Thalea

THALEA PCP

CHALLENGE

BRIEF



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SEVENTH FRAMEWORK PROGRAMME

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# Content

# 1 Introduction

The goal of the THALEA[2] project is to develop a software to create a technologically advanced cockpit in which a team of specialists can support and advise intensive care[1] units (ICUs) in smaller hospitals or rural locations unencumbered by distance. Telemedicine in ICU also known as tele-ICU, typically uses a combination of videoconferencing technology, telemetry of vital signs, and transfer of usual clinical documentation artefacts, such as treatment plans, progress notes in electronic medical records or digitalized documents to allow off-site intensive care specialists and/or critical care nurses to assist remote ICUs in the treatment of critically ill patients.

Following reports of improved patient safety, care processes and outcome the use of telemedicine technology in intensive care has spread rapidly in the United States. In Europe, telemedicine in the field of ICU is, for various reasons, not widely adopted. One of the reasons preventing widespread use of tele-ICU is lack of a versatile and interoperable Telemedicine platform for communication between remote ICU and tele-ICU-centre intensive care medicine. Therefore, in 2012 the THALEA Consortium was built in order to define requirements for a new ICU telemonitoring and telemedicine system that will provide solutions to the challenges faced in the ICU field. THALEA is not only researching how telemedicine and telemonitoring can be used to improve the treatment of ICU patients, it is also a pilot project for a new type of tender procedure known as Pre-Commercial Procurement (PCP).

## 1.1 European situation in social systems and intensive care – why THALEA

ICU patients suffer from multiple organ failure or other life-threatening conditions. Therefore they require continuous sophisticated organ support and invasive monitoring in an ICU. However (due to demographic changes and longer life-expectancy) the European intensive care landscape faces major challenges. Such as a decreasing supply of physicians and other health-care workers, an increasing demand for ICU care, rising health care costs and declining reimbursements, an increasing demand for (high) quality care, and an increasing demand for mobility.

As a result an increasing number of hospitals struggle to offer medical treatment on a sufficiently high level. This is especially true for smaller, regional hospitals with smaller ICUs. In addition evidence shows that patient outcome depends on the number of ICU patients treated; in other words the more patients an ICU treats, the more lives are saved due to increased experience. In severe sepsis and septic shock this correlation (the more lives saved, the more patients with this disease are treated in an institution) has been clearly demonstrated. On the other hand, evidence shows that therapy in severe sepsis and septic shock is time critical. In consequence, association of rural hospitals with a regional tele-ICU centre located for example in a university hospital, helps rural hospitals to share experience and form a virtual high-volume centre for this acutely live-threatening condition.



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[1] Intensive Care is defined as care for patients with one or more acutely threatened or disturbed vital functions. These patients are in need of continuous monitoring. Intensive care is given in a dedicated Intensive care unit, by trained medical specialists and specialized nurses.

[2] THALEA (Telemonitoring and Telemedicine for Hospitals Assisted by ICT for Life saving co-morbid patients in Europe As part of a Patient personalised care program of the EU)

Evidence already suggests that — in addition to efficiency and safety outcome improvements — ICU telemedicine also results in major outcome improvements[3] in critically ill patients. Examples are a lower mortality rate, a decrease of the average length of ICU stay of 20-50 %[4] (which will compensate for the lack of ICU beds) and a higher average quality of life.

## 1.2 THALEA PCP Objectives

Intensive Care Telemedicine is a driving force for addressing all the challenges mentioned above. It enables the limited number of medical specialists to reach a broader population of patients, unencumbered by distance. Furthermore, it reduces inefficient use of healthcare resources, optimizes access to the best available resources for patient care, and can also reduce variability in applying standards of care. Also it uses remote monitoring to anticipate problems before they even arise.

The objective of the THALEA PCP project is to develop a new technical platform to create a technologically advanced ICU-cockpit. By integrating data from different Patient Data Management systems in remote ICUs, an overview is given over medical conditions of many ICU-patients in remote ICUs. In order to assist a team of intensive care specialists, working in a tele-ICU centre, shares expertise, permits visual communication and the transmission of medical, imaging and health informatics data from one site to another and gives telemedical support to remote intensive care units. In figure 1, a graphic visual representation of the THALEA solution is shown.

The solution shall provide an ICU telemedicine and telemonitoring system that allows tele-ICU centres to monitor whole ICU populations in order to identify unstable patients, who will benefit from timely and focused advanced measures of intensive care medicine, regardless of where they live. Beyond this rapid assessment and treatment of unstable patients the solution shall support implementation of evidence-based guidelines by tracking workflows and providing decision support.



[3] Several ICUs in major US hospitals have already used central monitoring techniques for some time now and the figures are proving how successful this modern approach can be. Before telemonitoring, the average ICU mortality rate was 13.6 per cent. This figure dropped to 11.8 per cent with the introduction of telemonitoring and targeted interventions. The average length of stay on these ICUs also dropped from 9.8 to 6.4 days. Remarkably, more patients went home after their ICU stay after telemonitoring, which means they enjoyed a higher average quality of life than patients who were not able to return home after receiving more traditional treatment (C. M. Lilly, S. Cody, H. Zhao et al., "Hospital mortality, length of stay, and preventable complications among critically ill patients before and after tele-ICU reengineering of critical care processes" *Journal of the American Medical Association*, vol. 305, no. 21, pp. 2175‑2183, 2011)

[4] Lilly et al. JAMA, June 1, 2011; Vol. 305, 21, Wilcox and Adhikari Critical Care 2012, 16:R127

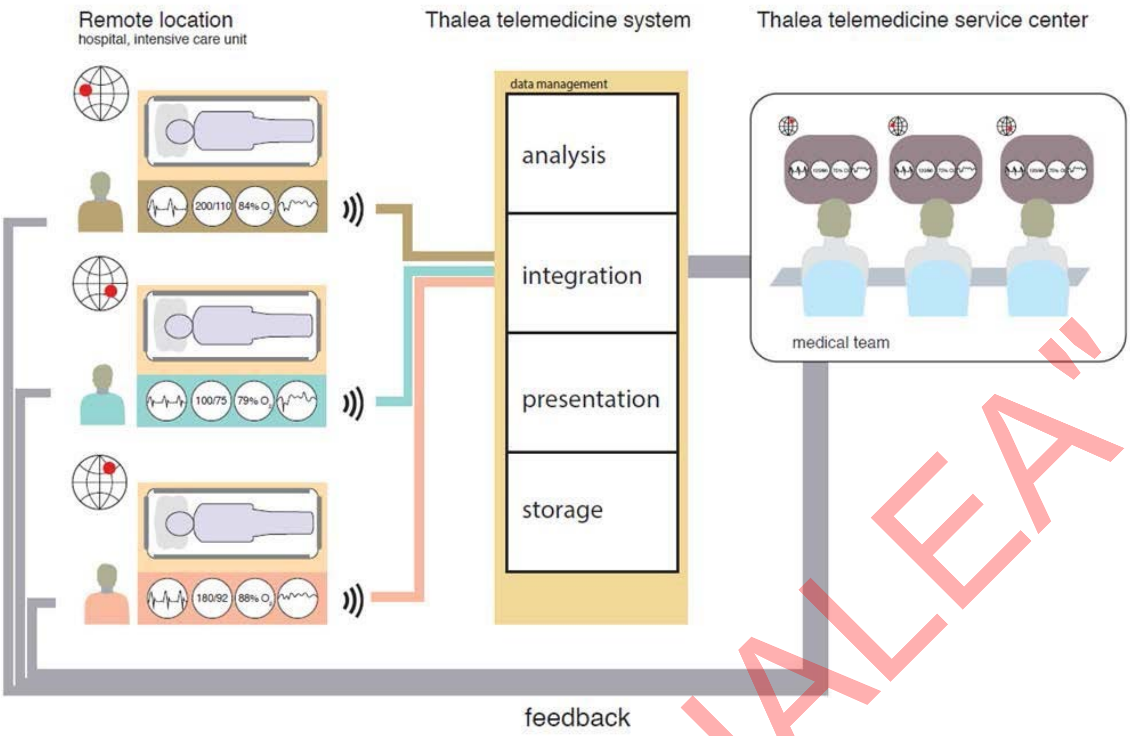


*Figure 1.* The THALEA solution

ICU telemonitoring systems that would meet these requirements are not yet on the market, but can be developed and tested within the THALEA PCP period of 2-3 years. Furthermore, THALEA is evaluating how telemedicine and telemonitoring can be used to improve the treatment of ICU patients. Thereby helping to close a knowledge-gap in telemedicine in Europe.

## 1.3 THALEA functionalities and solutions

The THALEA consortium intends to contribute to current developments in ICT standardization, compatibility and data protection in cross-border data transfer in the eHealth area. THALEA will also contribute to personalized health care by means of an ICU telemedicine application. Through PCP, telemedicine ICU care programs will be more effective and personalized solutions will be feasible, making it possible to treat patients in a more patient oriented way.

THALEA‘s core functionality is providing a data integration service, that will be able to transform various data formats received from different subsystems (PDMS, HIS) into one central data format for every kind of information. The basic functionalities of the THALEA Intensive Care Telemedicine System will be as follows:

- The combined data from all monitored patients will be condensed by a data analysis service into relevant clinical information (which in turn can be used in large scientific studies) and logically displayed by the data presentation service.
- THALEA continuously monitors, analyses and presents all relevant patient data in optimal graphical format.
- THALEA triggers alerts and notifies.
- THALEA provides two-way audio-visual bedside connection between patient/medical team and Telemedicine Centre.
- THALEA will detect changes in patients’ condition based on repeated score calculations and predefined triggers (threshold values, trends, clinical events).

- THALEA provides protocol recommendation.
- THALEA system developer will add or upgrade new data sources and interfaces
- THALEA provides treatment results analyses for benchmarking.
- THALEA supports logistic and administrative functions: bed occupation, staffing, discharge criteria.
- THALEA is conform data protection and privacy legislation and compliant as a medical product with European legislation.
- THALEA has a modular structure to grant adjustment measures.

## 1.4 Market Consultation

As a preparation for the THALEA PCP procedure, the THALEA consortium carried out a market consultation in the form of a web based survey from December 20th 2013 to February 28th 2014. The market consultation was instrumental in preparing an adequate procurement procedure with the right and feasible scope because it allowed the consortium to gain insight into the market, current and future developments of telemonitoring and telemedicine systems. In order to gain this knowledge, companies in the EU were invited to fill out an online questionnaire. 23 responses were received from five different EU countries. Of those 96% were from industrial companies and 4% from technological institutes and universities.

These responses helped to formulate a better description of the innovation THALEA is looking for and they further helped to define the system requirements. All respondents have expressed an interest in submitting a tender for the THALEA call.

More information on the market consultation can be found on the THALEA website: http://www.thalea-pcp.eu/market-consultation.

# 2 Challenge

The main purpose of THALEA PCP is to develop a solution that assists ICU telemedicine centres to improve the quality of care of critically ill patients. Tele-ICU centre provides an additional surveillance, tele-rounds, and advisory for regional ICUs. However, the local physician remains in charge of the patient and is responsible for the treatment. The THALEA solution shall display the physical status and relevant therapies of patients located in different regional “real-world” ICUs in a condensed view, providing an overview over larger numbers (100-150 per workplace) of patients. The graphical representation shall enable users in the tele-ICU centre to differentiate patients in terms of physiological stability, instability like evolving organ dysfunction. The primary screen should serve as a kind of radar, giving a tele-ICU operator an overview comparable to an air traffic controller in a control room. For a more differentiated view the system shall provide a standardized view for every patient; providing best available and structured information as well as a decision support function, enabling the critical care specialist in the tele-ICU centre to support regional ICUs. The system shall be piloted in five, mainly academic, hospitals (THALEA consortium partners) in Belgium, Finland, Germany, the Netherlands and Spain. The pilot system shall be capable to demonstrate provision of functionality in different countries in a rotating test scenario.

The preferred data source for the THALEA System are Patient Data Management Systems (PDMS).

## 2.1 State of the Art

Information of the implementation rate of information technology in intensive care settings in Europe, as well as descriptions of the technologies used, is scarce. Currently, the degree of adoption and integrations of IT on ICUs varies from digital handover of laboratory and radiology studies into electronic patient records in a fully dedicated clinical information management systems covering security relevant areas, like computerized physician order entry systems and clinical decision support features. On the other hand, units with paper based documentation and information transfer with only basic electronic bedside monitoring exist as well.

THALEA aims at those ICUs that use Patient Data Management Systems (PDMS). Main goals in applying PDMS in daily practice are fulfilling legal requirements in documentation, provision of treatment data as a basis for billing and as a tool for quality assurance in terms of process quality and outcome variables. This is achieved by a database structure (mostly some SQL or analogue relational database), underlying a graphical presentation of a traditional patient chart. Most PDMS offer automatic import of vital signs and relevant data of ICU therapy as ventilator parameters, data from advanced cardiovascular monitors, and infusion pumps. Due to their structure and the solved interfacing issues towards medical equipment, PDMS seem an ideal data-source for remote monitoring, decision support and telemedical assist systems. But still one major drawback is a lack of interoperability and inconsistency in underlying manufacturer specific data-models. Scarcity of structured and comparable data for comprehensive analysis is a common situation in all different PDM-Systems as every manufacturer sells its own proprietary database model.

## 2.2 Problem

Concerning telemedicine services, there is a significant lack of interoperability and standardization between different patient PDMSs. At present, systems mostly operate in a closed or isolated way, without compatible interfaces. Relevant data is remotely not easily accessible for professionals, which may cause delay in treatment of critically ill patients. Highly interoperable, manufacturer-independent telemedicine-platform for detection of ICU-patients at increased risk for deterioration or death is missing.

Challenges are currently in real-time processing of data. Lacking interoperability when it comes to real time processing of vital-parameters, laboratory values or routine clinical procedures as, for example physical examination or findings from patient observation, are essential problems. Thus far, industrial companies have not been inclined to solve interoperability challenges on their own.

These issues can be addressed by developing a solution acting as a middle layer. This add-on module takes on the task of extracting content from individual applications and their respective data sources. Main advantage of such procedure will be the acquisition of highly reliable data and necessity only for minimal adaptations in existing systems with respect to generally acknowledged content in clinical documentation. More information can be provided automatically by enrichment of the collected data through machine learning, artificial intelligence, and pattern recognition. Furthermore, this can be visualized and presented in a clear and uniform way to the ICU professionals.

## 2.3 Solution

Analysis of user needs and requirements for tele-ICU systems lead (among others) to the following consideration:

ICUs and telemedicine centres for Intensive Care need a platform allowing fast overview over patient's condition in terms of physical conditions, relevant workflows and compliance with treatment protocols of several ICUs at one glance – comparable to an air-traffic control room. Real-time detection of acute instability, impeding organ dysfunction or creeping deterioration should trigger statements within the application. These statements shall be convertible into alarms or workflow recommendations of various levels. Automatic detection of critical patients is possible by reviewing their data without any interruption.

The ICU telemedicine system should enable telemedicine centres to:

- monitor remote populations of ICU patients;
- detect deterioration of the condition of ICU patients on different levels like repeated calculations of severity of illness score or with organ specific measurements, for example increase need for vasoactive medication
- initiate early treatment interventions like fluid resuscitation in septic shock or extracorporeal circulatory support
- track workflows; like initiation of appropriate hemodynamic monitoring in unstable patients or coronary interventions in patients with myocardial infarction
- improve compliance with treatment protocols like sepsis resuscitation bundle or preventive care bundles like a so called VAP-bundle
- recognize patterns and trends in patient monitoring data; for example rising blood lactate levels or cardiovascular instability despite adequate fluid therapy
- standardize ICU-registry and enable benchmarking

As interoperability is one of the cornerstones of the system it will be useful that companies are active in communication with HIS and PDMS system manufacturers.

## 2.4 Future perspective

Identified need for remote monitoring, communication, and benchmarking in intensive care medicine would be solved with telemedicine technology by developing a highly interoperable, manufacturer independent system that enables regional or national monitoring in order to screen larger numbers of ICU patients and that supports detecting ICU patients at increased risk. Telemedicine and telemonitoring of the remote ICUs can be used to reduce mortality, decrease length of hospital stay, and decrease adverse events.

*More detailed functional specifications and illustrative use cases are provided in the THALEA PCP Functional Specification*.

## 2.5 Expected effects

Dissemination of novel treatments, protocols, and methods is a slow but progressive process in medicine (WHO, 1973). Average time for dissemination lasts 16 years. Telemedical concepts will help to promote the dissemination of best practice approaches. Common campaigns like the Surviving Sepsis Campaign (SSC) have shown that collaborative projects help to accelerate the efforts to bring knowledge and best practices to the bedside.

THALEA is expected to create a prototypical product to provide a link between different PDMS of ICUs. This enables continuous remote monitoring performed by experienced remote-ICU experts. Expertise and experience of a tele-Intensivist and/or a tele-ICU nurse are available 24/7 to remote hospitals within the region. The remote hospital can receive treatment protocol recommendations and nursing guidance.
Remote hospitals can ask for a second opinion in difficult situations from the ICU telemedical centre, e.g. in audio-visual treatment conferences. The telemedical system enables guidance in medical procedures performed by intensivists in the remote hospitals.

The main advantages of data extraction and transfer from existing PDMS systems are reduced demand for additional user training, necessity of only minor adaption in PDMS systems involved, and existence of already validated input from the primary system.

All in all, the tele-ICU system should increase the quality of information in consultation situations and also increase the quality of documentation in these situations. Utilization of a tele-ICU system should bring better treatment results, effective utilization of resources within the region, unification of treatment protocols, and avoidance of unnecessary patient transfers between hospitals.

Besides the development of software for a critical care data centre or control centre for remote monitoring, design of the THALEA software supplements establishment of a European registry on ICU therapies and outcomes in terms of interoperability and standardization.

## 3 Conclusion

Telemedicine solutions are already in use but an interoperable manufacturer independent platform is still missing. Demand for both telemedical cooperation and technical solutions will grow considerably over the next years. ICU care should use their potential to the full. Many challenges for ICU care exist; they have to provide high quality care with fewer resources.

The black and white picture of here presented ICU process is:
THALEA provides a control room display with intelligent integration of a variety of medical information of 100 ICU patients on one screen. Algorithms based graphical representation, providing an overview over patients and organ systems, help tele-ICU experts to identify patients in critical conditions or with impending deterioration. It will also help to keep an appropriate level of awareness even during periods associated with heavy workload or staff shortages in the local ICU.

THALEA provides the IT- technical part of the shared expertise ICU network-equation:

Local experts for patients + local monitoring + remote monitoring + remote expertise for processes = improved safety, improved outcomes and more lives saved.

**Directions how to enter this PCP competition can be found in the THALEA PCP General Conditions or for more information you can visit our website: www.thalea-pcp.eu**

# Appendix A: Clinical Focus Areas

## Graphical presentation

ICU is a data rich environment. Presentation of collected data should support the work of ICU professionals when they analyse the patient information. Graphical presentation of patient data in HIS refers in many cases to graphical presentation of traditional patient chart. PDMSs on the other hand store continuously clinical data from on-line vital-sign monitors or manually entered inputs. The large amount of collected data should support the work of ICU professionals. However, identification of relevant data can be a challenging task due to vast amount of data available. There is room for improvement in presenting and visualizing patient data even in modern solutions that are in the market today.

In ICU environment, many Intensivists and ICU nurses find it efficient to view patient clinical parameters in graphical format presented as trend curves. Main interest related to monitoring of clinical parameters is typically in detecting changes in the clinical status of a patient. By following trend curves, development of patient condition can be efficiently tracked. With short data refresh rate and relevant selection of curves to display on screen, trend curves can provide large amount of real-time information to ICU professionals at a glance. Exact information value of certain point on a curve can be checked by taking cursor or pointer on the selected point which needs a closer look. Alternatively, development of patients' clinical parameters can be presented in numeric format on large information tables. Interpreting these tables can be time-consuming and requires more orientation from ICU experts.

Utilization of graphical presentation varies significantly between different ICUs. In the ICU of Oulu University Hospital, trend curves are the main choice to present the development of physiological parameters of a patient. There are also many ICUs in Europe where graphical presentation of clinical information is not utilized due to e.g. PDMS related limitations or personal preferences of intensivists.

Presentation and clear visualization of large amount of the collected ICU data is a challenge that shall be solved by designers of the bidding companies/institutes as part of the THALEA PCP.

## Medical contribution

Patients can suffer hundreds of diseases but significant prevention of harm can be achieved by focusing on a comparably few life threatening conditions, workflows, and preventive measures that have been supported by evidence. The focus of THALEA will be on data presentation combined with detection and filtering of a selection of relevant clinical data as well as pattern recognition, thus preventing information overspill. In THALEA advanced algorithms and concentration on relevant parameters will help to provide specific signals to users in a telemedicine centre thereby avoiding inefficient alarming and consecutive alarm-fatigue as caused by unfiltered bed-side-monitor alarms.

Clinical focus is on exploitation of capabilities of scalable and configurable multi-parametric alarms or notifications from a variety of input parameters from different PDMS Systems and/or (depending on level of integration of the subsystems below) hospital information systems, laboratory systems and Picture Archiving and Communication Systems (PACS) made computable in a semantic interoperable tele-ICU System.

Functional specifications comprise standardised history of patients, with clinical usable coding of pre-existing diseases, current disease or health associated complaints (f.i. angina pectoris, dyspnoea, elevated body temperature) and their time course, current and pre-existing medication and non-pharmacological therapies and clinical interventions in ICU-patients.

Common clinical Scores and indicators have to be implemented in THALEA. Minimum Dataset is SAPS II, SOFA, GCS, pO2/FiO2, CI, Marshall score, in addition functional descriptors of brain function, cardio circulatory descriptors, pulmonary function in spontaneously breathing and ventilated patients, immunologic risk, scores in renal function, severity scores for acute pancreatitis, severity score for ARDS and burn injury. For configurable alarms, on basis of these parameters, users shall set threshold alarms as well as trend-alarms and or a combination of both via graphical user interfaces.

For retrospective research and outcome studies diagnoses and medical interventions have to provide the possibility to be transformed into widely accepted clinical codes of diagnoses and severity grading of specific diseases. Furthermore, the system has to code or make proposals on coding of common clinical entities. Identification of those entities on basis of combination of different ICD codes is judged as insufficient.

The following list provides **non-exhaustive examples** of functions. THALEA has to identify the following circumstances/ co-morbidities and/or provide signals to human users about:

- relevant risk-factors and co-morbidities of adverse outcomes in critical care: like allergies, obesity, active cardiac conditions, pulmonary disease
- preventable conditions and comorbidities in ICU
- compliance with preventive measures, best practice workflows and organisational issues: use of Fast hug protocols, daily definition of therapeutic goas, daily sedation break and spontaneous breathing trial, VAP bundle, interventions to decrease CLABSI, early initiation of appropriate anti-infective therapy
- unmodifiable risk factors: age, immunosuppression, transfusion limitations,
- evolving risk factors for unwished secondary conditions: prolonged weaning, renal failure, extubation failure, unexpected death, central line associated blood stream infection (CLABSI)
- missed workflows: missing anticoagulation, missed DVT prophylaxis, insufficient monitoring of vital signs,
- deteriorating organ dysfunction in different time-spans i.e. 2-4 hours, one day, several days, not only identified on basis of laboratory and or functional parameters but also identified by escalating therapy-regimes
- negative event notifications (-inhalative Nitric oxide without pulmonary artery catheter, SIRS+ Organ Dysfunction without further diagnostic evaluation or therapies)
- prolonged antibiotic therapy, or inappropriate antibiotic therapy based on susceptibility testing as well as clinical course
- lung protective ventilation (including appropriate PEEP FiO Ratio ,airway pressures, Tidal volume, appropriate target in pO2 or SpO2 and corresponding FiO2)
- nosocomial or community acquired infection, sepsis, severe sepsis and septic shock[5]

Conditions have to be detected with only minor user actions. Suggestion for existing diseases shall be made by the system and acknowledged by human users (i.e. physician in telemedicine centre or in local ICU). The experts' judgment shall also serve as input for optimization of diagnostic algorithms.



[5] A comprehensive overview can be found with: Schurink, C.A. et al., *Computer-assisted decision support for the diagnosis and treatment of infectious diseases in intensive care units.* Lancet Infect Dis, 2005. **5**(5): p. 305-12.

Alerts should be defined by a tele-ICU critical care specialist. The system shall provide combinations of different alerts and notifications, for example time reminders combined with clinical measurement or events with text. For example timed reminders on missing actions (when no negative fluid balance until hrs, or not increasing cardiac index above L/min/$m^2$until xx o´clock)

**A minimum set of functions providing comparability and a fair bidding contest can be found in the THALEA Functional Specification document.**

# Appendix B: Challenge Related Recent Initiatives

## The Research Agenda in ICU Telemedicine

In the statement from the critical care societies collaborative, Kahn et al. (2011)[6] define areas that should be further researched in ICU telemedicine. They have developed a research agenda which addresses methodological and knowledge gaps. Following areas of research are pointed out to be assessed through future research:

- Standardized approach to assessing the pre-implementation ICU environment
- Standardized lexicon for defining the telemedicine intervention should be developed
    - type of technologies comprising the system
    - timing of monitoring (continuous vs. intermittent)
    - role of the ICU telemedicine nurses and physicians
    - training and composition of the ICU telemedicine team
    - goals of the telemedicine program
- Impact of telemedicine on the structure and organization of the ICU itself and its interaction with institutional critical care governance
    - How telemedicine enhances or disrupts the traditional chain of command and how telemedicine enhances or disrupts the existing workflow patterns of the interdisciplinary care team?
    - What are the organizational barriers to telemedicine adoption and how ICU telemedicine acceptance by bedside clinicians could be influenced
    - What new skills and staff positions are required to manage and operate the system?
- Process topics related telemedicine delivery:
    - What factors influence the quality of the clinical recommendations by telemedicine clinicians?
    - How does communication effectiveness influence uptake of telemedicine recommendations?
- Effect of telemedicine on critical care outcomes from the perspective of the patient, the provider, the health-care system, and those responsible paying for care (e.g. cost effectiveness)
- Risk-adjusted mortality tied to discrete time periods
- Patient-centred areas of research: Effect of ICU telemedicine to diagnostic accuracy and timeliness, health-related quality of life, end-of-life care, patient and family satisfaction
- Research related to hospital operational outcomes: Effect of ICU telemedicine to length of stay, readmission rate, case volume, patient throughput, ICU bed availability, inter hospital transfers (rate and timing)
- Outcomes from the health-system perspective, cost-effectiveness of ICU telemedicine

Kahn et al. (2011) conclude their article by stating that true value of ICU telemedicine is not depending on existence of technology. Instead, it depends more on how well the technology is leveraged by ICU physicians and nurses and what are its effects on workflow and team integration. These observations should be taken into account when new ICU telemedicine systems are taken into use.

Related initiatives include also the EU FP7 projects SILVER and DECIPHER, as they both use the PCP process to develop innovative solutions in the field of healthcare.



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[6] Kahn et al. (2011). The Research Agenda in ICU Telemedicine – A Statement from the Critical Care Societies Collaborative. American College of Chest Physicians 2011. 140(1): 230–238.