Randomized clinical trials have demonstrated that implantable cardioverter defibrillators (ICDs) reduce all-cause mortality in select primary prevention populations. Reduced left ventricular ejection fraction (LVEF) remains the most widely used criterion for identifying patients at high risk for sudden cardiac death in these trials and for selecting potential candidates for ICDs.

However, ICD therapy has been underutilized although it has been shown to prolong survival in select patients with reduced LVEF. Specifically, implantation rates of ICDs, with or without cardiac resynchronization therapy, in eligible candidates without contraindications or documented reasons for nonreferral are estimated to be only between ≈35% to 51%. Optimal implementation of evidence-based, guideline-recommended ICD therapy into clinical practice may potentially translate into substantial prevention of heart failure deaths.

The purpose of our study was to determine if a simple clinical reminder directed to the providers of potentially eligible patients for ICD via the electronic medical record (EMR) system would increase appropriate referral for ICD implantation.

**Background**—Many patients who are candidates for implantable cardioverter defibrillators (ICDs) are not referred for potential implantation. We sought to determine if a simple provider reminder would increase referrals.

**Methods and Results**—We identified consecutive patients from January 2007 through July 2010 in the VA Palo Alto Health Care System with a left ventricular ejection fraction <35% on echocardiography. Patients were excluded using available administrative data only (no chart review) if they were known to have an ICD, if they were ≥80 years old, or if they did not have a current primary care or cardiology provider within the system. We randomized patients to no intervention or a clinical note to the provider in the medical record. The outcomes were referral for consideration of defibrillator implantation (primary) and documented discussion (secondary). Of 330 patients with left ventricular ejection fraction ≤35%, 128 were known to have an ICD, 85 were no longer followed in the healthcare system, and 28 were ≥80 years old, leaving 89 patients to be randomized. Forty-six patients were randomized to intervention and 43 to control. Eleven of 46 (24%) intervention patients were referred for consideration of ICD implantation during the following 6 months versus 1 of 43 (2%) control patients (P=0.004). Overall, 31 of 46 (67%) intervention patients versus 19 of 43 (44%) control patients had documentation discussing potential candidacy for defibrillators (P=0.05).

**Conclusions**—In patients with low left ventricular ejection fraction, a simple electronic medical record–based intervention directed to their providers improved the rates of referral for ICD implantation.

**Clinical Trial Registration**—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01217827.

(Circ Heart Fail. 2014;7:140-145.)

**Key Words:** death, sudden, cardiac ■ defibrillators ■ guideline adherence ■ randomized controlled trial ■ reminder systems
Methods

Patients
We identified all ECGs obtained from January 2007 through July 2010 at the VA Palo Alto Health Care System (VAPAHCS). We identified consecutive patients with LVEF ≤35%. If a patient had >1 ECG during this period, we used data from the most recent ECG. We excluded patients if they already had a defibrillator (using local records), if they were ≥80 years old, or if they did not have a primary care physician or cardiologist at the VAPAHCS. We elected to use an age cut-off in our trial to limit submission of reminders for patients who were unlikely to be ICD candidates because of competing comorbidities or shortened life expectancy. In addition, this age group is minimally represented in primary prevention trials establishing the benefit of ICDs.1-4

Study Protocol and Intervention
Patients meeting the study criteria were randomized with a computerized random number generator to no intervention (control) or intervention (reminder), which consisted of a clinical reminder stating potential eligibility for an ICD. The reminder (Appendix) was a standardized note that (1) noted the patient’s potential eligibility for ICD, (2) listed specific potential exclusion criteria for ICD therapy, and (3) explicitly listed the method for patient referral for an ICD using the EMR. Options suggested included referral to cardiology clinic, electrophysiology clinic, or directly to the electrophysiology laboratory. The reminder further requested (but did not require that) the physician to addend their intended action by indicating the specific reason for nonreferral or planned referral action from the aforementioned list of options.

The reminder was directly incorporated into each intervention patient’s permanent EMR. In addition, notification that the reminder was inserted into the EMR was sent to the patient’s primary provider or cardiologist (if also followed in a facility cardiology clinic) for their signature indicating that they reviewed the reminder. Such notifications appear each time a provider opens the EMR system to access the care of any patient. Notification for cosignature is removed by either going to the reminder and cosigning the note or deleting the request for cosignature. In all cases, the reminder remained in the patient’s EMR. The institutional review board at Stanford University approved the protocol. The trial was registered with clinicaltrials.gov (NCT01217827).

Baseline data were collected from the records to describe the population, which included previous diagnoses and VA prescriptions (non-VA prescriptions were not available).

Outcome Data
Six months after randomization, a trained adjudicator (P.G.) reviewed all patients’ EMRs to determine if defibrillator implantation was addressed. The primary outcome was referral for consideration of defibrillator implantation <6 months of randomization, defined as an encounter by a cardiac electrophysiologist in which ICD consideration was documented as part of the evaluation. The secondary outcome was documentation of a discussion of ICD candidacy. We could not completely blind the outcome data abstractor to the randomization group of each patient because the reminder note was part of the medical record. For this reason, we confirmed the abstractor’s findings with a second reviewer. At a mean follow-up of 2 years, we determined survival and reviewed the patient’s medical record for cause of death (post hoc analysis). We used the provider’s documented cause of death if death occurred in the hospital. If death occurred elsewhere (another hospital, outpatient, or unclear), we labored it as unknown unless recent clinic notes indicated the patient was in the end stage of their disease (eg, New York Heart Association [NYHA] class IV, metastatic cancer).

Statistical Analysis
All patients randomized to the intervention received the clinical reminder. An intention-to-treat analysis was used for all outcomes. Thus, all patients were included in the analysis even if they did not have a clinic visit with their provider during the 6-month follow-up period. We used \( t \) test to compare continuous variables, \( \chi^2 \) tests (with Yates correction for continuity) to compare categorical variables with cell values >5, and Fisher exact test to compare categorical variables with cell values ≤5. Survival was displayed using Kaplan–Meier graphs, and log-rank statistic was used to compare differences between the 2 randomized groups. The study was designed to have 80% power (α error, 0.05) to detect a 20% absolute increase in defibrillator referral. We planned to randomize ≥90 patients. All analyses were performed with STATA version 10 (Statutory LP, College Station, TX). All significance tests were 2-sided. A \( P \) value <0.05 was considered statistically significant.

Results
We identified 330 patients with LVEF ≤35% over 3.5 years as shown in Figure 1. Patient characteristics and medication use were similar for the 2 randomized groups. Per our initial review, 128 patients already had an ICD, 85 were no longer followed at VAPAHCS, and 28 were ≥80 years old, leaving 89 patients to be randomized. Forty-six patients were randomized to the reminder, and 43 to control (Figure 1).

The mean age of patients was 65±7 years, 97% were men, and mean LVEF was 27±4%. Comanagement with a facility cardiologist was ongoing at the time of randomization in 67% of patients, and 4% of patients were comanaged by both a nonfacility cardiologist and a facility cardiologist (Table 1). All differences at baseline between the reminder and control groups were not statistically significant (\( P > 0.05 \)). A previous discussion regarding ICD was noted in 31 of 89 randomized patients (35%) after additional detailed chart review. The provider electronically acknowledged receipt of the reminder in 44 of 46 cases (96%).

Outcomes
By the end of 6 months of follow-up after randomization, 11 of 46 (24%) reminder patients met the primary outcome (referral for ICD evaluation) compared with 1 of 43 (2%) control patients (\( P = 0.004 \); Figure 2). A cardiac electrophysiologist’s evaluation was completed and an ICD implanted <6 months of randomization in 4 reminder patients compared with no

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Figure 1. Flow of study participants through the trial, including exclusions, is displayed. After randomization, we found evidence of a prior ICD discussion for 10 patients in the intervention and 5 in the control arm. However, all patients were analyzed with an intention-to-treat design.
control patients. The secondary outcome, documentation of an ICD discussion, was met in 31 of 46 (67%) intervention patients versus 19 of 43 (44%) control patients (P=0.05).

Detailed 6-month outcome data are shown in Table 2. Overall, 5 patients died (1 reminder, 4 control) without previous ICD discussion; 3 patients had already been referred for an ICD despite initial screen (2 reminder, 1 control); 24 patients were deemed not suitable for candidacy by the provider (11 reminder, 13 control); 11 patients refused an ICD (7 reminder, 4 control); and an ICD was not addressed in 34 patients (14 reminder, 20 control). Three patients in the reminder group and 5 in the control group did not have documented contact with their provider during the 6-month follow-up period. All differences in secondary outcomes between the reminder and control groups were not statistically significant (P>0.05). In the 24 patients deemed not suitable for candidacy for ICD by the provider, 15 (17% of all 89 patients) were still undergoing medication optimization (8 reminder, 7 control), 5 (6%) had a repeat LVEF >35% (1 reminder, 4 control), and 4 (4%) did not have expected survival with good functional status for ≥1 year (2 reminder, 2 control).

By 2 years after the reminder, 7 of 12 patients referred for ICD had the ICD placed (2 of these outside of the VA system). For those 5 not implanted, the reasons were development of NYHA class IV symptoms, improvement in LVEF >40%, patient refusal, technical difficulties expected with implantation, and unclear in 1.

Long-term survival is shown in Figure 3. During a mean follow-up of 2 years, there were 26 deaths (17 in control group and 9 in reminder group). Patients randomized to the reminder group had a slightly better survival over the next 2 years compared with those not receiving a reminder in their medical record (P=0.03). Cause of death for the control arm was heart failure in 3, cancer in 3, others in 2, and unknown in 9 (2 outside hospitals and 7 at unknown locations, all unexpected based on previous history). For the reminder group, it was heart failure in 2, cancer in 2, others in 2, and unknown in 3 (all 3 at unknown locations and unexpected based on previous history). Two of the deaths occurred among patients with a previous ICD (both inpatient heart failure).

Analysis Limited to Those Without Known Previous ICD Discussion

For 15 patients (17%), the provider reported that there was a discussion regarding ICDs before our sending the reminder (10 reminder, 5 control). With these 15 excluded, 9 of 36 in the reminder group were referred for possible ICD implantation compared with 1 of 38 without a reminder (P=0.006).

Predictors of Referral

Sixty-seven percent of patients in both the reminder and control groups were comanaged by a cardiologist in this trial. Seventeen percent of patients were referred for ICD if comanaged with cardiologist(s) as compared with 7% of patients managed only by a primary care provider (P=0.2). Previous ICD discussion was associated with a nonsignificant trend for more referrals for ICD evaluation (19% if previous discussion versus 10% if no previous discussion; P=0.2). Age, sex, and
baseline ejection fraction were also not associated with referral for an ICD.

**Discussion**

This randomized trial demonstrated that an EMR-based clinical reminder to providers of patients with reduced LVEF improves the rates of referral for consideration of ICD implantation.

Multiple strategies to overcome low utilization of ICDs in eligible candidates have been considered. Recently, the participation in performance improvement registries has shown efficacy in improving adherence with guideline-recommended therapies, including ICD therapy. However, improving dissemination strategies for ICDs remains critical. A broad systematic review conducted by the National Institute for Health Research’s Health Technology Assessment Program in 2004 that analyzed diverse randomized trials involving healthcare guideline dissemination and implementation strategies suggested modest benefit with reminders. Specifically, the authors reported a modest improvement in performance across interventions of 14.1% in 14 cluster randomized comparisons for reminders, 8.1% in 4 cluster randomized comparisons of dissemination of educational materials, 7.0% in 5 cluster randomized comparisons of audit and feedback, and 6% in 13 cluster randomized comparisons of multifaceted interventions involving educational outreach. Our results are consistent with these estimates.

We have previously shown that clinical reminders are effective in improving heart failure care. One trial randomized 1546 consecutive patients with reduced LVEF to a reminder of β-blockers or no reminder. Seventy-four percent of patients randomized to reminder received β-blocker prescription compared with 66% of patients (P=0.002) not receiving the reminder. The reminder was estimated to be highly cost-effective compared with other accepted medical interventions. Per a follow-up survey, the reminder was recalled by 76% of physicians and viewed favorably with a recommendation for continuation by 85%. Our ICD reminder was more intensive in that a notification of the reminder was sent to the provider. This may explain the greater effect of the ICD reminder compared with the more passive reminder placed in the echocardiography report.

Developing an effective reminder system for device-based therapies poses several unique challenges. Defibrillator therapy, as opposed to medication use, has more complex indications, is more invasive, and may be more risky to patients, including procedural risks and inappropriate shocks. Unlike medications, ICD consideration requires most providers to refer the patient to a specialist as opposed to initiating therapy on his/her own. To overcome some of these potential barriers, our reminder included directions for referral and explicit response options, including reasons for nonreferral. Furthermore, it should be noted that our electronic reminder required that the provider either acknowledge that the reminder was received or delete the request for acknowledgment. This active interaction was associated with a 96% provider acknowledgment rate and may be important for reminder effectiveness.

We designed this intervention with the goal of creating a low-cost and simple system that could easily be incorporated into clinical practice and EMR workflow. One strength of our study was that candidates for intervention (namely, patients <80 years of age with LVEF ≥35%, no record of ICD placement, and no follow-up at our facility) could be determined electronically without chart review. This makes it easy to implement the intervention at any facility with an EMR with searchable databases. It is directly applicable to >1100 clinics and hospitals within the VA healthcare system because all use the same EMR. Chart review was not performed to select patients; thus, several patients already had a discussion regarding ICDs. However, we found that the reminder led to a change in opinion regarding ICD placement. This has occurred because the patients’ clinical status may have changed or their views of risk and harm from an ICD may have changed.

Another potential benefit of the reminder is an increase in documentation of a discussion regarding ICD placement. Such documentation is a new performance measure of the American College of Cardiology, American Heart Association, and American Medical Association Physician

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**Table 2. Six-Month Outcomes After Reminder of ICD Candidacy**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Reminder</th>
<th>Control</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>46</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Referred for an ICD, primary outcome, N (%)</td>
<td>11 (24)</td>
<td>1 (2)</td>
<td>0.004</td>
</tr>
<tr>
<td>Evidence of ICD discussion, secondary outcome, N (%)</td>
<td>31 (67)</td>
<td>19 (44)</td>
<td>0.05</td>
</tr>
<tr>
<td>Nonreferral after discussion, N (%)</td>
<td>20 (43)</td>
<td>18 (42)</td>
<td></td>
</tr>
<tr>
<td>Had an ICD, N (%)</td>
<td>2 (4)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Not an ICD candidate, N (%)</td>
<td>11 (24)</td>
<td>13 (30)</td>
<td></td>
</tr>
<tr>
<td>Refused ICD, N (%)</td>
<td>7 (15)</td>
<td>4 (9)</td>
<td></td>
</tr>
<tr>
<td>No evidence of discussion, N (%)</td>
<td>15 (33)</td>
<td>24 (56)</td>
<td></td>
</tr>
<tr>
<td>Died without discussion, N (%)</td>
<td>1 (2)</td>
<td>4 (9)</td>
<td></td>
</tr>
<tr>
<td>Survived without discussion, N (%)</td>
<td>14 (30)</td>
<td>20 (47)</td>
<td></td>
</tr>
</tbody>
</table>

ICD indicates implantable cardioverter defibrillator.

*Percent of total. Referral occurred in 11 of 31 (35%) of those with a discussion in the reminder group compared with 1 of 19 (5%) in the control group (P=0.02).

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**Figure 3. Survival after randomization.** There were 26 deaths (17 in control, 9 in reminder) during long-term follow-up. Survival was slightly better for those randomized to the reminder (P=0.03).
Consortium for Performance Improvement.24 We found that 70% of intervention patients versus 51% of control patients had documentation discussing potential candidacy for defibrillators at 6 months after the reminder. Although this did not reach statistical significance (P=0.09), it is likely that the reminder prompted the provider to write a note based on previous discussions or to have a new discussion with the patient. The reminder provides education regarding who is and is not an ICD candidate, and this could lead to higher levels of documentation of an ICD discussion.

There are several potential limitations in the study. Our analysis involved predominantly male patients, which may limit the generalizability of these findings. This study was not powered for the end point of actual defibrillator implantation, although we think that defibrillator evaluation rather than implantation is a more meaningful end point in the context of patient-centered care. Thus, larger studies in other care settings are needed to confirm the findings. We excluded patients ≥80 years of age, although some of these patients may be appropriate ICD candidates. Because the reminder note was part of the medical record, we could not completely blind the outcome data abstractors to the randomization group. Although there was a small observed survival benefit with the reminder, the difference was borderline-significant, and larger studies are needed to confirm this finding. Finally, the reminder benefit we observed may be an underestimate if significant contamination had occurred where a provider had patients in both control and intervention groups and a reminder for 1 patient influenced his/her care for other patients.

In summary, a simple EMR-based intervention routed to the patient’s provider(s) increased the rate of referral for an ICD. Specifically, in our study, ≥22 additional patients were referred for ICD consideration for every 100 reminders sent. Importantly, patients could be identified electronically, allowing for low-cost implementation of this intervention at any facility with an EMR.

Appendix

ICD Candidacy Review Note

The patient may be a candidate for defibrillator (ICD) therapy because of LVEF ≤35% and no VA records of a previous defibrillator. If you would like to consider your patient for possible ICD, options include:

A. Referral to cardiac electrophysiology clinic (recommended) ["Outpatient Orders"→"Consult"→"Cardiology EP/Arrhythmia Clinic Consult Palo Alto"]
B. Referral to cardiology clinic ["Outpatient Orders"→"Consult"→"Cardiology Outpt Clinic"]
C. Direct referral for defibrillator implantation ["Outpatient Orders"→"Procedure"→"Palo Alto"→"Electrophysiology"]

Not all individuals are appropriate candidates for defibrillator therapy referral.

Potential responses for nonreferral are listed below. You may respond via an addendum to this note with any of these reasons for nonreferral.

1. The patient already has a defibrillator.
2. Other physicians manage the patient’s cardiac disease.
3. More information is needed to determine candidacy for defibrillator (including patient preference).
4. This patient is not an appropriate candidate for defibrillator because:
   A. The patient refused.
   B. The patient does not have a reasonable expectation of survival with good functional status for approximately >1 year.
   C. The patient is NYHA class IV with drug refractory congestive heart failure and is not a candidate for cardiac transplantation or cardiac resynchronization therapy.
   D. The patient has significant psychiatric illness that may be aggravated by device implantation or that may preclude systematic follow-up.
   E. The patient has potential for improvement in his cardiac function, for example, because of active medical therapy optimization or planned intervention/revisionalization procedure.
   F. The patient is asymptomatic (NYHA class I) with nonischemic cardiomyopathy.
   G. The most recent LVEF is >35%.

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