Title Page

Article Type: Observational study

Title: Benefits Of An ICD Mhealth App For Physician Referrals and e-Health Education (ICD TEACH)

Running head: ICD TEACH mhealth app

Authors:
1) Sumeet Gandhi
McMaster University, Hamilton Health Sciences, Hamilton, ON

2) Carlos A. Morillo
Libin Cardiovascular Institute of Alberta, University of Calgary and Population Health Research Institute

3) JD Schwalm
McMaster University, Hamilton Health Sciences and Population Health Research Institute, Hamilton, ON

Correspondence:
Sumeet Gandhi
237 Barton Street East, DBCVSRI, C3-108
Hamilton ON, L8L 2X2
Fax: 905-577-1474
Phone 905-577-1423
Email: Sumeet.gandhi@medportal.ca

Word count (excluding title page, abstract, tables/figures, references):

Disclosures:
All authors have participated in the work (conception, design, article drafting) and have reviewed and agree with the content of the article. None of the article contents are under consideration for publication in any other journal or have been published in any journal. No portion of the text has been copied from other material in the literature (unless in quotation marks, with citation). I am aware that it is the author's responsibility to obtain permission for any figures or tables reproduced from any prior publications, and to cover fully any costs involved. Such permission must be obtained prior to final acceptance.

Keywords:
Mhealth, smart phone app, implantable defibrillator cardioverter, ICD, physician decision, e-health
ABSTRACT

BACKGROUND:
Smart phone apps or mhealth technology have demonstrated early success in improving patient and physician outcomes.

METHODS:
The goals of the ICD-TEACH pilot study were to design a smart phone app/mhealth technology with a novel physician decision support algorithm, implement a direct referral mechanism for ICD implantation from the app, and assess its overall usability and feasibility with physicians involved in the care of these patients.

RESULTS:
A total of 17 physicians agreed to participate in the pilot study with 100% post study survey response rate. Physicians worked in an academic practice, which included both inpatient and ambulatory care. System Usability Scale was applied with average score of 77 including the 17 participants (>68 points above average). In regards to the novel physician decision algorithm for ICD referral, 11% strongly agreed and 78% agreed that the algorithm for device eligibility was easy to use. Only one patient was referred through the direct referral system through the mhealth app during the pilot study of 3 months. Feasibility assessment showed 46% strongly agreed and 55% agreed that the mhealth app would be utilized if integrated into an electronic medical record where data is automatically sent to the referring arrhythmia clinic.

CONCLUSION:
ICD teach pilot study revealed high usability features of a physician decision algorithm however we received only one direct referral through our app despite supportive feedback. Specific reasons from our physician survey included the lack of integration into an electronic medical record. Future studies should
continue to systematically evaluate smart phone apps in cardiology to assess usability, feasibility, and strategies to integrate into daily workflow.
INTRODUCTION

Guideline recommended primary and secondary prevention of sudden cardiac death (SCD) in high-risk patients includes the implantation of an implantable cardioverter-defibrillator (ICD)\(^1\)\(^-\)\(^2\). Despite continuing medical education and physician-based interventions, there still remains a large population of eligible patients who may not be receiving such therapy\(^3\). Identifiable reasons for the lower than expected physician-ICD referral rate have been attributed to misperception about the benefit of ICD therapy and patient eligibility, as well as the lack of awareness of the device implantation process. To understand barriers of knowledge and potentially minimize care gaps that exist between evidence-based recommendations and current practice for ICD referral, an online questionnaire was conducted predominantly including community based family physicians and general internists. In this small sample of 24 physicians, 41% of participants were not familiar with current ICD implantation guidelines, as well a small number also believed ICD therapy did not improve quality of life. When asked about different methods to optimize referrals, a tablet or mobile phone app to help identify potential patients was highly selected (Figure 1).

Smart phone apps or mhealth technology are part of daily life, with continued growth gaining popularity amongst healthcare providers. Incorporated into the daily lives of both physicians and patients, mhealth has the ability to provide evidence-based guidance in an interactive, engaging, and user-friendly format with instant knowledge acquisition\(^4\). As an adjunct to behaviour modeling, the intervention of mhealth has demonstrated early success in improving patient and physician outcomes\(^5\). The purpose of the ICD-TEACH study was to design a smart phone app/mhealth technology with a novel physician decision support algorithm, implement a direct referral mechanism for ICD implantation from the app, and assess its overall usability and feasibility with physicians involved in the care of these patients.

METHODS
ICD-TEACH was a single center pilot study to assess the usability and feasibility of mhealth for ICD physician decision support and direct referral to a regional arrhythmia centre. The initial design and development of the mhealth/smart phone app included strategic collaboration from an information technology company and key stakeholders including arrhythmia specialists (electrophysiologists), general cardiologists, as well as key members of the hospital administrative team. The mhealth app included an interactive user-friendly algorithm to determine patients eligible for ICD implantation with instant feedback and the option for direct referral to our regional arrhythmia referral centre in Ontario, Canada (Table 1). The mhealth app also provided education targeted to physicians about ventricular arrhythmias, congestive heart failure, sudden cardiac death, procedure information, current guideline recommendations for device therapy, quality of life, day-to-day/frequently asked questions, and the ability to refer patients to a regional arrhythmia clinic, embedded within the app (Figures 1-3).

The next phase of this pilot study included rollout of the mhealth app to cardiology and internal medicine physicians to assess the usability and feasibility of the mhealth app. A convenience sampling method was used to recruit general internists/cardiologists that refer to our local tertiary care centre. Physicians were eligible to participate if their current practice pattern included patients with congestive heart failure and were current smart phone user (Apple, Android, or Blackberry based platforms with access to mobile data).

Participating physicians were asked to independently review a document about the mhealth app and project goals. Instructions were provided to review the app content, and assess patient eligibility for ICD therapy using the algorithm. Physicians were asked to incorporate the mhealth app in daily clinical practice and avail of the decision support algorithm and direct referral feature to the arrhythmia clinic. A physician survey was conducted after initial mhealth app use (within 3 months) about physician’s overall satisfaction with the app, compliance,
the reason for non-compliance, technical or hardware problems encountered while using the app, and suggestions on improvement. Reminders were provided via email at one week, four weeks, and three months to reiterate the benefit and promote the ICD mhealth app.

The primary outcome of this study was to assess the feasibility of incorporating a mhealth app into daily clinical practice. A descriptive analysis was undertaken, based on the structured questionnaire regarding satisfaction of completing the task, overall compliance, the reason for non-compliance, technical or hardware problems encountered while using the app, and suggestions on improvement. We also tracked the number of referrals to the regional Arrhythmia service clinic through the app. Our usability assessment included the System Usability Scale incorporated into the survey, which has been validated for health-care related smart phone apps; this scale consists of specific questions evaluating mhealth technology with a 5-point Likert scale\(^6\). A score >68 points is above average and indicates adequate usability. The authors had full access to the data and take full responsibility for its integrity. The study was approved by the Hamilton Integrated Research Ethics Board (HIREB Project #15-208).

<table>
<thead>
<tr>
<th>Table 1: ICD TEACH algorithm</th>
<th>Strong Recommendation</th>
<th>Weak Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the patient's LVEF less than 55%?</strong></td>
<td>Rule 1</td>
<td>Rule 2</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>The patient's EF is:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Above 54%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36% - 54%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31% - 35%</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Less than or equal to 30%</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Does the patient exhibit indications of:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ischemic heart disease or prior myocardial infarction</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Non-ischemic cardiomyopathy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None of the above apply</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Ischemic cardiomyopathy:** Has at least 40 days passed since the most recent MI or 3 months post-revascularization? Non-ischemic cardiomyopathy: Has at least 3 months passed with the patient on optimal medical therapy?

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Is the patient's expected survival with a good functional status greater than or equal to one year?**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**The patient has Familial or personal history of Arrhythmogenic right ventricular dysplasia, Brugada Syndrome, Catecholaminergic Polymorphic Ventricular Tachycardia, Long QT syndrome, Short QT syndrome, Hypertrophic cardiomyopathy?**

<table>
<thead>
<tr>
<th></th>
<th>Answer does not affect algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

*All recommendations based*
RESULTS

Survey Results

Physician recruitment occurred from January 1 – January 30, 2017. Participating physicians were able to use the app for a total of 3 months, final survey results and the pilot study was completed by May 1\textsuperscript{st}, 2017. A total of 17 physicians agreed to participate in the study with 100% survey response rate. Physicians worked in an academic practice, which included both inpatient and ambulatory care. 13 (76%) participants were general cardiologists/residents, 4 (26%) were general internal medicine specialists. 14% of respondents agreed that the current paper/fax based system for device referral was difficult, while 29% disagreed and 57% were neutral. 21% agreed that they enjoyed using the current system for ICD referral, while 21% disagreed. Participating physicians thought the app was not difficult to download or install on the smart phone device, and did not take too long to download.

In regards to usability, the System Usability Scale was applied with average score of 77 including the 17 participants (>68 points above average). In regards to the novel physician decision algorithm for ICD referral, 11% strongly agreed and 78% agreed that the algorithm for device eligibility was easy to use (Figure 5). For the direct referral option to our regional arrhythmia centre, 88% agreed and 12% strongly agreed the direct referral process was also easy to use. When asked about if they would use this mhealth app for direct referral, 25% strongly agreed, 50% agreed, 13% disagreed, and 13% were neutral. Respondents felt the education material was beneficial such as procedure information (75% agreed, 25% strongly agreed), device therapy information (29% strongly agreed, 57% agreed), and common frequently asked questions (14% strongly agreed,
71% agreed. 67% disagreed that the current traditional paper/fax based system was more efficient, while 17% agreed.

The majority of physicians felt that this mnhealth app should be available to all physicians in the province of Ontario (43% strongly agreed, 43% agreed). As well, when asked if entering patient information into the app was difficult, 9% strongly disagreed and 46% disagreed. When asked if they did not trust/rely on the app to submit private information, 27% disagreed and 9% strongly disagreed while 46% were neutral, 9% agreed and 9% strongly agreed. 28% of respondents disagreed/strongly disagreed with the comment that they did not need an algorithm for device if a patient needed an ICD, while 54% were neutral and 18% agreed/strongly agreed.

Feasibility/Uptake of Mhealth App
Physician referrals using the mhealth app were tracked during the study period. Only one patient was referred through the direct referral system through the mhealth app during the pilot study of 3 months. Feasibility assessment showed 46% strongly agreed and 55% agreed that mhealth app would be utilized if integrated into an electronic medical record where data is automatically sent to the referring arrhythmia clinic. This was also reflected in the free text comments provided by physicians at the end of the survey. 91% agreed and 9% strongly agreed that the mhealth app should be available in a web/browser format. Further feedback included that during the pilot study, overall patient encounters where patients needed to be referred for device referral was low. Physicians also mentioned that in their current practice, it would be easier to fill out a referral form than submit through the app, and that most cardiologists did not frequently need a decision algorithm for device referral.

DISCUSSION
The results of the ICD TEACH pilot study revealed that our novel ICD decision algorithm and direct referral mechanism was easy to use with adequate usability.
Physicians did not find entering patient information cumbersome, felt comfortable submitting patient information through the mhealth app, and believed the algorithm tool should be disseminated widely. The education materials provided regarding procedural information, device therapy, guideline summaries, and frequently asked questions were useful and informative. Despite the majority of physicians stating that they would use the direct referral mechanism, we received only one direct referral through the mhealth app during the study period.

Several challenges were faced in integrating this mhealth technology into the routine practice of physicians. We initially anticipated 40-50 physicians for enrolment into the pilot study however after recurrent contact through email, the response to the recruitment email (accept or not accept) was low. Although speculative, this may be due to the fact that physicians already have a current system that they feel is efficient, and did not want to spend additional time learning a new system if significant efficiency was not to be gained. This may be reflected in that we only received one direct referral through the mhealth app. Our survey results suggested that cardiologists did not need an algorithm for device implantation, as well the current paper/fax based system was efficient enough for daily use. Our population of cardiologists and general internists whom participated in this pilot study worked in a tertiary care/urban centre and may have different perceptions than physicians in rural settings, who may not have timely access to subspecialty referral. The ICD TEACH app may have more benefit with physicians practicing in rural areas, medical students/resident physicians, as well as primary care physicians looking for further education about ICD referral as well learning guideline based indications for ICD through the algorithm.

Important insight gained from our pilot study through the survey and free-text comments is that the optimal utilization of a mhealth app with a decision algorithm and direct referral mechanism should be linked directly to an electronic medical record (EMR) system. In this manner, once the decision to refer a patient
for ICD is made, the EMR system would auto-populate the patient information fields and also send the appropriate information to the arrhythmia clinic (such as patient history, medications, blood work, and key investigations). A limitation of our pilot study is that our current healthcare network does not have EMR or an electronic referral mechanism; we may have seen more direct referrals if the ICD TEACH app was integrated into an EMR software.

With the rise of healthcare related mhealth technology, it is important that the medical community evaluate such tools in a systematic manner. Cardiovascular societies and healthcare organizations should look to formally test healthcare mhealth apps for usability and feasibility to gain further insight and feedback, in the form of pilot studies or focus group testing. Our process proved quite beneficial, as our usability assessment showed the mhealth app was adequate. However, our feasibility assessment highlighted several key pitfalls before this technology can be optimally integrated into our regional healthcare network as a part of daily workflow.

**CONCLUSION**

ICD teach pilot study revealed high usability features of a physician decision algorithm and direct referral mechanism for ICD implantation. We received only one direct referral through our app despite supportive feedback. Specific reasons from our physician survey included the lack of integration into an electronic medical record, as well perceived efficiency of the current paper/fax based system. Future studies should continue to systematically evaluate smart phone apps in cardiology to assess usability, feasibility, and strategies to integrate into daily workflow.

**ACKNOWLEDGEMENTS**

The design and development of the smart phone app was funded by an education grant from Boston Scientific Canada. Pilot study was supported by an educational grant from McMaster University (QUEST Resident Research Award).
REFERENCES


3. Cardiac Care network. 2006.

**Figure 1: Questionnaire results**
Figure 2 ICD-TEACH initial dashboard at login
Figure 3 Indication survey: Once completed the indications survey, the algorithm provides a recommendation for ICD (based upon the *Canadian Cardiovascular*...
Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines). Users were also given the option to directly refer to the arrhythmia clinic.

**Figure 4** Direct referral: Option to directly refer to the arrhythmia clinic.
**DIRECT REFERRAL**

Please note: if you would like to include a full indications report with your referral, please return to the home menu and select "Indications Report".

**PRIVACY AND CONSENT**

Upon submission of this online form, you confirm that verbal consent and permission was obtained from the respective patient to submit his/her personal and medical information for the purpose of online referral.

You agree to keep all username and password information strictly confidential, to not share with any individual or third party.

Please select a reason for referral

- ICD / Pacemaker
- Syncope
- Atrial Fibrillation

---

**SUCCESS**

Thank you. A representative will contact your office regarding appointment details, as per standard practices.

SEND REFERRAL

PREVIOUS

---

**Figure 5** Post study survey results
The algorithm for device eligibility was easy to use

- 78% Agree
- 11% Strongly Agree
- 11% Neutral