Published in final edited form as:

Am Heart J. 2010 October ; 160(4): 605–618. doi:10.1016/j.ahj.2010.07.011.

Addressing Disparities in Sudden Cardiac Arrest Care and the Under-Utilization of Effective Therapies

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Disclosures

Sana M. Al-Khatib: Receives research funding and speaking fees from Medtronic and Biotronik. She also receives research funding from the National, Heart, Lung and Blood Institute and from the Agency of Healthcare Research and Quality.

Susan Campbell: None.

Mark Carlson: None.

Chris Chiames: None.

Nakela L. Cook: None.

Anne B. Curtis: Receives research funding from Medtronic and St. Jude Medical and consulting, speakers' bureau, and/or fellowship support from Medtronic, St. Jude Medical, Biotronik, Sanofi-Aventis, and Biosense Webster.

Gregg C. Fonarow: Receives research funding from National Heart Lung and Blood Institute; serves as a consultant for Novartis, Medtronic, and St. Jude Medical; and receives honoraria from GlaxoSmithKline, St. Jude Medical, and Medtronic.

David L. Hayes: Serves on an advisory board for St. Jude Medical, Boston Scientific, and Pixel Velocity and receives honoraria for speaking from St. Jude Medical, Boston Scientific, Medtronic, Sorin Medical, Biotronik, Blackwell-Futura.

Adrian F. Hernandez: Receives research support from Johnson & Johnson, Amylin, and Merck & Co; and receives honoraria from Amgen, AstraZeneca, & Medtronic.

Melissa H. Kong: Receives research funding from Biotronik and was supported by a Ruth L. Kirschstein-National Service Research Award (Kirschstein-NRSA) National Institutes of Health (NIH) [grant number 5-T32-DK-007731-15]. The contents of this work are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.

Edward L. Lyons: None.

Eric D. Peterson: Receives research funding from Bristol Myers Squibb, Sanofi Aventis, Merck, Lilly, and Johnson & Johnson.

Andrea M. Russo: Receives research funding from Medtronic, Boston Scientific, and Biotronik and honoraria from Medtronic, Boston Scientific, and St. Jude Medical.

Gillian D. Sanders: Receives research funding from Medtronic.

Samuel F. Sears, Jr.: Receives research funding from Medtronic and St. Jude Medical, honoraria from Medtronic, Boston Scientific, St. Jude Medical, and Biotronik and serves as a consultant to Medtronic.

Kevin L. Thomas: Receives research funding from Medtronic, honoraria from St. Jude Medical and serves on an advisory board for Medtronic and Boston Scientific.

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Abstract

Sudden cardiac arrest (SCA) is the most common cause of death in the United States. Despite its major impact on public health, significant challenges exist at the patient, provider, public, and policy levels with respect to raising more widespread awareness and understanding of SCA risks, identifying patients at risk for SCA, addressing barriers to SCA care, and eliminating disparities in SCA care and outcomes. To address many of these challenges, the Duke Center for the Prevention of Sudden Cardiac Death at the Duke Clinical Research Institute (Durham, NC) held a think tank meeting on December 7, 2009, convening experts on this issue from clinical cardiology, cardiac electrophysiology, health policy and economics, the US Food and Drug Administration, the Centers for Medicare and Medicaid Services, the Agency for Health Care Research and Quality, and device and pharmaceutical manufacturers. The specific goals of the meeting were to examine existing educational tools on SCA for patients, health care providers and the public and explore ways to enhance and disseminate these tools, to propose a framework for improved identification of patients at risk of SCA, and to review the latest data on disparities in SCA care and explore ways to reduce these disparities. This paper summarizes the discussions that occurred at the meeting.

Introduction

Although sudden cardiac arrest (SCA) is the most common cause of death in the United States, SCA and sudden cardiac death (SCD) are often under-recognized as public health threats not just by the public and patients, but also by health care professionals. Given the unpredictability and multiple etiologies of SCA and/or SCD, significant challenges exist at the patient, provider, public, and policy levels with respect to raising more widespread awareness and understanding of SCA risks, identifying patients at risk for SCA/SCD, addressing barriers to SCA care, and eliminating disparities in SCA care and outcomes.

It is now well established that prevention of SCA/SCD involves modification of risk factors for coronary artery disease and heart failure (HF), use of cardiac medications, like beta-blockers,^{1,2} angiotensin converting enzyme inhibitors,^{3,4} aldosterone antagonists,^{5,6} and use of implantable cardioverter defibrillator (ICD) therapy.^{7,8} All of these interventions are important and require widespread awareness and understanding of SCA/SCD and prompt identification of patients at risk. Additionally, it is important to consider both optimal medical interventions as well as device therapy in high risk populations. The American College of Cardiology and American Heart Association (ACC/AHA) 2008 practice guidelines specifically emphasize the importance of achieving optimal medical therapy in a given patient before an ICD is considered.⁹ Yet despite this evidence and guidelines, studies consistently demonstrate that there is under-utilization of both medical therapy and devices in routine clinical practice.^{10–12}

Recognizing the importance of these issues, in December 2007 the Duke Center for the Prevention of SCD convened a Think Tank meeting of experts in many aspects of SCA prevention. Participants concluded that significant barriers to implementation remain with respect to identification of patients at risk as well as acceptance of ICD therapy by patients and physicians. To facilitate dissemination of ICD therapy, the meeting participants highlighted the need to focus on educating patients and health care providers about SCD prevention and ICDs by developing tools that could help health care providers identify patients in their practice at risk of SCA.¹³ Similarly, in April 2008, the National Medical Association organized a meeting of national experts on SCA prevention to start a national dialogue about addressing disparities in care in SCA prevention.¹⁴ They also identified the need for improved physician and patient awareness and education with regards to SCD disparities.

In response to the output of these two meetings, the SCA Thought Leadership Alliance (SCATLA) was formed. The Alliance held its initial face-to-face meeting on December 7, 2009 in Washington, DC, to create actionable SCA awareness, education, and policy initiatives that address disparities by 1) evaluating existing tools and 2) informing and enhancing policies and treatment. This paper summarizes the discussions that occurred at the meeting.

Disparities in SCA

The reported annual incidence of SCD varies from 180,000 to over 450,000 deaths across the general U.S. population.^{15–20} However, several studies have documented age, race, and gender differences in the risk of SCD.^{15,21–24} Additionally, a recent cohort study of over 10,000 patients with cardiac arrests due to ventricular fibrillation or pulseless ventricular tachycardia at 247 hospitals within the National Registry of Cardiopulmonary Resuscitation revealed that black patients with in-hospital SCA were less likely to survive to discharge compared with white patients (unadjusted RR 0.73, 95% CI 0.67 – 0.79).²⁵ When the results were adjusted for the hospital site at which patients received care, the racial differences in successful resuscitation diminished (RR 0.92, 95% CI 0.88 – 0.96). Furthermore, it was found that black patients were more likely to receive treatment at hospitals with worse outcomes, and these disparities in care were present in the acute resuscitation as well as post-resuscitation phase.²⁵ Another prospective, observational study of 4,653 consecutive out-of-hospital cardiac arrests examined 30-day survival after hospital discharge and found that while the incidence of out-of-hospital cardiac arrests was higher among blacks and Hispanics (10.1/10,000 v. 6.5/10,000) compared with whites (5.8/10,000), age-adjusted survival was much lower among blacks and Hispanics than among whites.²⁶

Disparities in SCA Prevention

Treatment gaps and variation in care exist among numerous evidence-based therapies despite overwhelming clinical trial evidence, expert opinion, national guidelines, and a vast array of educational conferences.^{11,12,27–29} These gaps and disparities tend to be larger for newer therapies, particularly when they are more expensive and when a series of steps are required to determine eligibility. Additionally, recommendations for medication and device therapies are continually and rapidly evolving. As these therapies become increasingly complex and often interdisciplinary, collaboration becomes necessary among multiple health care providers, which can also be challenging.

Studies have also documented disparities in SCA care and underutilization of ICDs in vulnerable populations, including blacks and women.^{30–32} After the publication of numerous RCTs demonstrating survival benefit with ICDs in patients with documented ventricular arrhythmias or left ventricular dysfunction, these differences in utilization have widened as the indications for device therapy have expanded.³³ These inequalities may further contribute to worse cardiovascular outcomes for these vulnerable populations.^{34–36}

A recent analysis of data from 7,830 patients enrolled in the National Registry to Advance Heart Health (ADVANCENT) revealed that 41% of all eligible white patients had an ICD compared with only 30% of all eligible black patients ($p < 0.001$).³⁵ Similarly, an observational analysis of 13,034 patients enrolled in the AHA's Get With the Guidelines-Heart Failure (GWTG-HF) quality-improvement program who were admitted with HF and left ventricular ejection fraction $\leq 30\%$ and discharged alive found that only 35.4% of eligible patients received or had plans to receive an ICD.³⁰ Patients who received an ICD were 40% less likely to be female and 30% less likely to be black, independent of other patient characteristics and hospital factors.³⁰ Even more recently, using the data from the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE-HF) to determine patient and practice characteristics associated with ICD implantation among cardiology practices, it was shown that both eligible women and blacks were less likely to receive ICD therapy.³⁷

Another study examined sex differences in ICD use for primary and secondary prevention of SCD using the U.S. Centers for Medicare & Medicaid Services (CMS) claims database from 1999 to 2005 to identify eligible patients and whether they received ICD therapy.³⁶ This study found that compared with women, men were 3 times more likely to receive an ICD for primary prevention and 2.5 times more likely to receive an ICD for secondary prevention of SCD.³⁶ However, sex and race/ethnic disparities exist not only in terms of ICD utilization, but also in terms of resuscitation and survival after cardiac arrest.

Reasons for Treatment Gaps and Variation in Care

Sex and race/ethnicity-based disparities exist in the delivery of evidence-based SCA care.³⁰ ³⁶ Analysis of the Acute Decompensated Heart Failure National Registry (ADHERE) revealed significant variability among participating hospitals in terms of conformity to quality-of-care indicators and clinical outcomes with substantial gaps in overall performance.²⁸ Other studies have also shown that nationally produced treatment guidelines are often adopted slowly and inconsistently in clinical practice.^{38–40} Many of the barriers to the implementation of evidence-based, guideline-recommended care are structural, attitudinal, and/or educational and improving practice requires that all of these barriers be addressed.⁴⁰ Additional possible reasons for this underuse include concerns over safety fueled by device/lead recalls, limited device longevity, durability of benefit, periprocedural complications, negative effects of shocks on quality of life; skepticism about the applicability of RCTs to general clinical practice; provider knowledge gaps, lack of clinical decision support systems and performance measures; and cost.¹³

In the outpatient setting, there is significant practice variation in cardiac care and the use of evidence-based, guideline-recommended therapies.⁴¹ Differences in training, guidelines familiarity, documentation of indications and contraindications to therapy, documentation of the actual care provided, and the implementation of tools and systems that facilitate the provision of recommended care may contribute to the wide variation in care metrics across outpatient cardiology practices.⁴¹ This wide variation in practice may also contribute to disparities if women, minorities, and older patients are more commonly treated in settings with larger gaps.⁴²

Addressing Disparities in SCA Care

Although it is clear that disparities in SCA care exist in the U.S., the driving forces underlying these disparities remain incompletely elucidated, but are likely due to a number of contributing factors at the patient, provider, public, and policy levels (Table 1). In light of the large treatment gaps between the guidelines and clinical practice that exist for HF and other patients at risk for SCA as well as a large number of patients who are having hospitalizations and fatal events that

could have been prevented, processes are clearly needed to translate knowledge and evidence-based guidelines into improved performance and ultimately better patient outcomes. Each step in the cyclic process from concept, to evidence generation, to guidelines and performance measures development, to practice performance, and ultimately patient outcomes, presents opportunities to address disparities in SCA care through continual feedback, education, and benchmarking that ultimately improves our ability to deliver effective, equitable, and efficient patient-centered care (Figure 1, adapted from Califf *et al.*'s Cycle of Quality.⁴³) The implementation of evidence-based guidelines in clinical practice may be further facilitated by clinical decision support tools, systems and information technology, and electronic medical records (EMR).

Minimizing Barriers to SCA Care

To better address barriers to SCA care, steps must be taken at the patient, physician, public, and policy levels as shown in the proposed framework (Table 2). At the patient level, culturally-relevant educational programs to increase patients' knowledge of how to access care and participate in medical decision-making should be implemented. Navigator and support programs that assist patients in accessing care, understanding options, clarifying their health goals, obtaining financial resource information, and following through with treatment plans should be made readily available. The goal for patient-centric education and support is to increase decision-making satisfaction and increase "patient acceptance" of preventative therapies to yield optimal health outcomes from longevity to quality of life.⁴⁴

Culturally relevant education and empowerment of patients is essential for eliminating disparities. An example of a patient-enabling tool is Celgene's Patient Support Coordinator Program. This program serves as a dedicated, central point of contact staffed by trained professionals who provide personal assistance to patients concerning reimbursement, insurance claims and appeals, Medicare issues, co-pay assistance programs and services, information about pharmacies, prescriptions and Celgene's patient assistance program. More research evaluating such programs and other interventions that improve patient and physician relationships is necessary to advance the field and provide evidenced-based tools that will decrease disparities.

One such study underway is the Educational Videos to Improve Patient Decision Making and Racial Disparities in Implantation of ICD therapy Via Innovative Designs (VIVID-01). To explore patient-level factors and decision-making, the VIVID investigators will examine whether an educational video increases patient knowledge about HF, the risk for SCA, and therapies to prevent SCA. This study will also evaluate patient satisfaction with this method of education and whether or not racial concordance between the patient and the health care provider further improves patient satisfaction with treatment decisions and disease knowledge (ClinicalTrials.gov identifier: NCT00918125). Additional analyses of IMPROVE-HF may help to determine if implementation of a cardiology practice-based performance improvement program for HF care helps to narrow or eliminate sex and race based disparities in the use of evidence-based HF treatments, which are effective for SCA prevention/treatment.

At the physician level, providing incentives to practices that reduce barriers, promote adherence to evidence-based guidelines, and demonstrate improvements in the delivery of care to vulnerable populations has a great potential to reduce disparities in SCA care. Additionally, the use of community health workers and the implementation of multidisciplinary treatment and preventative care teams will enable physicians to provide culturally and linguistically appropriate resources to communities.

At the public level, community programs targeting underserved populations should harness efforts to improve public awareness and education. Finally, at the policy level, a systematic

approach to education, awareness, and prevention should be developed. Policymakers should advocate for quality/performance measures supporting the use of evidence-based guidelines as well as funding for future research and evidence generation focused on evaluating interventions that improve patient and physician communication. Disparities ultimately represent deficiencies in the quality of health care delivery and the existence of such disparities highlights the need for multidisciplinary disease-management systems that simultaneously address the barriers to equitable care. Reforms that address health care disparities should promote the consistency and equity of health care delivery by supporting the use of evidence-based guidelines and quality improvement initiatives. Additionally, quality improvement assessments must report performance measures by race/ethnicity, gender, age, and primary language. However, quality and performance improvement initiatives will help only if used consistently in all health care delivery venues.

Bridging the Gap Between Knowledge and Clinical Practice

To improve the quality of SCA care and outcomes, tools and systems are needed to translate clinical trial evidence and national guidelines into routine clinical practice. Several methods to facilitate the implementation of guidelines were recommended in the 2005 ACC/AHA Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult.⁴⁵ Academic detailing or educational outreach visits was a Class I recommendation supported by level of evidence A (data derived from multiple RCTs or meta-analyses).⁴⁵ A second Class I recommendation is the development of multidisciplinary disease-management programs for high-risk patients not only to facilitate the implementation of practice guidelines, but also “to attack different barriers to behavioral change.” Chart audits, performance feedback, and the use of reminder systems were designated as Class IIa recommendations also supported by level of evidence A.⁴⁵

Patient-Level Tools for Education on SCA Risk Factors and Prevention

To raise SCA awareness, educational tools and other avenues of information must be readily available to patients and the public. We inventoried existing educational tools about SCA risk factors and prevention from national organizations including the ACC, AHA, Heart Rhythm Society (HRS); from special interest groups including the American Black Cardiologists (ABC), National Alliance for Hispanic Health; Sudden Cardiac Arrest Association, and WomenHeart; and from ICD manufacturers, including Boston Scientific, Medtronic, and St. Jude Medical. Currently available resources for patients and the public are mostly based on knowledge dissemination, but are increasingly focused on awareness, involvement, and behavioral change. As an example, the HRS recently launched the “Apples to Oranges” public awareness campaign aimed at educating the public on the difference between a heart attack and SCA. Educational tools targeting patients and the public were reviewed at the meeting and are summarized in Table 3.

Provider-Level Tools for Identifying Patients at Risk for SCA

In addition to educational tools for patients and the public, clinical resources for health care providers are needed to improve their awareness of SCA, their ability to identify patients at risk for SCA in clinical practice, and to improve their adherence to evidence-based, guidelines-driven practice patterns. Educational tools focused on health care professionals are listed in Table 4. Available tools include treatment algorithms based on published guidelines, tools for identifying key clinical characteristics, printed materials, EMR, and quality improvement studies such as IMPROVE-HF. After these tools are effectively employed, clinical attention needs to focus on factors that help patients make fully informed decisions about their care,

including information about the likelihood the patient's desired outcomes such as quality of life are achieved.

IMPROVE-HF is the largest, most comprehensive quality improvement study for HF patients in the outpatient setting. This study was designed to enhance the quality of care for HF patients by promoting the adoption of evidence-based, guideline-recommended therapies. To that end, the investigators evaluated utilization rates of 7 guideline-recommended therapies—1) use of ACE-inhibitors and/or angiotensin II receptor blockers; 2) use of beta-blockers; 3) use of aldosterone receptor antagonists; 4) use of anticoagulation therapy in patients with atrial fibrillation; 5) use of ICDs; 6) use of CRT; and 7) documentation that HF education was provided—and encouraged sites to attend an educational workshop to set treatment goals and develop a customized clinical care pathway.⁴¹ Critical to identifying patients at risk for SCD is documentation of New York Heart Association (NYHA) Class and QRS duration; however, these measures are often missing. Over one-third of patients in IMPROVE-HF did not have a NYHA functional class documented or inferred.⁴¹ Without documentation of such parameters used to determine eligibility for device-based therapies to prevent SCD, it remains difficult to accurately identify at-risk patients. Additionally, IMPROVE-HF aimed to improve practice performance, providing not only toolkits, workshop materials, evidence-based algorithms and practice pocket cards, clinical trials and current guideline information, and customized patient assessment and management forms to help practices identify at-risk patients, but also providing on-demand performance feedback via Practice Profile Reports. These reports enabled practices to compare and contrast performance measures across all physicians within a practice and benchmark performance both locally and nationally.

Modeling some of these practice improvement features, a Missouri cardiology practice developed leading-edge technology in the form of Emerge SureCare, an electronic solution that leverages the EMR framework with synchronous collection of discrete patient data elements to create interactive practice treatment protocols consisting of relevant and reliable decision options, order sets, integrated action verification, and outcomes data collection. Subsequent evaluation of the effectiveness of this tool based on independent chart audits revealed that recognition of patients at risk for SCA improved from 70% at regional clinics in the same practice not using Emerge SureCare to 93% at the main clinic where Emerge SureCare was instituted ($p < 0.001$).⁴⁶

The development of effective clinical decision support tools starts with the guidelines. Using the evidence-based guideline recommendations as a framework, the development of an EMR data structure that facilitates real-time queries during the outpatient visit to generate reminders for the next appropriate clinical action enables documentation of action and ultimately results in definitive therapy. Lessons learned from IMPROVE-HF and Emerge SureCare demonstrate that the implementation of a systematic approach to screening patients at risk for SCA is necessary. Screening of patients should include documentation of patients who meet criteria for SCA prevention, but should also allow documentation of appropriate exclusions for a particular therapy. The development of a targeted and layered clinical decision support tool with an integrated reminder system is important for identifying patients at risk for SCA for consideration for ICD/CRT therapy. Both IMPROVE-HF and Emerge SureCare have shown that utilization of electronic clinical decision support is effective in improving practice performance and deserves more widespread dissemination.

System-Level Tools and Criteria for Assessing Acceptability of Existing Educational Resources

Equally important to developing and disseminating patient- and provider-level educational tools about SCA, is assessing the acceptability and quality of these tools at a system-level.

Educational tools should target four primary audiences: 1) patients; 2) providers; 3) the public; and 4) policymakers. As such, acceptability criteria should be tailored to the intended audience. One model for evidence-based decision-making highlights the importance of taking into account the clinical state and circumstances, research evidence, and patient preferences and actions, all in the context of clinical expertise.⁴⁷ Toward this end, several criteria can be used to evaluate the acceptability of an educational tool including: appropriateness of scope and purpose; rigor; clarity and presentation of materials; cultural proficiency and appropriateness.

Currently, there are two decision aids available to help patients make better-informed decisions. The first is DISCERN (<http://www.discern.org.uk>), which is a questionnaire that assesses the quality of written information on treatment choices for a particular health problem by providing information about a publication's reliability and the quality of information on treatment choices, as well as support for shared decision-making. Another tool is the International Patient Decision Aids Standards (IPDAS) Collaboration (http://www.ipdas.ohri.ca/IPDAS_checklist.pdf) that helps people participate in their health decisions and helps patients start discussions with their providers by preparing them for decision-making based on their health condition, treatment options, and personal values. While both tools assess the quality of written information on treatment choices for a health problem, neither assesses the effectiveness of such material in reaching outcomes goals.

To assess the acceptability of such educational tools, criteria should focus on content, development, and effectiveness to ensure that a patient's decision-making is informed and values-based (Table 5). Improving the match between a patient's decision and his/her values ultimately makes the decision and the decision-making process more satisfying. Just as such criteria are applied to patient decision aids and educational tools, criteria can also be applied to assess the acceptability of tools for health care providers, the general public, and policymakers. Acceptability criteria for provider tools share many of the features of the criteria used to assess patient educational tools (Table 6). For provider tools, acceptability criteria should focus on practice guidelines awareness and adherence, as well as improved patient-provider communication and shared decision-making. Similarly, educational tools aimed at the public should be evaluated based on the tools' ability to increase public awareness and improve risk prevention.

Improving Practice Performance for SCA Care

Practicing in the landscape of rapidly evolving recommendations for pharmacologic and device therapies, which have become increasingly nuanced, can be challenging, and coordination of care becomes more dependent on multidisciplinary collaboration among health care providers (primary care providers, cardiologists, HF specialists, electrophysiologists). As such, new approaches to improving the use of proven, guideline-recommended, life-prolonging therapies are needed.⁴⁸ This complex intersection of evidence and practice was highlighted by IMPROVE-HF data on the large practice variation in HF quality of care in U.S. cardiology practices, which revealed a very broad frequency distribution of conformity rates of practice.⁴¹ To standardize practice and minimize variation, the gap between evidence-based medical knowledge and routine clinical practice must be bridged. Employing clinical decision support tools that will aid implementation of evidence-based and guideline-recommended care, improve communications, and enhance adherence, will be important in ultimately improving SCA quality of care and outcomes.

As a result of the large practice variation documented among the IMPROVE-HF practice sites, performance improvement initiatives were created with the primary objective of observing a relative 20% or greater improvement compared to baseline in at least 2 of the 7 previously listed performance measures at 24 months over the aggregate IMPROVE-HF practice sites.

To accomplish this goal, the registry tracked utilization via chart reviews of medicines, devices, and patient education; identified treatment gaps as compared to treatment guidelines and evidence from large clinical trials; advanced understanding of best approaches to identify appropriate HF patients for indicated medical and device therapies; and assisted practices in closing treatment gaps by offering practical information and disease management tools.³⁸ The comprehensive education and implementation toolkits developed through IMPROVE-HF include webcasts and online education and resources via <http://www.IMPROVEHF.com>. Preliminary data using these tools presented at the 2009 Heart Failure Society of America (HSFA) annual scientific meeting demonstrated improvements in 6 of 7 measures with a 30% improvement for ICD and CRT utilization.⁴⁹

Another resource for physicians developed by the SCA Prevention Steering Committee is the SCA Prevention Pathways and Tools (Appendix A), designed to facilitate optimal patient care for those at risk of SCA, including patients with prior myocardial infarction and those with HF.⁵⁰ This set of comprehensive education and implementation tools is intended for both hospital and outpatient use by physicians, nurses, other hospital staff, and in some cases, by patients. The goal of the SCA Prevention Pathways and Tools is two-fold: 1) to increase awareness and patient access to diagnostics and life-saving therapies and 2) to promote guidelines awareness and adoption among all physicians and clinicians. To optimize the effectiveness of these tools, each part of the toolkit was developed in conjunction with a steering committee of nationally recognized leaders in the field of quality improvement and SCA, who provided key insights and external review. The steering committee identified the desired inpatient, outpatient, and patient educational toolkit components and then both adapted existing tools and developed new tools. The toolkit was reviewed by an expert nurse committee for “usability” and hospital and practice pilot site feedback was obtained and used to further refine the tools. Patient educational materials were reviewed for cultural sensitivity and the appropriateness of the educational level. These tools can be accessed online at: (http://journals.lww.com/critpathcardio/Fulltext/2009/06000/Sudden_Cardiac_Arrest_Prevention_Pathways_and.6.aspx).

Many challenges exist surrounding the implementation of HF or SCA performance improvement systems that can be scaled beyond cardiology practices and remain sustainable. Simple tools have been proposed such as stamps, chart stickers, templates, or an electronic health record to document vital data. There is now also increased focus on quality measurement and improvement at the national level among policymakers and support seems to be growing among providers. As an example, in 2005, the ACC/AHA Heart Failure Performance Measures Writing Group rejected all 3 of the proposed outpatient HF performance measures—1) aldosterone antagonist use in eligible patients (due to insufficient data to support the use of these drugs as a performance measure); and 2) ICD use in eligible patients; 3) CRT use in eligible patients with NYHA Class III-IV symptoms—at the time, citing insufficient numbers of qualified cardiac electrophysiologists in every community to implant ICD/CRT devices and to monitor follow-up in these HF patients as well as to ensure that complications are addressed as patients progress from Class III to IV HF. However, a recent retrospective cohort study of 111,293 ICD implantations performed from January 2006 to June 2007 and submitted to the ICD Registry found that rather than the availability of and access to electrophysiologists, device implantation decisions are influenced by other factors including preexisting referral patterns, financial remuneration, and patient preference.⁵¹ In the 2010 draft for public comment, the writing group has proposed to make ICD counseling in eligible patients a HF performance measure. The use of aldosterone antagonists and the use of CRT in eligible patients were still rejected as performance measures. Clearly, ongoing data collection and improved mechanisms for capturing treatment challenges, data gaps, and impact are needed.

Future Research Needs

In 2009, the top four priorities of the Institute of Medicine Comparative Effectiveness Research were: 1) health care delivery systems; 2) racial and ethnic disparities; 3) functional limitations and disabilities; and 4) cardiovascular and peripheral vascular disease. Having identified the existence of disparities in SCA care, these mismatches should be addressed by focusing research and funding on evidence generation that will advance our knowledge and understanding of why these disparities exist and how best to address them. Clinical registries are naturally positioned as engines for evidence development. In-hospital registries can inform cross-sectional studies and when linked with claims data can be used for longitudinal studies. One example is the Organized Program To Initiate Lifesaving Treatment In Hospitalized Patients With Heart Failure (OPTIMIZE-HF)/GWTG-HF registry that was matched with Medicare Claims (n=4,685 patients aged 65–84 years old).⁵² Likewise, in-hospital registries paired with device/drug information and longitudinal outcomes can be used to assess comparative effectiveness, and when paired with biomarker/genetics samples and longitudinal outcomes can fuel translational discoveries. Taking advantage of these synergistic processes is a cluster RCT like the Effectiveness of Public Report Cards for Improving the Quality of Cardiac Care: EFFECT Study.⁵³ This population-based cluster randomized trial of 86 hospital corporations in Canada examined whether the public release of data on cardiac quality indicators effectively encourages hospitals to pursue activities to improve health care processes and patient outcomes.⁵³ Additionally, personalized performance improvement interventions are now being compared with standard of care to generate site data reports, personalized feedback via teleconferences, comprehensive toolkits, and focused webinars.

New research networks have been created to leverage these registries including the DEcIDE Research Network and National Heart, Lung, and Blood Institute's (NHLBI) Cardiovascular Research Network (CVRN). One of the primary projects of the CVRN is focused on evaluation of ICDs for primary prevention in community practice (<http://www.cvrn.org/projects/principal/index.html>). Similarly, the NHLBI funds the Prediction of ICD Therapies Study (PREDICTS) and Vest Prevention of Early Sudden Death Trial (VEST) studies, which share an observational cohort on whom extensive risk stratification testing is performed in addition to the collection of biological samples with the goal of predicting which patients require ICD implantation. The NHLBI has also funded a Resuscitation Outcomes Consortium (ROC) to evaluate the treatment of people with out-of-hospital cardiac arrest or life-threatening injury to improve resuscitation outcomes (<https://roc.uwctc.org/tiki/tiki-index.php>).

More research is needed to answer ongoing questions regarding ICD efficacy in special populations like women, minorities, and older patients. Just as the reasons for the disparities in SCA care are incompletely understood at this time, the barriers to the widespread practice of evidence-based medical care for SCA remain unclear and also represent a potential research area. For example, how do we improve variation in clinical practice? What is the best strategy for increasing implementation of evidence-based medicine? What are the best tools or systems to support the quality of care initiatives?

Many other questions remain for which evidence generation is needed. Research needs include, but are not limited to, studies on the optimization of access to device therapy for all eligible populations; patient decision making processes and expectations; risk stratification of ICD- and/or CRT-eligible patients to better target therapy to those patients most likely to benefit from it; cost-effectiveness studies; and effects of age, sex, and race on procedural complication rates and risk/benefit ratios for device implantation. In addition, studies are needed on quality of life and patient acceptance of device technologies; and long-term outcomes and risk factors

for patients receiving ICDs in general clinical practice compared with trial populations and those at academic centers.⁹

Next Steps

To help inform and develop guidelines for addressing disparities in SCA care, we have synthesized the available tools for both patients and providers. Review of these tools during the SCATLA proceedings revealed: 1) the lack of standardized nomenclature across resources and 2) a wide variation in estimates of SCD incidence in the U.S. “Sudden cardiac death” and “sudden cardiac arrest” are often used interchangeably, which is incorrect and likely represents a barrier to a unified, multidisciplinary approach to education, awareness, and prevention. The 2006 ACC/AHA/ESC Guidelines document defines both SCA and SCD, and we support the use of these definitions. SCA is defined as “an unexpected circulatory arrest, usually due to a cardiac arrhythmia occurring within an hour of the onset of symptoms, in whom medical intervention (e.g., defibrillation) reverses the event.”⁵⁴ SCD is defined as “death from an unexpected circulatory arrest, usually due to a cardiac arrhythmia occurring within an hour of the onset of symptoms.”⁵⁴ Regarding the true magnitude of SCD in the U.S., we performed an analysis of all available estimates of the incidence of SCA and/or SCD in the U.S. the results of which were summarized in a separate manuscript.

Given the complex landscape of SCA care, addressing current disparities in SCA care requires coordinated education and awareness efforts at the patient, provider, public, and policy levels to address both perceived and actual barriers and to develop level-specific tools. Likewise, at each level, these tools must be evaluated for acceptability in terms of content and effectiveness regarding improved implementation of evidence-based care as well as improved outcomes. Hospital-based and outpatient performance improvement programs and the use of pathways, protocols, and disease management programs can significantly increase the utilization of evidence-based, guideline-recommended therapies. SCA performance measures and quality improvement indicators should also be used to optimize the effectiveness of existing tools. However, more needs to be done to ensure high quality care for patients with HF and for those at risk for SCA and to identify gaps in existing performance measures. Future research should include the use of SCA registries with availability of benchmarking at the individual physician, practice, and regional level; more inclusive studies with more representative patient enrollment in RCTs; and applied research on how to affect physician-patient decision-making and guideline-adherence.

Conclusions

Despite overwhelming clinical trial evidence, expert opinion, national guidelines, and a vast array of educational conferences, evidence-based, life-prolonging drug and device therapies continue to be underutilized with significant disparities in SCA care and use of ICDs in vulnerable populations, including blacks, women, and the elderly. In light of the large treatment gaps between the guidelines and practice patterns for HF and other patients at risk for SCA, processes and tools are clearly needed to bridge knowledge deficiencies and improve implementation into clinical practice.

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Appendix A

The SCA Prevention Steering Committee's development of the SCA Prevention Pathways and Tools is funded in part by Medtronic, Inc.

Appendix B

Participants in the meeting:

Participants from Academia: Sana M. Al-Khatib, MD, MHS (co-Director); Anne B. Curtis, MD; Gregg C. Fonarow, MD; John Fontaine, MD; David L. Hayes, MD; Adrian F. Hernandez, MD, MHS; Melissa H. Kong, MD; Eric D. Peterson, MD, MPH (co-Director); Andrea M. Russo, MD; Gillian D. Sanders, PhD (co-Director); Samuel F. Sears, PhD; Kevin L. Thomas, MD; Clyde W. Yancy, MD

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Participants from the US Food and Drug Administration: Brian Lewis, MD; Bram Zuckerman, MD

Participant from the National Institutes of Health/National Heart, Lung and Blood Institute: Nakela L. Cook, MD, MPH

Participant from Agency for Healthcare Research and Quality: Steven Phurrough, MD; Anne E. Trontell, MD, MPH

Participants from national professional societies and special interest groups: Susan Campbell, MPH; Chris Chiames; Michelle LaRue, MD; Kathryn M. Pontzer; Lisa Tate

Participants from Industry: Thomas Bernhardt, MD, PhD; Mark Carlson, MD; Nina Goodheart, MBA; Arnold Jacobson, MD, PhD; Julie Kemp; Michael Landreville; Edward L. Lyons; Chas McKhann, MBA; Dan Schaber, PharmD; Tamara Shipman, BSM; Kenneth Stein, MD; Andra Thomas; Eric Winston, MBA

Coordinating Staff: Marelle Molbert from the Duke Clinical Research Institute.

Figure 1.
Addressing disparities in SCA care: Cycle from conceptualization to implementation

Table 1

Possible reasons for disparities in ICD utilization at the patient, provider, and public level

Patient level	<ul style="list-style-type: none"> • Women and racial minorities may be more concerned about the safety of the procedure or the safety of the ICD • Women might be more concerned about the potential effect of the ICD on quality of life or their body image • Women and racial minorities may be more skeptical about the benefits of ICD therapy • Women are usually the care-givers in their family; they may not want to take any time away from the ones that they take care of to have the ICD implanted or followed up • Women and racial minorities may seek a different type of decision making process beyond the medical pros and cons and include a broader set of biopsychosocial considerations Other cultural influences including aspects of spirituality, family, and traditional sex roles
Physician level	<ul style="list-style-type: none"> • Biases and personal beliefs • Concerns over the lack of applicability of clinical trial results to women and racial minorities, as women and racial minorities were not well-represented in the RCTs of ICDs • SCD occurs less frequently in women than in men, and therefore perhaps women may not benefit as much • Concerns over cost and cost-effectiveness
Public level	<ul style="list-style-type: none"> • Issues surrounding access to SCA care • Lack of awareness

Table 2

Recommendations for addressing barriers to SCA care

Patient level	<ul style="list-style-type: none"> • Implement culturally relevant patient education programs to increase patients' knowledge on how to access care and participate in medical decision making • Endorse patient navigator programs that will assist minority patients in accessing care, obtaining financial resources, and following through with treatment plans • Include ongoing plans for addressing setbacks and advances on both physical and mental functioning
Physician level	<ul style="list-style-type: none"> • Provide incentives to practices that reduce barriers and adhere to evidence-based guidelines and demonstrate improvements in the delivery of care to vulnerable populations • Provide benchmarking to allow practices to compare themselves to other regions • Support the use of community health workers and implement multidisciplinary treatment and preventative care teams • Provide culturally and linguistically appropriate resources to communities
Public level	<ul style="list-style-type: none"> • Harness grass roots efforts to improve awareness and education • Mobilize the importance of understanding and preventing SCA
Policy level	<ul style="list-style-type: none"> • Develop a unified approach to education, awareness, prevention • Develop a plan for increasing the "safety net" of patients with financial hardship • Fund research focused on evaluating interventions that improve patient and physician relationships

Table 3

nal tools/resources for patients and the public

Source	Type of Tool				
	Conferences	Public Awareness Campaigns	Local Support Networks	Print/Media Materials	Online Resources
American College of Cardiology (ACC)	<ul style="list-style-type: none"> Planned live patient education conference in 2010 with Georgia Chapter of ACC 			<ul style="list-style-type: none"> Educational pamphlets on ventricular arrhythmias and sudden death 	<ul style="list-style-type: none"> CardioSmart (includes video library)*
American Heart Association (AHA)					
Heart Rhythm Society (HRS)		<ul style="list-style-type: none"> Apples and Oranges 		<ul style="list-style-type: none"> SCA patient education materials 	<ul style="list-style-type: none"> www.HRSONline.org http://ceondemand.org/hrs/ram/splash.php
American Black Cardiologists (ABC)					
National Alliance for Hispanic Health		<ul style="list-style-type: none"> !Vive tu vida!: Get Up! Get Moving! Campaign 		<ul style="list-style-type: none"> Partnership with Univision Communications, Inc. television; Salud Magazine 	<ul style="list-style-type: none"> Helpline: SU FAMILIA; National Hispanic Family Health Helpline
Sudden Cardiac Arrest Association		<ul style="list-style-type: none"> Community events; Public service advertising 	<ul style="list-style-type: none"> Recognition of local SCA Heroes 	<ul style="list-style-type: none"> Translations of "Living with an ICD" into 8 languages 	<ul style="list-style-type: none"> www.inspire.com/groups/sudden-cardiac-arrest-association/ Survivor stories and patient education videos on website Postings of community events, health fairs, public service advertising
WomenHeart	<ul style="list-style-type: none"> Survivors trained as community educators at Science & Leadership 	<ul style="list-style-type: none"> Partnership with NHLBI's The Heart Truth/Red Dress campaign; 	<ul style="list-style-type: none"> 60 networks meet monthly 	<ul style="list-style-type: none"> 659 million media impressions in lay-press/general interest magazines; 	<ul style="list-style-type: none"> www.womenheart.org; Active online patient community with 2800 registered members; Monthly Heart-to-Heart e-newsletter

Am Heart J. Author manuscript; available in PMC 2011 October 1.

Source	Type of Tool					
	Conferences	Public Awareness Campaigns	Local Support Networks	Print/Media Materials	Online Resources	Other
	Symposium at Mayo clinic	<ul style="list-style-type: none"> Disseminated 99,500 Red Bags of Courage® 		<ul style="list-style-type: none"> Distributed 1.2 million pieces of printed educational materials through <i>WomenHeart Champions</i> 		OWH and <i>Dear Abby</i>
Boston Scientific		<ul style="list-style-type: none"> <i>Close-the-Gap</i> (CTG) Initiative screenings and awareness events on national and at local level 		<ul style="list-style-type: none"> <i>Heartistry</i> toolkit; Brochures, pamphlets, manuals, flyers <i>Victim-to-Survivor</i> DVD SCA Awareness Month Card 	<ul style="list-style-type: none"> www.youtube.com/yourhearthealth; www.twitter.com/yourhearthealth; facebook communities for CTG 	<ul style="list-style-type: none"> CTG heart pins & cards, awareness bracelets, bookmarks
Medtronic, Inc				<ul style="list-style-type: none"> Patients/Families educational DVDs, brochures 	<ul style="list-style-type: none"> Patients/Families educational websites 	
St. Jude Medical		<ul style="list-style-type: none"> <i>HeartSafe 180</i> campaign 	<ul style="list-style-type: none"> Local public awareness, educational programs (e.g., Heart Beat Buffalo) 	<ul style="list-style-type: none"> Brochures, pamphlets, manuals, posters, DVDs available in English and Spanish 	<ul style="list-style-type: none"> www.HeartLibrary.com 	

Table 4

per health care providers

Type of Tool						
Practice Guidelines	Professional Training/Support	Research Registries	Print/Media Materials	Online Resources	Other	
<ul style="list-style-type: none"> • Ventricular Arrhythmias and Sudden Death, 2006; • Device Based Therapy of Cardiac Rhythm Abnormalities, 2008 		<ul style="list-style-type: none"> • National Cardiovascular Data Registry (NCDR-ICD Registry) 	<ul style="list-style-type: none"> • Journal Scan 	<ul style="list-style-type: none"> • Cardiosource; • Accel (audio); • Featured events from annual meeting; 	<ul style="list-style-type: none"> • Cardiovascular Recognition Program (CVRP) 	
<ul style="list-style-type: none"> • Ventricular Arrhythmias and Sudden Death, 2006; • Device Based Therapy of Cardiac Rhythm Abnormalities, 2008; • ECC Guidelines 	<ul style="list-style-type: none"> • Cultural Competency Initiative 	<ul style="list-style-type: none"> • National Registry of Cardiorespiratory and Resuscitation Investigators (NRCRI); • GWTC-HF; • GWTC-Stroke 				
<ul style="list-style-type: none"> • SCA 360 Resource Center 	<ul style="list-style-type: none"> • SCA 360 Resource Center 	<ul style="list-style-type: none"> • ICD Registry 		<ul style="list-style-type: none"> • SCA-related webcasts for self-study 		
<ul style="list-style-type: none"> • Cultural proficiency training for health care professionals; • Alliance/ Merck Ciencia (Science) and Scholars Program 	<ul style="list-style-type: none"> • Cultural proficiency training for health care professionals; • Alliance/ Merck Ciencia (Science) and Scholars Program 		<ul style="list-style-type: none"> • Training manuals for health educators 	<ul style="list-style-type: none"> • Developing Spanish versions of Cardiosource 	<ul style="list-style-type: none"> • Partnerships with AHA and ACC; • Proyecto Ciencia 	

Am Heart J. Author manuscript; available in PMC 2011 October 1.

Type of Tool							
Practice Guidelines	Professional Training/Support	Research Registries	Print/Media Materials	Online Resources	Other		
	<ul style="list-style-type: none"> • <i>Close-the-Gap</i> Initiative 				<ul style="list-style-type: none"> • Partnerships with national organizations 		
	<ul style="list-style-type: none"> • SCA Prevention Pathways and Tools; • Physician continuing education programs 				<ul style="list-style-type: none"> • Partnerships with national organizations 		
<ul style="list-style-type: none"> • Publication of ACC/AHA/HRS Guidelines booklets 	<ul style="list-style-type: none"> • SCA 360 Resource Center; • Peer-to-peer Physician Education Programs; • EP and Cardiology fellows training seminars; • Allied Health Professional seminars 		<ul style="list-style-type: none"> • Presentations on SCA 	<ul style="list-style-type: none"> • www.SJMPProfessional.com; • www.HeartFailureProfessional.com; • www.InsideCardiacArrest.com 	<ul style="list-style-type: none"> • Partnerships with national organizations 		

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Table 5

Criteria for assessing patient educational tools

Criteria Focus	
Content	
<i>Does the patient decision aid...</i>	<ul style="list-style-type: none"> • Provide information about options in sufficient detail for decision-making? • Present probability of outcomes in an unbiased and understandable way? • Include information that reflects expectations for the quality of daily life and long-term functional capacities? • Include methods for clarifying and expressing patients' values? • Include attention to the effects of therapy on personal and family functioning? • Include structured guidance in deliberation and communication?
Development	
<i>Does the patient decision aid...</i>	<ul style="list-style-type: none"> • Present information in a balanced manner? • Have a systematic development process? • Use current scientific evidence that is cited in a reference section or technical document? • Disclose conflicts of interest? • Use plain, accurate, culturally appropriate, and standardized language?
Effectiveness	
<i>Using the patient decision aid, does the patient...</i>	<ul style="list-style-type: none"> • Recognize a decision needs to be made and with what timetable? • Know the options and their features? • Understand that values affect decision? • Discuss values with their practitioners? • Improve the match between the chosen option and the features that matter most to the informed patient?

Table 6

Criteria for assessing provider tools for identifying patients at risk for SCA

Criteria Focus	
Content	
<i>Does the provider tool...</i>	<ul style="list-style-type: none"> Promote guidelines awareness and adherence? Provide treatment algorithms for clinical decision-making based on published guidelines? Present probability of outcomes in an unbiased and understandable way? Include structured guidance in deliberation and communication?
Development	
<i>Does the provider tool...</i>	<ul style="list-style-type: none"> Have a systematic development process? Use current scientific evidence that is cited in a reference section or technical document? Interface into existing electronic medical records structures? Function in real-time to process queries during the outpatient visit?
Effectiveness	
<i>Using the provider tool, does the provider...</i>	<ul style="list-style-type: none"> Document left ventricular ejection fraction, NYHA class, and QRS duration? Recognize a decision needs to be made? Understand the therapeutic options and their risks/benefits to the patient? Understand that patient values affect the decision? Receive reminders for next appropriate clinical actions? Identify and document exclusions, if clinical actions are not appropriate for individual patients? Document clinical actions taken? Receive feedback on performance or other benchmarking information?