ORIGINAL RESEARCH

How Well Do Results From Randomized Clinical Trials and/or Recommendations for Implantable Cardioverter-Defibrillator Programming Diffuse Into Clinical Practice?

Translation Assessed in a National Cohort of Patients With Implantable Cardioverter-Defibrillators (ALTITUDE)

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***Background*—**Inappropriate implantable cardioverter-defibrillator programming can be detrimental. Whether trials/recommendations informing best implantable cardioverter-defibrillator programming (high-rate cutoff and/or extended duration of detection) influence practice is unknown.

***Methods and Results*—**We measured reaction to publication of MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy; 2012) and the Consensus Statement (2015) providing generic programming parameters, in a national cohort of implantable cardioverter-defibrillator recipients, using the ALTITUDE database (Boston Scientific). Yearly changes in programmed parameters to either trial-specified or class 1 recommended parameters (≥185 beats per minute or delay ≥6 seconds) were assessed in parallel. From 2008 to 2017, 232 982 patients (aged 67±13 years; 28% women) were analyzed. Prevalence of MADIT-RIT–specific settings before publication was <1%, increasing to 13.6% in the year following. Thereafter, this increased by <6% over 5 years. Among preexisting implants (91 171), most patients (58 739 [64.4%]) underwent at least 1 in-person device reprogramming after trial publication, but <2% were reprogrammed to MADIT-RIT settings. Notably, prevalence of programming to ≥185 beats per minute or delay ≥6 seconds was increased by MADIT-RIT (57.4% in 2013 versus 40.2% at baseline), but the following publication of recommendations had minor incremental effect (73.2% in 2016 versus 70.8% in 2015). High-rate cutoff programming was favored almost 2-fold compared with extended duration throughout the test period. Practice changes demonstrated large interhospital and interstate variations.

***Conclusions*—**Trial publication had an immediate effect during 1 year postpublication, but absolute penetration was low, and amplified little with time. Consensus recommendations had a negligible effect. However, generic programming was exercised more widely, and increased after trial publication, but not following recommendations. **(*J Am Heart Assoc*. 2019;8:e007392. DOI: 10.1161/JAHA.117.007392.)**

Key Words: guideline adherence • guidelines • implantable cardioverter-defibrillator • programming • remote monitoring

Cardiac implantable electronic devices (CIEDs; including implantable cardioverter-defibrillators [ICDs] and cardiac resynchronization therapy devices [CRT-Ds]) form an important therapy in patients with heart failure. Current practice points emphasize quality-of-care measures (ie, appropriate candidate selection and minimization of procedural risks).[1] However, management downstream to implant has received less attention. This is important because devices introduce potential risks (eg, unnecessary ICD therapies) that may erode the survival benefit afforded by the implant. The MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy) was the first large-scale randomized clinical study to show that device programming affects patient morbidity and mortality.[2] The importance of these results, in conjunction with subsequent randomized trials showing similar findings, motivated publication of the 2015 Heart Rhythm Society/European Heart Rhythm Association/Asia Pacific Heart Rhythm Society/Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLAECE) Expert Consensus Statement on optimal ICD programming and

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Clinical Perspective

What Is New?

- Among patients with heart failure, there are scant data for optimizing implantable device function, compared with guideline-directed medical therapy, although both affect patient outcome.
- This nationwide analysis of patients with cardiac implantable electronic devices connected by remote monitoring revealed that a landmark publication for optimizing implantable cardioverter-defibrillator programming had little impact on prevailing practice over a time scale of several years (in contrast, the prevalence of generic programming measures to avoid shocks was higher).
- This deficit was most pronounced among patients with preexisting implants, and the publication of the Consensus Statement did not affect practice appreciably.

What Are the Clinical Implications?

- Remote monitoring databases generated by connected devices may be leveraged to inform of device-specific programming and required changes, without need for in-clinic routine examination, which may be reserved for those patients requiring optimization.

testing, assigning a class 1A recommendation to optimization of programming, using generic programming sets.[3–5] However, the speed and extent to which these publications affect real-world practice is relatively unknown and little investigated. (In comparison, pharmacological therapy among patients with heart failure has been well examined and indicates a gap between evidence and practice, which may persist for years.[6–8]) Testing this presents challenges because national registries (eg, National Cardiovascular Data Registry and National Implant Sample) do not register device parameters and do not collect follow-up data.[9,10]

Remote monitoring of patients with networked implantable cardiac devices automatically generates continuously updated databases with detailed device-specific data. Potentially, these could be leveraged to reveal shifts in practice.[11] Therefore, we used the ALTITUDE database of Boston Scientific ICD and CRT-Ds followed on the LATITUDE remote monitoring system to measure the influence of 2 separate landmark publications (namely, the MADIT-RIT trial and then consensus recommendations), hypothesizing that diffusion of trial results for ICD programming into the general US population would occur slowly and be incomplete.

Methods

The design and methods of the ALTITUDE research program to prospectively analyze data from implanted ICD and CRT-Ds have been described previously.[12] Briefly, beginning in 2006, the ALTITUDE study has been updated with data from the LATITUDE US remote monitoring system (Boston Scientific, Marlborough, MA) for clinical research purposes. Uploaded LATITUDE data include device parameters, clinical diagnostics, and episodes that can be leveraged to provide important longitudinal information. Participation in the ALTITUDE initiative is elective and governed by a data use agreement allowing for the use of such deidentified data for research purposes in accordance with Health Insurance Portability and Accountability Act regulations (institutional review board approval and informed patient consent are not required). Less than 10% of LATITUDE centers decline to contribute data to ALTITUDE. The data and study protocol for this clinical trial may be made available to other researchers in accordance with Boston Scientific's Data Sharing Policy (http://www.bostonscientific.com/en-US/data-sharing-requests.html).

In the current analysis, we measured reaction to publication of the MADIT-RIT (November 2012[2]) and the Consensus Statement on optimal ICD programming (November 19, 2015[5]). The MADIT-RIT showed that dual-chamber ICD or CRT-Ds programmed to high-rate cutoff (>200 beats per minute [bpm; "arm B"]) or duration delay (initial 60 seconds' monitoring delay at >170–199 bpm, a 12-second delay at 200–249 bpm, and a 2.5-second delay at ≥250 bpm ["arm C"]) plus Rhythm ID detection were associated with fewer first inappropriate therapies (defined as shock or ATP) and reduced mortality compared with standard/conventional programming (2.5-second delay at >170–199 bpm and a 1-second delay at ≥200 bpm [arm A]).[2] The class 1 recommendations in the Consensus Statement (which integrated principles from MADIT-RIT and the following ADVANCE (Avoid Delivering Therapies for Nonsustained Arrhythmias in ICD Patients) III trials and reduced these to a generic programming set) advised optimal programming for slowest tachycardia therapy zone limit ≥185 bpm, tachyarrhythmia detection duration ≥6 seconds, or their combination.

All Boston Scientific ICD and CRT-D patients implanted from 2008 to 2017 (ie, several years before and after publications) in the ALTITUDE database were queried in August 2017 (Figure 1). Programming patterns were assessed yearly. Analysis was conducted at 3 levels, and each of these separately in parallel for responses to MADIT-RIT publication and consensus recommendations. Use of optimized device settings was assessed (1) for prevalence before and after publication in the whole cohort (2) among fresh implants (ie, de novo and replacement devices) contrasted before and after publication (3) among devices implanted before but undergoing reprogramming after publication (ie, to test whether recommended settings were used during reprogramming). Furthermore, we assessed programming practice by age, sex, and hospital size and teaching status. Geographic variations across the United States were derived by binning patients into groups by state of residence.

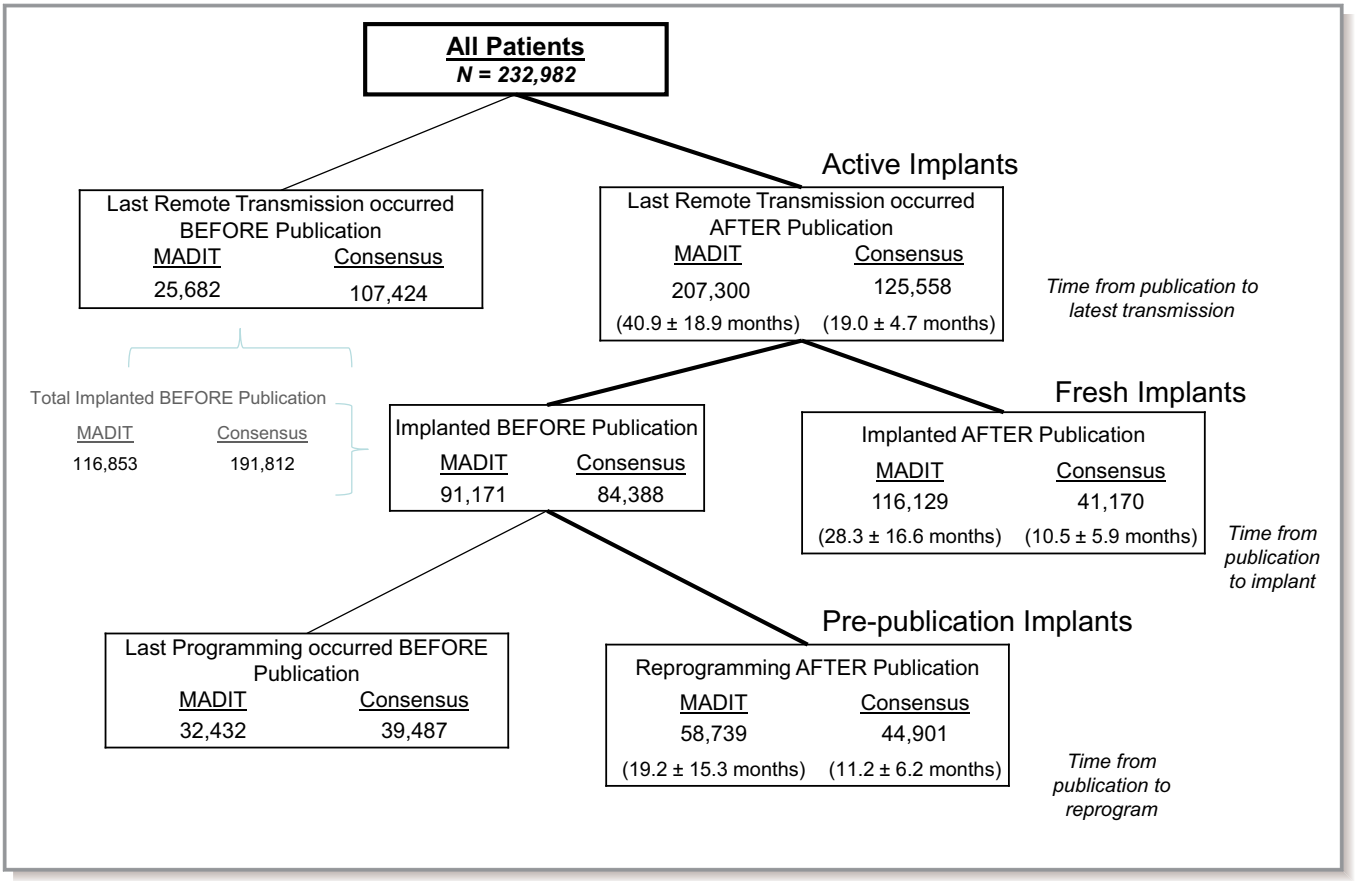


Figure 1. Analysis flowchart for patients on remote monitoring in the ALTITUDE database. Patients maintaining connectivity were grouped as "Active." Groups were analyzed by 2 separate milestones (ie, publication of MADIT-RIT [Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy] and Consensus Statement). Active refers to patients with remote transmission(s) after publication (ie, providing a method for evaluating change in programming).

The study complies with the Declaration of Helsinki, and informed consent was waived under the common rule.

Summary statistics of continuous and categorical variables are presented as mean±SD and number (proportion) of patients, respectively. Odds ratios were calculated from logistic regression models adjusted for age and sex. Statistical significance was defined as $P<0.05$. χ^2 Tests were used to compare proportions.

Results

A total of 232 982 patients receiving devices implanted between 2008 and 2017 were queried in August 2017, 58 months after MADIT-RIT and 21 months after publication of the Consensus Statement (aged 67±13 years; women, 66 290 [28%]; ICDs, 133 538 [57%]; CRT-Ds, 99 444 [43%]) (Figure 1). Half (116 853 [50%]) were implanted before and the other half (116 129 [50%]) were implanted after MADIT-RIT publication. In parallel analysis, most were implanted before (191 812 [82.5%]) and 41 170 (17.5%) were implanted after publication of consensus programming recommendation.

First, we evaluated the overall prevalence in our cohort of programming optimization before and after publications. The prevalence of strict MADIT programmed settings was <1% for either arm B or arm C in implants before publication of MADIT-RIT (Figure 2A) (556/116 853 [0.5%]) (arm B=0.3%; arm C=0.2%). In the following year, implants were more likely to be programmed to trial settings (15 838/116 129 [13.6%]; $P<0.001$ compared with implants before publication), driven by arm B programming (10.6%), whereas arm C programming remained low (3%). The odds ratio of receiving MADIT-RIT arm B or C programming was 33 (95% CI, 30.3–35.9) (47 [95% CI, 41.6–52.3] for arm B and 14 [95% CI, 12.3–15.9] for arm C) after publication compared with implants before publication ($P<0.001$ for all comparisons). (These odds ratios are high, despite low absolute penetration, because prepublication values were extremely low.) However, after this initial change in practice patterns, rates of programming extended negligibly (<6%) during following years, illustrated by rapid plateauing of the curves. Thus, most implants (84%) during our study time period of 5 years after MADIT-RIT publication retained settings with therapy rates <200 bpm without extended delay.

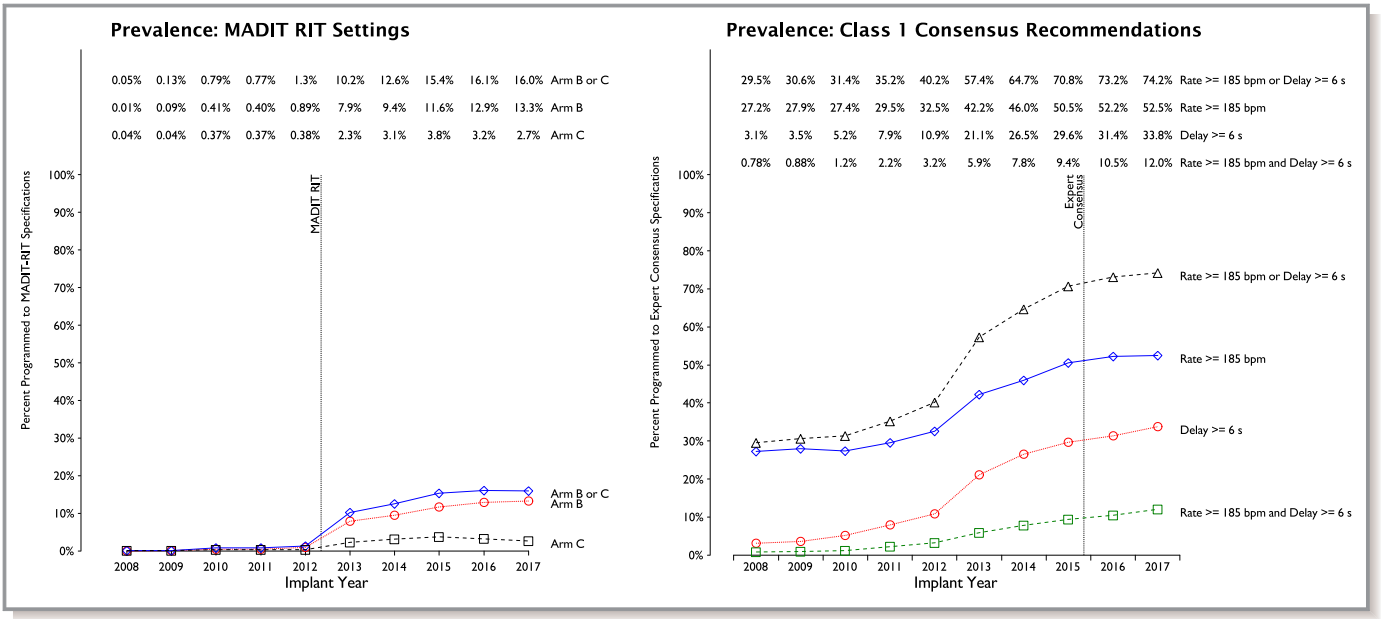


Figure 2. Programming of MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy (Left) and settings according to the Consensus Statement (Right)), among new implants before and after trial publication. All patients in the flowchart evaluated separately by year of implant. Bpm indicates beats per minute.

We then evaluated the prevalence of consensus-recommended programming (Figure 2B). The use of either high rate or extended delay increased slightly from ≈30% to 40% in the 5 years between 2008 and 2012, then stepped up markedly to 57.4% in 2013 (after MADIT-RIT publication). It then increased slowly in subsequent years. Notably, prevalence was 70.8% immediately before consensus publication and 73.2% in the year after. Thus, publication itself had an extremely slight impact on practice, which had evolved in the years prior. High-rate programming was preferred to extended-delay parameters throughout the study period. The prevalence of either of these optimized programming sets was 45% (86 248/191 812) before MADIT-RIT publication versus 73.5% (30 247/41 170) after publication of recommendations (odds ratio, 3.5; 95% CI, 3.5–3.6).

We then examined the details of the changes in the programming parameters, contrasting these between de novo implants (including generator changes) before and after respective publications. When changes occurred, these were dominated by higher-rate programming rather than extended delay (Figure 3).

Finally, we assessed reprogramming practice among devices that had been implanted before publication(s) and followed after, asking the question whether those patients who already had received implants before publication received updated programmed settings (Figure 4). From the overall cohort, 207 300 patients sent at least 1 transmission after MADIT publication on November 6, 2012, and 125 558 had a transmission after November 19, 2015, when consensus recommendations were published. Most were fresh implants (116 129 patients after MADIT publication and 41 170 after consensus programming publication). The remainder constituted devices implanted before publication of MADIT-RIT (91 171) and consensus recommendations (84 338). Of these, 36% (32 432) and 47% (39 487) respectively, underwent no reprogramming changes after publication while continuing follow-up. The remainder (a majority) of patients underwent at least 1 in-person device reprogramming (64.4%, n=58 739 in MADIT-RIT; 53%, n=44 901 in consensus group) during 20 and 11 months of follow up after publication (November 6, 2012, and November 19, 2015). However, only 2.0% (1165/58 739) were programmed to strict MADIT-RIT settings (arm B, 1.1%; and arm C, 0.8%), representing an increase of only 0.7% from a baseline value of 1.3%. The sharp difference in practice between fresh implants after publication compared with prepublication implants being reprogrammed to trial settings after publication is shown in Figure 5 and resulted in an odds ratio of 7.25 (95% CI, 6.82–7.69). Similarly, after publication of consensus recommendations, when existing implants were reprogrammed, recommended programming was instituted in only 8.5% of patients (3816/44 901).

Notably, younger patients were more likely to be programmed according to consensus recommendations, with a linear decrease with age (Table). Women had slightly better odds. Patients following at larger and/or teaching hospitals more often received evidence-based programming. Programming patterns demonstrated moderate geographic heterogeneity across the United States in the proportions of ICD

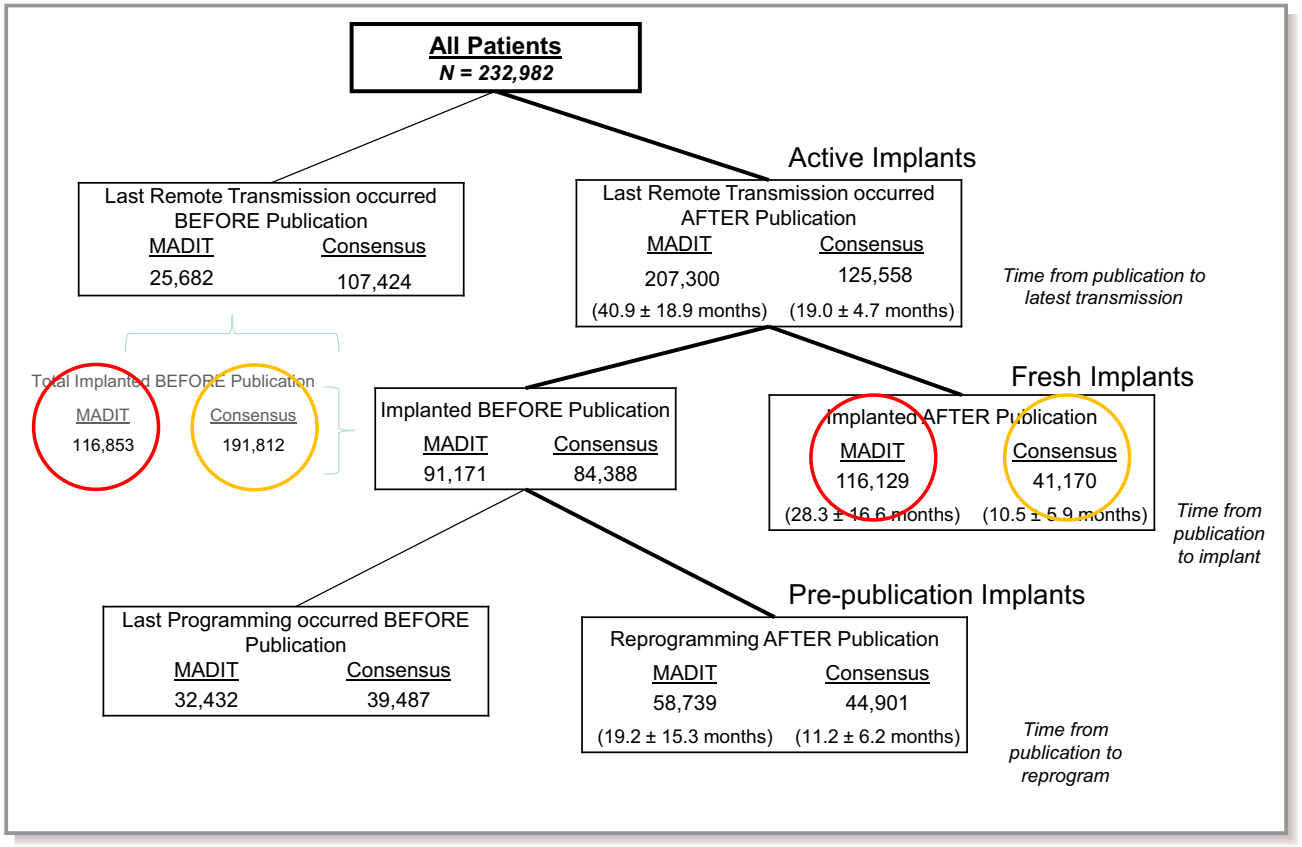


Figure 3A. Groups ringed in red (MADIT RIT: Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy trial) and yellow (Consensus Statement) are compared for programming extended delay vs high rate, before and after respective publications (Figure 3B). Bpm indicates beats per minute.

recipients programmed to MADIT-RIT or consensus-recommended settings (Figure 6).

Discussion

In this investigation of evidence-based shock reduction programming in the United States, we discovered that publication of a major landmark trial had minor immediate impact in practice, and degree of penetration (adjudicated by strict adherence to trial results) amplified little with time. However, programming to generic settings was greater. Later publication of consensus recommendations affected practice relatively little. Connectivity of current era ICEDs may provide a mechanism for surveillance (and rectification) of device programming in large populations.

This is the first study to investigate, in a large "real-world" population of patients with CIEDs, the responses to a landmark trial and subsequent recommendations on optimized ICD programming. Unnecessary ICD therapies, which are reported to account for 30% of delivered shocks, erode the benefits of ICD in populations with heart failure, and their reduction is a management priority. Our results are revealing. MADIT-RIT was the first large randomized trial to test and show device programming strategies that reduced unnecessary ICD therapies and improved patient survival.[2] Expectedly, before MADIT-RIT publication, the prevalence of trial-specified extended duration and/or high-rate cutoff programming (arms B and C) was extremely low. Publication drew an immediate reaction, but absolute effect was slight, and adoption extended little with time, remaining at <20% prevalence 5 years later (Figure 2). Practice was inconsistent among subgroups. The management of those patients with already implanted devices before and after MADIT-RIT/consensus recommendations was especially striking. Almost one-third of patients with available device programming data underwent no reprogramming. Among the remainder undergoing at least some form of device reprogramming, the settings used aligned with trial or consensus recommendations in only a tiny minority (ie, the opportunity presented for device optimization by the in-person encounter was neglected during routine follow-up).

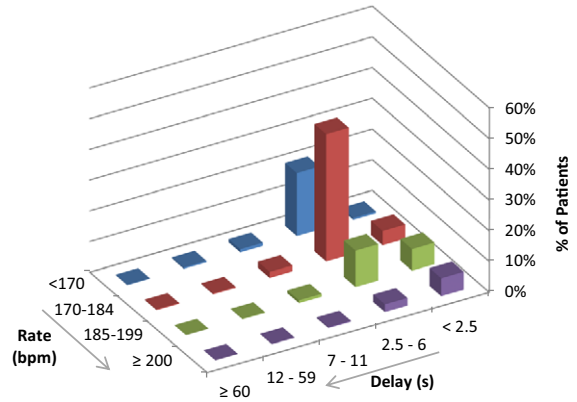
The virtually neutral response to international recommendations is startling (Figure 2B). One earlier study had called for such a Consensus Statement, anticipating that this would increase the practice of evidence-based shock

Programmed Rate and Delay in *de Novo* Implants

Pre- vs Post- MADIT-RIT

N=116,853

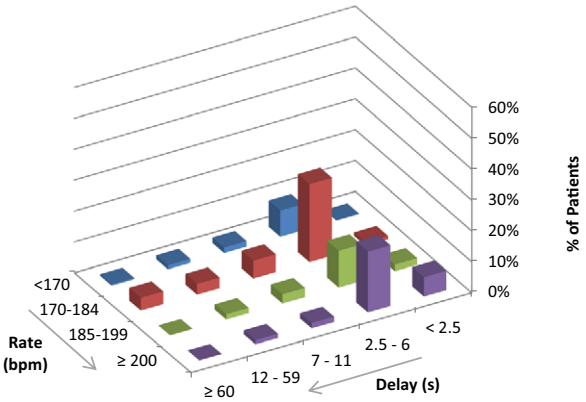
Implanted Prior to MADIT-RIT Publication



	≥ 60	12 - 59	7 - 11	2.5 - 6	< 2.5
<170	0.1%	0.4%	1.0%	20.5%	0.6%
170-184	0.3%	0.3%	2.0%	41.5%	4.6%
185-199	0.0%	0.1%	1.0%	11.8%	7.0%
≥ 200	0.0%	0.1%	0.3%	2.6%	5.9%

N= 116,129

Implanted After MADIT-RIT Publication

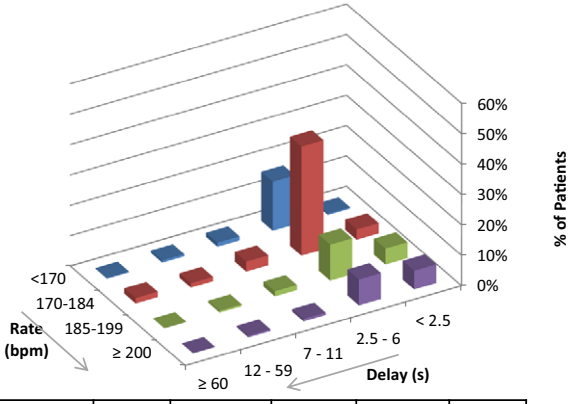


	≥ 60	12 - 59	7 - 11	2.5 - 6	< 2.5
<170	0.4%	1.3%	1.8%	8.5%	0.2%
170-184	4.2%	3.5%	5.7%	25.2%	1.1%
185-199	0.0%	1.7%	3.1%	11.9%	2.1%
≥ 200	0.0%	1.4%	1.7%	19.8%	6.3%

Pre- vs Post- Consensus Recommendation

N=191,812

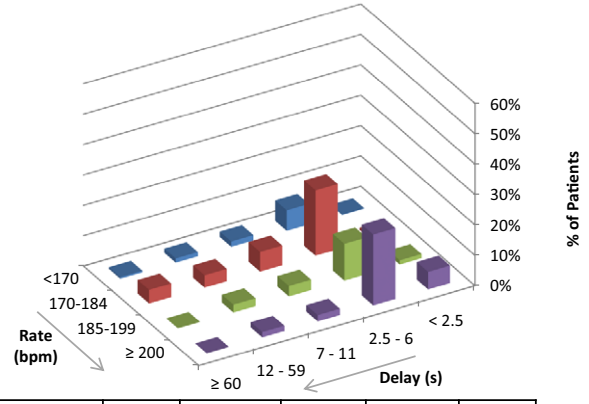
Implanted Prior to Consensus Publication



	≥ 60	12 - 59	7 - 11	2.5 – 6	< 2.5
<170	0.2%	0.7%	1.3%	16.2%	0.4%
170-184	1.8%	1.4%	3.3%	35.9%	3.4%
185-199	0.0%	0.6%	1.7%	11.8%	5.3%
≥ 200	0.0%	0.5%	0.8%	8.5%	6.2%

N= 41,170

Implanted After Consensus Publication



	≥ 60	12 - 59	7 - 11	2.5 - 6	< 2.5
<170	0.5%	1.4%	1.7%	6.8%	0.1%
170-184	4.5%	4.0%	6.5%	21.5%	0.7%
185-199	0.0%	2.5%	3.5%	12.1%	1.4%
≥ 200	0.0%	1.7%	2.1%	23.3%	5.8%

Figure 3B. Continued.

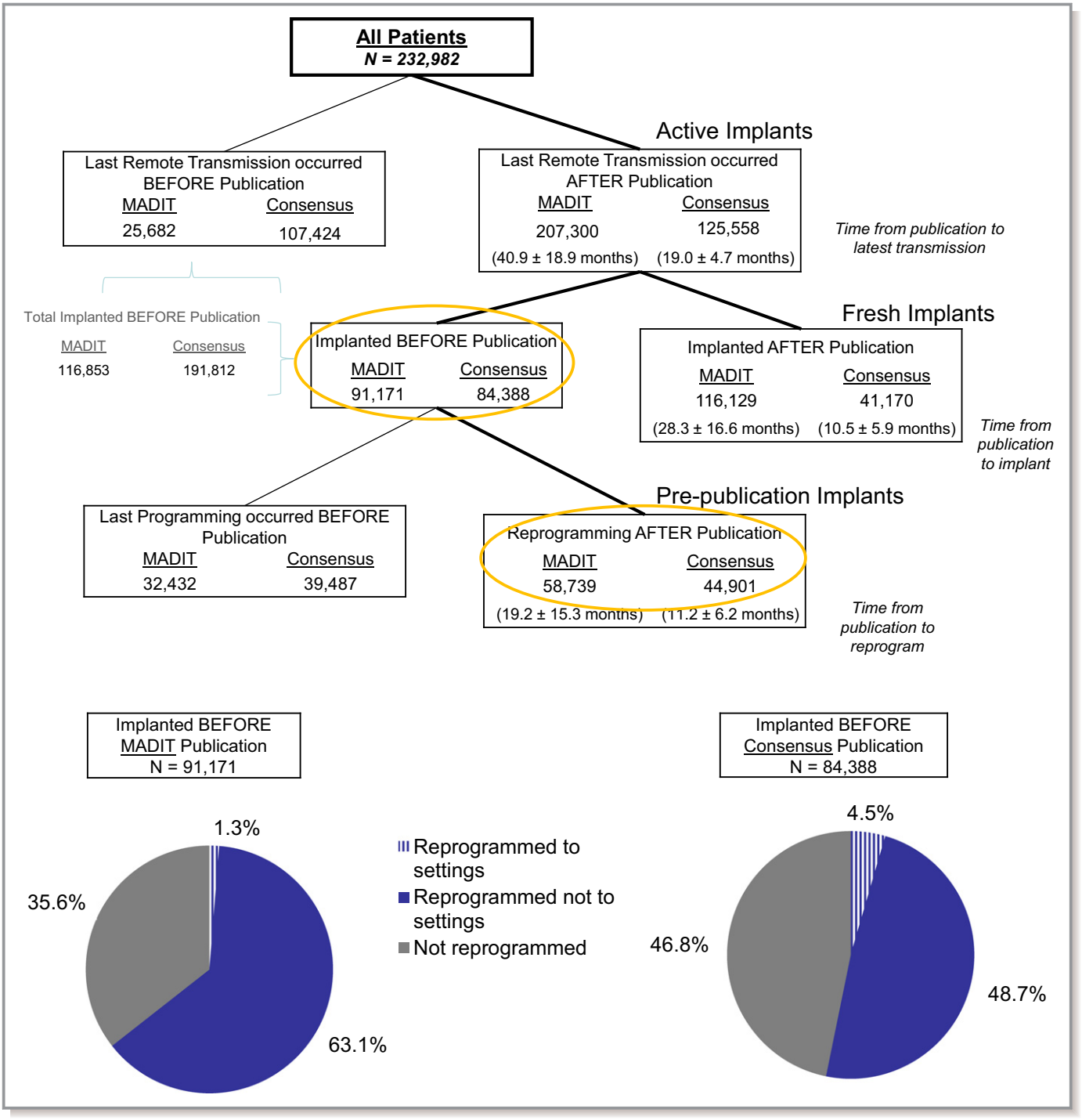


Figure 4. Reprogramming practice among patients implanted before but seen after publication of MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy) or consensus recommendations (contrasted groups are ringed in yellow [top]).

reduction programming, but herein we show that this did not occur.[13] Publication of expert consensus documents is triggered by the availability of strong evidence coupled to a clinical need and marks an important milestone in practice. Evidence-practice gaps between such documents and medical management of patients with cardiovascular disease have been long recognized in sample patients drawn from clinics and even randomized trials.[6–8] We show a similar phenomenon to occur in CIED management at, and downstream to, implant in a large nationwide cohort. Thus, lack of optimized programming, according to the Consensus Statement (if not MADIT-RIT), persisted in almost 30% of patients 1 year after announcement of recommendations.

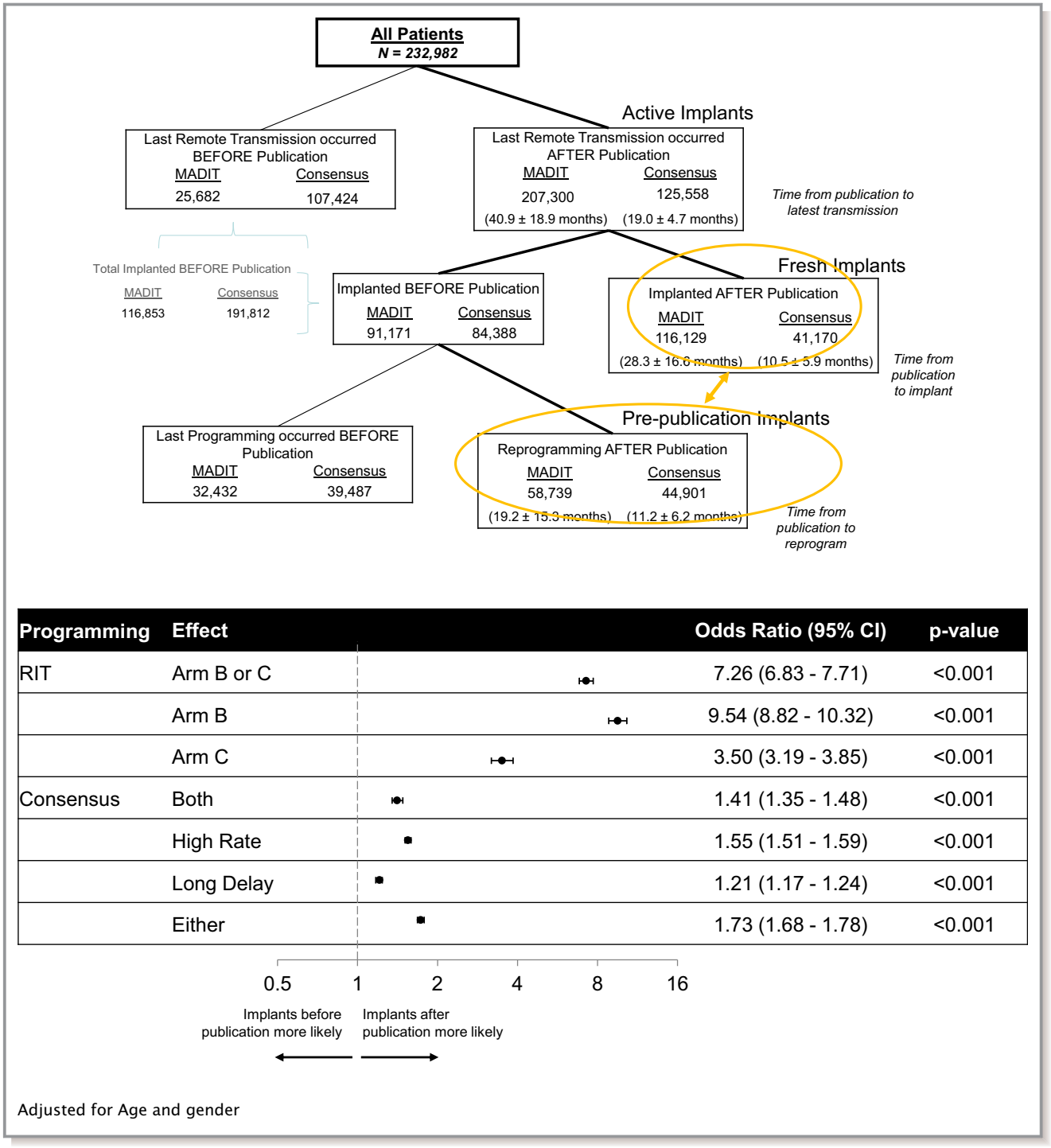


Figure 5. The odds ratios of programming optimization in patients receiving de novo device vs those undergoing device reprogramming. Among all patients who transmitted data after the publication date, fresh implants are more likely to be programmed to MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy) or consensus-recommended settings compared with existing implants (contrasted groups are ringed in yellow [top]). Adjusted for age and sex.

Our results revealed important, and large, practice trends in nationwide practice outside adoption of MADIT-RIT and before the Consensus Statement. There was an ≈40% prevalence of generic programming settings (aligning with and therefore foreshadowing the future Consensus Statement) in the years before MADIT-RIT publication, indicative of an awareness in the community to program outside nominal device settings despite lack of randomized trial data at that

Table. Demographic Influences on Programming Practice

Characteristic	Comparison	MADIT-RIT (Arm B or C)		Consensus (Rate ≥185 bpm or Delay ≥6 s)	
		Odds Ratio (95% CI)*	Type 3 *P* Value	Odds Ratio (95% CI)*	Type 3 *P* Value
Implant period	(2) Between MADIT-RIT publication and consensus recommendation vs (1) before MADIT-RIT publication	29.96 (27.33–32.84)	<0.001	3.83 (3.75–3.91)	<0.001
	(3) After consensus recommendation vs (2) between MADIT-RIT publication and consensus recommendation	1.36 (1.31–1.41)		1.64 (1.60–1.69)	
Age, y	<50 vs ≥80	1.16 (1.08–1.25)	<0.001	4.49 (4.32–4.68)	<0.001
	50–59 vs ≥80	1.36 (1.28–1.45)		2.15 (2.08–2.22)	
	60–69 vs ≥80	1.29 (1.21–1.36)		1.56 (1.52–1.61)	
	70–79 vs ≥80	1.20 (1.14–1.27)		1.24 (1.20–1.27)	
Sex	Female vs male	1.04 (1.01–1.09)	0.026	1.09 (1.07–1.12)	<0.001
Hospital beds	≥500 vs 6–24 beds	10.75 (2.67–43.34)	<0.001	8.49 (5.91–12.20)	<0.001
	400–499 vs 6–24 beds	11.88 (2.95–47.92)		5.75 (4.00–8.27)	
	300–399 vs 6–24 beds	9.48 (2.35–38.22)		6.12 (4.26–8.80)	
	200–299 vs 6–24 beds	7.66 (1.90–30.90)		7.21 (5.02–10.36)	
	100–199 vs 6–24 beds	12.48 (3.09–50.31)		7.91 (5.50–11.36)	
	50–99 vs 6–24 beds	7.57 (1.87–30.61)		7.40 (5.14–10.66)	
	25–49 vs 6–24 beds	15.86 (3.74–67.26)		11.70 (7.79–17.57)	
Teaching hospital	Yes vs no	1.73 (1.62–1.84)	<0.001	1.48 (1.44–1.53)	<0.001

Bpm indicates beats per minute; MADIT-RIT, Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy.
*Odds ratio of programming to specified setting, comparing group 1 with group 2. Odds ratio >1 indicates greater odds of programming to specified setting for group 1.

time. MADIT-RIT exerted an immediate effect on this practice: prevalence increased to >70%, but then increased only slightly in subsequent years. Thus, MADIT-RIT triggered a large change in programming practice but not necessarily to its own results. (Interestingly, even among those programmed according to MADIT-RIT, physicians overwhelmingly chose to program a high-rate cutoff [arm B] rather than an extended detection delay [arm C], although the results in the 2 arms of the trial were similar [Figures 2 and 3].) Thus, implanters exercise a great deal of individual discretion when undertaking reprogramming. The wisdom of such interpretation and extrapolation of trial data have been questioned recently.[14] Transferring settings shown to be beneficial from a trial using one manufacturer's system to another's platform appeared to be harmful. No patient with manufacturer-specific programming validated in a clinical trial failed to receive appropriate therapy. In contrast, most patients who did not receive timely ventricular fibrillation shocks had ICD programming that deviated from these tested parameters, suggesting that differences in sensing and detection methods among manufacturers are important to safety. However, our results show that such extrapolated settings are used widely.

Our nationwide cohort reveals significant heterogeneity in programming practice at multiple levels. There were sex differences, in favor of women and of age (a linear decrease with age for consensus-based programming, Table). Patients following at larger and/or teaching hospitals more often received evidence-based programming. There were large geographic differences, which have been observed also in overall use rates of ICD therapies and postimplant monitoring practice[10,15–17] (Figure 6).

Solutions to improve penetration of optimized programming in community practice are required. Change of nominal settings by the manufacturer may be beneficial, but will only cater to fresh implants. This will not address programming adjustments that may become necessary during the life of the device (which may now exceed 10 years), as new data emerge and understanding of programming optimization deepens. Thus, in our study, 36% of patients implanted before publication simply underwent no reprogramming changes in response to publication. More telling are the results from the larger group of patients (n=50 426 or 59%) who did undergo at least 1 in-person device reprogramming after trial publication: trial-specified settings were used at a negligible rate even when reprogramming was being undertaken for other reasons during in-clinic evaluation. These results suggest that strategic reprogramming to prevent future shocks is not considered a priority in those who may have not received

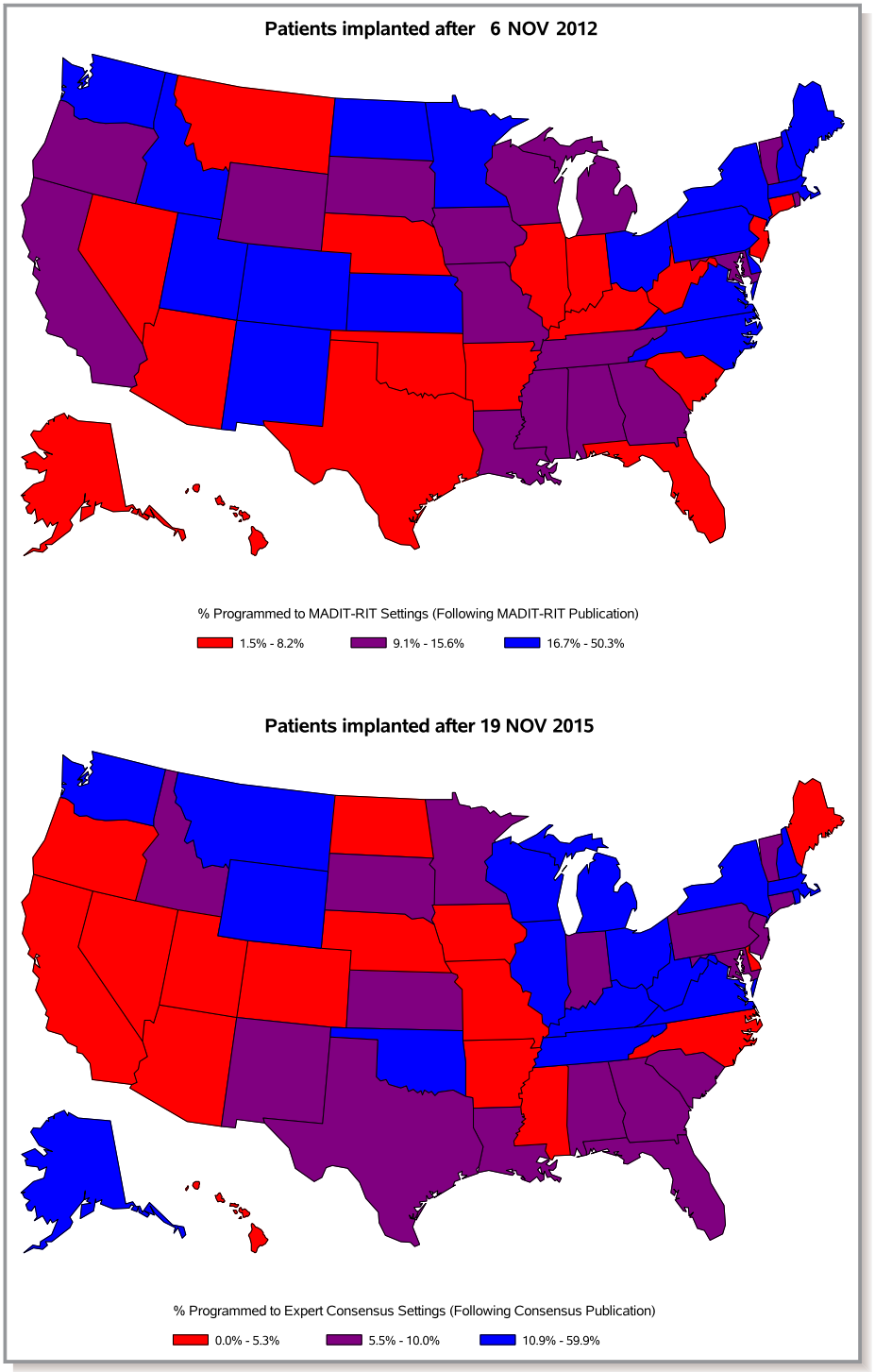


Figure 6. Geographical (interstate) variations in programming practice throughout the United States. MADIT-RIT indicates Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy.

ventricular therapies. The consequences of such inaction are potentially serious, as shown in a recent analysis of a separate remote monitoring database linked to administrative claims[18]: therapies (appropriate and/or inappropriate) triggered a cascade of expensive, and potentially harmful, investigations and interventions.[18]

Remote monitoring may provide a quality improvement mechanism. Practice gaps can be identified, as shown in this study. These patients may be contacted and reprogrammed for adjustment of device settings according to evolving guideline settings. This demands active review by the follow-up clinic and then feedback to physicians. One prior study of a

much smaller and selected patient cohort (without using remote monitoring) noted that a prevalence of programming for delayed detection for ventricular fibrillation was only 19%.[13] Implementing a feedback mechanism, by delivering center-specific therapy programming reports detailing adherence to specified targets, and accompanying training, resulted in a 20% improvement. This included the patient group who had received implant before trial or consensus publications but were followed up after (ie, the group that appeared to be most vulnerable in our study). The adoption of optimized programming settings resulted in a 25% reduction in risk of all-cause shocks. Hence, surveillance of prevailing practice followed by feedback with an accompanying implementation scheme yields positive effects. Remote monitoring facilitates this process; it is a less onerous method compared with reliance on in-person clinic evaluations and interrogated data. Moreover, it can reach a large number, if not all, patients relatively easily and effectively, and reduces patient attrition to follow-up.[19,20] Data such as center performance in comparison to others in the same geographic region, then to overall data, and then to the best performing centers are readily available. Periodic review, coupled to feedback to center, may be effective in improving adherence to strategic programming. (A previous randomized trial testing remote monitoring-based feedback generally [not specifically to programming adherence] demonstrated a large reduction in inappropriate therapies and related hospitalizations.[21]) Such a system may facilitate identification and redress of demographic and geographical health iniquities, as revealed in the large interstate variation in programming practice[18,22] (Table, Figure 6). Moreover, programming recommendations can be updated as required. For example, although we studied dual-chamber pacemaker-defibrillators only (because MADIT-RIT excluded single-chamber [VVI] ICDs), recent data indicate that programming a long detection is associated with a lower risk of therapies, shocks, hospitalization, and death among patients implanted with VVI units also and practice guidelines may be extended to this set of CIEDs.[4] The results of the current debate on merits of extrapolating manufacturer-specific programming sets to generic recommendations may lead to the need for future adjustments. Progress can be tracked and updated by remote monitoring mechanisms. This aligns with recommendation of remote monitoring as a standard follow-up mechanism and the shift in incentives from the quantity of services to include a quality metric ("value-based reimbursement") by the Department of Health and Human Services.[23–25]

Strengths and Limitations

This study illustrates the ability of remote monitoring to comprehensively track device programming, automatically, in large populations for important CIED-related data that are not recorded in national registries.[9,10,26] Our large nationwide cohort is likely representative of US practice because it mirrored the mix of device types and sex and age distribution observed in other national registries.[9] However, it is restricted to a single manufacturer's remote monitoring database. Because we studied only patients using remote monitoring, there is a possible selection bias. However, this patient group has been associated with best hospital practice, motivated patients, and greater patient survival.[12,17,27] Hence, our results are even more striking. Remote Monitoring database analysis is particularly suited to the current study because this reflects nationwide community practice. Our study population included patients receiving devices for both secondary as well as primary prevention, although MADIT-RIT tested settings for primary prevention devices. However, prophylactic devices constitute most (70%) of contemporary US implants[9] and long detection intervals are equally applicable for secondary prevention.[28] Hence, the absence of implant indications in this remote monitoring database does not affect the conclusions of the current analysis. The reasons for in-clinic reprogramming decisions and specifically why most did not align with trial specified or even with broader consensus style parameters cannot be discerned from this study. We did not adjudicate shocks or atrial fibrillation, nor assess patient outcomes, because the link between these and the tested programming parameter sets were established in prior randomized controlled trials.[2–5]

Conclusion

Capitalizing on the full therapeutic potential of ICDs and CRT-Ds demands not only appropriate patient selection for implant but also attention to downstream CIED management, including optimized programming adjusted according to changing needs. However, our real-world assessment indicated that significant inertia exists in translation of results of trials testing best programming practice, and subsequent recommendations, into clinical practice. Automatic remote monitoring may provide the means to both track and resolve this challenge and apply future updates, in the evolving management of CIEDs.

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