Medical CPS: Opportunities and Challenges

Oleg Sokolsky
PRECISE Center
University of Pennsylvania

Insup Lee, Rahul Mangharam, George Pappas, Rajeev Alur
University of Pennsylvania

John Hatcliff  Julian M. Goldman  Mats Heimdahl
Kansas State University  MGH/Partners  University of Minnesota

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What is a Medical CPS?

• For the purpose of this talk: A collection of **interoperable** medical devices cooperating over the **network** to provide care for a **single patient**
Opportunities of Medical CPS

• Sound record-keeping in real time
  – Close connection to EMR
• Continuous monitoring of patient state
  – Reduced load for nurses
• Sensor fusion
  – Improved diagnostic and decision support
• Physiologic closed-loop control of the treatment process

Promise: more consistent treatment, fewer errors
Challenges of Medical CPS

• General challenges:
  – Interoperability between medical devices
  – Network introduces new patient hazards
  – Ad-hoc assembly at bedside
  – Security vulnerabilities
  – Usability challenges

• Challenges in closed-loop control
  – Control design under extreme uncertainty
  – Safety of closed-loop systems
Regulatory Approval of MCPS

• Current approach to certification:
  – Consider every configuration separately

• Cannot be used for MCPS assembled at bedside
  – Multiple devices in the same category
  – Variation in clinical scenarios
Modular Certification

• An MCPS instance addresses a clinical scenario
• Key idea:
  – Treat clinical scenarios as virtual medical devices
• Replace approval of MCPS instances with
  – Certify the scenario
    • Assuming fixed interfaces to constituent devices
  – Certify the interoperability platform
  – Certify devices w.r.t. interfaces

Joint work with J.M. Goldman, J. Hatcliff, A. King, I. Lee, and many others
Closed-loop Glucose Control

- Promote the quality of glucose regulation
- Reduce caregivers’ workload
  - Alert caregivers only to adverse events
- Improve patient safety

![Diagram showing the integration of a Patient, Glucose Meter, Caregivers, Controller, and Infusion pumps, indicating network connections and alerts.](Diagram.png)
Insulin Protocol Evaluation

• Hospitals use insulin infusion protocols
  – Insulin dosage is calculated by fixed tables/rules
• Computer simulation reveals weaknesses
  – Severe undershooting (hypoglycemia)
  – Significant oscillations of BG level (BG variability)
Model Complexity Trade-off

- State-of-the-art glucose metabolism models
  - High-dimensional (>10) non-linear model
  - Most states are not directly observable
  - Model parameters (>15) are patient dependent and not easily measurable

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<th>Simple linear models</th>
<th>Non-linear maximal models</th>
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In silico Protocol Enhancement

• Patient model: UVA/Padova T1DM Simulator©
  – Based on a maximal model (Man et al., 2007)
  – Validated against data collected from 57 real patients

• Protocol enhancement by a Proportional-Derivative controller
  – Classical PID tuning cannot be used with this model
    • The “optimal” controller setting is found by sampling P,D parameter space over the set of virtual patients
  – PD controller overcomes the weaknesses exhibited by the old protocol while preserving its strengths
  – Falls back on rule-based protocol in critical range
Security of MCPS

• MCPS involve remotely-controlled actuators
  – Intruder can directly harm the patient
• Connected to the hospital infrastructure
  – Increased opportunity for external attack
• Does this make the network as critical as the most critical component in MCPS?
  – Huge regulatory burden and cost increases
Security Analysis for MCPS

- An attack-consequences model allows us to reason about criticality levels of MCPS components
- Implications for hazard analysis and regulatory approval
- If alarm subsystem is well protected, network criticality level can be reduced in some cases

Research Issues

• Better patient models
  – Currently, impact on high fidelity
  – Need models more suitable for control design

• Easier control design, better decision support
  – More observability, less noise
  – Innovation in medical sensors

• Usability
  – Beyond traditional HCI