

# Letters

## RESEARCH LETTER

### Data Breaches of Protected Health Information in the United States

Reports of data breaches have increased during the past decade.<sup>1,2</sup> Compared with other industries, these breaches are estimated to be the most costly in health care; however, few studies have detailed their characteristics and scope.<sup>1</sup>

**Methods** | We evaluated an online database maintained by the US Department of Health and Human Services describing data breaches of unencrypted protected health information (ie, in-



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dividually identifiable information) reported by entities (health plans and clinicians)

covered under the Health Insurance Portability and Accountability Act (HIPAA).<sup>3</sup> Under the Health Information Technology for Economic and Clinical Health Act of 2009, breaches involving the acquisition, access, use, or disclosure of protected

health information and thus posing a significant risk to affected individuals must be reported.<sup>4</sup>

When data breaches affect 500 individuals or more, the report must include the name and state of the entity breached, the number of records affected, the type and source of the breach, and the involvement of any external vendor using protected health information. Examples include the theft of unsecured laptops, dissemination of data in emails, and improper disposal of patient records. Reports are made online via form templates.<sup>3</sup>

We included breaches affecting 500 individuals or more reported as occurring from 2010 through 2013, accounting for 82.1% of all reports.<sup>3</sup> We quantified the frequency and geographic locations of breaches, adjusting for 2013 population estimates from the US Census Bureau.

Based on categorical templates, we grouped breaches as occurring via theft, loss or improper disposal of data, unauthorized data access or disclosure, hacking or information technology incidents, or other and missing (n = 2). We described

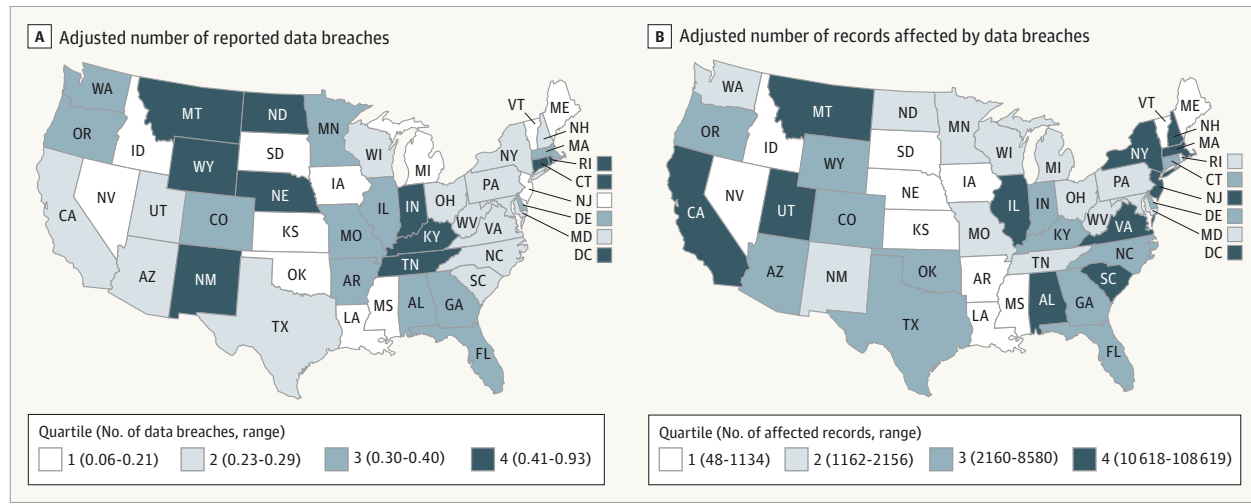
**Table. Characteristics of Data Breaches of Protected Health Information Affecting at Least 500 Individuals Reported by Entities Covered by the Health Insurance Portability and Accountability Act**

	Overall	Year of Data Breach				P Value <sup>a</sup>
		2010	2011	2012	2013	
Total No. of data breaches reported	949	214	236	234	265	.07
Total No. of records affected, in millions	29.0	5.1	11.6	3.4	9.0	.88
No. of data breaches affecting at least 1 million records	6	1	3	0	2	.37
Data breach by media type, No. (%) [95% CI]						
Portable electronic device or laptop	310 (32.7) [29.7-35.7]	77 (36.0) [29.8-42.7]	72 (30.5) [24.9-36.7]	78 (33.3) [27.5-40.0]	83 (31.3) [26.0-37.2]	.09
Desktop, email, or EMR	148 (15.6) [13.4-18.0]	32 (15.0) [10.7-20.4]	25 (10.6) [7.2-15.2]	43 (18.4) [13.9-23.9]	48 (18.1) [13.9-23.3]	
Paper	212 (22.3) [19.8-25.1]	50 (23.4) [18.1-30.0]	55 (23.3) [18.3-29.2]	52 (22.2) [17.3-28.0]	55 (20.8) [16.3-26.1]	
Network server	101 (10.6) [8.8-12.8]	16 (7.5) [4.6-11.9]	25 (10.6) [7.2-15.2]	29 (12.4) [8.7-17.3]	31 (11.7) [8.3-16.2]	
Other	178 (18.8) [16.4-21.4]	39 (18.2) [13.6-24.0]	59 (25.0) [19.9-31.0]	32 (13.7) [9.8-18.7]	48 (18.1) [13.9-23.3]	
Data breach category, No. (%) [95% CI]						
Theft	552 (58.2) [55.0-61.3]	139 (65.0) [58.3-71.1]	142 (60.2) [53.7-66.3]	141 (60.3) [53.8-66.4]	130 (49.1) [43.0-55.1]	.003
Loss or improper disposal	105 (11.1) [9.2-13.2]	24 (11.2) [7.6-16.2]	21 (8.9) [5.9-13.3]	28 (12.0) [8.4-16.8]	32 (12.1) [8.6-16.6]	
Unauthorized access or disclosure	140 (14.8) [12.6-17.2]	16 (7.5) [4.6-11.9]	39 (16.5) [12.3-21.9]	36 (15.4) [11.3-20.6]	49 (18.5) [14.2-23.7]	
Hacking or IT incident	67 (7.1) [5.6-8.9]	10 (4.7) [2.5-8.5]	20 (8.5) [5.5-12.8]	14 (6.0) [3.6-9.9]	23 (8.7) [5.8-12.8]	
Other	85 (9.0) [7.3-11.0]	25 (11.7) [8.0-16.8]	14 (5.9) [3.5-9.8]	15 (6.4) [3.9-10.4]	31 (11.7) [8.3-16.2]	
Data breach involved external vendor, No. (%) [95% CI]	273 (28.8) [25.9-31.7]	54 (25.2) [19.8-31.5]	76 (32.2) [26.5-38.5]	70 (29.9) [24.4-36.1]	73 (27.6) [22.5-33.3]	.39

Abbreviations: EMR, electronic medical record; IT, information technology.

<sup>a</sup> Calculated using linear regression or  $\chi^2$  tests.

Figure. Adjusted Number of Data Breaches and Affected Records Between 2010 and 2013 by State and Quartile



Adjusted values were calculated by dividing the number of breaches and the affected records by 2013 population estimates from the US Census Bureau based on the state in which the breach was reported. The data quartiles are per

100 000 residents. The Figure does not display data for Hawaii, Alaska, or Puerto Rico.

the media through which breaches occurred as electronic (including network server; desktop computer, email, and electronic medical records; or laptop computer and electronic portable devices), paper, or other.

We compared annual data with  $\chi^2$  tests and linear regression using Stata version 13.1 (StataCorp) with a 2-sided significance level of  $P < .05$ . The Kaiser Permanente Northern California institutional review board determined that this study did not qualify as human subjects research.

**Results** | We evaluated 949 breaches affecting 29 million records between 2010 and 2013. Six breaches involved more than 1 million records each and the number of reported breaches increased over time, although the trend using linear regression did not reach statistical significance ( $P = .07$ ; **Table**). Breaches were reported in every state, the District of Columbia, and Puerto Rico. Five states (California, Texas, Florida, New York, and Illinois) accounted for 34.1% (95% CI, 31.2%-37.2%) of all breaches. However, when adjusted by population estimates, the states with the highest adjusted number of breaches and affected records varied (**Figure**).

Most breaches occurred via electronic media (67.4%; 95% CI, 64.4%-70.4%; **Table**), frequently involving laptop computers or portable electronic devices (32.7%; 95% CI, 29.7%-35.7%). Most breaches also occurred via theft (58.2%; 95% CI, 55.0%-61.3%). The combined frequency of breaches resulting from hacking and unauthorized access or disclosure increased during the study period (12.1% in 2010 to 27.2% in 2013;  $P = .003$ ). Breaches involved external vendors in 28.8% (95% CI, 25.9%-31.7%) of reports.

**Discussion** | Between 2010 and 2013, data breaches reported by HIPAA-covered entities involved 29 million records. Most data breaches resulted from overt criminal activity. The persistent threat of theft and the increase in hacking raise serious security concerns.

Our study was limited to breaches that were already recognized, reported, and affecting at least 500 individuals. Therefore, our study likely underestimated the true number of health care data breaches occurring each year. Some entities or patients may have been involved in more than 1 breach.

We were unable to assess the costs or the effect on operations caused by these breaches and the accompanying increased data security measures. We were also unable to calculate the rates at which breaches occurred based on the number of total US records or entities at risk.

Given the rapid expansion in electronic health record deployment since 2012, as well as the expected increase in cloud-based services provided by vendors supporting predictive analytics, personal health records, health-related sensors, and gene sequencing technology, the frequency and scope of electronic health care data breaches are likely to increase.<sup>2,5,6</sup> Strategies to mitigate the risk and effect of these data breaches will be essential to ensure the well-being of patients, clinicians, and health care systems.

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**Author Contributions:** Dr Liu had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

*Study concept and design:* All authors.

*Acquisition, analysis, or interpretation of data:* Liu.

*Drafting of the manuscript:* Liu.

*Critical revision of the manuscript for important intellectual content:* All authors.  
*Statistical analysis:* Liu.  
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*Study supervision:* Chou.

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**Correction:** This article was corrected on May 21, 2015, to fix wording and data errors in the text and Table.

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## COMMENT & RESPONSE

### Aspirin for Prevention of Cardiovascular Events in Older Japanese Patients

**To the Editor** The study by Dr Ikeda and colleagues<sup>1</sup> on low-dose aspirin for primary prevention in patients who are at risk of cardiovascular events was stopped early for futility with regard to the primary outcome, which was “a composite of death from cardiovascular causes (myocardial infarction, stroke, and other cardiovascular causes), nonfatal stroke (ischemic or hemorrhagic, including undefined cerebrovascular events), and nonfatal myocardial infarction.”

However, the study does not really look negative because the authors stated, “aspirin significantly reduced incidence of nonfatal myocardial infarction ... and transient ischemic attack.”

Also, the study used enteric-coated aspirin. If uncoated aspirin had been used, the results may have been more positive. For many years, there has been a controversy about aspirin resistance.<sup>2</sup> It now seems that aspirin resistance may be due to enteric coating. Grosser et al<sup>3</sup> found aspirin resistance in 40% of study participants given enteric-coated aspirin, and in none of those given uncoated aspirin.

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**Conflict of Interest Disclosures:** The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

1. Ikeda Y, Shimada K, Teramoto T, et al. Low-dose aspirin for primary prevention of cardiovascular events in Japanese patients 60 years or older with atherosclerotic risk factors: a randomized clinical trial. *JAMA*. 2014;312(23):2510-2520.
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**In Reply** As stated in our article, there was a significant reduction in the incidence of nonfatal myocardial infarction and transient ischemic attacks, which were predefined secondary end points. Because we did not find a significant reduction in the primary end point, the study has to be interpreted as negative.

Further study including more patients or for longer periods may produce different results, as may analyzing ischemic stroke and intracranial hemorrhage separately. In addition, certain types of patients may benefit from aspirin for primary prevention.

We chose to use enteric-coated aspirin rather than uncoated aspirin because enteric-coated aspirin produces fewer gastrointestinal complications than uncoated aspirin. Gastrointestinal complications related to aspirin use are of considerable concern in Japan, and we were not aware of clinical studies showing solid evidence of superiority of uncoated aspirin for primary prevention at the time our study protocol was developed.

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### Long-term Survival Following Bariatric Surgery in the VA Health System

**To the Editor** The study by Dr Arterburn and colleagues<sup>1</sup> found lower mortality among obese patients in the Veterans Affairs (VA) health system receiving bariatric surgery compared with matched controls not receiving surgery. The authors did not account for several relevant sources of selection bias introduced by the VA bariatric surgery eligibility criteria.<sup>2</sup>

For example, candidates must be free of nicotine for 3 months prior to surgery. Despite a high prevalence of smoking among veterans,<sup>3</sup> patients were not matched on smoking status. This raises the possibility of overrepresentation of smokers in the comparison population.

Additionally, psychometric surveys and clinical interviews were used to preoperatively screen veterans for exclu-