

# PIPC BEST PRACTICES FOR CER COMMUNICATION

## Background

Comparative effectiveness research (CER) has the potential to improve patient and physician decision-making by providing evidence-based information of which treatments work best, for whom, and under what circumstances. This research, if done in a patient-centered manner, can empower patients to better understand and take charge of their health care decisions. However, without keeping the individual patient in mind, this research may confuse the patient or caregiver if not relevant to their individual needs or leave treatment options out of reach for people who fall outside “average” results. Therefore, how research gets communicated to doctors, patients and other decision makers represents an important factor in realizing the opportunity for CER to support patient-centered, evidence-based medical care.

Developing appropriate principles for the communication of CER results reflects PIPC’s long-standing commitment to high-quality, patient-centered CER. In 2010, PIPC Chairman Tony Coelho, published an article in *Health Affairs* laying out a framework for specific elements of patient-centered CER, including highlighting the importance of communicating CER results in ways that are patient-centered, stating, “It is essential that results from this research do not end up on a shelf somewhere, ignored by patients and providers as too hard to understand. Instead, the results need to be communicated in language that doctors and patients can understand and apply to a set of individual circumstances. Because the institute’s stated purpose is to inform health care decision-making, how the research results are communicated is critical.”<sup>1, 2</sup>

Building on our prior work related to the conduct and use of comparative clinical effectiveness research<sup>3,4</sup>, PIPC in 2012 organized a series of roundtables involving more than 29 medical societies and over 20 disability organizations, as well as leading patient organizations and practicing physicians. The development of these best practices for communicating CER results responds to a need identified in these Roundtables, which found a “lack of standards for how to effectively communicate research results, and a

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1 Coelho, Tony, (2010). A Patient Advocate’s Perspective On Patient-Centered Comparative Effectiveness Research. *Health Affairs*, vol. 29 no. 10, 1885-1890, October, 2010.

2 Coelho, Tony, (2010). A Patient Advocate’s Perspective On Patient-Centered Comparative Effectiveness Research. *Health Affairs*, vol. 29 no. 10, 1885-1890, October, 2010.

<sup>3</sup> Partnership to Improve Patient Care, *White Paper: A Procedural Framework for the Conduct of Comparative Clinical Effectiveness*. [http://improvepatientcare.org/pipc-admin/pdf/9fb58f\\_White%20Paper.pdf](http://improvepatientcare.org/pipc-admin/pdf/9fb58f_White%20Paper.pdf)

<sup>4</sup> Partnership to Improve Patient Care, *White Paper: Priority-Setting for Comparative Effectiveness Research: A Review of Key Elements*. [http://improvepatientcare.org/pipc-admin/pdf/dbfe1e\\_White%20Paper.pdf](http://improvepatientcare.org/pipc-admin/pdf/dbfe1e_White%20Paper.pdf)

lack of proper tools to assist patients and physicians in applying research information to a specific set of unique patient circumstances.” In these roundtables, PIPC heard clearly from leading provider and patient representatives that they value patient-centered CER and want to help develop effective tools for disseminating results in support of high-quality, patient-centered care.<sup>5</sup>

In addition to the information gleaned from these Roundtables, PIPC drew on available literature and resources related to CER communication, including relevant provisions of existing statute<sup>6</sup>, standards for the development and use of patient decision aids<sup>7</sup>, and guidance on dissemination and shared decision-making.<sup>8</sup>

The Patient Protection and Affordable Care Act (ACA) created a new context for CER that is to be prioritized, conducted, and communicated in ways that are patient-centered. The intent behind establishing a patient-centered CER program was to generate CER that can serve as a resource to assist in health care decision-making, thereby reducing disparities in our health care system. While traditional peer-reviewed articles or journals will continue to help inform the scientific and clinical community on such CER findings, it is essential that the results also be communicated in a manner that keeps patient interests at its core. As such, the statute supports the gold-standard of peer-reviewed academic journals while also providing a useful starting point in considering best practices for patient-centered CER communication.

In light of PCORI’s mandate to conduct comparative clinical effectiveness research, CER communication tools and materials should present patients with sound, clinical evidence to help inform their individual decision-making process. Based on the focus on patient care management found in PCORI’s research agenda, it is clear that the communication of the results of that research will have a direct impact on individual patient decision-making. Therefore, as PCORI begins to play a more active role in CER communication, PIPC believes these proposed best practices represent elements for all CER organizations to consider when communicating CER results to physicians and patients. While this document reflects extensive research and engagement with the patient and provider communities, we also consider it to be a living document that will continue to evolve based on feedback we receive.

## **Best Practices for CER Communication**

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<sup>5</sup> Summary of The Partnership to Improve Patient Care’s 2012 Roundtable Series on Incorporating Clinical Expertise into Patient Centered CER [http://pipcpatients.org/pipcadmin/pdf/7998cd\\_PIPC%20Roundtable%20Summary%202012.pdf](http://pipcpatients.org/pipcadmin/pdf/7998cd_PIPC%20Roundtable%20Summary%202012.pdf)

<sup>6</sup> ACA §3506, adding §936 of the Public Health Service Act; ACA §6301, adding §937 of the Public Health Service Act

<sup>7</sup> International Patient Decision Aid Standards Collaboration. [http://ipdas.ohri.ca/IPDAS\\_checklist.pdf](http://ipdas.ohri.ca/IPDAS_checklist.pdf)

<sup>8</sup> American Medical Association. <http://www.ama-assn.org/resources/doc/cms/a10-cms-rpt-7.pdf>

The best practices described below are intended as recommendations for organizations seeking to communicate and distribute the findings of CER in a way that is patient-centered. The ACA laid out requirements for the communication of CER including identifying limitations, transparency, and a prohibition on issuing recommendations or guidelines as part of a research conclusion. These best practices are intended to expand on those requirements as well as offer specific recommendations on other ways to ensure that research results are communicated to patients and physicians effectively, and maximize the value of a patient-centered CER study to health care decision-making for an individual set of circumstances.

**CER Communication should rely on significant input from patients and providers in the development of materials and implementation of dissemination program.**

Involving clinical experts, practicing physicians, and patient organizations is vital to ensuring that CER study results are disseminated in a manner that maximizes the ability of physicians and patients to apply the findings of CER to a specific health care decision. As content and tools are developed to support dissemination of CER findings, patients, physicians and other providers should play a significant role in providing input to ensure relevant, high quality information is appropriately communicated. Further, the increasingly complex nature of health care and the growing field of personalized medicine dictate the need for relevant clinical and scientific expertise when communicating CER study results, in order to ensure that results are communicated accurately, ethically, and to the correct audience.

PIPC's roundtable discussion with disability organizations stressed the importance of engaging patients, clinicians, and other experts as plans to communicate and distribute CER information are developed. They stated, "The roundtable of people with disabilities recommends that PCORI develop protocols for dissemination of research findings in consultation with organizations and individuals representing people with disabilities to ensure that research results and communication tools, including patient decision support tools, meet certain criteria for accessibility and represent policies that are proven to enhance clinical practices and patient understanding in persons with disabilities."<sup>9</sup> During an interview about Physician views on PCORI, AMA president Dr. Ardis Hoven, highlighted the importance keeping physicians involved in the dissemination of CER, stating, "...it's going to be important for PCORI as they do their work to be sure physicians are involved, that physicians are at the table in the

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<sup>9</sup> PIPC/AAPD Roundtable Summary and Recommendations. [http://pipcpatients.org/pipc-admin/pdf/6670f6\\_PIPC%20Disability%20Roundtable%20Summary.pdf](http://pipcpatients.org/pipc-admin/pdf/6670f6_PIPC%20Disability%20Roundtable%20Summary.pdf)

discussions with them, and that we are part of the dissemination of information to physicians and their patients.”<sup>10</sup>

**CER communication tools should be developed through systematic, transparent processes with active patient engagement.**

In order for CER communication materials and tools to be useful for physicians and patients when making informed health care decisions, there must be confidence that they were developed through a systematic, transparent process, including providing an opportunity for public input at key decision points and making materials and tools available to public. The 2013 PIPC public-opinion poll emphasized that when it comes to communicating the results of a particular CER study, people prioritize accuracy, transparency and improving access to personalized and high-quality care. By very wide margins, people want good information communicated in a manner that makes it relevant to their individual health needs.<sup>11</sup>

As organizations begin to create these tools, it is important to meet certain criteria in the development process: (1) scoping and design; (2) development of a prototype; (3) initial testing with patients and physicians in an iterative process; (4) testing in a “real life” setting; and (5) production of a final product<sup>12</sup>. While material and tool developers may emphasize unique aspects in the development process, these are key features that should be recognized in the development and evaluation of CER communication materials and tools.

**CER communication tools should present results in ways that are useful and comprehensible.**

The findings from CER must be communicated in a manner that is useful and comprehensible for physicians and patients. It is essential that results from this research be communicated in a language that physicians and patients can understand and apply to a set of individual circumstances, and that enables them to accurately assess the trade-offs inherent in choosing one medical intervention of option over another. With understandable, evidence-based information about available options and possible outcomes, physicians and patients will be better equipped to make an informed decision that is aligned with their preferences.

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<sup>10</sup> Lundberg, George, MD (2012) Conversations with...Ardis Hoven, MD, Medpage Today, September, 2010. <http://www.medpagetoday.com/Columns/ConversationsWith/34774>

<sup>11</sup> PIPC Press Release, <http://www.pipcpatients.org/newsroom-detail.php?id=193#.UfgdANLkvw0>

<sup>12</sup> International Patient Decision Aids Standards Collaboration. Background Document - Chapter A: Using a Systematic Development Process. <http://ipdas.ohri.ca/IPDAS-Chapter-A.pdf>

Building on input from prior PIPC roundtables, communication of research findings must be done in “consultation with organizations and individuals representing” physicians and patients “to ensure that research results and communication tools, including patient decision support tools meet certain criteria for accessibility and enhance clinical practices and patient understanding.”<sup>13</sup> The International Decision Aid Standards (IDAS) specify inclusion of patients early in the development of communication tools in order to ensure that users of patient decision support have reassurance that there was a systematic development and review process that primarily involved patients and clinicians. This is to remedy the issue of patients and physicians being largely excluded from the development and testing process. IDAS notes that “to date, only about half of patients’ decision aids appear to have been field tested with patients and even fewer have been reviewed by clinicians.”<sup>14</sup>

**CER communication should help providers and patients relate average study results to the needs and preferences of the individual patient, including clearly presenting both the strengths and limitations of study results.**

While it is clear that the development of CER will help patients and their physicians make care decisions that meet patients’ individual needs and preferences, the strengths and limitations of the research must also be appropriately presented. This concept is consistent with the ACA, which required that final PCORI study results be presented in a format that includes the limitations of a particular CER study.

Because of the individuality in patient preferences and circumstances, there are inherent limitations and uncertainties in how specific CER findings will affect each individual patient. By understanding and communicating the limitations of specific CER, and incorporating other relevant information, physicians and patients can better choose an appropriate treatment or response. Ultimately, this research is meant to support physicians’ and patients’ decisions, not dictate what those decisions should be.

Presenting the limitations of a study is particularly important to patients and physicians as the results of CER will represent “a statistically significant treatment effect across a population on average that do not necessarily work for all treated patients; they may be ineffective for some patients and harmful for others...Communications of CER findings and other evidence must be adaptive and targeted. These messages should address strengths and limitations of this evidence, and how specific it is for patient subgroups.”<sup>15</sup>

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<sup>13</sup> PIPC/AAPD Roundtable Summary and Recommendations. [http://pipcpatients.org/pipc-admin/pdf/6670f6\\_PIPC%20Disability%20Roundtable%20Summary.pdf](http://pipcpatients.org/pipc-admin/pdf/6670f6_PIPC%20Disability%20Roundtable%20Summary.pdf)

<sup>14</sup> International Patient Decision Aid Standards Collaboration. <http://ipdas.ohri.ca/IPDAS-Chapter-A.pdf>

<sup>15</sup> Goodman, Clifford, Ph.D. (2009) *Comparative Effectiveness Research and Personalized Medicine: From Contradiction to Synergy*, The Lewin Group for the Personalized Medicine Coalition, October 28, 2009, page 23. [http://www.npcnow.org/system/files/conferences/download/Lewin\\_CER-PM.pdf](http://www.npcnow.org/system/files/conferences/download/Lewin_CER-PM.pdf)

It is imperative that limitations be shared openly, as some research may not lead to any definitive treatment decisions, but rather call attention to the need for further research.

The results of CER are highly nuanced and require a great deal of care in adaptation so as to not overstate or understate the results of research or recommendations in ways that would suggest standardizing care at the individual patient level. A 2012 Journal of the American Medical Association (JAMA) article written by researchers at Tufts University and the Mayo Clinic, found that that recommendations based on medical evidence, including CER, can be valuable to clinicians in providing information about “multiple potential solutions to be considered at the individual patient level”, but that looking to the results of a singular study or recommendation based on group data to provide “one right answer” about how and when to initiate an intervention ignores the myriad of scientifically valid ways to define, select, and analyze medical evidence.

**CER communication materials should be designed to enhance patient and provider decision-making at the point of care, and integrate efficiently into providers’ work flow.**

Once developed, CER communication tools and materials must be incorporated into the health care delivery system in a manner that enhances the physician and patient interaction and fosters patient-centered care. Aligning with previous recommendations, this should be done appropriately, with constant regard to individual needs and preferences as well as for the physicians’ role and input. However, a recent study has shown that there are potential barriers to the adoption of shared decision-making tools, which may limit patient engagement and result in less optimal care.<sup>16</sup>

Patient-centered communication tools should be readily available to physicians at the point-of-care, reducing the day-to-day care delivery burdens placed on physicians when working with patients. By ensuring that these tools are accessible, physicians can better engage their patients in their care, leading to treatment choices that are more concordant with patients’ wishes. In the American Medical Association’s (AMA) policy statement regarding patient-provider communication tools, the AMA acknowledges these tools can benefit patient outcomes, but that more work needs to be done to identify how to best fit these processes into current clinical practice so as not to create an additional administrative burden for physicians. According to the statement, “The AMA supports the development of demonstration and pilot projects to help increase

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<sup>16</sup> Mark W. Friedberg, Kristin Van Busum, Richard Wexler, Megan Bowen, and Eric C. Schneider. “Shared Decision Making: A Demonstration Of Shared Decision Making In Primary Care Highlights Barriers To Adoption And Potential Remedies” *Health Affairs*. 2013 32:2268-275

knowledge about integrating shared decision-making tools and processes into clinical practice.”<sup>17</sup>

**Communication tools and materials should provide sufficient information on the range of relevant health care or medical options.**

CER communication tools, such as patient decision aids, are meant to engage patients and caregivers in informed decision-making with health care providers and should include sufficient evidence on the full range of treatment and care options available to the patient. Evidence communication programs, such as shared decision-making are intended to enable values-based decisions with a patient’s clinician.<sup>18</sup> They should provide information about trade-offs among treatment options, explaining, where appropriate, why there is a lack of evidence to support one option over another, and help facilitate the incorporation of patient preferences and values into an overall treatment plan. Such tools should not be viewed as a definitive or strict treatment guideline for all patients.

**Research Results Included in CER Communication Programs Should Rely on Data from Rigorous Study Designs**

Methodological standards can help ensure that CER produces information that is meaningful, unbiased, timely, and actionable. At the outset, CER must be conducted under sound methodological standards to ensure that the research produces high-integrity and sound clinical evidence. The increased emphasis on generating evidence of “real world” comparative effectiveness of health care interventions in recent years has brought to the forefront the need for sound methods to match these goals. For example, CER entities often support study designs other than randomized control trials in response to the demand to efficiently generate data on “real world” effectiveness.

This basic set of methodological challenges has been recognized in many recent, authoritative reports on CER. For example, in its 2009 report on national priorities for CER, the Institute of Medicine noted “a significant need for new and better research methods for studying comparative effectiveness...” and that, “Current study designs, both experimental and nonexperimental, must be further refined if CER is to be scientifically valid, efficient, and credible. In systematic reviews, for example, research is needed on how to identify and use evidence from observational studies on intervention effectiveness, and also on how to assess a heterogeneous body of evidence. Similarly, the Federal Coordinating Council on Comparative Effectiveness Research report in 2009 emphasized the need for robust research methods, highlighting needs such as “the

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<sup>17</sup> American Medical Association Shared Decision Making Policy., H-373.997 Shared Decision-Making

<sup>18</sup> International Patient Decision Aids Standards Collaboration. Background Document – An introduction.  
<http://ipdas.ohri.ca/IPDAS-Introduction.pdf>

development of methods for linking and using databases for CER” and “the development of new methodologies for pragmatic trials.”

Presenting the study methodology clearly can also help ensure that findings are integrated into a physician’s clinical practice. The 2013 Deloitte annual survey of physicians solicited the views of more than 600 physicians across primary care and specialty, and included questions related to the best ways to integrate CER into clinical practice. The survey findings indicate that physicians place great importance on how findings are presented when it comes to deciding whether or not to integrate findings into clinical practice. Deloitte found, “Nine in 10 believe that study methods and approaches must be communicated in detail to allow clinicians to understand, interpret, and critique the research.”<sup>19</sup>

**CER communication tools should be continuously updated to keep up pace with changes in evidence base, clinical practice, and medical technology.**

Having a systematic process for ensuring that the research findings being used to inform decision-making tools and materials will ensure that physicians and patients are making decisions based on current information. Health outcomes research, including CER, is a constantly growing and changing area of inquiry. Based on a recent study, 23% of systematic reviews are no longer relevant after two years and 15% of reviews will expire after one year<sup>20</sup>. Therefore, it is vital that materials and decision aids be continuously updated in order to assist physicians and patients in making informed health care decisions. Keeping CER communication tools up-to-date will become increasingly important as Personalized Medicine and rapid learning in health care based on large data sets becomes more prominent.

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<sup>19</sup> 2013 Deloitte Survey of U.S. Physicians. [http://www.deloitte.com/view/en\\_US/us/Insights/centers/center-for-health-solutions/a5ee019120e6d310VgnVCM1000003256f70aRCRD.htm](http://www.deloitte.com/view/en_US/us/Insights/centers/center-for-health-solutions/a5ee019120e6d310VgnVCM1000003256f70aRCRD.htm)

<sup>20</sup> Kaveh G. Shojania, MD; Margaret Sampson, MLIS; Mohammed T. Ansari, MBBS, MMedSc, MPhil; Jun Ji, MD, MHA; Steve Doucette, MSc; and David Moher, PhD How Quickly Do Systematic Reviews Go Out of Date? A Survival Analysis. *Annals of Internal Medicine* 2007;147:224-233.