Patients with implantable cardioverter-defibrillators (ICDs) are burdened with frequent visits to their doctors. Current guidelines suggest that patients should be seen every three to six months to have their devices interrogated and to make adjustments. The majority of these visits do not result in programming or device changes. Given the growth in the number of patients receiving ICDs, the burden on clinics to meet these interrogation guidelines is increasing. The Lemos-T Safely RedUceS RouTine Office Device Follow-up (TRUST) trial, published in this issue of Circulation, reports the results of an intervention that could improve the quality of care for patients with ICDs by decreasing the number of ICD follow-up visits while simultaneously providing closer monitoring of the ICD. The Institute of Medicine has stated that quality health care is care that is safe, effective, patient-centered, timely, equitable, and efficient; the TRUST trial should be both praised and criticized based on these quality domains.

The TRUST trial was a large, multi-center, randomized trial of 1339 patients designed to test a new home monitoring (HM) system against routine medical care for the ongoing surveillance of ICDs. The HM system evaluates a patient’s ICD daily through a remote monitoring device that allows clinicians to intervene earlier if and when abnormalities are detected. As such, patients would then only have to have their ICDs interrogated in person once a year. The authors specified two a priori primary end points for their HM trial, one for efficacy and one for safety. The efficacy end point was to show that HM decreased the number of office-based ICD follow-up visits; the safety end point (appropriately powered to test noninferiority) was to show that the HM system did not increase death, stroke, or surgical interventions when compared to routine care. This trial was designed with an excellent use of real-world inclusion criteria: recipients of single and dual chamber ICDs with HM implanted for class I/II indications. The authors clearly achieved their stated goals, demonstrating a significant reduction in hospital encounters from 3.8 visits per patient/yr in the control group to 2.1 visits per patient/yr in the intervention group, with no increase in death, stroke, or surgical interventions in patients treated with HM. However, the decrease in scheduled hospital encounters was partially offset by a significant increase in unscheduled encounters from 0.5 per patient/yr to 0.78 per patient/yr, mostly due to visits following event notifications from the HM device. Results of the TRUST trial have already led to approval of the HM system by the Food and Drug Administration.

This high-quality trial is difficult to criticize based on its aims. Of the Institute of Medicine domains of quality, the authors clearly demonstrate that HM is effective (or at least efficacious) in decreasing visits, safe in that it does not increase mortality, and timely in its ability to detect problems more quickly. Also, reductions in visits to the clinic will likely result in a finding of improved efficiency, although a formal cost-effectiveness analysis that considers the cost of the HM system as well as the costs of the increase in unscheduled visits should be performed. While the TRUST trial should be praised for what it accomplished, it should also be criticized for what it did not consider. The quality of the TRUST trial fell short in its patient-centeredness. Indeed, it appears that the trial was designed with the belief that multiple follow-up visits are a burden that primarily falls on the providers.

A good basis for interpreting the TRUST trial is to draw comparisons with the prostate-specific antigen (PSA) controversy. There was never a debate that the PSA test detects prostate cancer earlier, and the test was widely adopted by the medical community without any evidence of improved outcomes. Finally, after two decades of use, two large, randomized trials studying the effects of PSA screening were published. Only one of the two trials actually demonstrated a benefit, showing a reduction in death from prostate cancer of seven per 10 000 men screened over nine years. This benefit was coupled with an additional 340 diagnoses of prostate cancer, 177 prostatectomies, and 97 radiation therapies. The second trial did not demonstrate any benefit of PSA testing at all. Rather than being a story of saving lives, the story of PSA testing has been one of false positives, frequent biopsies, indolent cancer, patient anxiety, impotence, and incontinence.

Considering the lessons learned from PSA, the TRUST trial leaves some important questions unanswered. Namely, what are the benefits and harms of detecting “actionable events,” and what do patients think of HM?

Is Detecting “Actionable Events” Beneficial? In the TRUST trial, the authors also conclude that HM “allows more rapid detection of actionable events,” defined as
any event that prompted either an initiation/up-titration of an antiarrhythmic and ICD reprogramming/system revision. In the Discussion section, they assert that this is “potentially life-saving.” Unfortunately, their trial was not designed to test this, nor does their data support this assertion. Similar to PSA testing, we are left wondering if earlier diagnosis is actually a good thing at all. Also, did all electrophysiologists follow the same evidence-based protocol for medication titrations and programming revisions? A trial with a longer follow-up period designed to assess if intervening on actionable events actually improves clinical outcomes would be more valuable then the present study.

Is Detecting “Actionable Events” Harmful?

All therapies in medicine should be evaluated with the question: are the benefits worth the burdens and harms? In the absence of outcome data showing that early intervention on “actionable events” is beneficial, the question must then be asked: is detecting actionable events harmful? What if detecting an actionable event earlier leads to potentially harmful antiarrhythmic therapy in much the same way that a positive PSA can lead to unnecessary and potentially harmful interventions? For example, suppose a patient has several episodes of asymptomatic, self-terminating ventricular tachycardia prompting a phone call from their electrophysiology clinic stating, “Your heart is acting funny, please come into clinic as soon as possible,” or “One of the leads in your defibrillator appears broken, please call back quickly.” One can imagine a patient rushing anxiously to the clinic while thinking that they are moments from death. To indulge this argument even further, suppose this anxiety sparks a catecholamine induced, proarhythmic state leading to an ICD discharge?9 Here, this otherwise potentially inconsequential rhythm that would have previously been noticed at a routine follow-up has now caused harm. Again, this is analogous to a man with a positive PSA being told he has prostate cancer, and men who are told they have prostate cancer often develop depression, anxiety, and a reduction in quality of life.10

Further, could reducing contact with the patients lead to consequences unrelated to the ICD, such as an increase in heart failure exacerbations? In some clinics, patients will see their heart failure physician on the same day that they have their device interrogated. Would fewer interrogations lead to less monitoring of their heart failure and/or decreased adherence with medical therapy? Alternatively, while the authors report a reduction in hospital encounters for ICD follow-up, there may not be a reduction in encounters from the patient’s perspective, as they may still be seeing their cardiologist every three months. The only difference to these patients is that their ICDs are interrogated once a year rather than every visit.

What Do Patients Think of HM?

When therapies involve trade-offs, patients’ perspectives are of paramount importance. A notable omission from this report is how many patients approached to be in the trial ultimately did not consent to enrollment. Why was the average enrollment per site only 15 patients over the 30 months of recruitment? Perhaps a large portion of patients declined enrollment because they preferred the reassurance of coming into the clinic to see their provider. Perhaps some patients distrusted technology or disliked the Orwellian thought of being continuously monitored in their homes. Unfortunately, the authors of the TRUST trial did not report what patients thought of HM. Presumably, most patients with ICDs will prefer HM (this author would), and the decrease in office visits will be seen as a blessing. But this should be studied, not assumed.

Given a lack of benefits and a host of potential harms, current PSA guidelines suggest that the decision to embark on PSA testing should be a shared decision between a patient and a provider.11 To achieve high-quality, patient-centered care, the decision to have HM should also be shared with the patients. In this shared discussion, patients should not be told that HM will save their lives through early detection. Rather, patients should be told that there is a safe way to decrease the number of visits to the office, and they should be warned of a potentially frightening phone call.

The investigators deserve congratulations for their well-conducted study and nicely-written article. The field of cardiology has led the medical world in effectiveness and safety, and the TRUST trial is no exception. The Institute of Medicine would be pleased to see that HM is safe, effective, timely, and likely efficient (pending a formal cost-effectiveness analysis). In this regard, HM deviates sharply from the PSA debacle. To move the care of patients with ICDs, and the entire field of cardiology for that matter, into the next strata of quality, the field must become more patient-centered. Patients’ perspectives, goals, and values should guide all medical trials, guidelines, and decisions.

Acknowledgments

Dr Matlock would like to acknowledge Larry Allen, Michael Ho, Jean Kutner, and Nia Mitchell for their comments on previous versions of this manuscript. However, the opinions expressed in this article are entirely those of Dr Matlock.

Disclosures

None.

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Key Words: Editorials implantable cardioverter-defibrillator patient-centered care
Big Brother Is Watching You: What Do Patients Think About ICD Home Monitoring?
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Circulation. 2010;122:319-321; originally published online July 12, 2010;
doi: 10.1161/CIRCULATIONAHA.110.966515
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2010 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/122/4/319

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