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To: Dr. Joe Selby, Executive Director, PCORI

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Re: Comments In Response to the "Draft National Priorities for Research and Research Agenda" Document

This memo is in response to PCORI's solicitation for comments concerning the "Draft National Priorities for Research and Research Agenda". My comments will address specifically the "communication and dissemination" priority, i.e., where the draft document notes, "how to optimally communicate" and "the rapid transfer of evidence". These comments are my own.

I am writing for two reasons. First, it is well documented the quality of health service delivery in this country is woeful. You are well aware uncontrolled patient harm is, as Kaiser Health News reported last week, "epidemic". All cause harm occurs in one-third of hospital admissions, in 2010 faulty medical care contributed to 15,000 Medicare patient deaths per month and medical errors are, in sum, a leading cause of death in this country. I am writing also because my experience (that includes six years as AHRQ's Evaluation Officer) leads me to conclude the paradigm we use to deliver and improve health care is grossly ineffective.

If you choose an ineffective "communication and dissemination" or similarly a "knowledge transfer" or "systems improvement" paradigm, that is if you choose to leave unexamined how knowledge is ultimately created you will simply continue the status quo, i.e., continue do little to improve health care outcomes and the institute's emphasis on "patient-centeredness" will be beyond disingenuous.

Consider the possibility that knowledge is neither an “it” nor a “thing” nor is knowledge “communicated and “disseminated” or transferred as is typically understood. Instead, knowledge can be thought of as ultimately the product of real time social interaction between the health care provider and the patient – and this has significant implications for health care service research and delivery improvement.

The prevailing way health care delivery improvement is pursued has proven to be ineffective. Why? In improving health care delivery we inherently, unavoidably make assumptions about how we know. The assumptions we make, or the paradigm¹ we use, to create new knowledge also simultaneously explains the method or process we use to improve delivery. Simply stated the accepted paradigm we use is one where we assume knowledge is first produced and then simply “communicated and disseminated”. For example, the WHO terms it the “know-do” gap, the NIH “roadmap” program is designed to accelerate “from bench to bedside” the transfer of knowledge to practice. AHRQ defines their efforts as “knowledge transfer”. These and similar others assume an ability to “disseminate” mechanistically and linearly discrete knowledge. However, this paradigm does not usefully explain how we know and the know-how of improving health care delivery. Does creating knowledge actually precede the delivery of care only then to be “disseminated”? Can, instead, delivery be understood as inherently a common every day real time activity?

Despite the current “epidemic” of patient harm there remains little debate or even awareness about how quality improvement efforts need to proceed since the assumed paradigm is well accepted. That is the need to produce ever more evidence and a commensurate need to develop more and more “dissemination” or knowledge management infrastructure to expedite the transfer of evidence from the researcher to the clinician and others. These assumptions are unquestioned. They are pervasive.

The Accepted Paradigm

The paradigm used to advance research evidence or knowledge (and practice improvement) is one where knowledge is first created as an “it”, “thing” or “commodity”. As such, we then connect what we know with what we do via a stepped or sequential communication process whereby the knowledge “it” or “thing” is “disseminated” or transferred from one individual to another. Individual A sends it to individual B. Generating new knowledge or learning is a private matter and once obtained new knowledge transfers like money. Learning and knowing is an individual activity since new knowledge exists as rarified mental content. This paradigm is based on a Cartesian world view that is reductionist, mechanistic and linear.

Understandably then improving health care delivery takes on technical or engineering properties. Improvement, as Don Berwick argues, means “re-engineering” health care or there is a need to “wed engineering sciences more effectively with health care”. This means largely driving out variation or bringing to ever larger “scale” uniform care delivery via manufacturing processes such as Six Sigma and Toyota Lean Production. In the examination room it makes sense to talk about a provider meeting a

¹ The word paradigm is used intentionally, i.e., in the context of Thomas Kuhn’s The Structure of Scientific Revolutions (1962) where Kuhn argued there is no research absent a conceptual paradigm and whatever paradigm chosen explains how we understand knowledge and our methods for and standards of solutions.

pre-defined norm, standard or a guideline and to then talk about a patient's compliance with that guideline.

The process for improving health care delivery means the use of so called "sound science" to produce "right" knowledge or the use of explicit rules by which scientific propositions to improve health care can be obtained. This means the generation of new knowledge preferably by randomized control trials or at least by systematic reviews, e.g., the Cochrane Collaborative's work – and likely PCORI's. The next subsequent task is to "disseminate" or transfer new knowledge or have it travel along a continuum or a "translational highway" to be brought to, again, ever larger national scale. To use the journal title, the effort becomes an "implementation science" challenge.

One of the frequently cited works that informs this paradigm is the Diffusion of Innovation by Everett Rogers. This paradigm also underlies the work by evidence-to-practice "dissemination" researchers for example Jonathan Lomas and John Lavis. They, similarly, emphasize the "push" (by researchers) and "pull" (by clinicians) of research evidence-to-practice and the role or function of "knowledge brokers" or "boundary spanners" who serve to bridge the gap between researchers and clinical practitioners. In sum, in this paradigm, both the nature and role of knowledge is again assumed. As an "it" or "thing" knowledge inherently, or *a priori*, provides certainty and meaning, it's self-announcing and self-executing.

More generally this paradigm makes assumptions about our understanding of how people are related to one another. If we assume a Cartesian world, one of discrete things and dualisms, i.e., society and nature, subject and object, individual mind and the social, the provider and the patient, then we accordingly can understand and explain ways of sense making where we are able to transfer one thing from one domain to another or from one mind to another. Ralph Stacey terms this "sender - receiver" or where one person first creates or learns new knowledge and then "disseminates" or transfers the knowledge "it" to another person. One sends, the other receives.

The paradigm thus provides the rationale for how we understand or approach improving the quality of health care delivery. For example, sender - receiver underpins continuing medical education and related professional development activities as well as many knowledge management and research "dissemination" programs, other quality improvement and organizational structure or system re-design efforts, it serves as the underlying rationale for EBM, performance measures, quality indicators, report cards, check lists, pay-for-performance, and other approaches or programs all endeavoring to "disseminate" or transfer research to practice to improve health care delivery.

Regrettably, progress made in improving health care delivery using this paradigm has been, to be unduly polite, slow. For example, despite over 1,200 CDC guidelines to prevent HAIs, hand washing, likely the most simple and effective task in all of health care delivery, frequently has no better than 50 percent adherence rates. Paradigm testing, Kuhn said, occurs when "persistent failure to solve a noteworthy puzzle has given rise to crisis." Times like now. Since Kuhn argued paradigms are incommensurable and cannot be proved or disapproved, consider an alternative.

An Alternative Paradigm

Let's assume knowledge does not, like money, have a "thing-like" additive reality. For example, unlike material realities, the knowledge of one hundred physicists is not one hundred times the knowledge of one of them. Let's assume knowledge does not arise first in the mind of the individual to be transferred as mental contents from one to another. Instead, the creation of knowledge begins with the response to a gesture and continues to build in the on-going back and forth of the "gesture and response" (also Stacey's phrase) of people interacting. Knowledge creation is then inherently a social act, the property of mutual adaptation. Knowledge is not then meaning independent. No one individual owns knowledge, it cannot be stored or managed or simply "communicated and disseminated" or transferred. In sum, people make sense of the world together. Reality is a negotiated interpretation, as John Searle argues. (Beyond the scope here, this paradigm also has profound implications for how we understand causality, human agency, management and ethical obligation.)

From an organizational perspective, because no one can ever step out of the process of interacting to manage (or obtain "super agency"), managing is only meaningful or understandable in the sense of an organization's conversational life or as self-organizing social networks or communities of practice that develop. Here, improvement via systems, systems thinking or systems improvement is a conceit since they are simply an abstraction of human interaction – which is all there is. From an improvement or evaluative perspective, the unit of analysis is relationships or the quality of interactions not the individual or what the individual mind knows. In Aristotelian terms, delivering health care ultimately exists in the realm of *phronesis* where knowing, improving, changing is a deliberative, dialogic process. Medical science and technology obviously play an essential informative role but health care delivery and improvement amounts to an applied natural science. People, physicians and patients, unlike objects in nature, are always self-interpreting (reflective and reflexive) entities. That is, there is ultimately no new knowledge, quality improvement, or no change absent a response to a gesture.

Consider two examples. In the PBS series "Remaking American Medicine", Dr. Anne Peters, a Los Angeles diabetologist, is profiled as a physician achieving high quality outcomes. We are told that Peters believes effective treatment means "creating an entirely new relationship with patients" and that she understands her work as "embarking on a partnership." One of her patients observes, "traditional doctors tell you what to do," with Dr. Peters, "we're in this together." Peters' highly interactive approach ultimately explains her success. Instead of an all-too-typical authoritative approach used to somehow achieve patient compliance, Peters' efforts are aimed at reaching concurrence or commensurability. Peters is interested in what is medically true about the patient's condition but moreover in learning, based on the patient's own goals, what is most useful in effecting treatment. Here, more relevant than the technical expertise is the ongoing, back-and-forth interaction of gesture and response.

Similarly, Dr. Warren Warwick's success with his cystic fibrosis patients can be explained as gesture - response. In his profile of Warwick, Atul Gawande details the back and forth interaction between Warwick and a young female patient where Warwick tries to make sense of the woman's reduced lung capacity by persisting in asking her about coughs, colds, treatment frequency, etc. Eventually Warwick

learns his patient has a new boyfriend and job and for these reasons she had been skipping her treatments. Knowing this, Warwick is now able to work out an agreement with his patient to reverse her functional decline. (Not surprisingly, we also learn Warwick is disdainful of clinical guidelines telling Gawande they are “a record of the past and little more.”)

Gawande profiled Warwick moreover to argue health care delivery varies widely thereby resembling a bell curve distribution. The ever-increasing number of delivery performance guidelines and other related metrics will inevitably lead, Gawande says, towards finding some doctor’s care below average or below a norm. Though somewhat tangential, this conclusion deserves attention.

To identify an average or evaluate against an average, label an average the norm and structure delivery accordingly, as appears increasingly the case, is to say the least problematic. In The Normal and the Pathological, Canguilhem argued that what’s statistically average is not the same thing as what’s normal. They are, he said, “two different concepts” because what’s normal exists for individuals alone. The line between what’s normal and what’s pathological is imprecise if not indeterminate because people live in endlessly varying natural and socio-cultural environments that measurably affect their biological functioning. One should not interpret the average as a sign of the norm since the norm “is not deduced from, but rather expressed in the average.” “A human trait,” Canguilhem said further, “would not be normal because frequent, but frequent because normal.” Health and disease are then “not biologically scientific and objective” rather they are “biologically technical and subjective.” To say more, a guideline is benign or dependent on the meaning given in the setting in which it manifests. Knowledge of what may be true is not axiomatically the same thing as knowledge of what’s useful. Reasons are not causes. Evidence of an intervention is not by definition evidence for that intervention. Science determines only the strength of evidence which exists for a hypothesis. It’s human agreement about what constitutes value that creates new knowledge or meaning.

Martin Wood’s work is particularly relevant here since he argues that evidence “is not pure source.” Where knowledge production begins and implementation begins is unclear. Knowledge is rarely if at all discrete or fixed, preformed, pre-existent, self-evident, it is not, per Wood, “situated knowledge.” Providers do not simply “apply disembodied scientific research to the situation around them. They interpret and (re)construct its local validity and usefulness.” “Promoting an innovation . . . is not the uncomplicated “dissemination” of findings to a largely passive audience It is connecting or reconnecting research with its supplementary other, practice.” The path of innovation is therefore “neither natural or inevitable but constantly negotiated and aligned.” The “body of evidence” as generally understood is a fiction. There are, Wood argues, “simply more or less competing reconstructions of evidence.” “Evidence cannot be viewed as a relatively neutral medium but exists only as a stabilized moment in an indeterminate process of becoming.” It is rarely constructed *in situ*. What’s needed is to “stop dealing with research and practice as uncontaminated, unified” in a coherent linear manner. It is, “a mixed up affair.” We need to “shift away from notions that research evidence and clinical practice are diametrically opposed.” There is, in the end only “practice becoming research and research becoming practice”. Similarly, Richard Freeman argues since new knowledge emerges or is organic, research evidence it is not simply available “to be looked at and learned from, rather it is produced or generated in the act of looking.” What’s “lost in translation” is ironically translation.

Implications

As suggested, knowledge production and practice improvement are not separate activities but inherently intertwined or processes inherently social occurring in real time. Practice as Thomas Schwandt argues is not assumed to stand “in subsidiary relationship to scientific knowledge.” Practice or the process of health care delivery is more than simply a site or a context for applying scientific knowledge. Practice, like knowledge, is not a “thing” like entity or system but more an unfolding of events. Hence Schwandt argues what’s important or what deserves notice are primarily relationships or the quality of interactions. “There is no knowledge apart from the active engagement or involvement of the knower with that which is to be known” and knowing or innovating as Schwandt explains are simply “ways of going on with one another.”

If a gesture - response paradigm more usefully reflects the process of health care delivery, what does it suggest for improving quality? What would this alternative paradigm as a quality improvement change model imply when knowledge is not an “it” or a “thing” and where research evidence cannot simply be “communicated and disseminated” or transferred?

What’s suggested is that the fundamental way to improve quality or innovation in health care is by arranging delivery designs that improve interaction between the provider and patient. Paul Uhlig argues since “health care emerges from relationships” the key to health care transformation is in optimizing the patterns of provider - patient interaction. “Patterns of organization should reflect patterns of interaction,” Uhlig says, “and patterns of organization should match patterns of patient need.” As the Peters and Warwick examples show attention should be paid to what is actually going on in conversation between actors. Anthony Suchman terms this “relationship-centered care.” In writing about improving health care effectiveness Bar-Yan makes an analogous point when he argues the fine scale task of providing individualized care should not be corrupted by the health care industry’s otherwise motivation toward large scale, undifferentiated functions.

The importance of the qualities of interactions cannot be over-stated. Focusing on what is “actually going on” is all that matters since again knowledge or change emerges only between two people interacting in real time. We ultimately produce nothing of consequence outside these interactions. Unfortunately instead we focus on “what we should do”. We talk about, what our attention becomes focused on, is the knowledge “it” or “thing” or managing or directing the knowledge “it”. Consider the lion share of studies on improving health care delivery. The focus typically is on the properties or attributes of good care. For example, we incessantly write about business and practice improvement models, measurement, information technology, or reimbursement, not what people are actually doing with one another. All these activities are merely “as if” exercises or again conceits since nothing is ultimately produced outside of interaction between provider and patient, or again what is “actually going on” between the two. Seeing or recognizing people in their contexts means everything since knowledge is a process of action.

Beyond an emphasis or focus on the real time interactions between provider and patient, assuming this alternative paradigm naturally leads to other questions about the process of how we know and knowing

how to improve quality health care delivery. Improving health care delivery certainly does involve research but asking by and for whom is ultimately essential if we understand ourselves as inextricably social. Our relation to the other is the foundation of knowing, not the reverse. The actual, ultimate production of research is then in its use because meaning always attaches to the individual. It is the product of the recipient not the function of the source. In this sense knowledge or innovation does not precede the delivery of care. Providers are always unavoidably engaged in the common, every day effort of improving the quality of health care delivery. Consider the possibility.

I complete bibliography can be readily provided.

A few initial recommendations:

1. Whether you term it a “paradigm” or not, PCORI will adopt a paradigm or model to “communicate and disseminate”. I suggest examining whether the assumptions underpinning the model are coherent, or moreover useful. Here, I obviously suggest the predominate model is not useful or effective.
2. Moreover, I’d recommend PCORI undertake (if it’s to be “patient centered”) an on-going study of the quality of interactions between providers and patients and as well between and among providers since care delivery is increasingly team based. E.g., what criteria constitutes a quality interaction, how can interactions be modeled, measured and improved, and what needs to be done organizationally to support and/or maximize quality interactions between providers, patients (and their family caregivers). While at ARHQ I found, e.g., social network analysis tools useful.

To lend further evidence to my argument (and recommendation 1 and 2) AHRQ announced today its R 18 “Patient-Centered Outcomes Research Dissemination”, about which you are aware. The RFA notes in part “dissemination of existing knowledge,” “using multi-factorial mechanisms,” “research dissemination infrastructure,” “systems engineering,” “toolkits,” “geo informatics,” “systems”, “blogs, wikis, webinars,” etc. Nowhere in the RFA’s “research objectives” is there any mention whatsoever of recognizing, much less improving, the interaction or the quality of interaction between the provider and the patient. Nor of course is there any recognition of the basis for, or usefulness of, the myriad of tools or techniques identified to “communicate and disseminate” knowledge, i.e., what paradigm or model is being assumed.

3. Concerning research knowledge not being self-announcing, what can PCORI do to encourage providers (and patients) to better understand their own role/awareness in “knowledge” creation or moreover in innovating, changing or improving outcomes. Might this be a part of #4 under PCORI’s fifth priority “Accelerating Patient-Centered and Methodological Research” (at pg. 5)?
4. Regarding the second priority, “Improving Healthcare Systems”, a “system” is merely an abstraction. Again, there are only people interacting. Similarly, the belief in “scaling up” health care improvement is an unhelpful or an un-useful abstraction. Being such, I’d recommend largely abandoning.