

Readability and Content of Patient Education Material Related to Implantable Cardioverter Defibrillators

Patricia H. Strachan, PhD, RN,

Assistant Professor, School of Nursing, McMaster University, Hamilton, Ontario, Canada

Sonya de Laat, MA,

Research Assistant, School of Nursing, McMaster University, Hamilton, Ontario, Canada

Sandra L. Carroll, PhD, RN,

Assistant Professor, School of Nursing, McMaster University, Hamilton, Ontario, Canada

Lisa Schwartz, PhD,

Arnold L. Johnson Chair in Health Care Ethics, Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada

Katie Vaandering, BScN,

BScN Student, School of Nursing, McMaster University, Hamilton, Ontario, Canada

Gurjit K. Toor, BScN, and

BScN Student, School of Nursing, McMaster University, Hamilton, Ontario, Canada

Heather M. Arthur, PhD, FESC

Professor, Heart and Stroke Foundation of Ontario, and Michael G. DeGroot Endowed Chair in Cardiovascular Nursing, McMaster University, Hamilton, Ontario, Canada

Abstract

Background—Implantable cardioverter defibrillators (ICDs) are increasingly offered to patients for primary prevention of sudden cardiac death. Candidates for ICD receive ICD-related patient education material when they make decisions to consent or decline a primary prevention ICD. Printed patient education material directed at ICD candidates has not been the focus of direct appraisal.

Objective—We evaluated the readability and content of ICD-related print education materials made available to patients who were enrolled in a study involving patient decision making for ICD from 3 ICD sites in southern Ontario, Canada.

Methods—All ICD print materials referred to during interviews and/or that were available in ICD site waiting rooms were collected for analysis. Readability testing was conducted using the SMOG (“simple measurement of gobbledygook”) and Fry methods. The material was evaluated according to selected plain-language criteria, thematic content analysis, and rhetoric analysis.

Results—Twenty-one print materials were identified and analyzed. Documents were authored by device manufacturers, tertiary care hospitals, and cardiac support organizations. Although many documents adhered to plain-language recommendations, text-reading levels were higher than recommended. Twelve major content themes were identified. Content focused heavily on the positive aspects of living with the device to the exclusion of other possible information that could be relevant to the decisions that patients made.

Conclusions—Print-based patient education materials for ICD candidates are geared to a highly literate population. The focus on positive information to the exclusion of potentially negative aspects of the ICD, or alternatives to accepting 1, could influence and/or confuse patients about the purpose and implications of this medical device. Development of print materials is indicated that includes information about possible problems and that would be relevant for the multicultural and debilitated population who may require ICDs. The findings are highly relevant for nurses who care for primary prevention ICD candidates.

Keywords

decision making; implantable cardioverter defibrillator; patient education; primary prevention; Readability

The implantable cardioverter defibrillator (ICD) is a device designed to protect at-risk individuals from sudden cardiac death (SCD) due to potentially lethal ventricular arrhythmias. Persons who are at risk for SCD according to cardiovascular guidelines but who have not yet sustained such an arrhythmic event are increasingly being offered an ICD as a primary prevention intervention.^{1,2} These individuals have severe damage to or weakening of their heart muscle or have a genetic predisposition to developing potentially fatal arrhythmias that can lead to SCD.

Educational strategies to assist patients with ICDs have focused on the generation and evaluation of such interventions as peer support groups,³ online supports,⁴ and nurse-directed patient education programs,⁵ among others. Most of these educational strategies focus on the postimplantation period. Research into patient education material available to patients before implantation is sparse. Although there have been reviews of informed consent for ICD patients,^{6,7} supplementary print material directed at patients and generated by device manufacturers and hospitals for cardiac devices or procedures has not been the focus of direct appraisal.

Patient education material is most often evaluated for its readability, in which a grade level is assigned to reflect the ease with which information might be understood.⁸ Numerous studies have shown correlations between low literacy levels and lower levels of health.^{9,10} Plain-language guidelines and recommendations exist for the generation of print health education.^{11–13} Recent evaluation of text-based patient education material has focused on analysis of the content and structural functionalist linguistics embedded within the text.¹⁴ The persuasive power of words has been analyzed in healthcare providers' communications regarding behavior modification,¹⁵ decision making,¹⁶ and adherence to treatment.¹⁷ Evaluation of the use of persuasion in direct-to-consumer advertising is a common theme of analysis.¹⁸ Direct-to-consumer advertising has been analyzed for its persuasive overtones

based on the premise that persuasion is more appealing to audiences than instructional information is.^{18,19} To our knowledge, no analysis exists in relation to any of these aspects of the print materials directed at patients who are offered an ICD, yet such patient education materials are routinely offered to and sought out by patients who are in the process of accepting or declining the intervention.

Print patient education materials are one of a variety of tools offered to and sought out by patients who are undergoing health-related interventions such as ICD implantation. As such, these materials may be used to ensure that consent for interventions is informed, that patients understand the purpose, risks, benefits, and implications before and after the procedures offered to improve their health. In this article, we report on our evaluation of print material made available to patients who were candidates for an ICD for primary prevention indication. The material was evaluated with respect to its readability, content, and rhetorical messages. Although it is beyond the scope of this article to address the time or way in which patients used these materials or the influence of specific materials, the findings have significance for the creation of print educational material directed at ICD candidates and for medical professionals who use such materials while assisting ICD candidates during the informed consent, decision-making, and postimplantation time periods.

Methods

We report on a subset of data from a larger study exploring patients' decision making to accept or decline an ICD for a primary prevention indication from 3 sites in southern Ontario, Canada.²⁰ Ethics approval for the study was obtained from all 3 study sites. During interviews with participants who had accepted or declined an ICD for primary prevention, participants were asked to identify and share with the interviewer any written material they had obtained about the ICD before or after their decision to accept or decline the ICD. The analyzed materials were documents available to participants (and to the public-at-large) in ICD waiting room areas and/or given to them by their physicians or nurses at some point before or after their decision to accept or decline the ICD. Pamphlets related to ICDs were gathered during the recruitment process from waiting areas of the 3 sites and retrieved from the recruitment sites after the interviews by a research assistant. We conducted readability testing and content analysis focusing on the themes represented in the educational material and the rhetoric implied in its messages.

We were conscious that each member of the investigative team had preexisting beliefs, interests, and experiences that could affect the analysis. We began by surfacing these in team meetings and adopted a dialectical approach to the analysis. Meeting and analysis notes were kept to record issues, questions, and decisions at each phase of the analysis process. Analysis was conducted by P.H.S. (a nurse scientist with expertise in qualitative methods), S.d.L. (a master's-prepared research assistant), and 2 fourth year nursing students (G.K.T. and K.V.).

Two readability tests, the SMOG ("simple measurement of gobbledygook")²¹ and Fry²² methods, were used to cross-check the grade-level calculations. The SMOG method samples 30 sentences combined from the beginning, middle, and end of the document to provide an

overall average grade level. The Fry method plots 3 samples of 100 words on a grade-level graph to determine readability scores. Both of these testing methods were developed in the late 1960s to facilitate readability testing, and both have been used extensively in the generation and evaluation of medical education material, with SMOG being endorsed by the National Institutes of Health in preparing government documents.²³ Two analysts (K.V. and G.K.T.) independently conducted SMOG and Fry analysis on all documents, and we met to discuss and critically review issues that arose in applying the readability assessment tools.

Because readability cannot be measured by syllable count and sentence length alone, we also developed analysis criteria (Table 1) based on the recommendations from several authorities on the development and evaluation of patient education material.^{12,13,24,25}

In addition, we analyzed the text for content and rhetorical tone. Content analysis informed by Krippendorff²⁶ structured this aspect of the methodological approach. Following Krippendorff, we questioned the material, incorporated relative context, and generated inferences about the data. Thematic content analysis of the 21 print documents was done by 3 team members (P.H.S., G.K.T., and K.V.). We began by developing an a priori list of themes based on a scan of the documents. Two of the analysts (G.K.T. and K.V.) independently coded each of the documents using the a priori list as a guide. Several subthemes were identified and the team met to review the analysis, discuss and challenge coding decisions, establish interrater reliability, and reach consensus. Finally, 12 overarching content themes were identified.

We then used a rhetorical lens to analyze and explore language and images in the documents for persuasive tones, thereby extending the analysis beyond descriptive content analysis. Whereas content analysis incorporates reflection on the meaning and messages being conveyed, rhetorical analysis aims to highlight the literary and visual symbols used to persuade readers and viewers to the author's intended message. The texts were reviewed in their entirety for persuasive tones that appeared mainly in metaphors, in bolded statements, in adjective and adverb use, and in the juxtaposition of images with text. The attribution of meaning to text and images is culturally constructed and can be misunderstood depending on personal and historical circumstances.²⁷ Three team members (P.H.S., S.d.L., and G.K.T.) reviewed the texts independently for rhetorical messages and tone. Before and at points during the analysis process, the analysts encouraged and challenged each other to reflect on their interpretations and surface preexisting biases. After several rounds of this process, consensus about the rhetorical meaning was achieved.

Findings

The participants from the larger decision-making study represent the demographics of study individuals who were offered an ICD for primary prevention. We highlight relevant demographics in Table 2.

Overall, 21 educational documents were reviewed. All material was intended for patients who had primary or secondary indications for an ICD. The materials reviewed had publication dates ranging from 2005 to 2008, with 1 document from 2000. Twelve documents were published by ICD manufacturers, 6 were sitespecific hospital publications,

and 3 were published by 2 different cardiac support organizations. Hospital documents tended to be easily reproducible letter-size pages or booklets that contained few (if any) colors and minimal illustrations. Manufacturer and support organization publications were more often full-color, glossy pamphlets with photographs and illustrations throughout. Generally, the information that related to anatomy, physiology, pathophysiology, device function, and therapeutic intent was consistent across all the materials. Inconsistencies that occurred tended to be in relation to perioperative care. Device manufacturer documents tended to focus on anatomy, pathophysiology, the purpose and function of the ICD, and impact of the device on lifestyle. Hospital-generated material focused more specifically on function of the ICD and perioperative management.

Overall, documents published by device manufacturers had lower readability scores and more simple design layouts. However, these documents also contained more persuasive language and images than did those published by hospitals and support organizations. Consistent messages were found across all the documents and contradictions were minimal; however, the depth and breadth of the content in each document varied.

Language, Word Use, and Readability

Although readability testing considers the number of polysyllabic words per text sample (number of words or number of sentences), it does not make visible the use of scientific jargon or the use of active and passive voice. All but 5 documents contained complicated scientific jargon, and an active voice was used in all documents. Scientific jargon was commonly used to describe clinical symptoms such as ventricular tachycardia or bradycardia. In most cases, these terms were followed by an explanation, but not always a simple one. In other cases, jargon was used unnecessarily. For instance, one pamphlet stated that the hospital will “try to interrogate the device” if an ICD recipient died at some point in the future. Because jargon may use few syllables, and active/passive voice cannot be measured in readability tests, the scores listed in Table 3 are only a partial measurement of the documents’ readability. The analysis we undertook extends further than traditional readability by incorporating the document design features and language use.

In some cases, a large discrepancy in readability scores existed within a document; this can be attributed to the randomness of the selected text sampled by the independent analysts. We subsequently calculated an average readability score for the final measure. There was a large variation in the readability of the materials; the reading level ranged from grade 9 to 15 and from 9 to 19 years of age or more. Ninety-five percent of the documents in our sample scored a higher than a grade 8 reading level. Half of the documents’ readability scores were in the upper high school, lower university years range (grade 11 and higher). All 3 author types (manufacturers, hospitals, and support groups) are represented in the half of documents requiring higher reading abilities. The 3 lowest scoring documents were from a device manufacturer, hospital, and cardiac health support organization respectively.

Typography

All but 1 document (a hospital-manufactured, photocopied information pamphlet that appears to have been reduced in size during reproduction) used 11 or 12 font type. Three

hospital-manufactured documents used 14-point font. The majority (66.6%) used a Serif font similar to Times New Roman. All but 3 incorporated typographic cues such as bullets and numbering to facilitate directing readers, and all used subheadings to help organize content.

Graphics, Illustrations, and Tables

All but 3 of the documents provided illustrations/images on the pamphlet's front cover. None of the covers contained an ICD in its main picture. A total of 6 documents, 4 from device manufacturers, did not have any internal images. Generally, internal images did not have captions explaining their representations, and more often, the images did not correspond to the nearby text. For example, one device manufacturer repeatedly included images of male seniors playing with a child, presumably a grandchild, or playing golf, next to text about ventricular tachycardia or warning signs of SCD risks. Six documents contained images of the ICD, the heart muscle, or both that provided a visual representation of (a) the ICD's implant location in relation to the heart, (b) the parts of the heart, or (c) parts of the ICD.

Layout, Space, and Paper

Only 5 documents, all from device manufacturers, used glossy paper. The others used uncoated, matte paper. Hospitals were least likely to use full color; the 6 documents reproduced in black and white were from this source. All of the documents incorporated white space in their design, avoiding filling up all areas of the page with text and illustration that could tire or overwhelm the reader. All but 2 used visual cues such as shaded boxes and arrows to help guide readers through the material. Contrast between the text, images, and paper was also used successfully in almost all cases.

Audience Relevance and Appropriateness

The documents did contain material relevant to their intended audience—mainly older adults. The language and words used, although of a high literacy level, were neutral in terms of being directed at any specific audience. There was no mention of age or age-related activities, neither were specific terms relating to any one cultural group used. The accompanying images in the documents that included images of people (mainly those from device manufacturers) were culturally diverse and age specific: older adults of various ethnic backgrounds.

Content Analysis

The patient education documents were analyzed for content. Twelve themes, listed in Table 4, were identified that reflected the descriptive content of the documents. The themes were used to subsequently analyze the consistency of and rhetoric in the document messages.

Rhetoric and Language

Metaphors and persuasive language were used throughout the documents from all 3 publication sources (manufacturer, hospital, and cardiac organization). Compelling lifesaving aspects of the ICD, monitoring functions, and promotional messages were presented with strong language and exclamation marks. Manufacturers of ICD compared the

device to “It’s like having a paramedic with you at all times.” Hospital-generated publications explained that “ICDs have saved the lives of hundreds of thousands of people around the world” and that the device “allows you to lead a life that is as good as or better than you could before ICD treatment.” Other statements similar to “Talk to your doctor today!” and the ICD “stops certain deadly heart arrhythmias before they kill” were found in the manufacturer and support organization documents, respectively. Furthermore, the images included in many of the documents, mainly those from ICD manufacturers, were persuasive in that they presumably represented ICD recipients living active, healthy, happy lives. Even potentially frightening or negative information was presented in a positive light. For instance, one device manufacturer pamphlet about coping with an ICD includes the heading “Pay attention to feeling alive and well.”

Discussion

The patient education materials that ICD candidates use to assist them to make an informed decision to accept or decline the ICD are critically important. The information made available in patient education documents is crucial to free and informed consent. It is therefore imperative that information endorsed by those who offer ICDs is not confused with marketing material that is intentionally persuasive. Information for consent ought to be open to options and free from hyperbole or other techniques used to lead to an affirmative response. Any use by clinical care providers of manufacturers’ documentation ought to be balanced with realistic information about risks and harms associated with the technology and treatment.

Evaluation of the patient material used by participants in a larger decision-making study who were offered an ICD for primary prevention reflects that efforts have been made to inform patients about many important aspects of the ICD.²⁰ However, there were areas in which readability, content, and intended messages could be improved. The print documents examined in this study constituted the only written documents patients identified as available to them for any purpose in relation to the ICD. Given that none of these documents had as its expressed intent, a focus on the decision to accept or reject an ICD, it is important to keep in mind that the intent with which the materials were produced, made available to patients, and used by them may be different.

Despite attempts to the contrary, many patient education documents continue to be produced that have higher than recommended reading levels and layout features that inhibit ease of comprehension.^{24,28–30} Although a high percentage of Canadians can read at a high school level or above, nearly 42% of Canadians have low literacy skills.³¹ In the United States, approximately 30% of adults older than 65 years operate at a below basic literacy level³² and an estimated 90 million people (or 36% of the population) function at a basic or below basic level of health literacy. Based on these figures, most plain-language guidelines suggest that reading levels should generally not exceed grade 8, although depending on the audience, this could range between grades 5 and 10.^{11,12,23} It follows that patient education material should be easy to comprehend not only for those with poor literacy skills but also for those with low health literacy skills.

Both authors of patient education literature and healthcare professionals need to keep in mind that reading may be a difficult skill for some and that reading about medical procedures, in particular, may be even more difficult.³³ Variables such as age and health can also have an impact upon literacy. According to the US National Center for Educational Statistics,³⁴ adults older than 65 years exhibit a reduction in literacy skills, particularly when it comes to comprehending new information (as opposed to information recall). Furthermore, the state of one's health can affect a person's comprehension and decision-making abilities.^{34,35} These issues are likely relevant for the average ICD recipient in Canada, who is 64 years of age and living with ischemic heart disease and varying degrees of heart failure symptoms.³⁶

Plain-language guidelines^{11-13,23} suggest that education material should limit use of specialized language, avoid long sentences, incorporate an active voice, and incorporate diagrams or images along with visual and typographic cues, with an effective use of white space and contrast to facilitate reading and comprehension. These criteria have been recommended for low-health-literacy cardiovascular patients.²⁵ Overall, the material we reviewed did that. Where documents fell short was in their use of specialized language and glossy paper or in the use of only black and white productions. Technical jargon, although sometimes unavoidable, was consistently present and not always necessary or simply explained. Glossy paper has also been shown to be more difficult for people with vision problems to see the text properly,^{11-13,23} and the efficient use of color, contrast, and white space can contribute to reading comprehension.^{11-13,23}

The documents reviewed addressed essential themes including the relevant physiology, device descriptions, the implantation procedure, device maintenance, and postoperative and post-ICD shock care. However, there was some information noticeably lacking. The only ICD complications imparted were related to risks associated with the implantation process itself or possible emotional and psychological adverse effects. There was scant mention of potential misfires or of the device possibly not working when it should and no mention of product advisories or of end-of-life issues such as the potential to turn off the device (except for 1 source that discussed removal of the device in the event of cremation). The lack of consideration of death by any other cause by those who choose ICD for primary prevention discourages patients from comprehensive end-of-life and advanced care planning.³⁷

Conversely, the focus of the material was on the potential positive benefits of having an ICD. Particularly from, but not exclusive to, device manufacturer material, there was an emphasis on the lifesaving and exclusivity aspects ("your new ICD lifestyle") of the implant. Positive statements, although not false, are highly loaded. Language is not value neutral.¹⁴ In applying a rhetoric lens to the content analysis, the cultural construction of the messages being imparted to the readers was apparent. The text and images represent realities that hospitals and manufacturers want to promote and highlight and may not reflect all information that may be relevant for patients. Other realities such as (a) ICDs are not intended to improve quality of life or (b) ICD shocks have been shown to reduce quality of life, especially if shocked 3 or more times,^{38,39} were not the focus of the messages (neither literally nor figuratively). The persuasive tone could strongly affect individuals when deliberating about the device.

Images can also be persuasive. Patients (intended audiences) were represented by photographs of male and female seniors of various ethnic backgrounds. That few pamphlets included images of people in their middle age suggests that the device is targeted to seniors, presumably only active seniors (as that is what is represented in the images). Alternatively, other images suggest that the ICD can help improve activity (which is not the purpose of a standard ICD). Including images of younger ICD recipients and explaining clearly that a standard ICD will not correct symptoms or improve physical health would assist patients to correctly interpret print education materials.

Studies have shown that as little as 20% of verbal information is retained by patients,⁴⁰ but when used in conjunction with print material, retention rates are around 50%. When using print material to support consultations, medical professionals should keep in mind the messages embedded in the material, the fact that patients may interpret the meaning differently at different stages of the patients' health trajectory, and that variable literacy and health literacy skills can have a negative impact on patients' comprehension and, therefore, their decision making. It is also important that patient education materials be created and made available to diverse populations, including those for whom English is a second language. Print material should be current and reflect the most up-to-date information about ICDs.

Patients receive print information developed as hospital publications and from device manufacturers. Hospital material is often created in-house by individual departments or patient education committees. It is also common that education material be made in association with a device manufacturer. The expense of producing patient education materials makes the use of those developed by device manufacturers understandable. Manufacturer's documents arguably⁴¹ straddle the definitions of patient education material and direct-to-consumer advertising. Considering that many hospitals may substitute in-house documents for those given freely by manufacturers, there is an onus on healthcare practitioners who encourage patients to use industry-prepared documents to consider the readability, content, and rhetoric in relation to individual patient contexts. They should also assist patients to filter the hyperbole and persuasion to ensure that they obtain balanced information (interpreted to their specific context).

Development of print materials is indicated that includes information about possible problems and that would be relevant for the multicultural and diverse population who may require ICDs. Criteria for the development of print materials should be in accordance with guidelines from authorities in this regard.^{11-13,25} Future studies should evaluate the impact and effectiveness of print and other educational materials in assisting patients to make a decision for an ICD.

Limitations

We analyzed the print material that study participants reported receiving; it is possible that they forgot about other publications they received. It is beyond the scope of this article to evaluate how ICD candidates used these print materials in assisting with decision making. We do not know how nurses and physicians who gave the print materials to the patients may

have supplemented and/or individualized the information or responded to questions raised by the information. Although slightly more than half of patients who may have used these materials had postsecondary education or higher, we do not know their literacy level or their health literacy level, and consequently, we do not know whether there was a match between the reading level of the participants and the texts of the ICD patient education materials.

Conclusion

Print materials available to patients who are candidates to receive ICDs offer patients with a high reading level an opportunity to be well informed about the positive aspects of ICDs. The use of persuasive language and the failure to include some of the negative consequences of ICDs that have been reported by some patients (and in the literature) reflect gaps that exist in the comprehensiveness of the print information that patients currently receive.

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References

1. Connolly SJ, Hallstrom AP, Cappato R, et al. Metaanalysis of the implantable cardioverter defibrillator secondary prevention trials. *Eur Heart J*. 2000; 21(24):2071–2078. [PubMed: 11102258]
2. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med*. 2009; 346(12):877–883.
3. Vogt A. Establishing an ICD support group. *Adv Nurse Pract*. 2006; 14(9):59–60.
4. Dickerson SS. Technology-patient interactions: Internet use for gaining a healthy context for living with an implantable cardioverter defibrillator. *Heart Lung*. 2005; 34(3):157–168. [PubMed: 16015220]
5. Serber E, Finch N, Leman R, et al. Disparities in preferences for receiving support and education among patients with implantable cardioverter defibrillators. *Pacing Clin Electrophysiol*. 2009; 32(3):383–390. [PubMed: 19272070]
6. Luderitz B, Wolpert C. The patient's informed consent for pacemakers and ICD implantation: how to write and how to explain it. *Z Kardiol*. 2003; 92(5):377–383. [PubMed: 12966829]
7. Withell B. Patient consent and implantable cardioverter defibrillators: some palliative care implications. *Int J Palliat Nurs*. 2006; 12(10):470–475. [PubMed: 17167379]
8. Bastable, SB. *Nurse as Educator: Principles of Teaching and Learning for Nursing Practice*. 3. Sudbury, MA: Jones and Bartlett; 2008. p. 667
9. Weiss B, Hart G, Pust R. The relationship between literacy and health. *J Health Care Poor Underserved*. 1991; 1(4):351. [PubMed: 1932458]
10. Weiss B, Palmer R. Relationship between health care costs and very low literacy skills in a medically needy and indigent Medicaid population. *J Am Board Fam Pract*. 2004; 17(1):44. [PubMed: 15014052]
11. Canadian Public Health Agency. *Directory of Plain Language Health Information*. Ottawa, Ontario, Canada: Canadian Public Health Association; 1999.
12. Centers for Disease Control and Prevention. *Scientific and Technical Information Simply Put*. 2. Atlanta, GA: Office of Communication; 1999.

13. National Cancer Institute. Clear and Simple: Developing Effective Print Materials for Low-Literate Readers. Bethesda, MD: US Department of Health and Human Services; 1994.
14. Kealley J, Smith C, Winser B. Information empowers but who is empowered? *Commun Med*. 2004; 1(2):119–129. [PubMed: 16808695]
15. Orbell S, Kyriakaki M. Temporal framing and persuasion to adopt preventive health behavior: moderating effects of individual differences in consideration of future consequences on sunscreen use. *Health Psychol*. 2008; 27(6):770–779. [PubMed: 19025273]
16. Karnieli-Miller O, Eisikovits Z. Physician as partner or salesman? Shared decision-making in real-time encounters. *Soc Sci Med*. 2009; 69(1):1–8. [PubMed: 19464097]
17. Smith VA, DeVellis BM, Kalet A, Roberts JC, DeVellis RF. Encouraging patient adherence: primary care physicians' use of verbal compliance-gaining strategies in medical interviews. *Patient Educ Counsel*. 2005; 57(1):62–76.
18. Holmes ER, Desselle SP. Evaluating the balance of persuasive and informative content within product-specific print direct-to-consumer ads. *Drug Info J*. 2004; 38(1):83–98.
19. Huh J, DeLorme DE, Reid LN. Media credibility and informativeness of direct-to-consumer prescription drug advertising. *Health Mark Q*. 2004; 21(3):27–61. [PubMed: 15739826]
20. Carroll SL, Strachan PH, de Laat S, Schwartz L, Arthur HM. Patients' decision-making to accept or decline an implantable cardioverter defibrillator for primary prevention of sudden cardiac death. *Health Expect*. Epub ahead of print.
21. Mc Laughlin H. SMOG grading -- a new readability formula. *J Read*. 1969:639–646.
22. Fry E. A readability formula that saves time. *J Read*. 1968; 11:513–516.
23. Executive Secretariat. The plain language initiative. Bethesda, MA: National Institutes of Health; 2003. <http://execsec.od.nih.gov/libaccess.lib.mcmaster.ca/plainlang/guidelines/evaluating.html> [Accessed July 27, 2011]
24. Hill-Briggs F, Smith A. Evaluation of diabetes and cardiovascular disease print patient education materials for use with low-health literate populations. *Diabetes Care*. 2008; 31(4):667–671. [PubMed: 18202245]
25. Dennison Himmelfarb C, Hughes S. Are you assessing the communication “vital sign”? Improving communication with our low-health-literacy patients. *J Cardiovasc Nurs*. 2011; 26(3):177–179. [PubMed: 21483247]
26. Krippendorff, K. *Content Analysis: An Introduction to Its Methodology*. Vol. 2. Thousand Oaks, CA: Sage Publications; 2004.
27. Kress, G. *Linguistic Processes in Sociocultural Practice*. Geelong, VI: Deakin University Press; 1985.
28. Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *N Engl J Med*. 2003; 348(8):721–726. [PubMed: 12594317]
29. Weih M, Reinhold A, Richter-Schmidinger T, Sulimma AK, Klein H, Kornhuber J. Unsuitable readability levels of patient information pertaining to dementia and related diseases: a comparative analysis. *Int Psychogeriatr*. 2008; 20(6):1116–1123. [PubMed: 18588726]
30. Ache KA, Wallace LS. Are end-of-life patient education materials readable? *Palliat Med*. 2009; 23(6):545–548. [PubMed: 19460831]
31. Barr-Telford, L., Nault, F., Pignal, J. *Building on Our Competencies: Canadian Results of the International Adult Literacy and Skills Survey*. Ottawa, Ontario, Canada: Minister of Industry; 2005.
32. Kutner, M., Greenberg, E., Jin, Y., Boyle, B., Hsu, Y., Dunleavy, E. *Literacy in Everyday Life: Results From the 2003 National Assessment of Adult Literacy*. Washington, DC: US Department of Education: National Centre for Education Statistics; 2007.
33. Institute of Medicine. *Health Literacy: A Prescription to End Confusion*. Washington, DC: National Academies Press; 2004.
34. Kutner, M., Greenberg, E., Jin, Y., Paulsen, C. *The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy (NCES 2006-483)*. US Department of Education. Washington, DC: National Center for Education Statistics; 2006.

35. Morrow D, Clark D, Tu W, et al. Correlates of health literacy in patients with chronic heart failure. *Gerontologist*. 2006; 46(5):669–676. [PubMed: 17050758]
36. Lee DS, Birnie D, Cameron D, et al. Design and implementation of a population-based registry of implantable cardioverter defibrillators (ICDs) in Ontario. *Heart Rhythm*. 2008; 5(9):1250–1256. [PubMed: 18774098]
37. Strachan PH, Carroll SL, de Laat S, Schwartz L, Arthur HM. Patients' perspectives regarding end-of-life issues and implantable cardioverter defibrillators. *J Palliat Care*. 2010; 27(1):6Y11.
38. Juan EA, Pollack M. Phantom shocks in patients with an implantable cardioverter defibrillator. *J Emerg Med*. 2010; 38(1):22–24. [PubMed: 18394854]
39. Kamphuis HCM, de Leeuw JRJ, Derksen R, Hauer RNW, Winnubst JAM. Implantable cardioverter defibrillator recipients: quality of life in recipients with and without ICD shock delivery. *Europace*. 2003; 5(4):381–389. [PubMed: 14753636]
40. Moulton B, Franck L, Brady H. Ensuring quality information for patients: development and preliminary validation of a new instrument to improve the quality of written health care information. *Health Expectat*. 2004; 7(2):165–175.
41. Verdino R. Direct-to-consumer advertising of implantable defibrillators: a shocking development or just keeping pace with the times? *Expert Rev of Cardiovasc Ther*. 2007; 5(4):607–609. [PubMed: 17605635]

What's New and Important

- Print-based patient education materials aimed at implantable cardioverter defibrillator (ICD) candidates are developed for a highly literate population.
- Print-based educational materials to assist patients in their decisions about an ICD are lacking.
- Manufacturer's ICD patient education material focused on the positive, persuasive, and lifesaving aspects of the ICD to the exclusion of alternatives or potentially negative issues such as product recalls and inappropriate shocks and failed to discuss alternatives to accepting an ICD and end-of-life issues such as deactivation.
- The development of ICD print materials that take an educational versus marketing approach is indicated, should include information about possible negative ICD-related issues and challenges, and should be relevant for a diverse and low (health) literate population who may be offered an ICD.

Table 1

Print material evaluation criteria

Evaluation Criteria	Definition
Language, word use and readability	Use of scientific jargon, multisyllabic words, active/passive voice, sentence length
Typography	Font size, font type (serif/sans-serif), typographic cues, subheadings, capital headers
Graphics, illustrations and tables	Cover graphic, graphic simplicity, captions, text beside illustration, distract or reflect message in text
Layout, space and paper	Glossy/matte, color/black and white, simple layout, visual cues, white space, contrast, color usage
Audience relevance and appropriateness	Intended audience, language that reflects audience, images culturally appropriate

Evaluation criteria extracted from the Canadian Public Health Agency,¹¹ Centers for Disease Control and Prevention,¹² and National Cancer Institute.¹³

Table 2

Participant characteristics

Male, n	33
Female, n	11
Age, mean (SD), y	65 (12.5)
Age range, y	26–87
Mean LVEF*	27%
≥ 2 co-morbid health conditions (diabetes, COPD, etc.)	52%
Post-secondary education or higher	52%
Residing ≤ 50 km from tertiary centre	52%

Abbreviations: COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction.

Table 3

Readability scores of select ICD patient education material

Title	Reading Level (SMOG)	Reading Level (Fry)	Author Type
A Heart Attack Survivor's Guide to Avoiding Sudden Death	Grade 12	16 years	Manufacturer
All About ICDs	Grade 11	17 years	Manufacturer
ICD Coping Strategies	Grade 11	12 years	Manufacturer
Questions about Driving Living with your ICD	Grade 10	>19 years	Manufacturer
Questions about Traveling Living with your ICD	Grade 11	10 years	Manufacturer
Questions about therapy Living with your ICD	Grade 12	>19 years	Manufacturer
Questions about Lifestyle Living with your ICD	Grade 9	9 years	Manufacturer
Questions asked by those who live with an ICD patient Living with your ICD	Grade 10	14 years	Manufacturer
Patient Registration and Identification Cards Living with your ICD	Grade 11	19+ years	Manufacturer
Questions about activities and intimacy Living with your ICD	Grade 10	15 years	Manufacturer
What's inside an ICD?	Illustration pamphlet; not enough words	15 years	Manufacturer
More Help for Heart Device Patients Electromagnetic Compatibility Guide	Mainly lists: not enough words	16 years	Manufacturer
You and Your ICD (Implantable Cardioverter Defibrillator)	Grade 9	8 years	Manufacturer
Cardiac Rehabilitation & Secondary Prevention Program	Grade 15	18 years	Cardiac support organization
Take Control: Actions to Lower Your Risk	Grade 10	18 years	Cardiac support organization
ICD: Arrhythmia Service	Grade 12	18 years	Hospital
We're here to help you	Grade 13	>19 years	Hospital
Frequently Asked Questions Pre-ICD (Implantable Cardioverter Defibrillator) Placement	Grade 11	14 years	Hospital
Pacemaker, ILR and ICD Procedure Patient Information	Mainly point form: not enough words	15 years	Hospital
Implantable Cardioverter Defibrillators (ICDs)	Grade 12	17 years	Hospital
The Patient's Guide to the Implantable Cardioverter Defibrillator	Grade 9	19 years	Hospital

Abbreviations: ICD, implantable cardioverter defibrillator; ILR, insertable loop recorder, SMOG, "simple measurement of gobbledygook."

Table 4

Content themes of implantable cardioverter defibrillator patient education material

Theme	Content	Publication sources
Purpose and function of the ICD	Risk for sudden cardiac death: arrhythmias such as ventricular tachycardia, ventricular fibrillation, and bradycardia (2) Purpose of the ICD: variously described as “a device that monitors and treats abnormal heart rhythms” Function of the ICD: explication of the device’s monitoring and data storage capabilities, how it detects and treats arrhythmias, and general parts descriptions	ICD manufacturers, hospitals, cardiac health support groups
Anatomy, physiology and pathophysiology	Anatomy and physiology of electrical and mechanical systems of the heart, basic heart anatomy, ejection fraction, normal and abnormal heart rhythms Pathophysiology of sudden cardiac arrest, heart attack, heart failure, and arrhythmias such as ventricular tachycardia, ventricular fibrillation, and bradycardia	ICD manufacturers and hospitals
Diagnostic tests	Echocardiograms One hospital provided information on other possible tests including multi-gated angiography (MUGA), electrophysiology study (EPS), their graded exercise test, and electrocardiograms	ICD manufacturers and hospitals
Pre-operative instruction	Fasting before the procedure, taking medications prior to the procedure, and having someone drive the patient to and from the hospital for the procedure	Hospitals
Implantation process	Decisions around implant site, description of incision(s), explanation of lead placement, testing to ensure correct function, and description of sedation and day surgery	Two hospitals
Post-operative care	Care instructions and suggestions for up to six weeks post-implantation Incision care, signs of infection, exercise, refraining from heavy lifting and physical activity, pain management, medications, and other short-term medical care issues	Hospitals
The ICD shock	Shock event and post-shock instructions, the sensation of the shock, possible transfer of shock to others, post-shock follow-up care, abnormal heart rhythm symptom, indications to seek medical attention, importance of support from family and friends, and refrain from leaning on counters or hard surfaces The shock was described as a, “kick in the chest” (22) by many sources. It was indicated to “stop what you are doing” (22) when receiving a shock by many sources.	ICD manufacturers and hospitals
Maintenance of the ICD	Importance of follow-up visits and content of these visits Device checked for proper function bring; data retrieved and reviewed; ICD settings can be adjusted during appointments; ICD replacement procedure; having a medic alert bracelet and keeping files up to date; battery life; carrying ICD identification at all times; keep diary of medications and shocks; bring all medications to appointments; check-up for incision site	ICD manufacturers and hospitals
Lifestyle	Short-term and long-term lifestyle changes including preparing for and preventing a possible shock Activities of daily living such as, travelling, intimacy/sex, driving, leisure activities (i.e. bowling, golf, etc.), and returning to work Restrictions around being near electrical & magnetic fields (i.e. medical diagnostics, household appliances), diet, and medications Support groups were suggested in manufacturer generated documents. Appearance of the incision and what to wear was also discussed	ICD manufacturers and hospitals
Complications	Risk of infection Implant procedure risks Inappropriate or missed therapy Psychological obstacles	ICD manufacturer and hospital
End-of-life Issues	Only one document provided a statement that the device can be buried with the deceased individual or removed if they are to be cremated.	Hospital
Additional Resources	Sources for additional information on the device, procedure, and patient care.	ICD manufacturer, hospital and cardiac health support organizations