

## Research Letter

## Heart Rhythm Society's survey assessing cardiac implantable electronic devices and magnetic resonance imaging

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As the number of patients with cardiac implantable electronic devices (CIEDs) continues to grow because of expanding indications and longer lifespans, access to magnetic resonance imaging (MRI) for this population has become a significant issue. The 2017 Heart Rhythm Society (HRS) expert consensus statement outlined protocols for scanning both MRI-conditional and non-MRI-conditional CIED systems.<sup>1</sup> In the United States, the Centers for Medicare & Medicaid Services expanded coverage to include non-MRI-conditional systems ("off-label MRI") under specific conditions.<sup>2</sup> However, real-world access to MRI for CIED patients, particularly those with non-MRI-conditional devices, remains unclear. To inform advocacy efforts, HRS convened a Task Force to examine this issue. Concurrently, the HRS Health Policy and Regulatory Affairs Committee conducted a survey to assess current electrophysiology (EP) clinicians' experiences. In May 2024, the survey was distributed to HRS members and attendees of the HRS Scientific Sessions, with responses collected digitally at HRS-online.<sup>3</sup>

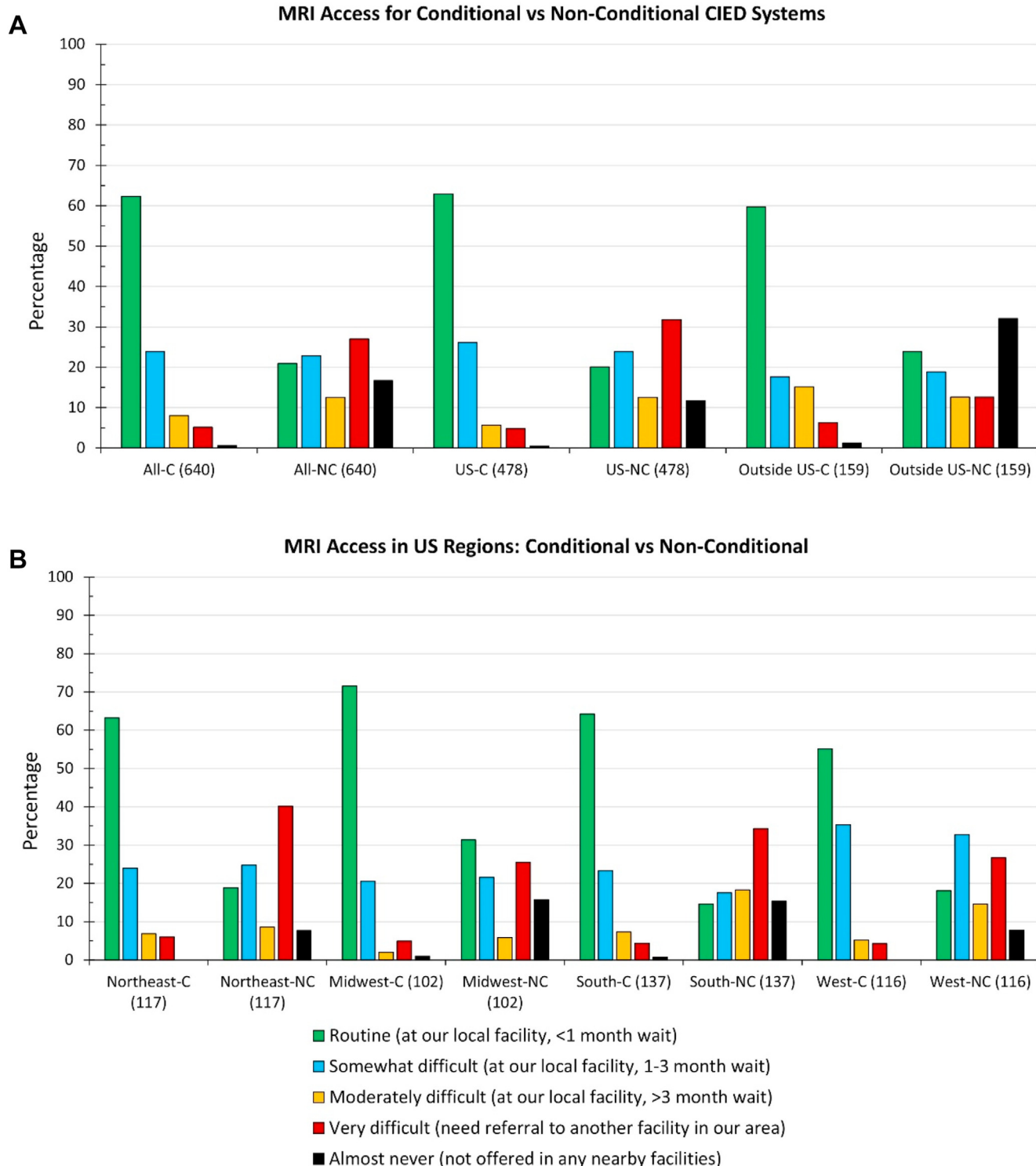
Of 640 survey respondents managing CIED patients, 478 (75%) were based in the United States (55% physicians, 37% allied professionals) and 159 (25%) were from outside the United States (78% physicians, 16% allied professionals).

### Access for MRI-conditional and non-MRI-conditional CIEDs

For patients with MRI-conditional systems, 62% of respondents reported "routine" MRI access (at-home facility, <1 month wait), whereas 24% experienced a wait of 1–3 months and 14% reported >3-month wait or had to refer patients elsewhere (<1% indicated MRI was not available at any nearby facility). Responses were similar for US and international respondents (Figure 1). In contrast, for non-MRI-conditional systems, MRI access was "routine" for only 21% of respondents, whereas 23% reported a 1- to 3-month wait and a 56% majority faced delays of >3 months or had to refer patients elsewhere (17% indicated that MRI was not available at any nearby facility, with international respondents more likely to report this; Figure 1A).

Overall, 70% of respondents were "somewhat" or "generally" comfortable gauging MRI risk for non-conditional CIEDs. When asked about specific scenarios, most respondents approved MRI for mixed-vendor systems with MRI-conditional components or combinations of conditional and non-conditional components, especially in non-pacing-dependent patients. The combination of an MRI-conditional CIED with another MRI-conditional cardiac device was

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**Figure 1**

Responses regarding magnetic resonance imaging (MRI) access. Total respondents for each group are in parentheses. CIED = cardiac implantable electronic device; C = conditional; NC = non-conditional.

approved by 94%. There was more caution for abandoned or epicardial leads (only 42% would “sometimes” or “always” approve these cases).

Only 51% have a formal protocol at their local institution for scanning non-MRI-conditional CIEDs, and 74% have had difficulty obtaining an off-label MRI that was low risk. Overall,

38% were dissatisfied with existing facility protocols for CIED MRI (including for conditional systems), 45% thought their local MRI facility’s accommodations for CIED patients are inadequate, and 49% expressed that clinical care is “often” or “very often” adversely affected for non-MRI-conditional CIED patients because of delays in MRI.

### Challenges in MRI coordination

For coordination, 69% of EP clinicians are asked about MRI suitability at least once per week, which 79% find disruptive to their job workflow. Moreover, 70% of respondents thought their device team's work for the typical non-conditional CIED patient to undergo MRI is either "somewhat" or "very" excessive, as seen in the 50% of respondents who estimate >30 minutes (27% estimate >60 minutes) dedicated by their device team to this type of MRI. Respondents believe payment for EP services to support MRI in CIED patients is "inadequate" (38%) or "very inadequate" (48%).

### Advocacy for improved MRI access

When asked about additional efforts to improve MRI access for CIED (especially non-conditional) patients, 90% thought that regulatory agencies such as the US Food and Drug Administration and the Centers for Medicare & Medicaid Services need to "moderately" or "significantly" increase their efforts, whereas a similar 83% responded so for CIED manufacturers and 92% for MRI facilities. In fact, 72% of respondents believed that a CIED manufacturer with MRI-conditional labeling for a mix of its generator and other manufacturers' leads would gain a moderate or significant competitive advantage, and 95% of all respondents strongly believed updating MRI-conditional labeling to mixed-brand systems is a medium- or high-priority task for industry and regulatory agencies (to be accomplished in <5 years). Many individual comments clamored for additional guidance and member sharing of safety protocols.

### Conclusion

Although limited in scope, these survey results highlight the challenges experienced by EP clinicians and underscore the need for dialogue with the CIED industry, regulatory

agencies, and radiologic societies and facilities as we advocate for expanded and efficient MRI access for patients with CIEDs (especially non-MRI-conditional systems) while maintaining safety. A Task Force formed by HRS leadership and the Health Policy and Regulatory Affairs Committee is developing strategies to engage stakeholders in addressing these concerns. Acknowledging the challenges that radiology teams and facilities face, HRS remains committed to collaborating with all parties to improve patient care by promoting research, education, and optimal health care policies and standards.<sup>4</sup>

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