AAMC Project to Document the Effects of HIPAA on Research

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ACE Annual Meeting, Sept. 13, 2004

AAMC HIPAA Survey -- Purposes

To Document the Effects of HIPAA on Biomedical and Health Sciences Research by

- **Creating database of case reports, research functions affected, and problems encountered**
- **Documenting impacts on research: delayed, hindered, abandoned, foregone, or benefited**
- **Probing costs, broadly defined**

AAMC HIPAA Survey -- Steering Committee Members and Collaborators

- American College of Epidemiology
- Academy for Health Services Research
- International Society of Pharmaco-Epidemiology
- American Academy of Pediatrics
- American College of Cardiology
- American Society of Clinical Oncology
- American College of Preventive Medicine
- Association of Schools of Public Health
- The Society of Behavioral Medicine
- Society of Research Administrators
- RTI Health Solutions
- Collaborators – AAMC Member Institutions

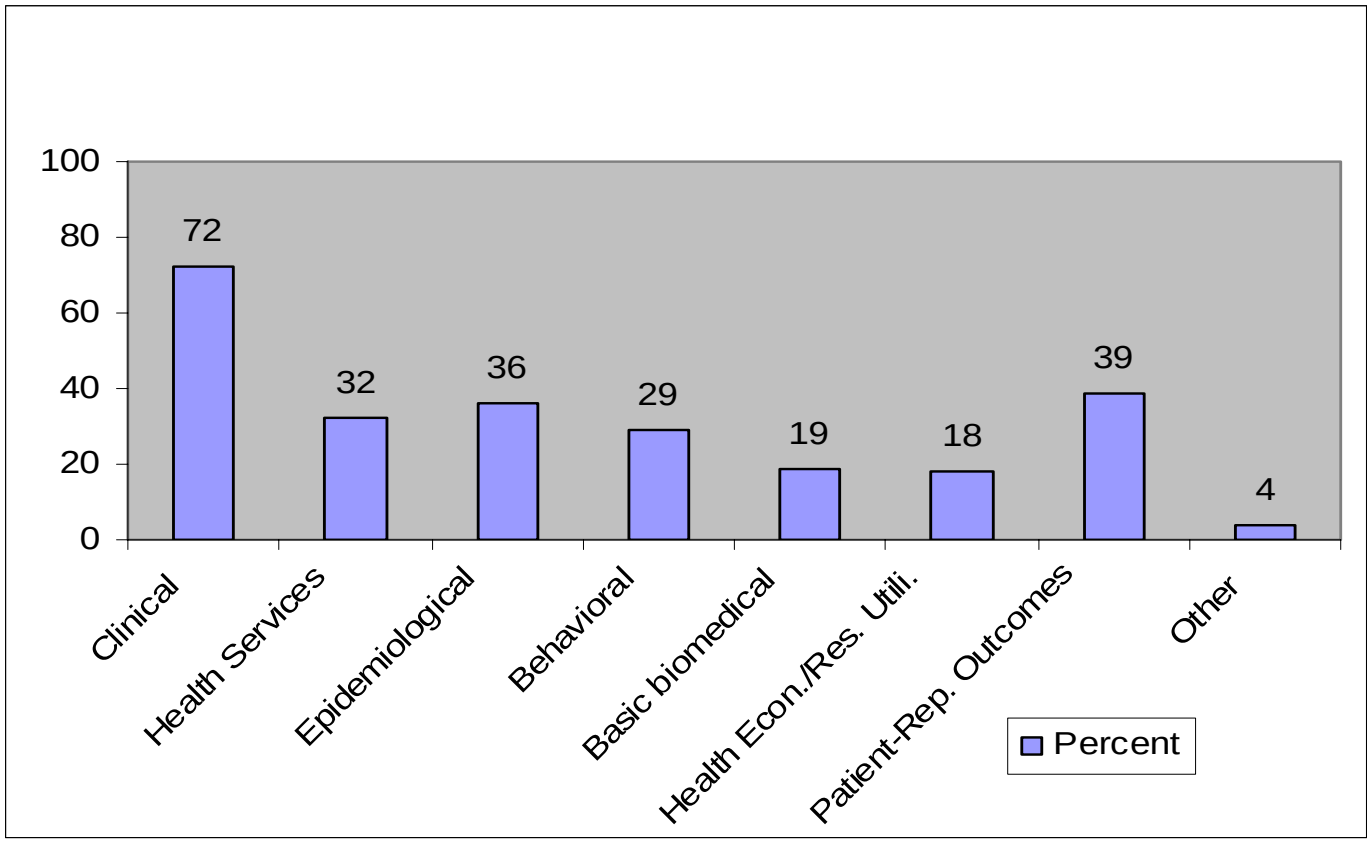
Targeted Respondents

- Investigators
- IRB personnel
- Privacy officials
- Research administrators
- Deans
- Others involved in the conduct and oversight of research

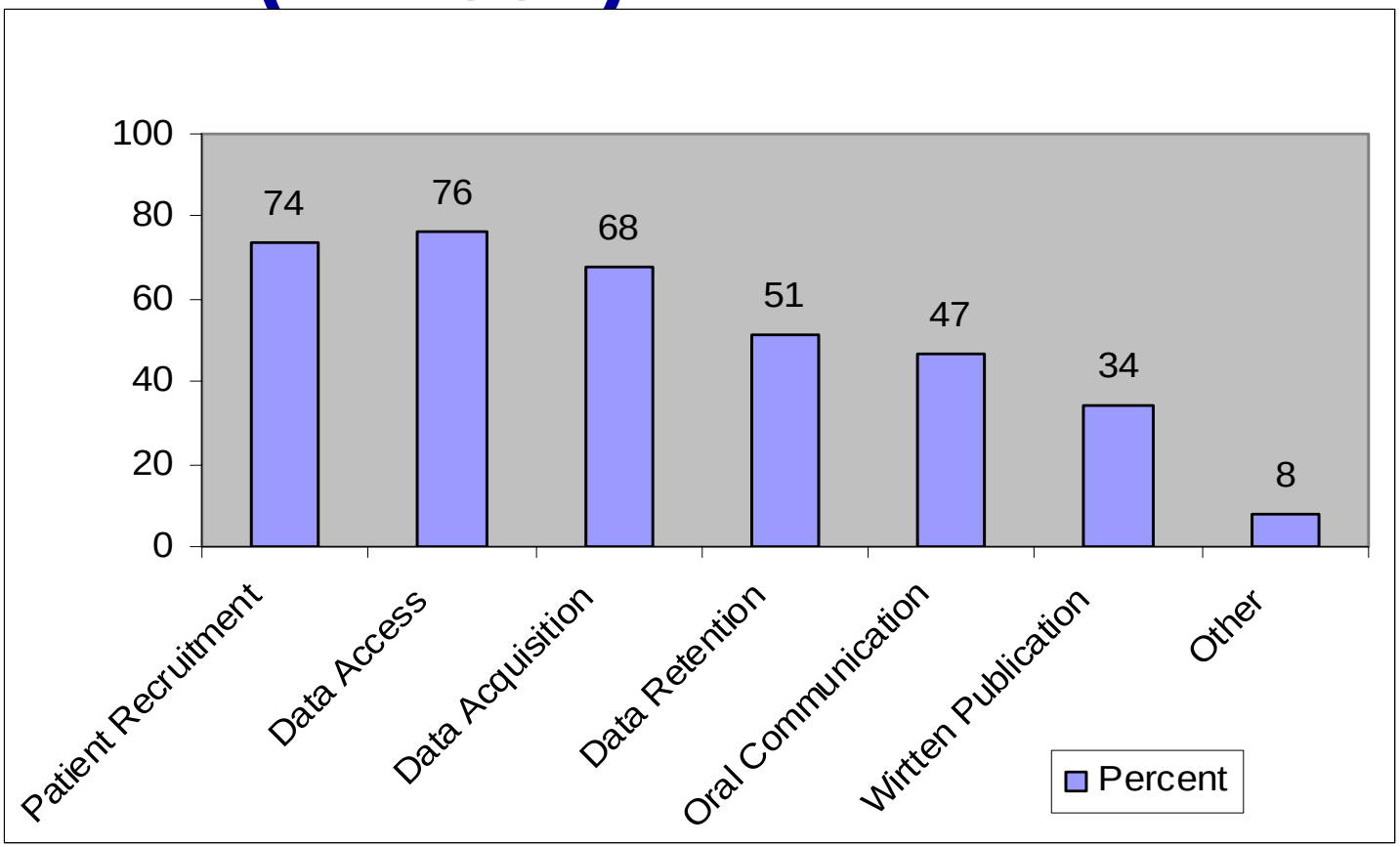
Interpretation of Responses -- Cautions:

- Data set is relatively small
- Questions were asked in earliest phase of HIPAA compliance
- Initial interpretations of new requirements tend to be very conservative or excessive and may become less so with passage of time and increasing experience
- Responses may target areas for future assessment

Types of Research Affected by HIPPA (n = 331)



Research Functions Affected by HIPAA (n = 331)



Types of Effects of HIPAA on Research

- **For participants:**
  - **Confusion/distraction**
  - **Recruitment impaired or prevented**
  - **Diminished access to opportunities to participate in research**
  - **Informed consent burdened/complicated**

Types of Effects of HIPAA on Research, cont'd.

- **For researchers:**
  - **Difficulty in collaborations**
  - **Additional bureaucracy/staffing needs**
  - **Impact on quality/costs of research**
  - **Conflicting interpretations of HIPAA requirements**
  - **Confusion regarding requirements; loss of confidence that HIPAA steps taken are adequate**

Sample – Recruitment

- **“HIPAA has just about made it impossible to obtain research participants.”**
- **Recruitment of clinic patients has become a large issue that has yet to be resolved.”**
- **“Recruitment is more difficult and obtaining patient information from other providers has become more difficult.”**
- **“HIPAA has shut down our recruitment of subjects for a phase III chemoprevention study.”**

Sample – Confusion/Distraction for Participants

- **". . . additional consent form tends to confuse more than inform participants."**
- **". . . the required HIPAA Authorization is confusing for participants to understand."**
- **"Subjects are overwhelmed by added length to consent form and repetition of several points already made in body of main consent…."**

Sample – Informed Consent

- **“My greatest concern is that the requirement for all these various authorizations to be signed overshadows the importance of the research informed consent document and process.”**
- **“I am worried, actually, that subjects are now paying LESS attention to the consent process because they are given so many pages to read and sign.”**

Sample – Informed Consent

- **". . . Instructions/information is laborious for a family to read when already needing to read a 4-6 page consent for emergency tx. in times of crisis/trauma . . . my fear is that they will not take the time to thoroughly read the consents as they are overwhelmed by the situation, all the pages to read and will just want to sign without being fully informed…."**

Sample -- Bias

- **“The complexity of the authorization form intimidates some potential participants. My concern is that by not including those people in the study, we are not including a ‘true’ cross-section of the population…. Will this lead to only including college-educated people in studies? . . . ‘form comprehension’ bias….”**

Sample – Burdens on Research

- **". . . Significant increase in the cost of research, . . . layers of paperwork . . . and levels of documentation that add to the burden of conducting research."**
- **"Reduced enrollment of patients, difficult access of records, increased difficulty and expense to get protocols approved."**
- **"It has significantly encumbered my research and has created an environment of paranoia, distrust, and frustration at my university."**

Sample – De-identification and Quality of Research

- **". . . Increases errors when using only de-identified material…."**
- **"It has severely limited my ability to obtain long term follow-up for patients participating in national registries…."**

Sample – De-identification and Research Direction

- **". . . Some of the involved states refused to release precise crash location data out of concern that this represented identifying information about the individuals involved (since it could conceivably be linked to public records). It is impossible to study important topics like the proximity of trauma centers to injury location without access to this sort of data."**

Sample – De-identification and Research Direction

- **Increase in . . . time and money for redacting identifiable information for limited data sets and deidentified data, forced to make decisions about current need for data items when research is open ended and has unforeseen questions that will later arise….”**

Sample – Multiple Organizations and Collaborations

"The major difficulty for us has been establishing multi-site trials and getting everyone to collaborate in this newly derived, fear-of-litigation driven system. We have no solution and I fear good research will begin to die out soon."

Sample – Multiple Organizations and Collaborations

- **“Many health care providers no longer participate/submit data to several observational pregnancy exposure registries as a result of HIPAA.”**
- **“. . . am now limited in my collaborations with researchers….”**
- **“Multi-site trials used to be more feasible.”**

Sample -- Costs

- **"HIPAA has resulted in an unprecedented economic loss for our practice…. In private practices research will be negatively impacted because of the undue burdens imposed by the regulations."**
- **"The main cost was that the project had to be abandoned. It is simply not feasible for me to obtain this data in any other manner."**
- **"25% increase in support for research nurse to keep tract of additional paper work for two ongoing projects…."**

Sample – Interpretations of HIPAA

- **“Solutions are just guesses.”**
- **“. . . considerable heterogeneity in the interpretation of the HIPAA confidentiality rules, and in their implementation across covered entities….”**
- **“higher level of uncertainty that the correct procedures are being followed.”**

NCAB Survey: Feedback from NCI Cancer Centers, Cooperative Groups, and Specialized Programs of Research Excellence

- To assess the impact of HIPAA on oncology clinical research
- To have an opportunity to influence HIPAA's implementation

AAMC and NCAB Surveys -- Consistent Findings

- Negative impact on informed consent process
- Confusion of subjects
- Negative impact on subject recruitment
- Possible increase in selection bias
- Additional burdens on research process

AAMC and NCAB Surveys -- Consistent Findings

- Alteration or abandonment of research direction
- Increased costs
- Impaired ability to collaborate
- Inconsistent interpretations of HIPAA requirements

AAMC Recommendations

1. **Where there is informed consent and IRB approval, eliminate requirement for authorizations (or waivers) for research uses**
   a. If protocol is approved by IRB, increase in privacy protection that authorization provides is negligible
   b. If informed consent is waived, retain HIPAA's specific waiver criteria
   c. Retain requirement for authorizations and waivers for research uses if research is not subject to IRB review
   d. Inter-institutional collaboration is especially burdened because of necessity to review others' authorizations and waivers for HIPAA compliance

AAMC Recommendations

2. **Harmonize HIPAA and Common Rule re privacy protections**
   a. **Inconsistent requirements create confusion; cause delay/obstacles to research**
   b. **Eliminate dual approval process**

AAMC Recommendations

3. **Relax standard for de-identification**
   a. **Especially problematic for research requiring data contributing to understanding of disease associations or exposures and genotype data for rare diseases**
   b. **Necessity for more realistic standard of de-identification, not based on extreme assumptions**
   c. **De-identification standard can incorporate unique identifiers, provided they are not shared with researchers**

AAMC Recommendations

4. **Eliminate accounting of disclosures for research**
   a. **For research involving fewer than 50 subjects:**
      i. **Huge regulatory burden**
      ii. **Impact on community providers and hospitals as research participants**
      iii. **Resulting shrinkage of research base for epidemiologic and health services research**
      iv. **Negligible increase in privacy protection**

AAMC Recommendations

b. For research involving 50 or more subjects:

- **i. In major academic research entities, list of protocols will be extensive**
- **ii. Burden to assist the individual "in contacting the [sponsoring] entity and researcher" is unreasonable**
- **iii. Burden is a negative incentive for institutions to participate in research involving many subjects**

AAMC Recommendations

5. **Shift from organizational to functional focus**
   a. **Standards for CE status, HE status, or ACE status are too exacting**
   b. **Standards don't reflect current organizational integration among medical schools, hospitals, and practice plans and complexity of organization structures**
   c. **Standards create barriers to interdisciplinary and inter-institutional research**

SACHRP Recommendations: Summary

1. Exempt research disclosures from accounting of disclosure requirements
2. Align standards for deidentification more clearly with the Common Rule
3. Requirements for recruitment (identifying, contacting participants) should distinguish between researchers affiliated with CEs and true “external researchers”; all affiliated researchers should be treated alike; removal of PHI from premises should be allowed, with appropriate precautions

SACHRP Recommendations, cont'd.

4. **Databases and tissue banks: future uses of data/materials**
   - **When IRB approves a consent form permitting certain future uses under the Common Rule, HIPAA shouold also permit such uses with authorization or waiver**
   - **Common Rule standard for waiver of consent/authorization should be followed for removing tissue for subsequent use**

SACHRP Recommendations, cont'd.

5. Compound authorization (collection plus future use) should be allowed, assuming DHHS permits research authorizations to authorize certain future uses
6. Exempt research (as determined by IRB) shouldn't require research authorization

SACHRP Recommendations, cont'd.

7. International research
   - Provide clear guidance on HIPAA's application in international context
   - Clarify that PHI collected outside U.S. by researcher affiliated with CE isn't subject to HIPAA solely because of the affiliation
   - Clarify that IRB can waive authorization in international context
   - Clarify that IRB may approve alteration of authorization requirement to adapt its elements as may be culturally appropriate for the study

SACHRP Recommendations, cont'd.

8. Public Health Research:

- **Broaden exemption for uses and disclosures for public health activities to assure federal and state agencies, whose primary purpose includes the prevention or control of disease, injury, or disability, or the analysis of data in alliance with public health and public benefit agencies, are included, even if they are not compelled to collect PHI**

Summary of AAMC Recommendations:

1. **Modify requirement for authorization and waiver for research*+**
2. **Harmonize HIPAA and Common Rule re privacy protections*+**
3. **Relax de-identification standard*+**
4. **Eliminate accounting of disclosures for research*+**
5. **Shift from organizational focus to a functional focus+**

***Consistent with NCAB Recommendations**

+Consistent with SAHCRP Recommendations

Guiding Principles

- **Research must be conducted ethically and with scientific integrity**
- **Protection of human participants is of paramount importance**
- **Standards must clarify duty of researchers to safeguard privacy of participants**
- **Standards should maximize utility of de-identified information**
- **Protection of medical information from harmful use is crucial**

Guiding Principles, cont'd.

- **Preservation of vitality of research enterprise, including**
  - **population-based research (epidemiological, health services, environmental and occupational health research)**
  - **registry research**
  - **outcomes and public health research**
  - **genetic longitudinal research**
  - **post-approval assessment of safety and efficacy of drugs and devices**
  - **retrospective studies required to understand systemic causes of medical error**
- **Reduction of disincentives to researchers and research institutions**