The Impact of Patient Access Pathways on Postmarketing Drug Safety Studies Using Cancer Registry Data

Kirk Midkiff,[1] Alicia Gilsenan,[1] Rebecca D. Martin,[1] Yun Wu,[1] Daniel N. Masica,[2] Elizabeth B. Andrews[1]

[1]RTI Health Solutions, Research Triangle Park, NC, United States; [2]Eli Lilly & Co., Indianapolis, IN, United States

ABSTRACT

BACKGROUND: Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in 2003 has had a measurable impact on researchers' ability to invite patients to participate in research. This impact has not been well characterized in studies using cancer registry data in the United States (US) for drug safety studies. An ongoing 10-year surveillance program enables assessment of patient access pathways and their impact on the research process.

OBJECTIVE: To characterize the impact of various patient access pathways across 14 registries (10 state; 1 Surveillance, Epidemiology, and End Results [SEER] regional; 3 comprehensive cancer centers) participating in a surveillance study.

METHODS: A variety of patient access pathways for release of information are required by the registries before patients with osteosarcoma can be interviewed regarding prior medication exposure. Registries were grouped into categories of similar patient access pathways. We performed a descriptive analysis of the impact of the pathways on telephone interview completion rates.

RESULTS: Between June 2004 and December 2008, 14 registries joined the surveillance program; five distinct pathways for accessing patients were identified. Of these pathways, the one that yielded the highest interview rate among identified cases (46%) was the one in which the patient's medical doctor (MD) is notified and allowed to decline before RTI-HS contacts the patient by telephone. The lowest interview rate (19%) was for the pathway requiring doctors and patients to complete a release form prior to telephone contact.

CONCLUSIONS: More restrictive patient access pathways correlated with lower interview rates and impeded progress in the conduct of this drug safety study. No breaches of patient confidentiality have occurred in any of the five consenting pathways used in this study; therefore, an increased privacy benefit from the more restrictive pathways is not likely. Actual study experience could be useful as institutions consider revising privacy policies regarding HIPAA.

Conflict of Interest Statement: The authors are employees of RTI Health Solutions (RTI-HS) and Eli Lilly & Co.

BACKGROUND

- The Institute of Medicine (IOM) Committee recently concluded: "HIPAA Privacy Rule does not protect privacy as well as it should, and that, as currently implemented, the HIPAA Privacy Rule impedes important health research."[1]
- Implementation of the rule in 2003 has had a measurable impact on the ability to conduct research; however, this impact is inadequately characterized when conducting research with cancer registries. We took the opportunity to examine the impact of different patient access pathways in the ongoing Adult Osteosarcoma Surveillance Study.

Adult Osteosarcoma Surveillance Study Design

- Surveillance study initiated in 2002
- Primary objectives: To identify and interview 40% of newly diagnosed cases of osteosarcoma in adults aged 40 and older in the US, for a duration of at least 10 years. To identify incident cases, if any, who have a history of treatment with the drug of interest
- Case ascertainment: cancer registries with a large adult population in the catchment area and the ability to participate.
- Exposure ascertainment: patient or proxy telephone interview
- Analysis: Compare observed exposure with expected exposure
- Precision: Sufficient size to detect a tripling in risk by end of study

Figure 1. Participating US Registries and Residence of Cases Identified by Participating Registries in the Current Adult Osteosarcoma Surveillance Study

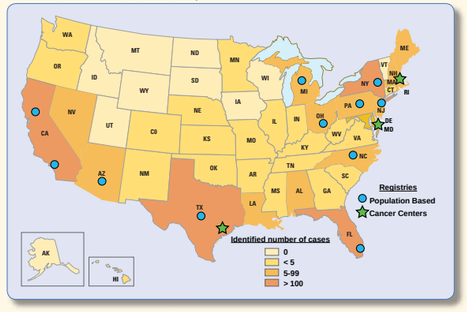
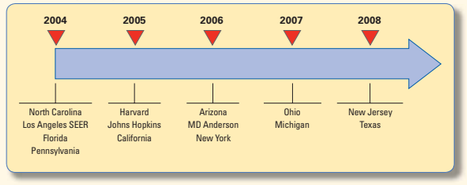


Figure 2. Year Registry Began Contributing Cases



OBJECTIVE

Assess the potential impact of various patient access pathways across registries that contribute cases to a long-term cancer surveillance study.

METHODS

Design

- Descriptive analyses of the different patient access pathways and their impact on interview completion rates

Approach

- 14 registries were collapsed into 5 patient access pathway categories to assess the a priori assumption that more complex pathways would result in lower interview rates
- Factors considered:
  - Patient access pathway
  - Year registry began participating (i.e., lag time); primary study seeks to interview all patients diagnosed from 2003 onward irrespective of the date the registry began participating

Data Source

- Deidentified case and administrative files of the Adult Osteosarcoma Surveillance Study

Analysis

- Descriptive stratified univariate and bivariate analysis of interview rates by patient access pathway and year registry began participating

Patient access pathways

MD notification only (n = 4 registries): RTI-HS sends notification to patient's physician. If physician does not object within a set time period, RTI-HS is allowed to initiate contact with the patient.

Patient release required (n = 3 registries): Registry must obtain permission from the patient before their contact information can be released to RTI-HS. This category also includes registries where RTI-HS must attempt to obtain a response form from the patient prior to making telephone contact.

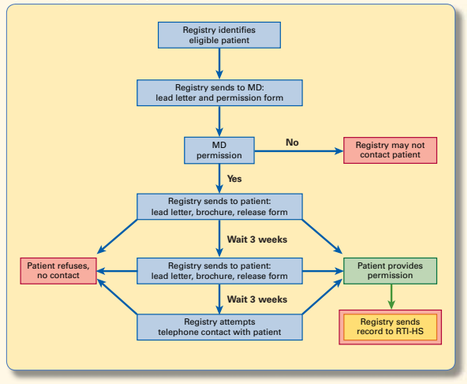
MD notification and patient release required (n = 2 registries): Registry must contact the physician, allowing the physician a set time period to object, and must obtain a release form from the patient before the patient may be contacted by RTI-HS to participate in the study.

MD permission to contact patient required (n = 4 registries): Registry or RTI-HS must contact the physician and obtain permission from the physician before RTI-HS may contact the patient to participate in the study.

MD permission to contact patient and patient release required (n = 1 registry): Registry must contact the physician and then the patient and obtain permission forms from both parties before the patient contact information can be released to RTI-HS.

- Figure 3 displays the most complex patient access pathway, MD Permission to Contact Patient and Patient Release Required. This must be carried out before RTI-HS can attempt telephone contact with the patient.

Figure 3. Example of the Most Complex Patient Access Pathway



RESULTS

- Results presented are based on data current to March 31, 2009.
- Figure 4 shows that 21% of cases identified by participating registries are not reported to RTI-HS with contact information.

Figure 4. Impact of Patient Access Pathway on Study Accrual

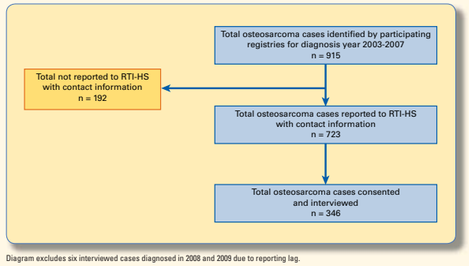


Diagram excludes six interviewed cases diagnosed in 2008 and 2009 due to reporting lag.

- Table 1 shows that the registries with less complex patient access pathways tended to have higher interview rates than registries with more complex pathways.

Table 1. Patient Access Pathway and Interview Rate in Decreasing Order of Interview Rate

Registry (Year Added)	Type of Patient Access Pathway	Total Identified	Total Interviewed	Interview Rate*
North Carolina (2004)	MD notify only	40	23	58%
CA - LA SEER (2004)	MD notify only	42	23	55%
Arizona (2006)	MD notify only	21	9	43%
California (2005)	MD notify only	148	63	43%
New York (2006)	MD notify and patient release	126	54	43%
MD Anderson (2006)	Patient release only	90	36	40%
Harvard (2005)	MD permission	47	19	40%
Pennsylvania (2004)	Patient release only	75	28	37%
New Jersey (2008)	MD permission and patient release	32	11	34%
Johns Hopkins (2005)	MD permission	3	1	33%
Michigan (2007)	MD notify and patient release	75	24	32%
Florida (2004)	Patient release only	119	37	31%
Ohio (2007)	MD permission	50	12	24%
Texas (2008)	MD permission	47	6	13%
Total		**915**	**346**	**38%**

*Interview rate among identified cases = (# interviewed)/(# identified by participating registries).

- Table 2 shows that registries that began contributing cases during the first 3 years of data collection had higher interview rates when compared with registries that began contributing cases later.

Table 2. Interview Rate by Year Registry Added

Year Registry Added (No.)	Total Identified	Total Interviewed	Interview Rate*
2004 (4)	276	111	40%
2005 (3)	198	83	42%
2006 (3)	237	99	42%
2007 (2)	125	36	29%
2008 (2)	79	17	22%
Total (14)	**915**	**346**	**38%**

*Interview rate among identified cases = (# interviewed)/(# identified by participating registries).

- The interview rate did not vary substantially when stratifying by both the complexity of the patient access pathway and the year the registry was added to the study.

CONCLUSIONS

- The complexity of the patient access pathway appears inversely related to the interview rate.
- Interview rates trended lower at registries where MD permission was required.
- The year the registry began participating appeared related to the interview rate; however, registries with fewer complex requirements were recruited first, which confounds lag time.
- These results support conclusions in the recent IOM report that an overly cautious approach to HIPAA may be impeding research.

REFERENCE

1. Institute of Medicine (IOM). Beyond the HIPAA Privacy Rule: enhancing privacy, improving health through research. Washington, DC: The National Academies Press. 2009.

CONTACT INFORMATION

Kirk Midkiff, MPH

Senior Research Epidemiologist
RTI Health Solutions
200 Park Offices Drive
Research Triangle Park, NC 27709

Telephone: +1.919.541.6638
Fax: +1.919.541.7222
E-mail: kmidkiff@rti.org

Presented at: 25th International Conference on Pharmacoepidemiology & Therapeutic Risk Management
August 16-19, 2009
Providence, RI, United States