

# Challenges of Medical Cyber Physical System

Syedda Mujeebunnisa

B.E, M.Tech, Assistant Professor, Department of BCA, Bapu Degree College, Yeshwanthpur, Bangalore, India

**Abstract:** *Cyber-physical systems (CPS) can be viewed as a new generation of systems with integrated control, communication and computational capabilities. Like the internet transformed how humans interact 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 include 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, such as smart medical technology, assisted living, environmental control, and traffic management.

### 1.2 Advantages Of Cyber Physical Systems (CPS)

CPS is a promising 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 the compliance with networking standards. CPS involves multiple computational platforms interacting over communication networks.

#### 1.2.2 Interaction between Human and System

Modelling and measuring situational awareness-human perception of the system and its environmental change in parameters are critical for decision making. This is an absolute necessity for complex and dynamic systems. Some CPSs include human as an integral part of the system which makes the interaction easier because usually humans are difficult to model using standalone 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 exhaustive tests in simulations and prototypes. CPS is designed to be able to evolve and operate with new and unreliable environment. CPS is able to demonstrate

unknown system behaviour to study further and evolve into a better system.

#### 1.2.4 Better System Performance

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

#### 1.2.5 Scalability

CPS is able to scale the system according to demand utilizing the properties of Cloud Computing. Users are able to acquire necessary infrastructure without investing additional resources. CPS is inherently heterogeneous as it combines physical dynamics with computational processes. The physical domain may combine mechanical motion control, chemical processes, biological processes, and human involvement. The cyber domain may combine networking infrastructure, programming tools, and software modelling. CPS can provide design methodologies and tools that support those methodologies, which scale to large designs and promote understanding of complex systems.

#### 1.2.6 Autonomy

CPS can provide autonomy due to having sensor-cloud integration. Typically, CPS is a closed-loop system, where sensors make measurements of physical dynamics. These measurements are processed in the cyber subsystems, which then drive actuators and applications that affect the physical processes. The control strategies in the cyber subsystems are adaptive and usually predictive.

#### 1.2.7 Flexibility

Present systems based on CPS provide much more flexibility compared to the earlier research efforts in WSN and Cloud Computing alone.

### 1.2.8 Optimization

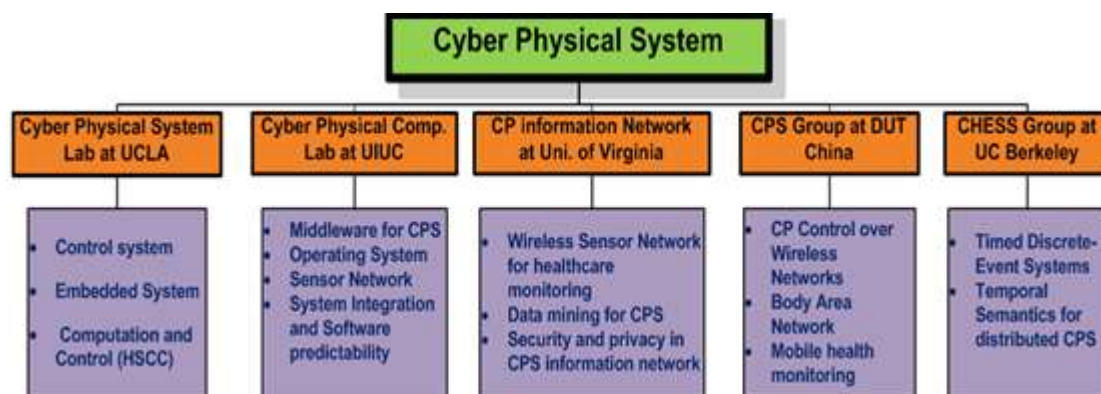
Present biomedical sensors and cloud infrastructure offer large optimizations for variety of applications. This capability opens the pathway for CPS to optimize the system in wide extent.

### 1.2.9 Faster Response Time

CPS can provide faster response time due to faster processing and communication capability of sensors and

cloud infrastructure. Fast response time can facilitate the early detection of remote failure, proper utilization of shared resources such 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 and network connectivity. Instead of stand-alone devices that can be designed, certified, and used to treat patients independently of each other, we will be faced in the near future with distributed systems that simultaneously control multiple aspects of the patient's physiology.

The combination of embedded software controlling the devices, networking capabilities, and complicated physical dynamics that patient bodies exhibit makes modern medical device systems a distinct class of cyber-physical systems, which we refer to as medical CPS (MCPS). Development of safe and effective MCPS will require new design, verification, and validation techniques, due to increased size and complexity. Model-based technology should play a larger role in the MCPS design. Models should cover devices and communications between them, but also, equally importantly, patients and caregivers.

## 4. Background and Trends

The field of medical devices is currently undergoing a rapid transformation. The changes bring new challenges to the development of high-confidence medical devices, but at the same time they open new opportunities for the research community. The main trends that have emerged 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 possibilities that software-based development of medical device systems is offering. A prime example of the new functionality is seen 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 of the most technology-intensive procedures and requires one of the largest-scale medical device systems. Used to deliver precise doses of radiation for cancer patients, the treatment requires precise guiding of the proton beam from a cyclotron to patients, 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 are increasingly equipped with network interfaces. Interconnected medical devices, effectively, form a distributed medical device system of a larger scale and complexity that has to be properly designed 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 today are limited in functionality and tend to rely on proprietary communication protocols offered by major vendors. There is, however, a growing realization among clinical professionals that open interoperability between different medical devices will 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 to provide an open standards framework for safe and flexible interconnectivity of medical devices, in order to improve patient safety and health care efficiency. In addition to developing interoperability standards, MD PnP initiative collects and demonstrates clinical scenarios where interoperability leads to improvement over the existing practice.

One example that illustrates how patient safety can be improved 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 surgical operations. 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 the X-ray image be taken without the blur caused by moving lungs, 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 two devices can be used in several ways to ensure that patient safety is not compromised, as discussed in. One possibility is to let the X-ray machine pause and restart the ventilator automatically. A safer alternative, although presenting tight timing constraints, is to let the ventilator transmit its internal state to the X-ray machine. There typically is enough time to take an X-ray image at the end of the breathing cycle, when the patient has finished exhaling until the start of the next inhalation. This approach requires the X-ray machine to know precisely 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 anaesthesiologist monitors sedation of a patient during an operation and decides when an action to adjust the flow of sedative needs to be taken. There is a concern in the medical community that such reliance on “human in the loop” may compromise patient safety. Caregivers, who are often overworked and operate under severe time pressure, may miss a critical warning sign. Nurses typically care for multiple patients at a time and can be distracted at a wrong moment. Using an automatic controller to provide continuous monitoring of the patient state and handling of routine situations would be a big relief to the caregiver and can improve patient care and safety. Although the computer will probably never replace the caregiver completely; it can significantly reduce the workload, calling the caregiver's attention only when something out of the ordinary happens.

#### **4.4 Continuous Monitoring and Care**

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

diagnostic evaluation of vital signs in real-time and make constant care possible.

### **5. Challenges and Opportunities**

As can be seen from the trends described above, the cross-cutting nature of Medical CPS (MCPS) transcends the informational, physical, and medical worlds, and raises significant scientific 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 medical devices opens the way for the dynamic construction and deployment of MCPS to implement custom clinical scenarios that best suit the needs of a given patient. Dynamism in MCPS deployment, in turn, poses a new challenge for ensuring patient safety in these custom scenarios. While safety analysis of dynamically created scenarios is an open problem, one can envision 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. Medical device systems for patients with complicated conditions may involve application of several treatments simultaneously, which affect several body systems in complicated and often insufficiently understood ways. These treatments also can interfere with each other. Effects of each treatment can differ widely from patient to patient. Critical variables are often not directly observable, adding to the uncertainty. Control theoretic methods designed to operate under high parametric uncertainty, such as supervisory adaptive control, may be helpful 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 for the safety analysis of scenarios

#### **5.5 Adaptive Patient-Specific Algorithms and Smart Alarms**

Medical devices are typically designed for groups of patients with similar medical conditions. However, the staggering range of patient responses to the same treatment and variation of vital signs for the same condition make this approach very generic and inefficient.



## 5.6 User-Centered Design

Caregiver errors in using medical devices are a major source of adverse events. Undoubtedly, some of these errors are due to stress and overload that caregivers experience daily. However, a large number of these errors can be attributed to poor user interface design. 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 of medical devices needs to take into account user expectations.

## 5.7 Infrastructure for Medical-Device Integration and Interoperation:

Currently, distributed MCPS are built by a single manufacturer using proprietary communication protocol. While this approach may make regulatory approval easier, it limits the benefits of inter-device communication and stifles creativity of medical professionals. Open interconnectivity standards for MCPS, such as the ICE standard proposed via the MD PnP initiative, lay the groundwork for medical device interoperability. Yet, for these standards to be effective, development and deployment platforms should be developed.

## 5.8 Security and Privacy:

While networking capabilities let medical devices acquire functionality that was never possible previously, they also open the door to a host of new potential problems. Security and privacy concerns are some of those new problems. An attacker who penetrates an MCPS network has the potential to harm and even kill patients by reprogramming devices. The extreme approach, taken by most device manufacturers today, is to limit the functionality that can be invoked through the network interface. In most cases, the device can send out data, such as sensor readings or 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 about to undergo a substantial transformation, both in terms of doctors' and caregivers' expectations of what MCPS can do for them, and in terms of how these systems are developed and approved. The challenges facing MCPS are formidable, yet they present vast opportunities for research with immediate practical impact. This paper summarized the challenges and outlined the most promising research directions.

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