

Current and Future Opportunities for, Challenges, and Barriers to Adoption of Connected Healthcare

IEEE CHASE
June 2016

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Current and Future Opportunities for, Challenges, and Barriers to Adoption of Connected Healthcare

Q & A session

Q1: Data security: how do we ensure data security on the device and during data transfer to ensure FDA approval of the device and software applications, especially as we all want to move to a “bring your own device” model for ambulatory patients?

Q2: Data fidelity: Will we achieve clinically-acceptable automatic detection of clean and noisy data? What approaches are most promising?

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IEEE/NIH 2016

Special Topics Conference
on Healthcare Innovations and Point-of-Care Technologies

Mexico, November 9-11, 2016

CasaMagna Marriott Cancun Resort

Keynote SpeakerRoderic Pettigrew, MD, PhD
Director, NIBIB, NIH**Invited Speakers and Panelists**Steve Schachter, MD,
CIMIT, Harvard Medical
SchoolJim Gallarda, PhD, Gates
FoundationJulian Goldman, MD, MGH
and Partners HealthCarePaul Pearlman, PhD, NCI
Jie Chen, PhD, University of
Alberta, CanadaErica Forzani, PhD, Arizona State
University**Conference Co-Chairs**Atam P Dhawan, PhD, NJIT
Paul Pearlman, PhD, NCI**Program Co-Chairs**Ki Chon, PhD, University
of ConnecticutEmilio Sacristan, PhD,
CI3M, Mexico**International Program Co-Chairs**Srinidhi Tridandapani, MD,
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Switzerland**Program Committee**

Tiffani Lash, PhD, NIBIB

Mary Rodgers, PhD, NIBIB

Erin Iturriaga, MSN, NHLBI

Amy Kraftt, PhD, NIAID

Christine Kelley, PhD, NIBIB

The IEEE EMBS Special Topic Conference on Healthcare Innovations & Point-of-Care Technologies will be held in Mexico from 9-11 November 2016. This conference will focus on healthcare innovations and point-of-care technologies, and their clinical translation to address challenges in global quality healthcare. The proposed conference will provide an international forum with clinicians, healthcare providers, industry experts, innovators, researchers and students to define clinical needs and technology solutions towards commercialization and translation to clinical applications across different environments and infrastructures. Panel discussions and open forum sessions along with research presentations will focus on the development, clinical translation, commercialization, implementation and user-compliance of innovative healthcare and point-of-care technologies in clinical (hospital, emergency, acute, chronic and primary care), non-traditional (consumer) and under-resourced settings.

Conference themes would include a topical coverage of (but not limited to):

- Healthcare Innovations: Devices, Systems and Services with applications to monitoring, diagnosis, therapeutic, surgical, emergency care and interventional protocols.
- Point-Of-Care (POC) Technologies Clinical Translational of Healthcare Innovations and POC technologies
- POC Technologies in Under Resources Settings
- Lab-on-a-chip
- Devices for Molecular Epidemiology
- Compliance and Acceptance of POC Technologies
- Evidence-based Medicine
- Personalized, Preventive and Precision Medicine
- mHealth Innovations
- Wireless Communications and device data control and fusion
- Critical Care
- Medical and Healthcare Data Communication, Security, Privacy
- Infrastructure Independent Care
- Integration of innovations and point of care diagnostic devices into systems of healthcare
- Regulatory challenges (US and International)
- Global Healthcare Challenges

Important Dates:**4-page papers**Submission opens:
May 9, 2016Submission deadline:
July 1, 2016Accept /reject notification:
Jul 21, 2016Final submission deadline:
Aug 8, 2016**Student Paper Award**Submission deadline:
July 1, 2016**1-page papers**Submission opens:
May 15, 2016Submission deadline:
July 15, 2016Accept /reject notification:
Jul 25, 2016Final submission deadline:
Aug 15, 2016**Hotel Reservation**Group Rate Cut Off:
Oct 8, 2016

Current and Future Opportunities for, Challenges, and Barriers to Adoption of Connected Healthcare

Florence Hudson
Senior Vice President & Chief Innovation Officer
Internet2

IEEE CHASE
June 2016



Aspirational view of Connected Healthcare



But...what are the risks?

- Trust?
- Identity?
- Privacy?
- Protection?
- Safety?
- Security?

TIPPSS

<http://bit.ly/1EJnTjv>

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The evolution of today's Connected Healthcare reality

- Number of connected devices is increasing with the goal to improve patient care and create efficiencies in the healthcare system: 10-15M medical devices in US hospitals today, with an average of 10-15 devices allocated per bed
- Growing “Bring Your Own Device” paradigm for providers and patients
- Proprietary/closed devices and systems are “assumed” secure
- Inadequate teamwork between medical providers, device vendors, technology innovators, cybersecurity experts, insurance companies, regulators, patients, to assess & address vulnerabilities
- ROI not agreed for improved security needs across ecosystem
- Rate of innovation is slow, and will continue to be unless we work as a Collaborative Innovation Community



“Only when we work collaboratively and openly in a trusted environment will we be able to best protect patient safety and stay ahead of cybersecurity threats”

- Dr. Suzanne Schwartz, FDA’s Center for Devices and Radiological Health

- FDA recommends that manufacturers adhere to the **NIST Framework for Improving Critical Infrastructure Cybersecurity** (Identify, Protect, Detect, Respond, and Recover).
- Calls for the creation of an Information Sharing Analysis Organization (ISAO) to collect cyber security threat information that is shared amongst value chain participants.
- **Failure to maintain cybersecurity** can result in compromised device functionality, loss of data availability or integrity, or exposure of other connected devices or networks.
- FDA guidance applies to the **full life cycle of a medical device** with embedded software, including firmware, and software that acts as a medical device.
- FDA recognizes that medical device security is a **shared responsibility**:
 - Healthcare facilities
 - Providers
 - Patients
 - Medical device manufacturers

Sources: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf>
<http://www.modernhealthcare.com/article/20160119/NEWS/160119860?template=print>



“If people will follow the guidance, it represents basic common-sense principles for engineering or developing new devices.”

- Mac McMillan, Co-Founder and CEO of CynergisTek, Inc.

- FDA recommendations **address “basic” cyber security components** for manufacturers to address: up-to-date operating systems, security patch management, and provide audit trails for device access
- **Device manufacturers will only need to report vulnerabilities to the FDA** when they compromise the device’s clinical performance with potential for serious, adverse health consequences
- Making the **guidelines into regulations** will further ensure public safety from an industry dependent upon compliance and regulations
- **Constant vigilance and guideline modifications** will be needed to stay abreast of the latest threats to public safety

Sources: <http://www.healthcareitnews.com/news/report-calls-out-weak-fda-stance-medical-device-cybersecurity-favors-stronger-regulation>
<http://www.modernhealthcare.com/article/20160119/NEWS/160119860>
<http://citech.org/wp-content/uploads/2016/02/CIT- Blog-FDA-Cyber-Security-Guidelines2.pdf>
<http://www.techtimes.com/articles/126019/20160120/fda-urges-medical-device-manufacturers-to-tighten-cybersecurity.htm>



Addressing TIPSS is essential to achieving safe, secure, scalable Connected Healthcare adoption

Trust
Intity
Privacy
Protection
Safety
Security



Across elements of connected ecosystem:

- Users
- Devices
- Gateways
- Communications
- Clouds
- Software
- Services
- Data

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Questions & Answers...
Thank You
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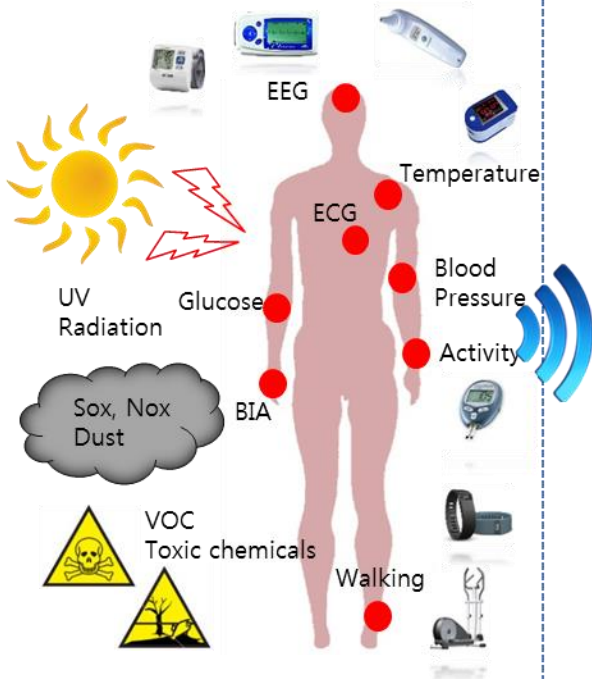
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Connected / Mobile Healthcare Ecosystem

Sensing



Collecting of health and Environmental data

- Device: Patch, watch, glasses
- Data: Blood pressure, glucose, heart rate, body temp., etc.

Hub / Gateways



Data transfer

- Transferring of collected data through mobile devices
- Fixed gateways for data collecting/transferring

DB / Analytics



Data analysis

- PHR, EHR data storing
- Analysis of collected data to find useful meaning

Service / Consultant



Healthcare service

- Providing healthcare service from the data analysis

Consumer Region

Provider Region

Samsung's Fitness Device Portfolio (current)



S Band



Gear Fit



S Health



Gear S



HRM Belt



Gear 2



Body Scale

Samsung's Direction to Mobile Healthcare

Smartphone with physiological signal sensing

- Blood glucose, body temperature, heart rate, SpO2, body fat, stress (Lifewatch)
- '12 CE approved



Lifewatch

Demonstration

Smartphone connected device

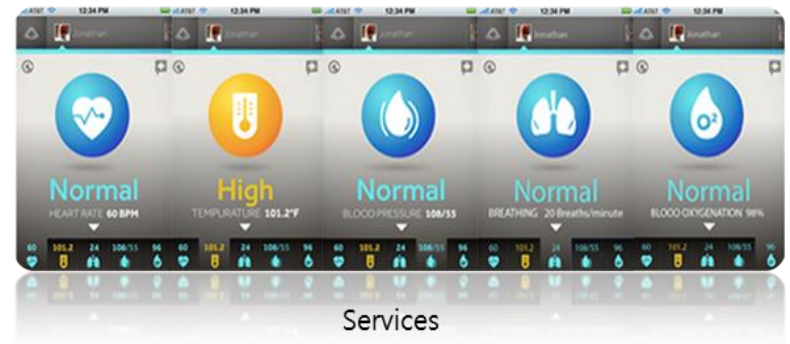
- Body temperature, heart rate, ECG, SpO2, body fat, stress (Scanadu)



SCOUT



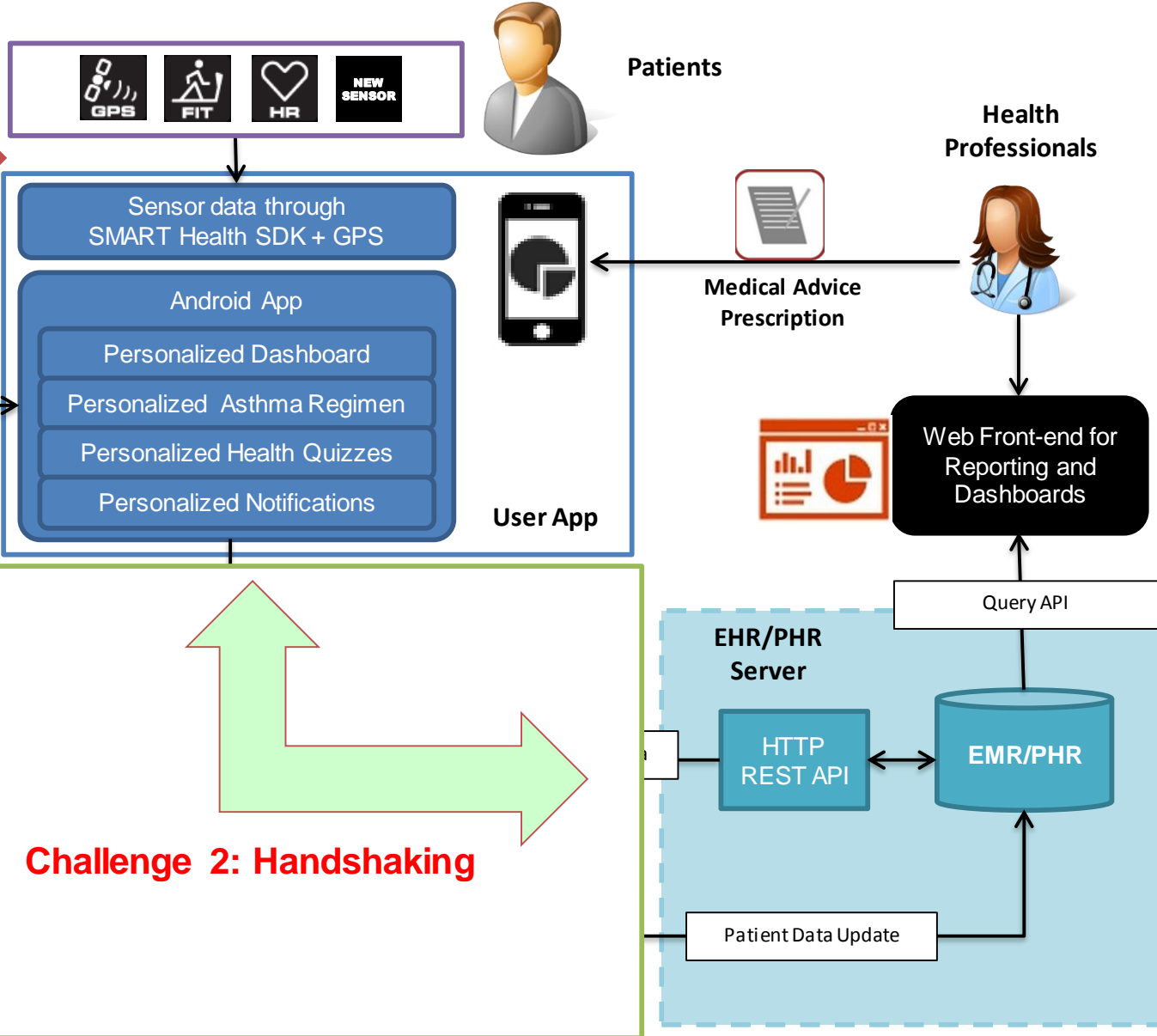
Demonstration



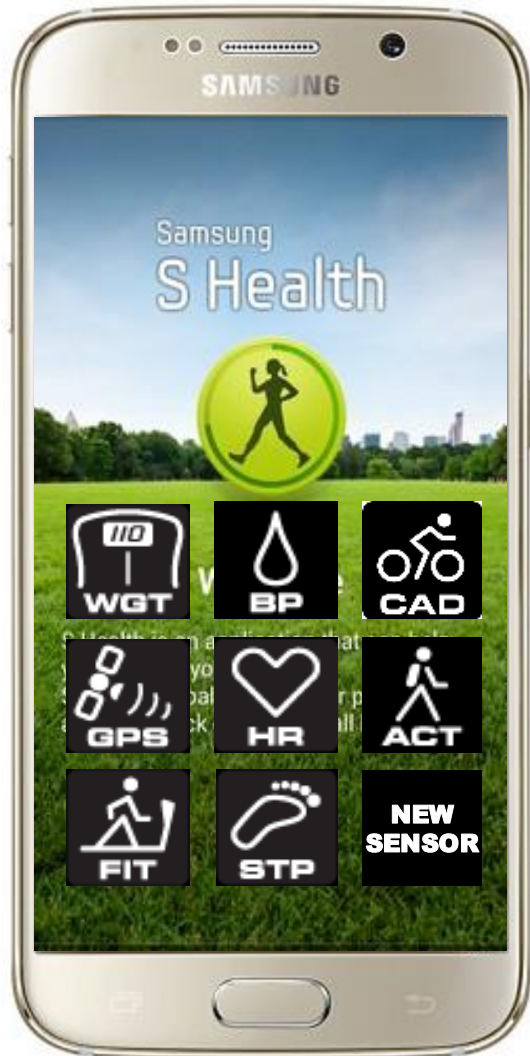
Services

Connected Healthcare System & Challenges

Challenge 1: Device Interoperability



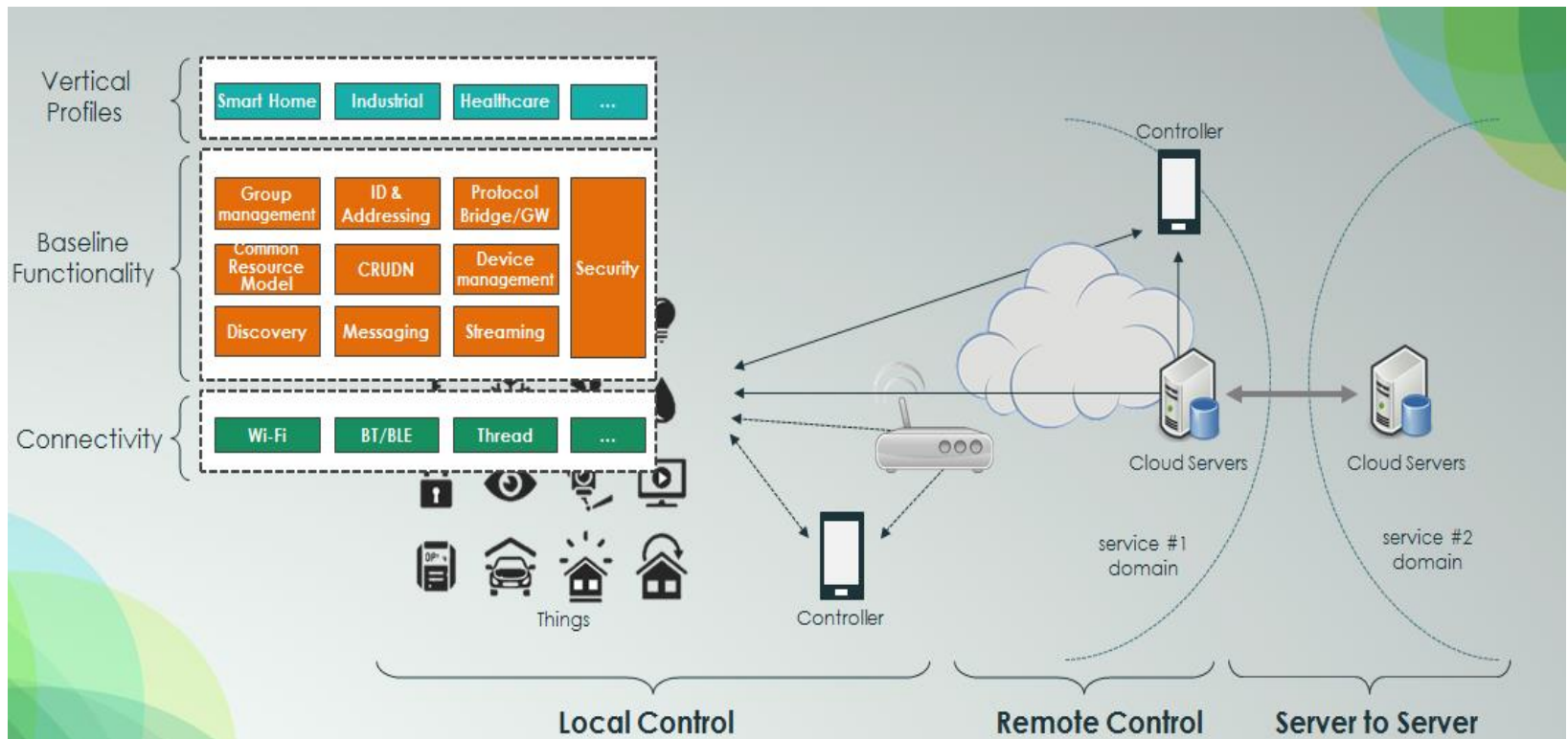
Challenge1: Device Interoperability



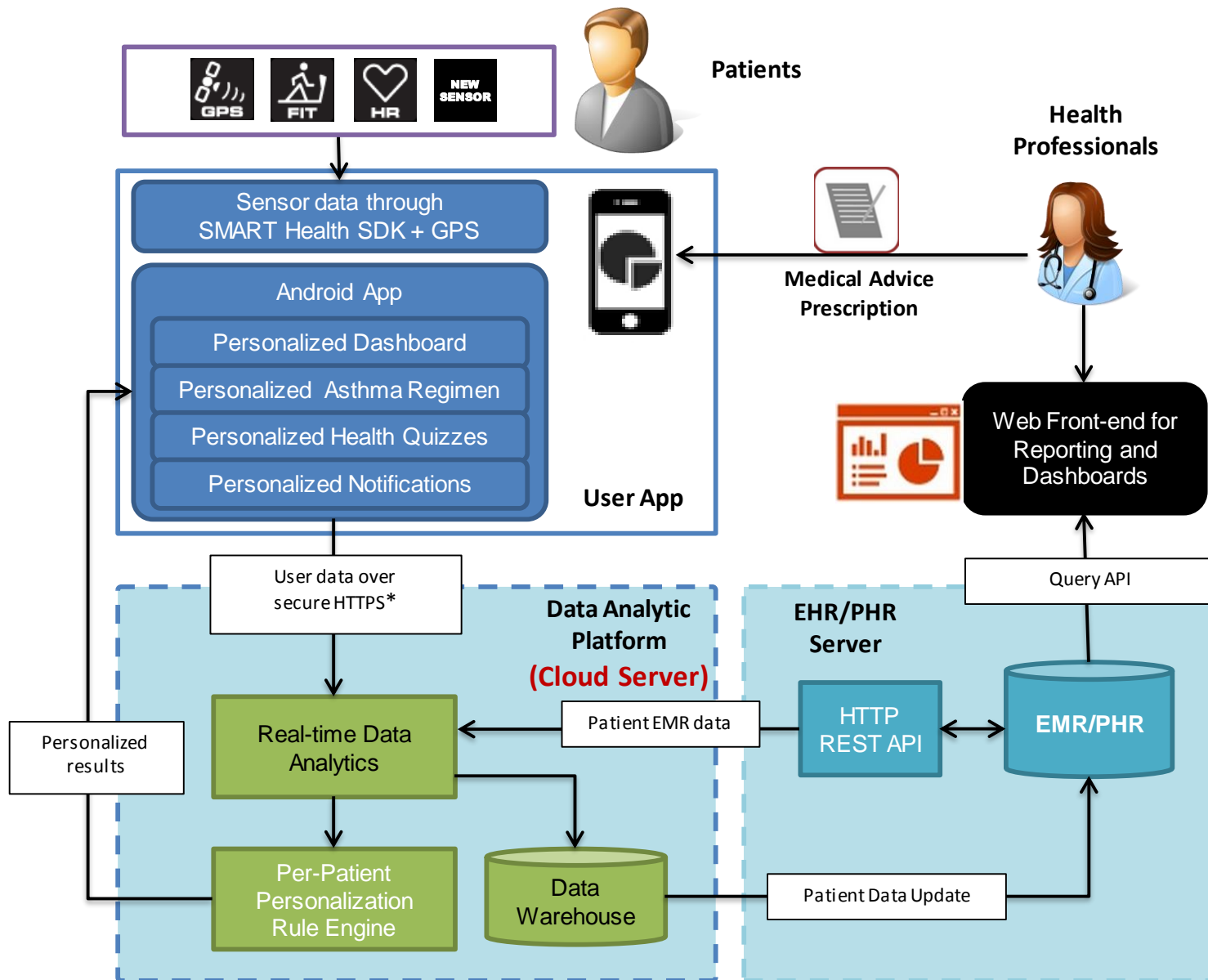
IEEE 11073 PHD	ANT+	Samsung
Pulse oximeter	-	Pulse oximeter
Basic electrocardiograph	-	ECG monitor(Heart Rate Monitor)
Blood pressure monitor	Blood Pressure	Blood pressure
Thermometer	-	Thermometer
Weighing scale	Weight Scale	Weighing Scale
Body composition analyzer		Body composition analyzer
International Normalized Ratio monitor	-	-
Glucose meter	Glucose (Draft)	Glucose meter
Peak expiratory flow monitor	-	Peak expiratory flow monitor
Cardiovascular fitness & activity monitor	Fitness Equipment, Heart Rate Monitor	Fitness device
Strength fitness equipment		
Independent living activity hub	-	-
Medication monitor	-	Medication
-	Bicycle Power	Bicycle PSC
-	Bicycle Speed and Cadence	(Power Speed Cadence)
-	Environment	-
-	Geocache	-
-	Multi Sports Speed & Distance Monitor	Speed and Distance Monitor
-	Stride Based Speed & Distance Monitor	
-	-	Sleep Monitor
-	-	Insulin Pen Data Logger

Standardization & Test Beds

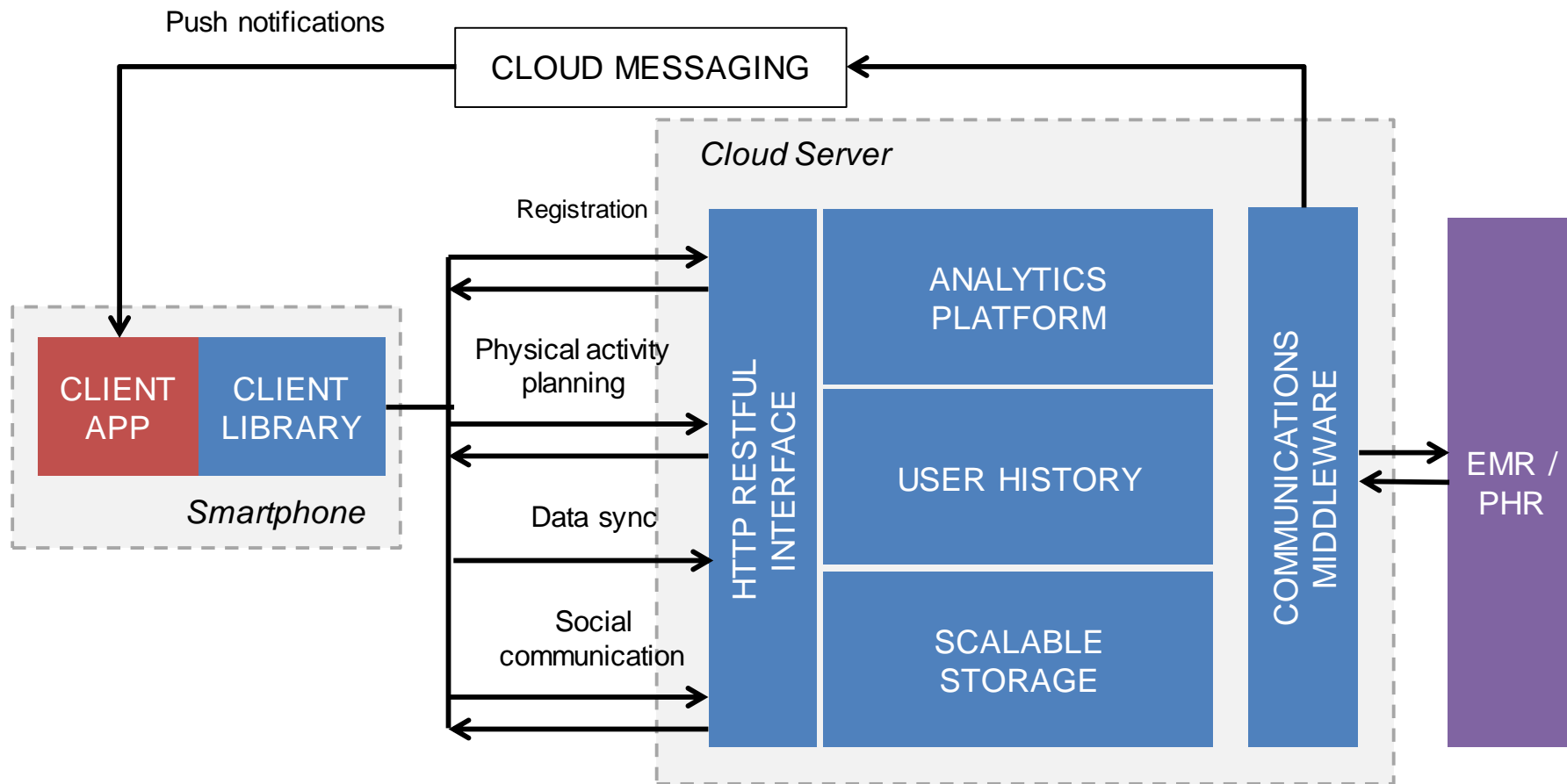
- Industrial Internet Consortium (IIC)
 - Application-specific testbeds
 - Build vertical eco-system
- Open Interconnect Consortium (OIC)
 - Standardization (Smart Home/IoT)



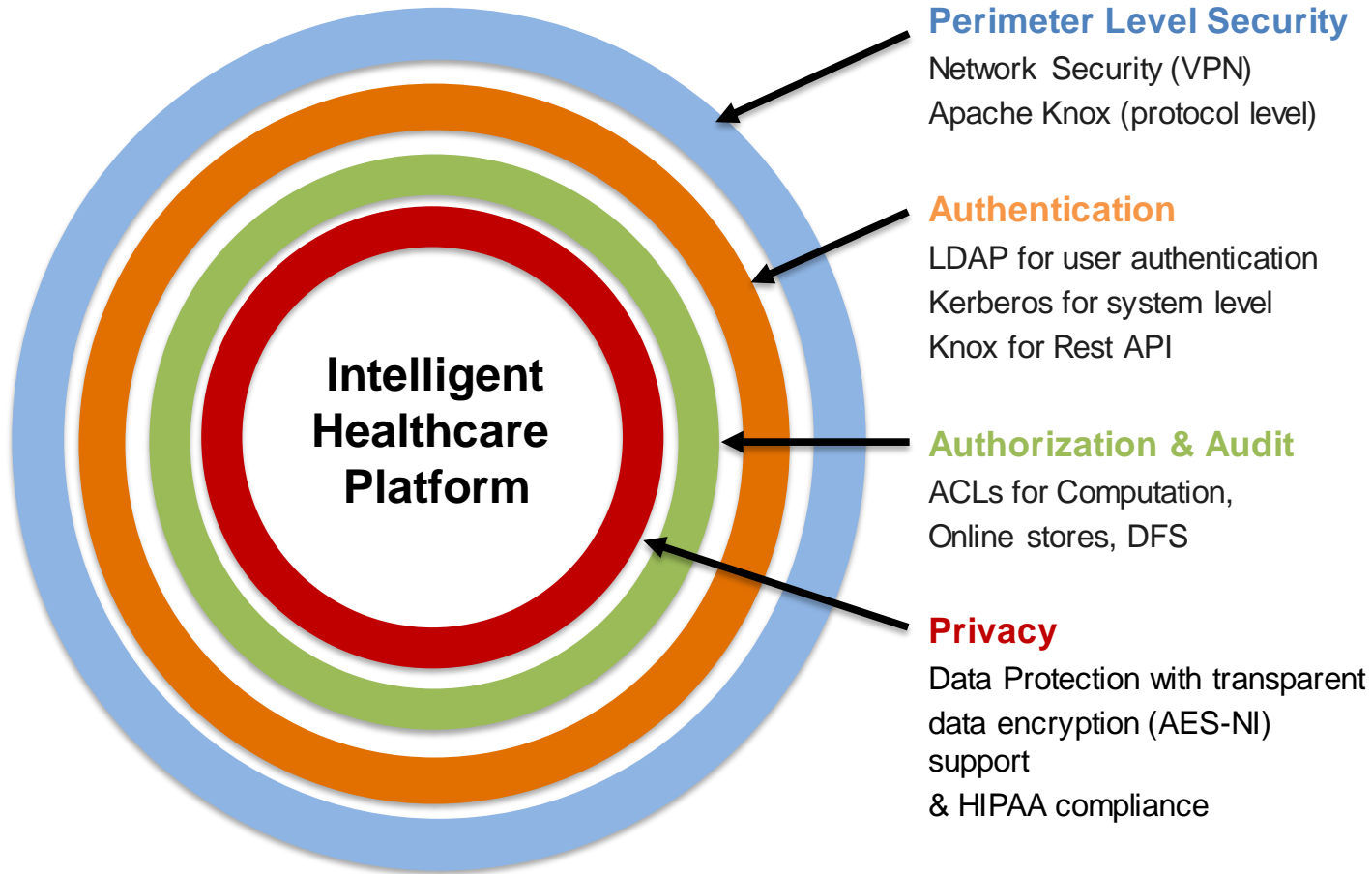
Challenge 2: Cloud-based Data Analytics



Challenge 2: Cloud-based Data Analytics



Security & Privacy





Health Research at the NSF

Wendy Nilsen, PhD

Program Director, Smart and Connected Health

Background NSF

- Health research can be found in many areas in NSF and within the mission of several cross-directorate initiatives
- It is a case of use-inspired basic research. The scientific advances in basic science can be in computing, information science, engineering or social or behavioral science. The benefit to health research is important, but second to the advances in basic science.
- Three major homes for this research:
 - Smart and Connected Health
 - Big Data
 - Cyber-physical Systems
 - Core Programs



Smart & Connected Health (SCH)

Inter-Agency Program

National Science Foundation

National Institutes of Health

NSF Solicitation NSF 13-543

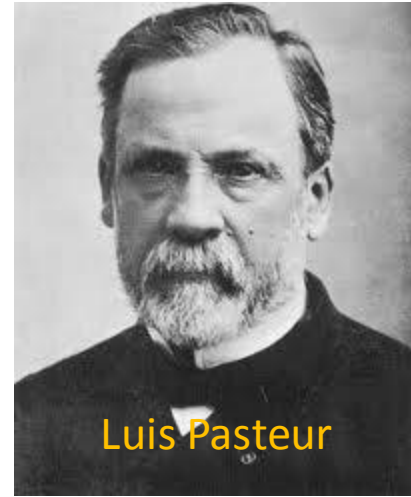
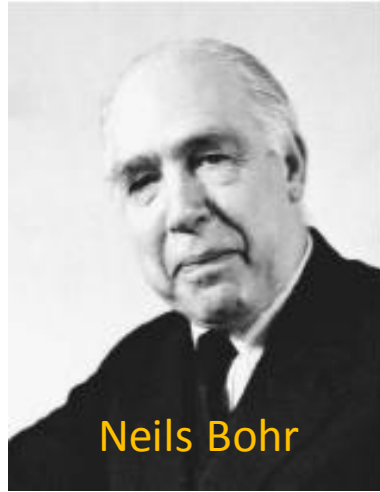
Wendy Nilsen, PhD

Program Director, Smart and Connected Health

Computer and Information Sciences and Engineering, NSF

Pasteur's Quadrant

Quest for Basic Understanding



Application Inspired:
Consideration of Use

Overarching Goals of SCH

- To transform health:
 - ✓ from reactive to **proactive**
 - ✓ from experienced-based to **evidence-based medicine**
 - ✓ From clinic-centered to **patient center care**
 - ✓ To wellness that extends to the **home**, workplace and community
 - ✓ Move focus from disease to **health** and **wellbeing** at the **individual, system, and organizational level**



Scope of SCH Program

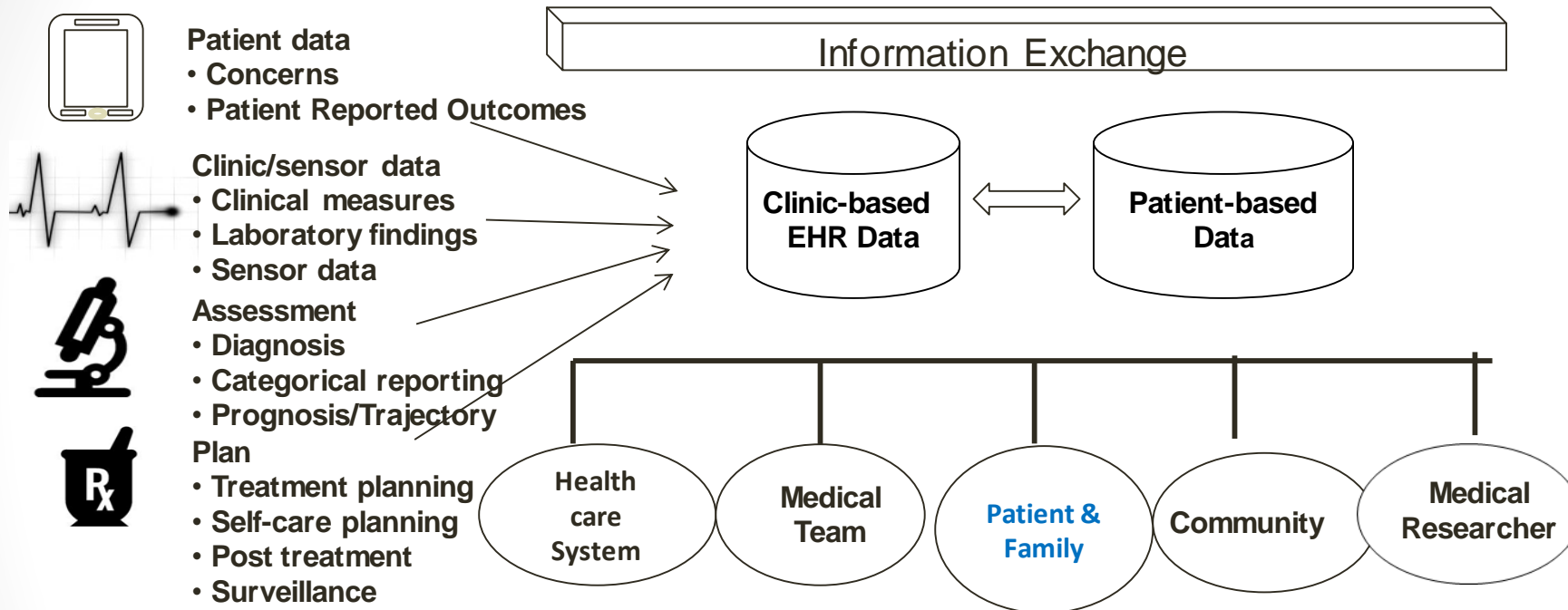
***Goal:** Seek improvements in safe, effective, efficient, equitable, & patient-centered health through innovations in fundamental computer & information sciences, engineering & social, behavioral & economic sciences*

- **Funded** work must include & address:
 - ✓ A key health problem
 - ✓ Fill in research gaps that exist in science & technology in support of health & wellness
 - ✓ Include a research team with appropriate expertise in the major areas involved in the work
- Activities should **complement** rather than duplicate core programs of NSF & NIH as well as those of other agencies (ex. Agency for Healthcare Research and Quality / Veteran's Administration)





Smart and Connected Health: People, Technology, Process



- Risk modeling
- Diagnostic support
- Treatment selection
- Guideline adherence
- Error detection/correction

- Social support
- Precision tailoring
- Reduce disparities
- Streamline care/Efficiency
- Create a health CPS culture

- Situational awareness
- Population health
- Continuity of care
- Identify side effects
- Inform discovery

Smart and Connected Health Research Areas

Digital Health Information Infrastructure

Informatics and Infrastructure

- Integration of EHR, clinical and patient data
- Access to information, data harmonization
- Semantic representation, fusion, visualization

Data to Knowledge to Decision

Reasoning under uncertainty

- Datamining and machine learning
- Inference, cognitive decision support system
- Bring raw image data to clinical practice

Empowered Individuals

Energized, enabled, educated

- Systems for empowering patient
- Models of readiness to change
- State assessment from images video

Sensors, Devices, and Robotics

Sensor-based actuation

- Assistive technologies embodying computational intelligence
- Medical devices, co-robots, cognitive orthotics, rehab coaches

What NOT to do!

The following will likely result in a declined proposal:

- Intellectual merit is exclusively focused in health/health care
 - ✓ SCH requires transformative advancements in computer science, engineering, behavioral and/or social sciences inspired by a need in health or healthcare
- Collaborations with medical providers who have no experience in research
 - ✓ Appropriate research collaborators are key to integrating technical advancements with challenges in the health field
- Proposal is written by yourself and health collaborator is only consulted just prior to submission
 - ✓ Proposed research should be influenced by health collaborators from its inception!
 - ✓ Consider attending grand rounds to immerse yourself in health challenges and meet collaborators, or attend technical conferences to meet computer scientists and engineering collaborators
- Propose clinical trials or traditional disease-centric medical, clinical, pharmacological, biological, or physiological studies



NSF SCH Contacts

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- **Mary Rodgers**, Division of Health Informatics Technologies, National Institute of Biomedical Imaging and Bioengineering (NIBIB), NIH, email: mary.rodgers@nih.gov
- **Tiffany Lash**, Division of Discovery Science and Technology, National Institute of Biomedical Imaging and Bioengineering (NIBIB), NIH, email: tiffany.lash@nih.gov



Examples of Funded SCH Work



Privacy-Preserving Framework for Publishing Electronic Healthcare Records

PIs: Heng Huang, Nan Zhang, & Liam O'Neill
UTA, GWU, UNTSC
NSF IIS #1344152, 1343976, & 1344072



Motivation:

- Real EHR privacy leakage is common today, even for data that meet HIPAA's "safe harbor" standard
- The community needs:
 - 1) *privacy verification* tools to evaluate privacy leakage for published EHRs
 - 2) *privacy-preserving* techniques that thwart re-identification while maintaining utility

Broader Impacts:

- A prototypical system for public health researchers, to detect privacy leakage and automate privacy protection over EHR
- Develop novel educational tools for new courses and laboratory classes on healthcare, data privacy, data mining, etc.

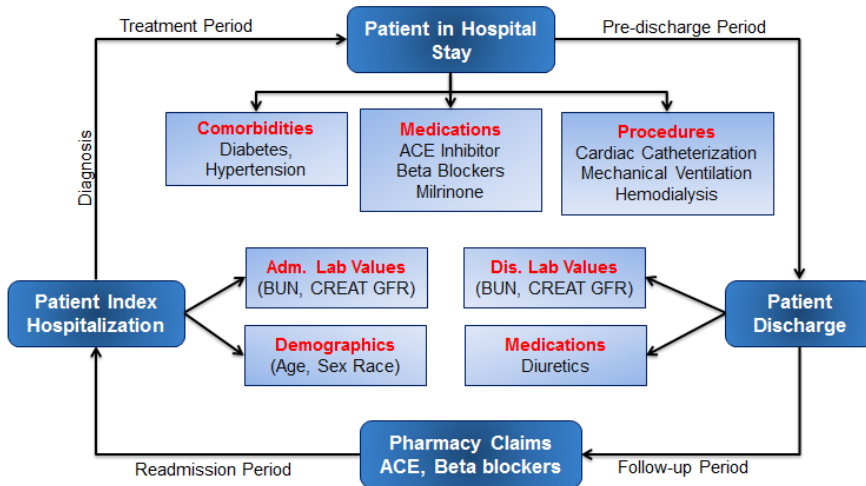
Transformative:

- Inter-disciplinary study applying computer science and "big data" techniques to inform public health policy
- Significantly enhance EHR publishing, health services research, and secondary data analysis

Technical Approach:

- Stage 1: Recover Protected Health Information (PHI) based on published data that has been "de-identified" via automated identification of data inter-dependency through data analytics and medical domain knowledge
- Stage 2: Develop software to perform de-identification in a safe and secure manner to prevent recovery of PHI





Motivation:

- Hospitalizations account for more than 30% of the \$2 trillion annual cost of healthcare in the United States.
- Healthcare data residing at multiple sites causes challenges for data integration and effective modeling due to privacy concerns and presence of different population groups.

Transformative:

- Identifying patients at risk of readmission can guide efficient resource utilization and can potentially save millions of healthcare dollars each year.
- Ability to leverage additional sources of information from other hospital records to improve the predictive power of the existing health records.

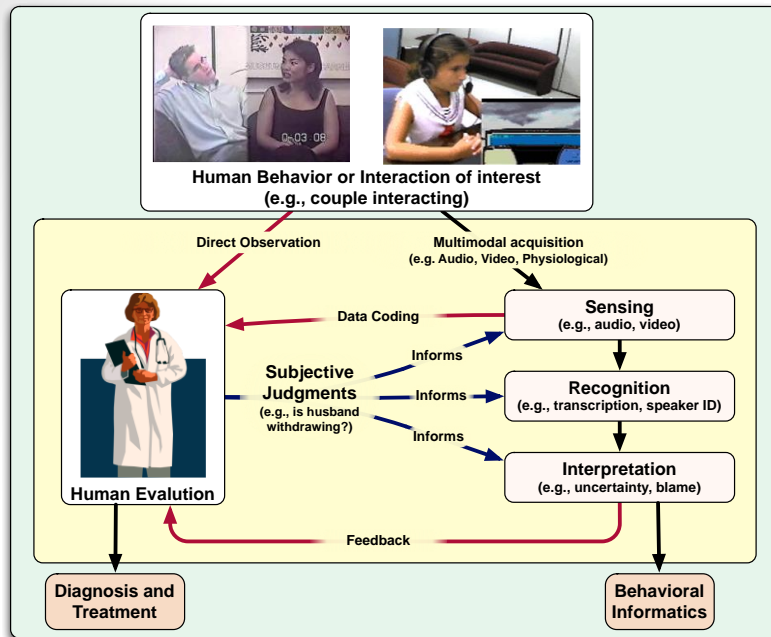
Broader Impacts:

- Big Data Analytics for Healthcare - Tutorial presented at major conferences such as KDD, SDM. Slides: <http://dmkd.cs.wayne.edu/TUTORIAL/Healthcare/>
- Upcoming new book: "Healthcare Data Analytics", to be published by CRC Press in 2015.

Technical Approach:

- Novel clinical feature transformation methods that can handle several complexities that exist in clinical data.
- Correlation based regularization strategies to incorporate correlation between variables in the data.
- Constrained regularization method for knowledge transfer.





Motivation:

- Transform observational behavior analysis through a computational framework
- Offer new analysis capabilities and empower the mental health experts
- Model emotionally-rich human interactions through signal processing and machine learning

Broader Impacts:

- Technologies can apply to other application domains, e.g. meetings, negotiations, focus groups
- Encourages cross-disciplinary exposure and knowledge transfer
- Identifies new behavioral metrics, e.g. vocal entrainment

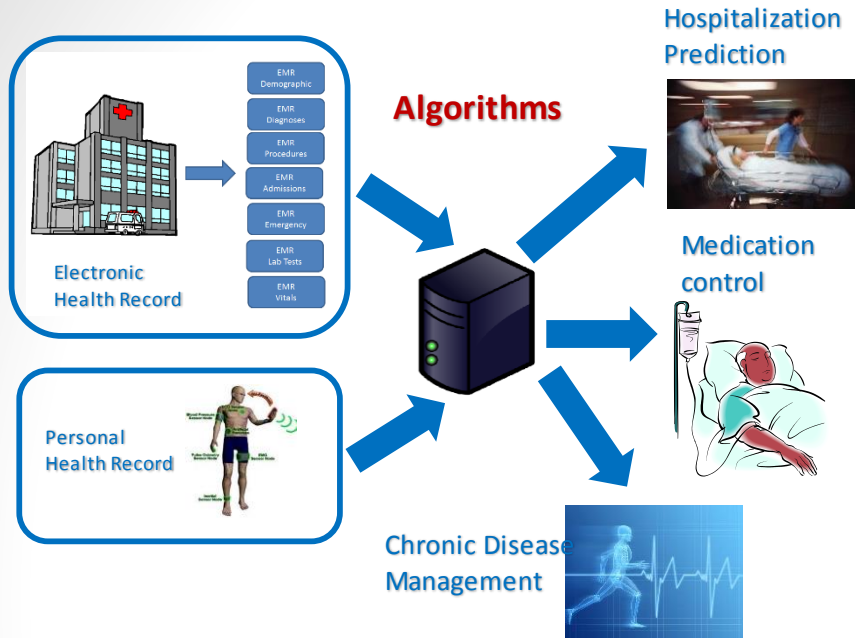
Transformative:

- Can improve mental healthcare and observational practice
- Can empower and provide new behavioral cues to experts (e.g. psychologists)
- Can enable scalability and knowledge discovery through big data

Technical Approach:

- Use real *couple therapy interactions*
- Use *Signal Processing* techniques on the acoustic, lexical and visual channels. Extract meaningful features (e.g. automatically transcribe, head motion)
- Use *Machine learning* to learn from human ratings





Motivation:

- Lots of data available in Electronic and Personal Health Records (EHRs and PHRs)
- Current practice: ineffective and expensive
 - Treat conditions when they become acute (in the hospital)
 - Apply generic, non-personalized treatment protocols
- Health Care system has **no ability** to process and learn from data

Broader Impacts:

- Prevent hospitalizations and treat individuals before a condition becomes acute
- Reduce the cost of hospital care (more than \$30B spent on preventable hospitalizations in the US each year)
- Leverage and learn from health data available in the hospital and directly from individuals (health monitors, lifestyle data, smart phone)

Transformative:

- Develop the capability to predict future hospitalizations from the EHR/PHR of an individual
- Prediction can lead to Prevention
- Develop personalized disease management plans
- Develop personalized & automated medication control

Technical Approach:

- Novel inference and classification approaches (k-LRT) leading to interpretable results
- Novel joint clustering and classification
- Anomaly detection
- Adaptive control for medication control



Other Funding Opportunities

- NSF CRII (16-565) and CAREER (15-555)
- NSF Big Data (16-512)
- NSF & NIH Cyber-Physical Systems (16-549)
- NSF CISE Core Programs



Better health through a relay between basic and applied science



Questions or Comments?

Wendy Nilsen

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