IOM Project Survey Findings on Health Research and Privacy

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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?
- How do the survey findings relate to the privacy and health research issues the IOM Committee is considering

Survey Methodology -- 1

- 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
- 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
- I will be covering selected demographics today

Health Demographics and Findings -- 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 Demographics and Findings -- 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)

Strengths and Weaknesses of Surveys

- As much art as science
- Representativeness of sample
- Selection of topics to explore
- Wording of questions
- Wording and randomizing of responses
- Using “very” and “somewhat”
- Order of Qs and imprinting
- How directly issues fit public experiences or topics in public debate
- What are fair conclusions to draw

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 <u>somewhat</u> in agreement
- No significant demographic variations for "Disagree"
- Raises Q: what kind of researchers respondents were thinking of?

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
- Rests on feeling of sensitive information disclosure to "unknown third party", even if no harm actual or likely

Groups Higher in Not Wanting Researchers to See their PHI

- Total sample ………………. 50% worried
- Higher by 5% or more:
  - East….56%
  - 50-64….59%
  - 65+….56%
  - Black….60%
  - Hispanics….56%

Not informed well in study….62%

Not comfortable in study….58%

Had a genetic test….55%

In Fair health….55%

Persons with disabilities….55%

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…

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 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:
  - 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
- Coded responses are on the TopLine sheets. Will be used in the Final Report
- Here I report the additional policy-oriented questions

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

- “To your knowledge, was any of your personally-identified medical or health information used in the study ever given to anyone outside the research staff?”
- Yes…. 2%
- No….. 59%
- Don’t know or can’t recall … 38%

Study Participation -- 5

- Only 10 respondents, about 2% of study participants, said their information had been disclosed. When asked to describe
  - 46% said provided to other medical and research institutions
  - 31% other
  - 20% not applicable
  - 3% no answer
- Our question obviously didn’t work; didn’t get to improper disclosures -- and sample too small to be used statistically

Study Participation -- 6

- “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

- 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 (as I reported in my pre-2007 round-up of privacy and health research yesterday, at Day One of this IOM meeting)
- 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

- The full question is reproduced in the Appendix to this ppt. a hard copy of which is being provided. And, participants today will also get the full text of this question in the TopLine document to be provided after this presentation

- For now, I will read the question and then present the five (randomized) alternatives we gave to respondents ……

Obtaining PHI for Health Research -- 3

- "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%

Obtaining PHI for Health Research -- 4

- “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…

Obtaining PHI for Health Research -- 5

- 16 groups were higher than the 38% wanting notice and specific consent, by 5% or more. For example:
  - Black……………. 45%
  - College grad….. 46%
  - 35K to 49K……. 45%
  - 50-64……………. 43%
  - Single women… 43%
  - Very interested in health research………… 46%
  - Participated in study….. 44%
  - Very informed/study…… 51%
  - Very comfortable/study.. 49%

  - Long-term health condition… 45%
  - Used mental health…………… 44%
  - Sexual condition……………… 49%
  - Had genetic test……………….. 48%

Why Want Notice and Express Consent

- We 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 of the Survey

- Large majorities of the public continue to hold and apply very strong privacy perspectives in the health area
- The majority does not believe current law and organizational policies provide enough privacy protection
- While a majority trusts health researchers on confidentiality, researchers do not get a free ride from the national majority
- Four in ten consumers would insist on notice and express consent for researchers to use their PHI, with many important demographic groups higher
- Has major implications for research efforts in EHR systems, online PHRs, disease databases or registries, etc.

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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 medic al 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 tghat 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 vthe 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…