

HIPAA and EMRs

Issues to Consider Before Implementing an EMR

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Goals

- Brief EMR and Paper records Overview
 - Basic Elements of EMRs and the Privacy Rule
- Vendor Selection Issues
- Privacy and Security Rule Implications
- Access by Physicians and Researchers
- Interoperability Issues
- e-Discovery and HIPAA Issues for EMRs



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EMR vs. EHR vs. PHR?

- **EMR**
 - An electronic platform for managing detailed medical information about multiple different persons, usually owned or operated by one health care provider or a small group of providers.
- **EHR**
 - Comprehensive aggregate set of clinical, demographic, financial and other information relating to a person, not limited to a single care provider.
- **PHR**
 - A person-specific and directed health record, not limited to a particular provider, which is controlled by the individual and tracks a person's health through their lives.

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Basic EMR

Logician - Peter Basch MD @ Washington Primary Care Physicians (WPCP) - 2/26/2004 12:35 PM - [Chart]

Go Actions Options Help

I Ama Dummy Patient ID: 10-0015001 Home: None Work: None
 23 Year Old Male (DOB: 06/27/1980) PCP: Peter Basch MD Insurance: Group:

Summary Problems Medications Alerts Flowsheet Orders Documents

Problems

SYNCOPE
 ALLERGIC RHINITIS
 ANEMIA, IRON DEFICIENCY
 HYPERPARATHYROIDISM
 DIABETES, UNCOMPLICATED, TYPE II
 S/P INGUINAL HERNIA REPAIR - LEFT
 THYROID NODULE
 DIABETES, UNCOMPLICATED, TYPE II
 L4/5 HERNIATION

Medications

PLENDIL TAB 2.5MG CR (FELODIPINE)
 NASONEX SUS 50MCG/AC (MOMETASONE FUROATE) 2
 PHENERGAN VC SYP /CODEINE (PHENYLEPH-PROMETH.
 PREVACID CAP 30MG DR (LANSOPRAZOLE) 1 qd prn
 CELEBREX CAPS 200 MG (CELECOXIB) 1 tab po qd
 ZOCOR TAB 20MG (SIMVASTATIN) 1 qd
 ZOCOR TAB 10MG (SIMVASTATIN) 1 qd
 EFFEXOR XR CR/4 27.5 MG (VENLAFAXINE HCL) 1 qd

Allergies

BIAXIN (CLARITHROMYCIN)

Directives

SEE ADVANCE DIRECTIVE ON F

Flowsheet: Enterprise/HEALTH MAINTENANCE

	Date	Value
COMPPHYSICAL	09/04/2002	H&P
HEIGHT	06/12/2002	60
WEIGHT	06/12/2002	140
TEMP ORAL	09/04/2002	99.0
BP SYSTOLIC	09/04/2002	112
BP DIASTOLIC	09/04/2002	70
PULSE RATE	09/04/2002	68
EKG	10/07/2000	NSR
SIGMOID	01/06/2003	normal
COLONOSCOPY	09/04/2002	wnl
CXR	09/04/2002	NAPD

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For Help, press F1

Advanced EMR

Logician - Harry S. Winston MD @ Southside Clinic (LOCAL) - 6/17/2004 7:33 PM - [Chart]

Go Actions Options Help

Desktop Chart Appts Reg Reports New View Print Internet Help EXIT

Judy S. Pullman CHECK PROTOCOLS Home: 503-299-7222 Work: 503-531-7036
 41 Year Old Female (DOB: 04/13/1963) Patient ID: 227-TEST011 Insurance: CHC (Gold Plan) Group: CHC3497

Find Pt. Problems Graph Handouts Update Phone Nt. Refills Edit Sign Append Route Organize

Summary Problems Medications Alerts Flowsheet Orders Documents

Document View: All

- All
- Hospital Documents
- Tests

Doc ID: 34 Properties

Physical Exam

General Appearance: well developed, normal, PERRLA, EOM, fundi visible

Ears, Nose, Mouth, Throat: TM normal, no lymphadenopathy

Neck: supple, no lymphadenopathy

Respiratory: clear to auscultation

Cardiovascular: regular rate and rhythm, pulses normal and symmetric, no murmurs

Chest: no scars, masses, tenderness

Gastrointestinal: soft, non-tender, no tenderness

Gastrointestinal: regular rate of pulsations, guaiac negative stool

Genitourinary: external genitalia normal, speculum exam normal, no adnexal masses or tenderness

Lymphatic: no cervical, axillary or inguinal adenopathy

Musculoskeletal: gait normal, muscle tone and strength WNL, no joint swelling, effusions, discoloration, crepitus

Skin: clear, good turgor, color WNL, no rashes, lesions, or ulcerations

Neurologic: normal mental status, normal reflexes, normal strength, sensation, and motion

Psychiatric: alert, oriented to person, place and time

Preventive Care Reminders:

Logician Message

Debbie Diabetes
 54 Year Old Female:

The following Tests are now due:

- Lipid Panel
- HbA1c
- Creatinine
- Microalbumin (urine)

The following Procedures are now due:

- Due for Colorectal Cancer Screening
- Due for Cervical Cancer Screening (PAP)
- Due for Breast Cancer Screening (Mammogram)

Would you like to see the Indications for these recommended Tests/Procedures? Click 'Yes' to see the Indications; Otherwise click 'No'.

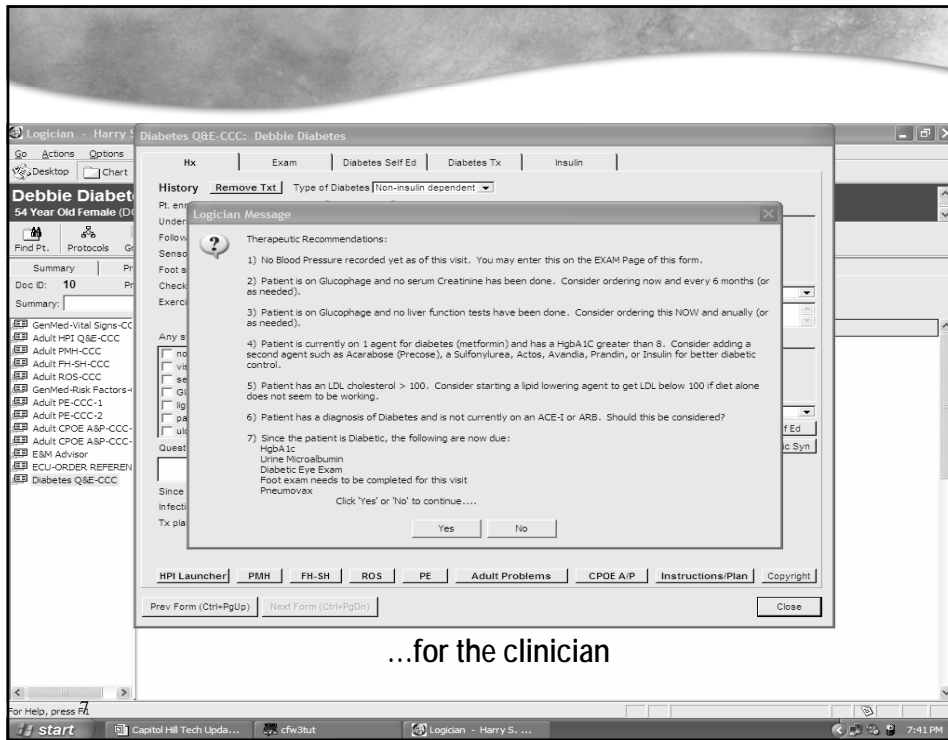
Yes No

Location	Status
SOUTH	Unsigned
SOUTH	Signed
SOUTH	Signed

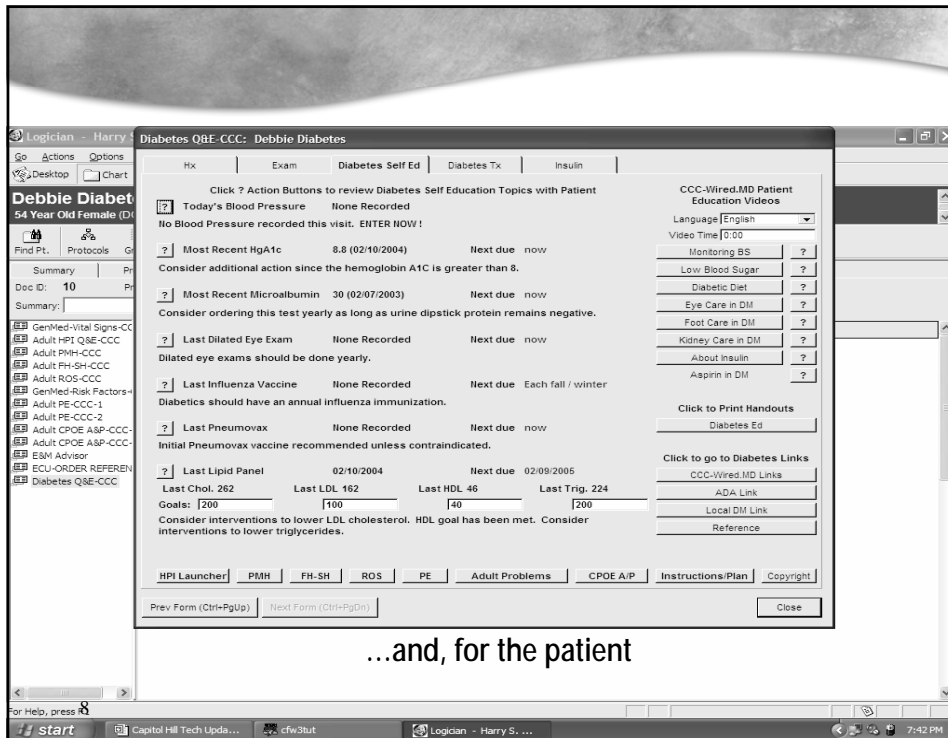
Decision support for staff

For Help, press F1

start Capitol Hill Tech Upda... cfw3kut Logician - Harry S. ... 7:33 PM



...for the clinician



...and, for the patient

How are Electronic Health Records Different From Paper Records?

- Volume of available data
- Duplicability of data?
 - Storage media costs low
 - No incentive to discard
- Data Accessibility and Searchability
- Dynamic/Changeable Content
- Potential for Data Loss
- Obsolescence of Legacy Systems
 - Not easy to migrate data into other systems?
- Metadata

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EMRs Presumed Benefits

- **Quality**
 - Better documentation
 - Online scheduling features
- **Safety and Clinical Outcomes**
 - Practice reminders
 - Medication management
 - Treatment protocols
- **Access**
 - Remote clinician access
 - Easier patient access
- **Administrative Efficiency**
 - Fewer FTEs required
 - Fewer manual chart pulls and related activities
 - Improved chart request compliance
- **Cost Reduction and Revenue Enhancement**
 - Materials and storage costs
 - Transcription costs
 - Labor costs
 - Copying expenses
 - Among others

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Competing Interests?

<i>Key Stakeholders</i>	<i>Primary Interests</i>
Payers and Govt.	Costs
Physicians and Clinical Staff	Not always certain (quality? safety? revenue enhancement?)
Health Care Administration	Make the physicians happy, costs
CIO/IT Staff	Costs and efficiencies
HIM Directors	Cost reduction, staffing containment, and efficiencies
Privacy/Compliance Officers	Compliance with laws
Security Officers	Technical specifications
Patients	Privacy, security, and quality

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Vendor Selection

"Choosing an EMR is like getting married. Unless you make a really lousy choice, you will be happier than before. It can take as long to find an EMR as a spouse, and it's a huge deal to divorce your EMR and wed another..."

Paul C - EMR Update, December 2006

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Vendor Selection

- Use reputable vendors
 - Be wary of new EMR vendors
 - Consider exploring whether the vendor's development and maintenance services are outsourced overseas?
 - Consider whether any subcontracting of these services are permitted?
- You need a team approach to EMR selection
 - Administration
 - Physicians
 - Others

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Contracting Issues

- No right for Vendor to cut off access for failures to pay license fees or other breaches
 - Clear statement of ownership of medical records
 - Don't permit medical records company to impair the entry, printing or downloading of PHI
- Customization issues
 - User testing and acceptance
- Free upgrades to comply with HIPAA or state law privacy and security requirements?

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Contracting Issues

- Business Associate?
 - Licensor relationship v. maintenance/tech support relationship
- Scanning existing paper records?
 - Several contract provisions to consider
- Adequate divorce/wind-down and data transition provisions?
 - Standardize formats?
 - Data should be easily transferable to other EMR systems?

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Privacy-Related Issues

- What is the Designated Record Set?
 - Is that different from the legal health record?
 - What about integration of records from other providers?
 - HIPAA doesn't require you to amend records from other providers - unless the originator can no longer act on the request for amendment. (45 C.F.R. §164.526(2)(i)).
 - Check state law requirements.
 - What about integration of other "super" protected records.
 - Psychotherapy notes/Mental health observations?

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Privacy-Related Issues

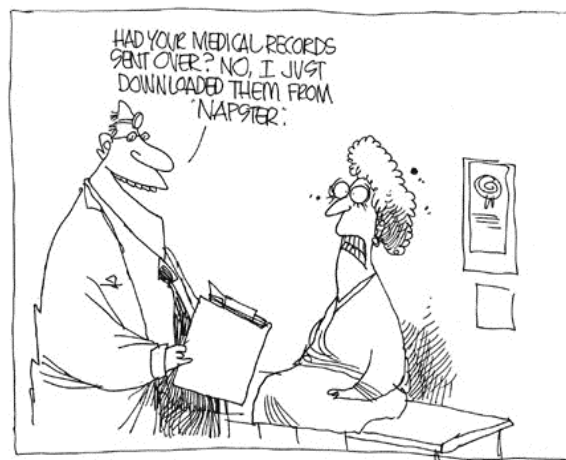
- “Minimum Necessary” Standard
 - Does the EMR permit you to limit use and disclosure “minimum necessary” PHI?
- Fundraising
 - Is the EMR being accessed and used for Fundraising purposes?
 - If so, can it run reports with only permitted PHI?
 - Would use of EMR for fundraising be an indicator of service area/treatment/condition?

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Patient Rights



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Patient Rights

- Notice of Privacy Practices (NOPP)
 - Review your NOPP - Do you now use or disclose PHI differently as a result of the EMR?
 - Any material change to:
 - uses,
 - disclosures,
 - individuals rights,
 - legal duties,
 - or other privacy practices stated in the NOPP require revision to the NOPP?

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Patient Rights

- Right to Inspect and copy PHI
 - Do you provide online or downloadable access to your EMR?
 - Covered Entities must provide the individual with access to their PHI in the form or format requested by the individual if it is readily producible in such form or format...(45 C.F.R. §164.524(c)(2)).
 - Do you print copies of EMR pages and will this result in much larger or costlier printing?
- Right to Amend PHI
 - How do you amend an EMR and maintain a record of the date and time of the amendment?

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Patient Rights

- Right to an Accounting of Disclosures
 - Does the EMR have a disclosure tracking module that permits you to track all non-TPO disclosures?
 - If not, how do you track disclosures?
 - Paper shadow file?
 - Central database?
 - Does your EMR automatically create disclosures for public health reporting?
 - HIV/AIDS/Communicable disease reporting?
 - Are these accounted for and how?

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Security-Related Features



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Security of Electronic Patient Information Systems

- Remember HIPAA Security Rule Requirements
 - Requires Technical, Physical and Administrative safeguards to protect PHI.
 - To maintain the security, confidentiality, integrity and availability of PHI.
 - Not accessible to people not authorized to see it
 - Not changed or deleted maliciously or by mistake
 - Readily accessible to authorized providers
 - Use of Passwords (generic, do not share, etc.)
 - Physical security (hardware, files, etc)

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Security of Electronic Patient Information Systems

- Need to understand whether ePHI can be downloaded from EMR and how?
 - Pay attention to insiders
 - Ability of staff to download EMR data onto thumbdrives, dvds, etc.?
 - Sell ePHI for profit?
 - Commit medical ID theft for friends and family?
 - Make sure Audit trail features are turned on and that you have access to them for a sufficient period.
- Does your EMR link to wireless handheld devices?
 - Are your security measures HIPAA-compliant?
- Access to EMRs and other Electronic Records
 - Just because you *can* access patient records doesn't mean you're *permitted*

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Access and Use of EMRs for Research



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Electronic Medical Records (EMRs) and Research

- Pros
 - Access to large volume of data
 - Can even access another Physician's patient records
 - Quickly and efficiently searchable and retrievable
- Cons
 - Large volumes of data
 - Easily transferable
 - No control after it leaves the facility
 - Inadequate controls over access and security?
 - Inability to control/determine the purposes of the access
 - Usually up to user to determine purpose of the access
 - Lack of audit trails?

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Issues for Researchers

- HIPAA Rules are the same for EMRs as they are for Paper Records
 - Permission to Access, Use, or Disclose PHI is always determined by **PURPOSE**
- Each time PHI is accessed it must be permitted by HIPAA mechanism
 - Authorization, Waiver, Review Preparatory to Research, Review of Decedent Information, Limited Data Set
 - Again – just because a physician/clinician can access and run reports from EMRs doesn't mean they're permitted to do so.

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Challenges that Apply to EMRs

- Most EMRs aren't designed to address HIPAA compliance
 - Usually no automated forms/approval mechanisms
- IRB Approvals almost always paper-based
 - Where do you stick the paper forms approving access to PHI for research when there is an EMR system?
- Who can have access – for which purposes?
 - Different rules for Workforce members vs. Non-Workforce members
 - Screening Prep. to Research?

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HIPAA and e-Discovery Implications

- Need to define the medical record
 - Will be the record of clinical information you provide to patients when they request access.
- But, new e-discovery rules could require you to produce native EMR records (including metadata) in malpractice litigation.
 - Need to understand the discovery rules (including HIPAA's provisions relating to Judicial and Administrative proceedings).

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Forms of Discoverable Electronic Health Information?

- Electronic Medical Record Data Sets
- Scanned paper documents
- e-mail communications with patients
- EKG Strips or other diagnostic device data
- Digital Images/Animations
- All associated metadata

- Would you produce all this stuff if you received an "any and all" subpoena?

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Scanning and Destruction of Existing Paper Records

- Destruction or Storage of Scanned Paper Records?
 - HIPAA requires availability and accessibility
 - What if scanned images are inadequate?
 - Skewed pages
 - Light contrast
 - Too dark
 - Pages stick together/missing copies
 - Folded edges
 - Post-its and other obstructions
- Quality Controls?
 - Vendor randomized sampling

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Impact of Interoperable EMRs or Access to EMRs by Other Providers

- Role-based access
 - Are you willing to permit access to your EMR to other providers?
 - Number of issues to consider
 - Cherry-picking of patients?
 - Other anti-competitive effects?
 - Do you require EMR users to sign a “user agreement” which describes their permitted uses and disclosures?
 - Do you supplement with training and education?
- Purpose-based access
 - May be okay for TPO purposes?
 - How do you limit access for only TPO purposes?
 - How do you process requests for non-TPO access?

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Site Visits to View/Demo the EMR

- EMR vendors often what to demo their systems at existing EMR client sites.
- Demonstrations of “live” patient data should not be permitted.
- Employ a camouflage level of software to appropriately “de-identify” the dataset.
- R&D on new EMR features should similarly not use “live” patient data.

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Important Take-Aways

- Privacy considerations should be carefully weighed when selecting an EMR vendor or when developing a “homegrown” system.
- The Privacy and Security Officers need to understand the details of how each EMR system functions.
- The Privacy and Security Officers should develop explicit guidelines concerning access, use, and disclosure by all users.
 - Policies and procedures may need to be materially altered
 - If so, NOPP needs to be reviewed and possibly revised
 - Training and Education Programs may need to be altered to address issues unique to EMRs.
- Consider a stringent user agreement which describes the permitted uses and disclosures from EMRs.

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Questions or Comments?

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