

Secondary Use of Health Data

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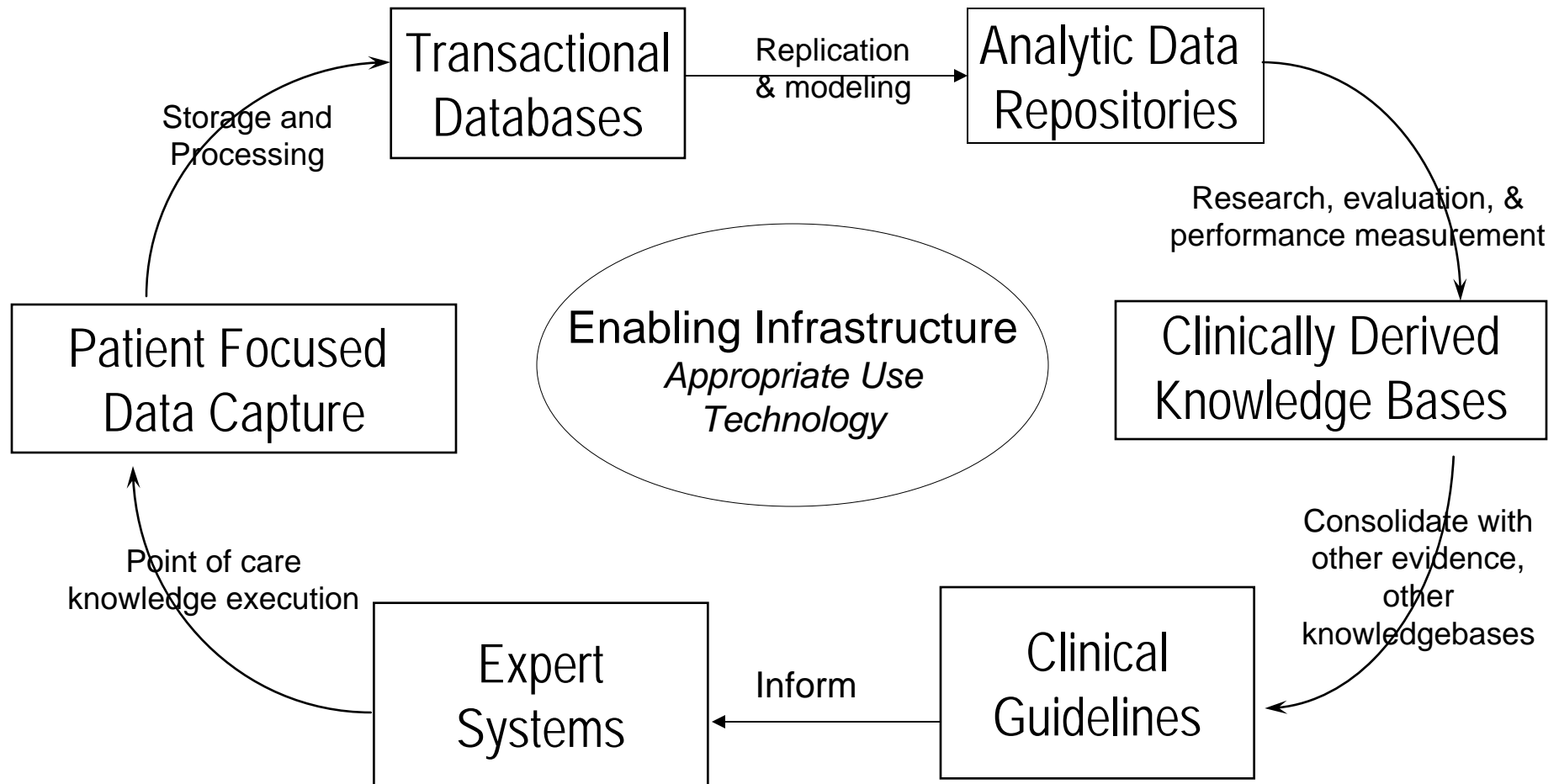
Introduction

Perspectives & Influences

- **Role at Mayo Clinic: Both research and operational**
 - Joint Appointments
 - Department of Nursing
 - Division of Nursing Research and Section of Nursing Informatics
 - Department of Health Sciences Research
 - Division of Biomedical Informatics
 - Sit on IRB, dept level research committees, medical record and data repository implementation committees
- **Memberships**
 - World Health Organization (WHO) Terminology Reference Group
 - American Medical Informatics Association
 - American Nurses Association (ANA) Committee on Nursing Practice Information Infrastructure
 - American Organization of Nurse Executives (AONE) Technology Committee
 - MN Dept of Health eHealth Steering Committee (past)

A Cycle of Health Data Use

Practice Based Evidence



Evidence Based Practice

Chute & Harris

Codified Guides to Appropriate Use of Health Data

Guides	Examples
Department of Nursing	Data management strategic plan
Mayo Clinic	Institutional policies
State of Minnesota	Statutes on Access to Health Records
Federal	HIPAA Common Rule

Federal Rules and Regulations

- HIPAA law
 - MN state law is stricter than HIPAA
 - Mayo Clinic implementation is stricter than HIPAA or MN law
- Common Rule
 - MN law does not address beyond authorization of records for research
 - Mayo Clinic implementation supports generalizability criterion with regard to intent to publish

State of Minnesota

Statute 144.335

- For health records generated on or after **January 1, 1997**, the provider must:
- (i) disclose in writing to patients currently being treated by the provider that health records, regardless of when generated, may be released and that the patient may object, in which case the records will not be released;

and

State of Minnesota

Statute 144.335

- (ii) use reasonable efforts to obtain the patient's **written general authorization**
 - describes the release of records in item (i),
 - does not expire but may be revoked or limited in writing at any time by the patient or the patient's authorized representative.

State of Minnesota

Statute 144.335

Lack of response

- (3) authorization may be established if an authorization is
 - mailed at least two times to the patient's last known address with a postage prepaid return envelope and
 - a conspicuous notice that the patient's **medical records may be released if the patient does not object**, and
 - at least 60 days have expired since the second notice was sent;
 - and the provider must advise the patient of the rights specified in clause 4

Mayo Clinic

Data Driven Implementation of MN Law

- Patient focus groups (unpublished, 1997)
 - Patients concerned about privacy
 - Understand the need for research
 - High level of trust for Mayo
 - Distrust insurance companies/government
- Study to determine authorization bias based on proposed MN law (Jacobsen, 1999)
 - 1994-1996 sample of Mayo Clinic patients
 - Overall, 3.2% declined authorization
 - Rate would be 20.7% if non-responses to authorization considered as refusal
 - Impact: MN law allows for presumed authorization if no response to subsequent mailings
- 2005 authorization bias (unpublished, next slide)
- Current efforts (2007) tied to genomics
 - New considerations related to genetic data
 - Active program to engage community in dialogue and decisions

Research Authorization Statistics

(n = 974,094 as of June 2005)

	Olmsted County	Referral patients	Total
Yes	64.9%	73.8%	72.4%
Implied yes	27.6%	23.3%	24.0%
No	7.5%	2.9%	3.6%

Mayo Clinic

Secondary Use of Data: Quality

- Embrace transparency with healthy dose of realism
 - Early participant in MN Dept of Health never-event reporting
 - Benchmark & share best practices across Mayo sites but do not send any numbers to Mayo Clinic Jacksonville
- Patient confidentiality, patient trust are primary
 - We apply MN law to internal uses of data as well as external uses
 - Examples from nursing
 - Magnet Hospital, but do not report patient level data to NDNQI
- We do not sell data to anyone

Department of Nursing

Established Principles

Guide Data Use Policies & Implementations

- Data are an asset and should be managed as a strategic resource
- Individuals using data must assume accountability for responsible use of those data
- Data sources are known and meet requirements for quality, integrity, and security

Department of Nursing

Established Principles

Guide Data Use Policies & Implementations

- The analysis, interpretation, and dissemination of data are completed in consideration of relevant professional, institutional, and regulatory standards
- Technical data standards are recognized and adopted that facilitate the integration and interpretation of data at multiple levels of data aggregation
- Data management tools and resources are accessible to support data acquisition, retrieval, analysis, and timely report generation in fulfillment of the departmental mission

An Example from the Literature

Conflicts with “my” Reality

- Medical Care, April 2007: 45 (4)
 - Study goal: Assess the accuracy of AHRQ FTR algorithm
 - Retrospective chart review at 40 UHC institutions
- Page 285

“Because this was a quality improvement benchmarking project, it was exempt from local institutional board review. Each institution maintained patient confidentiality according to internal protocols; authors not affiliated with UHC only had access to a limited data set and signed a data use agreement before receiving any data”

Impressions

From “in the trenches” Perspective

- Secondary use of data for medical record research is as important to patients as medical record privacy
- There is a public trust that privacy will be maintained and that a greater good will be achieved
- For research, patient confidentiality can be protected by existing mechanisms
- For quality purposes, protections are less clear except as implemented by individuals and individual organizations
- Key Challenge: Must clarify distinctions between research, quality improvement, and public reported measures of quality with regard to greater good
- Real risk to improving health outcomes through research or quality is any undermining of public trust in privacy or greater good