

IOM Project Survey Findings on Health Research and Privacy



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at the XV HIPAA Summit,
Washington, D.C., December 12,
2007

What the IOM Survey Set Out to Learn -- 1

- How does the public view the overall health privacy scene?
- **How interested is the public in health research?**
- How many persons have participated in a health research study?
- **What are the details and experiences in such studies?**
- How many persons were invited to have their PHI used in a health research study but declined -- and why?

What the IOM Survey Set Out to Learn -- 2

- What kind of notice and consent does public want before their PHI is used in a study?
- What kind of privacy harms worry those respondents who want to have express notice and consent before their PHI is used in health research?
- What are the significant demographic variations for key findings?
- What are the policy implications of these survey findings?

Survey Methodology -- 1

- **I was retained as consultant to IOM, to conduct the survey**
- **Questionnaire designed by Alan Westin and David Krane (Harris Interactive), with in-depth IOM Committee review and participation**
- **Conducted online by Harris Interactive, Sept 11-18, 2007**
- **2,392 respondents 18 or older**
- **Both closed and open end questions used**
- **Results representative of the total adult U.S. population of 255 million. Figures reported in millions are estimates.**
- **Final Report will be written by Alan Westin**

Survey Methodology -- 2

- **Standard demographics collected**
 - Region, age, gender, race, party ID, education, income, sexual orientation, disabilities, political philosophy, marital status, and employment
- **Custom demographics**
 - Health status, caregiver, six types of health conditions, had a genetic test
- **Custom respondent attitudes**
 - Ran nine sets of answers against all other questions
- **Will cover selected demographics today**

Health Situations -- 1

- **Overall, would you say your health is...**
 - Excellent..... 14% (32M)
 - Pretty Good..... 61% (137M)
 - Fair..... 22% (50M)
 - Poor..... 3% (7M)
- **Been a caregiver for family member with chronic or serious medical condition.... 23% (52M)**
- **Had a genetic test..... 5% (11M)**

Health Situations -- 2

- **Used psychologist, psychiatrist, mental health professional..... 27% (61M)**
- **Had a long-term medical condition such as diabetes or epilepsy 16% (36M)**
- **Had major physical or mental disability...11% (25M)**
- **Had serious illness such as heart attack, stroke or cancer..... 9% (20M)**
- **Had any sexually-related health condition.. 7% (16M)**
- **Had an alcohol or drug abuse problem..... 6% (14M)**

Overall Health Privacy Views -- 1

- **Respondents asked to agree or disagree with four statements about health privacy (random order)**
 - 1. “I generally trust my health care providers -- doctors and hospitals -- to protect the privacy and confidentiality of my personal medical records and health information”
 - **83% agree (30% strongly, 54% somewhat)**
 - **17% disagree (12% somewhat, 5% strongly)**
 - **Note 54% agreed only “somewhat”**
- **No significant demographic variations**

Overall Health Privacy Views -- 2

- **2. “Health researchers can generally be trusted to protect the privacy and confidentiality of the medical records and health information they get about research subjects”**
 - 69% agree (11% strongly, 58% somewhat)
 - 31% disagree (24% somewhat, 7% not at all)
- **Obviously less trust than providers**
- **Note 58% only somewhat in agreement**
- **No significant demographic variations for “Disagree”**

Overall Health Privacy Views -- 3

- **3. “The privacy of personal medical records and health information is not protected well enough today by federal and state laws and organizational practices.”**
 - **58% agree (17% strongly and 41% somewhat)**
 - **42% disagree (10% strongly and 33% somewhat)**
- **Only a few demographic variations in the “Agree” camp**
 - **65+--66%; in Fair Health--64%; had genetic test--67%**
- **The HIPAA Privacy Rule and its enforcement does not seem to have given a national majority much confidence in national health privacy protection**

Overall Health Privacy Views -- 4

- **“Even if nothing that identifies me were ever published or given to an organization making consumer or employee decisions about me, I still worry about a professional health researcher seeing my medical records.”**
 - Agree..... 50% (12% strongly and 38% somewhat)
 - Disagree ... 50% (15% strongly and 35% somewhat)
- **U.S. public divided right down the middle on this**
- **Discomfort with sensitive information disclosure to “unknown third party,” even if no actual or likely harm**

Belief That PHI Disclosed Improperly

- “Have any of the following organizations involved in your health care ever disclosed your personally identified medical or health information in a way you felt was improper” (select all that apply)
- Yes..... 12% for all organizations (represents 27M adults)
 - **A doctor who treated you..... 4%**
 - A hospital or clinic where you received services..... 3%
 - **A health insurance company of which you were a member....3%**
 - A life insurance company you applied to..... 2%
 - **A pharmacy/druggist you used for prescriptions.....2%**
 - An employer who had your medical or H insurance records...2%
 - **A government health program, such as Medicare.....1%**

Interest in Health Research

- **“How interested are you in reading or hearing about the results of new health research studies, such as the causes and prevention of diseases, effectiveness of new medications or treatments, findings of genetic effects, ways to enhance wellness, evaluations of medical facilities and operations, successful and unsuccessful diets, and similar topics?”**
 - 78% interested (31% very; 47% somewhat)
 - 22% not interested (14% not very, 8% not at all)
- **Not surprising -- parallels other survey findings**

Declined to Participate in a Health Study - 1

- **“Have you ever been asked to have your personal medical or health information used in a health research project but you decided not to participate?”**
- **Yes... 8% (represents 18M adults)**
- **Asked which of seven possible listed reasons for not participating, and to designate all that applied**

Why Declined to Participate

- **30%** -- concerned my personal information would not be kept private and confidential -- represents 5.4M adults
- **24%** -- worried that participation would be risky, painful or unpleasant
- **22%** -- didn't have trust in the people or organization conducting the research
- **16%** -- would not have helped my health conditions
- **6%** -- would not have helped the health of present or future members of my family
- **6%** -- didn't think the research was important
- **5%** -- would have been costly for me or my family

Participated in a Health Research Study

- **“Have you ever participated in a research study that used your personally identified medical or health information? This might have been a clinical trial, a university study, a public health study, a mental health project, a study of health services, or other type of medical or health research.”**
- **Yes... 13% (represents 29M adults) No...87%**
- **Provided 340 actual respondents (statistically adjusted to 308) whom we then questioned in detail about their participation.**

Study Participation -- 1

- **We collected basic statistical information of interest to the IOM:**
 - year research conducted; organization conducting the research; how participant recruited; what the research was about; what kind of personal medical or health information was used; whether testing a new drug or procedure was involved; and was genetic information used
- **Here I report the additional policy-oriented questions we posed to research project participants**

Study Participation -- 2

- **“How informed did you feel about the purposes and procedures of the study before it started?”**
 - 85% informed (50% very, 35% somewhat)
 - 15% not informed (12% not very, 4% not at all)
- **“Where did the researcher get your personal medical or health information used in the study?”**
 - 69% supplied in a questionnaire or interview; 38% sample of blood or tissue or test result; 25% medical record from doctor; 20% medical record from health care facility; 4% from a disease registry; 4% prescription record from a pharmacy. (7% other; 12% don't know)

Study Participation -- 3

- **“Were you given a promise that no personally identified medical or health information of yours used in the study would ever be given to anyone outside the research staff?”**
 - **76% yes**
 - **3% no**
 - **21% not sure -- interesting**

Study Participation -- 4

- **“Overall, which of the following statements best describes what you felt about participating in this health research study?”**
- **87% -- was a comfortable experience (58% very, 28% somewhat)**
- **13% -- not comfortable (10% not very; 3% not at all)**

Obtaining PHI for Health Research -- 1

- **Our key issue: Under what circumstances are consumers willing to have their PHI used in health research?**
- **Has been the central Q in more than a dozen surveys on health privacy issues since 1993**
- **Results have been uneven, with variations created by trigger words in the question -- the subject of the studies, the organization doing the research, etc.**
- **We struggled through five iterations to get the Q we felt captured the right elements...**

Obtaining PHI for Health Research -- 2

- Because our questionnaire was online, we were able to present a detailed set-up question, hopefully with all the right elements included
- **The full question is reproduced in the Appendix to this ppt.**
- For now, I will read the question and then present the five (randomized) alternatives we gave to respondents

Five Alternative Answers -- 1

- **“Researchers would be free to use my personal medical and health information without my consent at all” 1%**
- **“I would be willing to give a general consent in advance to have my personally-identified medical or health information used in future research projects without the researchers having to contact me” 8%**
- **“My consent to use my personal medical and health information would not be needed as long as the study never revealed my personal identity and it was supervised by an institutional review board” 19%**

Five Alternative Answers -- 2

- “I would want each research study seeking to use my personally-identified medical or health information to first describe the study to me and get my specific consent for such use” 38% (85.5M)
- “I would not want the researchers to contact me or to use my personal or health information under any circumstances” 13% (29.2M)
- But, 20% said they were Not Sure...

Demographic Variations -- “Want Notice/Express Consent”

- **16 groups higher by 5% or more than the 38% wanting notice and specific consent,.**
 - **Black..... 45%** **Very interested in health research..... 46%**
 - **College grad..... 46%** **Participated in study..... 44%**
 - **35K to 49K..... 45%** **Very informed/study..... 51%**
 - **50-64..... 43%** **Very comfortable/study.. 49%**
 - **Single women... 43%**
 - **Long-term health condition... 45%**
 - **Used mental health..... 44%**
 - **Sexual condition..... 49%**
 - **Had genetic test..... 48%**

Why Want Notice and Express Consent

- **Provided four possible reasons to this group, and asked respondents to choose all that applied:**
 - **“I would want to know what the purposes of the research are before I consent” 80%**
 - **“Knowing about the specific research study and who would be running it would allow me to decide whether I trusted them or not.” 62%**
 - **“I would be worried that my personally-identified medical or health information may be disclosed outside the study” 54%**
 - **“I would want to know whether the research could help my health conditions or those of my family” 46%**

What Harms Seen if PHI Disclosed

- **77% “I would feel violated and my trust in the researchers betrayed”**
- **67% “I could be discriminated against in getting health insurance”**
- **56% “I could be discriminated against in getting life insurance”**
- **44% “I could be discriminated against by an employer”**
- **39% “I could be discriminated against in a government program”**
- **33% “I could be embarrassed before friends, associates or the public”**

Implications I draw from the Survey -- 1

- Large majorities continue to hold and apply very strong privacy perspectives in handling their PHI, especially for secondary uses
- **58% do not believe current law and organizational policies provide adequate privacy protection or data security**
- While majorities generally trust health researchers to maintain confidentiality, a promise of non-identification and IRB review does not persuade a majority to give advance general consent
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- And majorities not persuaded by researcher complaints about costs or skewed samples under current HIPAA rules

Implications I draw from the Survey -- 2

- **Results strongly suggest that a notice and consent regime will need to be put into the important health research potentials of emerging EHR systems and Internet PHR depositaries -- could be opt-out as well as opt-in**
- **A major example of policies consistent with our survey findings is Microsoft's new HealthVault service -- with its solid notice and consent system for all uses of PHI from the user's file**
- **Even here, these systems will need to educate consumers on the high social value and ethical conduct of specific health research projects, and their privacy assurances**

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Appendix: Text of the Q on Providing PHI for Health Research -- 1

“When conducting health studies, researchers often want to select patients whose personally-identified medical or health information is contained in patient records. Sometimes, the patients will be invited to give general approval to have their records used in future health research. Or, the researchers may seek patient consent to join a specific study. For some studies, researchers seek to include the patient information automatically in the research, without seeking any consent.

“The researchers promise, as required by federal and/or state health privacy laws, that no personally-identified health information of research subjects will be disclosed outside the research group and that security measures will be applied to protect the data.

“Researchers must also have the project approved by a Human Subject Protection or Privacy Board. These groups decide whether the importance of the research and the safeguards promised outweigh potential risks to privacy or data security, or other risks to research participants.

Appendix: Text of the Q on Providing PHI for Health Research -- 2

“Some say that patient interests in privacy and data security are not protected well by such procedures, and there is little policing of researcher practices. It is argued that patients must be asked for consents -- either specific or general -- for all health research.

“Health researchers say many patients would not respond or agree to requests for permission, creating a sample that would not accurately reflect the group whose health condition or status are being studied. They also say obtaining permission for each health study would be very costly and time-consuming, and there is no pattern of health researchers disclosing the personal medical information of research subjects.

“In these situations [which of the following answers] is closer to your opinion?”

Five answers were given, in randomized order...