

Evaluating the Usability of CER for Patient and Provider Decision Making

A White Paper by Avalere Health and the National Health Council · September 26, 2013



The National Health Council would like to thank its sponsors:

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About The Dialogue

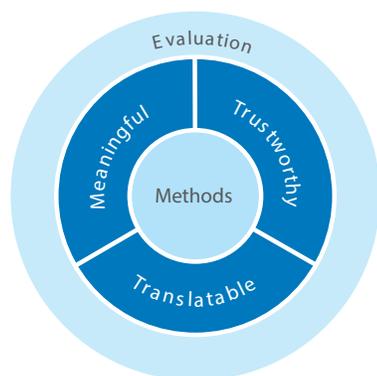
Avalere Health created The Dialogue as a forum bringing together leaders to discuss pressing issues facing healthcare. Through a series of invitation-only, in-person meetings; collaborative white papers; and interactive webinars, The Dialogue seeks to build consensus around ideas and solutions to address these issues.

Executive Summary /

Comparative effectiveness research (CER) has the potential to inform many decisions. Today, a common threshold for determining whether a CER finding should be disseminated to the public is its methodological quality. However, a study with high methodological quality is not necessarily one that patients and providers will find usable for their decision making.

This paper summarizes the proceedings of a Dialogue hosted by Avalere Health and the National Health Council (NHC) on July 10, 2013. The Dialogue was held as part of an effort led by the NHC to create a framework for evaluating the usability of CER findings. The goals of the Dialogue were to: 1) corroborate the need for a systematic approach to evaluate the usability of CER findings; 2) define what is meant by usable CER; 3) agree on key attributes of usable CER findings; and 4) discuss how these concepts can be applied in practice.

Usable CER is defined as a study that, based upon a user's perspectives and needs, asks the best question, applies the best methods, and is communicated via the best approach to the intended audience of users. Continuous evaluation of a study's use and impact is crucial to delivering CER that is more usable than what is now understood. Thus, the elements that define usable CER (research question, methods, and communication) plus evaluation comprise the essential components to generate usable CER.



To focus this work, the scope of the Dialogue and this paper were narrowed to the components of usable CER on which less work has been done to date. Dialogue participants identified two areas requiring greater attention: the *research question* and *communication that supports the interpretation and application of the study to decisions*. Based on these chosen focus areas, Dialogue participants identified attributes of usable CER. These attributes were organized into three domains: meaningful, trustworthy, and translatable. These domains, combined with appropriate research methods and evaluation, offer a framework for evaluating CER usability.

The attributes and domains of usable CER provide a foundation for the development of usability criteria that can be adopted to evaluate the usability of CER findings in individual care decisions by patients and providers.

While the concepts outlined in this paper could be applied broadly, the current effort strives to articulate a framework for evaluating CER in the context of patient and provider decision making. To ensure investments have the greatest potential to produce usable CER, such evaluations should take place both prospectively and retrospectively. Prior to the initiation of research, this evaluation could inform decisions by the research community about which questions to pursue, the proposals to fund, and the communication methods that could facilitate the adoption of study findings. Following research results, this evaluation would help patients and providers distill and prioritize the vast amounts of evidence available to them so they can more effectively identify findings most applicable to the decisions they confront.

Introduction /

Comparative effectiveness research (CER) promises to improve health outcomes in individuals and populations by helping patients, providers, payers, and policymakers make better informed decisions.¹ Based on this promise, substantial investments are being made in CER. And yet each CER study will not typically generate information that is usable for all these different types of decisions. Among the many efforts that have been launched to promote adoption of CER findings, none have explicit focus on evaluation of usability by patients and their providers.²

Studies suggest that patients and providers do not readily use CER findings in practice. Factors that impede adoption include study results that are often contradictory or ambiguous in terms of implications and use,^{3,4} perceptions that the research lacks relevance and fit in the real world,⁵ and results that lack cultural appropriateness or fail to consider the health literacy of an audience.⁶

On July 10, 2013, Avalere Health and the National Health Council (NHC) hosted a Dialogue in Washington, D.C. to discuss the concept of CER usability and a potential framework. Twenty-three invited guests, representing patient groups, provider groups, payers, industry, and the research community, participated in the Dialogue. (See page 18 for list of participants.) The participants were selected on the basis of their knowledge of this topic and organizational perspective of evaluating CER proposals or using CER for decision making.

Prior to the Dialogue, a working paper was produced that proposed definitions and domains that could form the basis of a framework for evaluating CER usability. The concepts in the working paper were based on research on existing frameworks and models aimed at better understanding the factors that lead patients and providers to use evidence. (See Appendix for select sections of the working paper.) This initial paper was shared with the group prior to the Dialogue and served as the catalyst for a discussion about the definition of usable CER and its attributes.

This paper provides the context within which this Dialogue occurred, frames the concepts of usability in the context of research findings, introduces a framework for evaluating CER usability, and presents a vision for how the framework could be applied in practice. It is the intent that the information in this paper serve as the foundation for the creation of criteria to evaluate usability of CER findings. Further, such usability criteria are intended to enhance patient and provider discussions of healthcare options and to facilitate assessments of future investment by research sponsors, researchers, and payers.

Background: The Current Paradigm /

Evidence-based medicine (EBM) is defined as the “conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”⁷ CER is often linked to the goals for EBM, based on a prevailing view that evidence comparing the benefits and harms of various interventions should enable more thoughtful decisions about care. This view has stimulated large amounts of spending by public and private organizations to support the development of information that gives patients and providers insights to support their healthcare choices.

There is also growing acceptance across the healthcare system that integrating patient perspectives in healthcare decisions can lead to improved outcomes. Focus has been directed at the generation of CER in particular, which is widely viewed as a process that would be enhanced by patient input and for which an engagement framework has been proposed.⁸ This focus is driven in part by the Patient-Centered Outcomes Research Institute (PCORI), which was created to fund research that engages patients throughout the research process.⁹

As investments in CER continue, it is important to consider how they will be leveraged in the future. The literature suggests it takes an average of nine years for interventions to be implemented even when they are recommended as evidence-based best practices.¹⁰ Evidence also suggests that racial and ethnic disparities exist in incorporating research findings into care.¹¹ Barriers to implementation often cited in the literature include study results that are contradictory or ambiguous in terms of implications and use,^{12,13} lack of time among providers to read research,¹⁴ and perceptions that the research lacks real world relevance and fit.¹⁵

While the barriers experienced by providers are more commonly known, barriers to use of CER by patients also exist. A focus group of patients conducted in 2009 revealed that many patients inconsistently define “evidence” and are unfamiliar with terms such as “evidence-based medicine.”¹⁶ When evidence-based medicine was described to them, many agreed with the concept broadly but expressed concerns about a “one-size-fits-all” approach to care.¹⁷ Other barriers to the application of evidence by patients include a lack of appropriateness to culture and degree of health literacy and a lack of widespread adoption of patient-centered care and shared decision-making models.^{18,19}

Some researchers have also criticized the current paradigm of CER, arguing that it assumes a linear process of evidence generation and dissemination while overlooking the complexity of individual decision making and the myriad influences on decisions.²⁰ Evidence creation, therefore, must occur in parallel with improving the quality of the interaction between the provider and patient.²¹

But results of a PCORI survey of patient, caregiver, and clinician attitudes toward CER showed strong support for research, with 70 percent of those surveyed agreeing that health research helps patients make better treatment decisions.²²

Barriers to research adoption by patients and providers and the complexity of care decisions underscore the need to articulate how CER can be of greatest use to patients and providers. An approach to evaluating CER usability is a necessary but long overlooked step toward fostering patient engagement in research and the improved application of evidence to decisions.

Laying the Foundation for Building Usability Criteria /

To develop a framework for evaluating the usability of CER findings, the literature on frameworks, models, and principles to improve various aspects of evidence generation, dissemination, and use was reviewed. (See Appendix for sources considered in developing domains for defining usability framework.) This review revealed several recurrent themes and attributes that were consistent with the goals of this effort. Shown in Figure 1, these themes informed a definition of usable CER and draft domains that could be the foundation for creating usability criteria. These draft concepts were presented in a working paper that served as the basis for a facilitated discussion at the July 2013 Dialogue. The following section outlines the discussion at this meeting.

Figure 1. The Foundation for the Creation of Usability Criteria



Definition of Usable CER

There are many ways that research findings can be used. Use of research has been characterized as instrumental, conceptual, or symbolic.²³ Instrumental use involves the application of research in concrete, direct ways; conceptual use involves using research for general enlightenment (that is, research that may change one's thinking but not necessarily one's action); and symbolic use involves using research as a persuasive tool to legitimize and sustain a position or practice.^{24,25,26} A framework for evaluating CER usability has potential applicability across each of these uses of research. However, as an initial step, the scope of the Dialogue and this paper were narrowed to focus on instrumental use, or the direct application of healthcare knowledge to decision making by patients and providers.

Usable CER is defined as a study that, based upon a user's perspectives and needs, asks the best question, applies the best methods, and is communicated via the best approach to the intended audience of users.

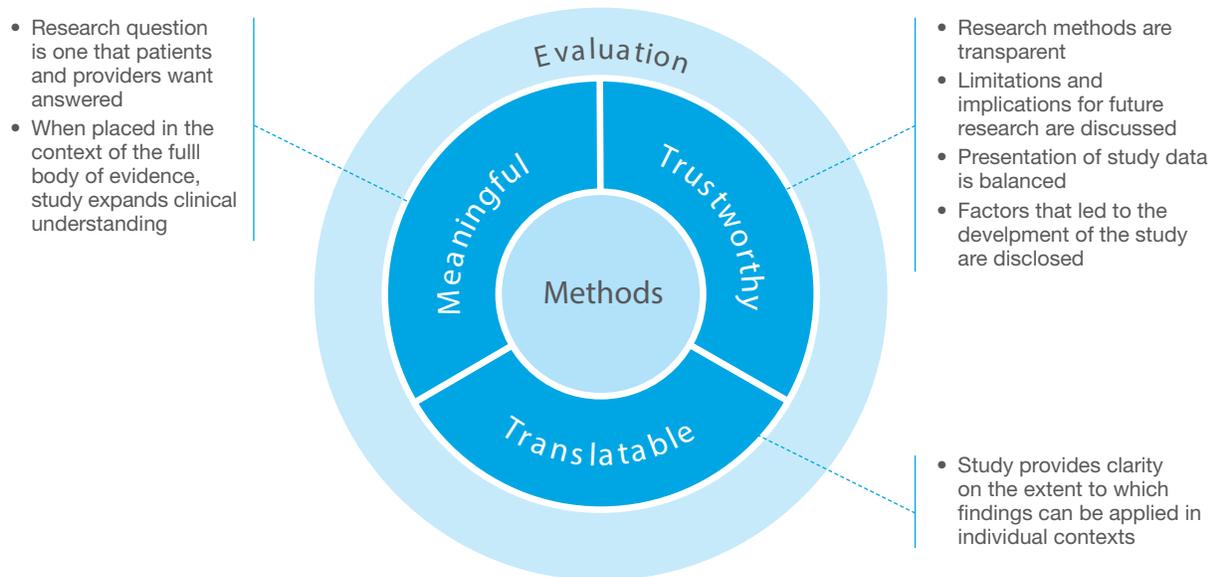
The elements that define usable CER (research question, methods, and communication) plus evaluation comprise the essential components to generate usable CER. Usable CER begins with the research question. Aligning the research question with those questions that patients and providers have identified as important is fundamental to achieving usability. The selection of research design and the conduct of research will affect the study's acceptance and, ultimately, its usability. In the communication of CER findings, all factors that have implications for the interpretation and application of the study's findings should be disclosed. Finally, there should be an evaluation of the study's use and impact once it is communicated to the intended audience of users. The value in this iterative component is the opportunity it provides to refine existing research questions and generate new questions that can enhance clinical understanding and thereby deliver CER that is more usable than what is now understood.

Framework for Evaluating Usability of CER

To focus this work, the scope of the discussion at the Dialogue was narrowed to the aspects of usable CER on which less work has been done to date. The group acknowledged the significant investments that have already been made in advancing methods, including standards for high-quality research. The group also noted that considerable resources are being invested in improving certain aspects of communication, namely in the arena of clear, comprehensible health communications to patients. In addition, the group observed that the evaluation component would need to come after the earlier components of the framework are addressed.

Dialogue participants identified several attributes of usable CER. These attributes were organized into three domains: meaningful, trustworthy, and translatable. Along with appropriate methods and evaluation, these three domains serve as the basis for a framework for the evaluation of CER usability as shown in Figure 2.

Figure 2. Framework for Evaluating Usability of CER Findings



Domain 1. Meaningful

In the context of usability, a meaningful study possesses two attributes: 1) it addresses an information need that has been identified by patients and providers; and 2) it expands (or has the potential to expand) current knowledge as reflected in the existing evidence base.

- **Research question is one that individual patients and providers want answered.** The research question should reflect questions that an individual patient/provider or set of patients/providers have identified as important for their decision making. Comparators should reflect options that patients would choose at the time the study is published. Endpoints should be those that patients care about. For example, while seizure control is viewed as the primary outcome of importance in treatments for epilepsy, other factors are equally important to patients with epilepsy, such as quality of life, ability to work, and ability to drive.²⁷
- **Study findings expand clinical understanding when placed in the context of the full body of research.** Because a single study is rarely definitive, understanding how it fits within the full body of knowledge will enable patients and providers to extract meaning from the study. When placed in context, it can be determined if a study strengthens or weakens the overall weight of evidence, resolves a clinical uncertainty, or fills a gap in knowledge. Understanding how a study relates more broadly to previous work enables patients and providers to draw implications that may be meaningful to them.

Domain 2. Trustworthy

Before an individual CER study can be accepted into the body of knowledge and its findings applied to decisions by patients and providers, it must be established as

trustworthy. Four attributes that reflect this domain include 1) transparency in research methods; 2) reporting of the study's limitations; 3) a balanced presentation of the study; and 4) disclosure of the factors that led to the development of the study.

- **Research methods are transparent.** To have confidence in research, a user, if he or she desires, should be able to review all of the methods. There should be sufficient information available on the study's methods to allow a researcher to reproduce the results or, at minimum, fully evaluate the study.
- **Limitations and implications for future research are discussed.** A discussion of the limitations of the study and its potential impact are important to interpreting a research finding and would allow patients and providers to derive credible conclusions about the potential application of the findings. To help advance the body of evidence, there should also be a discussion of the implications of the study's findings for future research.
- **Presentation of the study is balanced.** The presentation of a study should be balanced in its discussion of benefits and risks as well as include context that could affect the interpretation of the study. Such context may include whether a study represents a subset of a larger study that is unpublished.
- **Factors that led to the development of the study are disclosed.** These factors include financial and non-financial interests and relationships such as the sources of a study's funding, the role of funders in the study, and any conflicts. Omissions of factors such as these may invite skepticism that could reduce the acceptance of high-quality research.

Domain 3. Translatable

The third domain relates to the extent to which study findings are translatable; that is, whether the findings can be applied to individual contexts so that individual patients and providers can determine what is feasible and achievable given their environment and situation.

- **Study provides clarity on the individual contexts and patients to which the findings can be applied.** This attribute is consistent with existing concepts of generalizability, external validity, applicability,²⁸ and directness²⁹ which relate generally to the extent to which study findings can be applied in populations and settings that are broader than those studied.³⁰ While similar in direction, this attribute is narrower in its aim. While generalizability looks at the potential application of the study findings to a broader population, the attribute of "translatability" looks at its application to individualized scenarios, and patient, patient-caregiver, or patient-provider decisions. CER that possesses this attribute will provide clarity on how the study results can be applied given a patient's specific situation, personal health goals, beliefs, and treatment philosophies. For example, study results that indicate one intervention might be better than another based on an individual's treatment philosophy or a study that identifies cultural or economic factors that may affect its application would reflect this attribute.

Applying Usability of CER in Practice /

It is important to be able to apply the framework and identify the attributes in everyday decision making. Therefore, developing a tool that assists a user in evaluating usability of CER findings would be a practical next step. The domains and attributes that are outlined in this paper can serve as the basis for usability criteria that can be applied to identify research that has the greatest potential to be usable for patients and providers. To maximize the potential for research investments to produce usable CER, an evaluation of CER should take place both prospectively and retrospectively.

Prior to the initiation of research, usability criteria could be used by researchers and research funders to help them clarify, refine, and prioritize the research questions that are likely to yield results that would be usable to patients and providers in their determination of the best choices for their health and healthcare. Usability criteria may also contribute to evaluating the impact of a research funding proposal or a program of research. Moreover, usability criteria could guide thinking and planning around communication strategies of study results.

Following research results, usability criteria could aid patients and providers in distilling and prioritizing healthcare evidence so they can efficiently identify findings that are most applicable to the decisions they confront. Paired with tools that promote individualized care planning and shared decision making, usability criteria can help identify findings that could enhance the quality of the interaction between patients and providers.

Longer term, usability criteria would be applicable in the context of clinical practice guideline development, by better distinguishing the limitations and applicability of available evidence. Similarly, the usability concepts would provide a guidepost in payer coverage decisions.

Usability criteria have an important potential role further upstream in educating and training healthcare providers to identify usable CER. Emphasizing usability creates the potential to improve the generation and integration of research that is more compatible with concepts of patient-centered and patient-directed care.

Finally, there is the application of usability criteria to evaluation and measurement. Evaluating usability is fundamental to the continuous improvement of design, conduct, and dissemination of CER. There is an equally important role for measuring and evaluating implementation in real-time shared decision making. One of the most powerful applications of a usability framework, therefore, may be in the future design of metrics that accelerate the feedback loop to funders, researchers, and providers about how patients use CER information and what really influences patient choices.

Conclusion /

As significant resources continue to be invested in CER, greater focus needs to be placed on the generation of research that is usable in individual decision making and can improve the quality of interactions between patients and providers. Emphasizing usability can complement the considerable work that has been completed and is underway in research methods and promoting clear health communications. Longer term, the evaluation of CER usability creates the potential to improve the generation and integration of research that is more compatible with concepts of patient-centered and patient-directed care.

This paper summarizes the discussion at a Dialogue meeting that was attended by 23 thought leaders from across the healthcare community. The output of this discussion offers a basis for the development of usability criteria that can be used prospectively by researchers and funders to prioritize research questions, and retrospectively by patients and providers to identify CER findings that can be used to inform their decision making.

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Appendix: Selected Sections of Working Paper: *Usability Criteria: A Working Definition and Draft Domains to Support the Evaluation of the Usefulness of CER for Patient and Provider Decision-Making*

Note: In this working paper, the terms “useful” and “usable” were both used. Based on the discussion at the Dialogue, the terminology was simplified to “usable” and “usability.”

Approach /

To inform the development of potential domains for usability, Avalere Health researched existing frameworks and models aimed at better understanding which factors lead patients and clinicians to use evidence. The literature review focused on research about dissemination to identify key themes that could be adopted in a usability framework. Throughout this paper, the term dissemination is used to encompass related terminology, such as diffusion, knowledge translation, implementation, knowledge transfer, and research utilization. (Further defined in Table 1.)

Table 1. Definition of Terms Applied to the Dissemination Process³¹

Diffusion	The process by which an innovation is communicated through certain channels over time among members of a social system
Knowledge translation	The exchange, synthesis and ethically sound application of knowledge—within complex interactions among researchers and users
Implementation	The execution of the adoption decision, (i.e., putting the innovation or research into practice)
Knowledge Transfer	A systematic approach to capture, collect and share tacit knowledge in order for it to become explicit knowledge
Research Utilization	The process by which specific research-based knowledge (science) is implemented in practice

In March and April 2013, Avalere Health conducted two literature reviews using PubMed to identify dissemination frameworks and models that could be relevant to the development of usability principles. In the first review, Avalere Health searched for articles with the subject heading terms *information dissemination/methods* AND *evidence-based medicine* and the following words in the title or abstract: *usability of evidence* OR *useful evidence* OR *usefulness of evidence*. This search generated 16 articles. The second review sought articles published in the past five years with the subject heading terms *models, theoretical* OR *models, organizational* and the following words in all text fields: *communicating evidence* OR *translating evidence* OR *disseminating evidence*. This search yielded 54 articles. Finally, these searches were supplemented by additional sources recommended by experts from the field (primarily related to research methods and CER or communication principles), or identified by analyzing the references of papers generated through the search. Guided by a review of abstracts, Avalere Health examined research that specifically focused on frameworks or models to facilitate the uptake of evidence, and articles that identified individual components consistent with the aims of usability criteria.

Existing Frameworks and Proposed Usability Criteria /

The literature review did not uncover a specific body of literature addressing the creation of criteria by which patients and clinicians can evaluate the usefulness of evidence. In developing draft domains for defining usability criteria for CER, Avalere Health borrowed from frameworks, models, and principles to improve various aspects of evidence generation, dissemination, and use. (See Table 2.) A review of these frameworks and models revealed several recurrent themes and attributes that were consistent with the goals of usability.

Table 2. Frameworks, Models, and Principles Considered in Developing Domains for Defining Usability Criteria

Dissemination
Caplan's Principles for Appropriate Communication of Information in "Information Asymmetries in Health Care Putting Patients First"
Consolidated Framework for Implementation Research (CIFR) ³²
Diffusion of Innovations Theory
Health Belief Model ³³
Interactive Systems Framework (ISF) for Dissemination and Implementation ³⁴
Knowledge to Action Process
Practical, Robust Implementation and Sustainability Model (PRISM) ³⁵
Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) Framework ³⁶
Stetler Model of Research Utilization
Methods
Agency for Healthcare Research and Quality: Developing a Protocol for Observational Comparative Effectiveness Research
Agency for Healthcare Research and Quality Methods Guide for Comparative Effectiveness Reviews
Cochrane Handbook for Systematic Reviews of Interventions
Consolidated Standards of Reporting Trials (CONSORT)
Grading of Recommendations Assessment, Development and Evaluation (GRADE)
The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology ³⁷
Institute of Medicine Standards for Systematic Reviews ³⁸
Patient-Centered Outcomes Research Institute Methods Standards
STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)
Principles for CER
Good ReseArch for Comparative Effectiveness (GRACE) Principles
Drummond et al.'s Key Principles for the Improved Conduct of Health Technology Assessment for Resource Allocation Decisions
Luce et al.'s Principles for Planning and Conducting Comparative Effectiveness Research

Key themes from these frameworks were organized into domains that could represent the essential attributes of usability criteria and could serve as a guide for developing usability criteria (See Appendix 1). This paper proposes that usability criteria for the evaluation of CER should encompass each of the following six domains:

1. **Credible.** Was the study rigorously conducted and transparently reported? When accessing CER, patients and clinicians must be assured that the study results have been generated in a methodologically sound way and that the information has not been unduly influenced by external factors.
2. **Important.** Does the study provide timely new information that can advance the standard of care? Do the findings strengthen, weaken, or alter the weight of evidence? Patients and clinicians will seek to understand how a CER study fits within the existing body of evidence.
3. **Relevant.** Does the study address a high-priority research question, as defined by patients or clinicians, and include comparators and outcomes that patients or clinicians have identified as relevant? CER should address an information need that has been identified by patients or clinicians.
4. **Actionable.** Do the study's findings seem plausible? Do they seem feasible to implement? Patients and clinicians must have the resources and abilities to implement CER findings in varied settings and environments.
5. **Accessible.** Are the study results communicated in a manner that would be comprehensible to the end user? Communication of CER findings should be clear, concise, balanced, and objective.
6. **Adaptable.** Are the study results adaptable to differences in age, culture, ethnicity, geography, personal health goals, and spectrum of disease state? Are findings presented in a way that facilitates use of shared decision-making tools? To stimulate robust and high-quality dialogue between patients and clinicians, a CER study must pertain to the conversation by clarifying situational nuances that affect decision-making.

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