

SURGICAL RESEARCH



and
the new
privacy
laws

The Health Insurance Portability and Accountability Act (HIPAA) became effective April 14, 2003, with the goal of improving patient privacy and putting patients in greater control of their personal health information. HIPAA implementation has been costly on institutions and in legal departments.¹ Although the gold standard of clinical research (the randomized, prospective, controlled trial) is unlikely to be significantly affected by HIPAA because consent and protocol procedures are already comprehensive, evidence is coming forth that large registry studies are being negatively affected by consent bias, likely related to the requirement that consent be obtained retrospectively.²

by

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Surgical research and the progress therefrom, however, are usually not initially based on randomized, controlled trials. Randomized, controlled trials for carotid endarterectomy, laparoscopic herniorrhaphy, and colectomy have been published, for example, but the preliminary basis for these large studies were retrospective case-controlled series that compared one type of surgical option versus another. Data from these smaller retrospective reports were crucial to raise the important questions that influenced later, larger trials. In the recent past, institutional review board (IRB) approval for retrospective studies was a waiver of informed consent, as long as no intervention or patient contact was made. Since HIPAA implementation, informed consent must be obtained from patients for use of any of their personal health information (and/or tissue) based on the privacy rules, unless obtaining consent is “not practicable.” Although local IRBs may interpret this criterion differently, most are likely to interpret it conservatively in order to prevent possibly hefty fines or litigation.³

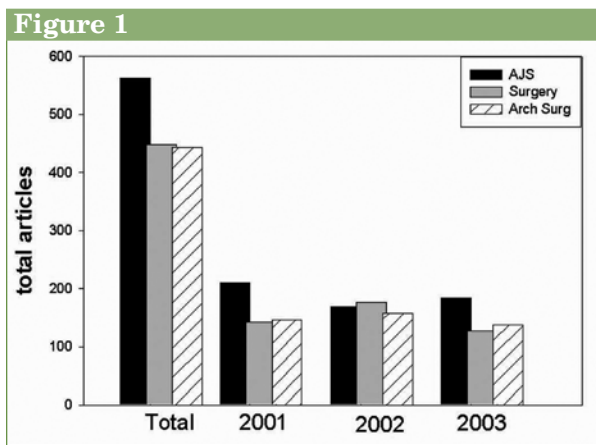
The aim of this brief report is to characterize the current state of surgical published research and to determine the types of articles published, notation of IRB, and origin of publication before HIPAA implementation.

Survey of clinical research journals

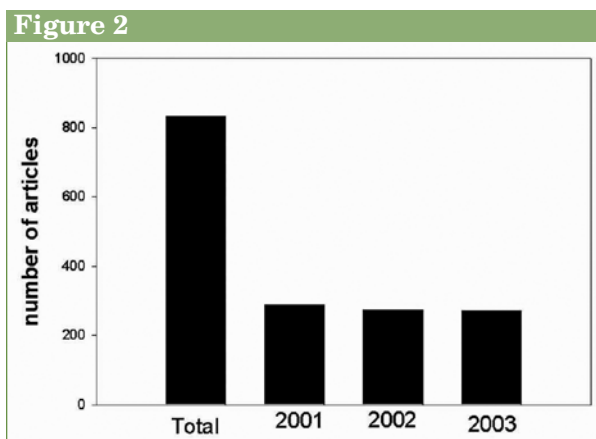
We reviewed three common surgical journals that are fully peer reviewed, to survey the distribution and type of clinical research publications. From January 2001 to December 2003, a total of 2,035 articles in the *American Journal of Surgery*, *Surgery*, and *Archives of Surgery* were characterized by Medline database abstract review. Abstracted data included type of article—specifically, clinical research, involving human subjects or their tissue, basic laboratory studies involving animals, or in vitro experiments—and miscellaneous articles involving small case series (fewer than four patients, reviews, organizations’ presidential addresses, and so on). Review of the abstracted data was done to determine the status of IRB approval, number of patients in the study, and duration of follow-up. The country of origin was defined as either U.S. or international.

The 2002 Science Citation Index for each journal was 1.7, 2.55, and 2.63, respectively. Clinical studies involving human subjects or their tis-

sue composed 71 percent of all articles in these journals and overall variation in article number between journals was not substantial (see Figure 1, this page). Similarly, over a three-year period, a slight majority of articles originated from the U.S. (57%) (see Figure 2, this page). Prospective surgical studies were documented in a mean of 23 percent of articles (no significant difference over the three years), whereas retrospective case series accounted for the remaining majority of human subject studies. IRB approval was documented in a



Clinical research articles over time in the *American Journal of Surgery* (AJS), *Surgery*, and *Archives of Surgery* (Arch Surg).



Clinical research articles over time originating from the U.S.

mean of 24 percent of human subject studies, without a significant difference per year (see Figure 3, this page). The mean number of patients included in these studies was 496, with a mean follow-up of 12 months. Basic science reports made up 9.6 percent, whereas miscellaneous topical reviews, technical notes, and small case reports (fewer than four patients) made up 19 percent of articles.

Negative impact of HIPAA

The potential negative impact of HIPAA on surgical research is significant. O'Herrin and colleagues recently reported that although overall applications for IRB approval increased, nearly 70 percent failed to complete the process, likely related to the markedly increased demands for documentation from the IRB.⁴ Based on approximately 500 clinical research articles published per year between these three journals, if one assumes a conservative 25 percent drop in retrospective case research data resulting from HIPAA-imposed obligations, then a potential decrease of 125 reports fewer per year will be made. This may have a negative impact on the following: trainees whose first research publication is often a case series; overall surgical research, as much surgical therapy is not ethical or practical for a randomized, controlled trial; and the ability to get background published data to put forth solid and fruitful hypotheses when proposing a randomized, prospective surgical trial. Although not specifically related to surgical research, others have called for preventive change for HIPAA on the national level.⁵

Possible solutions and compensations

Several solutions are suggested, and some silver linings are present. A first simple step would be a standard exclusion addendum for IRBs to uniformly allow waiver of consent for retrospective research. This might also take the form of an expedited IRB review process. An addendum to HIPAA specifically related to clinical research could be created, but this involves lawmakers and politics and might be unpopular, given the recent concern with patient data security.

The added burdens for retrospective clinical research might stimulate more externally funded, surgical investigator-initiated research with resultant higher impact on patient care. Put another way, if the administrative hurdles with the IRBs

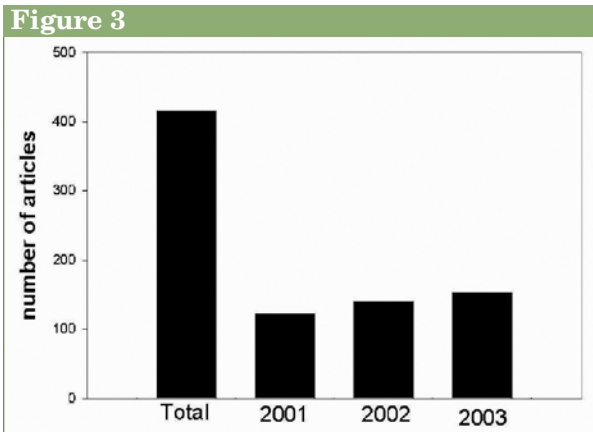



Figure 3. Clinical research articles with notation of Institutional Review Board approval.

are similar between retrospective and prospective projects, the investigator may choose a study of longer duration that might yield more rigorous data. Similarly, extended case series and anecdotal reports seemingly carry little weight in the era of evidence-based medicine.

Another potential compensation is the availability and use of large patient databases, which bring significantly more statistical power to determine treatment and therapeutic effects of surgical disease. For example, the use of the Medicare database to delineate the surgical volume–outcome effect is valid and useful and would not have been possible with single or even multi-institution evaluation.⁶ However, detailed patient-specific outcomes are less reliable with these databases that rely on codes from the *International Classification of Diseases, Ninth Revision, Clinical Modification*, often without hard chart confirmation. Studies combining these data sets often produce different conclusions.⁷ More detailed, prospectively acquired data are currently available from the Veterans Affairs Hospital System with the National Surgical Quality Improvement Program, and multiple articles have been published.⁸ Currently, this program has now moved to the nonfederal hospitals with a private sector academic consortium that is rapidly expanding. These data are robust for perioperative outcomes and risk factor analysis and, as these are deidentified patient data, HIPAA consent procedures do not apply.

Lastly, institution-wide deidentified databases could be constructed to allow detailed patient analysis that is prefiltered to eliminate any patient identifiers, at least for preliminary studies. If an interesting observation is uncovered, then formal IRB approval and consent for follow-up could then be obtained.

Currently, surgical research for the academician who is trying to balance personal time and increased operative and clinical supervision is harder than ever. The HIPAA burden is personal in terms of workload, and societal through the implementation of more obstacles for investigation of surgical questions. Certainly, support for a system-wide change would require a more formal, large-scale, longitudinal study of multi-institutional IRB and institutional research patterns. This report serves as a snapshot in time that may be useful for a review in several years after the full effects of HIPAA have become manifest. 

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