The Problem Of Regulatory Oversight And ICD Implantation

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Slightly over a year ago, the Department of Justice (DOJ) launched an investigation of a large number of institutions regarding concerns that implantable cardiac defibrillator (ICD) procedures were performed for reasons outside of the criteria set forth in Medicare's National Coverage Decision (NCD). This investigation occurred just after Al-Khatib and others published a report January 4, 2011 in *JAMA* [1]that suggested as many as 22.5 percent of implantable defibrillators implanted for primary prevention of sudden death were not evidence-based.

While the physician community took issue [2] with the Al-Khatib paper, the media firestorm it generated paired with the announcement [3] to the Heart Rhythm Society physician community that a federal investigation was underway, had a chilling effect on ICD implantation nationwide. Drs. Jonathan S.Steinberg and Suneet Mittal report on their experience with DOJ investigators under this heavy regulatory oversight [4] in the *Journal of the American College of Cardiology*.

Steinberg and Mittal's diplomatic account carefully describes the challenges of retrospective audits performed by lawyers from the Department of Justice and those of their targeted health care facilities. The DOJ identified 229 cases as potentially inappropriate cases based on Medicare code criteria. (This represented 8.7 percent of the de novo non-resynchronization ICD implants done for primary prevention at their institutions). After determining that some of these targeted cases were actually for secondary prevention or other coding transgressions, the authors could medically justify all but thirty-four (15 percent) (or a very low 1.5 percent of all ICD's implanted for primary prevention of sudden death) at their institution. As has been the case in most reports, the majority of outside NCD-directed ICD implants occurred because of timing violations—too close to the diagnosis of heart failure, heart attack and coronary intervention. These timing constraints constitute the primary issue before implanting doctors: their professional society guidelines do not–in all cases–recognize similar timing restrictions.

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Links:
[1] http://jama.ama-assn.org/content/305/1/43.short
[2] http://www.theheart.org/article/1214761.do

[3] http://drwes.blogspot.com/2011/01/doj-investigating-defibrillator.html
[4] http://content.onlinejacc.org/cgi/content/abstract/59/14/1270?etoc
[5] http://www.kevinmd.com/blog/2012/04/problem-regulatory-oversight-icd-implantation.html