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Challenges of Medical Cyber Physical System

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Abstract: ***Cyber-physical systems (CPS) can be viewed as a new generation of systems with integratedcontrol, communication and computational capabilities. Like the internet transformed how humansinteract with one another, cyber-physical systems will transform how people interact with the physical world. Medical Cyber-Physical Systems (CPS) refers to modern medical technologies in Which sophisticated and highly complex embedded systems equipped with network Communication capabilities are responsible for monitoring and controlling the physical dynamics of patients' bodies. These systems share a key characteristic: the tight integration of digital computation, responsible for control and communication in discrete-time,with a physical system, obeying laws of physics and evolving in continuous-time.The contributions made by this paper includes a survey of existing cyber-physical systems,depiction of the CPS scenario with respect to the essential components such as application, architecture, sensing, data management, computation, communication, security, and control/actuation and research challenges related to implementation of CPS in healthcare.***

Keywords: cyber-physical systems, cloud computing, health care, wireless sensor networks, security

1. General Overview of CPS in Healthcare

In this section, we provide an overview of CPS in general, its essential components, and characteristics.

1.1 What is cyber physical system (CPS)?

Cyber-physical system (CPS) connects the virtual world with physical world.It has the ability to add more intelligence to social life. It integrates physical devices, such as sensors and cameras, with cyber components to form an analytical system that responds intelligently to dynamic changes in the real-world scenarios. CPS can have wide ranging applications, suchas smart medical technology, assisted living, environmental control, and traffic management.

1.2 Advantages Of Cyber Physical Systems (CPS)

CPS is apromising solution for the integration of physical and cyber world due to several benefits such as the following.

1.2.1 Network Integration

CPS has the interoperability with WSNs and Cloud Computing. This may provide thecompliance with networking standards. CPS involvesmultiple computational platforms interacting overcommunication networks.

1.2.2 Interaction between Human and System

Modellingand measuring situational awareness-human perceptionof the system and its environmental change in parameters are critical for decision making. Thisis an absolute necessity for complex and dynamicsystems. Some CPSs include human as an integralpart of the system which makes the interaction easierbecause usually humans are difficult to model usingstandalone systems.

1.2.3 Dealing with Certainty

Certainty is the process of providing proof that a design is valid and trustworthy.Evidence can include formal proofs or exhaustivetests in simulations and prototypes. CPS is designedto be able to evolve and operate with new andunreliable environment. CPS is able to demonstrate unknown systembehaviour to study further andevolveinto better system.

1.2.4 Better System Performance

With the close interaction of sensors and cyber infrastructure, CPS is able toprovide better system performance in terms of feedback and automatic redesign. Better computational resources and cyber subsystems in CPS ensure thepresence of multiple sensing entities, multiple communication mechanisms, high-level programming language, and end-user maintenance which furtherensures the better system performance by CPS.

1.2.5 Scalability

CPS is able to scale the systemaccording todemand utilizing the properties of Cloud Computing.Users are able to acquire necessary infrastructurewithout investing additional resources. CPS is inherentlyheterogeneous as it combines physical dynamicswith computational processes. The physical domainmay combine mechanical motion control, chemicalprocesses, biological processes, and human involvement.The cyber domain may combine networkinginfrastructure, programming tools, and softwaremodelling. CPS can provide design methodologies and tools that support those methodologies, whichscale to large designs and promote understanding ofcomplex systems.

1.2.6Autonomy

CPS can provide autonomy due to havingsensor-cloud integration. Typically, CPS is a closedloopsystem, where sensors make measurements of physical dynamics. These measurements are processedin the cyber subsystems, which then driveactuators and applications that affect the physical processes.The control strategies in the cyber subsystemsare adaptive and usually predictive.

1.2.7 Flexibility

Present systems based on CPS providemuch more flexibility compared to the earlierresearch efforts inWSN and Cloud Computing alone.

1.2.8 Optimization

Present biomedical sensors and cloudinfrastructure offer large optimizations for variety ofapplications. This capability opens the pathway for CPS to optimize the system in wide extent.

1.2.9 Faster Response Time

CPS can provide faster response time due to faster processing and communicationcapability of sensors and cloud infrastructure. Fast response time can facilitate the early detection ofremote failure, proper utilization of shared resourcessuch as bandwidth.

2. Overview of Ongoing Research Work Related to CPS

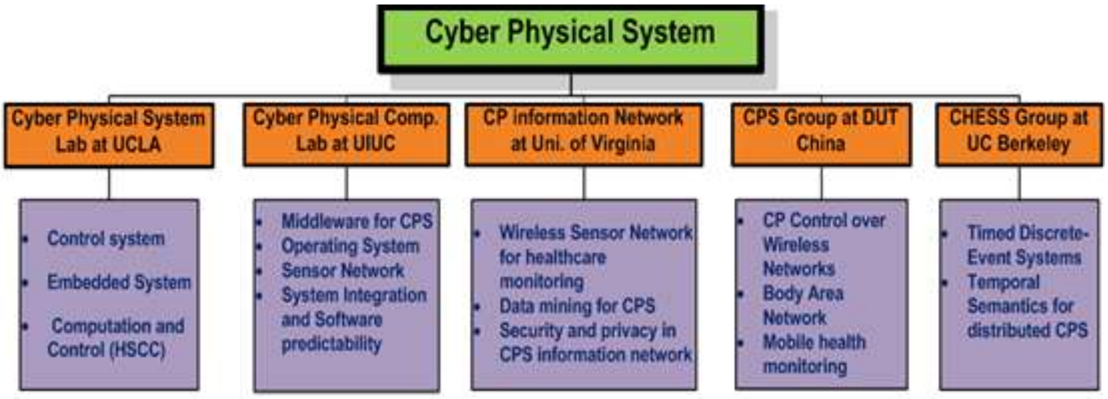

Figure 1: CPS related on-going work at some research labs

3. What is Medical Cyber Physical System

Medical device industry is undergoing a rapid transformation,embracing the potential of embedded software andnetwork connectivity. Instead of stand-alone devices that canbe designed, certified, and used to treat patients independentlyof each other, we will be faced in the near future with distributedsystems that simultaneously control multiple aspectsof the patient's physiology.

The combination of embedded software controlling the devices, networking capabilities, andcomplicated physical dynamics that patient bodies exhibitmakes modern medical device systems a distinct class ofcyber-physical systems, which we refer to as medical CPS(MCPS).Development of safe and effective MCPS will requirenew design, verification, and validation techniques, due toincreased size and complexity. Model-based technology shouldplay a larger role in the MCPS design. Models should coverdevices and communications between them, but also, equallyimportantly, patients and caregivers.

4. Background and Trends

The field of medical devices is currently undergoinga rapid transformation. The changes bring newchallenges to the development of high-confidence medicaldevices, but at the same time they open new opportunities for the research community. The main trends that haveemerged can be summarized as follows:

4.1 New software-enabled functionality:

Following the general trend in the field of embedded systems, introduction of the new functionality is largely driven by the new possibilitiesthat software-based development of medical device systemsis offering. A prime example of the new functionality isseen in the area of robotic surgery, which requires real-time processing of high-resolution images and haptic feedback. Another example is proton therapy treatment. It is one ofthe most technology-intensive procedures and requires oneof the largest-scale medical device systems. Used to deliverprecise doses of radiation for cancer patients, the treatmentrequires precise guiding of the proton beam from a cyclotron topatients, requiring adaptation to even minor shifts in position.

4.2 Increased connectivity of medical devices

In addition to relying more and more on software, medical devices areincreasingly equipped with network interfaces. Interconnectedmedical devices, effectively, form a distributed medical devicesystem of a larger scale and complexity that has to be properlydesigned and validated to ensure effectiveness and patient safety. Today, the networking capabilities of medical devices are primarily used for patient monitoring (through local connection of individual devices to integrated patient monitors or for remote monitoring in a tele-ICU setting) and for interaction with electronic health records to store patient data.

The networking capabilities of most medical devices todayare limited in functionality and tend to rely on proprietarycommunication protocols offered by major vendors. There is,however, a growing realization among clinical professionalsthat open interoperability between different medical deviceswill lead to improved patient safety and new treatment procedures.Medical Device Plug-and-Play (MD PnP) Interoperability initiative is a relatively recent effort that aims toprovide an open standards framework for safe and flexibleinterconnectivity of medical devices, in order to improvepatient safety and health care efficiency. In addition to developinginteroperability standards, MD PnP initiative collects anddemonstrates clinical scenarios where interoperability leads to improvement over the existing practice.

One example that illustrates how patient safety can beimproved by MD PnP is the interaction between an X-ray machine and a ventilator. Consider the scenario taken from X-ray images are often taken during surgicaloperations. If the operation is being performed under general anesthesia, the patient is breathing with the help of a ventilator.

Because the ventilator cannot "hold its breath" to let theX-ray image be taken without the blur caused by movinglungs, the ventilator has to be paused and later restarted.

There have been cases where the ventilator was not restarted, leading to the death of the patient. Interoperation of the twodevices can be used in several ways to ensure that patientsafety is not compromised, as discussed in. One possibility is to let the X-ray machine pause and restart the ventilatorautomatically. A safer alternative, although presenting tightertiming constraints, is to let the ventilator transmit its internalstate to the X-ray machine. There typically is enough time to take an X-ray image at the end of the breathing cycle, whenthe patient has finished exhaling until the start of the nextinhalation. This approach requires the X-ray machine to knowprecisely the instance when the air flow rate becomes close enough to zero and the time when the next inhalation starts.Then, it can make the decision to take a picture if enough time– taking transmission delays into account – is available.

4.3 Physiologically closed-loop systems

Traditionally, most clinical scenarios have a caregiver – and often more than one – controlling the process. For example, an anaesthesiologistmonitors sedation of a patient during an operation and decideswhen an action to adjust the flow of sedative needs to betaken. There is a concern in the medical community that such reliance on "human in the loop" may compromise patientsafety. Caregivers, who are often overworked and operateunder severe time pressure, may miss a critical warning sign. Nurses typically care for multiple patients at a time and can bedistracted at a wrong moment. Using an automatic controllerto provide continuous monitoring of the patient state andhandling of routine situations would be a big relief to the caregiver and can improve patient care and safety. Althoughthe computer will probably never replace the caregiver completely; it can significantly reduce the workload, calling thecaregiver's attention only when something out of the ordinary happens.

4.4 Continuous Monitoring and Care

Due to a high costassociated with in-hospital care, there has been increasing Interest in alternatives such as home care, assisted living, telemedicine, and sport-activity monitoring. Mobile monitoringand home monitoring of vital signs and physical activitiesallow health to be assessed remotely at all times. Also, there is a growing popularity of sophisticated technologies suchas body sensor networks to measure training effectivenessand athletic performance based on physiological data suchas heart rate, breathing rate, blood-sugar level, stress level, and skin temperature. However, most of the current systemsoperate in store-and-forward mode, with no real-time diagnosticcapability. Physiologically closed-loop technology will allow diagnostic evaluation of vital signs in real-time and makeconstant care possible.

5. Challenges and Opportunities

As can be seen from the trends described above, thecross-cutting nature of Medical CPS (MCPS) transcends theinformational, physical, and medical worlds, and raises significantscientific and technical challenges for the IT, medical, regulatory communities. Here some challenges which provide opportunities for R&D communities.

5.1 Executable clinical workflows:

The trend towards increased interconnectivity and interoperability of medicaldevices opens the way for the dynamic construction anddeployment of MCPS to implement custom clinical scenariosthat best suit the needs of a given patient. Dynamism in MCPSdeployment, in turn, poses a new challenge for ensuring patientsafety in these custom scenarios. While safety analysis ofdynamically created scenarios is an open problem, one canenvision a possible path to the solution based on rigorous modeling of clinical scenarios and their subsequent analysis.

5.2 Model-based Development:

With executable clinical work flow specifications, MCPS present a unique opportunity in the area of model-based development. We can introduce modeling beyond individual devices or even device systems, to the level of clinical scenarios that would serve as top level system requirements.

5.3 Physiological close-loop control

The use of automatic control in clinical scenarios raises the stakes for the application of control theory in medical applications. Medicaldevice systems for patients with complicated conditionsmay involve application of several treatments simultaneously, which affect several body systems in complicated and ofteninsufficiently understood ways. These treatments also caninterfere with each other. Effects of each treatment can differwidely from patient to patient. Critical variables are oftennot directly observable, adding to the uncertainty. Control theoretic methods designed to operate under high parametricuncertainty, such as supervisory adaptive control, may behelpful in this context.

5.4 Patient Modeling and Simulation

A closely related challenge is that of patient modeling. Patient models are needed for the design of closed-loop control, as well as forthe safety analysis of scenarios

5.5 Adaptive Patient-Specific Algorithms and Smart Alarms

Medical devices are typically designed for groupsof patients with similar medical conditions. However, thestaggering range of patient responses to the same treatmentand variation of vital signs for the same condition makethis approach very generic and inefficient.

5.6 User-Centered Design

Caregiver errors in using medicaldevices are a major source of adverse events. Undoubtedly, some of these errors are due to stress andoverload that caregivers experience daily. However, a largenumber of these errors can be attributed to poor user interfacedesign. If a device is hard to operate, has a counterintuitive interface, or responds to user inputs in an unexpected manner, user errors are much easier to occur. Design and validation ofmedical devices needs to take into account user expectations.

5.7 Infrastructure for Medical-Device Integration and Interoperation:

Currently, distributed MCPS are built by a singlemanufacturer using proprietary communication protocol. While this approach may make regulatory approval easier, itlimits the benefits of inter-device communication and stiflescreativity of medical professionals. Open interconnectivitystandards for MCPS, such as the ICE standardproposed via the MD PnP initiative, lay the groundwork formedical device interoperability. Yet, for these standards to beeffective, development and deployment platforms should bedeveloped.

5.8 Security and Privacy:

While networking capabilities let medical devices acquire functionality that was never possiblepreviously, they also open the door to a host of newpotential problems. Security and privacy concerns are some ofthose new problems. An attacker who penetrates an MCPSnetwork has the potential to harm and even kill patients by reprogramming devices. The extreme approach, taken bymost device manufacturers today, is to limit the functionalitythat can be invoked through the network interface. In mostcases, the device can send out data, such as sensor readingsor event logs, but not accept commands from the network.Although such an approach improves security of the system,it severely limits the ability to deploy closed-loop scenarios. Finding the right balance between flexibility and security is an important challenge for MCPS.

6. Conclusions

The domain of MCPS offers a unique set of challenges,distinct from any other CPS domain . The area is aboutto undergo a substantial transformation, both in terms ofdoctors' and caregivers' expectations of what MCPS can dofor them, and in terms of how these systems are developedand approved. The challenges facing MCPS are formidable,yet they present vast opportunities for research with immediatepractical impact.This paper summarized the challenges and outlinedthe most promising research directions.

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