Patient Participation Guide

January 2017

This guide was created to help you tell us what we should know about the patient experience. Often, patient experiences are not captured in research or other evidence. That is why we need to know what's important to you and your community. In this guide, you will see the various stages in our process, understand where we think we need your input most, and receive guidance on the types of input that can be the most influential at each stage.

What is ICER?

ICER, the Institute for Clinical and Economic Review, is a non-profit research organization that evaluates evidence on the value of medical tests, treatments and delivery system innovations. ICER was founded over 10 years ago with an ethical goal in mind: to try to provide a fair and objective analysis of evidence as the starting point for bringing all stakeholders—patients, doctors, drug makers, insurers, and others—together to seek better ways to help patients gain sustainable access to high-value care. We want to help create a health care system in which innovation is rewarded fairly, but without breaking the bank, so that all patients will be able to benefit from the very best treatments at a price they can afford.

What does ICER do?

ICER produces several evidence reports every year, each focused on a different topic. Each report includes:

- Information on the patient experience and patient views that can broaden our understanding of the value of different interventions.
- A review of evidence on how well each drug or other type of intervention works and how the risks and benefits compare with other care options
- An analysis of how the long- and short-term costs of the intervention line up with the added benefits for patients

Each report is developed with input from multiple sources, including patient advocacy groups, clinical experts, and manufacturers. When a final draft is completed, each report is the subject of a public meeting, during which an independent expert committee convened by ICER discusses the report and votes on the evidence and testimony presented. These three deliberative committees are:

- The California Technology Assessment Forum (CTAF),
- The Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC), and
- The New England Comparative Effectiveness Public Advisory Council (New England CEPAC).

Meetings are an important opportunity for all stakeholders to come together and collaborate on finding solutions to some of health care's most challenging questions and are one opportunity for patients and others to provide input. Based on the report and discussion at the meeting, ICER produces recommendations for insurers, manufacturers, clinical specialty societies, and patient groups. These recommendations suggest ways that the evidence on effectiveness and value can best be applied to coverage policies, pricing and payment negotiations, patient materials, and the future research agenda to achieve the ultimate goal: all patients will be able to benefit from the very best treatments at a price they can afford.

ICER listens to patients

ICER values input from all stakeholders, especially patients and patient groups. Patients are at the core of ICER's mission to help provide an independent source of analysis of evidence on effectiveness and value to improve the quality of care that patients receive. Without input from patients, our reports are missing critical information on how a condition affects day-to-day life, the financial and insurance challenges patients face in accessing their treatment, information about what outcomes or side effects are of most importance to patients, and much more.

We know our reports are better and more useful for everyone when they include the real-world patient perspective. But we also know that patients can be concerned about contributing to a process whose end result they cannot necessarily predict. We make sure that all stakeholders know that contributing information or advice to ICER is in no way an endorsement of our work.

Some examples of how we've incorporated patient perspectives include:

- Patients with psoriasis highlighted how significantly it affected their quality of life at work and school, and pointed to step therapy policies and insurance coverage as a key barrier to appropriate treatment. Our final policy implications reflected these concerns.

- Patient groups we spoke to about our review of abuse-deterrent opioid formulations highlighted the need to balance patients' needs for pain control with the risks of opioid misuse. This concern informed the context of our report.

- For a review of treatments for atopic dermatitis, patients highlighted added burdens of the disease- such as sleep disruption—that are not well-documented in typical clinical trials.

- We worked with a multiple sclerosis patient group to field a new survey to gather information on aspects of treatments that patients found most important to them. Data on responses from over 18,000 patients was included in our report and was an important complement to clinical data that was narrowly focused on relapse rates.

In a recent press release, the National Psoriasis Foundation's CEO commented on their work with ICER throughout the report process:

"The National Psoriasis Foundation is very pleased with the final recommendations and in the significant role we have played to provide input which informed the final report. The final report accurately reflects the challenges of living with psoriatic disease and it recommends insurers expand the tools physicians have available to care for patients managing this complex disease over a lifetime," said NPF CEO Randy Beranek.

Quick Guide to Participation

The overall report development process takes approximately 8 months between topic announcement and the final revision to the report following the public meeting. Below is a figure that summarizes key points where all stakeholders, including patient groups, can contribute to report development. The pages thereafter provide additional information on each step.

Topic and Timeline Announced Publicly

Give Open Input on a New Topic (Weeks 1-3)

A Draft Scoping Document is developed and posted.

Comment on the Draft Scoping Document (Weeks 4-6)

ICER reviews comments and posts a Revised Scoping Document.

A Draft Evidence Report and Draft Voting Questions are posted.

Comment on the Draft Evidence Report (Weeks 22-25)

A revised Evidence Report and Revised Voting Questions that include updates based on public comments are posted to the website.

Attend a Public Meeting (Week 30)

ICER's Evidence Report is publicly deliberated by one of three evidence review groups: CTAF, the Midwest CEPAC, or the New England CEPAC.

Final Evidence Report and Meeting Summary posted.

Topic and Timeline Announcement

ICER sends an email to all mailing lists at the beginning of a project to announce each new topic. At the same time, ICER publicly posts the timeline for the project on the Meeting page of the ICER website. This timeline provides dates for key steps in the process. When the topic is announced, the period for Open Input begins.

Give Open Input on a New Topic (Weeks 1-3)

What happens in this step?

- After topic announcement, the Open Input period runs for three weeks.
- While open input submissions are being accepted, ICER begins to develop a Draft Scoping Document

What information is most helpful?

At this stage, any information is helpful. We want to learn as much as possible from all stakeholders about the topic.

Some examples include:

- Outcomes that matter most to patients
- Benefits or disadvantages of new and existing treatment options
- Research publications or patient-generated data to supplement clinical trial data

You can use our Guide to Open Input for more suggestions on what is important for us to know.

How do I give input?

- All submissions can be emailed to publiccomments@icer-review.org
- There are no page limits
- Use the Guide to Open Input for ideas on what to submit
- Three weeks to submit comments

How does ICER use my input?

- ICER uses the information to help guide the scoping process. All submissions are considered throughout the scoping process and are incorporated into the Final Scoping Document.
- Information received towards the end of the Open Input period may not be considered for the Draft Scoping Document but will be taken into account in the revised version.

Draft Scoping Document

Based on independent research and conversations with clinical experts, manufacturers, policy makers, insurers, and patient groups, ICER develops a Draft Scoping Document that is posted on the website that outlines the plan of research, drugs or treatments to review, patient populations to include, and other related information. We encourage input on the specifics included in the draft scoping document.

Comment on the Draft Scoping Document (Weeks 4-6)

What happens in this step?

- The Draft Scoping Document is posted to the website and announced by email.
- The document is open to a **three-week public comment period**.

What information is most helpful?

- Input on what is included or left out of the scope that is most important to patients
  - E.g. patient subgroups, treatments, or additional benefits to include in the report
- Any additional patient-related resources
- Which clinical trial data are most related to patient-centered outcomes

How do I give input?

- ICER accepts comments for three weeks.
- The deadline is listed in the posting announcement and on the website.
- Email comments to publiccomments@icer-review.org.
- Comments must be sent as a Word document in 12-point Times New Roman font.
- Comments can be up to three pages (not including references).

How does ICER use my input?

- ICER reviews all comments received and considers what changes need to be made to the scope before work on the report begins. For example, ICER might include an additional patient subgroup, or consider an additional outcome measure.
- All comments will be made public on the ICER website.

Revised Scoping Document

ICER updates the scoping document based on comments. This document also includes a brief summary of information learned through open input and public comment. The document is posted to the ICER website, along with comments received.

Draft Evidence Report and Draft Voting Questions

The Draft Evidence Report includes background and context about the topic, reviews evidence, provides preliminary cost-effectiveness analyses, and summarizes how patient input was used to inform the draft. It reflects only ICER's independent analysis of currently available information and does not make policy recommendations. The Draft Evidence Report and Draft Voting Questions are posted on the ICER website, and an announcement is sent to ICER's mailing list.

Comment on the Draft Evidence Report and Voting Questions (Weeks 22-25)

What happens in this step?

- The Draft Evidence Report is posted on the website and announced by email.
- Stakeholders review and provide comment over a four week period.
- This is also the time to request to make an oral comment at the public meeting.

What information is most helpful?

- Suggestions for additional data
- Added details for context
- More explanation of additional benefits or disadvantages of a treatment
- Anything else that, from a patient perspective, the report misses

How do I give input?

- The specific deadline is in the announcement and is posted on ICER's website.
- Email comments to publiccomments@icer-review.org. We will confirm receipt.
- Comments must be in the following format:
  - Submit as an attached Word document
  - 5 page maximum (not including references)
  - 12-point Times New Roman font

How does ICER use my input?

- ICER carefully considers all comments and makes changes as needed. In the past, this has meant re-running cost-effectiveness analyses based on new information, or updating information about a specific patient subgroup.
- All changes are reflected in an updated Evidence Report published before the public meeting takes place.
- All comments will be posted publicly

Register for Oral Comment at the Public Meeting

This is also the period to request to speak at the public meeting. Each meeting includes up to 45 minutes for oral comment before the voting panel takes its votes. Comments are limited to five minutes. To request to speak, please follow the below steps:

1. Send request to ICER via email publiccomments@icer-review.org including the name, title, and organization of the proposed speaker.
2. ICER staff will confirm receipt of the request, and reply with a link to an online conflict of interest form that must be filled out accurately to complete registration.
3. Any reported conflicts of interest will be disclosed at the meeting, but will not prevent participation.

Since there may be more requests than can be accommodated during the meeting, and to help provide the opportunity for a broad range of perspectives to be heard, public comment slots will only be confirmed after the deadline for requests has passed. Priority for public comment slots will be given to patients with the condition under study and subject-matter experts from the patient advocacy, clinical, and research communities.

Public commenters may not use a slide presentation or distribute materials to the panel or audience members prior to, or during, the public meeting.

Evidence Report and Revised Voting Questions

The Evidence Report includes changes made based on public comments and includes value-based price benchmarks. It is posted to ICER's website, and an announcement is emailed to subscribers. Along with the report, a revised set of voting questions, all public comments received, and ICER's response to comments are posted to the website.

This version of the report is shared with the relevant voting panel in advance of the public meeting.

Attend a Public Meeting (Week 30)

What happens at the meeting?

- Report authors give an overview of report findings.
- Pre-registered speakers give oral public comments.
- The evidence review group votes on the strength of evidence for the topic under review. Report authors, clinical experts, and patient representatives are available to answer questions.
- A Policy Roundtable, composed of patients, doctors, insurers, and other stakeholders convenes to discuss how the evidence applies to real-world policy and practice.

How can I participate?

- **Attend:** Meetings are free and open to the public. We recommend registering in advance to ensure your spot. Registration typically opens when the Draft Evidence Report is posted.
- **Comment:** Register to give an oral public comment using the instructions above.
- **Watch:** A live webcast is offered for most meetings. ICER also posts a recording of the webcast on their website within a week after the meeting. More information is posted to the meeting page of the topic you're interested in.
- **Be a panelist:** One to two patient representatives are invited to participate in the Policy Roundtable.

How does ICER use my input?

- ICER uses Public Meeting discussions to inform the policy implications that are included in the final report.
- Public commenters are invited to submit a 250-word summary of their oral comment to be included in the final report.

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Final Evidence Report and Meeting Summary

The Final Evidence Report and Meeting Summary includes a summary of discussions, public comments, voting results, and policy statements from the Roundtable discussion during the meeting. It takes about one to two weeks to publish the Final Report. The report is posted to the ICER website and announced by email.

A short, summarized version of the report, called "Report-At-A-Glance," is posted alongside the full Final Report.

Additional Information

We hope this guide gave you a good overview of our process, and how you can get involved. Of course, there is more to our process than just what's here. Visit our website for more information. Here are some helpful links:

- To learn more about who ICER is and what we do (or don't do), read our Myths about ICER.
- For specific questions, check our list of Frequently Asked Questions (FAQs).
- To find out more about how we look at the effectiveness and value of drugs, tests, or treatments, visit the How We Do Our Work page.

Contact Information:

Still have questions? Contact us at info@icer-review.org, or get in touch with the key contact for the program you're interested in. We look forward to hearing from you!

MIDWEST CEPAC COMPARATIVE EFFECTIVENESS PUBLIC ADVISORY COUNCIL
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