Operational Electronic Health Record Data for Comparative Effectiveness Research: Limitations and Challenges

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References

Benin, A., Fenick, A., et al. (2011). How good are the data? Feasible approach to validation of metrics of quality derived from an outpatient electronic health record. *American Journal of Medical Quality,* 26: 441-451.

Bernstam, E., Herskovic, J., et al. (2010). Oncology research using electronic medical record data. *Journal of Clinical Oncology,* 28: suppl; abstr e16501.

Blumenthal, D. (2011a). Implementation of the federal health information technology initiative. *New England Journal of Medicine,* 365: 2426-2431.

Blumenthal, D. (2011b). Wiring the health system--origins and provisions of a new federal program. *New England Journal of Medicine,* 365: 2323-2329.

Botsis, T., Hartvigsen, G., et al. (2010). Secondary use of EHR: data quality issues and informatics opportunities. *AMIA Summits on Translational Science Proceedings*, San Francisco, CA.

Bourgeois, F., Olson, K., et al. (2010). Patients treated at multiple acute health care facilities: quantifying information fragmentation. *Archives of Internal Medicine,* 170: 1989-1995.

Boyd, D. and Crawford, K. (2011). Six Provocations for Big Data. Cambridge, MA, Microsoft Research. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1926431.

Chan, K., Fowles, J., et al. (2010). Electronic health records and reliability and validity of quality measures: a review of the literature. *Medical Care Research and Review*: Epub ahead of print.

Chute, C., Pathak, J., et al. (2011). The SHARPn project on secondary use of Electronic Medical Record data: progress, plans, and possibilities. *AMIA Annual Symposium Proceedings 2011*, Washington, DC. 248-256.

Collins, F. (2011). Reengineering translational science: the time is right. *Science Translational Medicine,* 3: 90cm17.

Denny, J., Miller, R., et al. (2009). Identifying QT prolongation from ECG impressions using a general-purpose natural language processor. *International Journal of Medical Informatics,* 78(Suppl 1): S34-42.

Finnell, J., Overhage, J., et al. (2011). All health care is not local: an evaluation of the distribution of emergency department care delivered in Indiana. *AMIA Annual Symposium Proceedings*, Washington, DC. in press.

Friedman, C., Wong, A., et al. (2010). Achieving a nationwide learning health system. *Science Translational Medicine,* 2(57): 57cm29.

Helfand, M., Tunis, S., et al. (2011). A CTSA agenda to advance methods for comparative effectiveness research. *Clinical and Translational Science,* 4: 188-198.

Hey, T., Tansley, S., et al., eds. (2009). *The Fourth Paradigm: Data-Intensive Scientific Discovery*. Redmond, WA. Microsoft Research.

Hripcsak, G., Friedman, C., et al. (1995). Unlocking clinical data from narrative reports: a study of natural language processing. *Annals of Internal Medicine,* 122: 681-688.

Jollis, J., Ancukiewicz, M., et al. (1993). Discordance of databases designed for claims payment versus clinical information systems: implications for outcomes research. *Annals of Internal Medicine,* 119: 844-850.

Kahn, M. and Ranade, D. (2010). The impact of electronic medical records data sources on an adverse drug event quality measure. *Journal of the American Medical Informatics Association,* 17: 185-191.

Kho, A., Pacheco, J., et al. (2011). Electronic medical records for genetic research: results of the eMERGE Consortium. *Science Translational Medicine,* 3: 79re1.

Kullo, L., Ding, K., et al. (2010). A genome-wide association study of red blood cell traits using the electronic medical record. *PLoS ONE,* 5(9): e13011.

Liao, K., Cai, T., et al. (2010). Electronic medical records for discovery research in rheumatoid arthritis. *Arthritis Care and Research,* 62: 1120-1127.

McCarty, C., Chisholm, R., et al. (2010). The eMERGE Network: a consortium of biorepositories linked to electronic medical records data for conducting genomic studies. *BMC Genomics,* 4(1): 13.

O'Malley, K., Cook, K., et al. (2005). Measuring diagnoses: ICD code accuracy. *Health Services Research,* 40: 1620-1639.

Parsons, A., McCullough, C., et al. (2012). Validity of electronic health record-derived quality measurement for performance monitoring. *Journal of the American Medical Informatics Association*: Epub ahead of print.

Rea, S., Pathak, J., et al. (2012). Building a robust, scalable and standards-driven infrastructure for secondary use of EHR data: The SHARPn project. *Journal of Biomedical Informatics*: Epub ahead of print.

Safran, C., Bloomrosen, M., et al. (2007). Toward a national framework for the secondary use of health data: an American Medical Informatics Association white paper. *Journal of the American Medical Informatics Association,* 14: 1-9.

Schneeweiss, S. and Avorn, J. (2005). A review of uses of health care utilization databases for epidemiologic research on therapeutics. *Journal of Clinical Epidemiology,* 58: 323-337.

Sox, H. and Greenfield, S. (2009). Comparative effectiveness research: a report from the Institute of Medicine. *Annals of Internal Medicine,* 151: 203-205.

Stanfill, M., Williams, M., et al. (2010). A systematic literature review of automated clinical coding and classification systems. *Journal of the American Medical Informatics Association,* 17: 646-651.

Thiru, K., Hassey, A., et al. (2003). Systematic review of scope and quality of electronic patient record data in primary care. *British Medical Journal,* 326: 1070.

Uzuner, O. (2009). Recognizing obesity and comorbidities in sparse data. *Journal of the American Medical Informatics Association,* 16: 561-570.

Uzuner, O., Goldstein, I., et al. (2008). Identifying patient smoking status from medical discharge records. *Journal of the American Medical Informatics Association,* 15: 14-24.

Uzuner, O., Luo, Y., et al. (2007). Evaluating the state-of-the-art in automatic de-identification. *Journal of the American Medical Informatics Association,* 14: 550-563.

Uzuner, O., Solti, I., et al. (2010). Extracting medication information from clinical text. *Journal of the American Medical Informatics Association,* 17: 514-518.

Voorhees, E. and Tong, R. (2011). Overview of the TREC 2011 Medical Records Track. *The Twentieth Text REtrieval Conference Proceedings (TREC 2011)*, Gaithersburg, MD. National Institute for Standards and Technology.

Wei, W., Leibson, C., et al. (2012). Impact of data fragmentation across healthcare centers on the accuracy of a high-throughput clinical phenotyping algorithm for specifying subjects with type 2 diabetes mellitus. *Journal of the American Medical Informatics Association,* 19: 219-224.

Weiner, M. (2011). Evidence Generation Using Data-Centric, Prospective, Outcomes Research Methodologies. San Francisco, CA, Presentation at AMIA Clinical Research Informatics Summit.

Wright, A., Pang, J., et al. (2012). Improving completeness of electronic problem lists through clinical decision support: a randomized, controlled trial. *Journal of the American Medical Informatics Association*: Epub ahead of print.

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Overview

- Opportunities
- Challenges
  - Early work
  - EHR data for quality assessment
  - EHR data for clinical research and comparative effectiveness research
  - Insights from health information exchange
- Future directions

Opportunities

- Many "secondary uses" or re-uses of electronic health record (EHR) data, including (Safran, 2007)
  - Personal health records (PHRs)
  - Clinical and translational research – generating hypotheses and facilitating research
  - Healthcare quality measurement and improvement
  - Health information exchange (HIE)
  - Public health surveillance for emerging threats

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Opportunities (cont.)

- Facilitated by
  - Incentives for "meaningful use" of EHRs in the HITECH Act (Blumenthal, 2011; Blumenthal, 2011), aiming toward the "learning healthcare system" (Friedman, 2010)
  - Continued investment in Clinical and Translational Research Award (CTSA) program (Collins, 2011; Helfand, 2011)
  - Facilitation of comparative effectiveness research (CER) (Sox, 2009)
- Science is entering the era of "big data" (Hey, 2009), but there are some provocations about which to be concerned (Boyd, 2011)

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Challenges

- Documentation is often what stands between clinical day and going home for dinner
- In other words, quality of data in EHR is often not the top priority for busy clinicians
- In addition, clinical records do not always tell a complete or accurate story, e.g., patients get care in many places or do not follow up

- What does the research show?

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Early work focused on coded data

- Jollis, 1993 – for patients admitted for cardiac catheterization for suspected ischemic heart disease, claims data found lacking for important diagnostic and prognostic information

Condition	Condition in Clinical Data		Kappa	Sensitivity*	Specificity*	Agreement*
	Present	Absent				
Diabetes mellitus	2488	10 330	0.83	0.83	0.98	0.95
Acute myocardial infarction	5032	7786	0.73	0.76	0.95	0.88
Hypertension	6558	6266	0.56	0.65	0.91	0.78
Mitral insufficiency	2415	9915	0.48	0.44	0.97	0.86
Congestive heart failure	1788	11 066	0.39	0.36	0.96	0.88
Peripheral vascular disease	1237	11 510	0.34	0.29	0.98	0.91
Old myocardial infarction	3003	9934	0.33	0.30	0.97	0.81
Hyperlipidemia	3916	8707	0.31	0.36	0.91	0.74
Cerebrovascular disease	997	11 783	0.19	0.14	0.99	0.92
Tobacco use	8195	4616	0.17	0.24	0.98	0.51
Angina	9720	3217	0.12	0.29	0.91	0.45
Unstable angina	7472	5465	0.09	0.14	0.96	0.49

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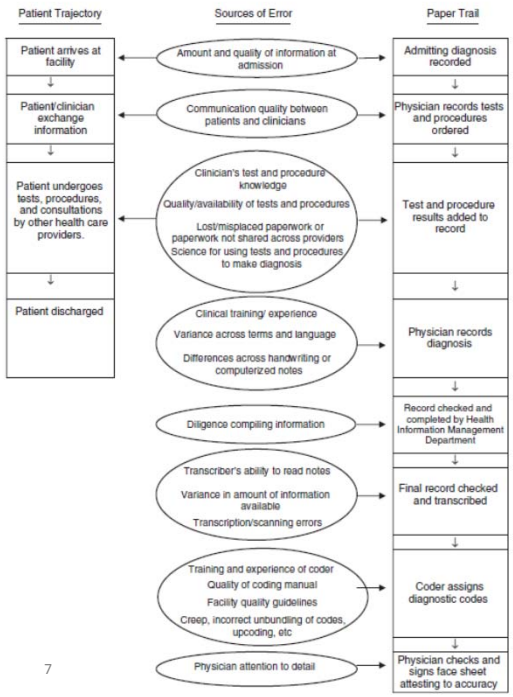
Coded data limitations (cont.)

- Many places for error in coding process (O'Malley, 2005)
- Claims data also have potential bias from incomplete data, although are plentiful and inexpensive (Schneeweiss, 2005)



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Bulk of more recent work has focused on quality assessment

- Systematic review by Chan (2010) identified 35 studies assessing data quality for reliability and validity of quality measures from EHR data; categorized into three areas
  - Accuracy
  - Completeness
  - Variability
- (Cited previous systematic review on older systems by Thiru, 2003)

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Continued research since Chan systematic review

- Kahn, 2010 – significant differences in rates of adverse drug events in a single institution's EHR based on how calculated
- Benin, 2011 – measuring quality metrics using EHR data required substantial validation to ensure accuracy
- Parsons, 2012 – quality measures underestimated by use of only EHR data; impacted by variations in workflow and documentation practices

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Some work has focused on quality of data for clinical research

- In Texas academic hospital, billing data alone only identified 22.7% and 52.2% respectively of patients with breast and endometrial cancer, increasing to 59.1% and 88.6% with a machine learning algorithm (Bernstam, 2010)
- At Columbia University, 48.9% of patients with ICD-9 code for pancreatic cancers did not have corresponding disease documentation in pathology reports, with many data elements incompletely documented (Botsis, 2010)
- Data from two medical centers in Minnesota were found to better predict Type 2 diabetes mellitus than from a single center (Wei, 2012)
- Alerting system to add 17 problems to patient problem lists accepted 41% of time (Wright, 2012)

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Data "idiosyncracies" for clinical research from EHR data (Weiner, 2011)

- "Left censoring": First instance of disease in record may not be when first manifested
- "Right censoring": Data source may not cover long enough time interval
- Data might not be captured from other clinical (other hospitals or health systems) or non-clinical (OTC drugs) settings
- Bias in testing or treatment
- Institutional or personal variation in practice or documentation styles
- Inconsistent use of coding or standards

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Much data is "locked" in narrative text reports (Hripcsak, 1995)

- Will natural language processing (NLP) help?
- State of the art and quantity of text increasing, but performance still imperfect (Stanfill, 2010)
  - How good is "good enough" for clinical research?
  - Possible uses interactively rather than unsupervised?
  - Research may guide improvement, e.g., challenge evaluations such as i2b2 (Uzuner, 2007-2010), TREC Medical Records Track (Voorhees, 2011), etc.

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Additional insight is provided by studies of health information exchange

- Study of 3.7M patients in Massachusetts found 31% visited 2 or more hospitals over 5 years (57% of all visits) and 1% visited 5 or more hospitals (10% of all visits) (Bourgeois, 2010)
- Study of 2.8M emergency department (ED) patients in Indiana found 40% of patients had data at multiple institutions, with all 81 EDs sharing patients in common (Finnell, 2011)

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Important not to forget the successes of discovery from the EHR

- Validation of genome-wide association studies (GWAS), many results from eMERGE, e.g.,
  - Red blood cell traits, built into a model, identified three of four previously identified loci (Kullo, 2010)
  - Combination of billing and clinical data predicted polymorphisms of a gene known to affect atrioventricular conduction (Denny, 2009)
- Designation of research cohort of patients with rheumatoid arthritis (Liao, 2010)
- Growing number of projects focused on advancing use of EHR data for clinical research
  - eMERGE (McCarty, 2010; Koh, 2011)
  - SharpN (Chute, 2011; Rea, 2012)

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Future directions

- CTSA Taskforce on CER and Informatics
  - Task force for two CTSA Key Function Groups addressing this issue with EDM Forum
- What is needed?
  - Identification of best practices and development of guidelines for optimal data entry, structure, and extraction
  - Research agenda to identify and implement optimal approaches

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