MDICx: Science of Patient Input Report: Communicating Benefit/Risk for Medical Devices

Liliana Rincon-Gonzalez, PhD | MDIC
Scott Goates, PhD | Abbott
Wendy Selig | WSCollaborative
Heidi Dohse | Tour de Heart
October 2, 2020
Agenda

- Introductions
- Presentations
  - Scott Goates
  - Wendy Selig
  - Heidi Dohse
- Q&A through Zoom Q&A box
- Recording and slides will be available on our website: https://mdic.org/mdicx-series/webinar-archive/
Scott Goates, PhD
Senior Advisor, Health Economics and Outcomes Research
Medical Devices, Abbott Laboratories

• His current role involves the design and execution of clinical and observational studies with patient reported and economic outcomes.

• Prior to joining Abbott, Dr. Goates worked at the Centers for Disease Control and Prevention where he conducted research and advised senior leadership on a wide variety of high priority public health issues.

• He chairs the Communication working group for the Science of Patient Input within the Medical Device Innovation Consortium.
Wendy Selig
Founder & CEO, WSCollaborative

- Wendy K.D. Selig is Founder and CEO of WSCollaborative, a firm that focuses on defining and implementing strategies for establishing winning cross-sector collaborations in the health care arena.

- Selig has held leadership positions with the Melanoma Research Alliance (MRA), the American Cancer Society (the Society) and the American Cancer Society Cancer Action Network (ACS CAN), the National Coalition of Cancer Research (NCCR), and Rising Tide Foundation for Clinical Cancer Research (RTFCCR).

- She is a consultant with MDIC
Heidi Dohse

Professional Patient Advocate and Heart Patient
Founder & CEO, Tour de Heart

- In 1982, Heidi was diagnosed with a rare heart arrhythmia. She underwent a successful AV ablation procedure leaving her heartbeat 100% pacemaker dependent. With the help of her pacemaker, wearable devices, and mobile apps Heidi has the insights she needs to compete in endurance cycling events around the world. In November 2019, she completed her first IRONMAN.

- Heidi is passionate about improving patient outcomes and uses her athletic events as a way to inspire other heart patients and showcase what is possible.

- Tour de Heart is a non-profit that provides information on using digital health tools / apps to empower individuals to live their best lives.
Best Practices for Communicating Benefit, Risk and Uncertainty for Medical Devices

Background

Scott Goates, PhD.
Communications Working Group Chair

October 2, 2020
Why was this Study Conducted?

- MDIC Science of Patient Input (SPI) seeks “to advance the art and science of patient engagement in regulatory science”
- Patient engagement is valuable throughout the medical device life-cycle
- Appropriate communication of risk, benefits and uncertainty required to ensure patient values are accurately reflected in decision making
- Little guidance on communicating risks, benefits and uncertainty in medical devices
What were the Study Aims?

• Familiarize medical device stakeholders with best practices for communicating benefits, risks and uncertainty to patients and providers
• Designed to be a practical resource
• Include real world case studies
• Identify knowledge gaps that may benefit from further research
Who is this Study For?

- Investigators
- Regulators
- Clinicians
- Industry Professionals
- Payors
- Patient Advocacy
Key Milestones

2017
- Project Proposal
- SOW

2018
- Literature Review (Exponent)

2019
- First Draft Completed
- Public comments

2020
- Incorporated Case Studies
- Published
Collaboration and Teamwork

Stephanie Christopher, Providence St. Joseph Health
Brett Hauber, RTI Health Solutions
Heather Howell, NSF International
Ross Jaffe, Versant Ventures
Franchesca Liao, LCGC, Illumina, Inc.
Suzanne Schrandt, Arthritis Foundation
Wendy Selig, WSCollaborative
Liliana Rincon-Gonzalez, MDIC
Desiree’ Steele, MDIC
SPI Committee, MDIC
MDIC Science of Patient Input Communications Report: Key Takeaways

Wendy Selig
Founder & CEO
WSCollaborative
Clinical Context

- Recruitment and consent of 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
- Provide notification of recall or changes made to a device.
Non-Clinical Context

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

- Internet
- Social media platforms,
- Within patient advocacy constituencies
- Peer-to-peer conversations & mentorship among patients and caregiver communities
Multiple Settings to Consider

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

- Benefit
- Harm
- Risk
- Patient Preference Information
- Risk Tolerance
- Uncertainty Attitude
- Shared Decision Making
- Patient Decision Aid
Key Factors: Communication in the Clinical Setting

- Relevant Provider Characteristics
- Relevant Patient Characteristics
- Relevant Message Components:
  - Content
  - Statistical Concepts
  - Formatting & Framing
Overall Approach

- Avoid solely verbal descriptions of uncertainty.
- Avoid fractions, decimals, and different denominators when presenting risks of multiple treatments.
- Describe the benefits and risks in absolute scales instead of relative terms.
- Use multiple formats simultaneously (e.g., verbal frequency, percent, and icon array/pictograph).
- Describe uncertainty in both positive and negative frames to avoid cognitive bias.
- Pre-test the communication format.
Patient Decision Aids

Development process includes:
• Participation of stakeholders in its development
• Gathering, selecting, and appraising evidence to inform its content
• Evaluation testing

Components of the PDA should 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
Leveraging Online Resources

- Include relevant benefit, risk, and uncertainty information in lay terms on public websites.
- Provide materials that can be accessible to patients through an internet search.
- Make frequent updates to ensure accuracy of content.
- Avoid misleading and reveal material facts.
- Benefit information should be accompanied by risk information.
- Include the most serious risks associated with the product.
- Provide a hyperlink to allow direct access to more complete risk information.
- The prominence of risk information should be comparable to the benefit information.
- If adequate benefit and risk information, as well as other required information, cannot all be communicated reconsider using that platform.
Building Partnerships with Patient Advocacy Organizations

- 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.
Resources
Best Practice Checklist for Successful Communication

01. Explicit description of the decision
02. Description of the health problem
03. Information on options and their benefits, harms and consequences
04. Values clarification (implicit and explicit)
05. Numerical probabilities
06. Personal Stories
07. Patient Preference Information
08. Presentation strategies to help understanding
Join MDIC on November 18

Patient Engagement Forum
An MDIC Event

November 18, 2020 • Virtual Event

A Convening of Patients, Physicians, Industry and Regulators

Register Today!
Best Practices for Communicating Benefit, Risk and Uncertainty for Medical Devices: Patient Perspective

Heidi Dohse
Founder and CEO, Tour de Heart

October 2, 2020

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
Patient Lifecycle vs. Product Lifecycle

Symptoms and Diagnosis
Beginning of the Patient Journey

Research and Product Development
Opportunity to engage patients to share experiences and participate in studies to improve outcomes.

Unintended Consequences
Multiple devices, leads extractions and surgeries take a toll on the body. The result can be complications from infection and scar tissue.

Therapy / Surgery / Procedure
Actions that impact the rest of the person’s life.

Monitor, Manage, Adapt
The process of learning to build trust in your body again. Feel safe enough to live your new normal.

Time / Recall / Other = New Device
The next device is implanted due to normal replacement, complications, or device recall.
Audience Q&A
Please submit your questions through the Zoom Q&A box

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Heidi Dohse Tour de Heart
Thank You!

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http://mdic.org

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https://mdic.org/program/science-of-patient-input/

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