Readability of "Dear Patient" device advisory notification letters created by a device manufacturer

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BACKGROUND In 2006, the Heart Rhythm Society (HRS) recommended that cardiovascular implantable electronic device (CIED) manufacturers use advisory notification letters to communicate with affected patients.

OBJECTIVE To evaluate the readability of the HRS sample "patient device advisory notification" letter and those created by 1 CIED manufacturer.

METHODS The HRS sample letter and 25 Boston Scientific Corporation letters dated from 2005 through 2011 were evaluated by using 6 readability tests.

RESULTS Readability (Flesch-Kincaid score) of the HRS sample letter was grade level 12.5, and median readability of the device manufacturer letters was grade level 12.8 (range 10.8–18.9). Similar results were obtained by using other readability scales. No letters had readability scores at the National Work Group on Literacy and Health's recommended reading level—fifth grade; the letters' readability exceeded this recommended level by an average of 7.7 grades (95% confidence interval 6.9–8.5; $P < .001$). Likewise, no letters had readability scores at the average reading level of US adults—eighth grade; the letters' readability exceeded this level by an average of 4.7 grades (95% confidence interval 3.9–5.5; $P < .001$).

CONCLUSIONS The readability of the HRS sample letter and those created by a CIED manufacturer significantly exceeded the recommended and average US adults' reading skill levels. Such letters are unlikely to be informative to many patients. CIED manufacturers should ensure that advisory letters are comprehensible to most affected patients.

KEYWORDS Advisory, device; Cardiovascular implantable electronic devices; Decision making, patient-centered; Ethics; Health-care communication; Health-care literacy; Recall, device

ABBREVIATIONS CIED = cardiovascular implantable electronic device; **FDA** = US Food and Drug Administration; **HRS** = Heart Rhythm Society

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Introduction

Cardiovascular implantable electronic device (CIED) malfunctions occur[1,2] and may involve any part of the CIED system (eg, pulse generator and lead). Device manufacturers monitor CIED malfunctions through reports by patients, clinicians, and field representatives. If a malfunction is severe or has a greater occurrence rate than anticipated, the manufacturer notifies the US Food and Drug Administration (FDA) and physicians by issuing a "safety alert," "recall," or "product advisory."[1,3] The FDA subsequently classifies the advisory (eg, "I" for serious and "III" for unlikely to cause harm).[4]

In recent years, thousands of patients have been affected by CIED advisories.[2,5,6] Timely identification of device malfunctions and communication of advisories are important for patient safety. However, patients affected by CIED advisories may experience psychological distress.[7–9] Because inadequate communication may contribute to this distress, manufacturers and clinicians should communicate clearly with and provide understandable information to affected patients.[1,10,11]

To promote transparency and communication regarding CIED advisories, the Heart Rhythm Society (HRS), in a 2006 position paper,[1] recommended that manufacturers use a "patient device advisory notification" letter to communicate with affected patients (ie, a "Dear Patient" letter). The HRS also recommended that the notification reside on the manufacturer's Web site and "be linked to [HRS's] website, the FDA enforcement reports, and to other notifications to facilitate easy access to all components of each individual device advisory."

Using a "Dear Patient" letter as a tool to communicate with patients about CIED advisories, however, necessitates attention to health literacy. Research has shown that

Portions of the Methods section describing the 6 readability scales were previously published in Mueller et al (BMC Med Ethics 2010;11:6), used under the terms of the Creative Commons Attribution License. Dr Mueller is a member of the Boston Scientific Patient Safety Advisory Board and an associate editor for Journal Watch General Medicine. Dr Sharma is the senior medical director at Boston Scientific Corporation. AL Ottenberg, MA, and PS Mueller, MD, are part of the Mayo Clinic Program in Professionalism and Ethics. **Address reprint requests and correspondence:** Dr Paul S. Mueller, Division of General Internal Medicine, Mayo Clinic, 200 First St SW, Rochester, MN 55905. E-mail address: mueller.pauls@mayo.edu.

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health-care-related materials (eg, medication labels and informed consent forms) are incomprehensible to most US adults.[12–14] Also, low health literacy is associated with poor health outcomes.[15] Given this situation, the National Work Group on Literacy and Health recommends a fifth-grade readability level for health-care-related materials.[13] Thus, "Dear Patient" CIED advisory letters that are difficult to read and understand may not serve their intended purpose.

In this study, we analyzed readability of HRS's "Dear Patient" letter[1] and 25 similar letters for actual CIED advisories created by a single manufacturer.

Methods

The study used methods as previously described.[16] We evaluated the HRS patient notification letter,[1] 7 letters created by Guidant Corporation (acquired by Boston Scientific Corporation in 2006), and 18 created by Boston Scientific. These letters were distributed to clinicians for use with patients from June 2005 through March 2011.

Readability

Readability analyses were performed by using Readability Studio for Windows (Oleander Software, Ltd). The 6 readability scales were the Flesch-Kincaid, Automated Readability Index, Linsear Write, New Fog Count, Simplified Automated Readability Index, and Flesch Reading Ease Scale Value; each attributed varied emphasis on variables as described below. Except for the Flesch Reading Ease Scale Value (which measures readability on a scale of 1–100), each test generated a grade level (range 0–19) or age (range 5–24 years) that represented the youngest reader who can process the material. For example, a score of 9.0 indicates that the text is written at a reading level of ninth grade. The 6 scales differ in how they determine grade levels of the text.

Flesch-Kincaid

It is influenced by sentence length and syllable count. Shorter sentences and less complex words lower the score.

Automated Readability Index

It is influenced by sentence length and character count. Shorter sentences and shorter words lower the score.

Linsear Write

It is influenced by sentence length and words containing 3 or more syllables. Shorter sentences and less complex words of only 1 or 2 syllables lower the score.

New Fog Count

It is a modified version of the Gunning Fog Index and influenced by words containing 3 or more syllables. Less complex words lower the score.

Simplified Automated Readability Index

It is a modified version of the Automated Readability Index and influenced by sentence length and character count. Shorter sentences and words lower the score.

Flesch Reading Ease Scale Value

It is influenced by sentence length and syllable count. It does not identify a reading grade level. Instead, it provides a score between 0 and 100, and the higher the score, the easier the read. Use of shorter sentences and less complex words increase the score.

Statistical analysis

Using 1-sample *t* tests, the mean readability scores (as determined by the Flesch-Kincaid readability scale) were compared with the recommended readability level of health-care-related materials from the National Work Group on Literacy and Health (fifth grade) and the average reading level of US adults (eighth grade). The Flesch-Kincaid scale was selected because it is the most commonly used of the 6 scales and the outcomes are validated.[17,18] All *t* tests and analyses for this project were conducted by using a statistical software package (JMP 9, SAS Institute Inc, Cary, NC).

Results

We examined the HRS sample letter and 25 letters from Boston Scientific. Generally, letters were 1 page long (only 2 letters were slightly longer than 1 page) and dated between July 2005 and April 2011.

The issue dates, sample text describing malfunctions, affected CIEDs, and Flesch-Kincaid scores of the 25 letters created by Boston Scientific are shown in the Appendix (Table A1). The Flesch-Kincaid readability score of the HRS sample letter (full text shown in Table 1) was grade level 12.5. The median Flesch-Kincaid readability score of the 25 Boston Scientific letters was 12.8 (range 10.8–18.9), which exceeded the fifth grade recommended readability level by an average of 7.7 grade levels (95% confidence interval 6.9–8.5; $P < .001$) and the eighth grade average reading ability of US adults by 4.7 grade levels (95% confidence interval 3.9–5.5; $P < .001$). The readability scores of the 25 Boston Scientific letters according to the Flesch-Kincaid scale are shown graphically in Figure 1 (organized chronologically by the letter date). No trend in the letters' readability scores during the 69-month period was noted.

An analysis of readability using the 6 scales is shown in Table 2. All scales showed similar estimates of readability, with none having scores at the eighth-grade level or lower.

The sample "Dear Patient" letter created by the HRS and an actual CIED advisory letter created by Boston Scientific were revised to bring their readability levels to below the eighth-grade level—the average reading level of US adults (Table 1).