MDIC White paper: Best practices for communicating benefit, risk and uncertainty

Introduction

The intent of this paper is to familiarize industry, regulators and other stakeholders with evidence-based practices for communicating the benefits, risks, and uncertainty of medical technology to patients and providers. It is written to be a useful resource for professionals across the medical device community, including:

- Scientists conducting clinical trials, who want to make sure trial subjects are fully informed
- Regulators considering device communications, including device labels,
- Clinicians who want to make sure that patients understand the risk, benefits and uncertainty of a therapy
- Many others

Appropriate communication of risks, benefits, and uncertainty is essential at every stage of the medical device life cycle. Products can be designed, and studies conducted based on the risk, benefit and uncertainty preferences of the target patient population. During approval and subsequent use of a device, manufacturers and regulators have an obligation to ensure that device benefits, risks and uncertainty are communicated in an understandable way. Similarly, in the clinical setting, patient centered care requires effective communication of benefits, risks and uncertainty between patients and providers. There is increasing awareness surrounding the importance of patient engagement during the treatment decision making process, as well as across the medical technology product development cycle by industry and regulators.

A literature search was conducted to inform this report and to understand what has been published regarding the most effective methods for communicating information related to benefits, risks and uncertainty. The most successful methods and tools are identified and outlined. Suggestions for how to develop additional, relevant materials to aid in the communication of benefits, risks and uncertainty to patients are also presented.

Educational tools and strategies for communication are discussed. The communication of risks, benefits or uncertainty can help regulators and manufactures understand how patients value these attributes as inputs to clinical investigation studies. These communication practices are intended to be applicable when technologies commercially available or under clinical investigational study are under consideration.

This report concludes with a gap analysis summarizing areas where continued research and additional guidance are necessary to expand and increase the use of effective communication of benefits, risks and uncertainty in a manner readily understood by patients.

1.0 - Background: Benefits, Risks, Preferences, Uncertainty and the Importance of These Concepts in Communicating with Patients

The purpose of this section is to help ensure a common understanding of terms used in this MDIC white paper and to outline why communicating the benefits and risk of medical therapy to patients is important. The key concepts discussed in this section -- benefits, harms, risks, preferences, and uncertainty -- can be thought of in multiple ways, particularly since they are often used in conventional speech as well as in research and clinical settings. The terms and concepts used in this white paper are based on those developed for the MDIC Patient Centered Benefit Risk Report: "A Framework for Incorporating Information on Patient Preferences Regarding Benefit and Risk into Regulatory Assessments of New Medical Technology" (Ho et al., 2016) (MDIC, 2015), and those used in the FDA guidance document "Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling" FDA, 2016).

Benefit, Harms, and Risk

The concept of "benefit" is generally well understood:

> A benefit is a favorable effect or desirable outcome of a diagnostic or therapeutic strategy. (MDIC, 2015),

If you ask patients or healthcare providers, they can generally understand and identify the benefits of a medical treatment.

The opposite of "benefit" is "harm":

> A harm is an unfavorable effect or undesirable outcome of a diagnostic or therapeutic strategy. (MDIC, 2015),

Again, if you ask patients or healthcare providers, they can generally understand and identify the potential harms of a medical treatment.

The concept of "risk" is more challenging given the opposite of "benefit" is not "risk", but "harm." So why the focus on "benefit-risk" instead of "benefit-harm"? This is where the concept of uncertainty first comes into play. Both benefits and harms are subject to uncertainty as to whether or not they will actually occur in an individual patient, so they are discussed in terms of the probability that they will occur. Such probability may be described in a variety of ways, including by proportions, percentages, relative risk, person-year rates, Kaplan-Meier rates, or other similar measures. To help the individual patient understand the benefits or harms that they might experience, we need to help them understand the probability of them experiencing a particular benefit or harm.

The word "risk" captures this concept of the probability of a harm: the greater the risk the more likely a harm is to occur. But the word "risk" also captures the concept of the severity of a potential harm: the greater the potential harm, the greater the risk to the patient. Therefore, the word "risk" incorporates both probability and severity:

> A **risk** is the qualitative notion of the probability and/or severity of a particular harm. (MDIC, 2015),

Risks are often described quantitatively as the probability or rate of occurrence of a particular harm, often combined with a categorization of the severity of the harm.

Patient preferences

The concept of a "preference" is generally well understood. When faced with one or more options, an individual makes a decision to choose one option over the other(s), thereby expressing their "preference" for one option over another. Such decisions might be rational or irrational, or based on quantitative or qualitative analysis. No matter the basis of the decision, a choice is assumed to be an expression of preference.

As discussed in the MDIC PCBR Report, it is important to note that a preference is different than a judgement (MDIC, 2015). A preference is the basis for a choice among options that an individual makes for themselves, whereas a judgement is the basis for choice among options that an individual makes that affects someone else. A physician may make a judgement about what treatment option he/she would recommend for a patient, but would express a preference if he/she was making a choice among treatment options for their own care When outlining treatment options for a patient, a physician might express what option she/he would prefer if it were her/his choice, but when asked to make a decision how to treat a patient, the physician makes a judgement about the best option(s) for that patient.

Therefore, a "patient preference" is the patient's assessment of the desirability of one treatment option over others available for that patient's condition. When a patient makes a choice about one treatment option over others, they are expressing their preference for that option.

The MDIC PCBR Report and the FDA Patient Preference guidance are specifically focused on helping stakeholders in the FDA regulatory process for medical devices think about collecting information about patient preferences regarding a specific technology or disease state. The definition of "patient preferences" in the MDIC PCBR report reflects this focus on collecting information on patient preferences:

> "Preferences are defined as 'qualitative or quantitative statements of the relative desirability or acceptability of attributes that differ among alternative health interventions,' a definition consistent with the use of the term in the patient preference literature." (MDIC, 2015),

Similarly, the FDA Patient Preference guidance defines "patient preference information (PPI)" as:

> "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." (FDA, 2016)

As discussed in both the MDIC PCBR report and in the FDA Patient Preference guidance, one valuable use of PPI beyond the regulatory approval process is in product labeling. If PPI is

used as the basis for an FDA approval, then it needs to be included in the product label. Such labeling may be helpful to physicians and healthcare providers in communicating the benefits and risks of a technology to patients both in identifying what benefit and risk attributes of the technology are most important to patients, and in providing patients with information on how other patients see the benefit-risk tradeoffs. In the end, however, each patient that considers using the technology will need to assess their own individual preferences about the benefit and risk profile of the technology versus other treatment options.

Individual Preferences and Risk Tolerance

Each patient involved in making choices about their care will express preferences among their treatment options. Patients incorporate information provided by healthcare professionals, particularly physicians, but may also seek information from other sources such as the Internet as well as information and opinions from friends and family. A patient's decision will reflect their desire for benefit traded off against their desire to avoid harms.

As outlined in the MDIC PCBR report, each patient has an inherent "risk tolerance," which is described as ". . . the degree to which a patient would accept greater probability or severity of a harm in exchange for a given benefit. . ." (MDIC, 2015) Uncertainty attitude "is a reflection of the degree to which uncertainty in the attributes of a treatment alters one's decisions about use of the treatment." (MDIC, 2015). Uncertainty creeps into information about benefits and risks in several ways. Because studies of benefits and risks often show the averages across the patient population, there is uncertainty about the likelihood that an individual patient might experience a benefit or risk. Additionally, in many
fields, different studies of benefits and risks of a procedure or technology might come to different conclusions about the probability of benefit and risks, so there is uncertainty about what the real benefits and risks are for the individual patient seeing an individual physician. There may also be uncertainty because an individual patient differs in some ways from the patient population(s) previously studied. Some patients are "uncertainty averse" and will gravitate towards options that offer the most predictable outcomes even if those outcomes may not be the best possible outcomes. Other patients are "uncertainty tolerant" and will accept less certainty of outcome for a treatment that offers the best potential outcome. Uncertainty attitude influences at a patient's risk tolerance. This concept is further explained with a graphical illustration of how uncertainty attitude affects risk tolerance on a population basis in the MDIC PCBR report (pp. 25-27).

It is important to understand that patients will vary in their preferences and risk tolerance, and this variation will be reflected in differences in their treatment decisions. When informed of the benefits and risks of various treatment options, patients are able to express their preferences for the treatment option that they want to pursue.

Communicating Benefit-Risk Information to Patients

A key input into a patient's decision process is information on the benefits and risks provided by physicians, other healthcare professionals, healthcare provider organizations, and companies offering medical technologies and pharmaceuticals. Indeed, among the patients' rights recognized by the American Medical Association Code of Medical Ethics, patients have the right "To receive information from their physicians and to have the opportunity to discuss

the benefits, risks and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment." (AMA, 2019). The appropriate communication of benefit risk information preserves the autonomy of patients, permitting them to make informed health care decisions based on their values rather than having those decisions made by others.

The movement towards "shared decision making" is an effort to encourage physicians and other healthcare providers to work with patients and their families to help patients make decisions about their healthcare. Shared decision making involves providing patients with accurate and unbiased information about the risks and benefits of different treatment options and enabling patients to work collaboratively with their healthcare providers to use the information to make decisions about their healthcare. The process often involves developing tools that communicate valuable information to patients in a way that is balanced and non-biased towards one option or another. As explained by one physician advocate of shared decision making:

"Clinicians can facilitate shared decision making by encouraging patients to let clinicians know what they care about and by providing decision aids that raise the patient's awareness and understanding of treatment options and possible outcomes. . . .

Through shared decision making, clinicians can help patients understand the importance of their values and preferences in making the decisions that are best for them. Experience has shown that when patients know they have options for the best treatment, screening test, or diagnostic procedure, most of them will want to participate with their clinicians in making the choice." (Barry & Edgman-Levitan, 2012)

The patient's ability to understand information can be evaluated by asking the patient to explain what each treatment option presented means to them. Balance in the presentation of information can also be assessed by asking patients not only their understanding of the information, but also assessing their responses to questions about the information, whether the information seems biased towards one option or another. Decision aids developed to facilitate patient education and shared decision making can be tested for their ability to present information in an understandable and balanced way with test populations of patients prior to more widespread use.

Why Focus on Best Practices for Communicating Benefit-Risk Information to Patients?

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

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

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

Medical device manufacturers and FDA staff are increasingly using patient preference information (PPI) in the design of and approval process for medical devices. Formal studies of patient preferences in specific conditions are both identifying the benefit and risk attributes of a treatment that are most important to patients, and are illuminating how patients as a group trade off the benefits and risks of treatment options. This information helps regulators put the outcomes and side effects identified in clinical studies in context of the outcomes and risks that are most important to patients.

Beyond the value of benefit risk information in informing the regulatory decision process, the combination of PPI and clinical outcomes/side effects information can shape the labeling of the technology for providers and patients. Because patients rarely read technology labels themselves, providers are expected to incorporate the clinical data embodied in labeling information, as well as additional studies of the treatment options, into the information that they communicate to patients. Medical device manufacturers and healthcare organizations may develop decision aids to help patients better understand the risks and benefits of treatment options.

While physicians, regulators, and others involved in healthcare delivery on a daily basis may be familiar and comfortable with the concepts and terms used in describing the benefits and risks, patients may not be as familiar with the medical terms or as facile in understanding the quantitative and qualitative aspects of clinical outcomes. Patients may not be able to appreciate what a particular side effect might involve or what the probability of a specific benefit or harm might mean. Patients may not have the medical sophistication or the understanding of quantitative concepts that providers do, which can make it a challenge for providers to communicate benefit-risk information to patients in a way that they can understand and use in their decision making.

2.0 What are key factors in communicating benefits and risks to patients?

This body of literature assesses a range of considerations in communicating benefit-risk information, identifying ways to most effectively communicate such information to patients. The relevant concepts identified in these studies can be sorted in to three groups: (1) concepts related to the information provider (e.g. physician, nurse, etc.); (2) concepts related to the patient; and (3) concepts related to the message itself. This section will summarize what is known about best practices for communication in these areas.

a) What characteristics of information providers are considered important in benefits and risks communication?

   i) Credibility: Physicians were rated as more credible sources of information than pharmaceutical companies in a study evaluating the impact of uncertainty on patients' decision making. (Longman, Turn et al. 2012).
   ii) Previous Experience and Training: Patients potentially undergoing a novel surgery rated physician's experience with the procedure as a salient factor in their decision making (Lee Char, Hills et al. 2013).

iii) Communication Style: Shared decision making, not being pushy, carefully choosing language, and explaining treatment outcomes enhanced patient engagement (Fisher, Ledfor et al. 2018).
iv) Relationship to Patients: Autonomy and sense of mutual respect between patients and healthcare providers could be as important as the treatment options available (Gainer, Curran et al. 2017).

b) What characteristics of patients affect their comprehension of benefit-risk information?

i) Demographics:
(1) Age: Participants 65 years and older noted an opportunity for input from another trusteed party as important (Pricee, Bereknyei et al. 2012).
(2) Language: When communication is NOT in participants' native language, there is less understanding of risks and benefits (Ankuda, Block et al. 2014).
ii) Literacy:
(1) Verbal Aptitude: Patients with higher verbal aptitude had better understanding of a medical device (Edlund, Edlund et al. 2015).
(2) Graphical Literacy: Participants with higher graphical literacy had better understanding of risk and benefit information with visual aids (Garcia-Retamero and Galesic 2010).
iii) Numeracy: Patients with lower numeracy did not benefit from more information presented to them (Fraenkel, Stolar et al. 2017). However, they benefit from having graphic representations (Garcia-Retamero and Galesic 2010). Numeracy was measured with the Subjective Numeracy Scale. Patients with higher subjective numeracy were less likely to remain on their current treatment in a study for rheumatoid arthritis (Frankel, Cunningham et al. 2015).
iv) Previous Experience: Probabilistic information can be dismissed by participants when it was not consistent with their previous personal and family experiences (Holmberg, Waters et al. 2015).

c) What characteristics of the material presented would need to achieve optimal comprehension of benefit-risk information?

i) Statistical considerations:
(1) Relative vs. Absolute Risk:
(a) Relative risk should be accompanied by absolute frequency. (There is a 3 fold increase for hear disease to 15%) (Bodermar, Meder et al. 2014).
(b) Treatment acceptance is higher with absolute risk (Hudson, Tool et al. 2011) Lavallie, Wolf et al. 2012).

(2) Probability vs. Frequency:

(a) Relative risk reduction is better understood than absolute risk reduction. (For example. 20% of patient have adverse outcome with treatment A, and 15% of patients have adverse outcome with treatment B. An relative risk reduction of 25% is better understood than an absolute risk reduction of 5%. (Akl, Oxman et al. 2011)
(b) Natural frequencies are better understood than probabilities. (For example, about every 1 in 8 U.S. women (about 12%) will develop breast cancer in

the course of her lifetime.1 in 8 is better understood than 12%. (Akl, Oxman et al. 2011).

(c) Frequencies are easier to interpret than probabilities. (For example, 5 per 100 is easier to interpret compared to 5%) (Garcia-Retamero and Hoffrage 2013) (Oudhoff and Timmermans 2015).

(d) Low numeracy patients rank frequency as higher risk than percentage (For example, a 1 in 20 risk would be perceived as higher than a 5% risk). (Peters, Hart et al. 2011).

ii) Formatting considerations:

(1) Uncertainty: When presenting uncertainty, point estimate is preferable to range (For example, 8% is more credible than 2-14%). (Lognman, Turner et al. 2012) (Sladakovic, Jansen et al. 2016).

(2) Graphs vs. Text:

(a) Single vs. Multiple Variables: Graphs involving a single variable are easier to comprehend than graphs involving multiple variables (Zikmud-Fisher, Fagerlin et al. 2010).

(b) Small vs. Medium/Large Numerators: Understanding of data is better with pictographs with small numerators, and better with bar charts with medium and large numerators (For numerators less than 100, pictographs are more easily understood. For numeratos larger than 100, bar charts are more easily understood). (McCAffrey, Dixon et al. 2012).

(c) Pictograph vs. Text/Tables: Pictograph information was preferred compared to text or tables (Tait, Voepel-Lesis et al. 2010).

iii) Framing Effects:

(1) Order of Presentation: Participants with higher numeracy were more likely to believe that benefits outweighed risks when benefits were presented first (Fraenkel, Stolar et al. 2017).

(2) Importance of Attributes: Patients who were presented with attributes they thought were most important first were more likely to choose treatment options aligned with their stated values (Bansback, Li et al. 2014).

(3) Positive vs. Negative Framing: Respondents perceived the risk to be lowest when information was framed positively vs negatively (For example. 10% for adverse outcome is perceived to be lower than 90% for positive outcome). (Peters, Hart et al. 2011).

3.0 What tools are available to help industry and providers effectively communicate risk and benefits?

Practices and tools

Patient decision aids can be developed as effective tools to communicate benefit, risk and uncertainty.

Patient decision aids are tools designed to help people participate in decision making about health care options. They provide information on the options and help patients clarify and

communicate the personal value they associate with different features of the options. (The International Decision Aid Standards: http://ipdas.ohri.ca/what.html). Although there are many tools available for the development of patient decision aids (see Appendix), the Ottawa Hospital provides an electronic training module with a step by step guide to develop patient decision aids. A summary from the electronic training is provided below.

Step by Step Guide on How to Develop a Patient Decision Aid (Ottawa Patient Aid Development Training):

1. Draft a patient decision aid on your topic of interest (consider using a template https://decisionaid.ohri.ca/eTraining/docs/Ottawa_PtDA_Template.doc): Start with searching for an existing patient decision aid on your topic of interest. If an existing decision aid is not available, use the template to answer questions regarding your role, the health condition, the options, and benefits and harms of the options, and what other preparation is needed for decision making.
2. Identify conceptual frameworks underlying Patient Decision Aids: Identify how the concepts in the Framework are mapped onto elements in the patient decision aid.
3. Apply international Patient Decision Aid Standards (IPDAS): Understand the IPDAS criteria for appraising the quality of patient decision aids and apply the standards to the aid developed.
4. Plan timeline and expert Panels: Understand the scope and timing of the development and draft a project plan. Understand the need of review panels and begin to plan panels.
5. Assess decisional needs of population: Understand the process of conducting a decision needs assessment in populations and plan a needs assessment.
6. Present information: Identify the information that needs to be included in the decision aid and identify gaps. Add a conflict of interest statement.
7. Present evidence and probabilities for benefits and harms: Conduct a systemic review of the topic of interest and create a summary of findings table.
8. Develop a value clarification component in a patient decision aid: Understand the importance of value clarification for patients. Understand the concepts and methods of value clarification. Develop a values clarification component in your decision aid.
9. Plan evaluation of patient decision aid: Plan an evaluation of the patient decision aid to meet minimal standards per IPDAS.
10. Consider optional IPDAS elements: Consider including additional elements suggested by IPDAS to include in the decision aid, such as personal stories and additional delivery methods.
11. (Optional) Register the patient decision aid in a public database

4.0 Challenges

Communication in Non-Clinical Settings

Most of the research we examined in the literature review focused on risk communication in interpersonal, clinical settings, and particularly the significant role that decision aids can play in shared decision making. But patients are increasingly likely to learn about a product's risks and benefits, not just through discussions with a clinician, but through internet searches,

social media, television and other channels where a provider is not immediately present. While there is a body of research on communicating health information in the media, it is worth considering how medical device manufacturers and regulators can convey device risk, benefit and uncertainty information through public media and social channels. The lack of guidance for manufacturers and regulators in communicating risk in traditional and social media is a gap that should be addressed (Moorhead et al., 2013).

Vulnerable Populations

There is substantial research documenting the difficulties in communicating risks and benefits to vulnerable populations who are more likely to have low literacy, low numeracy and language barriers (Stolar et al. 2017; Edlund, Edlund et al. 2015; Fraenkel, Ankuda, Block et al. 2014). While some research investigates how risks and benefits can be better communicated to vulnerable groups, this research focuses largely on public health initiatives, and is not immediately translatable to communicating the risks and benefits of medical devices. More research on communicating the risk and benefits of medical devices to vulnerable populations is needed.

Credibility

As noted above, research has found that patients perceive information from providers to be more credible than information from industry (Longman, Turn et al. 2012). While it is important that patients rely on providers to communicate accurate information about risk and benefits, the credibility gap between providers and industry represents a missed opportunity for industry to inform patients. Device manufacturers should seek ways to build credibility with the public. For example, a promising approach is to build partnerships with key opinion leaders and patient advocacy organizations to present information regarding risks and benefits. Device manufacturers may also utilize their resources to generate unbiased and unbranded education material for patients and providers. Medical device industry leaders have a responsibility to be worthy of the public's trust, and should work in concert with regulators, patient advocates and medical professionals to achieve that goal.

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6. Appendix

Resources for Developing Patient Decision Aids

Tools	Description	Source
User Checklist for patient decision aids	Outlines the content, development, process and effectiveness of decision aids (http://ipdas.ohri.ca/IPDAS_checklist.pdf)	The International Decision Aid Standards (IPDAS)
Patient decision aid development online tutorial	Provides information regarding how to draft a patient decision aid, apply IPDAS standards, present the information, and plan the evaluation the decision aid (https://decisionaid.ohri.ca/eTraining/)	The Ottawa Hospital
Decision aid for implantable cardiovascular defibrillators (ICD) development protocol	Provides information on development of a decision aid for ICD.	Carroll, McGillion et al. 2013
Option Grids	Provides an approach to develop decision aids to be used during provider visits.	Elwyn, Lloyd et al. 2013
TreatmentExplorer	A tool that attempts to incorporate individual patient clinical data to personalize the information communicated.	Franklin, Plaisant et al. 2016
Standards for Universal reporting for patient Decision and Evaluation Studies (SUNDAE)	Guidelines for evaluation of existing patient decision aids	Spucha KR et al. 2018
Existing Patient Decision Aid Inventory	Tools to search for existing patient decision aids	https://decisionaid.ohri.ca/AZlist.html https://www.med-decs.org/en/