The FDA-Approved Essure Device Counseling Order Fails to Promote Patient Empowerment

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The U.S. Food and Drug Administration (FDA) recently issued an order (U.S. Department of Health and Human Services, 2018a) that limits the sale of Bayer's (Whippany, NJ) Essure system for permanent birth control to those health facilities that provide structured information to patients on the benefits and risks of the hysteroscopically implanted metal coils, as higher rates of unintended pregnancy have been identified in real-world conditions compared to initial trial outcomes (Hurskainen et al., 2010). In early 2016, a black box warning (U.S. Department of Health and Human Services, 2016) was issued for the device and Bayer was ordered to conduct a postmarket surveillance study to gather additional data about the benefits and risks of Essure. This most recent order takes the black box warning a step further: issuing a document entitled "Patient-Doctor Discussion Checklist. Acceptance of Risk and Informed Decision Acknowledgement" (Bayer Healthcare, 2018). Physicians are required to provide and review this document with patients considering Essure and obtain a patient signature indicating consent. The checklist is accompanied by a 16-page patient brochure, one-half of which is devoted to safety information for the product.

The Essure brochure and checklist are an example of communication by regulation. Some providers will inherently oppose the idea of government encroachment in patient-physician communication. This is not our objection. We believe the FDA action aims, at least in part, to enhance patient education, and that this is a laudable initiative; however, we oppose this checklist and brochure because they are poorly executed. Below we delineate several of the central shortcomings of the approach by the FDA to regulating communication as exemplified by the Essure brochure and checklist.

FULFILL READABILITY STANDARDS

The FDA has several standards to promote user-friendly device labeling and information (U.S. Department of Health and Human Services, 2001), but the Essure materials fail to meet these. On a practical level, the FDA suggests using "well-mapped, carefully organized writing" and including a summary page with the most criti-

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cal information. However, these materials are more than 7,000 words long, contain no clear summary, and it would take the average adult reader more than 35 minutes to review (Rayner, Schotter, Masson, Potter, & Treiman, 2016). The document does use a table of contents and headers to organize writing, as recommended. A glossary of medical terms is provided, yet throughout the text, several of these terms are referred only to by their acronyms (i.e., TVU for transvaginal ultrasound and modified HSG for modified hysterosalpinogram).

The Essure brochure and checklist do not meet basic guidelines for readability. Both authors transferred the main body of the text (excluding headers) into the Microsoft Word Flesch-Kincaid reading level assessment, finding an overall Flesch-Kincaid reading level between 10th and 11th grade. To confirm these estimates, we also assessed the text using the New Dale-Chall calculator (Chall & Dale, 1995), available free online (http://www.readabilityformulas.com/new-dale-chall-readability-formula.php), which produced a readability level between 13th and 15th grade (college). Although there are several limitations to such assessments, including the overly mechanistic measurement of readability (McGee, 2010; Paasche-Orlow, Taylor, & Brancati, 2003), it is nonetheless clear that these materials would be considered generally difficult to read, as they fall above a 10th grade level. Certainly, these results surpass the 8th grade readability standard that the FDA Medical Device Section has set for itself (U.S. Department of Health and Human Services, 2001), and the more patient-centered goal of 4th to 6th grade. Readability is only one dimension of clear communication. Fulfilling readability guidelines does not assure that documents will be understandable. A clear recommendation within the FDA guidance is to conduct testing of the materials with the target audience of the device to ensure they are understandable. It is unclear whether user testing was undertaken; transparency in this regard could promote confidence that the materials were understandable to women interested in this device. In particular, consumer testing with people who have limited health literacy is needed. Testing conducted with highly educated and empowered participants is insufficient (Stone & Faughnan, 2018).

The problem of high readability in health communications persists despite federal efforts to encourage the dissemination of understandable documents in plain language through The Plain Writing Act of 2010. This Act (Plain Writing Act, 2010) provides training to government agencies to facilitate better communication of health information to the lay public. Medical communications remain indecipherable to many in the general population; the FDA has the authority and established standards to require manufacturers to conform and should do so.

FACILITATE LINGUISTIC ACCESS

The FDA presents the Essure brochure and checklist exclusively in English (U.S. Department of Health and Human Services, 2018b). Linguistic access in health care remains suboptimal, despite now long-standing National Culturally and Linguistically Appropriate Services standards that promote expanding services to non-native English-speakers (Estrada & Messias, 2015). Bayer provides a Spanish version of these documents on their website, but for the almost 65 million people who speak more than 300 languages in this country, their access to these materials in their native language is restricted by the absence of these documents in their language. Despite FDA efforts to expand linguistic access through a formal Language Access Plan (U.S. Food and Drug Administration, 2013), there are limited resources available in languages beyond English and Spanish. The FDA is in the position to require manufacturers to present materials in a broad array of languages and should do so (U.S. Department of Health and Human Services, 2013).

ACHIEVE CLARITY

The Essure brochure and checklist includes many phrases that may be unclear to a lay audience. Specialized vocabulary is frequently needed to communicate health-related ideas. Clearly defining medical terminology is an important aspect of promoting comprehension throughout the decision-making process. Terms such as sterilization, surgical bilateral tubal ligation, ectopic pregnancy, perforation, and migration are defined. Other important concepts are either defined in a glossary section but remain insufficiently described or are left undefined in the brochure/checklist. For example, the glossary includes the following definition: "Modified hysterosalpingogram (modified HSG): An x-ray of the uterus and fallopian tubes after contrast dye has been given for the Essure Confirmation Test." Given the importance of this test to confirm correct placement of the Essure device (and thus prevent pregnancy), a clearer description should be presented. Meanwhile, gynecological infections are not described or defined, yet it is important for a woman to understand what is meant by this term as she determines her own eligibility for the device.

Phrases such as, "I may not be able to rely on Essure" are similarly problematic for being overly vague. Information on the rate of Essure failure or any other details to

specify in what way Essure may not be reliable are not clearly presented. Alternatively, "I may not be able to rely on Essure" could be clarified by saying, "Essure may not prevent pregnancy," which makes clear the potential outcome of a failure. Such information would seem critical to how people could be informed about deciding whether to proceed or not proceed with Essure insertion.

EMPLOY CONSISTENCY

The Essure brochure and checklist are not linguistically consistent with several fundamental terms. For example, the document alternates between "birth control" and "contraception," which may be construed as two separate concepts. Ensuring that communications are relentlessly consistent is essential. Using multiple terms for the same construct can lead to unneeded misinterpretations.

FORMAT FOR EMPOWERMENT

The Essure checklist includes five spots for initials and then a final signature line. This is a medicolegal document entitled "Acceptance of Risk and Informed Decision Acknowledgement," which is attached at the conclusion of the brochure. In addition, the introduction explicitly emphasizes the signatory action, "You should not initial or sign the document, and should not undergo the procedure, if you do not understand each of the elements listed below." This framing prioritizes liability concerns over meaningful dialogue and informed decision-making. Laws and regulations that require lengthy technical forms stimulate rote signing. Interactive tools have been developed that promote greater patient engagement with risk/benefit information (McCaughey et al., 2016) and may help to overcome the emphasis on harvesting signatures, achieve patient empowerment, and have the benefit of liability protection. Legislative mandates to document the provision of information in this fashion encourages "empty ethics" (Corrigan, 2003), overemphasizing documentation rather than the social process of decision-making.

MOVING FORWARD

There will continue to be legislative and regulatory action that impacts communication with patients. In fact, there are several other examples with similar issues (e.g., Breast Density Notification, Patients' Bill of Rights and Responsibilities) (Gunn, Battaglia, Paasche-Orlow, West, & Kressin, 2018; Paasche-Orlow, Jacob, Hochhauser, & Parker, 2009). However, it is deeply unfortunate when the implementation of these policies undermines the very goals they aim to achieve. Every single patient-facing document should be viewed as an opportunity to promote patient engagement and empowerment. When legislation or regulation generate patient-facing materials, a full range of stakeholders, including patients and experts in health communication and adult education, should be involved. Adhering to plain language principles will help draft patient-facing materials but will not circumvent the need to test and refine materials with patients.

Sound medical decision-making requires active engagement of both the patient and provider. The nature of these particular documents does not promote patient engagement, suggesting that no population is served by requiring these documents during decision-making. Regulations must consider the structure of written materials, accessibility in terms of literacy, language, and content, as well as the intended audience. When materials are difficult to read, lack clear definitions, are inconsistent in their terminology, and require signatory action, patient empowerment may not be advanced and patient trust may be degraded.

Of note, Bayer announced the discontinuation of sales of Essure in the United States at the end of 2018, citing decreased profitability and demand (http://www.essure.com/assets/pdf/PP-250-US-1923-FINAL-News-Release.pdf). The role that the FDA regulations and requirements have played in the decline in use in comparison to mounting medicolegal concerns (Klimczak, Snyder, Borahay, & Phelps, 2017) is unclear. Nonetheless, the circumstances surrounding this device underscore the importance of effective implementation of patient education and decision tools. Cooperation among stakeholders is needed to ensure that health communications are aligned with their purpose, meet accepted communications standards, and are appropriate across diverse populations. Although this may seem ambitious, the foundational knowledge exists to support such an effort. The communication crisis posed by the Essure checklist has been averted as the device is now being removed from the market. However, we urge others to view this as a cautionary tale of how the way communications are delivered is no less important than the content itself and lead the way in implementing communications that meet the needs of all patients.

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