Data-Driven Pill Monitoring

Craig C. Douglas

University of Wyoming School of Energy Resources Distinguished Professor of Mathematics
Laramie, WY, USA

with Li Deng, Gundolf Haase, Hyoseop Lee, and Robert Lodder

Partial funding from the NSF, State of Wyoming, and KAUST
Introduction

Goals of the project
Foundations of the framework
Impacts

The framework

The ARS-ISP Device
Integrated Sensing and Processing
Networking
Generating the pill library

Conclusions
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.
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 fictitious, sensitive data about fictitious patients.
- Our fictitious 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) *redundancy* 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.
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.