



Best Practices for Communicating Benefit, Risk, and Uncertainty for Medical Devices

A Report of the Science of Patient Input Program
of the Medical Device Innovation Consortium (MDIC)

Table of Contents

Authors	3
About the Medical Device Innovation Consortium (MDIC).....	4
Executive Summary.....	5
SECTION 1 Opportunities for Communicating Benefit, Risk, and Uncertainty Information	7
1.1 Clinical Research & Regulatory Review.....	8
1.2 Inclusion of Patient Preference Information in Product Labeling	9
1.3 Shared Decision-Making.....	9
1.4 Patient Decision Aids	11
1.5 Direct-to-Consumer Advertising	11
1.6 Online Search for Health Information.....	12
1.7 Social Media Channels.....	13
1.8 Patient Advocacy Organizations	13
SECTION 2 Key Concepts	14
2.1 Benefit, Risk, and Harm	15
2.2 Patient Preference Information	15
2.3 Risk Tolerance & Uncertainty Attitude	16
SECTION 3 Key Factors in Communicating Benefit-Risk Information to Patients: The Clinical Setting	18
3.1 Relevant Provider Characteristics	19
3.2 Relevant Patient Characteristics	19
3.3 Relevant Message Components	20
SECTION 4 Best Practices and Available Tools for Device Developers.....	22
4.1 Overall Approach	23
4.2 Developing Patient Decision Aids	25
4.3 Leveraging Online Resources.....	27
4.4 Leveraging Social Media Channels	28
4.5 Working with Patient Advocacy Organizations	29
SECTION 5 Conclusion	31
SECTION 6 References	33
SECTION 7 Appendix	39



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About the Medical Device Innovation Consortium

The Medical Device Innovation Consortium (MDIC) is the first public-private partnership created to advance the medical device regulatory process for patient benefit.

MDIC was formed in 2012 to bring the FDA and industry together to share vital knowledge that can help bring safe, affordable, and effective devices to patients and providers more quickly. MDIC membership and participation is open to nonprofit, industry, and government organizations that are substantially involved in medical device research, development, treatment, or education; or in the promotion of public health; or that have expertise or interest in regulatory science.

MDIC is designed to pursue several strategies that support its mission:

- Create a forum for collaboration and dialogue
- Make strategic investments in regulatory science, utilizing working groups to identify and prioritize key issues, and to request, evaluate, and implement project proposals
- Provide and enable implementation of tools from these projects that drive cost-effective innovation

The activities and outputs from MDIC are intended to:

- Ensure that innovative technology is readily available to U.S. patients
- Provide industry and government with methods and tools that may be used to expedite medical device development and the regulatory process
- Reduce the risk and expense of clinical research
- Reduce time and cost of medical device development

MDIC members provide guidance and leadership through collaboration to develop solutions for regulatory, scientific, health, and economic challenges within the medical device and diagnostic industry.

MDIC Science of Patient Input Program

MDIC's Science of Patient Input (SPI) program provides a venue for continued collaboration to advance the art and science of patient engagement in regulatory science, including advances in methodologies and tactical considerations for integrating the patient's perspective and preferences in the design, clinical development, and regulatory review of innovative medical technologies.

Sample Projects in the SPI Program

Patient Input in Clinical Trial Design	Patient-Centered Outcomes Research in Parkinson's Disease
https://mdic.org/project/patient-input-in-clinical-trial-design/	https://mdic.org/project/patient-centered-outcomes-research/ https://mdic.org/project/may-18-2018-patient-centered-clinical-trial-design-workshop/
Patient-Centered Benefit-Risk (PCBR) Framework	Patient Preference Study in Heart Failure
https://mdic.org/project/patient-centered-benefit-risk-pcbr/	https://mdic.org/project/heart-failure-study/



Executive Summary

Appropriate communication of benefits, risks, 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 review, approval, and subsequent use of a device, manufacturers and regulators have an obligation to ensure that benefits, risks, and uncertainty associated with the device 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.

Recent years have seen tremendous research and development progress within the field of medical devices and an explosion of information about medical products becoming increasingly accessible to the public. Efforts dedicated to understanding patient preferences and approaches to risk-benefit trade-offs, have also grown, as have the use of shared decision-making (SDM) efforts between providers and patients and peer-to-peer mentorship within patient and caregiver communities.

The combined impact of these trends has created a need to identify and promote best practices resources for medical device developers as they communicate with providers and patients about the benefits, risks, and uncertainty associated with use of medical devices. As the art and science of patient engagement continues to advance within regulatory science, it is increasingly important to ensure that all stakeholders communicate benefits, risks, and uncertainties of medical devices in a way that maximizes each patient's understanding and ability to make informed treatment decisions.

The intent of this report, developed by the Science of Patient Input Communication Working Group of the Medical Device Innovation Consortium, is to familiarize all medical device stakeholders with evidence-based practices for communicating the benefits, risks, and uncertainty of medical technology to patients and providers. This report is designed to be a practical resource for professionals across the medical device community, including:

- Investigators who want to make sure trial participants are fully informed;
- Regulators, who consider content for device communications, including device labels;
- Clinicians, who want to make sure that patients understand the benefits, risks, and uncertainty of a therapy at the point of care delivery;
- Industry professionals, who want to support their companies in developing appropriate materials and messaging about their products;
- Patient advocacy organizations, who want to educate their constituency about treatment options that include the use of medical devices; and
- Payers who are evaluating evidence, data, and claims and communicating with patients.

While investigators, physicians, regulators, and others involved in healthcare delivery may be familiar and comfortable with the concepts and terms used by product developers and regulators in describing 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.



Although there are unique considerations in the field of medical device development, it is possible to borrow (and where necessary, adapt) approaches and tools for communicating benefit, risk, and uncertainty information from other medical product disciplines, especially in the area of drug development. As a basis for development of this report, a broad literature search was conducted to understand and leverage existing information about the most effective methods for communicating information related to benefits, risks, and uncertainty. Relevant methods and tools stemming from that review are incorporated into recommended best practices within this report. Throughout this report we have embedded discussion about identified gaps, challenges, and opportunities within existing literature and standard practice that may benefit from further research, stakeholder discussion, and development of best practice approaches.

Overview of the Report

This report is organized into the following sections:

Section One: Opportunities for Communicating Benefit, Risk, and Uncertainty Information

introduces discussion of opportunities for communicating benefits, risks, and uncertainty information.

Section Two: Key Concepts explains definitions of benefits, harms, risks, preferences, and uncertainty, and how they can be interpreted in multiple ways.

Section Three: Key Factors in Communicating Benefit-Risk Information to Patients: The Clinical Setting explores a range of considerations in effectively communicating benefit-risk and uncertainty information within a clinical care delivery setting.

Section Four: Best Practices and Available Tools for Device Developers highlights several sets of recommendations for review by medical device colleagues seeking to enhance their communications efforts surrounding benefit, risk, and uncertainty.

Section Five: Conclusion offers a summary of how the MDIC Science of Patient Input Program is collaborating to improve the industry's ability to include patient perspectives in the development, pre-market approval, and post-market evaluation of medical devices.

Section Six: References lists references cited in this report.

Section Seven: Appendix lists resources for developing patient decision aids.



**Section 1:
Opportunities for
Communicating Benefit,
Risk, and Uncertainty
Information**

SECTION 1

Opportunities for Communicating Benefit, Risk, and Uncertainty Information

There are multiple settings in the life cycle of medical devices in which it is important to present clear communications about the benefit, risk, and uncertainty associated with their use. These communications may be used to recruit and ensure informed consent for clinical trial participants, inform the content of a product label for a commercially available device, support discussions among providers and patients at the point of care delivery, and provide notification of recall or changes made to a device. Additional communications occur in non-clinical settings, including through the internet, social media platforms, within patient advocacy constituencies, and through peer-to-peer conversations among patients and SDM between providers and patients, and peer-to-peer mentorship within patient and caregiver communities.

1.1 Clinical Research & Regulatory Review

Device manufacturers often leverage online resources (websites and social media platforms) to identify potential participants for clinical trials. These outreach efforts provide opportunities to communicate institutional review board (IRB)-approved benefit and risk information to patients.

CASE STUDY: PATIENT RECRUITMENT FOR A CLINICAL TRIAL

A website was developed to recruit potential patients for a clinical trial. The site was initially developed by patient recruitment staff and website development staff with input from clinical trial site personnel (including indirect patient experience). All required clinical trial site reviews were obtained before use, including IRB and FDA review. After actual website and patient use, the website was modified based on patient use and understanding and optimized to find more potential patients for opting into the trial. Depending on the type and degree of modifications, subsequent site, IRB, and FDA review may have been required. This also included a Facebook website that had banners and questions for potential patients that, if interested, sent the patient to the trial website.

Specifically, the trial website briefly described heart failure, possible available heart failure treatments, and a discussion on the investigational device including device description, implant process, and experience to date with both benefits and risks. There also was a short patient testimonial, physician testimonial discussing heart failure, and personal experience with the investigational device. This was all site, IRB, and FDA reviewed and approved and was modified over time based on actual potential patient use and input. The trial website closed with a SDM discussion with the patient's physician or directed the potential patient to the nearest trial site for more information.

Source: CVRx Inc.

Formal studies of patient preferences in specific conditions are identifying the benefit and risk attributes of a treatment that are most important to the patient population and illuminating how various groups of patients evaluate and make trade-offs among those benefits and risks. This information supports the regulatory review process, allowing regulators to evaluate the outcomes and side effects identified in clinical studies in context with what has been shown to be of greatest importance to the relevant patient population.



The FDA has indicated willingness to work directly with medical device companies considering including patient preferences as part of their development processes, and there are increasing efforts to use patient preference information (PPI) in trial design and regulatory review processes to understand and respond to how patients evaluate benefit, risk and uncertainty about treatments. In its discussion of how PPI is increasingly used in regulatory decision-making, FDA's Center for Devices and Radiological Health (CDRH) highlighted multiple recent and ongoing activities (FDA, 2019). One company to pursue this approach, NxStage, shared its experience working with CDRH to develop a patient preference survey (MDIC, 2017). The combination of PPI and clinical outcomes/side effect information can also shape the labeling of the technology for providers and patients.

1.2 Inclusion of Patient Preference Information in Product Labeling

Currently, product labels and patient package inserts are the primary methods to present benefits, risks, and uncertainties, although all stakeholders are increasingly exploring ways to leverage digital communication tools for this information, including expanding the use of electronic labeling.

In its 2016 Guidance to industry, "Patient Preference Information (PPI) – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling," CDRH described ways in which PPI can be used in medical device labeling, especially if that information is used within the FDA review process. The 2016 Guidance noted the opportunity for inclusion of PPI in FDA's public decision summaries, which can be helpful to healthcare professionals and patients in making treatment decisions. PPI that is reviewed by FDA and supports FDA's approval or marketing authorization should also be described in the device labeling, with information about the benefits and risks of the treatment and diagnostic options under consideration (FDA, 2016).

With many medical devices, especially those that are implanted during surgery, patients may not see the actual device label or package insert. For this reason, device manufacturers sometimes place this information on their websites to enhance patient access. In addition, this information can be helpful to healthcare providers in communicating the benefits and risks of a technology to patients by identifying the benefit and risk attributes of the technology that are most important to patients and by providing information about how other patients have viewed these benefit-risk trade-offs. In the end, however, all patients that consider using the technology will need to assess their own individual preferences when it comes to evaluating the benefit and risk profile of that technology as compared with other treatment options.

1.3 Shared Decision-Making

A key input into a patient's decision-making process is information on the benefits and risks provided by physicians, other healthcare professionals, healthcare provider organizations, and companies offering medical technologies and products. The American Medical Association Code of Medical Ethics recognizes that patients have the right "[T]o 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).

In 2018, the National Quality Forum (NQF) urged SDM to become standard of care for all patients and issued a call to action for all individuals and organizations that provide, receive, pay for, and make policies for healthcare to embrace and integrate SDM into clinical practice as a standard of person-centered care (NQF, 2018). NQF articulated three necessary requirements for successful SDM:

- Clear, accurate, and unbiased medical evidence about reasonable alternatives—including no intervention—and the risks and benefits of each;



- Clinician expertise in communicating and tailoring that evidence for individual patients; and
- Patient values, goals, informed preferences, and concerns, which may include treatment burdens.

Through SDM, 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 and Edgman-Levitan, 2012). In 2018, the Centers for Medicare & Medicaid Services (CMS) issued a decision memo for implantable cardiac defibrillators emphasizing the importance of SDM: “We believe that a[n] SDM encounter prior to initial ICD implantation is a critical step in empowering patient choice in their treatment plan. The SDM interaction requires the use of an evidence-based tool to ensure topics like the patients’ health goals and preferences are covered before ICD implantation. We want to ensure that the patient receives more information than the risks and benefits of the procedure.” (CMS, 2018).

The trend toward regular use of SDM provides an important opportunity for medical device manufacturers to communicate benefit, risk, and uncertainty information about their products.

CASE STUDY: PATIENT PERSPECTIVE ON BENEFIT-RISK COMMUNICATIONS

In 1983, I was a 19-year-old professional athlete when I had my first dual chambered pacemaker implanted as a result of an atrioventricular ablation. The procedure left me with 100% heart block and completely device dependent. This was years before social media and the internet existed. I was not informed that there were different types of pacemakers available and I did not know what questions to ask. The process of shared decision-making is only useful when the patient knows enough to ask good questions relevant to decisions that impact the outcome they want. At the time, my concerns and questions were around the aesthetics of the device in my chest. Not knowing any better, how it would look and feel seemed important.

It was not until I attempted to go back to my active lifestyle as an athlete that I learned I should have asked more questions about the technology inside and how the device would regulate my heart rate. The nature of a dual chambered pacemaker regulating my heart 100% of the time was more complicated than I could have imagined.

After six months with the initial pacemaker, I was frustrated with the responsiveness of the device to my needs as an athlete. I consulted with my cardiologist/EP team about my concerns. My care team then explained to me that I would be better off with a different brand of pacemaker, one that had advanced sensors and features better suited for my needs and goals. Together we made the decision to replace the device after only six months. I felt much better, but it would have been nice to have had more information and we could have made a better decision the first time and not undergo an additional surgery.

After 37 years and seven pacemakers, I still find today that most pacemaker patients are never asked if they have a device brand preference based on personal goals. Patients receive whatever device the hospital has a contract with. It is when they join a social media group, or initiate a search on athletes and pacemakers, that they compare pacemaker features and functionality with others and learn they could have had a choice. It leads to frustration and in some cases, like me, replacement of the first device with another.

Source: Heidi Dohse, Heart Patient

1.4 Patient Decision Aids

Because patients may not see the actual device product label or may not read it thoroughly, providers are often expected to incorporate the clinical data embodied in labeling information (as well as additional studies of the treatment options and other information) in their communications with individual patients and their families. There is an opportunity to support this communication with decision aids and other tools that communicate valuable information to patients in a way that is balanced, non-biased, and easy to understand (e.g., plain language summaries or graphic representations of benefits and risks).

CASE STUDY: SUPPORTING PATIENTS IN MAKING TREATMENT DECISIONS

A mobile application was developed for patients with diabetes to advise patients on making decisions about insulin based on individual therapy parameters and improve the accuracy of insulin dose amounts compared to mental calculation. The app was developed by an R&D team, including human factors researchers who interacted directly and indirectly with patients to gather their input. The app features were designed with patients' perception, cognition, and actions in mind. Human factors researchers tested the app design with patients in multiple rounds of usability studies. Data that was collected from these studies were analyzed and design changes were made to improve the app usability and reduce the probability for risk-related use errors. The team, including risk management, assessed patient outcomes from the usability studies to determine if further risk-mitigating controls were needed. Risk-mitigating controls that were further implemented into the app included inherent safety and protective measures, and information to the patient.

Specifically, the app described variables needed for the algorithm to calculate an insulin amount. Healthcare professionals provided individual therapy parameters that were then saved during app setup, simplifying the need for patients to remember their values and apply them in advanced calculations. After the setup process was complete, patients were prompted to input real-time information, usually a blood glucose reading and carbohydrate intake, and the app would advise the amount of insulin (or carbohydrates) the patient would need to reach their target blood glucose. The app user interface was designed to prevent certain actions and inform the patient of other hazardous situations. The app design supported the patient by reducing memory recall of individual therapy parameters, reducing probability of mental calculation errors, and increasing visibility of essential information needed to achieve a desired outcome.

Source: Roche Diabetes Care, Inc.

Much of the research examined for this report focused on risk communication in interpersonal, clinical settings, especially the significant role that decision aids can play in SDM. While the literature was unclear on how different clinical settings (such as an outpatient office vs. an inpatient hospitalization vs. technology-enabled exchanges) may impact patient understanding of benefit, risk, and uncertainty, it is clear that providing information related to benefit, risk, and uncertainty for use in decision aids is an important opportunity for medical device developers.

1.5 Direct-to-Consumer Advertising

Presenting potential medical treatments to the patient through paid media advertising, known as direct-to-consumer (DTC) advertising, has been a mainstay of health communication for the pharmaceutical industry for many years. More recently, some medical device developers have entered this space, as patients and health consumers are increasingly seeking health information proactively (Medical Device and Diagnostic Industry online, 2016).



In October 2018, the FDA issued a Draft Guidance for Industry on “Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements.” This document was specifically focused on drugs and biologics, but it includes recommendations and concepts that may also be applicable to medical devices. This Draft Guidance reflects agency thinking on such topics as probability presentations, formatting quantitative efficacy or risk information, use of various types of visual aids, and inclusion of quantitative efficacy or risk information from the control group in communications (FDA, 2018).

In its December 2018 guiding principles for DTC communication, AdvaMed (a trade association representing device manufacturers) outlined the existing regulatory parameters (FDA and FTC) and embraced a set of principles, including ensuring that DTC communication should “present relevant risk information in clear language free from distraction and located conspicuously to ensure its importance is not minimized” (AdvaMed, 2018).

1.6 Online Search for Health Information

Use of the internet to find health information is almost ubiquitous, with one 2019 study finding that seventy-five percent of participants in a recent study of use of online resources reported having ever searched for health information on the internet (Madrigal and Escoffery, 2019).

The ability to find detailed information about virtually any health topic, including medical product details, creates opportunities and challenges for medical device developers seeking to communicate information about benefits, risks, and uncertainty associated with their products.

CASE STUDY: ONLINE SEARCH FOR HEALTH INFORMATION

First, there are the symptoms and then the diagnosis of a condition prior to a procedure and medical device decision. A patient’s desire for healthcare/medical device information is often due to one of two health-related experiences:

Symptom Search: When someone experiences symptoms and attempts to self-diagnose by searching the internet to determine whether to see a doctor.

Diagnosis Search: A primary care physician suggests that a person is showing signs of a condition during a visit for an unrelated issue. Typically, this message is delivered along with the need for more tests and a specialist in order to provide an official diagnosis.

The patient begins researching online to determine if his/her symptoms are serious, or to learn about a diagnosis and treatment options. However, without curated search results, human nature and self-preservation take over and can lead the person to focus on the worst-case scenario of a condition.

Often a person starts this search for information before the specialist is engaged and the tests are completed. There is a risk that a person will follow online search results to a wrong conclusion and create a negative expectation of device therapy. This can complicate the conversation with the physician and medical device product team if the patient has already worked himself/herself into a panic.

The information available to a patient searching the internet, whether correct or not, can impact how he/she will make a future risk-benefit decision on devices. The challenge is communicating the relevant information in a format that facilitates good decision-making and reduces fear and anxiety.

Source: Tour de Heart, Patient Advocacy Group

1.7 Social Media Channels

Patients and caregivers are increasingly leveraging social media platforms (Facebook, Twitter, Instagram, etc.) to seek information related to healthcare. Social media offers patients and families an opportunity to easily gather and share information among a community of others with similar experience. This can be a highly personalized, interactive, and efficient way to gather information and advice (Zhao and Zhang 2017). The growth of online communities of patients with shared experience can provide insights about a disease journey that may show similarities to information available in other ways but also may move beyond evidence-based information from published literature (Cordoş et al., 2017).

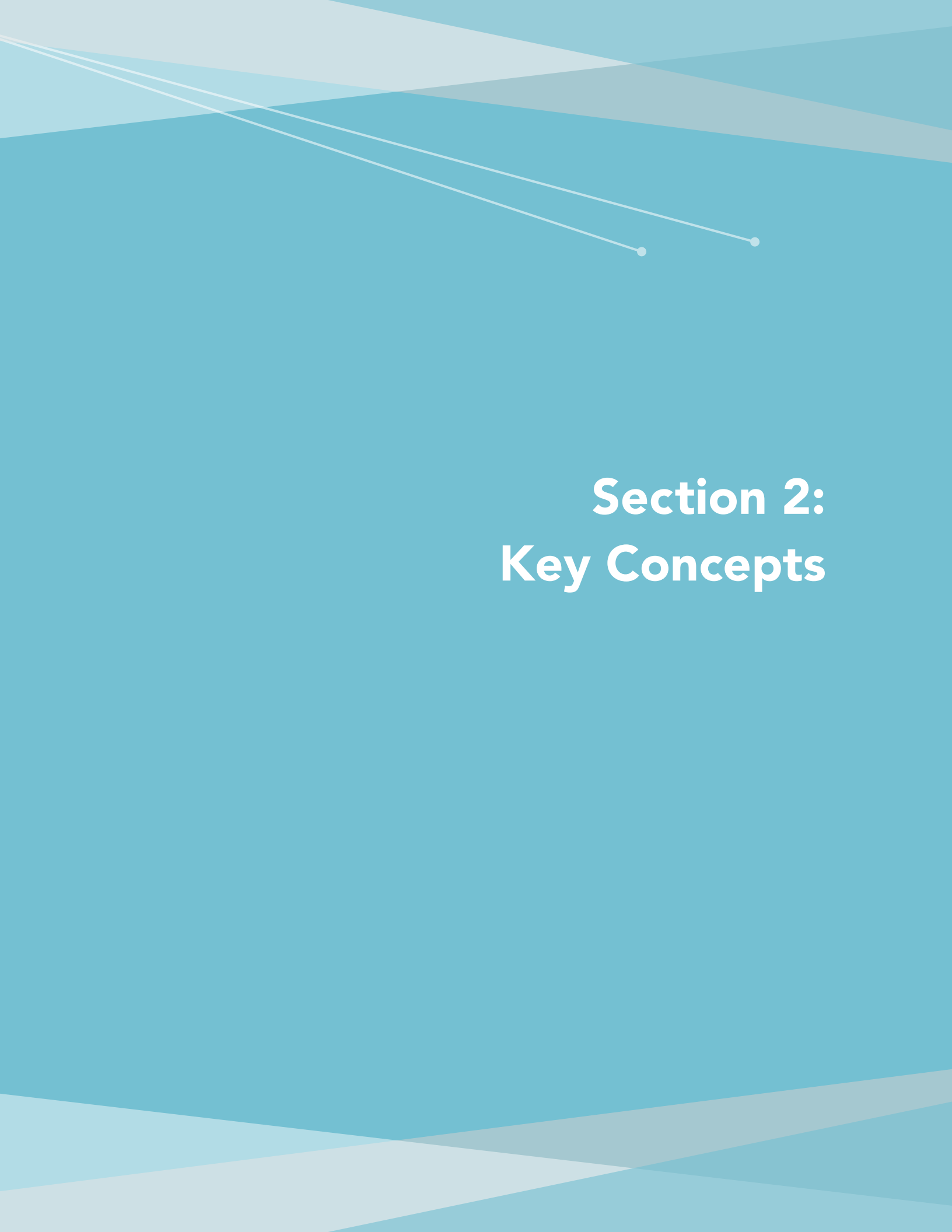
Recent studies to assess patient use of social media for health-related activities indicate that the benefit of finding information online is enhanced by the ability to find social and emotional support from peer-to-peer interactions. There are also potential downsides for patients, chiefly the potential for information overload, discordance, and questionable quality (Zhao and Zhang, 2017). Sometimes patients engage with Facebook and other online forums after an initial procedure with a device has been performed, creating timing issues for accessing information about benefit and risk relating to the device.

1.8 Patient Advocacy Organizations

Patients and caregivers often turn to non-profit patient advocacy organizations for information and support when confronting a serious illness. These organizations are traditionally viewed as honest brokers of objective information and they offer assistance for patients trying to understand and weigh treatment options. Recent research indicates that patients are much more likely to trust patient groups than therapy developers to provide the type of support they need in navigating their journey (Accenture, 2019).

Many patient advocacy organizations produce educational materials (often in conjunction or with support from industry partners) to educate their constituency about the disease and available treatment modalities, including lay-language discussion of the evidence about benefits and risks of various treatment approaches. In general, patient advocacy organizations produce unbranded non-product-specific materials for a class of treatment modalities, rather than one specific therapy or device. These materials can appear in patient guides, pamphlets, videos, blogs, and monitored discussion boards. Medical device manufacturers can assist in the development of these materials, including providing information about benefits and risks associated with the use of various treatment options.

Some organizations develop decision-aid tools for their communities, including key questions for patients and their caregivers to ask physicians when making treatment decisions. For example, the American Heart Association (AHA) has developed a heart failure tool kit for healthcare professionals called “Heart Failure: Partnering in Your Treatment” that includes a section to guide the discussion about what to expect from treatment (AHA, 2019). AHA also created a discussion guide piece for patients about the connection between heart disease and diabetes (AHA, 2019).



Section 2: Key Concepts

SECTION 2

Key Concepts

The key concepts discussed in this paper—benefits, harms, risks, preferences, and uncertainty—can be interpreted in multiple ways, particularly since they are often used colloquially in everyday speech as well as in a more technical manner within medical research and clinical settings.

Definitions for the terms and concepts used in this report 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 2016 FDA Patient Preference Information Guidance and the 2009 and 2018 FDA Draft Guidance documents on presenting efficacy and risk information (FDA, 2016; FDA, 2009; FDA, 2018).

2.1 Benefit, Risk, and Harm

Patients and healthcare providers can generally understand and identify the benefits of a medical treatment, including disease modification, symptom amelioration, extension of life, and improved quality of life.

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

The opposite of “benefit” is “harm,” which is also generally well understood:

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

However, within the current regulatory environment the focus is on “benefit” and “risk,” rather than “benefit” and “harm.” The concept of “risk” captures the probability of a harm: the greater the risk the more likely a harm is to occur. The word “risk” also captures an assessment of the severity of a potential harm: the greater the potential harm, the greater the risk to the patient. Therefore, the term “risk” incorporates both probability and severity:

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

Benefits and harms are subject to **uncertainty** as to whether they will occur in an individual patient, so they are usually 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. Patients deciding on a treatment option need to understand and evaluate benefit and risk by considering the probability that a particular benefit or harm might occur in their specific case. Recent publications have pointed to the impact of terminology in influencing how patients evaluate their options, including underscoring the distinctions between the terms “risks” and “harms” (Morgan, Scherer, Korenstein, 2020).

2.2 Patient Preference Information

When faced with more than one option, an individual decides to choose one option over the other(s), thereby expressing a “preference” for one option over another. Such decisions might be rational or irrational, or based on a quantitative or qualitative analysis of the probability of benefit and harm. No matter the basis of the decision, a choice is assumed to be an expression of preference.

As discussed in the MDIC Patient-Centered Benefit-Risk (PCBR) Report, it is important to note that a preference is different than a judgment (MDIC, 2015).

A preference is the basis for a choice among options that individuals make for themselves, whereas a judgment is the basis for choice among options that individuals make about something that affects someone else. For example, physicians may make a judgment about a recommended treatment option for a patient but would express a preference if making a choice among treatment options for their own care.

The MDIC PCBR Report and the FDA Patient Preference Guidance are specifically focused on assisting stakeholders in the medical device regulatory process seeking to collect and provide information about patient preferences regarding a specific technology or disease state. The FDA Patient Preference Guidance defines **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).

2.3 Risk Tolerance & Uncertainty Attitude

Patients involved in making choices about healthcare will express preferences among the available treatments. Patients incorporate information provided by healthcare professionals, particularly physicians, but may also seek information from other sources, including the internet, social media, patient advocacy organizations, and input from discussions with friends and family. A patient’s decision will reflect the desire for benefit traded off against the 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.

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 toward treatment 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. This concept is further explained with a graphical illustration 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 can express their preferences for the treatment option that they want to pursue.

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 probability of an event occurring within a specified period of time. Relative risk is the change in the probability of an event occurring described as a percentage increase or decrease from a baseline or comparator.

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.

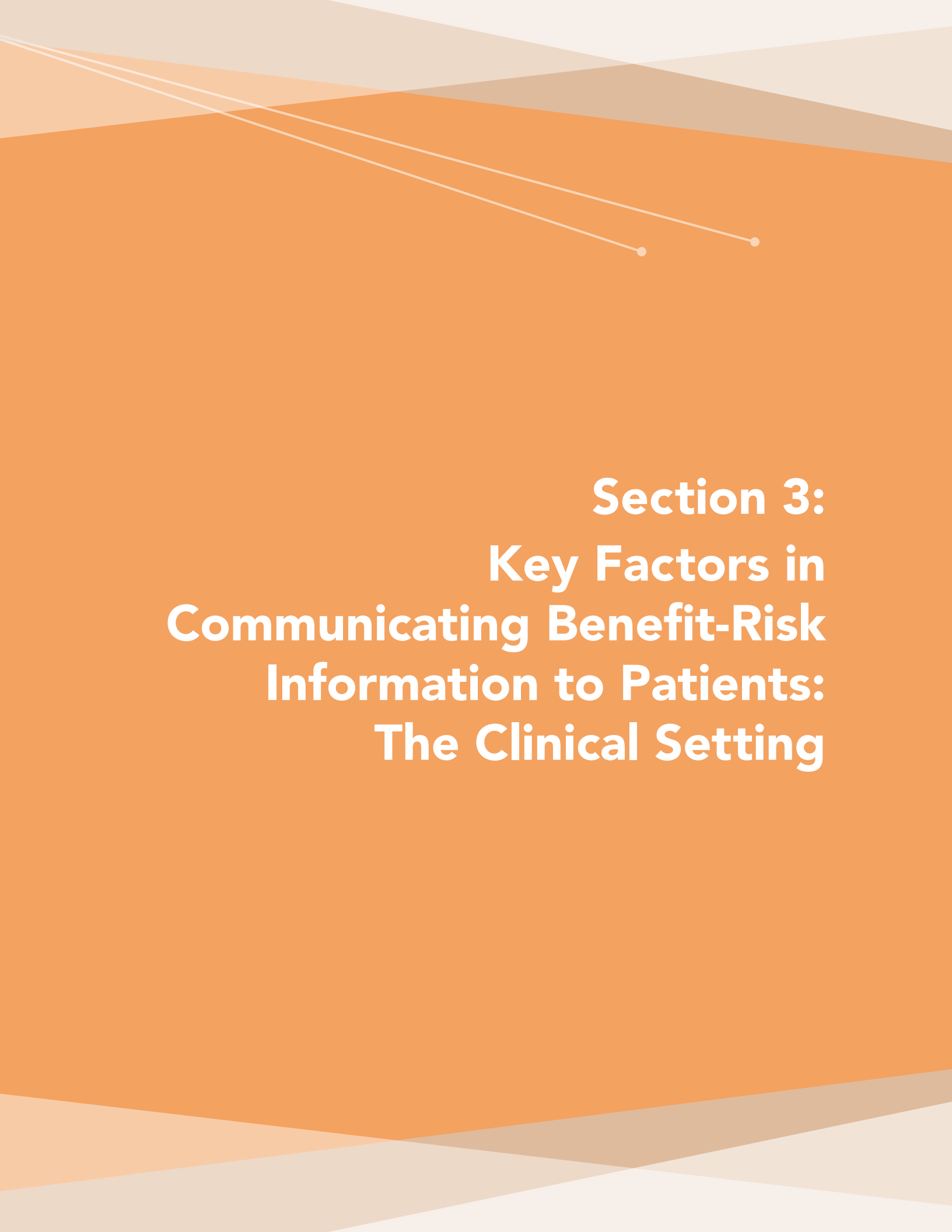
Graphical Literacy: The ability to understand information that is presented graphically.

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.



**Section 3:
Key Factors in
Communicating Benefit-Risk
Information to Patients:
The Clinical Setting**

SECTION 3

Key Factors in Communicating Benefit-Risk Information to Patients: The Clinical Setting

In December 2018, an MDIC-initiated landscape analysis review conducted by Exponent was provided to MDIC to serve as background source material for this project. The reviewed body of literature suggests a range of considerations in communicating benefit-risk and uncertainty information and identifies ways to most effectively communicate such information to patients within the clinical care delivery setting.

The relevant concepts identified in these studies have been sorted into 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 summarizes key factors within these areas that can improve comprehension of benefit-risk and uncertainty communication.

3.1 Relevant Provider Characteristics

Successful communication to patients of risk, benefit, and uncertainty by providers is dependent on a series of characteristics of the provider. Physicians were generally rated highly by patients and families for being credible sources of information (significantly more credible than pharmaceutical companies, for example) in a study evaluating the impact of uncertainty on patients' decision-making (Longman, Turner, et al., 2012). The extent of the physician's previous experience and training in the specific medical procedure or treatment under discussion is a salient factor in a patient's decision-making (Lee Char, Hills, et al., 2013).

Additional factors relating to providers include their approach to communication with patients, including their commitment to SDM, careful choice of language, avoidance of appearing to push a specific decision, and clear explanation of treatment outcomes (Fisher, Ledford, et al., 2018). Overall, autonomy and sense of mutual respect between patients and healthcare providers are often as important to the successful communication as the treatment options available (Gainer, Curran, et al., 2017).

3.2 Relevant Patient Characteristics

It is vital to "know your audience" to optimize communications approaches by tailoring the information based on the needs and characteristics of the patients. The Alliance for Healthcare Research and Quality (AHRQ) has developed a Universal Precautions Toolkit, which recommends starting with the assumption that all people may have trouble understanding complex health-related information (Brega, Barnard, et al., 2015).

Specific characteristics of the patient population, including age (Price, Bereknyei, et al., 2012), native language (Ankuda, Block, et al., 2014), and literacy must all be taken into account when designing the most effective communications approach. For example, older patients and those for whom English is not the first language may have a harder time comprehending information.

There are also key aptitudes that matter when it comes to a patient's ability to understand complex information about benefit, risk, and uncertainty. Patients with higher verbal aptitude and higher graphical literacy had better understanding of a medical device, especially when information about benefits and risks was presented in graphical format

(Edlund, Edlund, et al., 2015; Garcia-Retamero and Galesic, 2010). Conversely, patients with lower numeracy did not benefit from more information presented to them (Fraenkel, Stolar, et al., 2017). Increasingly there is also a need to gauge patients' digital literacy as technological tools are used to present information (Karnoe, Furstrand, et al., 2018).

Another relevant patient characteristic relates to previous experience with health issues. Probabilistic information can be dismissed by participants when it is not consistent with their previous personal and family experiences (Holmberg, Waters, et al., 2015).

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 (Edlund, Edlund, et al., 2015; Fraenkel, Stolar, et al., 2017). 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, providers, and caregivers is needed.

3.3 Relevant Message Components

Content:

The message itself is as important to medical decision-making as the messenger, the message recipient, and the format in which health information is provided. There is ongoing debate within the field of medical ethics about the extent of information that should be provided to patients to support their ability to make informed decisions about medical treatment. Studies have been done to evaluate the extent to which patients rely on an intuitive bottom line meaning of what is being presented related to risk, benefit, and uncertainty, rather than detailed numerical information.

These studies suggest it may be best to use an integrated approach to address numeric cognition, emotions, and qualitative "gist" representations (Reyna, 2008) of the medical information (Wilhelms, Fraenkel, et al., 2018; Wilhelms and Reyna, 2013).

Statistical Concepts:

Inherently, information about benefit, risk and uncertainty relating to medical devices is based on statistical evaluation of data. 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. CDRH Guidance (FDA, 2016) recommends describing the "benefits and risks in absolute scales instead of relative terms, which better inform the actual risks" (e.g., instead of describing a one-third or 33% increase in risk when switching from treatment B to treatment A, it may be more appropriate to state that 20% of patients have an adverse outcome with treatment A and 15% of patients have an adverse outcome with treatment B) (Akl, Oxman, et al., 2011). Likewise, natural frequencies are sometimes better understood and easier to interpret than probabilities. For example, consider the statistic that about 1 in 8 U.S. women (or 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; Garcia-Retamero and Hoffrage, 2013; Oudhoff and Timmermans, 2015).

There is evidence that patients are less willing to accept treatment risks when those risks are presented in relative terms (Hudson et al., 2011). Additionally, 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) and patients may be better able to interpret relative risk correctly than absolute risk (Lavallie et al., 2012). Finally, it has been shown that when relative risk is presented, it should be accompanied by absolute frequency (e.g., "there is a three-fold increase for heart disease to 15%" (Brega, Bodemar, et al., 2014)

Formatting and Framing:

When presenting uncertainty, providing information as a point estimate has been shown to be preferable to using a range (e.g., 8% is more credible than 2-14%). (Longman, Turner, et al., 2012; Sladakovic, Jansen, et al., 2016). Graphs involving a single variable are often easier to comprehend than graphs involving multiple variables (Zikmund-Fisher, Fagerlin, et al., 2010).

Overall pictograph information has been shown to be preferred compared to text or tables. (Tait, Voepel-Lewis, et al., 2010). In addition, it is generally better to rely on pictographs when using small numerators and bar charts when using medium and large numerators. For numerators less than 100, pictographs are more easily understood. For numerators larger than 100, bar charts are more easily understood. (McCaffery, Dixon, et al., 2012).

Order of presentation of information also matters. For example, participants with higher numeracy were more likely to believe that benefits outweighed risks when benefits were presented first (Fraenkel, Stolar, et al., 2017). Patients who were first presented with attributes they thought were most important were more likely to choose treatment options aligned with their stated values (Bansback, Li, et al., 2014). In addition, respondents perceived the risk to be lowest when information was framed positively vs. negatively (e.g., 10% for adverse outcome is perceived to be worse than 90% for positive outcome) (Peters, Hart, et al., 2011).



**Section 4:
Best Practices and
Available Tools
for Device Developers**

SECTION 4

Best Practices and Available Tools for Device Developers

Existing literature includes multiple best practices and tools that could be useful for medical device developers. In 2011, the FDA published a detailed set of commentary and suggestions for all stakeholders working to enhance communication of benefit and risk related to medical products. This “Evidence Based User’s Guide” included expert discussions for “evidence-based best guesses at best practices” of a range of topics, from basic processes, to design of communications through implementation (FDA, 2011).

Below we highlight several sets of recommendations for review by medical device colleagues seeking to enhance their communications efforts surrounding benefit, risk, and uncertainty. It should be noted that certain specific situations may require customization or adaptation to reflect unique considerations by discipline, disease state, provider/care delivery setting, or patient population.

4.1 Overall Approach

In its October 2016 Guidance to Industry “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), the FDA acknowledged that no single format for presenting benefit and risk information to patients is universally superior to other formats, but made the following overall recommendations:

- Avoid solely verbal descriptions of uncertainty. Patients may interpret what “low” and “high” risks are differently.
- Avoid fractions, decimals, and different denominators when presenting risks of multiple treatments. These are relatively difficult for cognitive processing.
- If possible, describe the benefits and risks in absolute scales instead of relative terms, which better inform the actual benefits and risks.
- If possible, use multiple formats simultaneously (e.g., verbal frequency, percent, and icon array/pictograph). Relative understanding of these formats varies from patient to patient. Moreover, one format may make the other formats easier to understand.
- If possible, describe uncertainty in both positive and negative frames (e.g., 20% chance of adverse events or 80% chance of no adverse events) to avoid cognitive bias.
- Pretest the communication format. Since patient populations vary, pre-testing the chosen format can improve the comprehension of the format by the study population of interest.



A 2011 publication within the oncology treatment setting proposed “Ten Steps to Better Risk Communication,” based on an illustrative review of existing evidence-based strategies. (Fagerlin, Zikmund-Fisher, et al., 2011).

The 10 proposed steps are:

1. Use plain language to make written and verbal materials more understandable.
2. Present data using absolute risks.
3. Present information in pictographs if you are going to include graphs.
4. Present data using frequencies.
5. Use an incremental risk format to highlight how treatment changes risks from preexisting baseline levels.
6. Be aware that the order in which risks and benefits are presented can affect risk perceptions.
7. Consider using summary tables that include all of the risks and benefits for each treatment option.
8. Recognize that comparative risk information (e.g., what the average person’s risk is) is persuasive and not just informative.
9. Consider presenting only the information that is most critical to the patients’ decision-making, even at the expense of completeness.
10. Repeatedly draw patients’ attention to the time interval over which a risk occurs.

In a 2013 *AMA Journal of Ethics* commentary (Wilhelms and Reyna, 2013), Wilhelms and Reyna recommended that communications of health risk and benefit information focus on an integrated approach to helping patients understand benefit, risk, and uncertainty information, including:

- Giving reasons for facts (e.g., provide context where possible).
- Beginning with the message in mind (communicate the essential bottom line and consider impact of positive vs. negative framing of the evidence).
- Using graphs that highlight the “gist,” selecting the most appropriate format depending on the goal (e.g., communicating relative risk may be best done using bar charts to call attention to small differences in risk while communicating absolute risk is best done using stacked bar graphs to draw attention to the denominator or comparator population).
- Remembering that even experts are susceptible to reasoning errors and the potential for bias.
- Explaining all combinations of potential outcomes (where multiple risks are possible) using visual representation to represent and account for all relevant distinctions among groups of patients studied.

4.2 Developing Patient Decision Aids

Patient decision aids (PDAs) can be developed as effective tools to communicate benefit, risk, and uncertainty, providing information about available treatment options and helping patients clarify and communicate the personal value they associate with different features of the options (NQF, 2016).

Decision aids developed to facilitate patient education and SDM can be tested among test groups of patients to determine if they present information in an understandable and balanced way. Patients' ability to understand information can be evaluated by asking them to describe what each treatment option presented means to them. Balance in the presentation of information can also be assessed by assessing patients' responses to questions about whether the information seems biased toward one option or another.

CASE STUDY: PRODUCT LABELING/PATIENT DECISION AIDS – COMPANY-CREATED INTERACTIVE PATIENT-FACING COUNSELING TOOL: CHALLENGES AND OUTCOMES

An interactive patient-facing counseling tool was developed by an internal marketing group with the primary purpose of providing physicians with a tool to discuss with their patients the treatment options for aortic valve disease. The group relied exclusively on specialty society derived, peer-reviewed, published treatment guidelines.

Best practices in communications would dictate patient-friendly, comprehensible, and focused information, prioritized around outcomes that matter most to patients, including information captured through patient preference studies. For example, patient preference studies indicate that patients prioritize their ability to recover quickly and be independent from future burdens on themselves and their caregivers. However, the tool focused on clinical endpoints like survival and stroke.

The company's traditional approach to developing communications materials was constrained by historic interpretations of FDA advertising and promotion regulations that require evidence-based and "fair and balanced" representation of all risks and benefits. While the outcome of the interactive tool was successful and implemented for use, it failed to incorporate patient preferences into the development of the document. Future efforts to align the materials with patient preferences, perhaps led by third parties or patient groups unencumbered by regulatory oversight, could result in materials that more accurately reflect the patient perspective, communicate key criteria relevant to patients, and support decision-making.

Source: Edwards Lifesciences

The Patient-Centered Outcomes Research Institute (PCORI) is partnering with the AHA on an initiative to establish the Decision-Making and Choices to Inform Dialogue and Empower AFib Patients (DECIDE) Center, which supports efforts to develop or adapt, and then test the effectiveness of, SDM tools. AHA and PCORI are jointly administering a peer-reviewed grant program to support this effort (PCORI, 2020).

There have been significant international collaborative efforts to develop quality standards for the development of PDAs. In a 2018 *British Medical Journal* article, Sepucha et al. published a 20-element checklist (Standards for Universal reporting of patient Decision Aid Evaluation studies or SUNDAE) that included key best practice elements of a decision aid (Sepucha, Abhyankar, et al., 2018). Among these are:

- Development process of the PDA that includes:
 - Participation of stakeholders in its development
 - Gathering, selecting, and appraising evidence to inform its content
 - Evaluation testing
- Components of the PDA that include:
 - Explicit description of the decision
 - Description of the health problem
 - Information on options and their benefits, harms, and consequences
 - Values clarification (implicit and explicit)
 - Numerical probabilities
 - Tailoring of information or probabilities
 - Guidance in deliberation
 - Guidance in communication
 - Personal stories
 - Reading level or other strategies to help understanding

There are many tools available for the development of PDAs (see Appendix). One example is the Ottawa Hospital electronic training module. The step-by-step guide for the development of PDAs provided by this module is summarized here:

1. Draft a PDA 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 PDA 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 PDAs: 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 PDAs and apply the standards to the aid developed (The International Decision Aid Standards: <http://ipdas.ohri.ca/what.html>).
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 PDA: 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 the PDA: Plan an evaluation of the PDA 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 PDA in a public database.

In 2016, the NQF issued a white paper on PDAs summarizing its national standards for certifying PDAs. NQF outlined the following baseline certification criteria:

- The PDA describes the health condition or problem for which a decision is required. The PDA identifies the target user.
- The PDA explicitly states the decision under consideration.
- The PDA describes the options available for the decision, including nontreatment when appropriate.
- The PDA describes the positive features of each option.
- The PDA describes the negative features of each option.
- The PDA clarifies patient values for outcomes of options by:
 - Asking patients to consider or rate which positive and negative features matter most to them; and/or
 - Describing the features of options to help patients imagine the physical and/or social, and/or psychological effects.

4.3 Leveraging Online Resources

Given the extent to which individual patients are conducting their own online searches to become educated about their disease and potential treatment options, it is important for medical device developers to ensure useful information is accessible outside of the clinical setting. Within the bounds of regulatory and statutory limitations, product developers should include relevant benefit, risk, and uncertainty information in lay-person terms on their public website and in materials that can be accessible to patients through an internet search.

Online information never fully disappears from search accessibility, creating the potential for outdated benefit, risk, or uncertainty information to continue in circulation. For example, device manufacturers should be cognizant of the need to clearly and proactively update all information channels if a product design change alters the known information about its benefits and risks.

4.4 Leveraging Social Media Channels

Some social media channels, including Facebook and discussion boards, offer the opportunity for closed groups or invited participation, where patients can share information with one another relating to treatment experiences. In these circumstances it is generally not clear what information is being shared and there is the potential for partial or inaccurate information to be circulated. Product manufacturers should engage with individuals or organizations (e.g., patient advocacy organizations, online community social network conveners, etc.) that convene and monitor these groups to ensure they have access to appropriate benefit, risk, and uncertainty information.

In other cases, such as Twitter or in sponsored online links, space and other content restrictions may make it difficult to provide detailed and complete information about benefit and risk. In 2014, FDA published a Draft Guidance for Industry on this topic (“Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices” (FDA, 2014).

The factors outlined in the Draft Guidance for consideration by industry seeking to leverage these channels to communicate benefit and risk information include:

- Benefit information should be accurate and non-misleading and reveal material facts within each individual character-space-limited communication (e.g., each individual message or tweet).
- Benefit information should be accompanied by risk information within each individual character-space-limited communication.
- Risk information should be presented together with benefit information within each individual character-space-limited communication (e.g., each individual message or tweet).
- The content of risk information presented within each individual character-space-limited communication should, at a minimum, include the most serious risks associated with the product.
- A mechanism, such as a hyperlink, should also be provided within each individual character space-limited communication to allow direct access to a more complete discussion of risk information about the product.
- The prominence of risk information should be comparable to the benefit information within each individual character-space-limited communication, taking into consideration any formatting capabilities available on the specific internet/social media platform.
- If a firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated within the same character-space-limited communication, then the firm should reconsider using that platform for the intended promotional message.

4.5 Working with Patient Advocacy Organizations

Research has found that patients perceive information from providers and patient advocacy organizations to be more credible than information from industry (Longman, Turner, et al., 2012; Accenture, 2019). While it is important that patients rely on providers to communicate accurate information about benefits and risks, there is opportunity for device manufacturers to expand their efforts in understanding patient preferences and developing tools to inform patients about benefit and risk.

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 transparent, 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.

In recent years, there has been significant effort to expand resources for product developers to assist in forming and maintaining productive relationships with patient advocacy organizations. In 2018, the Clinical Trials Transformation Initiative (CTTI) published "rules of the road" for working with patient advocacy organizations (termed patient groups by CTTI) that included the following suggested best practices for industry (Bloom, Beetsch, et al., 2018). While these recommendations were specific to engagement and partnership within clinical trials, they are also more broadly relevant to the conduct of partnerships with patient advocacy organizations to communicate benefit, risk, and uncertainty information to patients:

- Integrate an assessment of patient group expertise, assets, and value to your program.
- Match patient group expertise and assets to the specific needs of your program.
- Ensure that patient groups are essential partners and not token voices.
- Establish guiding principles and clear lines of communication to facilitate a fit-for-purpose process for collaborating with patient groups.
- Measure the impact of your engagement with patient groups.
- Establish ongoing relationships with patient groups and communicate openly with them on a regular basis.

The National Health Council (NHC) has issued best practice recommendations and principles to help guide industry in developing partnerships with the advocacy community, including specific recommendations for structuring fair-market-value compensation of individual patient advocates who provide advisory services to industry and recommendations for contracting with patient advocates (NHC, 2019; NHC, 2020). Overall principles that are relevant to partnerships to support communication of benefit, risk, and uncertainty include:

- Acknowledging the overall role and purpose of patient advocates and the environment required for it to operate effectively and efficiently, while at the same time acknowledging the need to protect the interest of the companies and patient advocates.
- Recognizing the limited capacity of most patient advocates to deal with the workload.
- Recognizing the lack of legal expertise and the potential legal consequences arising from agreements signed with companies.



- Recognizing the diversity of relationships between the parties, not limited to classical consultancy that is usually covered by these agreements.

Additionally, BIO (the Biotechnology Innovation Organization) has issued the following principles to govern industry partnerships with patient advocacy organizations, including recommendations (BIO, 2019) for how to:

- Foster partnerships and value independence.
- Advocate for partnerships that improve patient outcomes.
- Support patient advocacy organizations (including providing financial support).
- Value the privacy of the patient community.
- Respect standards of ethical conduct.



Section 5: Conclusion



SECTION 5

Conclusion

The members of the MDIC Science of Patient Input Program are collaborating to improve our industry's ability to include patient perspectives in the development, pre-market approval, and post-market evaluation of medical devices. As we continue to advance the art and science of patient engagement in regulatory science, we recognize the importance of ensuring communication to patients about the benefits, risks, and uncertainties associated with medical devices in a way that maximizes each patient's understanding and ability to make treatment decisions.

In this report, we provided a summary of key terms and a review of studies in which researchers have identified characteristics of the provider, patient, and the way in which the scientific and medical information is disseminated that can affect patients' comprehension and decision-making. We introduced PDAs as one type of tool to help industry and providers effectively communicate benefit and risk. We have also provided information about best practices, tools, and available resources for medical device developers.

While progress in these areas has been made and the body of literature on these topics is significant and growing, there are still gaps and there is more work to be done. We focused on the opportunity for industry to enhance communications activities for patients in clinical settings. The opportunities for additional work to help inform communications best practices in non-clinical settings are numerous, especially in reaching vulnerable populations and leveraging emerging digital technologies.

We look to MDIC stakeholders for continued collaboration to advance this research agenda and in support of the upcoming MDIC Framework for Patient Input in Medical Device Clinical Trials to develop and emphasize evidence-based tools for engaging with patients in the design of clinical trials.



Section 6: References

SECTION 6

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Section 7: Appendix

SECTION 7

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)	International Decision Aid Standards (IPDAS)
Patient decision aid development online tutorial	Provides information regarding how to draft a PDA, 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 ICDs.	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 PDAs	Sepucha 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/
National Standards for the Certification of Patient Decision Aids	Provides detailed information and standards about development of patient decision aids.	National Quality Forum, 2016 https://www.qualityforum.org/Publications/2016/12/National_Standards_for_the_Certification_of_Patient_Decision_Aids.aspx



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