MDIC Patient Engagement Forum: Communicating Benefit, Risk & Uncertainty

November 2020 Forum: Lessons Learned

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

March 8, 2021

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OVERVIEW

The Medical Device Innovation Consortium (MDIC) Virtual Patient Engagement Forum held on November 18, 2020, engaged approximately 100 participants, including patients, patient advocates, medical device leaders, regulators, healthcare providers, payers, and experts in communication and shared decision-making. Participants joined in a day-long, interactive meeting focused on communicating benefit-risk and uncertainty for medical devices. Content for the Forum included presentations, panel discussions, and interactive activities inspired by the best practices and examples contained within the recently released MDIC Best Practices for Communicating Benefit, Risk, and Uncertainty Report.

Throughout the Forum, participants heard from healthcare providers, experts in communication, regulatory officials, and patients, sharing their perspectives on benefit, risk, and uncertainty communications related to medical devices. Forum participants also engaged in two small-group Interactive Activities during which they had the opportunity to develop a sample communication for a hypothetical medical device by applying various best practices from the Communication Report.

The goal of the Forum was to familiarize a diverse group of medical device stakeholders with key concepts and considerations for successful communication with patients about benefits, risks, and uncertainty associated with the use of medical devices. Additionally, participants had the opportunity to learn directly from individual patients with diabetes, arthritis, chronic pain, and cardiovascular disease about their experiences with medical devices and the quest for information about how these products would impact their health and their overall lives.

Overall, this event offered the medical device community a platform from which to evaluate current communications efforts, identify gaps, and prioritize additional needs for advancing progress on this topic. Key lessons learned and themes emerging from the Forum provide the foundation for this report.

BACKGROUND

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 the review, approval, and subsequent use of a device, manufacturers, and regulators seek to ensure that information about the benefits, risks, and uncertainty associated with the device and needed for patients to make informed decisions is available and understandable. Similarly, patient-centered care requires effective communication of benefits, risks, and uncertainty among patients and providers.

Given the importance of patient engagement during the treatment decision-making process, as well as across the total product lifecycle for a medical device, there is a need to identify and promote best practice resources for medical device developers as they communicate with providers and patients about the benefits, risks, and uncertainty associated with the use of medical devices. As the art and science of patient engagement continue to advance within regulatory science, it is increasingly important to ensure that all stakeholders communicate the 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 the Communication Report, developed by MDIC's Science of Patient Input Communication Working Group, 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. As a prelude to the Forum, MDIC held an informational webinar to discuss the Communication Report.

By convening the community in an interactive forum setting, MDIC sought to engage a multi-stakeholder group in a discussion about various goals and approaches for communicating with patients about medical devices highlighted in the Communication Report, as well as provide an opportunity for stakeholders to work with its best practice recommendations and resources. Capturing lessons learned through real-time activities geared toward developing sample communications in a variety of formats, the Forum created an opportunity to identify gaps and areas where additional resources might be useful to support device manufacturers, regulators, clinicians, and patients.

"I'm excited that things I have been doing to engage patients are moving forward."
-Patient Advocate Participant

"I was challenged throughout the day and learned new things. Everything was so thought-provoking."
-Expert Participant

KEY FORUM THEMES AND LESSONS LEARNED

Throughout the Forum, participants had the opportunity to share their experiences and expertise, learning from one another and from engaging directly with best practice recommendations from the Communication Report through small-group, interactive activities.

What follows is a summary of the key themes, topics, and lessons learned from the Forum.

FDA Commitment to Patient Centricity

In opening and closing the Forum, Center for Devices and Radiological Health (CDRH) leaders emphasized the FDA's deep commitment to placing the needs of patients at the center of its work in overseeing the development of medical products. Dr. Jeff Shuren (CDRH Director) described patients as "the Center's most important customers," noting ongoing efforts since 2012 to advance patient preference, customer service, investment in the science of patient input, the establishment of a Patient Engagement Advisory Committee (PEAC) and development of a collaborative community at which patients have a "seat at the table." Dr. Michelle Tarver (CDRH Director of Patient Science and Engagement) reviewed FDA's focus on integrating patient preference information along the total product lifecycle for a medical device and efforts to collect real-world data for a better understanding of the patient journey. Alicia Witters (Director of Division of Communication) emphasized the importance of developing effective communications with patients based on real-world data and an understanding of the patient's journey with a medical device.

"We know that there is nothing that replaces the health care provider and patient conversation. But the availability of information to help patients make an informed decision is very important. It is also critically important to have patients involved in the generation of that information so that it is designed in a way that it meets the patient community's needs and can help address some of the questions that they may have when they're at that critical position of making a decision about their care."

-Regulator Participant

"The FDA is here to work collaboratively with patients and other public stakeholders, and we're committed to improving how we communicate about medical devices. We recognize it is in the interest of public health to ensure that communication about medical devices is as clear and accessible as possible."

-Regulator Participant

Total Product Life Cycle of a Device vs. Cycle of a Patient's Life

While sponsors often refer to the total product life cycle (TPLC) of a medical device, patient speakers during the Forum repeatedly emphasized the importance of remembering that a medical device, especially one that is implanted, lives with a patient throughout the cycle of his or her life and impacts a person's whole body and lifestyle. It is therefore critical to ensure that communications about benefit, risk, and uncertainty include clear information about how a device might affect a person over time. This includes details such as monitoring the ongoing effectiveness of a device, potential recalls, updates to technology, the impact of the removal of an implanted device, and other aspects related to understanding that all of this is happening within a single person's lifetime (the cycle of a patient's life).

"Understanding how medical device products integrate into the way you live your life and what you're doing are extremely important. And the more that a company can communicate that understanding of those perspectives and scenarios and put features in the context of what that means is certainly important."
-Patient Advocate Participant

Crucial Role of Providers

> "Each of us as an individual knows that how a device works in our bodies is going to be different. But when expectations do not match up, that is where the frustration comes in. It would be better to say, "I don't know," but let's co collaborate. Together, let's figure out the best course of action so that expectations are aligned with both the patient roles/ responsibilities and the doctor roles/responsibilities as part of the definition of a successful outcome."
>
> *-Patient Advocate Participant*

A consistent theme throughout the Forum was the important role of health care providers in ensuring that benefit, risk, and uncertainty information are communicated effectively to patients and their caregivers. Many patients never see the packaging and brochures associated with their medical devices (especially those that are implanted), and they may not even know the name of the product manufacturer.

Information related to device updates or recall is often provided first to physicians who then must transmit it to their patients. This contrasts with most other fields, in which consumers receive information directly from a product manufacturer (e.g. an appliance or a car). Health care providers must have the time and skills to conduct these types of communications and to know as much as possible about their patients' lifestyles and preferences to ensure that the most relevant information is presented in a timely and understandable way.

Cognition vs. Metacognition

Dr. Ruth Day (Duke University) discussed the topic of how people gather and assess information, presenting data to demonstrate the extent to which people overestimate how much they know. She presented several important concepts including cognition (the processes of knowing things, such as attention, comprehension, memory, problem-solving, and decision making), metacognition (knowledge about our own cognition i.e. what we think we know and how well we think we know it), cognitive accessibility (the ease with which people can find, understand, remember, and use information safely and effectively) and cognitive inaccessibility (which occurs anytime people have trouble with any one or more of these elements). Additionally, she distinguished between "declarative knowledge" and "procedural knowledge, noting the former refers to people's ability to **say** what they know while the latter refers to their ability to **apply** what they know.

Dr. Day's research evaluating these concepts involves evaluating patients' ability to access and apply the information they receive about medical devices comparing cognition, metacognition, and access results for those patients who receive the original product brochure with those who receive an enhanced version. The enhancements were based on validated cognitive principles and included clustering certain similar types of information and ensuring correspondence between text and pictures.

In evaluating the results of these studies, Dr. Day noted the importance of testing communications with actual patients and caregivers. Focus group work and survey work can be critical for finding out about patients' perceptions and preferences for information, attitudes, and ability to retain information.

Patient Decisions Aids to Support Effective Shared Decision Making

> ***"Patient care is optimized when both the patient and the provider meet as equal partners in the discussion of treatment plans, recognizing the unique insights that both the patient and the provider will bring to that discussion."***
> ***-Clinician Participant***

Effective shared decision-making (SDM) between a health care provider and the patient depends on clear and appropriate communication about the benefit, risk, and uncertainty associated with medical devices. In his keynote address during the Forum, Dr. J. Matthew Brennan (Duke) described how patient care is optimized when patients and their providers are equal partners and can engage in a structured conversation about medical decisions.

An important challenge in maximizing the use of PDAs to communicate about benefits, risks, and uncertainty within SDM relates to the need for trust that information is accurate, unbiased, and presented in a manner that can be absorbed and understood by patients. Engaging patients and patient advocates in the process of developing PDAs is a necessary step toward this objective. Additionally, given what Dr. Brennan described as "the wild west of product marketing" in the medical device field, there is a need to standardize development and establish a certification system for PDAs. Once these tools have been certified, they can be made broadly available (through a centralized repository) to patients, preferably without the need for healthcare providers to serve as gatekeepers.

Dr. Brennan described the important role that well-designed patient decision aids (PDAs) play in supporting these conversations. While there are efforts to create and use PDAs, these tools are not commonly used in the delivery of clinical care. This is a field where additional progress is

needed. For example, he noted a highly fragmented landscape for PDAs in which while there are more than 25 entities currently developing major PDAs worldwide, only 1 in 5 of these decision tools is ever used, and only 1 in 10 are disseminated broadly. As a result, most patients do not have access to these tools. He proposed the need for a centralized repository for PDA tools in the United States (along the lines of one managed by NICE in the United Kingdom or Ottawa Hospital Research Institute in Canada).

Context Matters When Presenting Numerical Probabilities

Recognizing that most patients are not trained to evaluate complex statistical concepts, care must be taken in determining how to communicate numerical probabilities associated with benefit, risk, and uncertainty information. There can be confusion about the distinction between "absolute" risk and "relative" risk, especially when patients are attempting to understand how this information applies in their specific cases. While relative risk may be more intuitive for a patient to understand (i.e., something is more or less likely to occur than something else), relative risk can be misleading about the public health burden of the risk. As a result, CDRH's 2019 Guidance "Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions" recommends communication of benefits and risks using absolute risk instead of relative risk.

While specific numbers are important, so is the context in which they are presented and understood. Using story-telling and a narrative format can provide a more complete picture and support enhanced understanding among patients and caregivers. Additionally, people are likely to approach the same information with different mindsets. For example, while some patients may evaluate a 1 in 10 chance for benefit as a hopeful probability (e.g. "someone will win the lottery so why wouldn't it be me?"), others may see an overwhelming likelihood of receiving no benefit. Similarly, a person with a positive mindset may look at a 1 in 10 chance that something bad will happen and see only a small risk, while the latter might focus on the potential negative outcome (e.g. "Tigger" vs "Eeyore" mindsets). It may be difficult for patients to make a connection between the truth of their individual experiences and population-based data and statistics.

Patient Empowerment and Transparency

> ***"It takes some learning from a patient perspective to understand that you have choice, agency, and ability to push back and ask follow-up questions or even seek out a second opinion."***
> ***-Patient Advocate Participant***

It is important to empower patients to participate in the shared decision-making process and provide them with a sense of "agency" in making choices about their care. For this to occur, patients need to know what questions to ask of their providers when discussing the use of medical devices. Supporting this process requires access to effective communication tools, as well as the opportunity for patients to share information with others who have had similar experiences. There is a sense among patients that the burden is on them (and their caregivers) to access the information they need for decision-making. Some people describe a burdensome "trial and error" approach to evaluating their options that should be supported with more accessible communications about the benefit, risk, and uncertainty.

Transparency is also needed, given that there are limits to what existing medical data and evidence from clinical studies can tell specific patients about their own unique likelihood of experiencing benefits and risks. While sponsors, investigators, and regulators endeavor to provide as much clarity as possible about a medical device through the literature, labeling, and marketing information, clinical studies cannot reflect the experience of every person who may use the product. By being transparent about these limitations, those who communicate information can build trust among patients and their caregivers.

> ***"It is critical that decision aids are developed in an unbiased environment with all of the stakeholders at the table using strict standards for evidence synthesis and data presentation. Consumer trust starts with a development process that draws in the expertise of all stakeholders, including industry, regulators, payors, clinicians, and patients."***
> ***-Clinician Participant***

Using Multi-Modal Approaches to Communicate

> "There's a fine balance between scaring people versus giving a very compelling visual that will stick with them."
>
> *-Patient Advocate Participant*
>
> "Think of the technology and social media, where peer support groups have exploded. As we all know, sometimes you get incredibly helpful information, and as we also know sometimes you get frightening information on there."
>
> *-Patient Advocate Participant*
>
> "I think the best strategies of communication are just to put as much information out there in various ways online and offline in the doctor's office."
>
> *-Patient Participant*

Patients and caregivers rely on a variety of communication channels and formats when engaging with health information. Information about the benefits, risks, and uncertainties associated with the use of a medical device should be available in multiple forms. The information provided during a visit would be most useful if it is in a format that can be taken home for review. A consistent challenge noted throughout the Forum was the time limitation on patient-provider interactions during office visits, pressuring providers to move through complex information quickly with their patients. Healthcare providers say it is important to avoid the use of medical jargon and confusing terminology, while personal stories can help patients and their caregivers connect with this information.

Given the wide diversity among patients concerning learning styles, language, literacy, and ability to access information, it is necessary to develop communications in multiple formats, including tangible written materials, graphic and visual representations, as well as audio-visuals. There is a clear need to "meet people where they are" in ensuring that these communications can be accessed and understood. Forum participants reported using Google searches to find information on medical devices contained on websites of professional societies, industry sponsors, and patient advocacy groups. They also frequently rely on social media networks such as Facebook and Twitter. Some patients also attend conferences (in person or virtually) and access conference materials online.

"We partner with those who have the expertise to communicate to our audience. I always tell the industry folks and my colleagues in medicine education: keep it simple, make it attractive, and help patients quickly see the potential benefits of a therapy."

-Patient Advocate Participant

"It's really important to understand what the caregivers are going through. We find that the caregivers get so much out of listening and understanding and learning and that really empowers them to understand how they can be part of the decision."

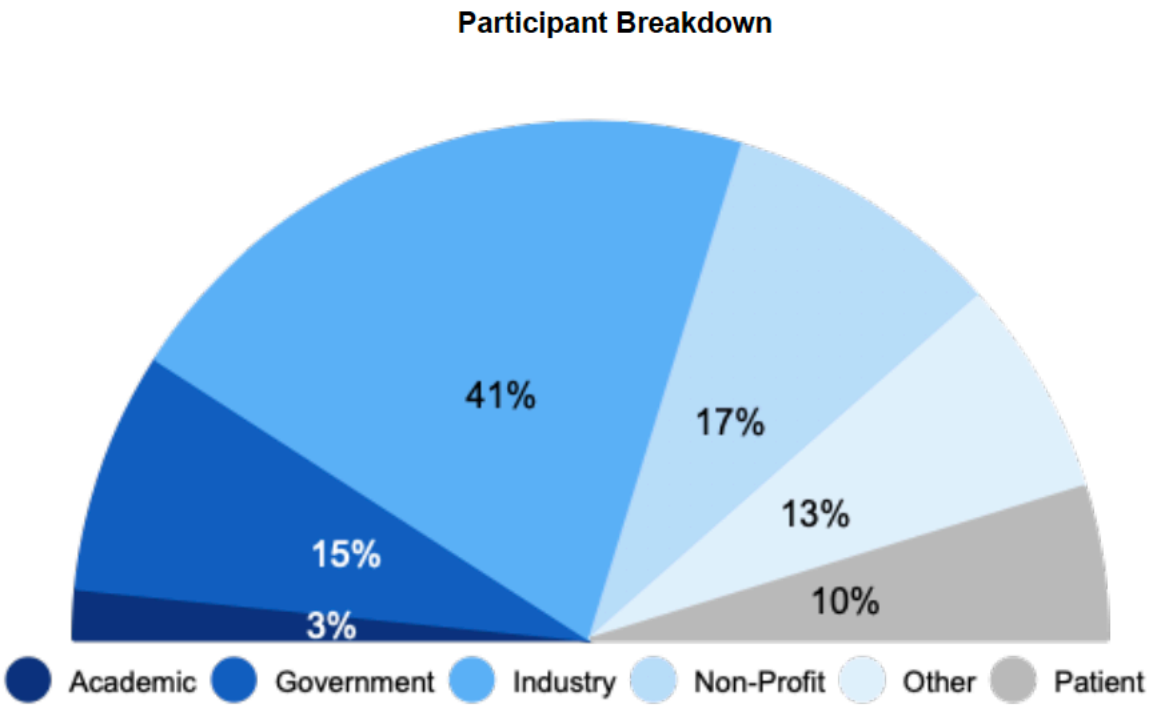
-Patient Advocate Participant

CONCLUSION AND NEXT STEPS

In follow up to the Forum, MDIC surveyed participants about areas of most interest and opportunities for continuing efforts by the multi-stakeholder medical device community. Respondents indicated an interest in future efforts to compare lessons learned from device sponsors who have incorporated these best practices. Other suggestions included discussing these topics in the context of in vitro devices and engaging a live patient critique of existing or new materials. Additionally, it was proposed that future activities should engage the payor's perspective. MDIC anticipates continuing to engage with these topics through further dissemination of the Communication Report and building upon lessons learned from the Forum to support ongoing innovation in these activities within the medical device community.

MDIC is grateful to all speakers and participants for their enthusiastic commitment to advancing this effort and improving communications of benefit, risk, and uncertainty information for medical devices.

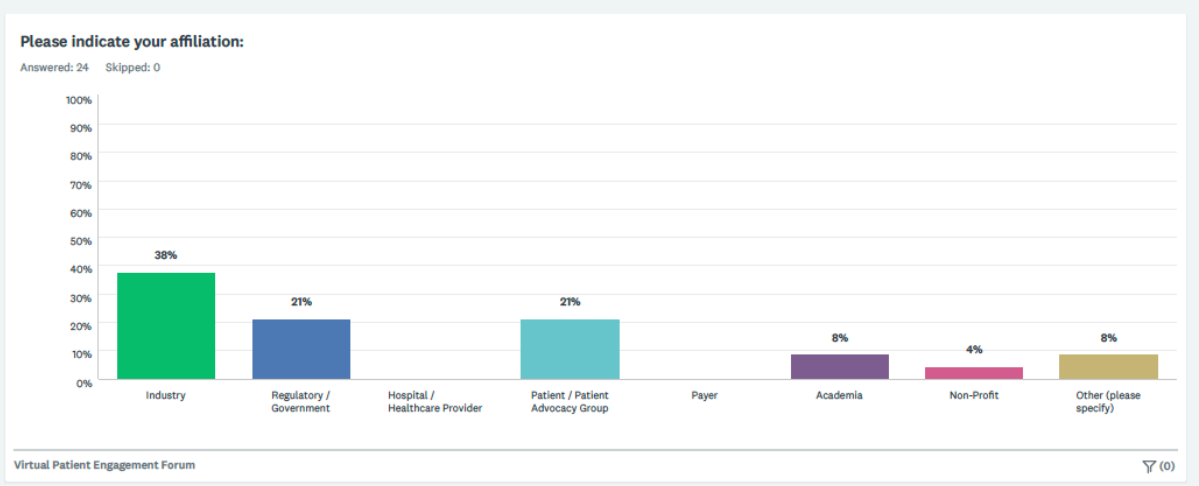
APPENDIX I: MEETING PARTICIPANTS BY CATEGORY

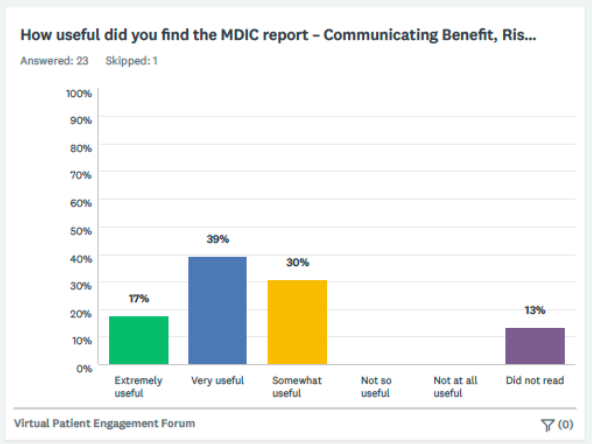


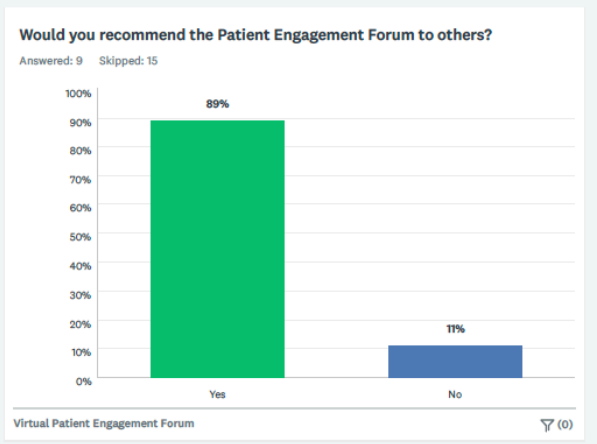
APPENDIX II: PATIENT ENGAGEMENT FORUM COMMITTEE MEMBERS

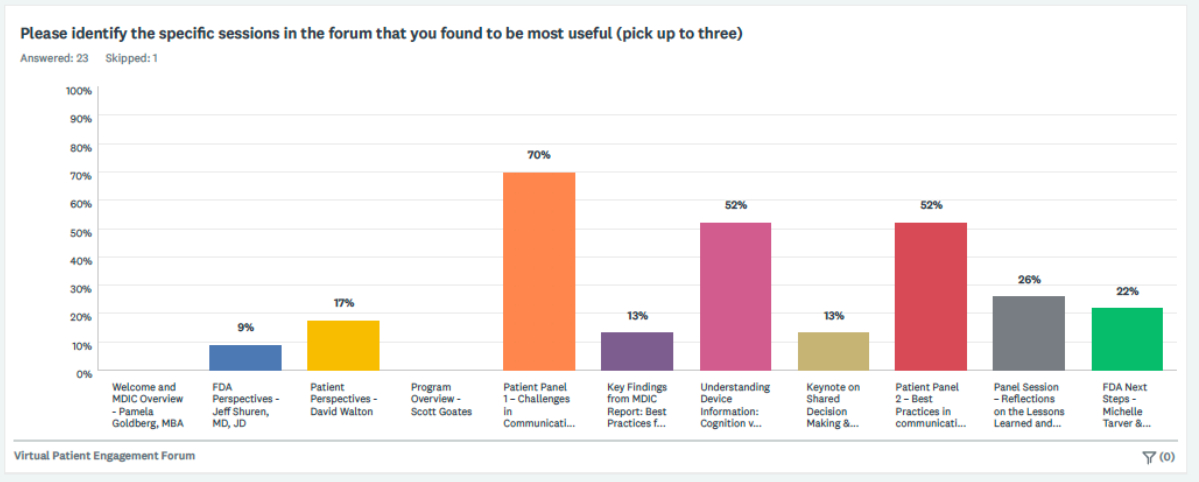
Scott Goates, PhD | Abbott
Sue Peschin, MHS | Alliance for Aging Research
Sarah DiGiovine | Alliance for Aging Research
Michelle Tarver, MD, PhD | CDRH
Anindita Saha | CDRH
Barry Liden, JD | Edwards Lifesciences
Heather Colvin, MPP | Johnson & Johnson
Heidi Dohse | Tour de Heart
Wendy Selig | WSCollaborative
Liliana Rincon-Gonzalez, PhD | MDIC
Marlene Jordana, MS | MDIC
Desiree' Steele | MDIC

APPENDIX III: SUMMARY OF POST-FORUM SURVEY FEEDBACK





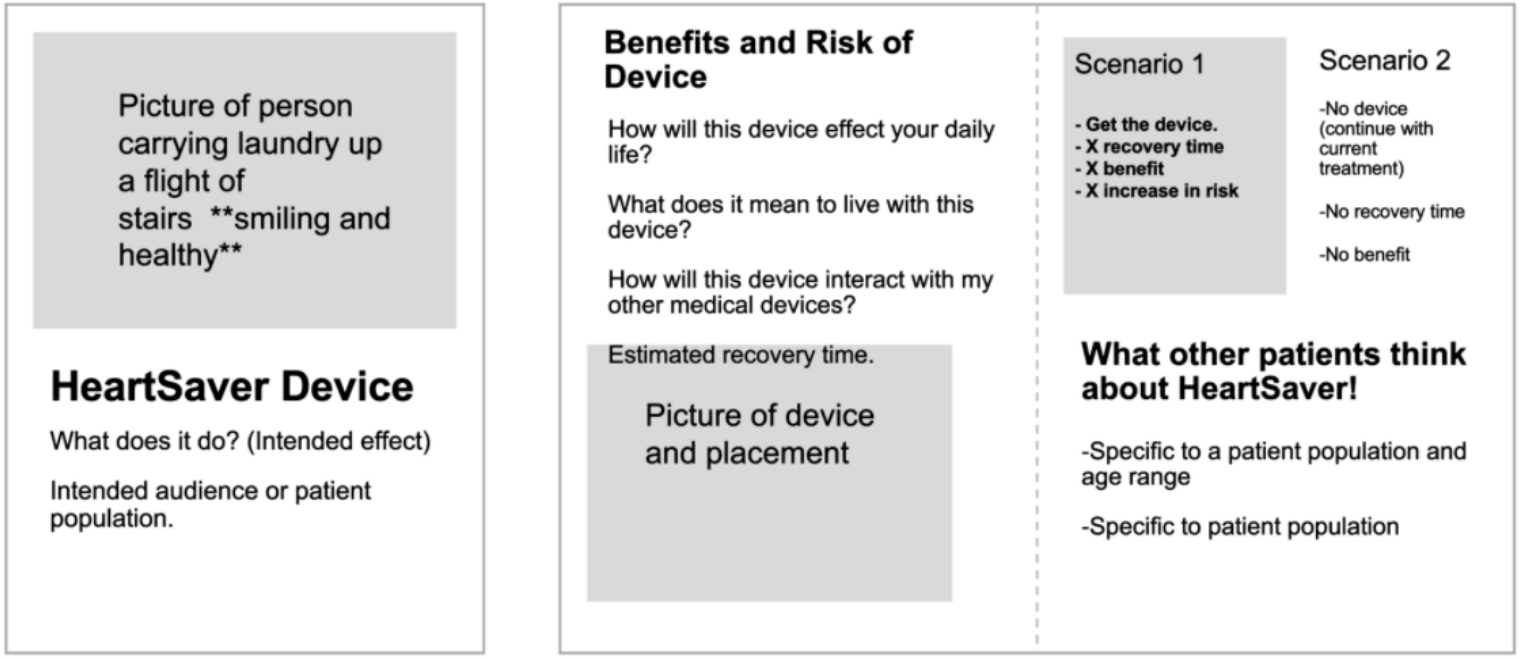




APPENDIX IV: INTERACTIVE ACTIVITY #2 EXAMPLES

Forum participants had the opportunity, in small break-out groups, to devise their own communication resource for patients and caregivers based on summary information about a hypothetical device for heart failure. Each group was asked to focus on one of the eight specific communication best practice elements highlighted in the Communication Report. Groups developed a variety of resources, including sample Facebook posts, brochures, and storyboards for brief videos. The groups were provided with a list of characteristics of a hypothetical device from which to develop their communication example. It should be emphasized that this exercise involved a hypothetical device not based on any actual device under development or in commercial use. The resulting example communications are therefore only illustrative and should not be construed as having any actual clinical or regulatory validity.

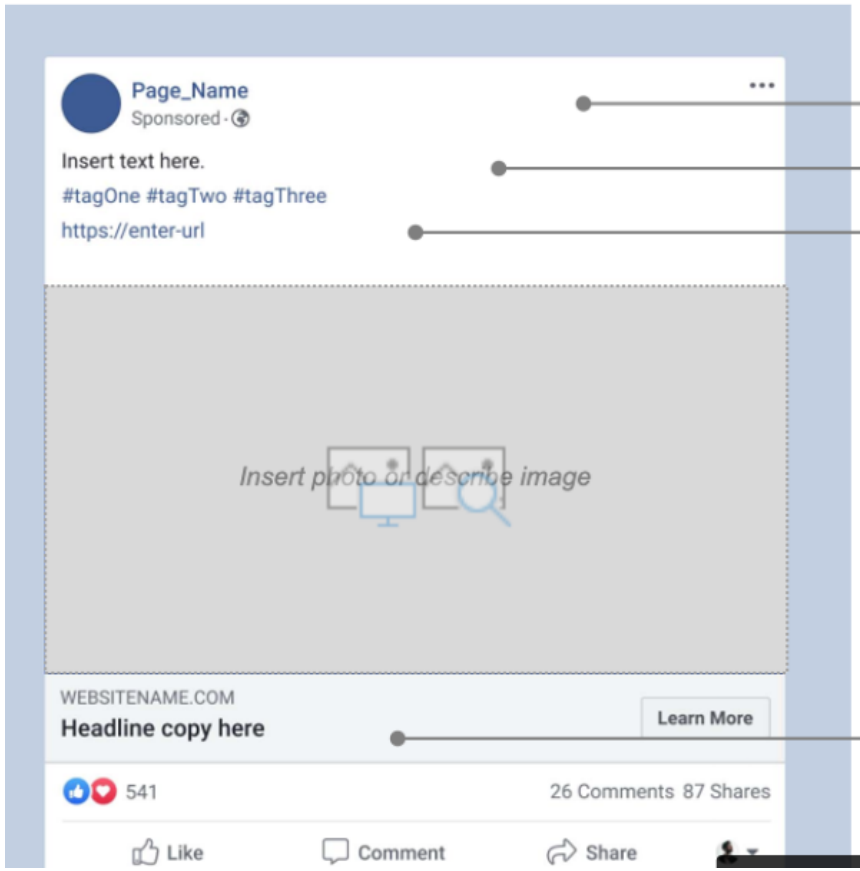
Brochure Template **GROUP INDIA**



COVER INTERIOR

Social Media Template

Foxtrot/Golf



HeartSaver (or device manufacturer)

7 out of 10 people receiving this treatment saw benefits including an increased ability to do normal daily activities like climbing stairs, doing housework, and resting without being out of breath

Those who saw benefits tended to live X years longer than patients who did not. (we would want to know what X is if we were doing this communication before we did the communication; calculated from the same data that told us 30% increase in years of survival with the disease)

The risks associated with the device include the following:

- 1 in 10 risk of death within 30 days of procedure
- 1 in 10 risk of complications

If you think this is right for you, talk to your doctor today!

Device manufacturer URL

HeartSaver – 7 out of 10 patients with heart failure see benefits!

Storyboard Template

Charlie + Delta

5s

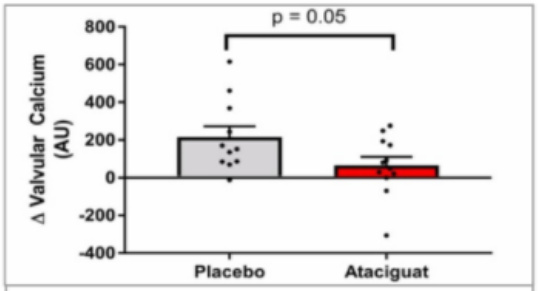
Do you have heart failure?

- discuss the risk of not getting treated

10s

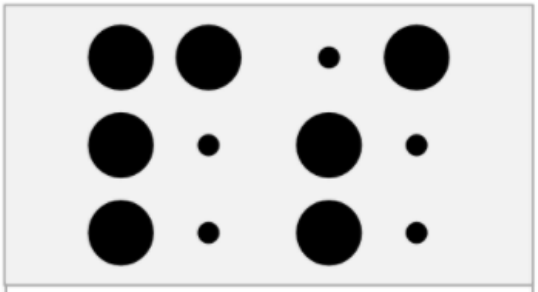
There may be a solution for you!
HeartSaver
- new technology, not a lot of alternatives

15s



Benefits
- Increases ability to perform the following activities of daily living without being out of breath:
  - Climbing stairs
  - Doing housework
  - Resting
- 30% increase in years of survival with the disease

15s



Risks/consequences
- 10% (10 out of 100) risk death within 30 days
- 10% (10 out of 100) risk of Complications: -
  - 2 extra days in the hospital
  - Surgical complications
  - Anesthesia complications

10s

Ask your doctor/uncertainties
-effective in 70% of the patients.
- show actual people in this scene

5s

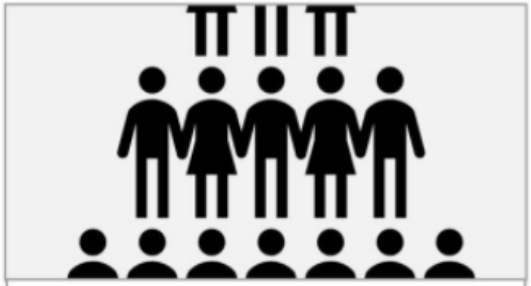
Use PDAs to discuss with your doctor

Storyboard Template

GROUP LIMA

Heart Failure happens when the heart muscle in unable to pump enough blood to meet the body's needs.

PREVALENCE: 1 in 5 Americans will develop Heart Failure, and 1 in 9 will die from it.



PATIENT POPULATION: Heart Failure is more likely to happen with age, however African Americans develop Heart Failure before the age of 50 at 20x the rate of whites. This impacts both men and women.

DEVICE: Fortunately, treatment is possible. HeartSaver can improve survival and quality of life with Heart Failure.

RISK vs. BENEFIT: Increased ability to perform physical activities and 30% increase in years of survival with Heart Failure, 10% possible risk of surgical complications or death.

Imagine climbing stairs again! Resting without being out of breath! Talk to your doctor about HeartSaver.

Contact information

For more information, please contact
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