

A framework for patient and consumer engagement in evidence generation

September 2012

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As ultimate end users of research, patients and consumers should have a voice in shaping its design and implementation. Patients and consumers bring unique and critically important perspectives to the healthcare experience, and can be important partners in generating new evidence. This is reflected in their preferences for treatment, in their expectations for shared decision making, and in their assessment of what constitutes a “successful” outcome.

This framework for patient and consumer engagement sets forth expanded opportunities for involving patients and consumers in comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) and Quality Improvement (QI). It builds off of a previous issue brief focusing on the ethical and instrumental reasons for patient and consumer engagement in CER and PCOR (developed as a part of the AcademyHealth Electronic Data Methods (EDM) Forum), and is informed by deliberations of the Consumer Patient Researcher (CPR) Roundtable, a collaborative forum convened by AcademyHealth.

Those participating in the CPR Roundtable endorse the principle that the perspectives and input of patients and consumers should be considered throughout the evidence generation process. This framework supports that philosophy and acknowledges that patients and consumers are important partners in research who have a shared interest in improving health and health care. Unlike previous frameworks (Mullins, 2012), (Concannon, 2012), (Deverka, 2012) that have focused on the classically defined research process (i.e., conceptualization of the question through to application), this framework seeks to expand the set of opportunities for engagement to include front-end technical and data infrastructure development* steps that are critical to the evidence generation process.

This framework acknowledges the need to build a rapid learning health care system (Institute of Medicine, 2007) – a concept that calls for the creation of a new research paradigm to improve the development and application of evi-

dence in healthcare decision making. A key requirement in this transformation is the expanded collection, development and use of electronic data (i.e., technical and data infrastructure development) to support research. And, as more researchers look to use these data to address important CER, PCOR and QI questions, the process of infrastructure development will only increase in importance to patients and consumers – who will want some assurance that their needs and preferences have been “baked in” to the goals of any given project. This essentially requires that new technical and data infrastructure initiatives support the types of research efforts that patients and consumers perceive as important, and that reflect their values and preferences. Also important is that any infrastructure components with a patient interface be designed with their participation in mind.

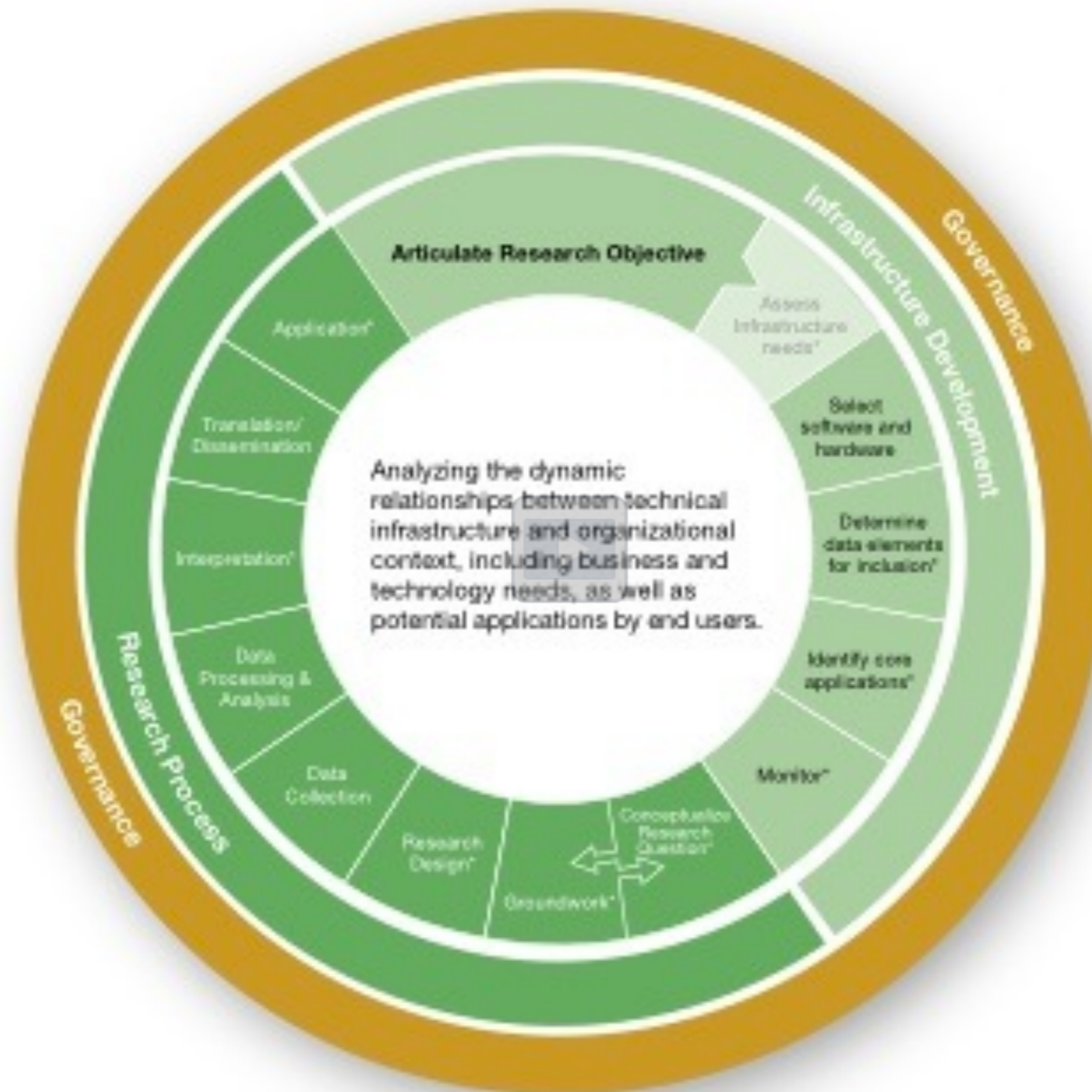
Recognizing the potential that exists for patients and consumers to positively influence and benefit from the development of these critical infrastructure resources, this framework proposes that the evidence generation process should integrate both the conduct of research and the development of technical and data infrastructure that is used to support such research. Based on CPR Roundtable discussions, and the experiences of several patient and consumer participants, the framework further specifies key opportunities for engagement in both the technical and data infrastructure development and research processes that are likely to be most opportune for patient and consumer engagement (as designated by an asterisks).

It is important to note that these activities all rely on a foundation of governance designed to facilitate trust among numerous stakeholders, including researchers, patients, and consumers. The framework emphasizes the important role of patients and consumers in developing and monitoring governance policies and processes that ensure data security and privacy, and address data access and conflicts of interest.

* Here technical and data infrastructure refers to the creation or modification of (primarily) electronic data resources and information technology systems needed to support the conduct of CER and PCOR.

An interactive framework for engagement

Patients and consumers bring unique and critically important perspectives to the healthcare experience, and can be important partners in generating new evidence. The proposed framework supports this philosophy and presents opportunities for engagement in an expanded spectrum of activities, including both technical and data infrastructure development and the conduct of research.



Engagement activities for infrastructure and research policies, processes and products

Patients and consumers can engage in specific aspects of both technical and data infrastructure development and research, sometimes serving in multiple roles simultaneously, through the following activities:

Contributing public input/public comment

Advising

Providing leadership

Serving on a team

Participating in a research study

Accessing tools/instruments

Reviewing

Participating in a virtual community

Serving as community liaison

Providing oversight, monitoring, evaluation

Training/mentoring

Providing direct feedback on various aspects of both infrastructure development and research via in-person and/or virtual meetings, surveys, community forums, and other both formal (e.g., Federal Register) and informal (e.g., email) mechanisms.

Linking key opportunities for engagement with specific activities

Engagement activities are likely to be differently applied depending on the specific step of the evidence generation process. It is worth noting that the CPR Roundtable considered all activities to be opportune for engagement in the highlighted phases of the Research Process. The graphic represents the CPR Roundtable's "best guess" as to which types of activities could best be deployed in each of the key opportunities for engagement



Future considerations and next steps

In working to define roles and opportunities for engagement, it is also important to consider that different skills and perspectives may be needed depending on the particular activity. For example, patients and consumers involved in defining research questions should ideally be familiar with the conditions being studied, but those engaged to provide input on research methods likely would require different expertise. Additionally, different skills, perspectives and resources may need to be deployed depending on the type of activity (e.g., advisory committee versus focus group), and expectations of time and expertise may vary by intensity and duration of engagement (e.g., multi-year versus single encounter).

Members of the advocacy community are well aware that training and support are required to ensure that patients and consumers can have a place at the decision-making table. Due to the technical nature of both components of evidence generation (i.e., technical and data infrastructure development and research processes), it is anticipated that the “lift” for patient and consumer participants could be onerous. While training programs exist to prepare patients and consumers to sit on review boards for the federal government and to understand certain types of research studies (e.g., randomized controlled trials and systematic reviews), additional efforts will likely be necessary to train consumers and patients to participate meaningfully in all phases of the evidence generation process.

AcademyHealth and the CPR Roundtable will continue to refine this framework, and to explore further the particular points in the evidence generation process that are most opportune for patient and consumer engagement. Forthcoming work will highlight promising examples of existing training efforts, and case examples of where and how engagement of patients and consumers in research has been done effectively.

To follow these ongoing discussions with the CPR Roundtable and for more information about the EDM Forum, see www.edm-forum.org. Definitions of all key terms referenced in this resource are available on the EDM Forum website under “Resources—Wiki Glossary.” To comment on the framework’s content and usability, or to provide examples of patient and consumer engagement in the evidence generation process, please visit <http://www.edm-forum.org/publicgrant/SubmitComments/>.

Methods: The background for this framework is informed by a structured review of the peer-reviewed and grey literature conducted by the EDM Forum. Observations from a number of AcademyHealth projects focused on technical and data infrastructure development to support research (e.g. Beacon Evidence and Innovation Network, HIT for Actionable Knowledge) that are relevant to the EDM Forum were incorporated. Staff engaged in a number of discussions with members of the CPR Roundtable to vet the conceptual framework, and to map out and define its component parts. Staff engaged members of the CPR Roundtable in reviewing drafts and solicited feedback on the final version from the EDM Forum Steering Committee.

Acknowledgements

About AcademyHealth

AcademyHealth is a leading national organization serving the fields of health services and policy research and the professionals who produce and use this important work. Together with our members, we offer programs and services that support the development and use of rigorous, relevant and timely evidence to increase the quality, accessibility, and value of health care, to reduce disparities, and to improve health. A trusted broker of information, AcademyHealth brings stakeholders together to address the current and future needs of an evolving health system, inform health policy, and translate evidence into action.

About the EDM Forum

The Electronic Data Methods (EDM) Forum is a three-year grant from the Agency for Healthcare Research and Quality (AHRQ) to facilitate learning and foster collaboration across a set of eleven comparative effectiveness research (CER) projects. Collectively, these projects are designed to build infrastructure and methods for collecting and analyzing prospective electronic clinical data. Specific areas of focus include the governance, clinical informatics, and analytic issues that are crucial to the design and use of electronic clinical data for CER and PCOR. The EDM Forum, and the connected research projects, are funded by the American Recovery and Reinvestment Act (ARRA). For more information, visit www.edm-forum.org.

About the Consumer Patient Research Roundtable

The Consumer Patient Researcher Roundtable is a convening activity of AcademyHealth that recognizes the shared interests of both patients and researchers (i.e., the desire for better health and health care), and facilitates dialogue and collaborative work. In addition to AcademyHealth staff, participating individuals include: Bryan Dowd, University of Minnesota; Deven McGraw, Center for

Democracy and Technology; Jason Goldwater, eHealth Initiative; Mark Gorman, Patient Advocate; Eva Powell, National Partnership for Women and Families, Musa Mayer, AdvancedBC.org, John Santa, Consumers Union, Shoshanna Sofaer, Baruch College; and Mike Stoto, Georgetown University.

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Acknowledgements

AcademyHealth acknowledges the members of the Consumer Patient Researcher Roundtable for their thoughtful input, guidance and review.

AcademyHealth also acknowledges the Agency for Healthcare Research and Quality (AHRQ) for its support of this work. The EDM Forum is supported by AHRQ through the American Recovery & Reinvestment Act of 2009, Grant U13 HS19564-01. AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. As 1 of 12 agencies within the Department of Health and Human Services, AHRQ supports research that helps people make more informed decisions and improves the quality of health care services. For more information, visit www.ahrq.gov.

Suggested citation

Rein A, Holve E, Hamilton Lopez M, and Winkler J. "A framework for patient and consumer engagement in evidence generation," EDM Forum, AcademyHealth, September 2012.

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