Data-Driven Pill Monitoring

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Goals of the Project

- Since the 1960's, the medication rate has not significantly decreased: 1 out of 10 of the medications given to patients in a hospital on average are incorrect.
- Develop a novel DDDAS framework for the development and deployment of *cheaper, better, and safer* next generation medical systems consisting of integrated and cooperating medical devices for guaranteed accurate and safe pill delivery to patients, whether in a medical facility, home, or while traveling.
- Extensible to numerous other areas outside of the medical field in which accuracy, multiple information sources, privacy, and similar identification methods are applicable.

Goals of the Project

- Design and implement an open source
  - medical device
  - drug database
  - pharmacist and doctor coordination framework

  and combine it with a model based component oriented programming methodology for the coordination of pill delivery.
- Develop a formal framework for reasoning about device and people behaviors and clinical workflows.
- Framework is critical to the success of project.

Foundations of the Framework

- Framework foundations will enable rapid development, verification, and certification of new medical systems and their device components for pill delivery.
- Black box recording capabilities will provide
  - forensic data for analysis of the model based approach,
  - failures of devices, clinical personnel,
  - multiple database coordination errors,
  - clinical scenario development and modeling, and
  - supply evidence for and to both speed up and simplify the regulatory approval process.

Foundations of the Framework

- Developing new and using existing open source tools supporting the framework
  - will speed up the project and possible certification of the framework and
  - improve the likelihood of its adoption by the medical community through technology transfers.
- Improving the quality of health care while reducing costs will be an outcome of the framework.

Impacts

- A leap in accuracy in pill dispensation at medical facilities of all kinds.
- Receiving the wrong medication (or incorrect dosage at some given time) kills more patients unnecessarily than the 8th leading cause of death in the United States (using a very conservative estimate for deaths), killing more patients than
  - AIDS,
  - traffic deaths, and
  - breast cancer.

Goals of the Project

- Improving pill dispensation and providing an automatic check of the
  - correctness of the dosage,
  - medical history, and
  - patterns of errors of specific health caregivers, including doctors to pharmacists to the person dispensing the pills,

  will reduce accidental deaths and allergic complications.

Impacts Real-Life Example: You Have a Stroke

- Someone else must answer a phone 24/7 to explain instantly your entire medicine and allergy history plus all medical processes that have been performed on you at possibly multiple hospitals over a small number of days since your stroke.
- There is absolutely no system in existence today that doctors can use to determine what has been done to you and if new medications will do more harm than good.
- The framework in this project will provide a prototypical system suitable for this situation as well as much more mundane ones that can still lead to sudden, completely unexpected death.

To Err Is Human Report

- A report from National Institute of Medicine (2002) with a lot of disturbing statistics about errors in medicine delivery.
- Two recommendations for accurate pill delivery:
  - Have a second person follow and check on the principal caregiver who is dispensing pills. This is time consuming and expensive.
  - Encourage the development of new devices and software systems to scan pills, patient identification, and check through a computer system that the pills are accurate.

We are developing an *acoustic resonance spectroscopy* device with *integrated sensing and processing* (ARS-ISP) as a *DDDAS* (or a *Cyber-Applications-System*).

Creating the (Test) Framework

- A mechanism to tie together all of a patient's medical, doctor, and pharmaceutical records together currently does not exist.
- We have to create databases to use in developing the overall framework that contain ficticious, sensitive data about ficticious patients.
- Our ficticious databases need to be dispersed over a wide area, which means that we will be asking recent collaborators in older research projects to provide cycles at geographically diverse locations.

The ARS-ISP Device

Piezo transmitter

Stainless steel holder

Pill

Stainless steel holder

Piezo receiver

The ARS-ISP Device

- The planned ARS-ISP devices (handheld versus tabletop) will use integrated sensing and processing acoustic resonance spectroscopy.
- Devices need to be small enough to be carried easily by a medical caregiver yet have enough capabilities to identify pills, patients, and communicate wirelessly with databases on potentially remote computers.
- Identify one pill at a time now, multiple ones in a paper cup eventually.

From the Databases

- The patient's medical history plus possible allergies and bad reactions to medications so that a patient is not accidentally given medications that are harmful or could cause death.
- The pharmacy or pharmacies that issues the medication(s) and that have the original prescription(s) so that the medications can be verified each time.
- Compare drugs to the patient's medical history to determine if the drugs are indicated for the conditions observed.
- Generate a warning if the prescribed dose falls into a range identified as an overdose in the package insert.
- The time frame that the medications can be given safely and the past history of when the medications were given.

Communications Scenarios Between Devices

- Broadcast that a nontrivial number of some type of pill registers as defective, indicating a bad lot of pills.
- Someone using a device is obviously having difficulties operating it correctly and requires assistance.
- Part of the network is down. The devices can form an ad hoc network to try to find a path to a device that can securely communicate with the rest of the overall network.
- A patient needs instant help due to a negative reaction to medication just given. Other caregivers using the devices should be alerted for other patients with similar or identical medications without violating patient privacy laws.
- A possible patient privacy violation.

Integrated Sensing and Processing

- We can deliver an infinite number of acoustic spectra, but that defeats the creation of a small, embedded ARS-ISP device that is useful in itself.
- We choose a small number of spectra, which changes slightly over time based on environmental and personnel factors.
- Once the spectrum of a sample has been collected, it will be classified to determine the substance present. The Bootstrap Error-adjusted Single-sample Technique (BEST) is the analytical basis of our ARS-ISP device, and the foundation for the pill chemical identification library. The BEST metric is a clustering technique for exploring distributions of spectra in hyperspace.

Integrated Sensing and Processing

- A sample spectrum will be compared to each substance in a biogeochemical and industrial library based on its direction and distance, measured in standard deviation units, from the known substances.
- BEST handles asymmetric standard deviations surrounding each substance nonparametrically.
- A sample within 3 standard deviation units of a substance will be considered to be composed of the matching substance while others will be classified as unknown substances.

Integrated Sensing and Processing

- For a given library entry, the BEST algorithm will be suitably approximated using multiple linear regression to substantially reduce computational requirements.
- The BEST standard deviation units will be precalculated before the ARS-ISP device is deployed in a large number of directions from the population means, and multiple linear regression will be used to fit the standard deviation contours as a function of direction.
- The BEST classification algorithm will be performed in situ, allowing a sensor to classify many samples, only producing error notifications when an interesting substance is found.

Networking

- Distributed processes execute on different ARS-ISP devices and cooperate by exchanging messages with a server to achieve a common objective.
- Required: Accomplish these tasks by specific deadlines, which are nearly immediate in time.
- The algorithms need to negotiate their requirements with the communication services in advance.
- Success depends crucially on the ability of the hosts and network to manage the communication to guarantee a pre-specified quality of service, such as deadlines, latency, and bandwidth, with a given probability over existing network protocols.

Networking Requirements with Guarantees

- *Scalable*: The overhead of schedulability testing (i.e., delay verification) is independent of the number of ARS-ISP device flows in the system.
- *Effective*: Schedulability testing maximizes system resource utilization to the greatest extent possible. It is highly accurate even though it does not rely on per-flow information.
- *Adaptive*: Resource allocation has to be cognizant of the dynamic fluctuations in resource availability. Better quality of services and better utilization of system resources results.
- *Compatible*: Our system must be compatible with current industrial practice.
- *Fault tolerance* of the server and how much (or little) *redundacy* is necessary to ensure an always up system.

Real-Time Issues

- Define real-time using scheduling/priority assignment: manipulate the service order in accordance to real time requirements.
- How to manipulate the queues.
- What can be expected (some kind of evaluation and/or assessment).
- Studies have shown that just manipulating queues is not necessarily sufficient to actually deliver real-time services.
- Challenge is how to develop and use a reservation system in the current IP based distributed system.

Networking

- The key here is to produce a schedulability test that can testify if a request can make its end-to-end deadline.
- The test must be scalable since our system is both very large and complex, which is an extremely difficult (and hence interesting) problem.
- Schedulability testing is the key to the delay guarantee approach and has advantages:
  - If a request is guaranteed at request time, the requestor gains immediate confidence that the system can successfully guarantee the request.
  - If the request is denied by the testing algorithm, the requestor can then quickly find several alternatives.
  - Testability can be applied directly to any adaptation scheme.

Generating the Pill Library

- Identification of pills is somewhat sensitive to the temperature and humidity conditions.
- The chemical library that the ARS-ISP device needs must be re-calibrated from time to time.
- The process requires recomputing the correct acoustic waves and downloading a new library to the devices.
- The computational time is nontrivial for a large number of pills and is well suited to cluster computing on any scale from a traditional or GP-GPU cluster to a Petascale system.
- The result is a small number of acoustic waves per pill based on solving complex optimization problems.

Conclusions

- Accurate pill identification is an important area with many interesting problems to overcome.
- The process can be formulated as a DDDAS.
- The health field needs what was described here as soon as possible.
  - First for caregivers in controlled environments.
  - Second for the general population for home use.
- Systems will only be delivered once patient privacy issues are overcome and new agreements on what can be shared and how are devised, which are government regulatory issues.
- Plenty of room for academic research to provide working examples for technology transfers and certification help.