Welcome to the SES February 2018 Webinar

Mobile Health Standards and Emerging Role of Cybersecurity in Healthcare (Cyberhealth)

Guest Speaker: Gora DATTA
HL7 International Ambassador

February 21, 2018
1:00 - 2:30 pm ET
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MOBILE HEALTH STANDARDS
AND
EMERGING ROLE OF CYBERSECURITY IN HEALTHCARE (CYBERHEALTH)

GORADATTA
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SES: Society for Standards Professional Webinar
Feb 21, 2018

- HL7 International Ambassador & Speaker
  - (founding) Co-Chair HL7 Mobile Health Work Group
  - HL7 2009 Volunteer of the Year Award Winner
- US Delegate to ISO/TC215 Health Informatics
- Chair IEEE Orange County
- Chair IEEE OC CyberSecurity
- Senior Member IEEE
- Senior Member ACM
- US (DHHS) SENIOR HEALTH-IT SME
- EHR MACRA & Meaningful Use Expert
- ICT Expert - Asian Development Bank, World Bank
- CHITO to US Ambulatory Physician Practices
- Group Chairman & CEO CAL2CAL Corporation
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ABSTRACT

With the phenomenal rise of mobile devices globally in the past decade, we have now entered the digital age – the agricultural age, the scientific age, the industrial age, the information age and now the digital age! This global transformation is bringing a change that is impacting our world in every way - how we interact, play, read, write, watch, study, research, work or even relax. Soon we will live in a world which is interconnected with Internet of Things (IoT).

Healthcare access & delivery is going through a seismic change…rapidly moving from paper to digital health. Health information technology (Health IT) is making it possible for health care providers to better manage patient care through secure use and sharing of health information. However, recent news headings (of WannaCry ransomware attacks in May 2017) are amply demonstrating the wake-up call….cybersecurity is redefining this changing world of digital health.

In this talk, we will review the digital health transformation that we are undergoing, the challenges of cyber-health that faces us and the emerging Mobile Health standards and other related standards that are foundational to the 21st century world of Digital Health [comprising of Blockchain, AR/VR/MR, Precision Medicine, Predictive Analytics, Machine Learning, Cloud Computing and Healthcare of Things (HoT)].
WHAT WAS NOT THERE IN 1918!

- NO Commercial Airline flights
- NO Penicillin
- NO (rotary dial) telephone
- NO TV
- NO Computers
- NO Internet
- NO Facebook
- NO Twitter…..(no Social Media)
HEALTHCARE
IN

THE PAST: 1918

THE FUTURE: 2118?

Let PRESENT guide us....
THE PRESENT
2018

THE CHANGING GENERATION
Changing Landscape: Paper to Digital

- **Stage 1: capture coded data**
  - 1) Capturing health information in a coded format,
  - 2) Using the information to track key clinical conditions;
  - 3) Communicating captured information for care coordination purposes;
  - 4) Reporting of clinical quality measures and public health information.

- **Stage 2: share information**
  - Focus on interoperability, disease management, clinical decision support, support for patient access to their health information, transitions in care, quality measurement, research, and bi-directional communication with public health agencies.

- **Stage 3: convert data to knowledge**
  - Focus on achieving improvements in quality, safety and efficiency, focusing on decision support for national high priority conditions, patient access to self-management tools, access to comprehensive patient data and improving population health outcomes.
Changing Landscape: Payment Model

20th Century Payment Model

- FEE FOR SERVICE (FFS) – Volume based
  - Payment is based on
    - # of Service provided

21st Century Payment Model

- P4P: Pay For Performance – Value based
  - Payment is based on
    - Improved health
    - Higher quality of service (Quality Measures)
    - Lower cost
WHY THE CHANGE?
What is driving this phenomenal growth?

**KEY DRIVERS**

- Increasing global population
- Aging population (not only a Developed world issue)
- Higher Life Expectancy (people living longer)
- Increasing Chronic diseases*: e.g., diabetes, obesity, heart disease
- Global reach of diseases
- Emergence of Personalized medicine
- Technological advances

*Chronic Disease is a long-lasting condition that can be controlled but not cured*
FUEL: MOBILE & IoT REVOLUTION!

- **Mobile phone market**
  - first billion mobile phones: 20 years
  - second billion phones: 4 years
  - third billion: 2 years
  - Fourth & fifth billion: 1 year – in 2013
  - 2014: nearly One Billion “smart” mobile phones sold globally
  - 2015 – > 1.2B units sold
  - 2016 – > 1.4B units sold
  - 2017 – > 1.5B units sold

- **IoT connected world by 2020**: projected to be **50 Billion devices**
HEALTHCARE MARKET SIZE

- **US GDP (2017)**
  - $19.4T (≈$19,386 Billion)*

- **US Healthcare spending: 18% of GDP = $3.5T**
  - (> Σ of healthcare spending of rest of the world!)

- **US Projected GDP by 2022**
  - $23T

- **US (projected) healthcare spending in 2020**
  - 20% of the GDP = $4.6T

* [https://www.bea.gov/newsreleases/national/gdp/gdpnewsrelease.hmt](https://www.bea.gov/newsreleases/national/gdp/gdpnewsrelease.hmt)
### Exhibit 9. Select Population Health Outcomes and Risk Factors

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<th>Country</th>
<th>Life exp. at birth, 2013&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Infant mortality, per 1,000 live births, 2013&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Percent of pop. age 65+ with two or more chronic conditions, 2014&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Obesity rate (BMI&gt;30), 2013&lt;sup&gt;a,c&lt;/sup&gt;</th>
<th>Percent of pop. (age 15+) who are daily smokers, 2013&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Percent of pop. age 65+</th>
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<sup>a</sup> Source: OECD Health Data 2015.

<sup>b</sup> Includes: hypertension or high blood pressure, heart disease, diabetes, lung problems, mental health problems, cancer, and joint pain/arthritis. Source: Commonwealth Fund International Health Policy Survey of Older Adults, 2014.

<sup>c</sup> DEN, FR, NETH, NOR, SWE, and SWIZ based on self-reported data; all other countries based on measured data.

21st Century Digital Health

mHealth4ALL
Mobile Health Scenarios

- Caregiver on the move
  - Hospitals, Clinics, Long term care, Hospice

- Patient empowerment
  - Patient involvement in care process across a wide range of lifestyles, including: support for long term conditions

- Independent living
  - Assisted living drawing on a range of mobile services

- Behavioral health
  - Behavioral health support anytime, anywhere

- Messaging (ranging from unsecure to secure)
  - Bridging the health divide

- Public/Population Health
  - Disaster Management to PH outreach
MOBILE HEALTH STAKEHOLDERS

MOBILE HEALTH: Not a vertical domain
But a horizontal framework that cuts across and impacts all health care domains
MOBILE HEALTH MARKET TREND

1. Main driver: Ever increasing global smartphone users
2. Young Customers will drive the market
3. MH apps leveraging features of smartphones or tablets
   - Location service
   - IM
   - Picture, Video
   - Gyroscope
   - Accelerometer
   - Micro payment service
4. MH apps native rather than web-based applications
5. Rise of MH app stores
6. 2nd generation mHealth applications will focus on chronic diseases
7. MH will push/expand/broaden the health business model
8. MH apps entering traditional (health) distribution channels
9. MH apps will bridge the global health divide
10. Evolving MH standards
There are over **165,000 mobile health apps**
- RIME OF THE MODERN TECHNOLOGIST - “mobile, mobile everywhere….none *talk* to anyone”
- 12% of mHealth apps account for more than 90% of all consumer downloads
- with nearly half of all downloads generated by just 36 apps

“If you build them, will they come?”

90% of MH (and financial) apps are vulnerable to critical security risks

Mobile Health app are *projected to become a regular part of our care* (over the next 5 years)
DOLLAR$ and NO CENTS!
MOBILE HEALTH MARKET SIZE

- 2016 projection: > $13B
- By 2017, *it is estimated*, the market for Mobile Health apps, will be…
  - > $26 billion
- By 2020:
  - > $50B
WORLD OF CYBERSECURITY*

- Ransomware damage cost: $325M in 2015 - $5B in 2017 (15x incr)
- 2016 Global “Cost” of cybercrime: $3T
- By 2021, this impact is expected to go up to $6T
- CyberSecurity spending to cross $1T by 2021 (currently around $80B)

NOW THE OPPORTUNITY

- Cybersecurity unemployment rate
  - 0 .....yes Zero!
- Cybersecurity jobs: Currently at around 1.2M / by 2021 = 3.5M!
- Online presence: from 2B today to over 4B by 2020

CYBERSECURITY EVENTS*
THREE MONTH SNAPSHOT (8 of 44 in 2017)

1. OneLogIn (5/31/17)
2. Kmart (5/31/17)
3. University of Oklahoma (6/14/17)
4. Washington State University (6/15/17)
5. Deep Root Analytics (6/20/17)
6. Blue Cross Blue Shield / Anthem (6/27/17)
7. California Association of Realtors (7/10/17)
8. Verizon (7/13/17)

* https://www.identityforce.com/blog/2017-data-breaches
CYBERHEALTH
US HIPAA BREACH DEFINITION

Under HIPAA (Health Information Portability & Accountability Act), a breach is defined as:

“…the acquisition, access, use or disclosure of PHI in a manner not permitted under [HIPAA] which compromises the security or privacy of the PHI.”

PHI=Protected Health Information

HEALTHCARE BREACHES OF 2017*

1. Peachtree Neurological Clinic (177k patient)
2. UC Davis Health (15k patients)
3. Verizon (14m customers)
4. BUPA Global Health Insurance (108k customers)
5. Indiana Medicaid (1.1m)
6. Cleveland Medical Associates (22k patients)
7. Airway Oxygen (500k patients)
8. California-based Dougherty Laser Vision

HEALTHCARE BREACHES OF 2017* (cont#2)

9. Feinstein & Roe MDs in Los Angeles (6k patients)
10. La Quinta Center for Cosmetic Dentistry (6.3k patients)
11. Coliseum Pediatric Dentistry of Hampton, Virginia
12. Torrance, CA Memorial Medical Center
13. Molina Healthcare (4.8m patients)
14. WannaCry ransomware – NHS, England & Scotland + 150 other countries
15. New Jersey Diamond Institute (15k patients)

HEALTHCARE BREACHES OF 2017* (cont#3)

16. Harrisburg Gastroenterology (93k patients)
17. Bronx-Lebanon Hospital Center (10k to million patients)
18. Aesthetic Dentistry, NY (3.4k patients)
19. OC Gastrocare (34k patients)
20. Tampa Bay Surgery Center (142k patients)
21. 500k children record from various pediatrics offices
22. Lifespan (20k patients)
23. HealthNow Network (918k patients)

HEALTHCARE BREACHES OF 2017*  
(cont#4)

24. Harrisburg Gastroenterology (93k patients)

25. ABCD Children‘s Pediatrics (55k patients)

26. Washington University School of Medicine (80k patients)

27. Metropolitan Urology Group (18k patients)

28. Denton Health Group (7 years of EHR backup data)

29. Brand new Day Health Plan (14k patients)

30. Singh and Arora Oncology Hematology (22k patients)

HEALTHCARE BREACHES OF 2017* (cont#5)

31. Verity Medical Foundation-San Jose Medical Group (10k patients)

32. CoPilot Provider Support Services (220k patients)

33. Cancer Services of East Central Indiana-Little Red Door ($43K ransom)

ANATOMY OF AN ATTACK*

* [https://www.sonicwall.com/SonicWall.com/files/95/9546a705-3f0b-412e-a2cf-1d4f7d4ab026.pdf](https://www.sonicwall.com/SonicWall.com/files/95/9546a705-3f0b-412e-a2cf-1d4f7d4ab026.pdf)
A REAL WORLD STORY
A REAL WORLD STORY (cont#2)

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A REAL WORLD STORY (cont#3)

MinorGate - Gateway to crypto currency!
A REAL WORLD STORY
(cont#4)

NICE PICTURE!
CCTV installation is a good idea?....WELL.....

These were manufacturer supplied details. The Practice has since updated these.
TELL-TALE: Elementary my dear Watson

- Disk is corrupted or some message asking to call Microsoft Support at 1-800…. NOW
- Application showing a user (that you don’t know of) is logged-in
- PC behaving strange/sluggish – can’t really say what is wrong but the feel of it
- It’s been a while since upgrades were run or AV was run
- Staff not trained on Security Risk Analysis
Next Steps.....(technical)

- Clear your calendar for the next many hours (days)!

- Ring-fence & isolate the impacted device(s)
  - No internet connection

- Figure out how to restart the device to boot mode - F2, F8, bang on all function keys! 😊
  - There is no standard
  - Change to boot off USB drive first

- Have your “Swiss army knife” ready way-way before....huh?
SWISS ARMY KNIFE

A bootable* portable disk with AV!

Next Steps.....(administrative)

- Know your Federal as well as State laws regarding data breach
- Inform your Provider(s)/Management immediately of any incident
- Inform the EHR vendor, ASAP
- Follow steps learnt during Security Compliance training

REMEMBER: What applies for patients, applies here as well!

PREVENTION IS FAR-FAR BETTER THAN CURE
MOBILE HEALTH STANDARDS

- HL7 Mobile Health
- ISO/TC 215
- IEEE 11073 family
The **HL7 Mobile Health Work Group** creates and promotes health information technology standards and frameworks for mobile health.

- [HL7 Mobile Health Wiki](#)
EMERGING Mobile Health Standards

- HL7 Emerging Standards
  - Consumer Mobile Health Application Functional Framework – cMHAFF
    - STU – Jan 2018
  - Mobile Framework for Healthcare Adoption of Short-Message Technologies (mFHAST)
    - Proposed STU – Sept 2018
  - FHIRFrame: MH API Interoperability Framework

- ISO/TC215
  - Graphical Symbols/Pictorial Representation in (Mobile) Health
Consumer Mobile Health Application Functional Framework (cMHAFF) Overview and Update
cMHAFF Scope and Goals

- Provide a standard as a framework for assessment of a mobile app’s foundational aspects:
  - Security
  - Privacy/consent
  - Risk assessment
  - Usability assessment
  - Data access privileges for consumers and others
  - Data export (sharing)
  - Transparency of conditions (disclosures)

- Assessment might include attestation, testing, endorsement, and voluntary or regulatory certification

- Out of scope: clinical/health content or functionality
HL7 mFHAST Standard

Mobile Framework for Healthcare Adoption of Short-Message Technologies
HL7 mFHAST Goal

- To provide standards for communicating health services through short message technologies (SMTs) (e.g. SMS, Instant Message, Twitter, etc.)
- To increase opportunities for consumer / patient engagement and timely communication
- To improve communication and response time among providers of health services
Graphical Symbol/Pictorial Representation in (Mobile) Health

a proposed standard of ISO/TC215 New Work Item (NWI)
Standards for Symbols

- Standards exist to enable rapid, non-verbal communication in domains such as transportation and occupational safety.
- No analogous standards exist for the health care domain.
- ISO has multiple standards guiding choice of text size, colors, shapes, and placement, among other things.
Potential applications #1

- Mobile devices could enable symbols related to healthcare needs to be accessed even on a locked screen.
Potential applications#2

- Multiple possibilities:
  - Aging Communities
  - Behavioral health
  - School health
  - Child health
  - Non-verbal Consumers
  - Care across language barrier
  - .........
IEEE 11073 Standards (recognized by FDA)

ISO/IEEE 11073 standard family defines parts of a system, with which it is possible, to exchange and evaluate vital signs data between different medical devices, as well as remote control these devices.

1. IEEE 11073-10101™ "Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature"
2. IEEE 11073-10201™ “Health informatics—Point-of-care medical device communication—Domain information model”
3. IEEE 11073- 20101™ “Health informatics—Point-of-care medical device communication—Application profile—Base standard”
5. IEEE 11073-20601a-2010™ “Health informatics—Personal health device communication—Part 20601: Application profile—Optimized exchange protocol”
IEEE 11073 Standards (cont.)

7. IEEE 11073-10415™ “Health informatics—Personal health device communication—Part 10415: Device specialization—Weighing scale”
8. IEEE 11073-10404™ “Health informatics—Personal health device communication—Part 10404: Device specialization—Pulse oximeter”
9. IEEE 11073-10421-2010™ “Health informatics—Personal health device communication Part 10421: Device specialization—Peak expiratory flow monitor (peak flow)”
10. IEEE 11073-10406-2011™ “Health informatics—Personal health device communication Part 10406: Device specialization—Basic electrocardiograph (ECG) (1- to 3-lead ECG)”
“THROUGH THE LOOKING GLASS”
HEALTHCARE IN THE 21st CENTURY (baker’s dozen)

1. Next generation: “iPAD™” kids

2. Blurred Lines:
   - Impact of Social Media
   - Concept of Privacy

3. Are we there yet: I want it NOW

4. Take Charge: Consumer Health, Patient Engagement, PGHD, PRO, SODH

5. Gene to genes: from Star-Trek (Gene Roddenberry) to Genetic Health – personalized medicine

6. Space – The Final Frontier: “Healthy” flights
…..21st CENTURY (cont.)

7. Back to the Future: Longitudinal Health Record
8. Live long & prosper: from provenance to preservation
11. “l'addition s'il vous plaît”: Mobile micro-payments
12. Take care: CyberHealth, Blockchain, UDI
13. Alexa dating Watson?: AI, Machine Learning, Bots
An Example Architecture
INTEGRATED DETECTION & MANAGEMENT OF CHRONIC CONDITIONS

MOBILE DEVICE PROCESSES

Capture Personal Details, Height, Weight, Waist Circumference

Capture Blood Pressure, Blood Glucose

Tobacco use

Alcohol use

Depression

Capture Blood Pressure, Blood Glucose

Compute Score and Generate Report

Score Updates

Cut off Marks (Smoker's)

Cut off Marks (CAGE)

Cut off Marks (Depression)

Cut off Marks (CHD)

CALDR+ (CHD Module) (existing)

CALDR+ (Smoker’s Module) (to be developed)

CALDR+ (Alcohol Use) (to be developed)

CALDSG (PHQ9 & HAD SCALE Module) (existing)

Report Generation Module

Clinician’s PC (existing)

Inbound Device Authorization Module (existing)

Outbound Device Relay Module

Server System

EMR Systems

Secured Web Service

Storage

Secured Storage

CALP

Settings Manager

External Diagnostic Device Manager

Profile Manager

IO Manager

Update Settings Manager

Questionnaire Manager

External Diagnostic Device Manager

MOBILE DEVICE PROCESSES

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# MOBILE SOLUTION – GREEN SOLUTION

![Image of mobile solution setup](image)

## Probs & Mgmt. (1/2)

**Date**: 2/3/2006  
**#1**

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<th>Item</th>
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### Lipitor
- **1**
- **4**

### Advil
- **1**
- **1**

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KEY TAKEAWAYS!

- Changing Landscape: Paper to Digital
- World of IoT & Mobile
- Life in 21st century: not your parent’s world!
- Understand the expectations of the current (and future) generation
- CyberSecurity is the unwelcomed but a permanent roommate
- Healthy advice: Prevention is always better than cure
As we transition to a digital record framework; use of Mobile Technology leads the way (in access, capture and dissemination of information)

As Mobile & IoT Devices become more and more ubiquitous, accessing our Information is only a few tap/swipe/transmit away!

“WASH YOUR HANDS” – CYBER HYGIENE is critical in the world we live in

LIFE IN 21st CENTURY
- Cloud connected, IoT driven, micro-services enabled, cyber-safe, Digital Health world
THANK YOU

goradatta@ieee.org
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Wednesday, March 21, 2018 at 1:00 PM ET
Scott Colburn - Director, CDRH Standards Program

Regulators Role in Improving Standards to Support International Harmonization – International Medical Devices Regulators Forum [IMDRF] Standards Working Group

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