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O'Herrin JK, Fost N, Kudsk KA. Health Insurance Portability Accountability Act (HIPAA) regulations: Effect on medical record research. *Annals of Surgery* 2004; 239(6):772-6; discussion 776-8.

HIPAA was implemented to reduce potential misuse of personal information and restrict access to medical records by insurers, employers, and clinical researchers. These authors used the UW-Madison Human Subjects Committee database to assess the impact of HIPAA on Applications for Exemptions from Institutional Review Board (IRB) approval. Believing that the new regulations would adversely impact medical records research, they evaluated the success and delays in processing Applications for Exemption between September 1999 and March 2003. The number of protocols submitted, the number of required revisions, and the number considered nonexempt (requiring full IRB review) were determined. They found that before 2000, applications for medical records research were rare (11 applications in 1999–2000). Anticipating the implementation of HIPAA regulations, the IRB instituted a new application process in 2001. During that year, an expedited process approved 92 of 103 research applications, with few requiring full IRB approval. In 2002–2003, submissions increased to 199 and approval without revision dropped to 59% ($p < 0.0001$) as the number requiring revision (25%) and full IRB approval (16%) increased significantly ($p < 0.0001$ and $p < 0.05$, respectively). Of the 31 requiring full IRB approval, 7 were pursued and 24 (77%) were abandoned. Although this study involved only one IRB, the authors conclude (probably correctly) that HIPAA appears to inhibit medical record and database research. Although they agree that ethical considerations in healthcare research are paramount, it is unclear whether or to what extent the HIPAA requirements augment patients' privacy. What *current HIPAA*

strategies do is to increase workloads for IRBs and researchers, and to increase the dropout rate for proposed studies when investigators are unable or unwilling to meet the regulatory requirements.

Ganzini L, Volicer L, Nelson WA, Fox E, Derse AR. Ten myths about decision-making capacity. *Journal of the American Medical Directors Association* 2004;5(4):263-7.

How clinicians judge their patients' decisionmaking capacity determines what role the patients play in decisions about their healthcare. Because so much hinges on this assessment, clinicians have an ethical obligation to understand this concept. This article, based on a report prepared by the National Ethics Committee (NEC) of the Veterans Health Administration (VHA), seeks to provide clinicians with practical information about decisionmaking capacity and how to assess it. A study of clinicians and ethics committee chairs, carried out under the auspices of the NEC, identified the following 10 common myths clinicians hold about decisionmaking capacity: (1) decisionmaking capacity and competency are the same, (2) lack of decisionmaking capacity can be presumed when patients go against medical advice, (3) there is no need to assess decisionmaking capacity unless patients go against medical advice, (4) decisionmaking capacity is an "all or nothing" phenomenon, (5) cognitive impairment equals lack of decisionmaking capacity, (6) lack of decisionmaking capacity is a permanent condition, (7) patients who have not been given relevant and consistent information about their treatment lack decisionmaking capacity, (8) all patients with certain psychiatric disorders lack decisionmaking capacity, (9) patients who are involuntarily committed lack decisionmaking capacity, and (10) only mental health experts can assess decisionmaking capacity. By describing and debunking these common misconceptions, the authors attempt to prevent

potential errors in the clinical assessment of decisionmaking capacity, thereby supporting patients' right to make choices about their own healthcare.

Friedman LS, Richter ED. Relationship between conflicts of interest and research results. *Journal of General Internal Medicine* 2004;19(1):51–6.

Good ethics and good clinical decisions begin with accurate information. We rely on information published in the most prestigious medical journals for this information. However, research regarding how conflicts of interest influence the presentation of findings by researchers has been limited. To evaluate the sources of funding for published manuscripts and the association between reported findings and conflicts of interest, these authors evaluated data from both print and electronic issues of *The New England Journal of Medicine (NEJM)* and *The Journal of the American Medical Association (JAMA)* for funding sources, areas of investigation, conflict of interest (COI), and presentation of results. They reviewed all original manuscripts published in 2001 within *NEJM* ($N = 193$) and *JAMA* ($N = 205$). Using three definitions for COI, including the criterion used by The International Council of Medical Journal Editors (ICMJE), they found that, depending on the COI criteria used, 16.6% to 32.6% of manuscripts had one or more authors with COI. Based on ICMJE criterion, 38.7% of the studies investigating drug treatments had authors with COI. Of particular concern, they found a strong association between those studies whose authors had COI and reported positive findings ($p < 0.001$). When controlling for sample size, study design, and country of primary authors, they observed a strong association between positive results and COI (ICMJE definition) among all treatment studies (adjusted odds ratio [OR], 2.35; 95% confidence interval [CI], 1.08–5.09) and drug studies alone (OR, 2.64; 95% CI, 1.09–6.39). They concluded that *COI is widespread among the authors of published manuscripts and these authors are more likely to present positive findings.*

Schoen C, Doty MM. Inequities in access to medical care in five countries: Findings from the 2001 Commonwealth Fund International Health Policy Survey. *Health Policy* 2004;67(3):309–22.

At a time when many countries are struggling with how to reorganize their health-care systems to best use available resources, these authors provide valuable information with their examination of five countries' inequities in access to healthcare and in their quality of care. This examination correlated healthcare access to individuals' income, and assessed whether these inequities persist after controlling for the effect of insurance coverage, minority and immigration status, health, and other important cofactors. The authors used a multivariate analysis of a cross-sectional 2001 random survey of 1400 adults in five countries (Australia, Canada, New Zealand, United Kingdom, and United States) to access difficulties and waiting times, cost-related access problems, and ratings of physicians and quality of care. They found that wide and significant disparities exist in access and care experiences between U.S. adults with above- and below-average incomes; these differences persist after controlling for insurance coverage, race/ethnicity, immigration status, and other important factors. In contrast, differences in the United Kingdom by income were rare. Although Australians report few significant access differences by income, they reported out-of-pocket costs more frequently than respondents in the United Kingdom. The results for New Zealand and Canada fell in the midrange of the five nations, with income differences most pronounced for services less well covered by national systems. In the four countries with universal coverage, adults with above-average income were more likely to have private supplemental insurance. Having private insurance in Australia, Canada, and New Zealand protects adults from cost-related access problems. In contrast, in the United Kingdom, having supplemental coverage makes little significant difference in access. Being uninsured in the United States resulted in significantly negative consequences for access and quality of care. The authors conclude that for policy leaders, the five-nation survey demonstrates that some health systems are better able to minimize financial barriers to access and quality care among low-income adults. However, as shown in Australia, Canada, and New Zealand, the reliance on private coverage to supplement public coverage can result in access inequities even within health systems that provide universal basic health coverage.