often error prone and time-consuming. The ICT of the EUMFH shall provide a reliable digital communication infrastructure to enable the implementation of shared, electronic data repositories. The ICT infrastructure will handle a broad variety of different communication protocols and clinical IT applications. For efficient digital work processes in the EUMFH, the ICT infrastructure is a crucial component. Thus, hardware and software backup systems and redundancy will be essential in the design to provide the required high availability of the ICT.

4.2 System users and stakeholders

The following users were identified during the drafting of the ICT concept.

- Medical staff
- Technical staff, medical technicians
- EUMFH Field Command
- EUMFH Headquarter
- Local authorities
- EU funding body
- WHO and other external organizations

The ICT infrastructure, and especially the software components it provides, will be used directly by the EUMFH medical staff, technical staff and by the EUMFH Field Command. These user groups differ in their primary use cases and thus their demands to the systems. The following subsections briefly described their relation to the information and communication technology of the EUMFH.

The **medical field staff** will operate most of the system's components during diagnosis and patient treatment. The ICT of the EUMFH needs to provide an infrastructure that ensure effectiveness and facilitates the operation capabilities of the system.

The **technical staff** of the IT department of the EUMFH will be responsible for setup, configuration, and maintenance of the hardware and software components of the ICT. This especially includes access control and user management as well as error recovery.

The **EUMFH field command** mainly focusses on strategic decision making and disaster intelligence. Available resources shall be effectively and efficiently applied. Thus, the ICT of the EUMFH needs to account for robustness, reliability, and fast error recovery to ensure mid-term planning capabilities. Additionally, the EUMFH Field command needs to immediately identify and to react to unforeseen bottleneck situations. To support these important command tasks, a real time overview of hospital resource allocation, logistics, and stocks as well as trend information is required.

External communication, for instance with **other field hospitals** or **local authorities** will also be handled by the ICT of the EUMFH. The external partners may have varying communication demands; however, they all expect a secure data transmission and state-of-the-art data protection mechanisms.

Depending on the available networking infrastructure in the disaster region, the limitations in bandwidth and data transmission volumes must be considered.

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4.3 Design philosophy and System constraints

The ICT concept describes the network and system components that are required for any type of communication. This includes data transmission, voice connections, as well as images and videos. The essential design principle stems from the requirements in logistics, scalability, and reliability.

The EUMFH ICT will have a modular structure. Subsets of the EUMFH shall be operational even if they are isolated. This supports the fast deployment and early readiness for treatment, and thus a fast response to disasters. For instance, the emergency module may be operational as soon as the module is deployed. ICT dependencies to other modules and departments shall be very limited. The modularity of the ICT also increases the flexibility in logistics and the scalability of the EUMFH, for instance if parts of the hospital are deployed in reduce scale for EMT2.

The decentralized operation of modules ensures a graceful degradation of the ICT functionalities in case of network failures. The modules are kept operable as long as possible, in the worst case in a temporary stand-alone operational mode. Additionally, each of the core technical functions requires a backup system for failure recovery. Depending on the criticality, these backup systems may be realized as hot-standby or cold-standby.

An effective operation of the EUMFH requires to avoid media breaks and extensive paper work. These manual work steps are error prone and time-consuming. Manual tasks such as transferring image data via CD-ROM or re-entering measurements from paper into the EPR shall be avoided. Thus, the ICT of the EUMFH is designed to provide a reliable digital infrastructure. By means of a comprehensive data communication infrastructure, electronic data repositories with automated backups, remote data access, and semi-automatic reporting can be realized.

The ICT infrastructure will handle a large variety of communication protocols and use cases. These may include

- Medical device data, measurements (usually to data repository),
- Image data (DICOM),
- Access to electronic patient record (web-based, HTTPS),
- Notifications and order data (HL7),
- Documents and reports,
- Control commands for component orchestration and network management,

- Teleconsulting including voice and video streams,
- Backup synchronization and uploads,
- Data exchange with external partners.

The modular structure of the ICT for the EUMFH allows to implement the concept in EMT1, EMT2, and EMT3 types. It provides operational flexibility, ranging from stand-alone operation of modules and cooperation with local facilities up to a full integration with the infrastructure. Although the ICT concept is primarily designed to manage communication within an EUMFH implementation, electronic interfaces to local health care providers, to other field hospitals, and to external specialized teams must be provided. This will enable a full, seamless integration of the EUMFH into the emergency and health care infrastructure.

The overall design of the ICT infrastructure stems from the aforementioned considerations and requirements.

4.4 Network concepts

The data communication network of the EUMFH will provide the essential backbone for the efficient integration of the various modules in a flexible and yet reliable manner. The essential aspect of such a multi-purpose networking are discussed in the following subsections.

4.4.1 Internal and external communication

The established networking hardware infrastructure of the EUMFH will be used for internal as well as external communication. Data exchange with the EUMFH Headquarter, other health care providers, and external organizations requires an uplink, a management of bandwidths and data volumes, and dedicated security mechanisms.

Within the EUMFH, the ICT network ensures a reliable, secure communication between devices in a module, data transmission between modules and with the command post. The ICT serves very different communication use cases. The communication within a module covers for instance the transmission of X-ray images from the imaging modality to the centralized data repository – the Picture Archiving and Communication System (PACS) in the radiology module. If a blood count is performed in a laboratory module, the resulting report is stored locally in a data repository of the laboratory information system[3] and is as well transmitted between modules to the requesting department. The ICT infrastructure also grants access to all data repositories for global analysis and strategic decision making by the EUMFH Field Command.

Due to the expected diversity of technical communication protocols and communication standards, a communication server must be established that handles the transformation of data between systems. Such servers in hospitals transform, for instance between different versions of the HL7 v2 standard or allow to connect proprietary protocols. However, the implementation of such a communication server will result in a single point of failure; and shall thus be realized redundant with a hot backup system.

The physical network will use well-established, cabled local area networks (Ethernet) and wireless communication (Wi-Fi, IEEE 802.11g/n) with a strong data encryption. The bandwidth of these network connections is physically limited and in the proposed concept most of the electronic data transmission

[3] e. g. the open source laboratory information system SENAITE http://www.senaite.com/

shares those hardware connections. Thus, the implementation of an effective Quality-of-Service (QoS) management is necessary. There, data transmissions are prioritized according to their criticality to ensure the required bandwidths for clinically critical applications. For instance, internal, inter-module communication of patient data will be prioritized over teleconsultation video streaming.

4.4.2 Physical structure

The ICT network for electronic data exchange is structured in three layers.

The primary network connects the EUMFH at the local site to the EUMFH Headquarter and external stakeholders. This layer is primarily used for reporting, management, and teleconsultations. It requires an uplink, which may be realized with a variety of physical connections, including satellite uplink or cellular connections. Thus, it may provide only very limited bandwidth, for instance in cases where the local telecommunication infrastructure is out of order and satellite communication (12 Mbit/s per uplink) must be used. The applications must be designed to adapt to these potential limitations of the primary network.

The secondary network will handle the communication between medical modules and with the command module. The network will be established via local cabling to provide a relatively reliable connectivity. As a fallback in case of cabling failures, a WiFi data transmission might be used to increase the reliability. The secondary network will provide bandwidths of up to 1 Gbit/s, which will be sufficient for most inter-module communications, including image data transmission and video conferencing.

The tertiary network connects the medical devices of one module to the managing workstation. This local, cabled network, is mainly used to distribute patient data to devices and to transmit device data and images to local data repositories. The tertiary network of a medical module will be designed to support stand-alone operation. Thus, the medical module is kept operational even if the connection to the overarching EUMFH network infrastructure yet not fully established or got lost due to hardware failures.

4.4.3 Security structure

Data of different criticalities and security requirements, for instance patient data to be protected from unauthorized access, will be transmitted by the ICT network. Thus, a multi-layered security concept is required. Critical communication, especially those using WiFi connections, shall use a strong

encryption (IEEE 802.11i, WPA2). Additionally, we propose a separation into three different security zones (restricted, access, web). The zones should be separated using a combination of firewall systems and gateways, which will filter messages and services and will provide a dedicated access control management (Routing layer 4-7). Figure 1 depicts the proposed network zones.

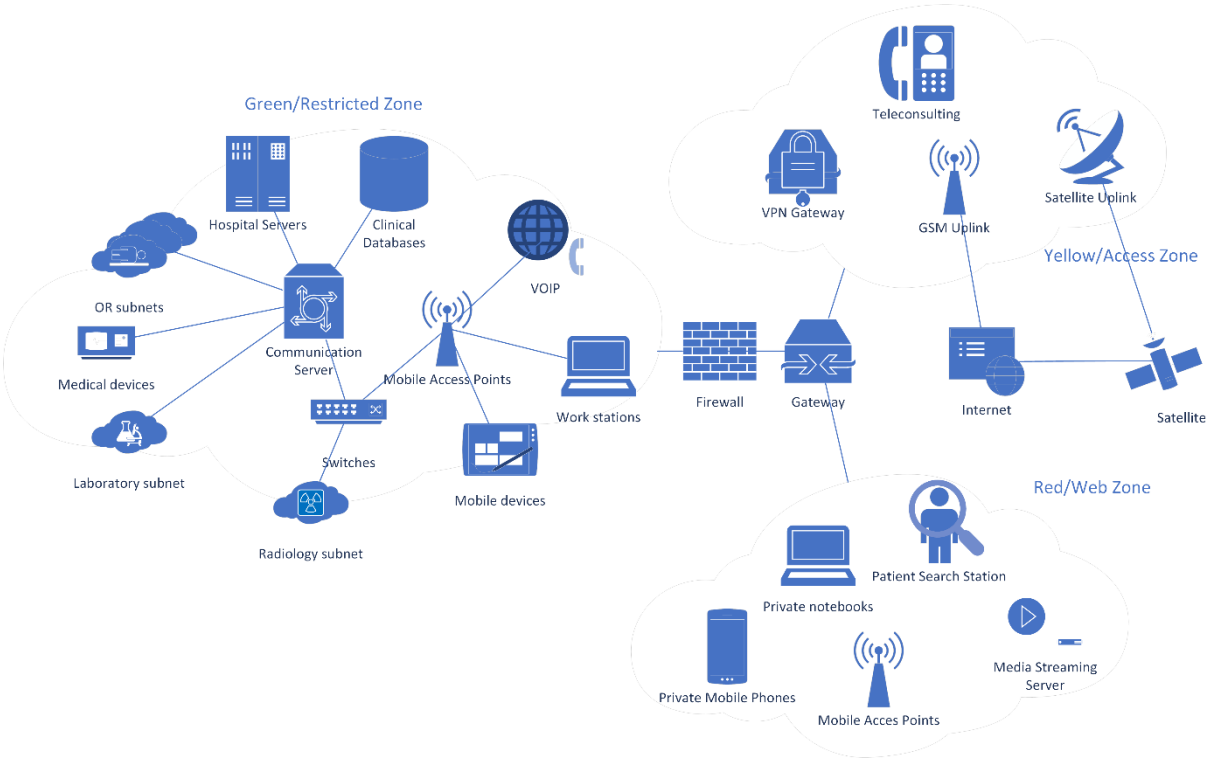

FIGURE 9 : SCHEMATIC DEPICTION OF NETWORK ZONES AND THEIR COMPONENTS

4.4.3.1 Green zone / restricted zone

The most critical data communication will be handled in the restricted network, which serves as the essential hospital network. It will contain all systems for clinical operations and biomedical systems. Its communication with the access zones will be restricted and heavily secured by gateways. The communication between the restricted zone and the access zone will be limited to assorted systems and services.

4.4.3.2 Yellow zone / access zone

The access zone will mainly provide secondary IT systems and gateways for telemedicine, video conferences, remote maintenance, and office applications. The access zone does not allow a direct access to the internet, but will use gateway servers, which are secured with IETF IPsec (RFC 4301), IETF TLS 1.2 or equivalent. By means of that, the access zone provides a mid-level security and interconnects the restricted zone and the web zone. The access zone will use the same networking hardware as the restricted zone, but both will be logically separated in channels.

4.4.3.3 Red zone / web zone

The web zone will provide informational services that are not essential for hospital operations, such as a staff compound network or a family board. Some of these services may be accessible from the internet, including a search for patients, websites for local authorities, for external stakeholders, or press. The network communication shall not contain any privacy-relevant information or sensitive patient data. The private end user devices of the staff will be integrated into the web zone as well. The services provided are not essential to the operation of the hospital and may be offline in case of insufficient uplink bandwidth.

4.4.3.4 Logical structure

4.4.3.4.1 DESIGN

The EUMFH ICT network will be logically separated into function-related subnetworks in each security zone. These subnetworks ease the maintenance of the network structures and the implementation of security measures and access control. The subnetworks should reflect the organizational structure of the EUMFH, which results in a functional grouping of network participants rather than a location-based structuring. However, in especially critical areas, such as operating rooms or command, physically separated networks may be established. Additionally, access control measures shall protect these critical infrastructures.

4.4.3.4.2 NETWORK ADDRESS MANAGEMENT

A basic network address management shall be implemented to ease the configuration and maintenance of the ICT networks. The address management will follow an initial pre-configuration with a dynamic allocation of addresses (DHCP, RFC 2132). Separate network address ranges are planned for

- Servers,
- Security zones,
- Network management components, including QoS and uplink management,
- Staff entertainment network,
- WiFi connections,
- End user devices,
- Clinical devices and systems,
    - Medical devices / biomedical systems,
    - Common hospital network computer (notebooks and tablets),
    - Voice over IP,
    - Printer, barcode reader, switches, and other peripheral devices.

4.5 Software and services

Client computers in the ICT networks should use a common set of software. Specialized software components for specific medical modules shall be avoided whenever possible. Instead, software systems may be implemented as local browser-based, client-serve applications. Basic applications, such as access to the electronic patient record or radiological images, will be provided by the web browser. The network infrastructure must be configured to grant access to network addresses depending on the security zones.

By emphasizing standard configurations for the client computers, the replacement of defective hardware is eased. However, a software tool for the automated distribution of software configurations for client devices should be implemented to fastened deployment.

In the current state of the specification, a default client will provide

- a web browser,
- a word processing and calculation software (for instance MS Word and Excel),
- a telemedicine application,
- a remote maintenance tool (TeamViewer or similar),
- a security toolkit,
- a PDF Reader/Creator,
- and package management tools (7zip, WinRAR, etc.).

4.5.1 Electronic patient record system

The Electronic Patient Record (EPR) system serves as the central component for the clinical management of the EUMFH. Its main purposes are the handling of patient data and the management of clinical pathways. Thus, it controls orders, patient transportation, and assists the documentation of examinations, diagnostic and therapeutic procedures, and patient care. From an ICT perspective, it is the main point of access to patient data for the medical users. It is essential for the operation of the EUMFH and shall be accessible from each medical module with highest system availability. A detailed description of the EPR system can be found in the EPR concept.

4.5.2 Cluster- and Storage-attached-network technologies

Reliability and high availability of the IT systems and the digital data repositories is crucial for the efficient operation of the EUMFH. Network functions and client-server applications should be kept alive even if network hardware partially failed. Additionally, servers, backup systems, and data storages (Storage-Attached-Network, SAN) should be placed separately to increase the reliability and fault tolerance of the overall ICT system. Redundant network connections with sufficient bandwidth need to be installed between these essential components. Whenever possible, documents, patient data, and images shall be stored in the data repositories instead of the devices and client computers.

Due to the use of data repositories, the client devices will only have limited capabilities if the secondary network is not available. For critical functions, redundant local repositories in the tertiary network must be provided to retain the modular concept and stand-alone operational modes. The synchronization of these local backup repositories will result in additional network traffic on the secondary communication backbone.

4.5.3 User directories and Rights management

Each member of the EUMFH staff will be identified in the ICT networks. The access rights will be managed by a role concept, where one or more roles are assigned to each individual. A consistent user management requires a centralized hospital-wide user directory. The user management can be linked to other network services using established network interfaces, such as LDAP or DirXML. The management of the user directories, of roles, and of network services will be handled by the IT department of the EUMFH.

4.5.4 Wireless networks

The medical staff, physicians and nursing staff, needs to have access to patient data from any location. Hence, mobile devices are proposed. Such devices need to be linked to the ICT networks using a WiFi connection. The data transmission must be encrypted using WPA2 (IEEE 802.11i) or similar. Additionally, Voice over IP communication might also rely on wireless connections to retain the mobility of the devices. Thus, an acceptable coverage of the EUMFH area with WiFi connectivity should be provided by the ICT infrastructure.

The web zone of the ICT network, where end user devices, especially laptops and smartphones, will be integrated, a wireless network will also be required. However, the demands on reliability and availability are less strict for these non-critical applications.

4.5.5 Telemedicine applications

Teleconsultation is an essential component of regional or interregional cooperation between health care providers. The expertise of a local team can be extended by connecting to specialists in European hospitals, local hospitals, or other field hospitals. A professional state-of-the art treatment can be offered even for critical or exceptional complex cases. However, these applications require a stable connection to the internet. In addition, telemedicine applications are especially critical concerning security because of the exchange of sensitive patient data. Thus, data correctness and integrity must be ensured, for instance by authentication, encryption with public-private keys, and electronic signatures.

In turn, the telemedicine applications may also be used by the medical staff to maintain their home affiliations while they are working in the EUMFH. They may be able to provide their expertise in assorted clinical cases or keep up the care for long-term patients.

4.5.6 Voice and video communication bandwidth

Voice and especially video communication with external partners requires a guaranteed bandwidth to be stable. Voice requires about 100 kBit/s and video at least 3 MBits/s. Time delays and jitter additionally limit the capabilities in case of bidirectional communication. Hence, these functionalities can only be provided with a stable uplink connection.

For voice communication within the EUMFH, the concept includes a DECT voice communication system (NG-DECT, IP-DECT). As a fallback, there are also common mobile radio system included in the communication concept to ensure voice communication capabilities even if no network connectivity is not available.

4.6 Network Setup strategy

The EUMFH should allow modules to operate even if the networking infrastructure is not fully established yet. Thus, the time until the first patient can be treated is shortened. The ICT concept is fully compliant with the modularity of the EUMFH.

As soon as the essential modules for triage and emergency are deployed, these modules may start to operate in stand-alone mode. This requires only the tertiary network, which connects devices to module clients and a local data repository, to be installed. The available ICT will be sufficient to register patients, record examination results, pre-plan orders, and document emergency treatment.

When more medical modules and departments are deployed and are connected via secondary network, patient and order data can be shared between medical modules, redundant synchronized data repositories become available, and voice communication (DECT and VoIP) is established. The secondary network also includes the electronic communication to the EUMFH Field Command.

The primary network will be established as soon as the uplink to the internet is deployed and connected to the ICT infrastructure. All uplink-based services, such as reporting to EUMFH Headquarter, teleconsultation, or informational web sites, can be provided afterwards. As these services are not essential to the initial operation of EUMFH, these will usually be installed late during deployment and setup.

4.7 ICT Kits overview

ICT Kits are predefined components, orchestrated to fulfill specific ICT functions of the field hospital. The modularization and prepacking of field hospital components eases logistic calculations as well as scalability and extensibility of the field hospital. Each kit contains required hardware and software to set up a module. The hardware and network components are preconfigured. The goal is to provide components that are immediately useable after power is provided.

ICT components need to be selected after defined assessment criteria:

- Compatibility to existing components in the clinical network
- Future-proofness of investments
- Software configuration options
- Port density
- Flexibility of interfaces
- Cost benefit ratio
- Failure safety and robustness

There are four ICT domains:

- Assessment
- Medical IT
- IT department
- Base camp

Each ICT kit can be assigned to one of these domains. The for each domain available ICT kits are described below.

4.7.1 Assessment team

4.7.1.1 ICT ASSESSMENT Kit

The ICT Assessment Kit encapsulates equipment for exploration, examination and measurement of the local landscape. The goal is to find a suitable place for field hospital deployment, since the deployment region might be undeveloped and/or insufficiently mapped. The equipment must be weatherproof and support longer operations without options for equipment recharge.

Components:

- a satellite phone for communication in undeveloped regions
- a landscape marker set
- a drone including a tablet for remote control
- GPS devices for orientation and marking
- a notebook with installed hospital planning software
- power banks to support longer operations

Phase: Deployment (1)
Dependencies: None

4.7.2 Medical IT

4.7.2.1 ICT Medical Kit

The ICT Medical Kit acts as a core component. It consists of IT equipment to support basic medical treatment (patient identification, admission, medical reporting, etc.) in the first hours of the field hospital. Later it can be extended to any other BMT module (Ward, ICU, etc.) for more specialized treatments.

Components:

- Notebook, docking station, peripherals and barcode reader for admission, transfer, dismission tasks
- Basic network components (WIFI router, switch, Ethernet cables) for interoperability with other module
- A VOIP phone for field hospital wide voice communication
- A printer for offline medical reporting
- A beamer, tripod and canvas
- Uninterruptible power supply to counteract power failures

Phase: Primary Treatment (2)
Dependencies: None

4.7.2.2 ICT STARTUP Kit

The ICT Startup Kit combines a portable power generator with an ICT Medical Kit. Its task is to provide a provisional, flexible power supply and enable the delivery of basic health services during the first

hours of the field hospital, until a more sustainable power supply and specialized health service modules are established.

Components:

- Portable power generator
- ICT Medical Kit

Phase: Primary Treatment (2)
Dependencies: ICT Medical Module

4.7.2.3 ICT STAFF Equipment Kit

The ICT Staff Equipment Kit consists of equipment to accompany the medical personnel on its clinical routine through the different parts of the field hospital. For that, the ICT Staff Equipment Kit contains tablet pcs to provide mobile access to the HER and other hospital systems as well as DECT phones to provide location-independent staff-to-staff communication.

Components:

- Tablet pcs and charging stations
- DECT phones and charging stations

Phase: Primary Treatment (2) and subsequent

Dependencies: ICT Department Module

4.7.2.4 ICT Voice Communication Kit

The ICT voice communication kit provides equipment for different types of voice communication. It enables communication between different field hospital modules (wards, ICU, etc.) as well as staff-to-patient communication, e.g. calling the next patient into the treatment room.

Components:

- DECT base Station and Radio-DECT-VOIP-Gateway
- Radio station and Mobile radios
- Outdoor speaker system
- Uninterruptible power supply

Phase: Primary Treatment (2) and subsequent

Dependencies: ICT Department Module

4.7.3 IT Department

4.7.3.1 ICT Department Kit

The ICT Department Kit represents the hospital's IT department. It is responsible to establish and maintain interoperability between the different systems of the field hospital. Beyond its tasks are IT device maintenance, IT infrastructure maintenance and expansion as well as user support (1st and 2nd level support). It contains all devices for the operation of a secondary ICT data network.

Components:

- Outdoor Wi-Fi antenna and outdoor ethernet cables
- Repeater
- Server and NAS
- notebooks, docking station, mouse, monitor
- Label printer, incl. toner
- Vacuum cleaner
- Uninterruptible power supply

Phase: Primary Treatment (2) and subsequent

Dependencies: None

4.7.3.2 ICT Supply Kit

The ICT Supply Kit consists of supplies and consumables that are needed for operation of the ICT network and devices during the daily routine for identification, protection, maintenance or as spare parts.

Components:

- Patient bracelets
- Toner
- Tablet folios
- Tape

- Power cables

Phase: Primary Treatment (2) and subsequent

Dependencies: None

4.7.3.3 ICT Cellular Uplink Kit

The ICT Cellular Uplink Kit is used to establish a communication uplink to other hospitals, enterprises, organizations (e.g. headquarter, WHO, etc.) and establish a primary data network. It is used If the field hospital is in a region with an existing infrastructure, where 3G or similar connectivity options are available.

Components:

- Dual SIM Gateway
- Satellite phones

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Module

4.7.3.4 ICT Satellite Uplink Kit

The ICT Satellite Uplink Kit is used to establish a communication uplink to other hospitals, enterprises, organizations etc. and establish a primary data network. It is used If the field hospital is in a region with an insufficient infrastructure, where 3G or similar connectivity options are not available.

Components:

- Ordered from Emergency.lu

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Module

4.7.4 Basecamp

4.7.4.1 ICT Base Camp Kit

The ICT Base Camp Kit contains ICT equipment for the hospital's leisure area. It provides accommodations, kitchen and recreation possibilities for the field hospital's personnel. Thus, the included ICT components support media streaming to personal electronic devices as well as the setup of a provisional cinema.

Components:

- Beamer and foldable wall as provisional cinema
- Outdoor Wi-Fi antenna and media streaming server for entertainment in the personnel quarters

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Module

4.7.4.2 ICT Command Kit

The ICT Command Kit sets up the local headquarter of the field hospital. It is used for disaster intelligence, hospital monitoring, team meetings, briefings of personnel and similar tasks. Additional to VOIP phones, it also consists of a separate satellite phone to handle emergencies and other treats.

Components:

- Beamer and foldable wall for presentations/meetings
- Notebooks, docking stations and peripherals
- VOIP phones for hospital intern communication
- Satellite phone for hospital extern communication and emergencies

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Module

4.7.4.3 ICT Patient Family Kit

The ICT Patient Family Kit allows to provide general information about patient being treated in the field hospital. This information is displayed on a screen at the entrance of the hospital, so that relatives are able to see if their family members have been brought into the field hospital and what their general condition is.

Components:

- Outdoor display
- Outdoor WiFi Antenna

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Module

4.8 Appendix 1

4.8.1 ICT Kits Components and Pricing

See separate excel file

5 EUMFH Biomedical Technology (BMT) Concept

VERSION 09th February 2018

5.1 Overview

5.1.1 Objective of the Document

This document describes the concept for medical and medical components of the European Modular Field Hospital from the perspective of biomedical engineering.

5.1.2 Biomedical Technology - Overview

The biomedical technology (BMT) concept focusses on medical devices, their connectivity and the integration with clinical IT systems. The requirements in terms of hardware and software interfaces are discussed, whereas the required information and communication technology (ICT) infrastructure is considered in the ICT concept in more detail. The concept formulates general conditions for the selection of concrete devices and discusses a modular networking strategy. The concept aims on a seamless integration of devices and electronic data repositories to minimize the manual workload and to ensure streamlined, efficient workflows.

At first, users and stakeholders are briefly described with their main demands to the biomedical technology. Stemming from their demands and the design principle of a digital infrastructure, general considerations are formulated. These especially include device networks and the associated networking capabilities and communication standards. Finally, the required kits, aligned with the clinical disciplines, are briefly summarized.

5.2 Users and stakeholders

The following main stakeholders, which have an impact on the biomedical technology concept of the EUMFH, were identified during the drafting of the concept.

- Patients
- Medical staff
- Technical staff, medical technicians
- EUMFH Field command

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- EUMFH Headquarter
- Local authorities
- EU funding body
- WHO and other external organizations

The main groups and their relation to the biomedical technology are briefly described in the following subsections.

The **patients** will differ in their state, their demographics, and their expectations depending on the disaster situation, the localization, and the operating time of the EUMFH. The primary demand of patients is the efficient diagnosis and effective treatment. Besides emergency care, this also includes the follow-ups that may be handled by local health care providers. Thus, a reliable state-of-the-art diagnosis, treatment, and documentation are essential to the patients. In turn, the biomedical technology must cover a broad set of clinical use cases and must be adaptable to situational requirements, during preparation and deployment phase, depending on the patients demands.

The biomedical technology in the EUMFH is operated by **physicians and nursing staff**. Their tasks and demands depend on their role and on the department (module) that they are associate with. To safely operate the devices and associated IT systems, tailored training sessions will be required. During the operation of the EUMFH, it may be necessary that staff is flexibly assigned to different modules. Thus, a limited number of different devices and IT systems shall be used to cover the clinical needs. Furthermore, user interfaces, instructions, and report forms must be adaptable to the operating team.

Besides clinical functionalities provided by the biomedical technology, the concept aims to reduce manual workload for configuration, information seeking, and reporting. This will ensure streamlined and efficient workflows in the EUMFH and an efficient use of the scarce resources.

Besides the medical staff, **technicians** will be required to maintain the medical devices and infrastructure components. The maintenance tasks will include the configuration of IT systems, devices and infrastructure components, the replacement of worn parts and defective equipment. Additionally, in case of reallocation of modules due to an adaptation to situational requirements, the technicians need to reorganize and reconfigure medical devices.

The **other stakeholders** will not operate the medical devices directly. However, the data obtained by the devices and upon their usage will be a valuable source of information. Hence, these stakeholders are secondary users. An automated analysis of the collected data and statistics will provide insights

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into the operational conditions of the EUMFH. Additionally, the secondary data of the biomedical technology will contribute to the information base for strategic decisions and evolutionary development of the EUMFH modules, kits, procedures, and training.

The available resources shall be effectively and efficiently applied. The EUMFH Field Command and needs to identify and to react to changing general demands. To, accumulated data from medical devices and IT systems provide indicators to support these management tasks. Furthermore, supply chains need to be coordinated partly based upon these data. Finally, accumulated data will be used to report to the EUMFH Headquarter, local authorities, and other organizations on the operational conditions and key figures of the EUMFH.

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5.3 General considerations for Biomedical technology

The medical devices, in diagnostics as well as in therapy, form the technological basis of the EUMFH. Whenever possible, stock devices shall be preferred. The medical staff is already familiar with these device classes on a general level, which shortens the training and increases safety and efficiency. Furthermore, these devices are easy to obtain and are quickly replaceable in case of failure. Yet, the application in the EUMFH demands several properties, which are described in the following paragraphs.

The language of the user interfaces should be configurable and consistent within one implementation of the EUMFH. The inclusion of a common user interface language in the training of the teams will support a safe operation of the devices.

Space and logistic capabilities are limited in disaster use cases. Hence, the devices should be as small, light-weight, and mobile as possible. This does not solely relate to the initial transportation and setup. In daily use, devices, such as an ultrasound probe, shall be mobile to ease dynamic relocation and adaptation of the technical setups. In turn, the ICT infrastructure needs to support mobile connectivity.

The interaction between devices and IT systems in the treatment of patients causes general demands. As far as possible, the devices should provide technical interfaces based on well-established standards, such as Digital Imaging and Communications in Medicine (DICOM), Health Level Seven (HL7), or IEEE 11073 Point-of-Care and Service-oriented Device Connectivity. This way, a device can store relevant data, patient-related measurements, and images in digital data repositories. These repositories avoid costly media breaks and allow for remote access, automatic analysis, and digital documentation. Most of these repositories, for instance a Picture Archiving and Communication System (PACS), which mainly stores radiological images, need to associate their data to the patient. Thus, systems and devices, which are providers of patient-related data, should be configurable and parameterizable with patient name and patient id, if applicable.

In summary, the following general considerations should be followed for the conceptualization of the biomedical technology of the EUMFH:

- Localization of user interfaces and a common language shall be supported
- Medical devices shall be mobile whenever possible
- Systems shall provide technical interfaces that implement established standards

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- Digital device data and image repositories shall be supported to avoid media breaks

5.3.1 Localization capabilities

In the intended implementations of the EUMFH, we expect multinational teams to operate the hospital. These teams may be reinforced by local assistant staff. Thus, the localization of user interfaces needs to be flexible and include at least one common language. For paper-based instructions, report forms and other relevant documents, English is the preferred language. For a concrete implementation of the EUMFH, a consistent user interface language may be chosen at deployment.

In later phases, a reconfiguration of the localization of the medical devices and IT systems may be required. If the hospital is handed over to local authorities for further use, then an adequate localization may be installed.

Remark: The term localization is a term from information technology. It refers to the concept that a technical system can be operated independently from the user interface language. Additionally, the user interface language shall be "localizable", e.g. changeable between two or more human languages.

5.3.2 Device networks and resource Strucutring

An organizational as well as a technical structuring of the technical resources, especially the medical devices, is required. It will ease the maintenance, reduce the communication overhead, and increase fail-safety and error recovery.

The devices and IT systems shall provide technical interfaces and thus form a hospital network. It will consist of different subnetworks that logically group the resources. These groups should follow the devices' main application and in general respect the department structure of the EUMFH. The following subsections describe the major subnetworks that need to be established within the EUMFH.

5.3.2.1 Radiology and imaging Subnetwork

The EUMFH will provide several imaging modalities, including radiological imaging, mainly for diagnostic purposes. This includes at least X-ray devices for bone fracture diagnosis and ultrasound devices for soft tissue imaging. To relate the images to a patient, the devices may use HL7 (ADT or similar) to retrieve the required patient and order data.

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The devices shall also provide a DICOM interface to distribute and to store the acquired images. The PACS, as a centralized communication and archiving system for medical images, will also be part of the radiology department. Most of the images will be generated in this context. However, ultrasound as well as X-ray imaging will also be used in the operating rooms. The images acquired there, will also be stored in the radiological PACS to ensure a consistent data storage and access to these data throughout the whole EUFMH infrastructure.

A reduction of network communication and redundant storage may be achieved by attaching only compressed versions of the images or extracted diagnosis-relevant images to the Electronic Patient Record (EPR) and the discharge report.

5.3.2.2 Laboratory Subnetwork

Analytics of blood and tissue samples will be performed with clinical laboratory devices. These devices will be grouped in a subnetwork. This subnetwork will also include a laboratory information system, which organizes orders and accumulates, communicates, and archives the acquired measurements. The relevant order data should be transmitted to the subnetwork via HL7 messages. Analogously, measurements and reports should be provided digitally via HL7 as well.

The samples will be identified and related to orders through physically attached codes, such as printed bar codes or RFID tags. By means of that, samples can be managed within the laboratory information systems, and data may be shared throughout the EUMFH.

5.3.2.3 Operating Room Subnetworks

Existing networking functionalities of medical devices, for instance imaging modalities such as ultrasound and X-ray, or anesthesia and patient monitoring, shall be retained. Each operating room will provide its own subnetwork, which links the present medical devices, the anesthesia, the control consoles and the data management. Such a network separation prevents unintended device communication and control access across operating rooms. Within the operating room, communication of the medical devices and of the IT systems will be handled by the subnetwork. There, the existing device interfaces will be used, preferably based on established, open standards.

Communication between the operating room subnetwork with the EUMFH overall infrastructure will be handled by gateways. Patient identification, order data and reports are communicated via HL7 gateway. DICOM communication is enabled for access to preoperative images and planning data as

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well as storage for intraoperative imaging modalities. Intraoperative tissue and fluid samples that need to be analyzed in the clinical laboratory, shall be labelled with a physical code (printed bar code, QR-Code, or RFID) which is digitally associated with the patient. The corresponding order data and reports will be exchanged with the laboratory information system via gateway as well.

5.3.2.4 Network communication capabilities

In this section, the requirements and recommendations for hardware interfaces and software communication protocols are summarized.

Medical devices that need to communicate their data should provide hardware interfaces for either cabled local area networks (Ethernet) or wireless communication (Wi-Fi, IEEE 802.11g/n). In case of wireless data transmission, encryption of all communicated data is required (IEEE 802.11i, WPA2). Medical devices with wireless communication capabilities shall follow these standards to supports network security and data integrity. This will ease the protection of data in externally accessible network segments.

All BMT networking should use IP-based communication. If available, established standards such as subsets of HL7 v2.x (ADT, ORM, ORU), DICOM, IEEE 11073, and HL7 FHIR, should be used. Additional standards for specific use cases may be included, for instance Unified Nations Electronic Data Interchange for Administration, Commerce and Transport (UN/EDIFACT) for administration and billing.

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5.3.3 Digitizing concept

Media breaks, for instance transferring imaging data via CD-ROM from the imaging modality to the intraoperative display, and paper-based reporting, for instance of blood analysis, result in extensive manual workload and are known to be error prone. Hence, the BMT concept generally aims on avoiding media breaks and paper-based information exchange. It also strongly aims to establish a digital storage, documentation, and archiving infrastructure for all BMT related data.

However, the EUMFH potentially needs to integrate existing medical records or imaging data that may be provided from external sources (local health care or other field hospitals) in various electronic or printed formats. Thus, data that are relevant to the biomedical technology must be digitized and potentially converted for integration. The digitized documents should be available in the data repositories afterwards. In the context of medical devices, this mainly refers to previously generated images, such as X-ray, CT and MRI, or blood analysis reports. The required hardware shall thus be integrated into the device networks.

Assorted reports, especially in case of patient discharge, may be printed depending on the local health care infrastructure. There, a meaningful subset of the acquired biomedical data, the images and further treatment instructions, such as medication, wound care, and additional consultations, must be provided to the patient. The adequate form of reporting (paper-based or electronic) as well as language localization depends on the region of the disaster and the available local infrastructure. The required infrastructure, software and printers, must be integrated into the device networks.

5.4 Teaching and Education

In order to establish a proper teaching and education program, all device vendors should provide two separate videos for use in the EUMFH training webinars:

- Video 1 that explains the operation of the biomedical device (max. 30min)
- Video 2 that explains error handling related to the device (max. 30 min)

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5.5 BMT KIT descriptions

5.5.1 BMT Emergency Kit

The BMT Emergency Kit consists of all required equipment to establish an emergency room. The emergency department is responsible for triage, patient allocation and provides first-level treatment in urgent/critical cases. Depending on the case severity and triage results, patients are treated in the green, yellow or red. While the green area is equipped for more simple cases with basic diagnostic equipment, the yellow and red area are outfitted with more sophisticated medical equipment to treat more severe injuries.

Components:

- Hemodynamic monitors, blood pressure machines, ECG machines
- Defibrillators, portable ventilators, portable suction devices in the yellow and red area
- Further components to be discussed

Phase: Advanced Treatment (3) and subsequent

Dependencies ICT Department Kit

5.5.2 BMT Radiology Kit

The BMT Radiology Kit provides all required components for a radiology department. Therefore, it includes a PACS to facilitate central image storage for the whole field hospital. Furthermore, it consists of portable modalities for diagnostics.

Components:

- PACS
- Portable ultrasound device
- Portable x-ray device
- Further components to be discussed

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Kit

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5.5.3 BMT Surgical Kit

The BMT Surgical Kit consists of all necessary furniture, instruments and equipment to setup a surgical wing with multiple separated operating rooms, anesthesia and a recovery area. Thus, it can support the whole surgical process from the patient preparation over anaesthetizing and operating to recovery.

Components:

- Anesthesia machine, monitor, syringe pumps, suction system, vital monitors
- Coagulators, aspirators, operating lights, power drills
- Further components to be discussed

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Kit

5.5.4 BMT Ward Kit

The BMT Ward Kit provides equipment to establish an inpatient ward for long-term patient monitoring, treatment and recovery. Depending on the ward specialty, additional medical equipment is required.

Components:

- Vital monitors
- Further components to be discussed

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Kit

5.5.5 BMT ICU Kit

The BMT ICU Kit enables the deployment of an ICU for intensive care and monitoring of critical patients. The kit consists of more advanced and specialized equipment for stabilization and reanimation than a ward kit.

Components:

- Vital monitors, suction devices
- ECG
- Defibrillator

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- Further components to be discussed

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Kit

5.5.6 BMT Gynaecology Kit

The BMT Gynecology Kit contains all required equipment to setup a specialized ward, that addresses the particular needs of pregnancies, child births and newborns.

Components:

- Doppler fetal monitor
- Gynecological tables
- Further components to be discussed (CTG, gyn. Instruments, new-born monitors, …)

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Kit

5.5.7 BMT Laboratory Kit

The BMT Laboratory Kit provides components to support a laboratory department to analyze samples (blood, urine, tissue, etc.). It contains medical devices for sample analysis as well as hardware and software components for order receival, documentation and sample management.

Components:

- Medical devices for sample analysis (to be specified)
- Notebooks, peripherals
- Preinstalled and preconfigured laboratory information system (LIS) software
- LIS Server
- Further components to be discussed

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Kit

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5.5.8 BMT Sterilization Kit

The BMT Sterilization Kit provides components and tools for the reprocessing (cleaning, maintenance, sterilization, etc.) of medical – mainly surgical – instruments. Beside of sterilization devices, it includes hardware and software components for order receival, documentation and instrument inventory management.

Components:

- Sterilization devices for medical instruments (to be specified)
- Notebooks, peripherals
- Preinstalled and preconfigured inventory management system (IMS) software
- Further components to be discussed

Phase: Advanced Treatment (3) and subsequent

Dependencies: ICT Department Kit

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5.6 Appendix 2

5.6.1 BMT Kit material Components and pricing

See separate excel file

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6 EUMFH ICT-platform concept for education and training ("EUMFH University")

VERSION 1.0 – 5th of october 2017

6.1 Purpose and requirements for the system

Currently, the EUMFH is estimated to require 140 or more staff members. This number would entail a number of approximately 2,000 people on the voluntary pool. These volunteers require a special qualification and a continuous (re-)training of their acquired abilities. Therefore, the training program should be organized in an efficient and sensible manner.

Currently, the training is scheduled to one fixed week of onsite training per year. However, due to the large number of volunteers in need of training, this scheduling is not sufficient: It will not be possible to train a large proportion of the volunteers within this short time span. On the other hand, a repetition of the training can be very cost intensive. Consequently, the majority of the training needs to occur outside of the originally allotted time span. And, as another consequence, the trainings need to be organized in a decentralized manner so as to enable volunteers from different places of origin to complete their training with as little disruption of their everyday lives as possible.

The new training concept will be henceforth referred to as EUMFH University. This document will exemplarily outline an ICT support platform concept for of the EUMFH University. The module allows for a decentralized cooperative learning and teaching platform for (future) EUMFH staff members.

The EUMFH University provides virtual course rooms and special working materials. These will allow for training in four phases of the EUMFH application life cycle:

- training of volunteer staff in idle time,
- training of EUMFH staff during the activation phase,
- training of incoming EUMFH staff during staff exchange during deployment, and
- training of local staff in preparation of the exit phase.

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6.2 System stakeholders

The European Union (EU) has much to gain from this program, apart from the obvious humanitarian aspects. Firstly, a well-organized operation leaves a lasting and positive impression on the affected country, resulting in a positive overall reputation. Additionally, the deployment of staff well-trained and the thorough training of local staff to take over the hospital will ensure a positive result of the whole project in general.

The EUMFH also gains a great amount of benefits from this program. First of all, during peacetimes and stationary times, staff training can take place in a coordinated manner, creating an adequate and equally trained pool of staff. Furthermore, a well-trained staff can get certified by the EUMFH Headquarter, ensuring that only verified staff is deployed. Also, the training program might function as refreshing course as well as briefing platform during activation. In addition, local staff can be trained as part of the exit strategy, using the same platform.

Thus, the government of the affected country benefits from a highly trained staff that is ready to operate the donated EUMFH equipment

6.3 Target users and philosophy

The EUMFH University's ICT platform supports cooperative learning and teaching. It provides a communication platform that enables discussions and the exchange of feedback between volunteers and trainers.

One of the key aspects of the program is the high emphasis placed on the self-responsibility and autonomy of the volunteers for registration and training. Only registered participants are allowed to take courses. Also, participants can only take classes after uploading all required certificates according to and determining their qualifications.

Furthermore, the training's success is verified by means of exams. The volunteers are required to take exams and earn diploma for the different courses. By applying this system, it is ensured that only those qualify for the expensive onsite exercises that have passed all necessary courses. This approach saves both time and resources.

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6.4 Example contents

Courses might comprise the following contents, depending on field of functions of the volunteer:

- Medical topics,
- Nursing topics,
- pharmacological topics,
- administrative work, and
- Logistical and technical contents (e.g. equipment maintenance, ICT network setup etc).

Furthermore, additional third party courses, such as UNDSS security courses, can be integrated into the platform if necessary.

The course can be taught using different educational approaches:

- lectures,
- hands-on demonstrations,
- virtual and/or augmented reality games,
- demonstration videos
- scheduled chats with trainers, and
- field exercises.

The completion of the courses can be tested using written or oral exams. Additionally, the system can provide digital learning certificates. Several courses can be combined to define different training levels. By being awarded a certificate, the volunteer is eligible to participate in the next training level or the exercise, provided he or she has been nominated by the respective member state country for this specific exercise.

The course contents are provided by the member states that are responsible for the respective module. In addition, they might be also responsible for training the volunteers at these modules. The platform is open to the participating member states to include their own module-specific course programs.

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6.5 Evaluation mechanisms, checks, and feedback

The platform enables feedback in both directions: from the volunteer to the course provider and vice versa. After the completion of the course(s), the student can participate in the evaluation of the course by providing feedback.

To verify that a student is certified to participate in an advanced course or to check if the students documents are not faked, an algorithm randomly selects volunteers that are required to show originals of their documents to a certified body or person in their home country. Furthermore, the student can be asked to present his or her original documents during the field exercises.

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6.6 Application scenario: training staff for the volunteer pool

To register, volunteers might provide the following information and documents:

- volunteer registration,
- name and contact data as stated in the volunteers register,
- desired position and available skills,
- essential cv data, and
- certification documents.

If a volunteer is lacking proofs or a necessary diploma, the staff manager receives a warning. After the gathering of all necessary files, the volunteer is eligible to take some of the courses, regarding his or her field of function. Then, the volunteer takes the course(s) and the required exam(s). On passing, he or she receives a digital certificate as proof. After the volunteer has passed all required trainings – including the main exercise – he or she is put in the pool of deployable and trained volunteers. If necessary, the volunteers need to repeat the exams within given times.

6.7 Application scenarios: mission member briefing and training for staff exchange

In general, volunteers are registered as mission members by the the EUMFH head quarter staff manager. The briefing material, such as readings, videos, or security information for the mission and with regard to the affected country are uploaded by the headquarter and are available for every mission member. They can download the material to peruse the information offline, e.g. on the plane. Specific material concerning the actual disaster site can be uploaded, as well. New team members on exchange can use the platform to get necessary information about the mission.

6.8 Application scenario: training local staff

In addition, local staff in trouble areas can be trained to take over the hospital as a donation after the termination of the original deployment. The local staff needs to be registered according to the outline under 7. After registration, they are eligible to take required courses and exams. That ensures that the local staff receives the same training as the EUMFH volunteer staff.

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6.9 Technical implementation, security and data safety

The technical implementation of the EUMHF University is based on the Moodle platform. Currently, Moodle is the world leader for eLearning platforms with more than 80,000 installations. Additionally, the purchase of the software is free of costs and open source, thus it might be adapted to arising needs.

Security related information is given to potential users before registration. Also, the Moodle system provides mechanisms to highly protect volunteer data and to display it only to authorized personnel.

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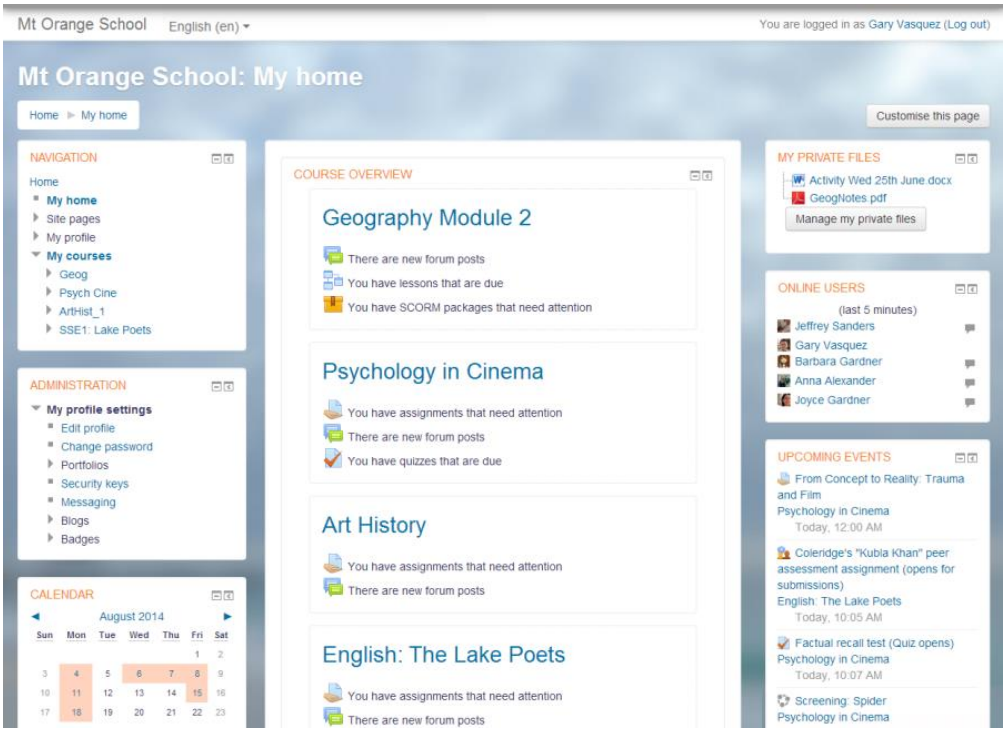
6.10Some example images for the concept

(All examples are taken from other Moodle courses for illustration)

COURSE OVERVIEW



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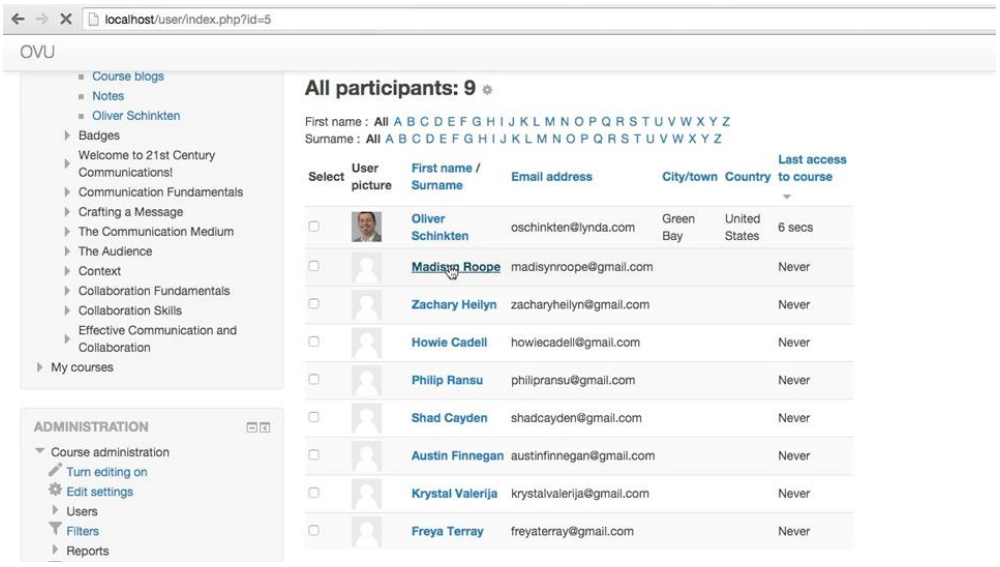
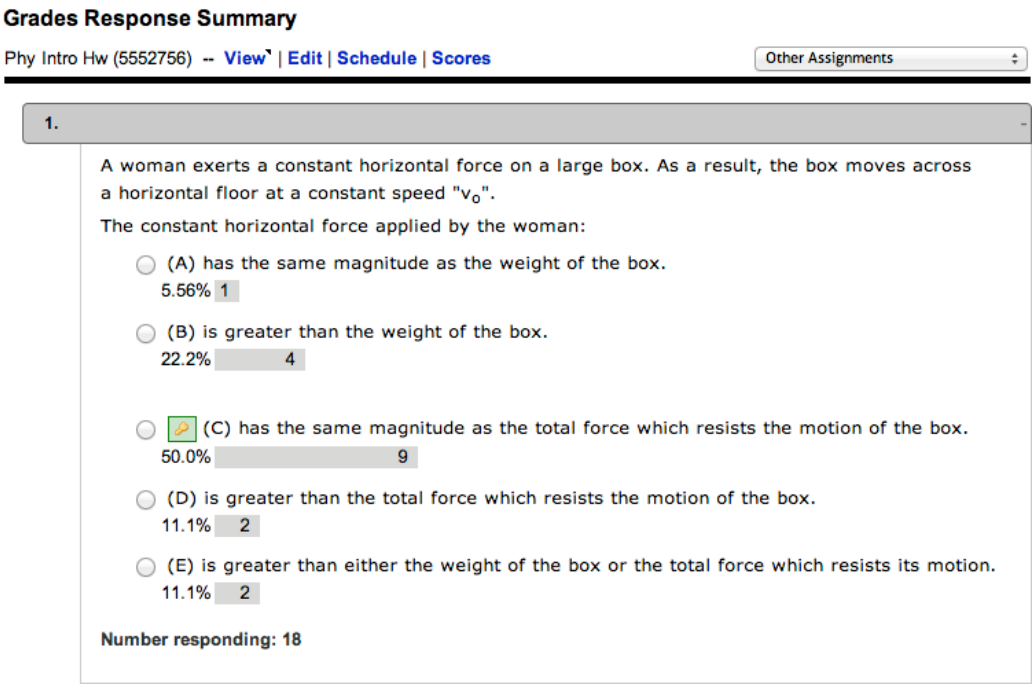
COURSE ENROLLMENT LIST EXAMPLE



PARTICIPANT-INDIVIDUAL TRAINING REPORT EXAMPLE



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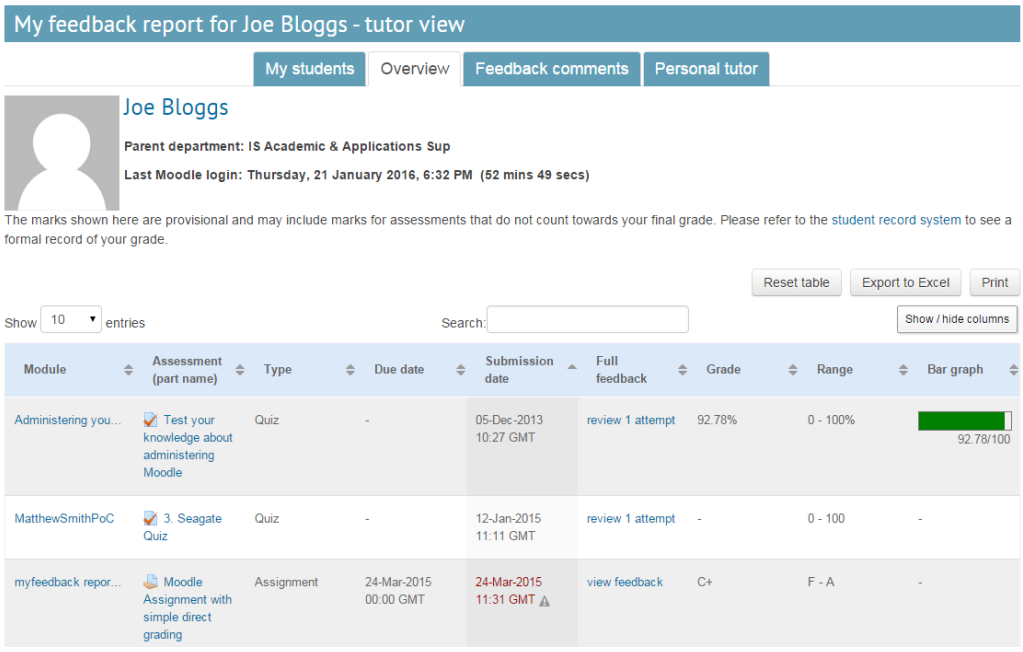

My feedback report for Joe Bloggs - tutor view

My students | Overview | Feedback comments | Personal tutor

Joe Bloggs

Parent department: IS Academic & Applications Sup

Last Moodle login: Thursday, 21 January 2016, 6:32 PM (52 mins 49 secs)

The marks shown here are provisional and may include marks for assessments that do not count towards your final grade. Please refer to the student record system to see a formal record of your grade.

Reset table | Export to Excel | Print

Show 10 entries | Search: | Show / hide columns

Module	Assessment (part name)	Type	Due date	Submission date	Full feedback	Grade	Range	Bar graph
Administering you...	Test your knowledge about administering Moodle	Quiz	-	05-Dec-2013 10:27 GMT	review 1 attempt	92.78%	0 - 100%	92.78/100
MatthewSmithPoC	3. Seagate Quiz	Quiz	-	12-Jan-2015 11:11 GMT	review 1 attempt	-	0 - 100	-
myfeedback repor...	Moodle Assignment with simple direct grading	Assignment	24-Mar-2015 00:00 GMT	24-Mar-2015 11:31 GMT	view feedback	C+	F - A	-

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7 Teaching schedules for EUMFH information and biomedical technologies

7.1 Purpose and content of the document

The document provides a first draft of teaching schedules for topics related to EUMFH medical information technology. All topics could be realized as webinars, so that they can be consumed remotely. The trainee finishes each educational topic with a short exam like-questionnaire.

7.2 Electronic Patient Record System (EPR) Teaching Schedule

TOPIC	MEDICAL STAFF	RELATED TECHNICAL STAFF
Motivation, general topics	20	20
Clinical Tabs	50	10
Clinical and administrative reports	10	10
Error handling and fallback strategies	30	10
Answering the topic related questionnaire	10	10
TOTAL [min]	**120**	**60**

7.3 Clinical Pathways, Telemedicine and Information Flow Teaching Schedule

TOPIC	MEDICAL STAFF	RELEVANT TECHNICAL STAFF
Motivation, general topics	10	10
Specific information pathways according to SOPs	20	20
Role and benefits of telemedicine in EUMFH	20	20
Answering the topic related questionnaire	10	10
TOTAL [min]	**60**	**60**

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7.4 Information and Communicaton Technology (ICT) Teaching Schedule

TOPIC	MEDICAL STAFF	RELEVANT TECHNICAL STAFF
Motivation, general topics	10	20
Security considerations (security instructions for ICT zones, logins, base camp network, using own devices etc.)	15	30
ICT logistical kits, network setup strategy	10	30
Biomedical technology connections	5	10
Error handling and fallback strategies	10	20
Answering the topic related questionnaire	10	10
TOTAL [min]	**60**	**120**

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7.5 Biomedical Technology (BMT) Teaching Schedule

TOPIC	MEDICAL STAFF	RELEVANT TECHNICAL STAFF
Motivation, general topics	10	10
BMT logistical Kits	15	30
Device-specific instructions (Should be provided by the device vendor as 10-30min videos)	*	*
Error handling and fallback strategies	5	10
Answering the topic related questionnaire	10	10
TOTAL [min]	**40+**	**60+**

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8 Appendices

Appendix 1 ICT Kits Components and Pricing

Appendix 2 BMT Kit material Components and pricing

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