Medical CPS: Opportunities and Challenges

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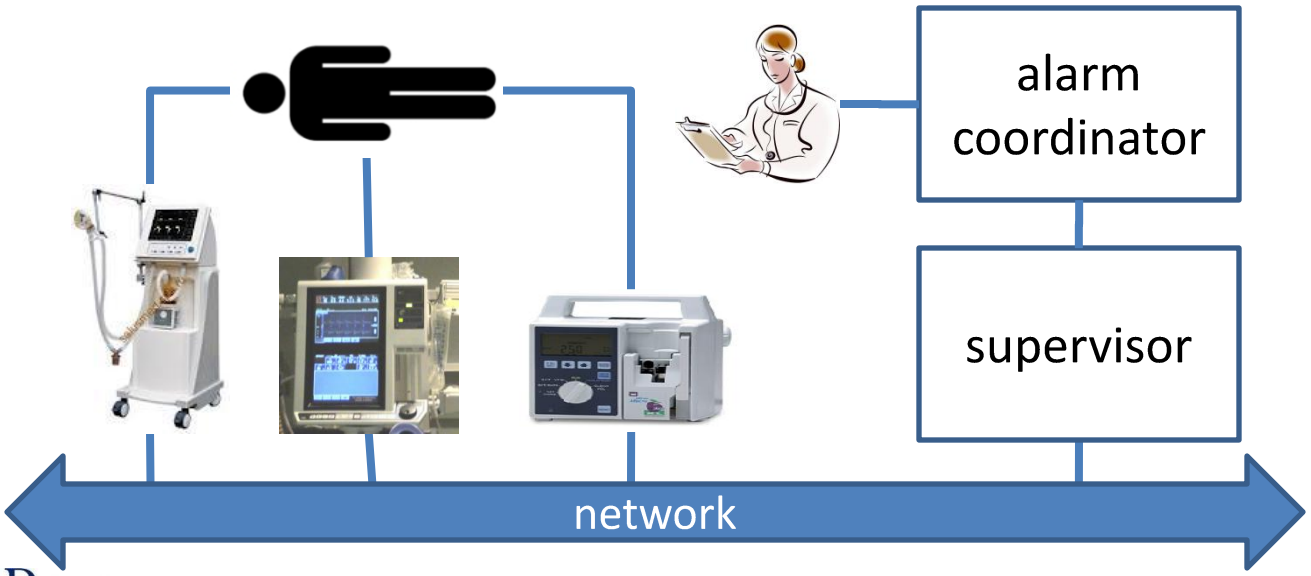
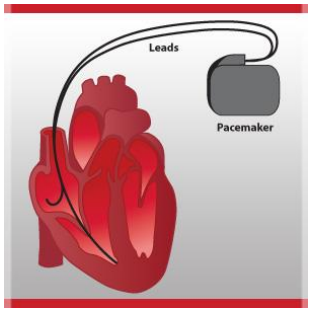
What is a Medical CPS?

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



[Other MCPS]



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

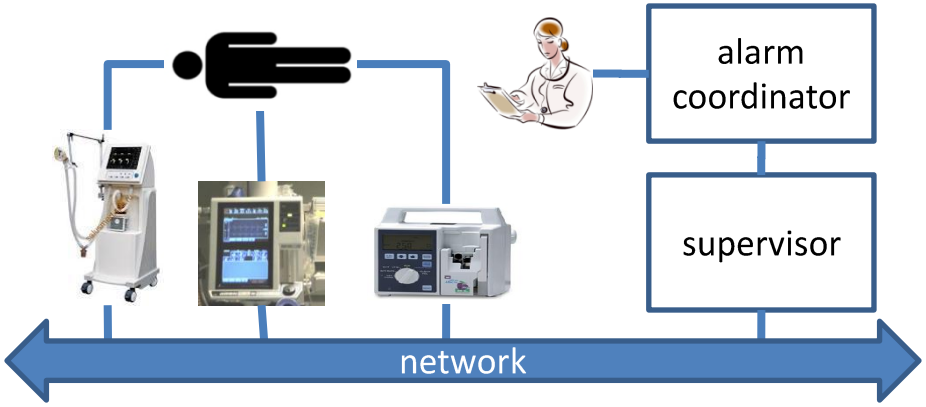
Promise: *more consistent treatment, fewer errors*

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

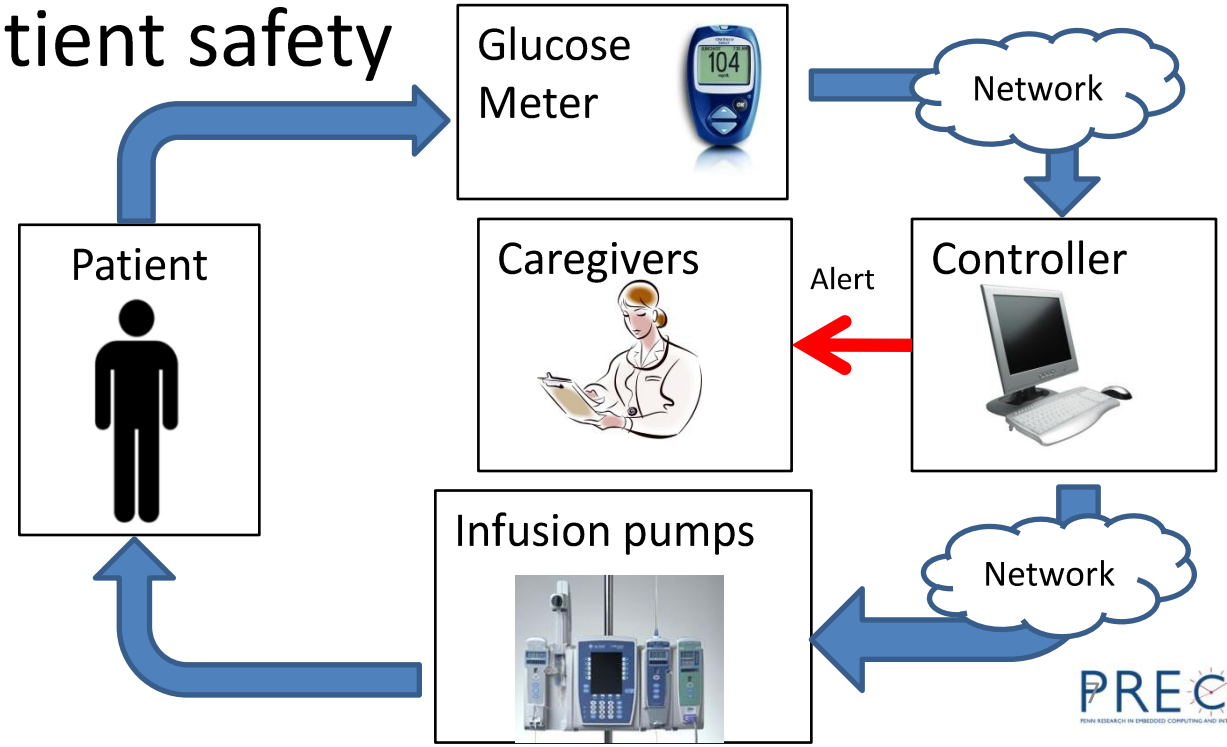
Modular Certification

- 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

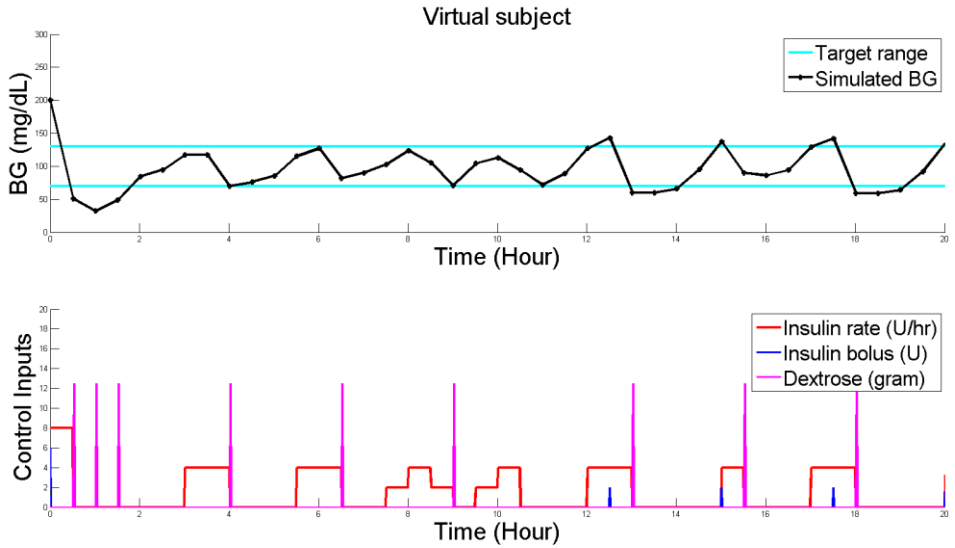
Closed-loop Glucose Control

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



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)



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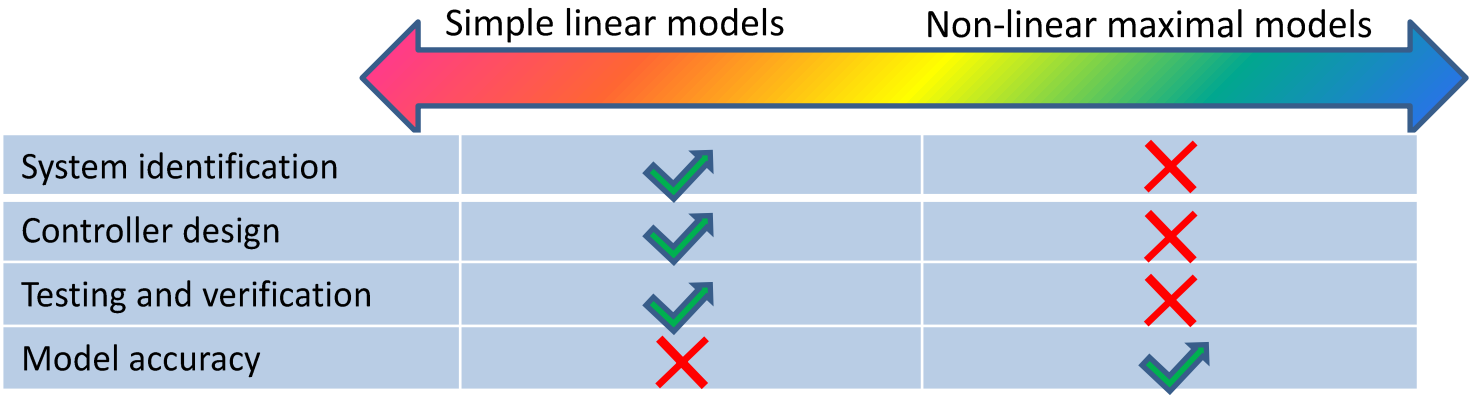
Model Complexity Trade-off

- 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



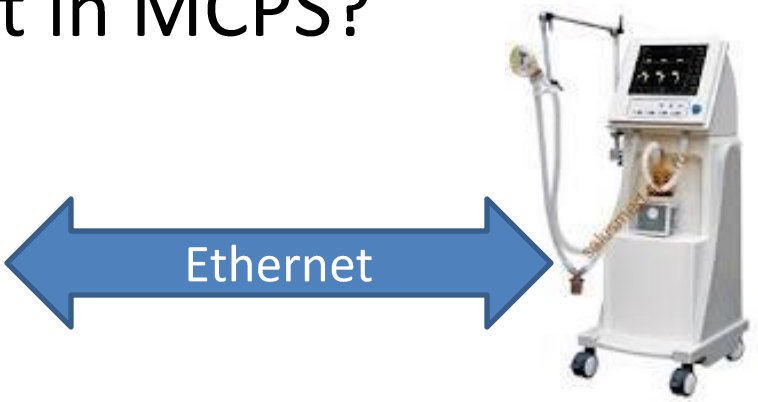
In silico Protocol Enhancement

- 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

Joint work with B. Kohl, S. Chen, I. Lee. Submitted for review.

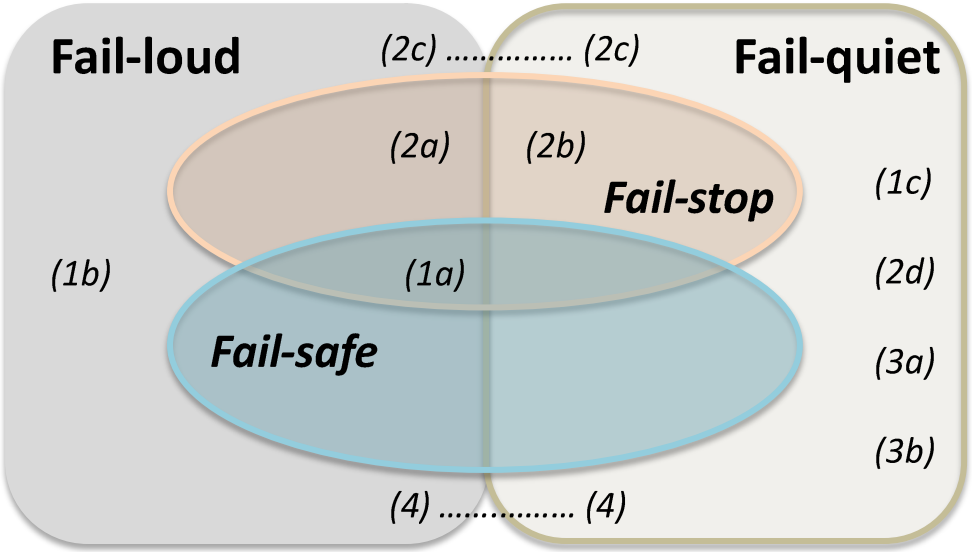
Security of MCPS

- 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

Joint work with E. Vasserman , K. Venkatasubramanian, and I. Lee. To appear in IEEE SnP

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