AJNR

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*AJNR Am J Neuroradiol* 2016, 37 (11) 2001-2002
doi: https://doi.org/10.3174/ajnr.A4932
http://www.ajnr.org/content/37/11/2001

# Regarding Off-Label Scanning of MR Conditional Devices

The article by Franceschi et al[1] highlights a safety issue of increasing concern for radiologists regarding the safe scanning of patients with implants, particularly active implantable medical devices such as deep brain stimulators (DBSs) or vagal nerve stimulators.

Implants are tested for suitability for MR imaging by the vendors, who may contract out the specific tests to independent experts. The results of the tests are then used by the vendors when they apply for device approval from the FDA. In addition, results from various modeling calculations may be presented. If the FDA is convinced by the results, they approve labeling of the device on the basis of the tests. I have often heard that this labeling is "guidance" from the FDA. However, the FDA does not provide guidance; it only approves "labeling." This distinction is important. The FDA only approves labeling for actual conditions in tests (experimental and/or modeling) that have been presented to them.

DBS systems and their labeling are an excellent example of this process. The danger is that heating or induced currents in the electrodes could cause brain injury to the patient. As noted by Franceschi et al, DBS systems from Medtronic are labeled "MR Conditional," with restrictive limits on the radiofrequency (rf) specific absorption rate (SAR) of 0.1 W/kg (head). This condition is so limiting that it often is not practical to image patients under this restriction and still produce images (especially T2-weighted) of sufficient quality. Thus, we have sites such as that of Franceschi et al attempting to optimize their protocols to provide an SAR as low as possible while still producing an image of acceptable diagnostic quality. Franceschi et al have found, as have other groups (eg, references 4-7 of the article), that these patients can be scanned without harm by using somewhat higher limits.

One might ask why vendors do not test under more realistic conditions. This is a good question and is illustrative of the somewhat opaque labeling-approval process. The vendor's concern in these cases may be for the FDA to approve the MR Conditional labeling. From the resulting labeling, we in the community do not know whether the vendor conducted the testing under the gentlest of conditions possible because the vendor prefers not to reveal to the FDA tests that would possibly endanger the labeling approval. In other words, there is motivation to have the device labeled MR Conditional, even if the test conditions may not result in diagnostic-quality images. Once the labeling is approved, it is up to the sites to decide whether they will follow the labeling. Scanning by using parameters that exceed the labeling limits is considered off-label use.

The situation is similar to that of pharmaceutical drugs. Drugs have FDA-approved labeling indicating suitability for treating specific conditions/illnesses. Intrepid clinicians may intuit that the drug may be useful for treating other conditions and may prescribe the drug off-label and accept the possible liability. They may then publish articles or otherwise communicate to colleagues that this drug seems to be effective for other uses. Eventually, a literature trail may develop, and a consensus is built that the drug is indeed a suitable treatment for this off-label condition. The drug company may even think the drug useful for this other indication, but it only conducted tests for the initial indications to gain FDA approval to market the drug. After all, clinical drug trials are expensive. However, once it becomes a somewhat established practice to prescribe the drug off-label, the drug company benefits from the sales for the new indication without having had to go through the process of additional FDA approval and labeling. After several studies have appeared in the literature, the drug company may then apply for new labeling approval from the FDA, submitting the published studies as evidence of safety and efficacy, without having to fund (expensive) studies.

A similar situation applies to implants. What are the incentives for a company to do more testing when the clinical community will do it for them? If clinical researchers are willing to accept the risks of developing off-label conditions, publishing their results, and building a case for safe scanning under conditions exceeding the label, a vendor's incentive to test for anything but the absolute mildest conditions diminishes.

This state of affairs impedes patient care. A risk-averse site may refuse to scan patients having these devices because they think they cannot produce sufficient-quality images without subjecting the patient to potentially unsafe scanning conditions, even

though there may be a clear need for the examination (eg, see reference 7 in Franceschi et al). However, there is no "guidance" for whether the limits were truly established or whether the vendor simply performed the minimum necessary to achieve the desired MR Conditional labeling.

What is the solution? First, I applaud the effort of Franceschi et al and others who are willing to undertake systematic optimization of parameters. However, perhaps the imaging community should urge more responsibility from the device vendors and the FDA. In fairness, as noted in Franceschi et al, the DBS vendor Medtronic has made recent advances in improving their DBS devices to be more robust in withstanding radiofrequency from a body coil, enabling full-body scanning. They have also revised the labeling for these new versions of the DBS to present the rf limits in terms of B1 + root mean square (rms) values; this revision is becoming popular because it is not model-dependent, while SAR is. The new DBS labeling of B1+rms of $\leq 2$ $\mu$T allows a higher power rf than the previous 0.1 W/kg SAR limit, thus improving image quality. I applaud this advance.

Even without additional testing, the labels could still provide more information. For example, in the case of the DBS devices, instead of simply saying that "an applied SAR up to 0.1 W/kg (0.05 W/lb) may be used," the labeling could say: "Tests using a sequence with an SAR of 0.1 W/kg resulted in a temperature rise of xxx degrees Celsius in a water-polyacrylate phantom of 2 L [or whatever the test conditions/models actually were]. Higher SAR conditions have not been tested." (To be fair, there are devices for which the labeling does provide this information.) This communication alone would give additional information for those making decisions about scanning ("guidance"!). In my opinion, MR Conditional labeling should not be approved unless the testing reflects conditions that would reliably produce diagnostic-quality images. (Note that I am not saying they have to be textbook-quality images.) Approval of labeling for unrealistically mild scanning conditions leads to uncertainty. However, the FDA and the vendors have no reason to change their practices without pressure from the clinical community, and I hope this commentary stimulates further discussion on this topic.

## REFERENCE

1. Franceschi AM, Wiggins GC, Mogilner AY, et al. **Optimized, minimal specific absorption rate MRI for high-resolution imaging in patients with implanted deep brain stimulation electrodes.** *AJNR Am J Neuroradiol* 2016 Jul 14. [Epub ahead of print] CrossRef Medline

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http://dx.doi.org/10.3174/ajnr.A4932