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

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## EHR and EDC

<table>
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<tr>
<th>Use</th>
<th>Data System</th>
<th>Description</th>
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<tbody>
<tr>
<td>Clinical Practice</td>
<td>EHR</td>
<td>A system for collecting clinical signs, symptoms, problems, diagnoses and test results to support routine clinical care.</td>
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<td>Electronic Heath Records</td>
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<td>Clinical Trial</td>
<td>EDC</td>
<td>A system for entering clinical trial data directly from remote investigator sites.</td>
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<td>Electronic Data Capture</td>
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Electronic Health Records

- National mandates for conversion from handwritten documents to electronic health records
  - Reducing medical errors
  - Cost saving
  - Time saving
  - Higher quality of care
Health Reform
Achieving Meaningful Use

HIT-Enabled Health Reform

2009
HITECH Policies

2011
2011 Meaningful Use Criteria
(Capture/share data)

2013
2013 Meaningful Use Criteria
(Avanced care processes with decision support)

2015
2015 Meaningful Use Criteria
(Improved Outcomes)
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

Electronic System

Patient Chart

CRF

Trial Database

EHR

EDC
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 → Trial Database

Electronic System

EHR → Hopefully No Error → EDC
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
“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
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.
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
Faulconer and de Lusignan (2004)
- COPD
  
  *FEV-1 (within 27 months): 90%*
  
  *smoking status: 10%*

FEV-1 Forced Expiratory Volume in the first second
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
References

- Department of Health and Human Services, Office of National Coordinator for Health Information Technology, Vision for meaningful use, *slide set*.
Thank you!