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Getting it on record – and getting it right

Good documentation avoids med-mal trouble

By Barbara Rabinovitz

Physicians should make sure that their patients' medical records are complete, accurate, up-to-date and, yes, even legible, advise doctors and lawyers familiar with the fallout of poor record-keeping.

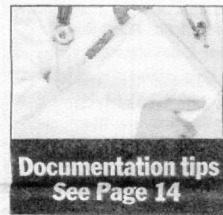
Medical-record documentation invariably comes into play in medical-malpractice cases, and the better the documentation, the more

likely it could contribute to a favorable outcome for a defendant physician – or help avoid litigation in the first place.

"It is the most important piece

of evidence in a medical-malpractice case," says Boston plaintiffs' attorney Andrew C. Meyer Jr., who has handled thousands of med-mal cases. When attorneys representing

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Documentation tips
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Hazards lurking in patient handoffs

Hospitals reduce legal risks by changing policies

By Eric Berkman

Handoffs of patients from one hospital unit to another are rife with serious medical errors – and hospitals in Massachusetts and beyond are developing new strategies to avoid the med-mal claims and litigation that can result.

Last year, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued rules that required hospitals to standardize their communication processes to reduce the risk of errors related to patient transfers, known as "handoffs," by January 2006 – or risk losing their accreditation.

According to JCAHO, communication problems in handoffs play a significant role in the majority of serious injuries or death from medical errors in a hospital setting.

"We've seen that approximately 70 percent of all serious adverse events are related to breakdowns in communication, typically at the point of handoff," said Dr. Richard Croteau, executive director for patient safety initiatives for JCAHO.

Cambridge attorney Martin Foster represented a hospital in a med-mal case where a staffer in one unit misunderstood the patient's medication dose and repeated the error verbally to the staffer taking over his care. Instead of getting the 30 grams of car-



Getty Images

diac medicine he should have received, he got 300 – and died before the error was caught. That case settled without going to suit, Foster said.

To avoid situations like that one and comply with the JCAHO rules, hospitals have been sharpening various strategies

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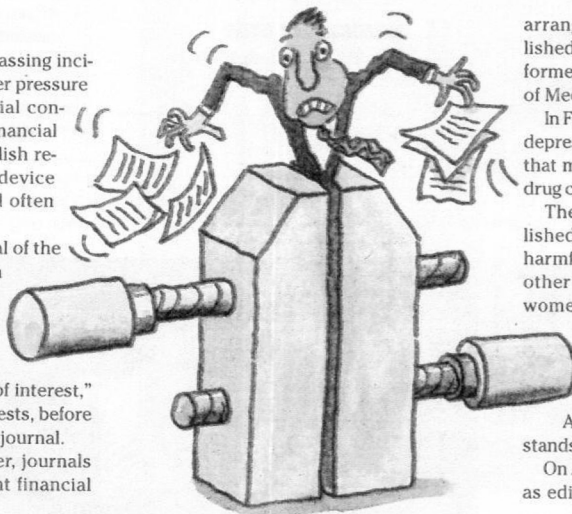
Under pressure, medical journals tighten disclosure rules

By Sylvia Hsieh

Following a string of embarrassing incidents, medical journals are under pressure to strengthen rules on potential conflicts of interest arising out of financial ties between doctors who publish research results and drug and device companies that sponsor – and often benefit from – such research.

Three incidents at the Journal of the American Medical Association in the last six months prompted it to announce new disclosure policies. Beginning next year, all authors will be required "to disclose all potential conflicts of interest," including specific financial interests, before submitting a manuscript to the journal.

"In one incident after another, journals have failed to disclose relevant financial



arrangements of authors who have published papers," said Dr. Jerome Kassirer, a former editor of the New England Journal of Medicine.

In February, a study published in JAMA on depression and pregnancy failed to disclose that most of the 13 researchers had ties to drug companies that make anti-depressants.

Then in May and July, the journal published two separate studies – one on the harmful effects of arthritis drugs and the other on migraines and heart disease in women. The journal later published corrections when it discovered that in both cases the authors had failed to disclose their financial arrangements with drug companies.

As a leading national publication, JAMA stands out for its errors, but it is not alone.

On August 28, Charles Nemeroff resigned as editor of the journal *Neuropsychophar-*

macology after it became public that he had financial ties to a device manufacturer whose product was the subject of a study that he co-authored.

The article gave a favorable review to a new treatment for depression without mentioning that Nemeroff sits on two advisory boards for Cyberonics, Inc., a Houston company that makes the chest implant device reviewed in the study.

Sheldon Krinsky, author of the book "Science in the Private Interest," has studied conflicts of interest in medical journals and says that journals only began adopting disclosure policies about ten years ago.

"My guess is that of the top 100 journals, about 50 percent have policies," Krinsky said.

But Dr. Marcia Angell, senior lecturer at the School of Social Medicine at Harvard University and former editor-in-chief of the

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Under pressure, medical journals tighten disclosure rules

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New England Journal of Medicine, said the problem is not so much the policies as enforcement of them.

"Journal editors have quite frankly been lax in enforcement," she said. "There's been a wink and a nod from medical journals and within medical [research] institutions."

Angell and other experts say that disclosure rules can only go so far in dealing with the influence of corporate-sponsored research.

According to Sandra Johnson, professor of law and Tenet Chair of Health Law and Ethics at St. Louis University, who is writing an article on this subject, financial interests among research doctors are widespread.

In a one-year period from 2005 to 2006, Johnson found that authors reported financial interests in about one-third of the articles published in JAMA.

"Financial conflicts of interest have been a bubbling issue for the past three to four years, but it's reaching a critical point now because the problems have finally been discovered to permeate the whole area," she said.

Stricter disclosures

Physicians engaged in research can now expect to disclose more information about their financial arrangements.

Krimsky said that a "gold standard" disclosure policy would require authors to disclose not only the existence of financial ties, but also the period of time and nature of those ties, including whether the author had consulting arrangements, equity interests or patent interests, whether the author was on the speakers' bureau or had

testified in legal proceedings as an expert, as well as who supported the research and whether those companies were involved in any product discussed in the article.

"There should be complete transparency," Krimsky said.

Kassirer added that doctors should also be required to disclose how much the financial ties are worth.

But journal editors are beginning to realize that authors are not always forthcoming about their financial ties, Angell said.

Journals may be able to improve the process by changing their definitions of conflicts of interest.

"Some policies say an author should disclose financial ties that 'could be perceived' as conflicts of interest. That is huge loophole," Angell noted.

Krimsky suggests that in certain cases, financial ties should be prohibited in the first place. "Someone who is overseeing a clinical trial should not be allowed to have a financial interest in a company or product that is part of that trial, because the appearance of independent honesty is lost," he said.

Some journals are considering banning authors who fail to disclose financial ties.

The Center for Science and the Public Interest advocates a three-year prohibition on authors who fail to disclose conflicts.

But Angell said she would wait to see if public embarrassment is a strong enough deterrent before banning authors.

"The problem with forbidding publication is suppose they have found a cure for cancer. You wouldn't want to exclude that," she said.

Tip of the iceberg?

Even the strongest of policies can only do so much.

This is because even if all financial ties are disclosed, it's impossible for readers to know whether the results are biased.

"Disclosure is ultimately not very useful. Yeah, it's a good thing to know, but what are you supposed to do with it?" said Johnson.

Kassirer agreed.

He gave the example of a doctor, before giving a lecture on the benefits of a drug, saying that he has a financial arrangement with the drug maker.

"Either he's telling you the complete objective truth, or he's biasing his remarks even if he doesn't appreciate he's doing it, or he knows very well that he's doing it because he will be invited to give more talks by the company," he said.

For a practicing physician reading a study in a medical journal, the same dilemma exists in interpreting the researchers' disclosures, said Johnson.

Disclosure is just the "tip of the iceberg," when it comes to the influence of corporate money in medicine, Kassirer said.

Pharmaceutical companies outspend the government by five times, not only for clinical trials for getting drugs approved, but for research after approval, Johnson said.

If all conflicts were prohibited, Angell noted, "medical journals wouldn't be able to publish anything, because most clinical trials are funded by companies."

To that end, some experts point to the research institutions as the frontline in

weeding out conflicts of interest.

According to an editorial by JAMA's editor-in-chief Catherine DeAngelis on the journal's website, she has asked the deans of medical schools on two occasions to investigate non-disclosure by authors and both times that resulted in "corrective action."

Companies often attach strings to research dollars, such as giving the company sole control over the results and whether they are published.

"That's where institutions must have clear conflict of interest policies that say to their faculty, 'You may not conduct clinical research on companies in which you have a financial interest, except for grant funds,'" Angell said.

Some academic universities have guidelines, but they vary widely, Johnson said.

Some medical journals, such as JAMA, have rules that they won't publish privately funded research performed by company employees unless there is independent data analysis.

But Johnson says these rules should go further and apply to research conducted by academic medical centers as well.

She said academic researchers are just starting to emerge from a "priesthood" view that they are not affected by conflicts of interest.

With the influx of vast amounts of corporate research dollars, "those days of a monastery view are waning," she said.

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