Testimony to
Ad Hoc Work Group
on Secondary Uses of Health Data
National Committee on
Vital and Health Statistics

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Background and Experience

- Health services researcher and medical sociologist
- President of Lovelace Clinic Foundation (LCF), a non-profit applied health research institute based in Albuquerque, NM
- Research affiliation with Lovelace Health System (large integrated system, including multi-specialty group practice, health plan, three hospitals)
- PI and Project Director, New Mexico Health Information Collaborative (NMHIC)

Retrospective Data Research

- **Lovelace Health System has been an excellent research and quality improvement "laboratory" for LCF**
  - Includes electronic claims/encounter data for all healthcare utilization for a patient population (diagnoses, procedures, lab results, pharmacy use) as well as numerous clinics and providers for testing interventions.
  - Applications: profile patterns of care, identify problems in quality, feedback comparative performance data to providers to help them improve care, guide the development of quality improvement interventions, permit the pre-post evaluation of interventions designed to improve care or cost-effectiveness.
  - These data essential in making Lovelace a national pioneer in disease management in mid-late 1990s—documented major improvements in care and cost-effectiveness in 17 conditions.

Creation of New Mexico Health Information Collaborative (NMHIC)

- **Key issue**: How to assure sustainability and further integrate these disease management programs into everyday practice and extend them to the broader community?
- **Promising answer**: health information technology (both EHRs and health information exchange)
- Mobilized 30 community partners to apply for AHRQ implementation grant to establish NMHIC, a health information exchange for New Mexico.
- AHRQ grant awarded to LCF in September, 2004
- 2006—AHRQ/RTI awarded NM a HISPC/PSP grant to examine privacy and security issues affecting health information exchange and develop solutions.
- Currently implementing one major PSP solution: **new state privacy and security legislation** covering transmission, storage, and use of electronic health information

Privacy Issues in Data Access

- We have extensive familiarity with state law, IRB, and HIPAA-related privacy issues associated with retrospective data-based research, with quality improvement interventions, and with designing and implementing a health information exchange.
- What is **“research” vs. “quality improvement**”? I chaired an IRB for 6 years and struggled with the distinction. Ambiguous area—generally both the Common Rule and HIPAA regs. consider it research if the primary purpose is to add to generalizable knowledge (ambiguity: projects often have dual goals of QI <u>and</u> research—and descriptive and observational research is much like QI)
- Access to retrospective data by LCF: **pre-HIPAA**: ask IRB for a waiver of individual consent because not feasible and minimal risk; **post-HIPAA:** ask IRB/privacy board for a waiver of patient authorization based on similar reasons in HIPAA regs.

Cost of Privacy Regulations

- **Key issue**: Different IRBs and organizations apply the Common Rule and HIPAA differently—and a hodge-podge of state laws further complicates data use in research.
- **Uncertainty of application** greatly increases the cost of research and delays the conduct of research and the translation of research findings into real-world improvements in practice and outcomes.
- **Legal fees and researcher time associated with HIPAA compliance** have been very burdensome for research organizations (our attorney is amazed by what large fees have been generated by a small research organization to comply with HIPAA and other regulations).
- Much of my time and that of my researchers is devoted to compliance with IRB and HIPAA regulations, **NOT** to research—very frustrating and de-motivating to researchers working to improve health care and health outcomes. (We often say: “We don’t do research—we do “regulatory”.)
- Creating an ongoing, accurate, efficient data warehouse that is HIPAA-compliant is central to our research yet very difficult to achieve.
- Most of our colleagues in the HMO Research Network have reported similar costs and frustrations (this is a consortium of 15 prestigious research divisions/affiliates of large integrated delivery systems, such as Kaiser).
- Although this is clearly not the intent, it often seems that the laws and regulations are not really protecting patient privacy, but rather “protecting” patients from the health benefits of good applied research.

What about Secondary Data Use and RHIOs/HIEs?

- Sustainability issues: growing recent interest in secondary use of data and data services to allow RHIOs to sustain themselves
- Our approach in New Mexico:
  - Initial emphasis **only on use of data for treatment**--purposeful avoidance of discussion of secondary use (except possible aggregate feedback to providers for QI)
  - **Reason**: HIE is a new and sometimes scary concept to providers and consumers, so we need to take baby steps first as education and trust develop (HIPAA issues easier as well).
  - **Federated system** selected to ease concerns of data providers—maintaining control of data is comforting. Secondary use is not just an issue for patients but also for providers, health systems, and health plans, who recognize proprietary value of data and are concerned about potential negative comparisons across organizations, as well as potential liability for disclosures.

Long-Term Vision for RHIOs

- Long-term vision should include secondary use:
  - One possibility: A national network of centralized data repositories operated by reliable and trusted neutral organizations with carefully designed privacy and security requirements governing access, de-identification procedures, storage, and use.
  - Such population-based data could provide enormous benefit to the cost and quality of health care in the U.S.: data to guide quality improvement, comprehensive data to improve public health and guide health policy.
  - **But—care must be taken to move slowly—**to listen carefully to privacy advocates—this is an early phase--a politically sensitive time where trust is easily broken.
  - It may be best to seek other means of sustainability first (e.g., user fees for treatment uses), although this could include payment to RHIOs for aggregate data analysis in support of quality improvement activities (e.g., feedback of aggregate RHIO-wide data to physicians for key performance indicators for all of their diabetes patients, instead of feedback data on their diabetes patients from just one health plan).

Issues of Bias from “Opting Out”

- Privacy and patient control are clearly extremely important and sensitive issues—BUT:
- **Any value to secondary data will be greatly diminished by “opting out”—**it will be biased information.
- There is every reason to believe that patients who choose NOT to have their data shared are different in important ways from those who agree to share their data.
- Thus, the **resulting data will be incomplete, biased, and of little use**, even for quality improvement—and even if there is a lot of it.
- Sadly, the very patients whose privacy rights are being protected through opting out will not have the opportunity to benefit from research on their illnesses that would be made possible with complete data.
- Only comprehensive data for all patients will support the essential quality improvement, public health, policy, and research applications needed to transform the quality, efficiency and costs of health care.
- We must find a way to allow transparency and patient control of their data—**<u>and</u>** to build the trust and privacy protections necessary to encourage virtually all patients to share their data.

Thank You!

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