Patient Preference Information (PPI) in Medical Device Decision-Making

The Center for Devices and Radiological Health (CDRH) recognizes that many people play critical roles in evaluating and communicating the benefits and risks of medical devices. However, only patients live with their medical conditions and make daily choices regarding their health care. Their voice and perspective are critical to understanding the impact of medical devices.

Patient preference information (PPI) is a type of patient experience data that incorporates the patient perspective in CDRH's regulatory decision-making.

On this page:

Related pages:

- Patient Preference-Sensitive Areas: Using Patient Preference Information in Medical Device Evaluation (/about-fda/cdrh-patient-science-and-engagement-program/patient-preference-sensitive-areas-using-patient-preference-information-medical-device-evaluation)
- List of Patient Preference-Sensitive Priority Areas (/about-fda/cdrh-patient-science-and-engagement-program/list-patient-preference-sensitive-priority-areas)

What Is Patient Preference Information?

Patient-preference information (PPI) captures the value that patients place on aspects of the medical device. PPI accounts for differing patient perspectives on benefits and risks that come with using that device or treating the condition. PPI is not the same as patient-reported outcomes which are part of a clinical trial and measure how patients feel and function.

Well-designed and conducted PPI studies elicit which attributes are important to patients, how important they are, and what tradeoffs patients are willing to make between attributes. PPI has also been referred to as health preference assessment, stated-preference health survey, health preference research, and broadly described as patient-centered research in the scientific literature.

Many groups are conducting patient preference studies, including:

- Patient groups
- Members of the medical device industry
- Researchers
- Healthcare providers
- Public-private partnerships

As the medical device community conducts more patient preference studies, CDRH gains a better understanding of the values patients have and the tradeoffs they are willing to make.

Patient Preference Information Helps CDRH Understand Medical Device Benefits and Risks

Patient preference information can inform the design of a medical device, impact how a clinical study is designed, and be used to understand the impact of the clinical study results on patients. This information can help CDRH by:

- Identifying unmet needs for patients early in medical device development
- Identifying the most important benefits and risks of a technology from a patient's perspective
- Assessing the importance of clinical study outcomes to patients
- Determining a meaningful change in study outcomes
- Clarifying how patients think about the tradeoffs of the benefits and risks for a given technology

- Showing how patient preferences on benefits and risks vary in different groups as well as their willingness to accept uncertainty

PPI has been used in multiple regulatory submissions and has informed CDRH's regulatory decision-making. Twenty-three patient preference studies sponsored by industry have been completed or are in process.

- CDRH conducted a patient preference information study that was used to inform deliberations surrounding the approval of a medical product – the first approved device for treating obesity (https://web.archive.org/web/20170405003019/https:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm430223.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Deliberations considered information from an FDA-sponsored survey on patient preferences related to obesity devices (https://web.archive.org/web/20170405003019/http:/www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevic UrologyDevicesPanel/UCM302781.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
- Ear infections are common in children and are often treated with antibiotics. Children who experience multiple ear infections may need ear tubes to prevent infections. These tubes are placed in the operating room. A medical device company developed a technique that allows the tubes to be placed in the doctor's office. The patient preference study helped inform the design of their clinical trial.
- Home hemodialysis has rare but serious adverse events that require having a caregiver present. A medical device company conducted a patient preference information study that showed some patients were willing to accept the risk in exchange of doing dialysis at home alone. This study informed expanding the labeled indications for the home hemodialysis device.
- Collecting qualitative feedback from patients helped enhance the safety of a continuous glucose monitor and insulin pump for children. CDRH discussed concerns with patients and parents about the safety of using an insulin pump in the young pediatric population. Based on this feedback, CDRH worked with the company to develop additional risk mitigations that included a lockout feature to prevent unintended insulin doses.

For more information, see How Patient Preferences Contribute to Regulatory Decisions for Medical Devices. (https://wayback.archive-it.org/8521/20180724174811/https:/blogs.fda.gov/fdavoice/index.php/2017/09/how-patient-preferences-contribute-to-regulatory-decisions-for-medical-devices/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

CDRH Collaborations, Studies, Articles, and Workshops on Patient Preference Information

CDRH is committed to integrating the patient voice into our decision-making. We acknowledge that patient preference information is an active and evolving research area. We continue to partner with patient groups, public-private partnerships, professional societies, and other stakeholders to advance the field.

Collaborations

- Medical Device Innovation Consortium (MDIC) - Science of Patient Input (https://mdic.org/program/science-of-patient-input/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Setting Scoliosis Straight Foundation (SSSF) (https://www.settingscoliosisstraight.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Centers of Excellence in Regulatory Science and Innovation (/science-research/advancing-regulatory-science/centers-excellence-regulatory-science-and-innovation-cersis)
- MDEpiNet (https://www.mdepinet.net/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- ISPOR (https://www.ispor.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Published Studies and Ongoing Projects

FDA scientists have collaborated with a variety of stakeholders to conduct patient preference studies to inform clinical trial design and medical device regulatory decision-making. These patient preference studies have included medical devices for:

- Obesity (https://www.ncbi.nlm.nih.gov/pubmed/25552232)
- Parkinson's disease (https://mdic.org/project/patient-centered-outcomes-research/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- Amputation (https://www.tandfonline.com/doi/abs/10.1080/17434440.2018.1470505) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Minimally invasive glaucoma (/science-research/advancing-regulatory-science/patient-and-provider-views-clinical-endpoints-qualitative-preference-study-minimally-invasive)
- Uterine fibroids
- Prostate Cancer
- Chronic Pain
- Adolescent scoliosis
- Heart Failure
- Kidney Disease

Blogs and Articles

- FDA Brings Patients into the Process (https://wayback.archive-it.org/8521/20170206022635/http:/blogs.fda.gov/fdavoice/index.php/2013/09/fda-brings-patients-into-the-process/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (09/20/2013)
- FDA's Patient Preference Initiative: The Need for Evolving Tools and Policies (https://wayback.archive-it.org/8521/20170206030820/http:/blogs.fda.gov/fdavoice/index.php/2015/09/fdas-patient-preference-initiative-the-need-for-evolving-tools-and-policies/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (09/16/2016)
- Why Partnerships are Key to the Science of Patient Input (https://wayback.archive-it.org/8521/20170206030703/http:/blogs.fda.gov/fdavoice/index.php/2015/10/why-partnerships-are-key-to-the-science-of-patient-input/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (10/02/2016)
- How Patient Preferences Contribute to Regulatory Decisions for Medical Devices (https://wayback.archive-it.org/8521/20180724174811/https://blogs.fda.gov/fdavoice/index.php/2017/09/how-patient-preferences-contribute-to-regulatory-decisions-for-medical-devices/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)(09/25/2017)
- Abstract: A Framework for Incorporating Patient Preferences Regarding Benefits and Risks into Regulatory Assessment of Medical Technologies (https://www.ncbi.nlm.nih.gov/pubmed/27712701)

FDA Workshops

- 2013 Workshop - The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes (https://wayback.archive-it.org/7993/20170112084903/http:/www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm361864.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- 2017 Workshop - Advancing Use of Patient Preference Information as Scientific Evidence in Medical Product Evaluation (/science-research/advancing-regulatory-science/advancing-use-patient-preference-information-scientific-evidence-medical-product-evaluation)
- 2020 ISPOR-FDA Summit - Using Patient-Preference Information in Medical Device Regulatory Decisions: Benefit-Risk and Beyond (https://www.ispor.org/conferences-education/conferences/upcoming-conferences/ispor-fda-summit-2020) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Planning to Conduct a Patient Preference Information Study?

Groups interested in starting or conducting a patient preference study should email CDRH-PPI@fda.hhs.gov (mailto:CDRH-PPI@fda.hhs.gov) and may consider requesting a pre-submission meeting, which is a type of q-submission meeting (/about-fda/page-not-found) (PDF - 215 KB) to discuss a potential or current patient preference study. We encourage medical device manufacturers and other stakeholders to consult with CDRH early when considering patient preference studies.

In considering PPI, the FDA remains committed to assuring that devices are safe and effective. The FDA encourages medical device manufacturers to consider the impact of PPI across the entire life cycle of a device. The inclusion of PPI does not change any review standards for medical devices.

For more information, refer to these guidance documents:

- 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 (/regulatory-information/search-fda-guidance-documents/patient-preference-information-voluntary-submission-review-premarket-approval-applications)
- Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications (/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de)

- Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-investigational-device)
- Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions (/regulatory-information/search-fda-guidance-documents/factors-consider-regarding-benefit-risk-medical-device-product-availability-compliance-and)

Contact Us

If you have questions about patient preference information, email CDRH-PPI@fda.hhs.gov (mailto:CDRH-PPI@fda.hhs.gov).