



MDIC Virtual Patient Engagement Forum Attendee Pre-read

Opportunities for Communicating Benefit, Risk and Uncertainty Information about Medical Devices

There are multiple settings throughout the lifecycle of medical devices in which it is important to present clear communications about the benefit, risk and uncertainty associated with their use, including:

Clinical Research & Regulatory Review	Direct to Consumer Advertising
Inclusion of Patient Preference Information in Product Labeling	Online Search for Health Information
Shared Decision Making (SDMO)	Social Media Channels
Patient Decision Aids	Patient Advocacy Organizations

Key Factors in Communicating Benefit-Risk-Uncertainty Information to Patients

Relevant Provider Characteristics

Physicians are generally rated highly by patients and families for being credible sources of information. The extent of the physician’s previous experience and training in the specific medical procedure or treatment under discussion is important to a patient’s decision making. It is also important that providers demonstrate commitment to shared decision making, careful choice of language, avoidance of appearing to push a specific decision and clear explanation of treatment outcomes. Autonomy and sense of mutual respect between patients and healthcare providers are often critical to successful communication.

Relevant Patient Characteristics

Specific characteristics of the patient population, including age, native language and literacy must all be considered when designing the most effective communications approach. Some patients have better understanding of a medical device, especially when information about benefits and risks is presented in graphical format. Increasingly there is a need to gauge patients’ familiarity with digital tools as these are frequently used to support communication efforts. Another relevant characteristic relates to patients’ previous experience with health issues.

Relevant Message Components

The message itself is as important as the messenger and the message recipient. The choice of format can be critical to a patient’s ability to process health information and make informed medical decisions. Some studies suggest it may be best to use an integrated approach that takes into account a patient’s ability to understand numbers and statistical terms, as well as the impact of their emotions and experiences on their decision-making. While statistical concepts are difficult for many lay people to comprehend, studies have shown that certain approaches and formats can lead to better understanding by patients and their caregivers.

Patient Preference Information

Patient preferences are those expressed by patients with regard to decisions concerning their health care and these are informed by their understanding of benefits and risks associated with various treatment options. Information about patient views of benefit and risk – patient preference information -- for a given technology can contribute to the body of knowledge about a product and thereby help inform how key stakeholders approach the benefit-risk assessment and shared decision-making efforts.



Key Terms

Benefit: A favorable effect or desirable outcome of a diagnostic or therapeutic strategy

Harm: An unfavorable effect or undesirable outcome of a diagnostic or therapeutic strategy

Risk: The qualitative notion of the probability and/or severity of a particular harm

Absolute Risk vs. Relative Risk: Absolute risk is the risk of having an event over a period of time whereas relative risk examines the risk of an event happening to people who use a medical product compared to those who do not.

Uncertainty Attitude: A reflection of the degree to which uncertainty in the attributes of a treatment alters one's decisions about use of the treatment.

Patient Preference: A patient's assessment of the desirability of various treatment options for the patient's condition.

Patient Preference Information: Qualitative or quantitative assessments of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions.

Preference Sensitive Decision: A patient's choice involves trade-offs that depend on the importance the patient assigns to the elements of the trade-off.

Shared Decision Making: A collaborative process that allows patients and their providers to make health decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.

Literacy: The ability to read and write.

Verbal aptitude: The ability to use the written language and understand concepts presented through words.

Graphical Literacy: The ability to understand information that is presented graphically.

Numeracy: The ability to understand and work with numbers.

Subjective Numeracy Scale: A self-report measure of perceived ability to perform various mathematical tasks and preference for the use of numerical versus prose information.

Framing Effects: A cognitive bias that impacts how people react to decisions based on how the decision is presented.

Gist Representation: Vague, qualitative representations that capture the meaning of the information.