

# **Health Insurance Portability and Accountability Act of 1993 (HIPAA) and Health Services Research**

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# HIPAA and Health Services Research

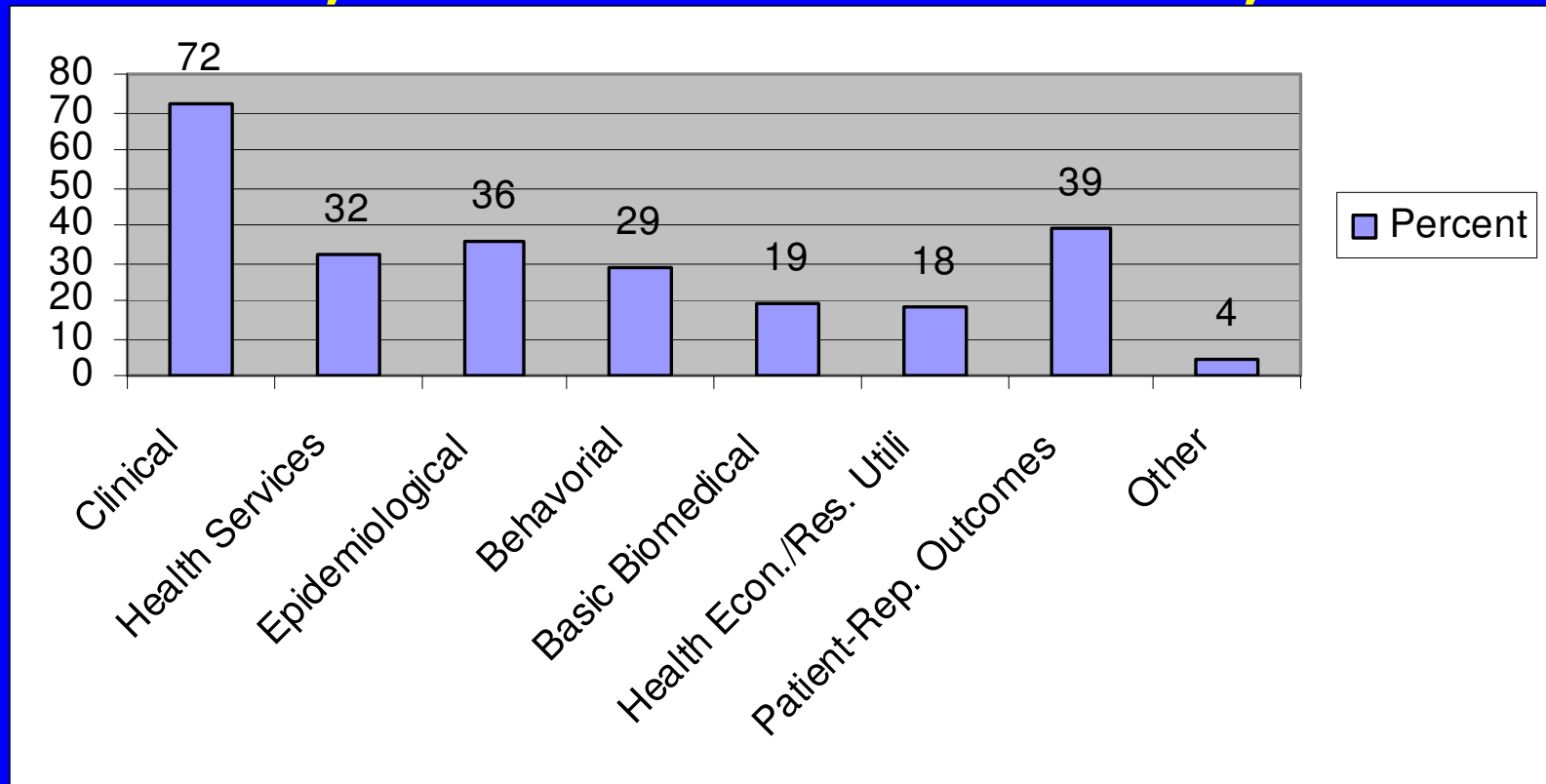
- HIPAA created new restrictions on the release of medical information for research
- Goal was to ↓ concerns about the way personal medical information was being used for non-patient care purposes
- Some unintended sequelae
  - Restrictions have fallen disproportionately on researchers
  - Particularly health services researchers who often focus on populations, representative and unbiased cohorts, and outcomes with vs. without an intervention or exposure

# EMPIRICAL DATA

- Survey data
- Numbers of recruited participants/ costs
- Distribution of recruited participants/ costs
- Registries
- Consent forms
- Multi-site study complexities

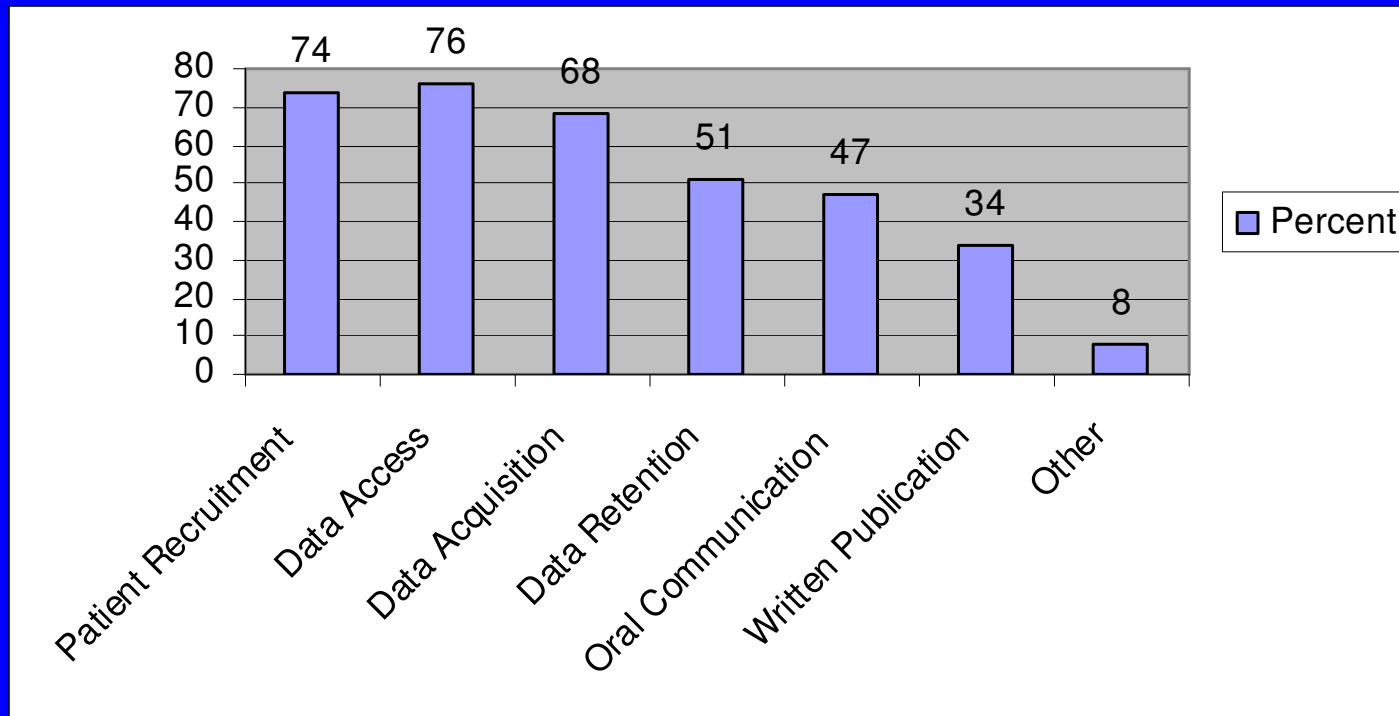
# Types of Research Influenced by HIPAA AAMC Survey 2004

n=331 investigators, IRB personnel, privacy officials, research administrators, deans



Conclusion: Participants eligible for research were subject to confusion, burdensome consent forms, and ultimately fewer research opportunities.<sup>4</sup>

# Functions of Research Influenced by HIPAA



Conclusion: Researchers found collaborations across organizations difficult, requiring more staffing and higher costs

# Numbers of recruited participants/ costs

# Effect of HIPAA on IRB Applications: U of Wisconsin

- <2000: applications for MR research were rare (n=11, 2000)
- 2001: a new application process with 92/103 (89%) apps approved by an *expedited* process with few requiring full IRB approval
- 2002-03: 199 apps; 25% required revision, 16% full IRB approval 59% approval w/o revision,
  - » Of 31 requiring full IRB approval, 7 were pursued while 24 (77%) were abandoned

Conclusion: HIPAA implementation strategies ↑ **workload and** ↑ **dropout rate for proposed studies** when investigators are unable or unwilling to meet the regulatory requirements

# Effect of HIPAA on Clinical Trial Recruitment

## Evaluating an educational strategy:

### The Selenium and Vitamin E Cancer Prevention Trial (SELECT)

Single Site Research Study:	Pre-HIPAA	Post-HIPAA	Post-HIPAA with revised protocol
Pts recruited per week (#)	7.0	1.9	7.1
Mean Personnel Time Spent Recruiting (hrs/pt)	4.1	14.1	5.4
Mean Recruitment Costs (\$)	49	169	65

Conclusion: Establishing HIPAA-compliant recruitment policies can overcome some HIPAA obstacles, although **Recruitment costs and time** are likely to be greater than those observed before HIPAA

Wolf 2006Jan;106(2):474-9.

# Effect of HIPAA on Patient Recruitment: Pregnancy Exposures and Pre-eclampsia Prevention Project (PEPP)

<u>Time Period Recruited</u>	<u># Women/Week</u>
Pre-HIPAA	12.4
HIPAA w/o waiver	2.5
HIPAA with waiver	5.7
Following waiver retraction	3.3

# Concerns About Selection Bias

# Randomized trial comparing the effect of opt-in requirement w opt-out direct approach: CRC screening

	Active	Passive
	% distribution	
Lives alone	25	20
>16 Yrs Education	82	70
Good health	89	85
+ Family hx CRC	23	10
Prior CRC screening	59	40
Agrees to FOBT	93	85
Active style of decision making*	75	45

# Effect of HIPAA on number and type of patients available for outcomes research

Michigan Study of Acute Coronary Syndrome	Pre-HIPAA N=1221	Post-HIPAA N=967
Type of consent	Verbal informed consent	Mailed consent forms to ask for permission to conduct telephone interview
% Pts Providing Consent	96%	34%
Characteristics of Consenting Patients		↑ pt age, married ↓ death rates at 6 mos
Incremental costs for complying with HIPAA Privacy Rule		1 <sup>st</sup> Yr: + \$8704 Later: + \$4559

Conclusion: The HIPAA Privacy Rule introduces **selection bias in data** <sup>12</sup> collection for patient registries Armstrong D. *Archives of internal medicine*, 2005, 165(10):1125-9.

# Urban family practice study

- Cross sectional survey of patients who gave consent for medical record access to researchers:
  - More likely: Older, Poorer health, Females
  - Less likely: African American

*Wolf, Archives of Family Med, 2000; 9: 1111-8*

# Recruitment of community-based controls w/in a case control study UK, 2003

- Low response rates
- Excess of health care workers in the sample
- Potential for selection bias in recruiting community-based controls within a case-control study under UK ethical restrictions.

# Registries

# Long Standing Value of Registries

- Registries or data banks provided invaluable information about:
  - the natural history of diseases
  - prevalence of various conditions in the general population
  - disease responsiveness to therapy
  - effects of unsuspected toxins
- Cancer registries have provided invaluable information about:
  - case clusters
  - the course of malignant conditions
  - changes, with time, in the behavior of various cancers

# Private Welfare vs. Public Health

- Data repositories are at risk of significant bias because concern about privacy has led to the requirement that **consent be obtained before an individual person's data can be included**
- Legislation protecting the privacy of personal health information stems from the recognition of past abuses
  - Unauthorized disclosure and use of individually identifiable information for marketing, recruitment, fund-raising and other purposes
  - Fear of discrimination by insurers, employers, and others
- **Public health is threatened by incomplete data more than individual privacy is threatened by disease registries**

*Ingelfinder and Drazen, NEJM, 2004*

# Ingelfinder and Drazen, *NEJM*, 2004

- Now that consent is required, universal inclusion of data may no longer be possible

# Cancer Registry, Hamburg, c 1950

- Hamburg cancer registry included data on all cases of cancer for > 50 years
  - Data were published annually for use by MDs making Rx decisions and counseling pts
  - Mid-1980s, Hamburg and Nordrhein-Westfalen passed laws requiring informed consent
- After the laws were passed, **<=70% of potential cases were included in the registry**
  - **Data became no longer available** since they were incomplete
  - Unsuccessfully attempted a two-part (trust center and registry) body; process deteriorated

# Program to Improve Care in Acute Renal Disease

- **Multicenter** registry to identify clinical characteristics and practice patterns associated with favorable and unfavorable outcomes among ARF pts in ICUs
- Registry used **no intervention**
- Informed consent required of **all subjects**
- **52% eligible subjects provided informed consent**
- Data were of limited usefulness

*Ingelfinger and Drazen, NEJM, 2004*

# Prospective Study of the Registry of the Canadian Stroke Network

- Intense efforts to obtain informed consent from patients with stroke, **only 39.3% of patients** in phase 1 of the study, and **50.6 %** in phase 2 provided consent for their inclusion in the registry
- Obtaining informed consent led to selection bias; the patients who were more seriously ill or impaired were left out...underscoring the inherent problems with registries that require written informed consent....They achieve only partial enrollment with vitiates the value of their data

# Increased Complexity of Research Consent Forms is Worrisome

- The addition of extensive language to satisfy the Privacy Rules authorization requirements often:
  - Confuses research participants, burdens the informed consent process, undermines recruitment
- Even w/o added privacy language, many participants cannot understand crucial aspects of the research
  - 3 extra pages of text, written in complex language ↑ participant's confusion
  - Distracts them from important information (e.g., risk of participation and right to withdraw)

# Survey of 100 top medical centers and 11 independent IRBs

- Analyzed the authorization language used to satisfy the Privacy Rule
  - Median length: **744 words**
  - Median 12<sup>th</sup>-grade reading level
    - well above 8<sup>th</sup> grade reading level mandated by most IRBs and the literacy level of most US citizens.

# Informed Consent Complexity at AMCs

Measure	Total IRBs n=111	Academic Medical Center IRBs n=100	Independent IRBs n=11	P-Value
SMOG reading level	13	13	13	0.2
Flesch-Kindcaid reading level	12	12	12	>0.2
Flesch reading ease score	39	38	42	0.07
# of pages	2	2	2	0.2
# of words	744	825	774	>0.2

# National Initiative for Cancer Care Quality

- Funded by ASCO
- 1<sup>st</sup> national study of cancer quality of care
- Clinically detailed measures of quality
- Breast and colorectal cancer
- Used National Cancer Data Base (NCDB) registry
- Identified cities, and all eligible hospitals
- 94 hospitals were eligible and agreed to participate

## NICCQ used NCDB data: Characteristics of Active Hospital Registries and Non-participating Hospital Registries

94 Hospitals	Active Hospital Registries n=65	Non-participating Hospital Registries n=29
Ownership***		
Public	11%	7%
Non-profit	83%	62%
Corporate	6%	31%
Teaching	44%	41%
Total hospital beds (n)	388	302
Oncology beds (n)	34	24
Oncology nurses (n)	31	39
Oncology services	97%	96% 26

\*\*\* p<.001 by chi-square comparing hospital ownership of active vs. non-participating hospital registries

## NICCQ: 77% of Hospital IRBs Declined Standardized Protocol, Preferring a Customized Approach

Hospitals (n=65)	Type of Customization Implemented by Hospital IRB
15 (23%)	None (survey vendor contacted patients)
31 (48%)	Unique consent form
10 (15%)	The registry itself (rather than survey vendor) notified the MD by mail of the patient's study eligibility
6 (9%)	Active consent from the physician prior to contacting the patient (protocol was to <i>notify</i> the MD and <i>consent</i> the patient)
3 (5%)	Active consent from the patient prior to releasing their contact information to the survey vendor (protocol was to have the survey vendor consent pts at the time of survey)

## NICCQ: MD Refusal Rates by Mailing Protocols

- Each registry was asked to identify 1 MD as the main contact MD for each patient
- Survey vendor mailed MD a letter on registry letterhead signed by the Cancer Liaison explaining the study, a brochure describing the NICCQ study, a letter of support from ACoS, a postage-paid return envelope, and a list of their patients who would be invited to participate
- The list had a check box for MD refusing permission to contact the patient, and a column for notes

Physician Mailing Protocol (Prior to Contacting Patient to Invite Active Informed Consent)	Number of Registries	Total Cases of Pts	Number of Doctor Refusals	Percent of Doctor Refusals
Physician <b>Notification</b> by Survey Vendor (followed by Pt consent)	49	4038	55	<b>1.4%</b>
Physician <b>Notification</b> by Hospital Registry (followed by Pt consent)	10	901	29	<b>3.2%</b>
Active Physician <b>Consent</b> prior to patient contact	6	537	107	<b>19.9%</b>
ALL	65	5476	191	<b>3.5%</b> <sup>8</sup>

# NICCQ: Patient Refusal Rates by Mailing Protocols

- If MD did not advise the survey vendor that the patient should not be contacted, two weeks after the physician mailing, a patient opt-out letter was sent. This letter provided a way for the respondents to indicate they did not want to be surveyed. Of the 162 respondents who returned the card and gave a reason for not wanting to participate, 60% said that they didn't like talking about their cancer. The rest said that they were too busy or marked multiple reasons.
- Patients who did not refuse survey vendor contact, were invited to provide active informed consent at the time of the survey.

Patient Mailing Protocol to Contact Patient to Invite Active Informed Consent	Number of Registries	Total Cases of Pts	Number of Patient Refusals	Percent of Patient Refusals
Passive Consent Packet Mailed by Survey Vendor	51	4250	193	5%
Passive Consent Packet Mailed by Hospital Registry	11	957	136	14%
Active Consent Required to Contact Patient	3	269	91	34%
<b>TOTAL</b>	<b>65</b>	<b>5476</b>	<b>420</b>	<b>8%</b>

# NICCCQ: Rates of Medical Record Consent by Survey Status

Consent status: → Survey status: ↓	COMPLETE Consent N=2142	REFUSE Consent N=650	BAD ADDRESS N=198	NOT ELIGIBLE N=198	NO PROXY AVAILABLE N=43	NO DATA N=1099
Completed Survey n=2404 (56%)	85%	5%	0.2%	--	--	10%
Proxy Cases <sup>5</sup> n=926 (22%)	10%	14%	21%	14%	5%	37%
Other Non- interviews <sup>6</sup> n=932 (22%)	0.3%	43%	--	--	--	56%
<b>TOTAL</b> n=4262 (100%)	50%	15%	5%	5%	1%	25%

# Proportion of Medical Record Volumes Received with a Current Informed Consent and HIPAA release form signed

## Los Angeles County, RAND UCLA CanCORS

Medical Record Status	N=4685 Volumes	% Volumes Accessed
Completed MR received	3719	79%
Incomplete MR received, Dead end	390	8%
MR not received	576	12%

# NICCOQ: Decomposing Challenges to Initiating Survey on Complete Study Cohort

<b>NICCOQ: Overall Patient Recruitment</b>	<b>N=</b>	<b>%</b>
Alive, Eligible, and Received 1 <sup>st</sup> Survey Mailing	3431	63
Deceased	831	15
Patient refusal (from opt-out mailing/ <b>before</b> packet)	420	8
Bad Address for Patient	276	5
Doctor refusal	191	4
Duplicate cases (same case from 2 registries or dup cases w/in registry)	135	3
Not Eligible (did not have cancer/not diagnosed in simple reference period)	80	2
Registry Problems (e.g., data incorrect, and other registry mistakes)	73	1
Invalid ACoS number (registry could not provide data)	22	<1
Doesn't speak English	5	<1
Patient out of Country	12	<1

# Patient Perspective Re Research

- Most pts agree to consent (Melton 1997)
- High trust that an org will protect privacy, predicts pts giving consent (Mechanic 1998)
- Researchers should not have to gain consent because low consent rates will result in invalid data (Lo 2005)
- Always appropriate to seek consent because pts want to be asked (Kass 2003)

# Linking Patient Perspective Regarding Medical Record Access to Crossing the Translational Chasm

- Pts want:
  - Knowledge that research is truly on behalf of patients
  - Full information about how their medical records are used for research
  - Assurance that the research benefits fellow patients
  - Knowledge about how their records may have contributed to new findings
  - High standards to ensure sensitive medical information is secure
  - Clear communications and consistent mechanisms to punish researchers who violate privacy

# **Patients' trust is the most powerful determinant of the kind of control patients want over how MRs are used for research**

- Pts who trust that their MRs are private and confidential are more likely to recommend a less stringent consent process, and sign consents
- Pts who perceive inadequate mechanisms to ensure privacy will retain more control over their MRs
- Clinical encounters influence the level of trust they place in researchers with whom they rarely interact

# Easing Tensions With Patients

- Building trust between patients and the research enterprise may be the essential element to engage pts in research and for medical records to flourish
- Patients want to know about on-going research and research results
  - 72% of HMO participants were more likely to participate in research if they were promised feedback on results (Purdy 2000)

# Earn Public Trust and Foster Public Accountability

- Pts should know more about the role IRBs (and Privacy Boards) play in regulating researchers' access to their medical records
- Researchers should educate the public about the general value of research and why MRs are necessary to conduct the research (Kass 2003)
- A publicly available data base should document manuscripts associated using NIH funds (U.S. H.H.S.< 2005)
  - to foster public accountability and
  - as a mechanism to earn public trust in the research enterprise

# Need highly secure systems in place to protect privacy

- Computerized databases must be sufficiently secure to prevent unauthorized access
- Patients must be confident that security systems are robust, even in the face of errant actions of careless individual/ clerk

# Researchers, Clinicians, and Systems Share Responsibilities for Predicting Research Engagement

Research engagement is predicted by:

- Trust elicited in clinical settings
- Respectful interactions between patients and those they frequently interact with
- Communications with patients about privacy protection policies
- Clear and consistent consequences for violations of patient privacy through willful or negligent actions
- Transparent systems for accountability and responsibility for patients to see

# Building Upon New Directions in Translational Research

- Transformative processes
- New collaborations
- Patient respect and centered care
- Build public trust