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MODELS AND COLLABORATION IN MEDICAL CYBER-PHYSICAL SYSTEMS DESIGN

The presentation introduces recent advances in networked embedded computing, namely cyber-physical systems (CPSs). CPS is characterized by a tight integration of embedded computing with physical processes, as well as use of advanced networking technologies. Cyber-physical systems demonstrate an extremely broad potential for new applications in general. Those in medicine can dramatically change numerous healthcare procedures and medical workflows. At the same time, designing of a cyber-physical system comprises many challenges. These challenges are related to required dependability, heterogeneity, multidisciplinary design team, and multirole human-machine interfaces among others. The main design strategies for cyber-physical systems are design model-based. They need however to be extended with knowledge modeling and support for distributed multidisciplinary collaboration.

1. INTRODUCTION

The use of eHealth technologies for improvement of the health care quality, fostering independent living for those needing care, while reducing medical costs, is an important objective of the Digital Agenda for Europe [1]. According to Neelie Kroes from European Commission [10] ”by increasing the use of telemedicine and tele-monitoring solutions one could: cut by up to 10% the hospitalisation of chronic heart failure patients, reduce the use of healthcare resources by diabetes patients by as much as 10% while ensuring that their condition is managed in the best way”. There is a strong awareness both at the European and at the governmental levels that eHealth technologies contribute significantly to welfare of European citizens. For example, telemonitoring [20] is an eHealth domain of rising importance, diversity and scale of applications that are resulting from progress in ICT. Excellent examples demonstrate its deployments for telecare of elder people [24], emergency monitoring and prevention [25], and home telemonitoring for chronic diseases [4]. It has been also deployed for years for assuring telecare of pregnant women [20].

Due to a confluence of factors, like dynamic progress in ICT and nanotechnologies resulting, among others in new materials, a new generation of intelligent systems can be realized that is characterized by: a strong integration of devices and physical processes, device miniaturization, dramatic increase in a computational power of devices, lower demand for energy supply, sensing of the environment, new actuation possibilities, like MEMS, as well as ubiquitous communication. These systems are referred as Cyber-Physical Systems (CPSs) due to the earlier

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mentioned tighter integration of cybernetic (or virtual) components of the system with physical ones. CPSs present a new level of integrated intelligence that is characterized by interaction and coordination of computing processes with physical processes [11][12][19]. They are being deployed in a vast and rising number of diverse applications.

In the car industry systems are developed that detect moving cars and enable automatic collision avoidance. CPS may constitute vastly dispersed systems comprising thousands of sensors that monitor electric power grids, environmental pollution, car or railway transport. New applications are emerging in civil engineering (smart constructions with embedded sensors) or robotics. Cyber-physical systems enable radically new applications in many other domains.

In the eHealth domain, cyber-physical systems enable provision of more complete care and treatment of a patient. In fact, Medical Cyber Physical Systems (MCPSs) are understood as dependable, interconnected, intelligent systems of medical devices that assure a holistic treatment of a patient. Literature [12] recognizes MCPS as a separate class of CPS due to a grouping of embedded software control of networked medical devices with complex safety- and often life-critical physical processes exhibited by patients' bodies [13]. Due to MCPS applications "around a patient" their $dependability$ [1][22] is of upmost importance. This dependability has many dimensions, like: $reliability$, $security$, $safety$, $privacy$, and $trust$ that must be resolved and assured through careful design verification, validation and final certification processes. A straightforward example is the application of the CPS for monitoring of life-affecting processes of a patient. Such a system comprises a network of sensors placed on a patient's body. It's referred as a $Body\ Area\ Network\ (BAN)$ or $wearable\ network$. Further medical examples comprise: intelligent implants, physiological closed-loop systems, plug and play smart medical devices, robotic microsurgery, glucose monitoring device, pulse oximeters, accelerometers monitoring falling and immobility, infusion pumps and many others.

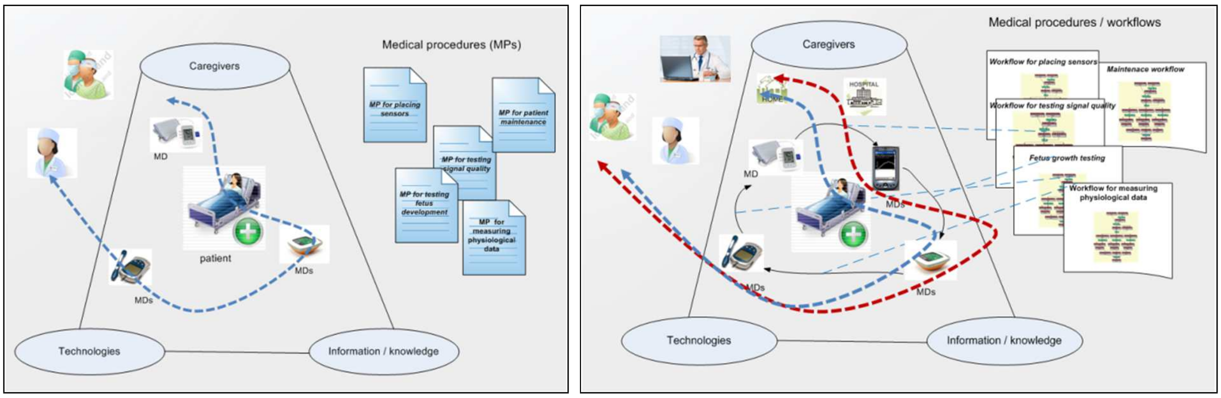
Proliferation of the Internet, in a form we know, has profoundly changed communication and collaboration among people around the world. At the same time, ubiquitous deployment of CPS that is directly related to integration of diverse distributed devices materializes a new network-based revolution referred as Internet of Things (IoT). While the traditional Internet connects a few billions of people, the Internet-of-Things is expected to connect around 30 billions of devices [23] in wireless networks by the year 2020. Internet of Things concepts when deployed to current medical scenarios revolutionize them resulting in ubiquitous networking of medical devices that can sense, collect, and compute medical data, but also can actuate different medical procedures, e.g. dose insulin or drugs. Alternatively, Internet of Services (IoS) concepts deployed to medical scenarios result in a common provision of various immaterial services, like a straightforward access to Electronic Health Records (EHR) of a patient, global communication and collaboration among various medical stakeholders.

The presentation explains background, justification, and selected challenges in designing a medical cyber-physical system.

2. TOWARDS A NEW EHEALTH SCENARIO

Traditional medical scenarios involve a team of caregivers that includes members in diverse roles, competencies, responsibilities and duties (attending doctor, doctor on duty, nurse, medical technician, or a patient's family member). The team is dynamic in the sense that its members change over time. Experience and competencies in the team are thus fluctuating. Information and knowledge considering patients' treatment and care are in a constant flow in the stakeholders' team. A part of the relevant knowledge is gathered in medical procedures, but the challenging issue is to recall and use relevant procedures in a "right place and time". Also preservation of the tacit knowledge in order to support learning processes in the team of caregivers is questionable. Furthermore, caregivers are using a large spectrum of medical devices that sense patient's medical parameters, and also perform some treatment. These medical devices generate lots of medical data that ought to be gathered, transformed and interpreted, possibly in real time.

In a traditional scenario separate procedures and teams are responsible for hospital, home, and mobile treatments. Home treatments, like monitoring, are rare and expensive. Thus, patients are expected to move to hospitals to receive a care.



(a) (b)

Fig. 1. Traditional medical scenario (a) vs. a new eHealth one (b).

With the proliferation of advanced IoT, IoS and MCPS technologies a new paradigm of medical care based on the network becomes feasible. It enables new eHealth scenarios with integrated medical devices, provision of eServices, and digitization of medical procedures in a form of electronic workflows. This is illustrated in Fig. 1. MCPS can enable a holistic treatment of a patient. Due to a multidisciplinary character of the caregivers' team, it's important that the MCPS is accessible through adaptable Human-Machine Interfaces (HMI), also workspaces, for $multirole$ users - caregivers, and in some cases, like telecare, also patients.

As already mentioned, a caregivers' team is often $dynamic$ in the sense that its members may change. A direct consequence in changing membership in the caregivers team is the need to learn adopted medical procedures ($medical\ task\ patterns$) and other sorts of team's tacit knowledge by a new team member. A system has thus to enable straightforward learning processes. Semi automatic realization of medical procedures and $workflows$ by the system should be enabled, as well as increased $interoperability$ of all involved medical devices.

The most advanced medical scenarios enable, so called $physiological\ closed-loop\ systems$, where a patient is in the closed care loop and is exposed to predefined semi-automatic treatment. Examples are such systems for diabetes and patients receiving some drugs. Dependability of closed-loop systems is central and the requirements in this respect are the strictest.

The new eHealth scenario is also importantly enabled by the advancements in the IoT technologies, as they support integration of all medical devices and allow seamless transfer of medical data "just in time in a right place". In addition, IoS technologies assure delivery of information and knowledge services, e.g. assure access to EHR (Electronic Health Records).

As the result of proliferation of new eHealth technologies, selected services can be moved in many cases to patients' homes.

3. CHALLENGES IN MEDICAL CPS DESIGN

Development of Cyber-Physical Systems requires integration of system design science with sensor network technologies and analysis of physical processes [11]. As already mentioned, Medical Cyber-Physical Systems (MCPS) are dependable, interconnected, intelligent systems of medical devices that assure a holistic treatment of a patient. It is thus obvious that human aspects of the MCPS characteristics are in the center of design objectives. Here under concern are: analysis of life-critical physical processes exhibited by patients' bodies [7][13][20], patient modeling, human- machine interaction (HMI), collaboration, management and eLearning in a multidisciplinary caregivers' team. MCPS must thus be upmost dependable.

Below, we are looking closer at the mentioned design challenges of the MCPS.

Human-Machine Interface

Human- machine interface (HMI) is important, as caregivers and patients act in different roles presenting varying experience and knowledge of medical procedures. MCPS utility is depending strongly on HMI. A smart HMI offers user-dependent *workspaces* that can be derived from HM interactions knowledge models. Such a solution that is based on so called visual active knowledge models has been demonstrated already [8][14].

A patient's behavioral model needs to be developed in order to analyze human - MCPS system interactions. A way and form of the HM interactions are of primary concern. The model investigates different roles of caregivers. This allows information flow "patient - system - professional caregivers (attending doctor, nurse)" analysis. Critical situations can be thus identified and mitigated.

$User - centric$ and *participatory design* approaches are required to develop a HMI of the system that will be user, including patient, friendly and will enable seamless human-system interactions. Interaction of medical staff and patients with the CPS needs field studies in order to elicit profoundly the design requirements.

Skills, capabilities, and knowledge of the medical staff are of utmost importance. This needs to be shared and constantly updated. Straightforward *eLearning* of adopted medical procedures (*medical task patterns*) should be supported.

The telecare team is usually a dynamic one, as doctors and nurses rotate to some extent in the hospital duties. The team members ought to follow strict medical procedures and patterns of good practices, nevertheless they may face unpredictable situations in health state of a patient, and in human operator's behavior of team colleagues. In such cases, *situational awareness* of the caregiver is of prime importance. HMI should enable it.

eLearning in a caregivers' team including a patient

In many eHealth cases, like telemonitoring, a patient consciousness participation to the medical treatment requires some support. A patient, or a family member, needs to understand basics from a monitoring action, e.g. from placing correctly sensors and performing a signal quality verification procedure. eLearning based on predefined task patterns should support a caregiver or patients in a way suitable for its role. Realization of such support tuned for a particular MCPS task is a challenge.

Integration and interoperability of medical devices

Interoperability of medical devices can be achieved by the deployment of the Internet-of-Things (IoT) concepts to medical devices as demonstrated by the Hydra middleware [2] and MDCF (Medical Device Coordination Framework) [9]. Many medical devices that are used, both in hospitals and at home, aren't IoT-based. In consequence, the eHealth care system components are hardly electronically interoperable. Standardization efforts are required in order to change this situation [15] and establish open frameworks for interconnecting medical devices into eHealth systems that consist of reliably integrated and interoperable networked components.

Support for semi-automation of medical workflows

Medical work procedures represented as medical workflows (medical task patterns) should be supported by MCPS. *Smart HMI* is expected to support invocation, and in some cases also definition of such workflows. Medical workflows predefine a flow of medical data and operations that has to be realized by caregivers, patients, and medical devices in order to realize a medical procedure. An integrated approach for managing medical workflows leads to more dependable eHealth systems.

An easy way of sharing *medical task patterns* enables eLearning in a caregivers team with a dynamic membership.

Collaboration in a multidisciplinary caregivers' team

A team of caregivers comprises members in diverse roles, competencies, responsibilities and duties. For example, in a case of telemonitoring of pregnant women, the team comprises: attending doctor, doctor on duty, nurse, medical technician, or a patient's family member. The monitoring MCPS should offer adaptable HM interfaces, also workspaces, for *multirole* users that enable collaboration, and both asynchronous and synchronous communication in the dispersed team. Authorized caregivers should also be assured a remote access to Electronic Health Record (EHR) of a patient.

Dependability of the system

Dependability represents the ability of the system to deliver service that can justifiably be trusted [1]. Dependability is a key objective of the smart medical CPS. Dependable CPS can be achieved if appropriate verification, validation and certification processes are conducted in particular, and a holistic design methodology has been adopted in general. Holistic design methodology takes into account various aspects, like verification, patients' models, models of HMI during early design phases. Reliability, security, safety, privacy, robustness and trust issues of the CPS ought to be carefully investigated and assured.

Collaboration-based holistic design methodology

One of the main design challenges constitutes an integration of collaboration issues in the multidisciplinary design team with a need to assure the highest dependability of the system which calls for a rigorous model-based development [21]. Holistic design, in our opinion, requires integration of various types of models, namely: design models at various levels of abstraction, knowledge models that represent HMI, and design task patterns that support collaboration and eLearning in a team.

4. CONCLUSIONS

Designing of the MCPS is a very demanding engineering endeavor. Design challenges related to it have been shortly explained. A new holistic approach is required in order to address these challenges that in particular are related to: Human-Machine-Interface (HMI), participatory design that includes members of the caregivers' team in diverse roles, advanced mixed-signal design due to unpredictability and life importance of selected human physical bio signals, automation of medical task patterns and collaboration, dependability, and formal model-based development to assure correctness of design.

Our approach concerning the model-based development is similar to the one presented in [21] as it stresses the need for integration of the multidisciplinary team. Additionally, the approach for mixed-signal design has been explained in [18]. We use knowledge-model-based architecture-driven design of the HMI that is based on Active Knowledge Models [6][8][14].

This knowledge model-based approach has been also proposed for elicitation of requirements concerning multi-role HM interface. The approach supports agile design of HMI, which in this context means the possibility to update and configure the functionality of the interface according to the role, abilities and experience of the involved person. The need for such an agile approach is justified by unpredictability of all telecare situations that are due to life-critical physical processes being monitored and complex Human - System interactions. The approach requires also support for collaboration in a dispersed team of caregivers in different roles.

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