HHS Public Access

Author manuscript

JAMA Cardiol. Author manuscript; available in PMC 2017 July 26.

Published in final edited form as:

JAMA Cardiol. 2017 July 01; 2(7): 711–712. doi:10.1001/jamacardio.2017.1674.

Coverage of Magnetic Resonance Imaging for Patients With Cardiac Devices:

Improving the Coverage With Evidence Development Program

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Magnetic resonance imaging (MRI) is an essential imaging modality, particularly for diseases of the central nervous system such as acute strokes, cord compression, or intracranial malignancies.[1] Historically, MRI has been contraindicated for patients with cardiac implantable electrical devices, eg, pacemakers and implantable cardioverter defibrillators, largely owing to safety concerns such as sudden device failure. More recent data now support the safety of performing MRIs in nearly all such patients under proper supervision.[2] Yet few hospitals have clinical programs to provide this service in part owing to rules affecting Medicare reimbursement because payment in this case is only provided through the "coverage with evidence development" program. This program was intended to provide patients with early access to investigational technologies or novel use of established therapeutics. The MRI experience shows the ways in which these coverage decisions can be implemented in a problematic way.

National Coverage for MRIs

In clinical practice, patients who have cardiac implantable electrical devices are much less likely to get MRIs, even for emergent cases.[3] That is because most of the device scurrently in clinical use do not have US Food and Drug Administration (FDA) approval for MRIs (some newer cardiac devices have been designed as "MRI-conditional" for use in an MRI environment). A growing literature has suggested that MRIs can nonetheless be performed safely in such patients if certain device programming and monitoring precautions are taken.[4] For example, the MagnaSafe registry included 1500 cases performed at experienced centers

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Conflict of Interest Disclosures: No other disclosures were reported.

Additional Contributions: We thank Peter J. Neumann, ScD, Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, for his thoughtful review of an earlier draft of the manuscript. No compensation was provided for this review.

with no acute adverse events (no deaths, generator/lead failures, losses of capture, or ventricular arrhythmias),[2] consistent with other contemporary single-center experiences.

One critical barrier to wider use has been the Centers for Medicare and Medicaid Services (CMS) determination that MRIs in patients with implanted cardiac devices do not meet the evidentiary bar for “reasonable and necessary” services. While Medicare automatically covers many categories of care delivery, CMS has the authority to identify specific procedures or services that will be subject to special review, following which, a national coverage decision is issued. This process is generally invoked for services that raise concerns regarding safety, quality, or cost or may be specially requested by industry, health care professionals, or other groups relating to a new technology. Approximately 10 to 15 services are subject to special review annually. In practice, most are ultimately granted coverage.

A small number of national coverage decisions are issuedas “coverage with evidence development” memoranda, which provide reimbursement with the important restriction that the clinical service must be paired with evidence collection according to a strict prespecified protocol that is intended to address knowledge gaps relating to the product.[5] The CMS website lists 22 procedures or services approved under the coverage with evidence development designation.[6] In addition to MRIs, these range from stem cell transplants and off-label medication use for specific malignancies to permanent device implants such as left atrial appendage occlusion systems and transcatheter aortic and mitral valve devices. Private insurers often adopt coverage models that closely mirror CMS decisions, therefore imposing similar restrictions on products or services.

In a national coverage decision in 2011, CMS concluded that “there is not adequate evidence to conclude that MRI use improves patient health outcomes for Medicare beneficiaries with” pacemakers or implantable cardioverter-defibrillators.[7] As the memo states, “CMS believes that the evidence is promising although not yet convincing that MRI will improve patient health outcomes if certain safeguards are in place to ensure that the exposure of the device to an MRI environment adversely affects neither the interpretation of the MRI result nor the proper functioning of the implanted device itself.” This memo was later updated to allow for coverage of devices approved by the FDA for MRI compatibility, which are relatively new in the United States and are relevant to only a fraction of the millions of patients living with pacemakers and implantable defibrillators.[4] Thus, MRIs for pacemaker and defibrillator systems that are not FDA approved as MRI compatible are covered only in the context of the few ongoing single-center CMS-approved prospective studies.[7]

But when has sufficient evidence been gathered? To date, the success of the MagnaSafe study has not translated into changes in device labeling (despite FDA involvement in its design) or CMS reimbursement for off-label MRIs. In fact, no criteria for what would be considered “convincing” are provided by CMS for this or any national coverage decision. While there are characteristics outlined for approved studies, these only describe in broad terms acceptable features of study design, without delineating exactly how end points should be defined.[5] Even if investigators reasonably infer what a useful end point would be, eg, the proportion of MRIs that are interpretable despite potential artifact from the cardiac device,

there is no guidance on what clinical effect size would be considered “convincing.” Although registered on clinicaltrials.gov, the approved protocols at the various individual institutions running coverage with evidence development studies are not transparent, making it hard to standardize end points and pool data.

Policy Recommendations for the Coverage With Evidence Development Model

There are several ways in which the coverage with evidence development process could be better implemented to meet the program’s goals. First, details of the protocols for all approved studies should be publicly available so that they can be replicated at additional study sites that can demonstrate the technical expertise, human participant protections, and other study infrastructure requirements. Ensuring consistent data collection instruments and end point definitions would move the evidence development process beyond disparate single-center experiences to more easily aggregated outcomes across institutions, increasing statistical power and the likelihood of detecting rare adverse events. To earn CMS coverage approval, study sites should commit to pooling data for analysis and presentation and put a process in place for timely posting of study results in alignment with other clinical trial reporting standards.

The CMS should also provide more clarity on what level of evidence will meet the “reasonable and necessary” standard for each service subject to coverage with evidence development. Few coverage with evidence development studies have led to changes in CMS coverage. Improving the rigor of CMS-mandated studies may enhance the ability of this approval pathway to generate meaningful data. This will naturally be specific to the service under review. The CMS may need to convene expert advisory panels to address issues with individual national coverage decisions, such as end point development and study design. These meetings can also help answer the question of what would be convincing enough data to meet the reasonable and necessary standard. With regard to the safety of MRIs for patients with cardiac implantable electrical devices, is the goal to define a specific risk of a serious complication with enough precision to guide patients and health care professionals through an informed decision? Or is there a specific adverse event rate that should be considered acceptable for use of MRIs in these clinical contexts? Failure to articulate the goals of coverage with evidence development likely delays the data-gathering process. The Magna-Safe data now strongly suggest that most MRIs can be done safely under strict protocols, and based on this and other supporting data CMS should be encouraged to reconsider its coverage accordingly.

The legislative mandate to identify “reasonable and necessary” care allows Medicare to avoid paying for unproven or unhelpful technology, preserving resources for interventions or services actually demonstrated to improve patient outcomes. The coverage with evidence development option is a useful model to provide patient access to a potentially essential but unproven service, but as the MRI case illustrates, invoking this pathway should be accompanied by a clear, hypothesis-driven exposition of what evidence is sought to resolve specific uncertainties. Doing so would support investigators motivated to address evidence

gaps and provide guideposts for patients and providers. At the same time, strengthening the scientific rigor of the coverage with evidence development process would reaffirm Medicare's role in diligently allocating national resources.

Acknowledgments

Both authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Kramer is supported by a Paul B. Beeson Career Development Award in Aging Research (K23AG045963) and the Greenwall Faculty Scholars Program and is a consultant to Circulatory Systems Advisory Panel of the US Food and Drug Administration and the Baim Clinical Research Institute for clinical trials related to medical devices (unrelated to this article). Dr Kesselheim's work is supported by the Laura and John Arnold Foundation, with additional support from the Harvard Program in Therapeutic Science.

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