

Electronic Health Record and Clinical Trials: Advantages and Data Quality Issues

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EHR and EDC

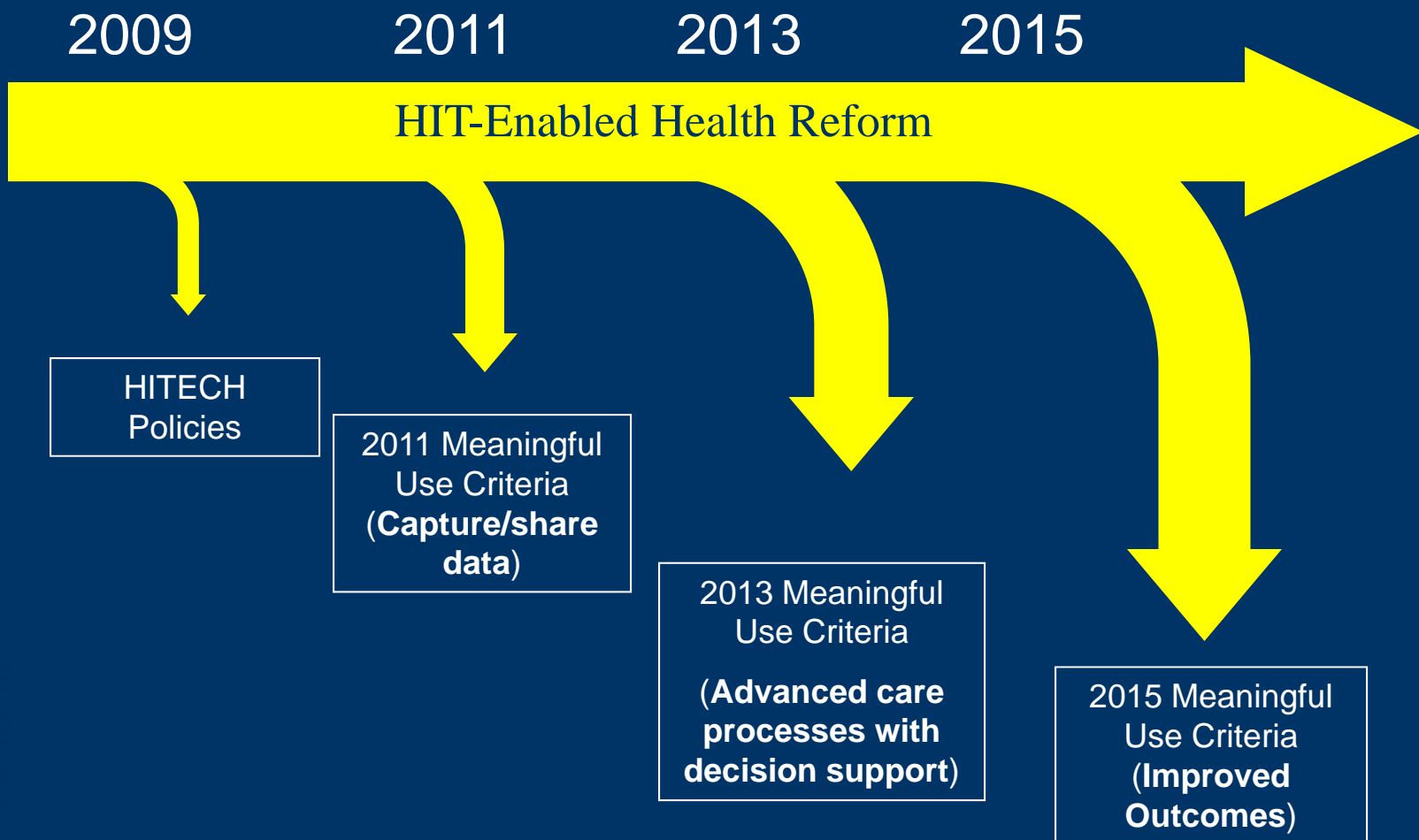
| Use | Data System | |
|-------------------|----------------------------------|--|
| Clinical Practice | EHR Electronic Health Records | A system for collecting clinical signs, symptoms, problems, diagnoses and test results to support routine clinical care. |
| Clinical Trial | EDC Electronic Data Capture | A system for entering clinical trial data directly from remote investigator sites. |

Electronic Health Records

- National mandates for conversion from hand written documents to electronic health records
 - Reducing medical errors
 - Cost saving
 - Time saving
 - Higher quality of care

Health Reform

Achieving Meaningful Use



Use of EHR in Clinical Trials

- Electronic health record systems (EHRs) can accelerate prospective clinical trials by:
 - Being interoperable with clinical trial EDC systems
 - Providing readily available patient data in EHR systems
 - Providing high quality patient data

Paper System



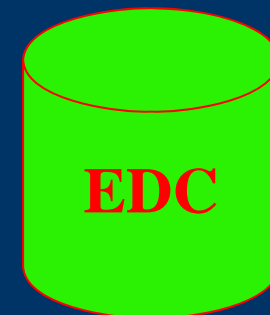
Patient Chart



CRF



Electronic System



Advantages

- Facilitate patient screening
- Accelerate patient recruitment
- Auto populate study data from EHR system
- Reduce cost of data collection and monitoring

Challenges

- Interoperability
 - Ability of two or more systems or components to exchange information and to use the information that has been exchanged [IEEE Standard Computer Dictionary, 1990]
 - Use of CDISC and HL7 Standards
- Security
- HIPPA and 21CFR Part 11 compliance
- System variations in multi site trials

Data Quality

Paper System



Patient Chart

Transcription
Error



CRF

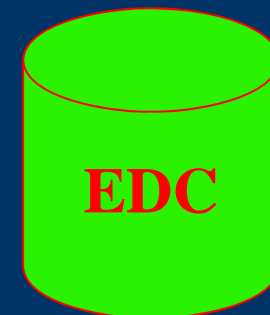
Data Entry
Error



Electronic System



Hopefully
No Error



Data Quality in Clinical Practice

- 98,000 people die annually due to medical malpractice during hospitalization
- Poor data quality is believed to be one of the main factors contributing to malpractice

Institute of Medicine, 2006

Data Quality in EHR

“Improving the quality of data, information, and knowledge in the U.S. healthcare system is paramount as we transition from paper to electronic health records.”

American Health Information Management Association (AHIMA), Oct. 2006

- A few examples of data quality in EHR from research literature

Data Accuracy in EHR

- Saigh et al. (2006)

- Primary care patients

- 55% of 97 encounters had active pain documented in free-text or the problem list, but a “no pain” entry in the data template*

Data Accuracy in EHR

- Persell, Dunne, et al. (2009)
 - Adult primary care patients
 - 28% of 500 charts had discrepancies in age, gender, blood pressure, mean total and HDL cholesterol, medications (antihypertensive, lipid-lowering, or antithrombotic), or smoking status*

Data Completeness in EHR

- Faulconer and de Lusignan (2004)

- COPD

- FEV-1 (within 27 months): 90%;*
 - smoking status: 10%*

FEV-1 Forced Expiratory Volume in the first second

Data Completeness in EHR

- Goodyear-Smith et al. (2008)

- Children

- Immunization receipt:*

- 70% for 6 weeks immunization
 - 60% for 3 months immunization
 - 55% for 5 months immunization
 - 20% for 15 months immunization

Use of EHR in EDC

- In the near future patient data will only be available in EHR systems
- With over 300 software vendors and over half a million physician practices in the US, great variation in EHR systems will exist for a long time
- International EHR systems add to the variation

Conclusion

- Accuracy and completeness of EHRs is lower than is needed for clinical trials
- All of the factors that affect EHR data quality and variability are not known
- Level of accuracy and completeness of data in EHRs should be evaluated for each clinical trial
- Standards such as CDISC and HL7 should be implemented widely to facilitate interoperability
- Data accuracy and completeness in EHRs require process improvement and institutional-wide training and education on data quality

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Thank you!