Thalea II

THALEA II PPI

Additional information OMC

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Content

1 Introduction

Developing 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 that was the goal of the THALEA[2] PCP project. 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. These include treatment plans, progress notes in electronic medical records and digitalized documents, in order 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 specialists. 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 was not only researching how telemedicine and telemonitoring could be used to improve the treatment of ICU patients, it was also a pilot project for a new type of tender procedure known as Pre-Commercial Procurement (PCP).

The current project THALEA II is the first follow-up PPI in healthcare. Public procurement of innovative solutions (PPI) shortens the route to market, sets free the potential of early adopters to implement an innovation and enables public procurers to efficiently answer market demands of innovative products. It will bring an innovative product to the European healthcare market aiming to mitigate negative impacts of one of the greatest European socio-economic challenges of the 21st century in healthcare: Ageing of society and workforce. This development challenges the healthcare sector, due to an imbalance between the increasing number of EU-citizens requiring care and the decreasing number of human resources on the caregiving side. Thus, there is an urgent need for innovative solutions disburdening healthcare professionals. There is evidence suggesting that telemedicine has the ability to mitigate these problematic pan-European challenges. The promising technology of THALEA II will be purchased and implemented helping to save more lives and as a result increasing patients' quality of life. This project will enhance European competitiveness and exceed research and development in comparison to the US and demonstrate the effectiveness of this approach with respect to deployment of innovations and procurement methods. Therefore, THALEA II procurers will purchase an innovative THALEA II solution using an open tender procedure.

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

ICU patients suffer from multiple organ failure or other life-threatening conditions. Therefore, these patients require continuous sophisticated organ support and invasive monitoring in an ICU. However, (due to

[1] Intensive Care is defined as care for patients with one or more acutely threatened or disturbed vital function. 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)

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
- 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 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. Furthermore, 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 in a university hospital, helps rural hospitals to share experience and form a virtual high-volume centre for this acutely live-threatening condition.

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 II-PPI 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. Additionally, it uses remote monitoring to anticipate problems before they even arise.

The procurers of THALEA II will purchase complete systems, offering necessary hardware and software for a highly-interoperable and -integrated Tele Intensive Care Unit (ICU)-Cockpit system that assists intensive care specialists in academic telemedical command centres. First line purpose of such an application will be real-time or near-to-real-time data extraction, aggregation, and presentation enabling an intensive care specialist in a telemedical ICU to oversee large patient populations in different ICUs. By integrating data from different Patient Data Management systems (PDMS) in remote ICUs, an overview is given over medical conditions of many ICU-patients in remote ICUs. This assists a team of intensive care specialists, working in a tele-ICU

[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

centre, by sharing expertise, permitting visual communication and the transmission of medical, imaging and health informatics data from one site to another. Furthermore, it gives telemedical support to remote intensive care units. In figure 1, a graphic representation of the THALEA II 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.

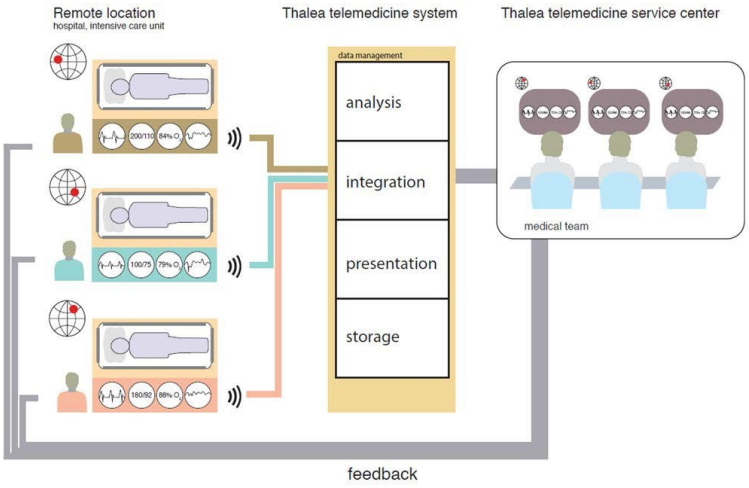

Figure 1. The THALEA II solution

ICU telemonitoring systems that would meet these requirements are invited to participate in the upcoming call for tender of THALEA II.

1.3 THALEA II - Functionalities and solutions

Core functionality of THALEA II solution is to provide Tele-ICU centres with 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 II 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 of 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 or 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 in the hospitals of the THALEA II consortium partners (Austria, Germany, Spain). The system has to be fully operable and certified according to the medical device directive (MDD).

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

The THALEA II solution has to contribute to current developments, such as:

- ICT standardization
- Interoperability
- Data protection in cross-border data transfer
- Personalized health care

By means of PPI, the developed solutions will be deployed and used in the health care market faster than average.

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 II solution should be as follows:

- THALEA II solution should present combined data from all monitored patients in a condensed view
- THALEA II solution should continuously monitor, analyse and present all relevant patient data in optimal graphical format
- THALEA II solution should trigger notifications
- THALEA II solution should provide two-way audio-visual bedside connection between patient/medical team and telemedicine centre
- THALEA II solution should detect changes in patients' condition based on repeated score calculations and predefined triggers (threshold values, trends, clinical events)
- THALEA II solution should provide protocol recommendation
- THALEA II solution should provide treatment result-analyses for benchmarking
- THALEA II solution should support logistic and administrative functions: bed occupation, staffing, discharge criteria
- THALEA II solution has to be conform with data protection and privacy legislation and compliant as a medical product with European legislation.
- THALEA II solution should have a modular structure to grant adjustment measures
- THALEA II solution developer should add or upgrade new data sources and interfaces

1.4 THALEA II - Market consultation

As a preparation for the THALEA II PPI procedure, the THALEA II consortium will carry out a market consultation in the form of a web based survey from December 20th 2018 to January 28th 2019. The market consultation will be used to prepare an adequate procurement procedure with right and feasible scope, because it allows 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 will be invited to fill out an online questionnaire. Please see the link below to this questionnaire:

https://thalea-omc.eu/index.php/469837?newtest=Y&lang=en

You can also visit the THALEA website for further information: http://www.thalea-pcp.eu

Concrete information regarding the upcoming call for tender will be made available via the THALEA II website and the Tender Electronic Daily (TED) platform of the European Commission.