

## Don't ask, don't tell: Financial disclosure lacking in literature on stents

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Most published research about coronary stents does not reveal information about authors' financial relationships that might bias their interpretation of scientific data, according to researchers at Duke University Medical Center.

Coronary stents are the basis of a multi-billion dollar industry, yet the scientific community remains divided over if, when and how they should be used.

Dr. Kevin Weinfurt, a member of the Duke Clinical Research Institute, tracked every article written about stents in biomedical literature in 2006. He found 746 articles written by 2985 authors in 135 journals. Eighty-three percent of those articles did not contain any disclosure statements at all.

Weinfurt says he was astonished by the extent of the problem.

"We actually did our own, informal Internet search on authors who expressly stated they had no interests to disclose and found that some of them held membership on stent manufacturers' advisory boards, or were consultants for stent makers and companies that made drugs related to stent use. One person had even founded a company that made stents, and yet had not disclosed that information," says Weinfurt.

The study appears in the online journal *PLoS ONE*.



Weinfurt says the study results are troubling because disclosure and transparency in research reports may be more important than ever. While two respected professional organizations representing medical editors' interests – the International Committee of Medical Journal Editors and the World Association of Medical Editors – encourage disclosure of authors' financial interests, Weinfurt notes that some journals don't ask for the information and some authors don't volunteer it.

When potential conflicts aren't reported, policy makers and the public lose their trust in medical research, says Weinfurt. This may be especially critical for those seeking trustworthy information about potentially life-saving devices, like coronary stents.

Stents are flexible metal tubes inserted into coronary arteries that help maintain healthy blood flow, often used in the wake of a heart attack. There are basically two types of stents: bare metal stents and drugeluting stents, and the medical and scientific communities have been debating for years over which may be superior.

Weinfurt says that researchers' statements about the efficacy and propriety of stents are closely evaluated because they directly affect not just stent makers, but also products that support stents and companies that produce alternatives to stents.

But he adds that they found little consistency in how author disclosures are made. "We feel this is symptomatic of a systemic problem that leaves patients and health care professionals with big gaps in knowledge and the inability to properly interpret important information," says Weinfurt.

Researchers found that a total of 168 authors had a disclosure statement in at least one article. Five companies were cited as the most frequent



source of support: Johnson & Johnson, Boston Scientific, Medtronic, Sanofi-Aventis and Bristol-Myers Squibb, with support most often given in the form of research support (25 percent), speaker fees (17 percent) and consulting (15 percent).

The study did contain one upbeat note, however. The researchers found that there was generally greater author disclosure in the more highly respected journals and in those that endorsed the International Committee of Medical Journal Editors' guidelines for manuscripts submitted to medical journals.

Dr. Robert Califf, director of the Duke Translational Medicine Institute, vice chancellor for clinical research at Duke and senior author of the study, says the findings point to the need for an Internet-based national repository of information – something analogous to the Web's clinicaltrials.gov for trials registration.

"We can't really tell if the problem resides with the authors or the journals, but it's likely a systems problem. A common repository of industry interactions could be a standardized source of conflict of interest information for all purposes," he says.

Source: Duke University Medical Center

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