

Now they've gone mobile...

Managing ESI within Health Information Systems



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Outline

- Introduction:
 - Legislative and regulatory overview
 - Updates from last year
 - Key areas of increasing concern
- Mobile applications, devices and ESI
- Mobile apps in litigation environment
- Patient Safety risks and ESI, suppression of discovery of safety defects, patient harms (Usability separate subject or as sub-section as major contributing cause to Safety risks?)
- Summary, HIT in litigation
- Wrap up, start up Q&A

Session Description

- **Session Description:** Relative latecomers to computerized records, electronic health record systems (EHRs) remain proprietary and risk-laden. Commonly absent records management functions considered requirements in other industries. EHRs are rarely designed for integrity or evidentiary inquiries, much less configured, tested, implemented, and/or operated for assuring trustworthy ESI. The rapid expansion of telemedicine, home-based and patient-worn medicating and monitoring remote systems expands variability and risk. These records may, unknown to users, provide overly revealing detail or, at the other extreme, only approximations or even corruptions of information, thus providing unique challenges in supporting legal proceedings.

Introduction

Spending Fiscal 2011 (in \$Millions)

Business activities supported by health care sector business records:

Medicare	554,299
Medicaid Federal	248,176
Medicaid State	159,474
Children's Health Insurance Program-Federal	8,393
Children's Health Insurance Program-State	3,622
Military Health Services	39,700
Veteran's Administration Health	50,082
Maternal and Child Health Programs-Federal	584
Vocational Rehabilitation-Federal	416
Substance Abuse and Mental Health Services Admin.	3,445

Total Federally Mandated Health Services Costs 1,068,191

Total Healthcare Spending-Public and Private 2,700,739

Introduction

Legislative and Regulatory

EHRs as Key Indicator of Federal Policy on eRecords

Legislative and regulatory events

Saving “Obamacare” Affordable Care Act

“Meaningful Use”

EHR Financial Incentives Program (\$17B+)

Introduction

Updates and Recent Events

2012 Holder/Sebelius on fraudulent electronic records

2013 Federal Health IT Authority Hearings on “Legal Records” in EHRs

2013 Dept. of HHS Office of Inspector General (OIG) report

2014 OIG report on HHS/Centers for Medicare and Medicaid Services (CMS) non-compliance

The 2014 E-Discovery and Information Governance National Institute
ABA AMERICAN BAR ASSOCIATION

Auditability Optional

December 2013 Dept. of HHS OIG Report (p. 15)

“...nearly half of hospitals (44 percent) reported that they can delete their audit logs. Although these hospitals reported that they limit the ability to delete the audit log to certain EHR users, such as system administrators, one EHR vendor noted that any software programmer could delete the audit log.”

Levinson, Daniel R., NOT ALL RECOMMENDED FRAUD SAFEGUARDS HAVE BEEN IMPLEMENTED IN HOSPITAL EHR TECHNOLOGY, December 2013, OEI-01-11-00570 p. 15 available at <http://oig.hhs.gov/oer/reports/oei-01-11-00570.asp>

D'Alessio, *et al.* v. Vanderbilt University, *et al.*, US District Court, Middle District of Tennessee (Nashville), Case No. 3:11-cv-00467

- “Vanderbilt also designed a software tool (VPIMS) to perpetuate its billing practices, the lawsuit claims.”
- “In reality, Vanderbilt has used the VPIMS to maximize its false billing...”
- “VPIMS’ purported improvements in billing efficiency are, in fact, largely a function of Vanderbilt’s development of mandatory default software settings that require its physicians, in all instances, to document that they meet Medicare’s conditions for payment.”

<http://www.tennessean.com/article/20130912/NEWS07/309120946/Vanderbilt-Medical-Center-fil-Medicare-fraud-suit?gcheck=1&ndick=check51>

Tested, Not Required In Use

(iv) Audit log protection. Actions and statuses recorded in accordance with paragraph (d)(2)(i) must not be capable of being changed, overwritten, or deleted by the EHR technology.

(v) Detection. EHR technology must be able to detect whether the audit log has been altered.

From “**2014 Edition EHR CERTIFICATION CRITERIA 45 CFR 170.314**”

Question...

What is mobile?

What is Mobile?



Mobile is Not Going Anywhere

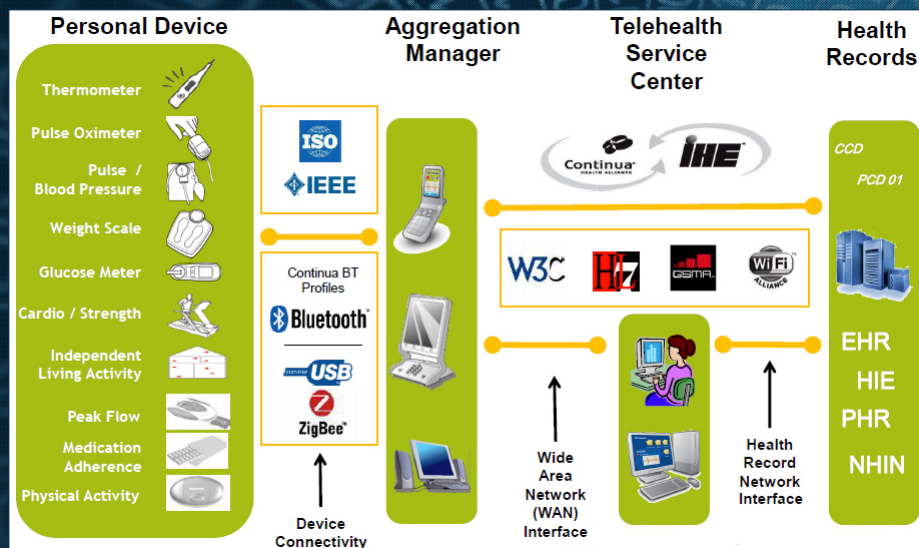
- Forbes:
...Business leaders are looking for change. The mobile enterprise and BYOD 2.0 is not about bringing devices to work; **it is about using devices for work**. How does business turn these shiny new toys into business tools? That means allowing employees to work with customers, **review contracts, write blog posts – do real work on mobile devices**.

Source: Forbes.com, BYOD As We Know it is Dead, Interview with Yaacov Cohen, CEO of harmon.ie (Oct. 4, 2013)
<http://www.forbes.com/sites/bobegan/2013/10/04/byod-as-we-know-it-is-dead/>

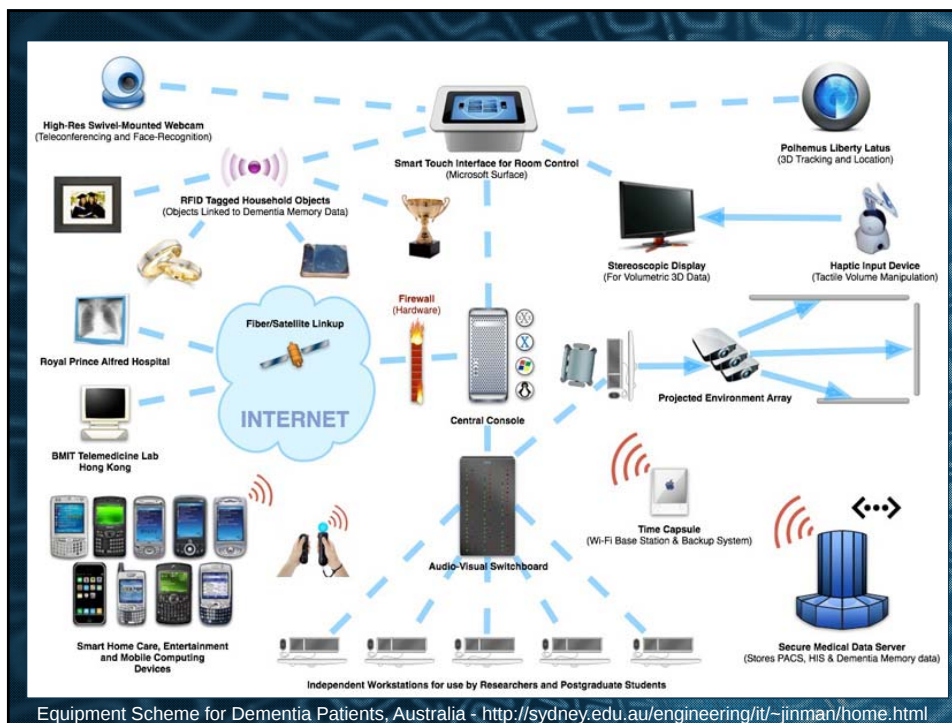
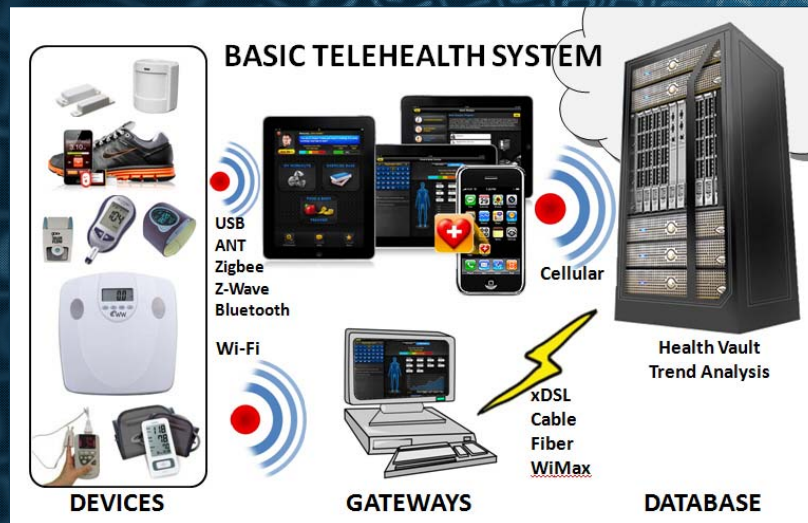
Question...

What is mobile *in* Healthcare?

What is Mobile *in* Healthcare?



What is Mobile *in* Healthcare?



What is Mobile *in* Healthcare?



What is Mobile *in* Healthcare?



Julius Knapp, Chief, Office of Eng'g & Tech., FCC, FCC Actions to Advance Mobile Health Technology, Mobile Health Technology Summit 2012 (from Hank Fanberg Texas HIT Summit Jan 2011)

What is Mobile *in* Healthcare?

The Smart Car

- Seat
 - Weight
 - Blood pressure
 - Breathing rate
- Steering Wheel
 - Pulse
 - EKG
 - Blood oxygen (PO_2)

Walter, Eilebrecht ET AL
Personal and Ubiquitous Computing
November 2010

Per Ubiquit Comput (2011) 15:707–715
DOI 10.1007/978-94-007-0356-4
ORIGINAL ARTICLE

The smart car seat: personalized monitoring of vital signs in automotive applications

Marian Walter · Benjamin Eilebrecht · Tobias Wartek · Steffen Leonhardt

Received: 3 April 2010 / Accepted: 20 November 2010 / Published online: 7 January 2011
© Springer-Verlag London Limited 2011

Abstract Embedded wireless sensors are important components of mobile distributed computing networks, and one of the target applications areas is health care. The preservation of mobility for senior citizens is one of the key issues in maintaining an independent lifestyle. Thus health technologies inside a car can contribute both to safety issues (supervision of driver fitness) as well as healthcare issues by monitoring vital signs imperceptibly. In this paper, three embedded measurement techniques for non-contact monitoring of vital signals have been investigated. Specifically, capacitive electrocardiogram (cECG) monitoring, mechanical movement analysis (thallotocardiogram, BCG) using piezo-film and inductive impedance monitoring were examined regarding their potential for integration into car seats. All three sensing techniques omit the need for electroconductive contact to the human body, but require defined mechanical boundary conditions (stable distances or, in the case of BCG, frictional connection). The physical principles of operation, the specific boundary conditions regarding automotive integration and the results during wireless operation in a running car are presented. All three sensors were equipped with local intelligence by incorporating a microcontroller. To eliminate the need for additional cabling, a wireless Bluetooth communication module was added and used to transmit data to a measurement PC. Finally, preliminary results obtained during test drives on German city roads and highways are

Keywords Distributed sensor network · Wireless sensor · Non-contact monitoring · cECG · BCG · MIT · Automotive · Vehicle seat

1 Introduction

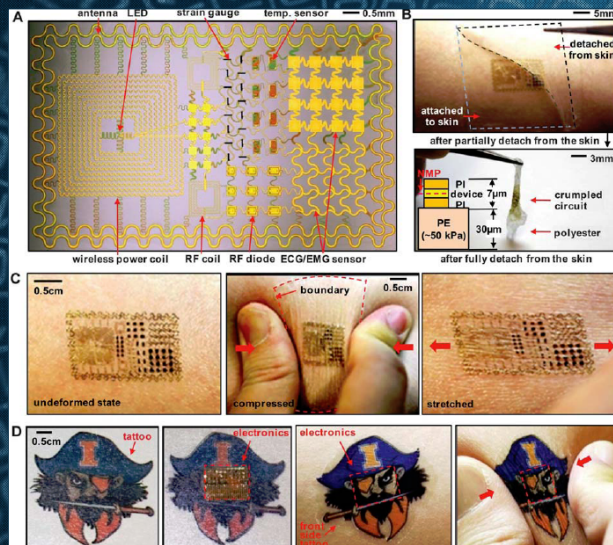
Research on wearable monitoring systems has attracted much attention and activities during recent years [1, 2]. It is thought that smart embedded sensing systems are one of the possible options to control future costs of health care in aging societies. The demographic changes that many countries are going to face will be accompanied by an increasing number of elderly car drivers, and thus automotive medical support is expected to attract further attention by insurers, health care providers or emergency services. Two typical use cases might be defined for such a scenario. Driver fitness monitoring is of major concern, when acute health problems impair the ability to drive safely. A car-integrated medical sensor system could be capable of detecting such critical conditions and initiate appropriate measures ranging from driver interventions (e.g. safety auto pilot) to emergency services (e.g. car to car or car to emergency communication services, qualified ambulance call). If the sensor system inside the car is able to acquire validated physiological data on a regular basis, the vital signs data can also be used in a broader context as



Julius Knapp, Chief, Office of Eng'g & Tech., FCC, FCC Actions to Advance Mobile Health Technology, Mobile Health Technology Summit 2012 (from Hank Fanberg Texas HIT Summit Jan 2011)

What is Mobile *in* Healthcare?

"We introduce a different approach, in which the electrodes, electronics, sensors, power supply, and communication components are configured together into ultrathin, low-modulus, **lightweight, stretchable "skin-like" membranes** that conformally laminate onto the surface of the skin by soft contact, in a manner that is mechanically invisible to the user, much like a temporary transfer tattoo."



Dae-Hyeong Kim et al., Epidermal Electronics, 333 Science 838 (2011); research out of the Univ. of Illinois at Urbana-Champaign

Consider: Your Phone = Life

- Your phone knows everything about you!
 - Who your friends are
 - Who you like the most/least
 - Who you like to talk to, who like to text
 - Where you are, where you've been, and maybe where you're going
 - What kind of music you like
 - Who you bank with
 - Your schedule

skype

LOL

☺



SkyDrive



romrom



Dropbox



Treasure Trove of ESI

- Locations
- E-mails
- Contacts & Call History
- Calendar Events
- Text / SMS / MMS
- Skype Chat
- Usernames and Passwords
- Photos (w/GPS)
- Notes
- App Data, Usage, and Search History
- Tasks
- Audio
- Serial No.
- Device ID
- Bookmarks
- Deleted applications, notes, contacts, etc.

Concerns with “Traditional” Mobile

- Many manufacturers; many OS versions (ios, Android, BlackBerry, Symbian, Firefox, Windows, Ubuntu, Bada OS, etc., plus each of their numerous versions)
- Lack of skilled forensic specialists with untested forensic technology
 - Technology innovation exacerbates issue because vendors cannot keep pace
- Cross-border collection/retrieval issues
- Many devices = many custodians
- Device ownership issues with move to BYOD
- Data retention and gathering

Mobile in Healthcare...

- What is the **cost** involved in gathering, storing, and reviewing this data?
- If your phone can show your life, then what do these mHealth devices show?



- What does proportionality mean when you live in a ‘smart house’ and drive a ‘smart car’?
- What does privacy mean when your tattoo can measure, store and share your vital signs?

Mobile is Growing in Healthcare

- Primary drivers of growth
 - Not enough doctors to treat growing and aging population
 - General desire across a number of stakeholders to save on healthcare costs (*i.e.*, Accountable Care Organizations, Shared Savings model, employer fitness programs)
- HIS, an analytics firm, predicts the telehealth market to grow from \$240 million in 2013 to \$1.9 billion by 2018 (Bruce Japsen, Forbes, ObamaCare, Doctor Shortage To Spur \$2 Billion Telehealth Market, Dec. 2013)

Mobile and Healthcare Litigation

Mobile and Healthcare Litigation

- Assessing Clinician Use -- Communication

- *The Bipolar Standard of Care.*

"It is not acceptable for physicians or licensed independent practitioners to text orders for patients to the hospital or other healthcare setting. This method provides no ability to verify the identity of the person sending the text and there is no way to keep the original message as validation of what is entered into the medical record." Joint Commission, Nov. 2011

VS.

Electronic Communications as Supporting Patient Care:

- *BYOD and Retention*
 - *Outside of the EHR*
 - *Security Rule*
 - *The Facetime Physical*
 - *Telemedicine*

Mobile and Healthcare Litigation

- Impact of Apps

- *Standard of Care*
 - *Distracted Doctoring*
 - *Product Liability Issues Complicated by FDA status*
 - *# 1 Determinative Factor of your Health*
 - *Collaborative Care & the Standard of Care*
 - *Crowdsourcing your medical advice*
 - *ESI Goldmine for patient statements, medical history and patient behaviors.*



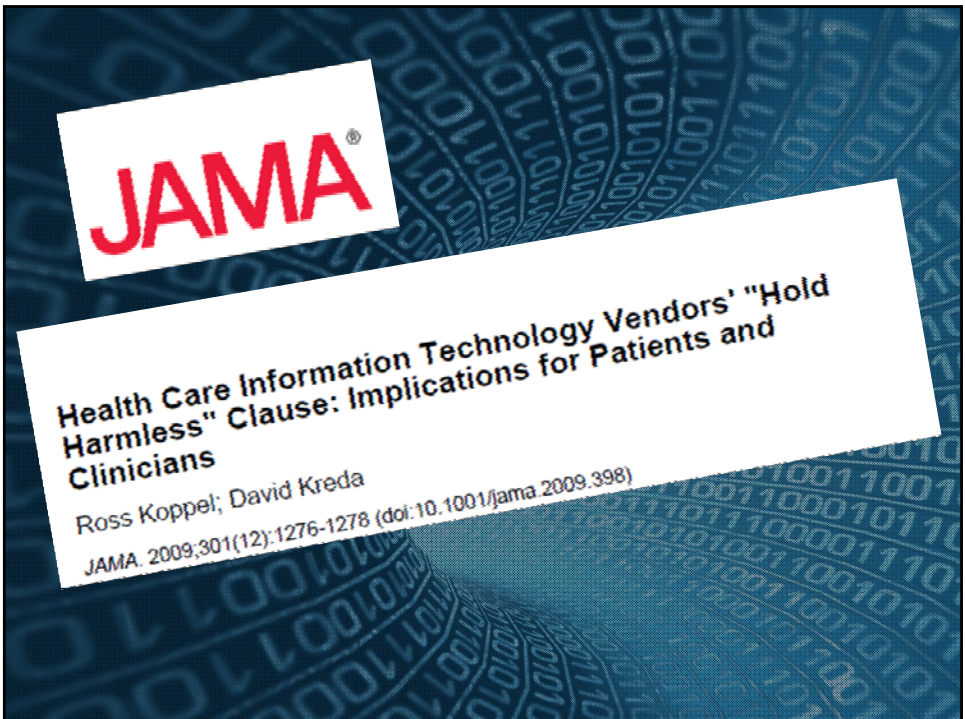
Usability and Safety



Now You See It; Now You Don't;
Now You See It; Now It's Changed:
Hold Harmless Clauses & The
Ephemeral Realities Of 'Copy & Paste'
In Electronic Health Records

Two Topics:
Several Patient Safety Dangers and
Liabilities

1. Hold Harmless and Non-Disclosure
Clauses: and
2. EHR-unique examples: Cut and
Paste/Copy and Paste



JAMA

**Health Care Information Technology Vendors' "Hold
Harmless" Clause: Implications for Patients and
Clinicians**

Ross Koppel; David Kreda

JAMA. 2009;301(12):1276-1278 (doi:10.1001/jama.2009.398)

1. Hold Harmless Clause

- What is it?
- Legal “logic:” Learned Intermediary
- Example...
- If vendor informed?
- Included in most HIT contracts?

Yes

- Ignored by buyers

Yes, until it's too late

Who wants it removed? ...and what happened?

- Patient Safety Dangers

1.5 Non-Disclosure Clause

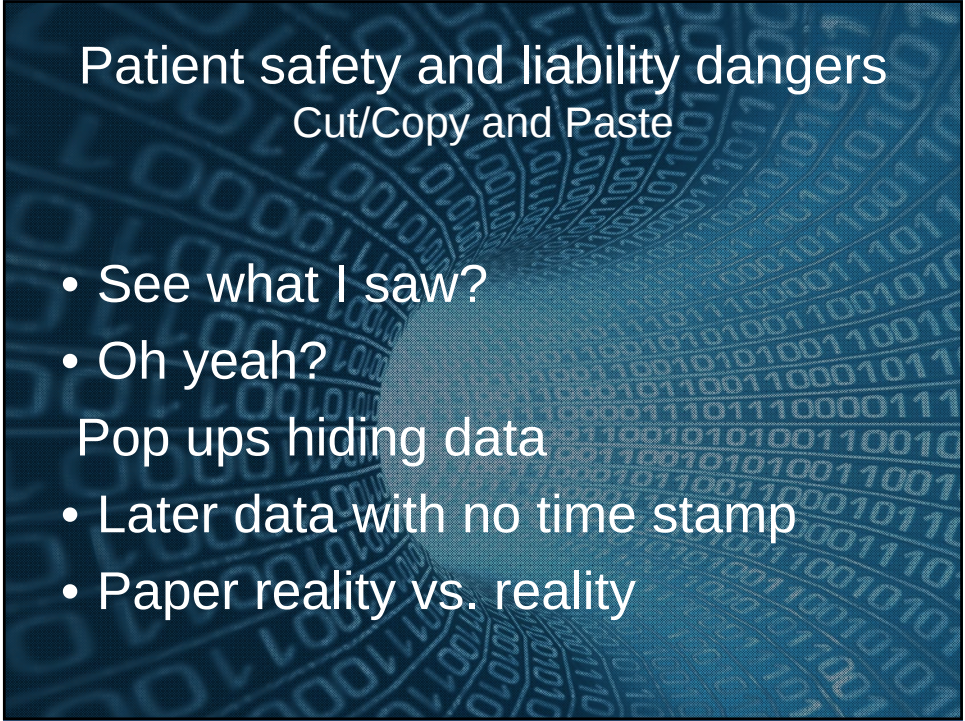
- What is it?
- IP protection and nothing pejorative
- Example?
- What's prohibited?
- In most HIT contracts?
- Noticed by hospitals?
- Who wants it removed? What happened?
- Patient Safety Dangers

Cut and Paste; Copy and Paste

CHEST March, 2014 Editorials
Illusions and Delusions of Cut, Pasted,
and Cloned Notes: Ephemeral Reality
and Pixel Prevarications
Ross Koppel, Ph.D., FACMI

Cut/Copy and Paste

- Has uses
- BUT...
- Chart Bloat
- Fraudulent billing and payments
- Confusion of authorship and ordering
“doc”
 - “Make me the author”
- Confusion of dates and progress



Patient safety and liability dangers

Cut/Copy and Paste

- See what I saw?
 - Oh yeah?
- Pop ups hiding data
- Later data with no time stamp
 - Paper reality vs. reality



HIT in Litigation

HIT Problems in Litigation

- Paper Chart Disconnect
- Non-Standardized Software Products
 - Metadata
 - Primary Data
- Inability to Produce Native Data
- Functionalities of EHR may make authentication problematic

41

41

Paper Chart Disconnect

- Cannot rely on chart printout.
 - Audit Trail a must.
 - EHR access if permitted/legal.
 - Early intervention with in-house tech/vendors regarding what could be missing.
- OR
- Early focus on depositions of the same.

42

42

Audit Trail

- The audit trails can include details about:
 - Late entry (authenticity)
 - Spoliation (Deleted Entries)
 - Records Tampering (Modified Entries)
 - Rule violation (Privacy & Security)

Non-Standardized Software Products

- Start with institutional resources if possible.
- EHR specialized experts that know the market invaluable.
- 700+ vendors
 - ONC Certified EHR list = 3873 EHRs (2919 Ambulatory and 954 Inpatient)
- Meaningful Use not focused on technical standards or business records' practices

Inability to Produce Native Data

- Access to the EHR.
- Just because you dealt with the same software product you can make no assumptions (functionalities, versions, modules).
- Screen shots?
- Access during eDiscovery depositions of in house technical or vendors
- Partner with in house and vendors for solutions
- “Read only” access/ Custom Tools

45

Functionalities of EHR may make authentication/credibility problematic

- Review of the full enterprise record usually a tip- off as to templated/populated material.
- May consider exploring templating tools available in this implemented software with your EHR deponents.
- Assess prevalence and relevance of templated material.
- Audit trails/functions to assess authorship concerns.
- You must consider results in your overall litigation strategy, whether you will use to attack the record, impeach the witness or both.

46

46

Northshore University Health System Case

- Upgraded EMR from time of Care, View Changes
- Impossible to Recreate Exactly What the Clinician Saw
- Different Displays of Data Based on User
- Audit Trail Confusing w/ Baffling Time Stamps, Missing "Pending" Orders in Chart
- Puts Clinicians on Defensive about Record

Electronic Medical Evidence

- EMR data does not correspond to a paper chart
- Authentication Problematic?
- Metadata
- Time stamps and Logs
- Time Overrides and Synching issues
- Deleted/Modified Entries

Summary

EHRs as high-visibility, high value digital records systems lacking accuracy and integrity

Federal policy disruptions to market forces increase uptake of defective and deficient systems

- Last year: Business operations and risk management defects and deficiencies
- This year: Safety defects and problem scope expansion into mobile devices, un-tethered systems

At odds with FRE presumptions of BR reliability

Results and Implications

Increasing risk of non-reliability of EHR-operating enterprises, EHR-sourced data and EHR-“artifact”/document production

“Mobile” is about exhuberance > rapacity

Acceleration of eDiscovery complexities, costs

Legal process pushback likely, necessary



Questions and Discussion

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- Testified before the Office of the National Coordinator for Health IT in Washington on HIT Liability concerns.
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