29th Annual Plenary Meeting

Remote Monitoring & the Interoperability of Things

Monday, October 5, 2015 • 8:30 am – 12:30 pm
The Sheraton Atlanta Hotel, Atlanta, GA

Including Keynote Speakers:

Sam Bierstock, MD
Founder and President,
Champions in Healthcare, LLC;
Executive Director,
The Global Medical Microtechnology Association

Joseph Corkery, MD
Senior Product Manager,
Google Cloud Platform

Taba Kass-Hout, MD, MS
Chief Health Informatics Officer, US Food and Drug Administration (FDA)

James Tcheng, MD
Professor, Duke University; Chair of the Informatics and Health Information Technology Task Force of the American College of Cardiology

*Health Level Seven, HL7, CDA, FHIR and the FHIR [FLAME DESIGN] are registered trademarks of Health Level Seven International, registered in the US Patent and Trademark Office.
8:30 – 8:35 am
**Welcoming Comments**

*Charles Jaffe, MD, PhD*
CEO, Health Level Seven International

8:35 – 9:10 am
**Keynote Session 1:**
**Handling and Delivering Healthcare Data in an Age of Ever-Evolving, Unimaginable Technologies**

Dr. Bierstock will highlight several examples of exciting devices available and in development for use in patient care. He will also share insight on the challenges associated with handling, filtering and delivering all of that data and the incomprehensible amount of endless and continuous data that will be explosively available 24/7. He will conclude with a discussion on making the delivery of data in a way that maximally improves clinicians’ ability to utilize it for decision making and action.

*Sam Bierstock, MD*
Founder and President, Champions in Healthcare, LLC and Executive Director, The Global Medical Microtechnology Association

9:10 – 9:40 am
**Keynote Session 2:**
**Health Care Interoperability in the Cloud**

Google’s mission is to organize the world’s information and make it universally accessible and useful. It’s hard to do this if your services don’t talk to one another and you can’t move data around easily. As such, the concept of interoperability is critical to our mission and to its success. There are numerous other examples of how lack of interoperability inhibits potential industry success and how the introduction of interoperability leads to booming ecosystems. As the health care industry continues to generate increasingly large amounts of data (e.g. genomics, imaging, etc.), managing that data and extracting meaning from it becomes especially difficult. The resources provided by the Cloud open up many new opportunities for analyzing health care data, but in order to be effective, the data needs to be mobile, accessible, and secure. Google is actively involved the Genomics space on the Google Cloud Platform. Multiple examples will be presented on our focus on interoperability in this space and its value as a model for health care interoperability in general.

*Joseph Corkery, MD*
Senior Product Manager, Google Cloud Platform

9:40 – 10:10 am
**Keynote Session 3:**
**The openFDA Revolution**

*Taha Kass-Hout, MD, MS*
Chief Health Informatics Officer, US Food and Drug Administration (FDA)
10:40 – 11:10 am

**Keynote Session 4:**
Value of Structured Data Capturing for Cardiology Reporting

While the concept of the structured report is well-established, adoption has not been embraced by physicians for a variety of reasons. A focus on multidisciplinary, data-intensive, workflow-oriented structured reporting, coupled with acceptance of structured reporting as a professional standard, will overcome the barriers and lead to general adoption.

*James Tcheng, MD*
Professor, Duke University, Chair of the Informatics and Health Information Technology Task Force of the American College of Cardiology

11:15 – 12:25 pm

**Panel Presentation:**
Clinicians’ Needs for Improved Interoperability and How HL7 Can Help

**Moderator:**
*Stan Huff, MD*
Chair, HL7 International Board of Directors; Chief Medical Informatics Officer, Intermountain Healthcare

*Frank Opelka, MD*
Medical Director, American College of Surgeons for Quality and Health Policy; Executive Vice President, Louisiana State University Health

*Steve Hasley, MD*
American College of Obstetricians and Gynecologists; Medical Director for Information Technology, Women’s Health, UPMC

*Michael Hodgkins, MD, MPH*
VP & CMIO, American Medical Association

*Dr. Phil Koczan, MBBS, FRCGP*
General Practitioner; Chief Clinical Information Officer, UCL Partners and North East London Foundation Trust

12:25 – 12:30 pm

**Closing Comments**

*Stan Huff, MD*
Chair, HL7 International Board of Directors; Chief Medical Informatics Officer, Intermountain Healthcare

Note: Plenary program agenda topics and speakers subject to change.
Keynote Session 1: Handling and Delivering Healthcare Data in an Age of Ever-Evolving Unimaginable Technologies

8:35 – 9:10 am

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Sam Bierstock, MD
Founder and President, Champions in Healthcare, LLC; Executive Director, The Global Medical Microtechnology Association
Dr. Sam Bierstock, MD, trained in internal medicine, is a board certified eye surgeon, holds a B.S. degree in Electrical Engineering, and is a nationally recognized authority on healthcare clinical information systems. He has served as Chief Medical Officer for IBM, and in executive positions for several major leading healthcare EHR and Informatics consulting companies. He is the founder and president of Champions in Healthcare, (www.championinhealthcare.com), a consulting company that identifies and provides business strategies for companies developing leading edge healthcare IT products and bringing them to market.

Dr. Bierstock is also the originator of the concept of “Thoughtflow ®” as opposed to “ Workflow” as the essential missing ingredient in clinical information systems to assure clinician adoption of information system technologies.

He has been a contributing editor for the Wall Street Journal and other national publications on healthcare IT matters. He has also appeared on all of the major television networks, on nationally syndicated radio and on National Public Radio.

Among his other activities, Dr. Bierstock has published three books, more than 100 articles, and lectured both nationally and internationally He is also the author of a hit song in tribute to our veterans, “Before You Go”, which has been downloaded for free more than 25 million times from the Internet, and sold more than 75,000 CDs. In 2007, he was awarded the George Washington Honor Medal Freedoms Foundation for his work on behalf of our nation’s veterans.
Handling and Delivering Healthcare Data in an Age of Ever-Evolving, Unimaginable Technologies

Sam Bierstock, MD, BSEE
Will Intelligent Devices working in Concert with Advanced Clinical Decision Support Systems Replace Physicians?
MEMS ≡ MicroElectronic Mechanical Systems

https://www.mems-exchange.org/MEMS/what-is.html
We are entering an age of incessant, endless streaming real time data – for the most part unformatted, non-standardized, non-interoperable, insecure and frequently proprietary – much of it sitting on private vendor servers
The Microtechnology Tidal Wave

MEMS & Microtechnology

Healthcare Industry

Survival Island
By the end of 2015, 500 million smartphone users across the globe will be using a healthcare app.

By 2018, half of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications

Margaret A. Hamburg, MD
Commissioner of Food and Drugs
mHealth Summit
Gaylord National Convention Center, National Harbor, MD
December 11, 2013
Examples of Types of Sensors

- Inertial measurement units (IMUs - including accelerometers, gyroscopes, magnetometer and barometers)
- Optical sensors (including optical heart rate monitoring, PPG and cameras)
- Wearable electrodes
- Chemical sensors
- Flexible stretch/pressure/impact sensors
- Temperature sensors
- Microphones
- Other emerging wearable sensors

An Exploding Market

- Sales of remote monitoring devices grew from $3.9B in 2007 to $10B in 2012
- Wearable devices market is projected to grow to $75 Billion by 2025 *
- 3 Billion Wearable Sensors will be in use in 2025 – 1/3 of which will have capabilities that we cannot yet imagine or predict **
- Initial focus: monitoring chronic conditions
- Over 600,000 of 2.5 million implanted devices in use (such as pacemakers) are linked to home networks for remote monitoring
- 500,000,000 people are using mobile health apps in 2015
- Apple app store offered 12,000 health related apps in 2013


** Wearable Sensors 2015-2025: Market Forecasts, Technologies, Players, Mr James Hayward and Dr Guillaume Chansin, Wearable Technology Report
“THE PROBLEM WITH POSITIONING FOR THE FUTURE IN MICRO & NANO TECHNOLOGIES IS THAT A TECHNOLOGY WILL EXIST IN 6 MONTHS THAT IS ENTIRELY UNIMAGINABLE TODAY”

45 trillion networked sensors are projected to be in use by in 20 years

- Wearable
- Implantable
- Digestible
- Lab-on-a-Chip
Relative Wearable Market Size in 2020

Relative Market Size by Wearable Sensor Type in 2020

- Chemical sensors
- Inertial Measurement Unit Sensors
- Biopotential sensors
- Optical Sensors
- Stretch and pressure sensors
- Other

IDTechEx
Trillion Sensors (T Sensors) Visions

- Mobile sensor market for volumes not envisioned by leading market research organizations in 2007, grew exponentially 212%/y between 2007 and 2012.
- Several organizations created visions for a continued growth to trillion(s).
  - Market research companies don’t yet see it.
  - Explosion to trillion(s) is likely to be driven by new applications not yet envisioned by leading market research organization.
- Forecasting thus needs visionaries!
Data Waterboarding

- EHRs
  - Clinical Decision Support
  - Guideline & Protocols
  - Clinical Alerts
  - Genetic Diagnostic & Treatment Profiles
- Micro & Nano Devices – from the unwell and the healthy populations
  - Wearables
  - Implantables
  - Digestibles
  - Extrinsic
  - Lab-on-a-Chip
- Real Time Remote Video Monitoring & Auditing
- Coding
Body Area Network: New Trend

- Addressing the needs of an aging population
- Lowering healthcare system costs
- Low power, Battery Operated Energy Harvesting

**Products**
- High-Performance MEMS
  - Accelerometers, Gyros
  - Pressure Sensors, uPhone
  - Strain Gauge
- RF Transceivers
- Analog precision human interface, e.g.: ECG
- Low power uC/MCU
- Power Mgmt, Signal condition, Thin Film Battery

**Benefits of MEMS-based Solutions:**
- Accuracy of Sensors
- Non-Invasive Technique
- Low Cost for Public Healthcare Service
- 24h Monitoring

Sensor Network: Sensors will talk to each other
# Wearable Sensors Galore

## Scanadu Scout - Scanadu
A handheld sensor that when placed against the forehead for 10 seconds allows you to analyze, track and trend your vitals, including temperature, blood oxygenation, heart rate, respiratory rate and blood pressure data to a smartphone with a 99% accuracy rate.

## Asthmapolis - Propeller Health
Sensor that attaches to the top of an existing asthma inhaler to keep track of medication dosage, time and place.

## Zio Patch - iRhythm Technologies
A small, band-aid-like partially passive sensor that records every heartbeat. Used in diagnosis of cardiac arrhythmias for up to 14 days of continuous wear.

## Wireless Blood Pressure Wrist Monitor - iHealth Labs
A wireless blood-pressure wrist monitor, weight scale, and pulse oximeter that transfers data to the iHealth MyVitals App.

## EPOC - Emotiv
The Emotiv EPOC uses sensors to tune into electrical signals produced by the brain to detect user thoughts, feelings, and expressions.

## First Warning - First Warning Systems
A breast health system to detect tumors earlier and cut the rate of false positives and negatives by measuring cell temperature changes created over time.

## Vitalink - VGbio
Wearable bio sensors that collect ECG, respiratory biomimicry, 2-wavelength pulse oximetry, temperature and 3-axis accelerometers. Data is collected by smartphone, transmitted to a server which provides clinicians early notification of negative change.

## Checklight - MC10
Captures head impact data during play, while being virtually invisible to the athlete.

## Helius - Proteus Digital Health
Wearable and ingestible sensors that work together to detect ingestions and physiologic data. The data is sent via bluetooth and the patient, caregiver and care team get smartphone alerts.

## SenseWear Armband - Jawbone
A personal, portable hand-sanitizer dispenser that healthcare professionals wear which transmits usage data wirelessly so that administrators can track compliance.

## Sympony CGM System - Echo Therapeutics
A non-invasive (needle-free), wireless, transdermal continuous glucose monitoring system.

## Visi Mobile System - Sotera Wireless
A smartphone-sized monitor that's attached to a patient's wrist. The information is fed directly into a patient's electronic health record wirelessly through the hospital's WiFi.

## Rapid Rehab System - Veristride
A custom gel insole to detect a person's gait, or walking pattern. Mainly for amputees who would like to reduce how much they limp when using prosthetic legs. The system also uses a smartphone application that wirelessly tracks the data.

Welcome to the Future

An Invitation to:

A Ride Through The Future
That You May Not Know You Are Already In
Wearing Your Computer

University of Pittsburgh Swanson School of Engineering

• Responsive hybrid material

• Fueled by an oscillatory chemical reaction and can perform computations based on changes in the environment or movement, and potentially even respond to human vital signs

• Self-oscillating polymer gels and piezoelectric micro-electric-mechanical systems creating a new reactive material system capable of performing computations without external energy inputs, amplification or computer mediation

• Different oscillatory patterns form a type of “memory”, allowing the material to be used for computation.

Sensor Studded Mobile Devices

AppleWatch
- Microphone
- Tri-Accel
- Tri-Gyro
- Dual-Pulse
- 11 sensors in a band

iPhone6
- 4 Microphones
- Tri-Accel
- Tri-Gyro
- Tri-Mag
- Pressure
- Light
- Proximity
- 32 SAW
- Image stabilization
- Fingerprint
- 2 Cameras

Microsoft's $199 Fitness Band Packs in 10 Sensors, Works with Windows Phone, iOS, and Android
[Link](http://www.dailytech.com/Microsofts+199+Fitness+Band+Packs+in+10+Sensors+Works+with+Windows+Phone+iOS+and+Android/article36803c.htm#sthash.2wDoqYux.dpuf)
Cellphone Diagnostic Testing Apps

**Uchek** (MIT) detects 25 diseases, such as diabetes, urinary tract infections, pre-eclampsia, glucose, proteins, ketones, and more.


**Preventice’s** smart bandage constantly tracks cardiac ECG and rhythm monitoring.

http://www.preventice.com/bodyguardian/howitworks/

**Fraunhofer’s** glucose, lactate and cholesterol sensors, pulse oximeter, and a fluorescence sensor for detecting biomarkers.


**Lapka** can detect radiation and organicity of food.

https://mylapka.com/pem
First Open Wearable Platform from Samsung

- **Simband**: modular wristband enabling multiple plugged-in sensors.

- First sensors developed by Imec:
  - **PPG** sensors that measure blood flow, heart rate, blood pressure, and other vital signs.
  - **ECG** sensor to measure the rate and regularity of a heartbeat.
  - Body temperature.
  - Galvanic skin response.
  - **Bioimpedance sensor** to monitor everything from blood flow to body fat.

- **Samsung Architecture Multimodal Interactions (S.A.M.I.)** is a data broker that enables wearable devices to upload information to the cloud.

http://www.samsung.com/us/globalinnovation/innovation_areas/
Wearable Tatooed Sensors

UC San Diego

MC10
Wearable Sensor based Clothing

Wearable Sensor based Clothing

Bio-sensing clothing for everyday life

Features

- Heart rate
- Breathing
- Activity
- Calories
- Emotive State
- Moments
- Smart Apparel
- Analytics

Wearable Sensor based Clothing

Wearable Sensor based Clothing

Washable T-shirt that can read a patient’s heart rate, blood pressure, cardiac irregularities

http://www.omsignal.com/

http://www.timesofisrael.com/israeli-ecg-t-shirt-monitors-hearts-saves-lives/#ixzz3ATObYkf2

NTT Docomo and Toray announced Hitoe (Japanese for "one layer") cloth with coated nanofibers and a square patch that does the sensing, measuring heartbeat and even offering metrics resembling a cardiogram.

http://www.engadget.com/2014/01/30/ntt-docomo-toray-smart-cloth/
Wearable Luxury Brands…

THE NEXT EVOLUTION
OF WEARABLE TECHNOLOGY

POLO
RALPH LAUREN

THE POLO TECH SHIRT

WE ARE PROUD TO BE THE FIRST LUXURY LIFESTYLE BRAND TO OFFER APPAREL THAT TRACKS AND STREAMS REAL-TIME BIOMETRIC DATA DIRECTLY TO YOUR SMARTPHONE OR TABLET.

BIOSENSING SILVER FIBERS ARE WOVEN DIRECTLY INTO THE CORE OF THE SHIRT

AVAILABLE 2015

30 EFFORT LEVEL

TECH SPECS

PROVIDES COMPREHENSIVE BIOMETRIC

TRACKS DISTANCE, CALORIES BURNT, INTENSITY OF MOVEMENT, HEART RATE, STRESS RATE AND MORE.
Wearable Jewelry

Wellograph Wellness Watch
9DOF + Heart monitor

Netatmo’s June bracelet
with UV sensor

Intel unveiled 3G snakeskin smart bracelet

Wearable Smart Shoes

Nike’s smart shoe insert with 8 sensors measures jump height, speed, performance.

Fall-Prevention Motorized Shoe for elderly people based on pressure sensors detecting loss of balance.

http://nocamels.com/2014/05/israeli-fall-prevention-motorized-shoe-is-a-step-in-the-right-direction/
Wearable Diagnostics

SensiVest™

A non-invasive lung fluid status monitor. Patients measure their lung fluid content daily in the comfort of their home. The simple measurement takes only 90 seconds to complete.

Measurement results may be automatically uploaded to the secure cloud application for a healthcare provider to review and act upon based on his discretion.

http://sensible-medical.com/
Wearable belts with position sensors and accelerometers that detect position and impending fall and deploy air bags to protect the hip.

Active Protective
http://www.activeprotective.com

Hip Hope
http://www.hip-hope.com

Hip-Hope unique Custom made sensors System logic and Algorithm make it finally possible to distinguish between real falls and misleading fall-like events.
Wearable Smart Bra…

Bra with autolock. When True Love is detected, the bra unhooks automatically from the front. The bra contains a heart-rate sensor. The app calculates the "true love rate," comparing the readings to activities like shopping, watching a horror movie, flirting, jogging, or receiving a surprise gift.

Smart Bra concept is aimed at helping people ward off emotional eating (Image: Microsoft) using ECG and EDA, an electrodermal activity sensor measuring skin conductance (moisture) and movement (respiration rate).

The sensor finds cancer by detecting tiny metabolic temperature changes caused by cancerous cells in a tumor. The temperature readings are sent to a global library where they’re run through a proprietary algorithm. Then the results are sent back to a user’s phone.

Fancy lingerie brand Victoria’s Secret is now selling a sports bra for around $75 with built in electrodes that hook up to a heart rate monitor.

http://news.cnet.com/8301-17938_105-57617747-1/bust-lock-down-bra-only-unhooks-for-love-true-love/

http://www.telegraph.co.uk/technology/microsoft/10499811/Microsoft-developing-smart-bra.html


Breast Health Exams

Glove Tricorder with pressure feedback loops, temperature sensors, accelerometers and later ultrasound pads to the tips of the glove, allowing doctors to see inside the breast to diagnose breast cancer and enlarged kidneys and other sub-dermal issues.

http://medsensation.com/

Breast lumps self-exams sensor
(mammogram replacement)

Wearables for Babies

Smart sock from Owlet Baby Care monitors infant’s quality of sleep, blood oxygenation levels, and skin temperature.
https://www.owletcare.com/

The Mimo baby monitor has respiration sensors, temperature sensors, the Mimo Kimono monitors baby movements and body position. Clinically validated sleep algorithms, you can know when your baby falls asleep, when they wake and how well they are sleeping.
http://mimobaby.com/

SmartOne infant monitor measures temperature, baby orientation and breathing.
http://mysensiblebaby.com/

Teddy bear measures child’s temperature, heart rate, and oxygen levels through his ‘smart paws’. Bear’s LED heart beats at the same rate as child’s, creating a bond between child and bear.
http://blogs.plos.org/globalhealth/2014/05/wiredhealth/

Smart diapers monitors urinary tract infection, prolonged dehydration, kidney problems.
http://www.indiegogo.com/projects/pixie-scientific-smart-diapers

http://www.indiegogo.com/projects/pixie-scientific-smart-diapers
Smart Balls

Connected smart basketball for iOS and Android to help improve shooting and ball handling skills – fast. Tracks makes and misses and learns and adapts to any player’s skill level.

http://www.94fifty.com/

http://micoach.adidas.com/us/smartball/
Sporting Along

Zepp sensors create 3D representations of a player's swing
http://www.zepp.com/

Sensor based tennis racket from Babolat

Onewheel: the self-balancing electric skateboard that gives you the feeling of flying
http://rideonewheel.com/
Sensors for Bikes

Power meter calculating pedaling power with 2% accuracy.

http://road.cc/content/news/130261-brim-brothers-finally-launch-zone-dpmx-cleat-based-power-meter

The Copenhagen Wheel contains a motor, batteries, multiple sensors, wireless connectivity, and an embedded control system. The Wheel learns how you pedal and multiplies pedal power 3x—10x.

https://www.superpedestrian.com/
Detecting Players’ Brain Injury

A green, yellow and red lights indicate moderate, medium and severe impacts, respectively, measured by acceleration sensors. The system also logs the total number of impacts.

S3 itself is a wireless helmet-mounted impact logger that transmits data to the Eurotech Everyware Cloud where it can be used to provide immediate information on the impact levels experienced by an athlete to coaches, doctors, and parents.

http://www.mc10inc.com/  
http://www.sensuss.com/news
Helping in Daily Life

Personal asthma wheeze monitor measures WheezeRATE™, or the percentage of breathing time a person spends wheezing, as a result of their airways narrowing, using Acoustic Respiratory Monitoring. It enables measurement of the response allergens and medications.

http://isonea.com/

Shake stabilized spoon for Parkinson disease patients eliminates 70% of the tremor.

http://www.liftlabsdesign.com/

The first sonic connected toothbrush provides daily feedback on the quality of brushing and helps all the family to improve brushing habits. The app analyses data and provides key feedback to improve over time through a new and fun experience.

http://www.kolibree.com/en/
Monitoring Sleep

Sense system includes:

- **Sense**, a device that sits on nightstand monitoring the conditions in your bedroom and disturbances at night.
- **Sleep Pill**, sleep tracking sensor that clips invisibly to your pillow
- **Mobile applications** that bring it all together

The app tells you how well you slept, or didn’t, by giving you a unique **Sleep Score** each night.

https://www.kickstarter.com/projects/hello/sense-know-more-sleep-better

Beddit is an ultra-thin film sensor that you place in your bed, under the bed sheet.

All you have to do is to sleep on it. Beddit connects wirelessly to your smartphone for a sleep analysis.

http://www.beddit.com/
Paying with Your Hand

Biyo senses the unique vein patterns in your palm to create the most secure and convenient password that you never have to remember.

http://biyowallet.com/
Brainwaves Driven Smart Toys

Brainwaves driven ears and tail from Necomimi ($69) express your emotional state before you start talking.

http://www.necomimi.com/
Sensing the Brain

Wireless neuroheadset based on 16 sensors detects:

- Thoughts
- Feelings
- Expressions
- Subconscious emotional states
- Facial expressions
- User-trained mental commands which can control existing and custom applications and games as if by magic.

ElMindA’s Brain Network Activation Analysis System uses dozens sensors that measure and analyze neural activity during specific brain processes, measuring it against a database of over 7,000 brain functions to see how a patient’s condition stacks up, to spot problems early, such as like Alzheimer’s, Parkinson’s and ADHD.

http://www.emotiv.com/epoc/

Cuffless Blood Pressure Measurement

Sotera Wireless’ non-invasive measures continuous blood pressure, along with pulse rate, skin temperature, electrocardiogram, blood oxygenation and respiration rate and temperature. FDA approved

Cnoga’s device spectrometrically measures noninvasively blood pressure, blood oxygen, and pulse.

HealthStats watch measures blood pressure using applanation tonometry.
Noninvasive Glucose Monitoring

Integrity Applications’ employs a combination of ultrasound, electromagnetic, and thermal technologies to obtain blood glucose readings.

http://www.integrity-app.com/

Minimally-invasive continuous glucose monitoring system based on skin permeation

http://www.echotx.com/symphony-cgm-system.shtml

Biosensors’ approach is based on electromagnetic impedance spectroscopy (EIS) and electromagnetic impedance tomography (EIT).

http://www.biosensors-tech.com/

Sensing glucose, heartbeat, skin resistance, quality of skin collagen, skin health and identifies nervous people based on color change of RGB lights passing through skin.

http://www.globes.co.il/en/article-1000877563

C8 MediSensors developed Raman spectroscopy based glucose sensor, raised $120M ($43M in 2012) and closed in 2013 after finding measurement instability. Apple hired several of former employees.
Personal Glucose Monitors

Contact lens embedded glucose monitor in tears being developed at Google, wirelessly communicates with mobile devices. Google partnered with Novartis to bring it to market.

Toilet embedded sensors measure blood glucose and albumin, free protein, urea, bilirubin, and others, for tracking health condition for type 2 and pre-diabetes, based on mid-IR spectroscopy.

http://www.nytimes.com/2014/07/16/business/international/novartis-joins-with-google-to-develop-contact-lens-to-monitor-blood-sugar.html?_r=0

http://www.pyreos.com/
Intelligent Pill Bottles

GlowCap® – Remembering so you don’t have to.

GlowCap® fits most prescription bottles and uses light and sound reminders to signal when it is time to take your medications. Inside the cap, a chip monitors when the pill bottle is opened and wirelessly relays alerts, through the AT&T Mobile Broadband Network, to you or your caregiver. A push button at the base of the lid makes refills easier than ever.

http://www.glowcaps.com/
Intelligent Pills

Digital Medicines

Tiny, Safe Ingestible Sensor
Grain-of-sand sized sensor made from dietary minerals, manufactured in drugs

Medicines Signal When Ingested
Unique, pill-specific signal inside body with no battery, radio or antenna

Monitor Therapy & Outcomes
Wearable patch measures ingestions & full panel of physiologic response metrics

Deliver Mobile User Experience
Applications translate data into knowledge, incentives and collaboration

©2012 Proteus
Implantable Devices

Intraocular lens with Batteryless Pressure Sensor for measuring Intraocular Pressure after Cataract Surgery

http://www.launchpnt.com/portfolio/biomedical/intraocular-pressure-sensor/

Wireless sensors that transmit cardiac output, blood pressure

Extendible bands to enable wireless transmission of an indication of the intraluminal characteristic

Antennas in Stents to transmit pressure, flow etc.
Contact Lens with Intraocular Pressure Sensor

http://www.slideshare.net/MikePinelisPhD/140804-25-most-interesting-medical-mems-sensors
Spectrometric Food Quality Measurement

SCIO scanner enables scanning food to get calorie counts, scanning pills to see what chemical compounds they're made of, and scanning your household plants and flowers to see if they need more water.

Tellspec food quality monitor based on spectrometer processing sensor data in the Cloud.

‘Star Trek’–style Tricorder

http://www.thetechgets.com/2014/05/scio-handheld-spectrometer-kickstarter.html


http://www.foxnews.com/tech/2015/04/02/how-your-smartphone-could-become-star-trekstyle-tricorder/
Breath Diagnostics

- Dogs are trained to detect medical problems based on breath due to their extreme smell sensitivity:
  - Low sugar level in diabetics or cancer.

- What can be smelled with chemical sensors:
  - Cancer
  - Cholesterol
  - Asthma
  - Lipid peroxidation
  - Metabolism
  - Neonatal jaundice, intestinal distress
  - Cystic fibrosis/bronchitis
  - Periodontal disease
  - Infectious disease (flu)
  - Etc.

- Stony Brook University in New York have developed a breath analyzer (right)
  - Technology utilizes single crystal nanowires that are created by electrospinning.
  - Configuration of metal and oxygen atoms in the nanowires defines which molecules are captured by the chip

Source: Dr. J. Stetter, SRI
Blood Testing based on Lab on Chip

- Stanford startup Theranos rolled out in 2014 the blood testing system after 10 year/$100M+ funding:
  - 1000x reduced blood volume for about 1000 blood tests.
    - Lab on Chip with fluorescent tags?
  - Providing results in 4 hours
  - With increased accuracy.
  - At a fraction of the lab cost.

- Focus: detecting the onset of disease in time for therapy to be effective

[Visit Theranos](https://theranos.com/)
Printed Paper Microfluidics

• Lab-on-Chip can be multilayer printed on paper

• Low-cost, easy-to-use, disposable, and equipment-free.

• Promising technology particularly relevant to improving the healthcare and disease screening in the no- or low infrastructure developing world.

• Applications:

<table>
<thead>
<tr>
<th>Health diagnostics (e.g., urinalysis, saliva analysis, sputum analysis, pregnancy test, blood type)</th>
</tr>
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<tbody>
<tr>
<td>Biochemical analysis (e.g., enzyme activity)</td>
</tr>
<tr>
<td>Environment monitoring</td>
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<tr>
<td>Food quality control</td>
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<tr>
<td>Forensic (e.g., detection of blood)</td>
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http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3365319/#c19
Infrared Vision for iPhone

The FLIR One is a $349 iPhone accessory. It’s a self-contained device with its own standard camera, infrared-based thermal imaging camera, its own SoC, and its own battery.
Increasing Imaging Sophistication Level...

World’s first cellphone based ultrasound imager.

http://www.mobisante.com/

World’s first portable Xray imager.
25lbs, MODIS™ 810 from Tribogenics is the world’s smallest self-contained imaging system. Battery powered and solar rechargeable. Unfolds in seconds to provide rapid imaging anywhere in the world for both diagnostic and industrial needs.

http://tribogenics.com/
Holographic Ultrasound Imaging

Ambulance Drone

- Ambulance Drone can deliver defibrillation to any patient in a 12 km$^2$ area within 1 minute.
- At that speed, survival rates can be as high as 80%.

http://alecmomont.com/projects/dronesforgood
Personal iPad-Size DNA Sensor

- Disruptive DNA-sequencing technology based on GENIUS™ electronic technology enabling fast, accurate, and low cost genetic testing.
  - Gene-Electronic-Nano-Integrated-Ultra-Sensitive

- Provides orders of magnitude improvement across all dimensions of cost:
  - Cost of instrument (few $k, as opposed to current $1M)
  - Cost per test ($10, as opposed to current $1000)
  - Cost of labor
  - Cost of informatics

- Enables the democratization of sequencing in a way never before possible.

http://genapsys.com/
Single-Crystalline Silicone Nanoribbon Skin

• Seoul National University developed a skin that can stretch over the entire prosthesis (or robots).

• Includes sensors and actuators:
  • Pressure
  • Temperature arrays
  • Humidity
  • Strain
  • Electroresistive heaters, and more.

• Stretchable sensors and actuators facilitate highly localized mechanical and thermal skin-like perception in response to external stimuli.

Electronic Skin for Robots

• University of Exeter have developed new technique to create the first transparent and flexible touch-sensor that could enable the development of artificial skin for use in robot manufacturing

• The new technique grows graphene in an industrial cold wall CVD system 100 times faster than conventional methods, reduces costs by 99% and has enhanced electronic quality

• Emerging flexible and wearable technologies such as healthcare electronics and energy-harvesting devices could be transformed by the unique properties of graphene

http://futurism.com/links/view/robots-may-soon-have-artificial-skin/
Skin-Like Color Display to Revolutionize Apparel

- Inspired by nature, few microns thick nanostructured surface changing the color as function of applied voltage was developed at University of Central Florida.

- The new method reflects the ambient light around it.

- The research has major implications for existing electronics, but the potentially bigger impact could be whole new categories of displays that have never been thought of.
  - Camouflage
  - Clothing
  - Fashion
  - “Why would I need 50 shirts in my closet if I could change the color and pattern?”

http://futurism.com/links/view/worlds-first-full-color-flexible-skin-like-display-developed/
Glass for Super-Fast Computers

• Glass can be manipulated to create a material that will allow computers to transfer information using light, which could significantly increase computer processing speeds.

• Research has found that it is possible to change the electronic properties of amorphous chalcogenides, a glass material integral to data technologies such as CDs and DVDs.

• By using ion doping, the team of researchers have discovered a material that could use light to bring together different computing functions into one component, leading to all-optical systems.

• The researchers expect that the results of this research will be integrated into computers within ten years.

3D-Printed Graphene Aerogels Improve Energy Storage

• New type of graphene aerogel developed at Lawrence Livermore National Laboratory will enable better energy storage, sensors, nanoelectronics, catalysis and separations.

• Graphene aerogel microlattices have engineered architecture via a 3D direct ink writing.

• The 3D printed graphene aerogels have high surface area, excellent electrical conductivity, are lightweight, have mechanical stiffness and exhibit supercompressibility (up to 90 percent compressive strain).

• Adapting the 3D printing technique to aerogels makes it possible to fabricate countless complex aerogel architectures for a broad range of applications.

The Role of the FDA

FDA on eHealth (March 21, 2013)

• FDA plans to regulate:
  – Small subset of mobile medical apps that present a potential risk to patients, if they do not work as intended.
  – Peripherals and apps that turn a mobile device into a medical device in some way (e.g., wireless glucometer).
  – Mobile apps that measure patients' vital signs or control devices such as CT scanners.

• FDA doesn’t plan to regulate:
  – Consumer devices such as the iPhone, tablets and app stores like iTunes and Google.
  – Mobile apps that provide access to electronic health records (EHRs).
  – Wellness, fitness and medical resource apps.
  – Medical apps with low risk to consumers, such as an e-book of medical information.
Exchanging Data through established standards is essential
It is just as essential to address the QUALITY and ACCURACY of the data
Thoughtflow ® – The Core of Clinical Practice

© Samuel R. Bierstock, MD, BSEE

www.championsinhealthcare.com
Thoughtflow® in the Paper World

© Samuel R. Bierstock, MD, BSEE
As CDS and Language Processing capabilities mature, next generation EHRs must support end-user Thoughtflow® in order to maximize their individual workflows.
Sensor Performance Parameter Definitions (SPD) Working Group
Officially Known As IEEE P2700 Standard for Sensor Performance Parameter Definitions

The MEMS Industry Group (MIG) is pleased to announce that its historic SPD doc is now on its way to becoming a standard recognized by IEEE. Officially known as IEEE P2700 Standard for Sensor Performance Parameter Definitions, voting has now commenced. Committee members must also be a member of IEEE to participate and they must enroll as an advanced corporate member of the ballot group by 05-Mar-2014, 11:59 p.m. U.S. Eastern Time. There is only one vote per company.

Please click here to gain access to the v.1 of the SPD doc (May 2013.)

Project timeline
• April 2014 - Voting has now closed.
• January 31, 2014 - The first meeting of the IEEE P2700 Working Group was held at The Hyatt Regency in San Francisco, California USA.
• November 2013, MIG hosted a topic table discussion on next steps during lunch at MEMS Executive Congress in Napa, CA.
• October 2013, IEEE Electron Devices Society confirmed sponsorship of the SPD.
• August 2013, MIG started discussions with the IEEE Standards Group.
• June 2013, Project leads Ken Foust of Intel and Carlos Puig of Qualcomm win Engineering Team of the Year at Sensors Expo for their work on the project.
• May 2013, MIG released the SPD doc to the MEMS industry at www.memsindustrygroup.org/spd. Read the complete press release here
The greatest challenge to our healthcare system as we move toward the end of the second decade of this century will be the effective delivery of this data to clinicians and decision makers, analysts and family members in a useful, actionable manner in an age when we have no idea of what new technologies will even exist six months from the present.
A Plug for our Aging Veterans

Please Visit
WWW.BEFOREYOUGO.US

to see and hear our tribute to our aging veterans of World War II, Korea and Vietnam — and send it to every veteran that you know and their families

It’s FREE and they deserve to hear our thanks
www.championsinhealthcare.com
www.medicalmems.net
info@championsinhealthcare.com
561 243-3673

Sam Bierstock, MD, BSEE
samb@championsinhealthcare.com
Keynote Session 2: Health Interoperability in the Cloud

9:10 – 9:40 am

Joseph Corkery, MD
Senior Product Manager, Google Cloud Platform
Joe Corkery, MD, is a Senior Product Manager at Google, where he is leading new healthcare and life science initiatives for the Google Cloud Platform. Prior to Google, Joe spent 15 years working in the area of computational drug discovery as a software engineer, product manager, business leader, and executive. He was most recently Senior Vice President, Business Development at OpenEye Scientific Software and head of their European operations. He continues to serve on their board of directors. He is also a member of the Forsyth Institute’s Leadership Council.

Joe received his M.D. from Harvard Medical School and his bachelor’s degree in computer science from Princeton University, where he graduated with highest honors.
Slides not available in advance for Joseph Corkery’s presentation
HL7’s 29th Annual Plenary

Keynote Session 3: The openFDA Revolution

9:40 – 10:10 am

*****

Taha Kass-Hout, MD, MS
Chief Health Informatics Officer, US Food and Drug Administration (FDA)
Taha Kass-Hout, a leader in the fields of health informatics and analytics for two decades, is currently the first Chief Health Informatics Officer of the US Food and Drug Administration (FDA). He leads innovations, such as openFDA and precisionFDA, and is an advocate for cross-cutting regulatory science initiatives at FDA. OpenFDA is a big data cloud platform that provides open-source Application Programming Interfaces (APIs) that has allowed software developers, researchers, FDA scientists, and the public to tap into adverse events, recalls, and labeling for medical products on the market. PrecisionFDA is the informatics cloud-based platform for ensuring the accuracy of Next Generation Sequencing (NGS) tests by crowdsourcing reference material and data and is part of President Obama’s Precision Medicine Initiative. Taha holds a Doctor of Medicine and a Master of Science (Biostatistics) from the University of Texas.
Slides not available in advance for Taha Kass-Hout’s presentation
HL7’s 29th Annual Plenary

Keynote Session 4: Value of Structured Data Capturing for Cardiology Reporting

10:40 – 11:10 am

*****

James Tcheng, MD
Professor, Duke University; Chair of the Informatics and Health Information Technology Task Force of the American College of Cardiology
James E. Tcheng, MD is a Professor of Medicine, Department of Medicine, Division of Cardiology, and Professor of Community and Family Medicine, Department of Community and Family Medicine of the Duke University School of Medicine. Dr. Tcheng received his MD degree from the Johns Hopkins University School of Medicine (Baltimore, MD) and completed his residency in medicine at Barnes Hospital / Washington University (St. Louis, MO). He completed fellowship training in cardiology at Duke University and joined the faculty of Duke in 1988.

Dr. Tcheng is a practicing interventional cardiologist and faculty of the Duke Clinical Research Institute (DCRI) and the Duke Center for Health Informatics (DCHI). He serves as Director of the Duke Cardiovascular Databank and is Director of Performance Improvement for the Duke Heart Center. He is faculty of the Medical Device Epidemiology Network (MDEpiNet) Coordinating Center of the DCRI. In addition, he is Chair of the Informatics and Health IT Task Force of the American College of Cardiology, is a member of the ACC National Cardiovascular Data Registry Management Board, and the ACC/AHA Task Force on Clinical Data Standards.

His clinical interests focus on the management of coronary artery disease, including percutaneous coronary intervention (angioplasty), stent implantation, laser angioplasty, and the treatment of chronic total coronary occlusions. His clinical research has focused on antiplatelet and anticoagulant therapies for cardiovascular disease. He has participated in numerous clinical trials and has also been the principal investigator or co-principal investigator of a number of multicenter studies, including the EPIC, PROLOG, EPILOG, EPISTENT, IMPACT, IMPACT II, TOTAL, PRIDE, ESPRIT, MEND-1, and ELECT Trials. He is an accomplished educator and is the 2015 recipient of the Duke Master Clinician / Teacher award.

Dr. Tcheng has led a number of initiatives spanning professional societies, regulatory agencies, government agencies, industry, and non-governmental organizations to develop clinical data standards, interoperability standards, and to integrate structured reporting into clinical workflows. His current work focuses on harmonizing the clinical and operational definitions and informatics of cardiovascular clinical data elements across academia, regulatory agencies, the life sciences industry, professional societies, and standards organizations, to improve the capture, communication, interoperability, and analysis of healthcare information.
Value of Structured Data Capture for Cardiology Reporting

James E. Tcheng, MD, FACC, FSCAI, FESC

HL7 29th Annual Plenary and Working Group Meeting
5 October 2015
Objectives

• Discriminate structured reporting (process) from the structured report (document)
• Describe the multidisciplinary, workflow-oriented structured data capture paradigm
• Identify use cases advantaged by structured data capture, using cardiac cath reporting as an archetype
• Acknowledge barriers to clinician adoption
• Summarize the roles and responsibilities of professional societies, vendors, and others to accomplish structured reporting
Structured Reporting in the Cath Lab

- The need for data healthcare delivery, quality measurement, performance improvement, device surveillance
- Structured reporting - what and why?
- ACC/AHA/SCAI Health Policy Statement on Structured Reporting
- Details, details, details
- Perspectives
Percutaneous Coronary Intervention (PCI)
It’s first “world registry” – circa 1979-80
### The Last 20 Years in CV Medicine …

<table>
<thead>
<tr>
<th>Year</th>
<th>Event/Development</th>
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</table>
| **1990’s** | Beginning of conversion from film, VCR tape to digital PACS → proliferation of modality-specific PACS  
Vendor-authored procedure reporting systems → data capture from modalities, used for operational purposes  
Rise of randomized clinical mega-trials → evidence generation, guidelines |
Emergence of registries, quality measurement  
Emergence of CVIS (PACS + reporting) systems |
| **2009** | ARRA HITECH Act → catalyst for EHR adoption  
• EHR model → replication of dictation paradigm |
| **Today** | Where’s the data?  
• Failure of the EHR model  
• Adoption of structured reporting still nascent  
• Data only via manual abstraction (i.e., RCT model) for quality assessment and metrics, registries, etc. |
Grand Challenge: Multiple Masters

- Government
- Public Health
- Payers
- Regulators
- Patients
- Industry
- Research
- Lawyers
- Oh yes ... clinicians

Recipients

Producers
Clinician Documentation 2015

- Mired in ancient paradigms
  - Authoring of novella encouraged (starts in med school)
  - Play by play description – fear of malpractice
  - Demonstration of physician prowess
  - Justification of actions

- 75% is garbage – E&M coding requirements
  - Fosters cut and paste
  - EHR “Meaningful Use” also contributes

- Team-based documentation actively discouraged
  - By regulation
  - By job description
  - By HIT (built to enhance the ancient paradigms)
Clinicin Desired State

• **Best approach** for the task – defined by usability, efficiency and effectiveness – not regulation!
  – Meld technical approach to best-practice workflow – even if this means disruptive change
  – Consistency at the task level (e.g., procedure reporting), rather than the system level (e.g., EHR) – one size does NOT fit all

• Capture **information as data** – but only where “data” are actually useful (e.g., conveying clinical / administrative info, risk calculation / stratification, predictive modeling)

• **Procedures** a “natural” for **structured reporting**
  – For device implants, this is where it all starts
• Create **structured reports** where there is inherently structured content (e.g., *procedure notes*)
  – Data (not words) populate report
  – Data acquisition, management by all members of the team

• Create (only) **elements** of structure in documents not inherently structured (e.g., *clinic / hospital notes*)
  – (Limited) data – summative assessments (e.g. CCS class)
  – (Limited) lexicon (<100 critical data elements for cardiology)
  – Data management by all members of the team

• ↑SPEED, efficiency, effectiveness, quality, productivity
• ↓repetition / redundancy
What is Structured Reporting?

- Data management integrated into workflow
- Data acquisition by those closest to (handling) the data → also improves data quality
- Multiple authors contribute to documents
- Reducing MD time to report completion, focuses MD on cognitive activities
- Improving clinical communication with care team, physicians, patients
- Paradigm: collect once, use many times (e.g., clinical report, PI analysis, data to registries)
What is Needed for Structured Reporting?

- **Vocabulary & data interoperability standards**
  - Inclusive of SDOs through registries

- **Best-practice workflows** (industrial engineering)
  - From cath order through data submission to registries

- **Professionalism expectations of CV clinicians**
  - Conversion from dictation to structured data model
  - Expected content and format:
    - *Procedure documentation (technical / procedure log)*
    - *Physician report (structured report)*

- **IT systems (vendors)**
  - Information model, systems aligned with clinical model
Standardized Cardiovascular Data for Clinical Research, Registries, and Patient Care

A Report From the Data Standards Workgroup of the National Cardiovascular Research Infrastructure Project

H. Vernon Anderson, MD,* William S. Weintraub, MD,† Martha J. Radford, MD,‡ Mark S. Kremers, MD,§ Matthew T. Roe, MD, MHS,‖ Richard E. Shaw, PhD,¶ Dana M. Pinchotti, BS,# James E. Tcheng, MD∥

Houston, Texas; Newark, Delaware; New York, New York; Charlotte and Durham, North Carolina; San Francisco, California; and Washington, DC

CV vocabularies – NCRI
Balloted via HL7
Available on NCI-EVS

Figure 1: Simplified View of a CDE in the caDSR Implementation of the ISO 11179 Metamodel

- Class I: Absence of rales over the lung fields and absence of S3
  - NCI Thesaurus Concept ID C77369
- Class II: Rales over 50% of the lung fields or the presence of an S3
  - NCI Thesaurus Concept ID C77220
- Class III: Rales over more than 50% of the lung fields
  - NCI Thesaurus Concept ID C77221
- Class IV: Cardiogenic Shock with systolic BP < 90, not responsive to treatment, and severe dyspnea
  - NCI Thesaurus Concept ID C77222
ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory

A Report of the American College of Cardiology Clinical Quality Committee

Developed in Collaboration With the American Association for Critical-Care Nurses, Asian Pacific Society of Cardiology, Canadian Cardiovascular Society, Health Level Seven International, Inter-American Society of Cardiology, Integrating the Healthcare Enterprise, Society of Thoracic Surgeons, and Society for Vascular Surgery

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Catheterization Procedure

**Referring Provider**
- Outpatient: Call or FAX to Comm Center with request for procedure, supporting H&P.

**Heart Center Communications Center**
- Receive and process request for procedure.
- Search HIS/EHR systems for demographic, registration, insurance data.

**Cath OP Holding Area**
- Patient arrives in OP Holding for cath procedure.
- Registration Clerk initializes encounter.
- Nurse checks paperwork and labs; performs and charts nursing assessment and medication reconciliation; executes orders; completes pre-cath checklist.
- Staff manages OP Holding schedule (whiteboard date of visit); participates in patient prep; communicates patient status with Cath Lab.

**Charge Nurse Cath Lab**
- Patient request for cath procedure posted to Cath schedule.
- Manages and controls cath schedule (whiteboard for day of procedure; assigns Attending, Fellow, Staff, Resources, Procedure Room; initializes Cath IT systems on-call for cath procedure.

**Physician Operator**
- Patient arrives in Cath Lab for procedure.
- Confirm patient identity, initials hemodynamic monitoring and radiographic modality systems.
- Orders, sedation, establishes vascular access; performs diagnostic procedure.
- Need for KP additional procedures.

**Monitor Tech / Nurse**
- Initiate Time-out.
- Documents and reconciles medications, sedation assessments, hemodynamics, inventory used, procedure details, contrast totals etc, in hemo monitoring system.

**Circulating Nurse / Tech**
- Confirms patient identity, preps patient.
- Performs clinical and sedation assessments, administers medications, provides supplies, tracks inventory on inventory control sheet.
- Final report filed in EHR; completes clinical and technical coding, inventory management and billing processes.

**Data Analyst**
- Obtains all written documents, procedure log (from hemo system), final procedure report (from physician), Inventory Control Sheet; performs reconciliation, enters procedures actually performed, corrects data errors, and audits for completeness.

**Operations and Quality Assessment**
- Aggregates data from procedure log and final procedure report; captures inpatient follow-up.
- Analyzes data for assessment and reporting: Appropriate Use, performance improvement, system and process improvement.
- Data transfers to ACC NCDR CathPCI, ACTION-WGTG, STS CT Surgery, other registries.
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<td>Existing clinical data History &amp; Physical Other documents Laboratories</td>
<td>History &amp; Physical Other documents Laboratories Consents</td>
<td>Pre-procedure evaluation packet Hemodynamics Catheterization images</td>
<td>Hemodynamics Catheterization images Measurements Calculations</td>
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<td>Patient identifiers Procedures Hemodynamics Findings Measurements Medications Inventory</td>
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<td>Advanced Practice practitioners Physician operator</td>
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<td>Physician operator</td>
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<td>Electronic Health Record Procedure Reporting system</td>
<td>Electronic Health Record</td>
<td>Radiography Modality Hemodynamic Monitoring system Procedure Documentation / Reporting system</td>
<td>Procedure reporting system</td>
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<tr>
<td>Form Factor (for Actors)</td>
<td>Desktop workstation</td>
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<td>Multiple workstations: Radiography Modality Hemodynamic Monitoring Procedure Documentation</td>
<td>Desktop workstation</td>
</tr>
<tr>
<td>Data Output</td>
<td>Schedule – to scheduling app Orders – to Electronic Health Record (EHR) system</td>
<td>Clinical data – to procedure reporting system (history section) Patient status – to scheduling system electronic schedule Orders – to EHR</td>
<td>Nursing documentation – to EHR Patient status – to scheduling system electronic schedule</td>
<td>DICOM Modality Worklist to Modality, Hemodynamic, and Procedure Documentation systems procedure log report and data for procedure report (procedure section) [See also IHE CATH, CRC profiles]</td>
<td>Procedure results – to procedure reporting system (results section) structured procedure report</td>
</tr>
</tbody>
</table>
Pre-Procedure

• **Who**
  – Ordering physician
  – Pre-procedure evaluation by operator

• **What information**
  – Patient demographics, requested procedure, scheduling logistics, procedure indications, clinical history

• **What information as data**
  – Demographics, ICD-9 indications, structured history

• **Output**
  – Structured H&P (data for risk modeling, quality measurement, and registry submission)
**Patient Information**

- **MRN:** Q45678
- **Last:** Testpatient
- **Suffix:** Dummy
- **First:**
- **Middle:**
- **Date of birth:** 10/07/1971
- **Age:** 43
- **Gender:** Female
- **Hispanic Ethnicity:**
- **Race:**

**Import Data From Prior History**

- **Admit source:**
  - Emergency Department
  - Transfer in from another acute care facility
  - Other

- **Procedure priority:**
  - Elective
  - Urgent
  - Emergency
  - Salvage

- **History:** The patient is a 51 year old male who presented at the ED with chest pain.

**Angina**

- **History of angina (ever):**
  - Onset month: March
  - Year: 2015
  - Not available

- **Angina at any time during current hospitalization**

- **Angina within 2 weeks**
  - Current CCS class (w/in 2 weeks): CCS I, CCS II, CCS III, CCS IV

- **Cardiogenic shock within 24 hrs**
- **Cardiac arrest within 24 hrs**

**Stress testing:**

- **(w/in 6 months):**
  - Test: ETT (no imaging), Stress echo, Stress nuclear, Stress MR
  - Result: Positive, Negative, Indeterminant, Unavailable
  - Ischemia: Low, Intermediate, High, Unavailable

**Pre procedure EF:**

- 65%
- **Pre procedure EF modality:** Echo, Nuclear, Cath, NR

**Anti-anginal meds:**

- Beta blockers
- Calcium channel blockers
- Nitrates
- Prazosin
- Other anti-anginals

**CAD Risk Factors**

- Cigarette smoking, current or recent (< 1 year)
- Hypertension
- Dyslipidemia
- Family history of premature CAD
- Type 1 diabetes
- Type 2 diabetes
- Therapy: Diet, Oral, Insulin, Other, None
- Prior MI
- Cerebrovascular disease
- Peripheral vascular disease
- Central (aorta, renal) vascular disease
- Cardiomyopathy / LV systolic dysfunction
- Chronic lung disease
- ESRD on dialysis (current)
- Prior valve surgery
  - Date (most recent)
- Prior PCI
  - Date (most recent)
- Prior CABG
  - Date (most recent)
During the Procedure

• Who
  – CV Technologist / Nurse

• What information
  – Procedure log (play by play), procedure data

• What information as data
  – Hemodynamics, medications, procedures performed, devices used / implanted, medications – basically everything

• Output
  – Structured procedure data (in tables)
Procedure Reports

Analyze and Recompile

• **Who**
  – Physician (with the aid of the computer)

• **What information**
  – Findings and interpretations (physician)

• **What information as data**
  – Compiled H&P, compiled procedure data
  – Structured findings

• **Output**
  – Procedure log
  – Procedure report
Duke University Coronary Angiography Report

Native Diagnostic Summary

Right Coronary Artery
Prox RCA - 30% Tubular
30% Tubular

Left Main
**NORMAL**

Left Circumflex Artery
OM1 - small
LPL1 - small
LPL2 - small
L PDA - large
**NORMAL**

Left Anterior Descending
Mid LAD - small
D2 - 30% Tubular
D3 - 40% Discrete
D3 - small

Comment: distal LAD with intramyocardial segment
Cardiac Catheterization Procedure Report

SUMMARY

Procedures
Left heart catheterization
Percutaneous coronary intervention: prox LAD, mid-distal RCA
Intra-aortic balloon pump

History
A 57-year old man with hyperlipidemia, hypertension, and a positive family history who presents with typical chest discomfort with exertion relieved with rest. A stress echocardiogram was positive for ischemia in the anterior and inferior distributions.

Encounter category
Elective cath, possible PCI
Key diagnostic findings
Right heart
- RA: 10 (mean)
- PA: 42/18, 26 (mean)
- Wedge: 16
- AV O2\(\Delta\): 4.5 vol% 
- CO: 4.5 L/min
- CI: 2.5 L/min-m2

Coronary artery disease (significant)
- Left dominant
- Prox LAD: 90%
- Mid-distal RCA: diffuse 80%
- OM3: 60%

Left ventricle
- EF: 48%
- EDP: 12
- Wall motion: mod anterior hypokinesis, mild inferior hypokinesis
- MR: 1+ mild

Interventions
1. 90% prox LAD: Integrity 3.0mm x 20mm stent (bare metal)
2. 80% mid-distal RCA: Xience 3.0mm x 28mm stent (drug eluting)

Complications
- Ventricular fibrillation

Notes
- Anterior takeoff of the RCA, unable to seat JR catheter, required AL1 guide. VE with cannulation of conus branch with AL1 guide. RCA lesion opened at 18 ATM. Successful PCI x2, recommend thienopyridine indefinitely.

Catheters
- JL 4, JR4, Pigtail, Amplatz 1, XB 3.5

Signature / eSignature / attestation
Pages 3+ – Everything Else

Patient demographics
Healthcare facility information
Operators, staff
Referring care provider information
History and physical (categorical) data
Previous procedures
High risk allergies (e.g., contrast)
Laboratory data
ICD diagnoses
AUC indications

Procedures performed
Logistics (e.g., time in, time out)
Baseline data (e.g. height, weight, eGFR)
Vascular access details
Hemodynamic support
… and the rest of the details …
CVIS Vendors

Roles and Responsibilities

- Best practice: data handling integrated with workflow; team-based documentation
- Usability: interfaces designed and built for maximum efficiency and effectiveness (human factors design)
- Input devices: specific to role (e.g. mobile devices, workstations, hemo system interfaces)
- Graphics: graphical input and display of anatomic findings and treatment results
- Data management: use of controlled vocabularies including permissible values, range / consistency / validation checking; patient-centric (not procedure-centric) data model
CVIS Vendors
Roles and Responsibilities

- Outputs: structured report per specifications of this HPS
- Interoperability: adherence to the IHE Cath Report Content (CRC) profile, Cardiac Cath Workflow (CATH) profile, and ACCF/AHA Task Force on Data Standards key data elements for cardiac imaging documents
- Partnership: with professional societies on developing the structured reporting environment
- Point person role: dissemination of best practices in structured reporting to the clinical community
What Did We Accomplish?

- **Problem: inaccurate data, incomplete reports**
  - Distributed responsibility for acquiring data to those closest to the data
  - Eliminated double documentation (prelim + final report)
  - Focused the physician on cognitive work (assessment, recommendations) – computer compiles 90% of report

- **Problem: inefficient use of human resources**
  - Each group captures data at point of care
  - Each group responsible for accuracy, quality of data

- **Problem: poor / redundant communication**
  - Was: 4+ days on average to produce final report
  - Now: before the end of the procedure (no prelim report)
Artifacts at @ACC.org

Health Policy Statement
Informatics and Health IT Committee
Clinical Quality Committee

Prototype procedure report
Style guide
IHE profile
Task Force on Data Standards documents
CV Informatics

- **ACC/AHA “Top 100” EHR Terminology**
  - Weintraub WS et al., *JACC* 2011; 5:202-22

- **NCRI Cardiology Clinical Trials Terminology**
  - Anderson HV et al., *JACC* 2013; 61:1835-46

- **ACC/AHA/FDA CV Endpoints Terminology**
  - Hicks KA et al., *JACC* 2014 Dec (epub ahead of print)

- **ACC/AHA/SCAI Cardiac Cath Structured Reporting**
  - Sanborn TA et al., *JACC* ePub: 28 March 2014
  - IHE Cath Report Content (CRC-technical supplement)
    - [http://www.ihe.net/Technical_Frameworks/#cardiology](http://www.ihe.net/Technical_Frameworks/#cardiology)

- **Coming soon:**
  - Echo controlled vocabulary, HRS Health Policy Statement on EP Structured Reporting, NCDR Consolidated Data Dictionary
CVIS – Future State?

Enterprise Information Systems

- Clinical Data Repository (EHR)
- Decision Support Repository
- Registration (ADT), Accounts, Scheduling, Labs, Pharmacy, CPOE, Inventory, Interfaces …

Cardiovascular Information System

- OP → Admission → Discharge → OP
- History, ECG, medications, events

ALL Modality Management
- Measurements
- Analysis
- Reports
- Image processing

Integration Broker

- MD task worklist, reporting, eSignature, communications engine, administration
- Meta-data / resources

Consistent MD experience
- Pre-cert / LCD / Appropriate use
- Clinical decision support
- Scheduling / “White Board”
- Registry / quality reporting
- Modality “Plug and Play”

CPACS - Enterprise
The World is Changing …
What Will the Next Decade Hold for Cardiology?

<table>
<thead>
<tr>
<th>Was</th>
<th>Will Be</th>
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<tbody>
<tr>
<td>Modality / lab centric</td>
<td>Images everywhere</td>
</tr>
<tr>
<td>Paper / dictation</td>
<td>Optimized IT form factors</td>
</tr>
<tr>
<td>Data definitions by vendor</td>
<td>International data standards</td>
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<tr>
<td>Locked-in data</td>
<td>Interoperable data</td>
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<tr>
<td>Niche / possessive data use</td>
<td>Open, overlapping data use</td>
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<tr>
<td>Invasive maintenance</td>
<td>Zero footprint</td>
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<tr>
<td>Local data</td>
<td>HIE / cloud</td>
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<tr>
<td>Post-care reporting acquisition</td>
<td>Point-of-care data</td>
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<tr>
<td>Clinical trials model</td>
<td>Informatics model</td>
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<tr>
<td>Individual is the weakest link</td>
<td>Teamwork is dreamwork</td>
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29th ANNUAL PLENARY—PANEL SESSION:
Clinicians’ Needs for Improved Interoperability and How HL7 Can Help
11:15 – 12:25 pm

*****

Moderator
Stan Huff, MD
Chair, HL7 International Board of Directors

Panelists

Frank Opelka, MD
Medical Director, American College of Surgeons for Quality and Health Policy; Executive Vice President, Louisiana State University Health

Steve Hasley, MD
Medical Director for Information Technology, Women’s Health, UPMC; American College of Obstetricians and Gynecologists

Michael Hodgkins, MD, MPH
Vice President and Chief Medical Information Officer, American Medical Association

Dr. Phil Koczan, MBBS, FRCGP
General Practitioner; Chief Clinical Information Officer, UCL Partners and North East London Foundation Trust
Frank Opelka, MD, serves as the medical director for the American College of Surgeons for Quality and Health Policy. Dr. Opelka also serves as the Executive Vice President for Louisiana State University Health which covers 10 cities across the state in a safety net blanket and involves two academic medical centers and their respective health science schools. His current areas of focus have involved developing solutions for leveraging clinical data through informatics to define quality and optimally use the healthcare resources. He has hosted clinical data ecosystem summits to define strategic problems and consider solutions in health IT. Dr. Opelka is a Professor of Surgery at LSU and George Washington University. He reviews for several national peer reviewed journals in surgical care. He has over 100 publications and national presentations.

Steve Hasley, MD
Medical Director for Information Technology, Women’s Health, UPMC; American College of Obstetricians and Gynecologists

Dr. Hasley graduated cum laude from University of Pittsburgh School of Medicine, where he worked with Jack Myers and Randy Miller on the Internist/Caduceus program. He did his OBGYN training at Magee-Womens Hospital in Pittsburgh, and then entered private practice. In 2006, he closed his practice, and joined E&C Medical Intelligence (now PeriGen), a vendor of a high level EMR/DSS for
inpatient obstetrics. He is currently the Medical Director for Women’s Health IT for UPMC. He is the program director for the nascent Clinical Informatics Fellowship at UPMC, and as of January 2016 will serve as the CMIO for the American College of Obstetricians and Gynecologists.

Michael Hodgkins, MD, MPH
Vice President and Chief Medical Information Officer,
American Medical Association

Dr. Hodgkins is a seasoned physician executive with more than 25 years’ experience in health services, clinical connectivity and e-business solutions. In his current role, he provides leadership and expertise in developing products and services across the AMA including the development of AMA’s strategy for digital health and medicine. In addition, he informs AMA policy with respect to health information technology, represents the AMA on the Sequoia Project board of directors and chairs the Carequality Steering Committee.

Prior to joining AMA, he was the Senior Vice President and Chief Medical Officer of NaviNet, Inc., (formerly NaviMedix) the nations' leading healthcare communications network and technology company. Before that, he was SVP and Chief Medical Officer for Kinetra, Inc., a health information network services joint venture of Eli Lily and EDS.

Dr. Hodgkins completed a residency in Internal Medicine and fellowship in General Internal Medicine and Epidemiology at the University of California, San Francisco where he was previously Assistant Clinical Professor of Medicine and Epidemiology. He has a background in health planning and policy analysis and his ongoing interests include the design, development and implementation of technology-based solutions and services to meet the needs of the evolving healthcare market. He has been an invited speaker at national and regional conferences and is often interviewed as a key opinion leader and subject matter expert.
Dr. Koczan has been a general practitioner in Chingford North East London for over 20 years, having succeeded to a single handed practice. He is a fellow of the Royal College of General Practitioners and a member of their Health Informatics Group.

He has spent his career developing skills in medical informatics and has an MSC in the subject from Bath University and the Royal College of Surgeons, Edinburgh. He is currently Chief Clinical Information Officer for UCLPartners, an academic health science partnership, and North East London Foundation Trust. He is also the London Digital Clinical Champion for the Patient Online project with NHS England, and the clinical lead for a 111 data integration project.

Dr. Koczan is particularly interested in bringing data together from different care settings to facilitate the development of integrated care initiatives that are patient–centric, support clinicians in the delivery of patient care and utilize data for risk stratification, research and quality and patient safety improvement.
Slides not available in advance for Frank Opelka’s presentation
There will be no slideshow for Steve Hasley’s presentation
AMA has worked to improve the quality of medicine and health care IT for decades.
A person could be cured by sitting in this “shooter box” and receiving an infusion of “Orgon energy.”

Orgon energy would relieve symptoms of every malady from cancer to impotence.
First Code of Medical Ethics—1847
Exposing Diploma Mills
Improving The Quality of Medical Education
Leading Physician Support for the ACA
Three Big Ideas Drive AMA Strategy Today

21st Century Medical Education
- Competency-based training pathways
- Health Care Delivery Science
- Shaping Tomorrow’s Physician Leaders

Restoring the Joy of Practice
- Focus on the Patient-Physician Relationship
- Reducing Administrative and Regulatory Burden
- Support for New Payment Models
- Improving EHR Usability

Advancing Medical Education

Sustainable Medical Practices

Improving Health Outcomes

Connect Clinic to Community
- Interoperable Health Care System
- Developing Quality Measures
- Focus on Digital Medicine
- New Collaborations and Partnerships
Partnering To Improve Health IT
Stepping Stones Towards Interoperability
Interoperability
A clinicians perspective from the UK

Dr Phil Koczan MBBS FRCGP
General Practitioner
CCIO UCLPartners and NELFT
Structure of the NHS

Overview of the NHS structure

Single Payer within NHS

Thousands of individual organisations

Comprises of:-

- Primary care
- Secondary care
- Community care
- Mental health care
- Social care (outside of NHS funding)
A brief history of NHS Computing

General Practice Computing

National Programme for IT

Current paradigm
  ◦ National Interoperability standards
  ◦ Regional/Local implementation
  ◦ New models of care
New models of care

Focus on urgent and emergency care initially

Move towards integrated care

Vanguard sites

Requires greater data sharing in near real time across multiple care teams that have input into a patient's care.
Interoperability Strategy

The development of an open environment for information sharing supporting emerging models of care based on open interfaces and open standards.

Key Priorities

- NHS Number
- Transfers of Care

Local Integrated Digital Care Records (IDCR) that link health and social care as main approach for delivering local information sharing needs.

Tools

- Interoperability Handbook
- Procurement Guide

Through my system I can directly access and contribute to summary and detailed care information.

Professional

Open APIs

Tight standards for key transfers of care

Open interfaces to enable information to flow across a care pathway and to be accessed across geographies.

Expansion of SCR for access by additional care settings and additional critical information.

Patient Record Index

Ability to locate patient record information that can then be accessed through open APIs.

Using my PHR I can access care information about myself and contribute information.

Summary Care Record

Open interfaces from national systems such as SCR to simplify access and contribution.

Citizen

NHS England
Example of proposed model for urgent and emergency care

- Self-care
  - Peer support
  - Voluntary Sector

- Emergency (999)
- Urgent (111)

- Meeting your urgent care needs as close to home as possible

- Taking you to the most appropriate hospital and maximising your chances of survival and a good recovery from life threatening conditions

- Includes specialist services such as those for heart attack, stroke, major trauma, vascular surgery, critically ill children
Increased clinical focus

Historically there has not been enough clinical engagement in system design.

Chief Clinical Information Officers (CCIOs) are bridging the gap between clinicians, technical teams and informatics departments.

Professional Records Standards Body (PRSB) – is developing the clinical content for sharing data between care settings.
Current issues

Standards are seen by many to be:-
- Complex
- Expensive
- Not suited for the current models of care

Move towards standardisation
- Migration to SNOMED. Move from Read codes is a significant challenge for suppliers

Use of clinical document standards
- Initial benefit from human readable documents
- Move towards more structured data

Consent
The future

Standards need to be a cost effective enabler of change

Bring together the standards development, clinicians and suppliers

We aim to be able to view a record of the patient which may contain data from different systems in real time and update the record from within the clinicians own clinical system.
HL7 Plenary Meeting Notes: