Workshop on Methods for Setting Research Priorities

Hosted by the Research Prioritization Workgroup of the Patient-Centered Outcomes Research Institute Methodology Committee

Executive Summary

March 6-7, 2012

Baltimore, Maryland

This workshop was conducted to support the Methodology Committee's development of a report to outline existing methodologies for conducting patient-centered outcomes research, propose appropriate methodological standards, and identify important methodological gaps that need to be addressed. All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee. This report is being made available free of charge for the information of the scientific community and general public as part of PCORI's ongoing research programs.

Questions or comments about this report may be sent to PCORI at info@pcori.org or by mail to 1828 L St., NW, Washington, DC 20036.

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Workshop on Methods for Setting Research Priorities

Introduction

The Research Prioritization Work Group of the PCORI Methodology Committee held a workshop in Baltimore, MD from March 6-7, 2012 to explore how selected methods might be used by PCORI to inform their process of establishing research priorities. This was accomplished through the review and discussion of contractors' pre-publication draft white papers focusing on methods for:

1. Involving patients in research topic generation
2. Use of gap analysis in establishing research priorities
3. Value of information analysis as a tool for research prioritization
4. Peer review for research prioritization

Over the course of two days, five PCORI-funded researchers presented their findings on each of the methods, invited external experts presented their reactions to contractor findings, and all attendees engaged in discussions to explore approaches for incorporating the methods into future PCORI research efforts.

The goal of the workshop was to provide guidance to PCORI's Board of Governors on methods for setting priorities.

Excerpts from PCORI's Enabling Legislation Regarding Resource Allocation

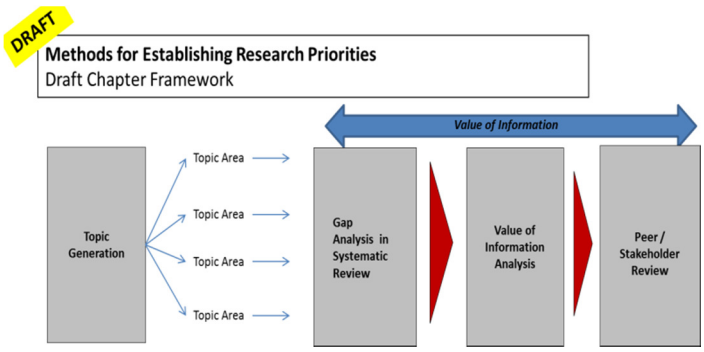
"PCORI shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions…."

"Research shall be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, or quality of life preferences and include members of such subpopulations as subjects in the research as feasible and appropriate."

Patient Protection and Affordable Care Act, 2010.

How Could the Methods Fit Together?

David Meltzer, MD, PhD, Chair of the Research Prioritization Work Group, introduced a draft framework for establishing research priorities—noting that this is only one framework of potentially many others. The framework begins with identifying topics to be studied through topic generation, using gap analysis in systematic reviews and value of information analysis as tools to surface the most important topics, and using peer review of research proposals to prioritize them.



Session 1: Approaches for Topic Generation

Methods for Involving Patients in Topic Generation for Patient-Centered Comparative Effectiveness Research – An International Perspective

Presenter: Petra Nass, PhD (Principal Investigator); Hayes, Incorporated

Dr. Petra Nass from Hayes, Inc. presented their draft paper on topic generation with the incorporation of the patient and stakeholder voice. The presentation focused on the usage of the collaborative and consultative processes as methods to involve patients in the topic generation process. The presentation emphasized the use of the James Lind Alliance (JLA) methodology.

Levels of Public Engagement

Public engagement can take place at different levels. Public engagement, eliciting the public's experience or knowledge, is a form of research that can be viewed as objective study of individual experience. It uses mostly qualitative social science research strategies and methods.

Dr. Nass focused on consultation and collaboration approaches to public engagement. In **consultation**, an organization encourages the public to contribute their views, perceptions, and experiences, and then incorporates consultation into the research process. In **collaboration**, the public is empowered to become active partner in an ongoing public-clinician relationship and the public members and researchers make decisions together. Each approach presents unique advantages and disadvantages.

Level of Engagement	Advantage	Disadvantage
Consultation	Can involve a large number of participants and elicit diverse perspectives	Public does not actively participate in decision making process
Collaboration	Outcome is a more diverse perspective where the public actively participates	Few participants can be involved making it difficult to capture multiple views

The most commonly used strategies for eliciting the public's voice in generating research topics were phenomenology, ethnography, grounded theory, action research, and surveys.

Methods and Processes to Generate Topics through Public Engagement

Interviews are the most common method for generating topics, especially one-on-one and focus group interviews that used semi- or unstructured formats. One-on-one interviews are helpful when talking about personal issues that participants may not feel comfortable talking about in public. **Photovoice** is a method in which patients take photos representing their health experience when they have trouble verbally. These photos are then used to guide the interview.

Observation can be used with patients who cannot speak for themselves. This method is used to evaluate treatment outcomes for children with autism.

Documents such as patient records or comments received by patients as well as **questionnaires** have been used to generate topics, but are considered more minimal forms of engagement.

Regardless of the method used, patient engagement generates mostly textual data that can be categorized into themes using content analysis. Content analysis is a very well established method to analyze textual data. Once themes are defined, they can be translated into research areas or topics.

An example case of a **public-clinician partnership process** of the James Lind Alliance (JLA) in the United Kingdom was shared. It used a process combining collaboration and consultation with lay members and clinicians with their peers. The consultation phase adds a geographically and demographically diverse perspective to the process. Systematic reviews were used to add additional topics and avoid duplication of research. The nominal group technique moderated the discussion to make sure that the lay members had an equal voice. The nominal group technique is an established moderating technique that has been used since the 1970s to facilitate consensus of processes in diverse groups. At least three studies have used this approach to generate topics and in this example a public-clinician partnership was used to develop research topics for urinal incontinence.

Eight patients and 13 clinician groups participated in this collaboration. The final database contained 226 research questions; of these 79 were unique questions from patients. Then the group together crafted a top 10 list of research questions that was distributed to funding research organizations. Since these prioritized research questions were established, five studies have been funded, of which three are in development. Five new systematic reviews have progressed and five questions are under consideration for funding.

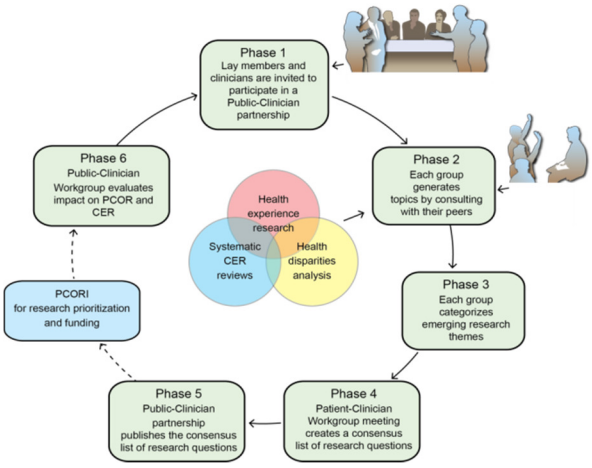
Dr. Nass' last example for how to generate topics through public engagement involved an advisory panel that identified research topics and priorities. The panel members were asked two open-ended questions: "What can researchers study to make your lives better?" and "What should we measure to see if your life is better?" The patients identified five research areas and considered quality of life as the most important outcome measure.

Recommendations to PCORI

Dr. Nass suggested the need for organizational support to be provided to the public before, during and after the engagement process. The support should clearly communicate the project goal, the roles and relationships of the researchers to the public, provide training to lay members, and give an equal voice to professionals and lay participants. Additionally, the topic generation process should use a variety of engagement methods to give participants a way to contribute that is appropriate and meaningful to them.

Hayes, Inc. also thought scientific data should play a role in the generation of topics, and could be used as part of an engagement process. Since PCORI focuses on comparative effectiveness research, it should probably be comparative effectiveness reviews. But they also decided that including health disparities research and health experiences research would help reach out to underserved populations and ensure that they are being considered.

Proposed Process Based on the JLA method



The process based off of the James Lind Alliance was greatly emphasized. The process starts with an advisory board inviting lay members to participate in a partnership. The partnership then generates research ideas. During this process, PCORI would support the public members in their selections. The group would categorize the research themes and afterwards, partners meet at a workshop and form research questions. At the end of the process, there would be a pre-prioritization step, like voting or any other simple method. The research questions would be submitted to PCORI and inform their process of prioritization and funding. At a later time, one should evaluate how the process impacted research and improved health outcomes, as well as how the process could be improved.

Key Points for PCORI

- Use a combination of collaborative and consultative methods to generate topics
- Use professionals as facilitators for public engagement
- Need organizational support at each step of the research process

Response from an Expert

Discussant: Evelyn Whitlock, M.D., The Center for Hearth Research, KP Northwest

Dr. Evelyn Whitlock focused on how to bring the proposed patient-oriented topic generation process to the US, how to engage other constituencies, discussion

of what U.S.-based organizations are doing that are similar to the JLA model, and the acceptability and generalizability of the recommendations made by Hayes, Inc.

Proposed PCORI Process of Public Engagement in Topic Generation

Dr. Whitlock proposed a six-phase process to generate priority setting partnerships (PSP) and topics. The PSPs would elicit broader input from health experience research, health disparities analyses, and consider systematic reviews.

She used a flow diagram from a topic generation on asthma from AHRQ as an example of the process. The example utilized a website survey, and database of select research sources that listed uncertainties. Each source was ranked then prioritized as a whole.

Dr. Whitlock's Recommendations to PCORI

In order for PCORI to utilize this approach, certain processes need to be put in place such as:

- ✓ Partnerships between professional societies and advocacy groups need to be created
- ✓ Usage of existing systematic reviews
- ✓ Usage of a variety of inputs for topic generation
- ✓ Need for structured support of partnerships
- ✓ Involve many constituencies in the partnership approach at each step of the process

Generalizability and Applicability

Dr. Whitlock pointed out that there is difficulty in transferring methods to the U.S. due to the lack of a national health budget or system. This would cause the production of results to be slow. Without infrastructure development, the approach might not produce similar results to JLA. Another important factor that Dr. Whitlock pointed out was that JLA method is condition focused.

Discussion

The discussion after the presentations was both lively and important for providing key feedback. The main points and questions are listed below.

Key Points

- Dr. Karl Claxton mentioned the National Institute for Clinical Excellence (NICE) who has their own framework for involving patients. It includes a lay committee; patient experts invited to a committee with clinicians, consultees are presented by patient groups, and a citizen's council who deliberates on social value judgments.
- Cross-cutting issues will come to the top of any discussion, even if you are dealing with a specific condition.
- The heterogeneity in the U.S. population challenges, some of what we've seen in the white paper.
- Patient experts and advocacy groups should be treated as consultees and not dominate the process.
- Need a hybridized approach that is both collaborative and consultative.
- Crowd sourcing could be considered in public involvement.
- More empirical work is needed in this area.

Key Questions Asked

- How do you identify the first step of picking a topic? Where does the topic generation process begin?
- Are there processes to make sure presentation should be less bias and more random?
- How can we adapt the experiences discussed to the US? What makes the US environment unique?
- How do we get people to think more broadly in terms of topics and cross cutting issues to help PCORI focus on aspects that are transferrable across conditions?

Session 2: Use of Gap Analyses in Establishing Research Priorities

Identifying and Prioritizing Research Gaps

Presenter: Tim Carey, MD, MPH (Principal Investigator); Cecil G. Sheps Center for Health Services Research, University of North Carolina – Chapel Hill

The second session of the day concentrated on using gap analyses for establishing research priorities. The white paper presented by Dr. Tim Carey focused on identifying research gaps derived from a systematic review leading to future research. He sought to answer, "how we assess gaps and then prioritize research from those gaps?"

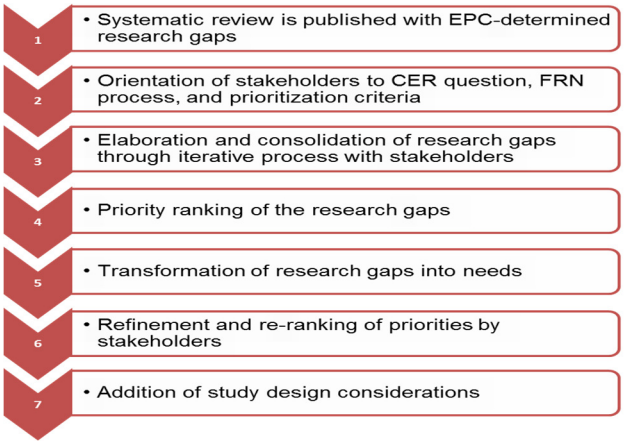
Importance of Finding Gaps through Systematic Reviews

As systematic reviews are the current standard for evaluating scientific knowledge, Dr. Carey suggested that they should be the platform to discover gaps. The identification and prioritization of research gaps has led to quicker generation of research.

Existing Methods

Dr. Carey explained the difficulty in using existing methods. This is due to the generalization of gaps in systematic reviews, prioritization of research gaps being uncommon in the reviews, and the fact that systematic reviews barely discuss future research needs.

Methods that have been used to prioritize gaps haven't been replicated but most systematic reviews use the PICOTS framework to describe research gaps. Carey also discussed AHRQ Future Research Needs (FRNs) pilot projects in order to extract gaps from a systematic review. The process they used is shown in the following diagram.



Stakeholder Engagement

Dr. Carey discussed the need for stakeholder engagement during the gap process. The two possible ways that stakeholders could become involved would be either advisory or determinative. Carey stressed the need to involve and train stakeholders even if there would be difficulties.

Identifying Research Gaps

In order to identify the key research gaps, Dr. Carey suggested the use of analytic frameworks. Stakeholders would then identify additional ideas using the GRADE rating system.

Priority Ranking

Dr. Carey also presented alternative ranking methodologies such as:

- Ranking 1-x
- Likert scale
- Pair-wise comparisons

If the number of gaps is large, the use of multiple rounds of prioritization would be suggested. Dr. Carey also stated that gaps could be combined or split, depending on preferred granularity.

Transformation of Research Gaps into Needs

In order to make the transformation, most organizations use the Population, Intervention, Comparator, Outcome, Timeframe, Setting (PICOTS) framework.

Conclusion

Multiple groups are currently conducting work in this area, and there was a lot of commonality within these groups. Criteria for gaps identification were common across the groups. There's broad consensus on the need for stakeholder composition, in that we need to work with these constituency panels. There is a need to train/orient the stakeholders, and a need for a prioritization of methods, but no consensus on what those methods should be.

Dr. Carey's Recommendations to PCORI

- Work with funders, advocates, and others to find the optimal format for FRN documents
- Evaluate stakeholder panel sizes and compositions in prioritization
- Evaluate reliability of stakeholder prioritization through replication studies
- Test different methods of prioritization
- Clarify role of gap identification and prioritization with other methods
- Collaborate with other PCOR programs in refining this area

Response from an Expert

Discussant: Christine Laine, MD, MPH, American College of Physicians

Dr. Christine Laine shared her response presentation on systematic review-based gap analysis. She focused on the positive and negative aspects of using systematic reviews for gap analyses and presented an example of the process.

Using Systematic Reviews

Dr. Laine argued both sides of the usage of systematic reviews. A positive she first mentioned was the large systematic review engine that is already in existence. Another positive listed was how heavily they are evidence- based. She presented the problems such as there are so many systematic reviews and half list vague gaps, which causes difficulty during prioritization.

"What Comparative Effectiveness Research is Needed"

Dr. Laine referenced the newly published paper "What Comparative Effectiveness Research is needed," which discusses finding gaps from systematic reviews. The paper presented a group who searched for gaps through low biased systematic reviews. While the group was able to extract them, it took an extremely long time. Laine made the important point "while the systematic review engine is in place, the engine for the process isn't."

The challenge of utmost importance is the ability to prioritize the gaps, and getting researchers to use the gaps for research questions.

Dr. Laine's Recommendations for PCORI

Dr. Laine argued that those who are funding or publishing systematic reviews should require identification of gaps as part of their work. She also proposed that using clinical guidelines (which are based on systematic reviews) would be a more efficient place to start rather than the reviews themselves because of the large volume and time required.

Discussion

The participants discussed the papers presented during the second session. Below are the key questions and points.

Key Points

- If a gap is not going away, then the focus should be on root causes of gaps.
- Biggest time taker in doing systematic reviews is getting stakeholders organized and scheduled; once the data is collected from stakeholders it's fairly straight forward.
- It may be better to start with guidelines rather than systematic reviews to manage the volume of topics/ gaps identified.

Key Questions

- How are we thinking about gaps that are never made in publications, or papers that do not ever get approved?
- Should there be criteria in prioritizing systematic review, where do the stakeholders fit in?

- How is the volume of systematic reviews manageable?
- Once gaps are identified, how are they turned into a prioritized list of research needs?

Session 3: Value of Information Analysis

Value of Information Analysis for Patient-Centered Outcomes Research Prioritization

Presenters: Evan R. Myers, MD, MPH (Principal Investigator, Duke Evidence-based Practice Center; David Rein, PhD (Primary Investigator), NORC at the University of Chicago

Dr. Evan Myers and Dr. David Rein both authored and presented white papers on Value of Information (VOI). VOI seeks to answer the question, "Should I make a decision based on the information I currently have, or should I collect more data before I decide?" This section synthesizes the points made during both presentations.

What is VOI?

It is an approach to research prioritization that uses Bayesian methods to estimate the potential benefits of gathering further information (through more research) before making a decision.

- ✓ Construct probabilistic decision model
- ✓ Estimate both optimal decision given current information and likelihood of that decision being wrong, along with consequences of wrong decision
- ✓ If cost of obtaining more information is less than costs/consequences of wrong decision, than collecting more data worthwhile

For any decision the alternative with the greatest net benefit (NB) is determined the most cost-effective. You could set a threshold for willingness to pay. Or you could evaluate the decision over a range of willingness to pay at incremental levels, minus the cost.

Net Benefit (NB) is estimated as $B_j \cdot \lambda - C_j$

B is the quantity of the benefit, λ is the willingness-to-pay per incremental unit of B, C is costs, and j references the alternatives

VOI estimates measure the expected difference of the NB when a decision is made with perfect information minus the NB made with uncertain information. There are two general forms of analyses that are done.

- ✓ Expected value of perfect information (EVPI), which looks at uncertainties across the whole decision framework, made incorporating all parameters
- ✓ Expected value of parameter perfect information (EVPPI), which uses the uncertainties associated with particular parameters using the decision making process.

Why is value of information (VOI) of interest to PCORI?

- VOI can provide guidance to PCORI in identifying which projects provide the most value to patients; PCORI would not use VOI to consider cost-effectiveness of alternative treatments.
- Limited research funding but unlimited research questions
- VOI offers a quantifiable and replicable methodology that can be used to prioritize topic selection

Alternatives Use of VOI Outside of a Cost-Effectiveness Framework

Cost-Benefit Analysis. Such approaches are commonly used in environmental and regulatory economics. Variation in patient preferences can be captured in such models. Data from certain stated preference models, such as discrete choice, would assist with incorporating preferences for both outcomes and process into the model.

Harm-Benefit Ratios or Other Multi-Criteria Decision Analysis. Such approaches can:

- ✓ Can consider adverse outcomes as "costs"

- ✓ Can express trade-offs between these "costs" and outcomes in same way one expresses trade-offs between costs and effectiveness
- ✓ Can illustrate uncertainty at different thresholds of "willingness-to-pay"
- ✓ Might be particularly useful for developing guidelines, especially in conjunction with formal framework such as GRADE

Challenges to Use of VOI to Prioritize PCOR

Information vs. Implementation. The implicit assumption behind VOI is that resolving uncertainty about outcomes will lead to greater use of effective treatments. But there are multiple examples of persistent use of ineffective or inefficient interventions of evidence, or resistance to recommendations based on new evidence. If further research is conducted that reduces uncertainty, but patient or provider behavior remains static, than value of research is overestimated.

Addressing Issues of Heterogeneity. The classic application of VOI in health care in the UK, as outlined by Dr. Benuse, is to perform the VOI analysis and estimate the per-patient expected value of partial perfect information then estimate it at the population level. That population-level expected value of partial perfect information sets the upper bound of a reasonable research budget. However, population VOI estimates depend on choices about a number of factors. Unstandardized choices about these factors complicate comparisons, which complicates research prioritization.

Limitations on Cost-Effectiveness Research and use of QALYs for PCOR. There may be statutory limitations on the use of cost-effectiveness and QALYs, and QALYs may not always be the best option anyway. Classic cost analysis in this country depends on the experience in the environmental and regulator economics, including at the federal level. It'd be an interesting discussion on why cost information analysis is mandated for patient safety regulations, but are excluded from healthcare discussions. It also might allow alternative methods for capturing patient preferences, including both revealed and stated preferences measures, which can be used for both valuing net and, in some cases, for predicting patient behavior**.**

VOI isn't using QALYs as a threshold as the legislature forbids, but rather as a way to prioritize. Benefits are usually measure in QALYs, but do not need to be. There are other measures of benefit that can allow for comparison across conditions with a meaningful scale.

Alternative Measures of Benefit

Measure	Definition	Advantages	Disadvantages	Notes
QALY	Value of 1 year lived in health state in units of years lived in perfect health	- Enables cross-condition comparisons - Semi-Meaningful scale	- Negative framing, difficult to communicate, unpopular - Sensitive to measurement error - Violates welfare/behavioral economic theory	- Much of existing VOI methods developed with QALYs as the basis
Willingness to Pay	Monetary value to avert one unit of a health condition (with units variously defined)	- Enables cross-condition comparisons - Meaningful scale - Intuitive to a wide lay audience	- Lesser theoretical issues - Time-consuming to measure for all conditions - Sensitive to measurement methodology	- Special case of contingent valuation - Global Burden of Disease study possible candidate
Multi-attribute Health Indexes	Generic, descriptive measure of health summarized in a single index measure.	- Enables cross-condition comparisons - Ordered scale - Existing population normed evidence - Simple algorithms facilitate decision making	- Measurement scales have no arithmetic meaning (i.e. may fail the meaningful scale test) - May be difficult to communicate	- Possible example is the EQ-5D - PCORI could develop its own index to fit its specific policy context

Computational Challenges in Estimating VOI. Developing decision analytic models is time consuming. Primary challenges include balancing speed of implementation against transparency, risk of major errors (precision, reliability), and applicability.

Other Challenges. There's limited expertise in both disease modeling and VOI. In the review performed, almost 40% of all of the papers came from one of three groups – two of the people are attending this workshop. There is a lack of stakeholder familiarity with concepts. There's a lack of published experience on actual use of VOI for research prioritization and there is a lack of coordination within U.S. funding agencies about the role and scope of VOI. There are some pilot programs at NCI right now, but it's unknown whether there's any kind of federal sharing of information on how we could reduce VOI, which would only actually help those who would be interested in doing them.

Response from an Expert

Discussant: Karl Claxton, PhD, Centre for Health Economics, University of York

Dr. Karl Claxton provided his perspectives on the application of VOI, cost-effectiveness, and use of health metrics based on UK's application. He presented various models for measuring VOI to reduce uncertainties in completing research. Dr. Claxton emphasized that VOI is in its infancy and the US can use its foundations in strengthening research prioritization.

Using QALYs

After much discussion over QALYs during the White Paper presentations, Dr. Claxton stressed the importance of separating QALYs from VOI. QALYs are used for VOI in the UK due to their selectively funded and constrained budget. While QALYs do not capture every important aspect of health, Dr. Claxton stated that they are simply a metric of health gained and lost. They are used in VOI analysis only because NICE uses them in the UK.

Presenting VOI

Dr. Claxton used graphs to illustrate usages of VOI. He used the example of determining cost effectiveness of funding a trial between two different drugs. He showed the point at which a trial should be conducted using inputs such as willingness to pay per QALY and clinical evidence .

Using VOI in the UK. Dr. Claxton described his experiences with NCCHTA and NICE using VOI. During his analysis he was able to answer a number of questions about various topics: do they need research, what type of research, which subgroups, which comparators, and which endpoints.

VOI Recommendation

Dr. Claxton's last point was to emphasize that PCORI needs to focus on commissioning research and not implementing it. He stated if evidence from previous research is found sufficient when completing a VOI, than other stakeholders have the duty for implementation.

Discussion

Key Questions:

- Is the usage of QALYs for VOIs legal?
- Do we know enough about VOI to effectively use it?

Key points:

- Dr. Joe Selby addressed the language of QALYs in the legislature as negatively disfavoring research on a group of a certain population (ex. rare diseases)
- VOI should be used, but only to determine what research should be done, leave out implementation
- US has used VOI at NCI and AHRQ
- VOI needs to be decoupled from QALYs
- The gap approach for guidelines should be combined with VOIs

Session 4: Peer Review of Research Funding Proposals for Research Prioritization

Peer Review: A Research Priority

Presenters: Theodore A. Kotchen, MD (Principal Investigator) and Ryan Spellecy, PhD; Medical College of Wisconsin

Dr. Ted Kotchen's presentation focused on the objectives of peer review of investigator-initiated research proposals.

Objectives of Grant Peer Review

- ✓ Maintain standards of scientific rigor and integrity
- ✓ Provide unbiased review
- ✓ Identify the most meritorious proposals
- ✓ Identify those proposals most likely to fulfill PCORI's research priorities and agenda while incorporating perspectives of patients, health care providers, and other stakeholders

Importance of Identification of Priorities and Agenda

It is important to identify research priorities and an agenda so participants know what they are applying for. Empirical studies on peer review show that there is reliability, validity, and fairness. As the people in peer reviews change, there is a likelihood of bias. A recommendation was that PCORI should look into

statistical models to evaluate bias. Clinical applications at NIH do not fare as well due to their improbability of reapplying or the lack of emphasis on human subject concerns.

Example from Quality Enhancement Research Initiative (VA) Peer Review

Dr. Kotchen brought in an example with similar intents as PCORI:

Quality Enhancement Research Initiative (VA)

- Find conditions and opportunities for improving health of veterans
- Find best practices
- Evaluate impact on veterans health
- Use peer review, similar to merit process of NIH
- Include health policy experts but not consumers or patient advocates

Administrative Approach

Dr. Kotchen discussed the administrative approaches that need to be considered in the process. Decisions need to be made on whether PCORI should contract the process out, separate the peer review from the program review, and whether it should be a two-step process with a pre-app, concept paper, and then pilot grants.

Involving Stakeholders

Dr. Kotchen also discussed how the involvement of stakeholders for peer review might differ from other parts of the prioritization process. There are many ways to capture their inputs such as scorecards, blended scoring, or separate scoring. The issue with this is the lack of research on involving stakeholders. Another major point of discussion from the presentation was the role of ethicists in the peer review.

Research Suggestions for Peer Review

- Evaluate effectiveness of peer review
  - Look at grant renewals, publications
  - Dissemination into clinical practice, long term outcomes
- Identify predictors of success in other arenas and incorporate them in peer review
- Asses approaches for a continuous improvement process
- Evaluate different inclusion modes for non-scientists

Recommendations to PCORI:

- ✓ Maintain core values of peer review: competence, fairness, and integrity
- ✓ As PCORI develops criteria, relate them to research priorities and agenda
- ✓ Support both investigator initiated and institute initiated projects
- ✓ Implement a two- stage peer review process
- ✓ Provide feedback and guidance to applicants

Response from an Expert

Discussant: Richard Nakamura, PhD, Center for Scientific Review (CSR) at NIH

Center for Scientific Review's Peer Review Process

CSR's responsibility is to complete independent and non-biased peer reviews for NIH. In the beginning of his presentation he showed the heavy workload that CSR has taken on and their ability to undertake the work with the staff in short timeframes. He discussed the evolution of the study section that has been around since 1946, which is now purely electronic.

NIH's Peer Review Process

Nakamara presented the review process from NIH and showed that they have a dual review system for grants which first go through a peer review and then go to the NIH Center of National Advisory Council who makes the award decision. He described the principles that they abide by where NIH has ownership of the process and the study section has ownership of the science.

CSR's Response

Nakamara displayed CSR's response to PCORI's goals.

- CSR would help if PCORI decides to create own review structure
- Need to adhere to CSR policies
- The process is heavily dependent on computer systems and it is hard to maintain separation from NIH
- Can allow for hybrid review

Discussion

Key Points:

- Lack of research on patient engagement role during peer review process
- Lessons learned from CSR's process were captured with surveys on stakeholder involvement throughout the process
- Should have two-stage reviews with the stakeholders
    - After the first stage, there should be feedback and support
- Variance on impact score is due to approach and conservatism
- More evaluation needs to be done on involving consumers and stakeholders during review process
- Issue of bringing in unique players in the grants process without extensive grants knowledge
- The cost of review is one-third of total budget where it should be put into actual research

Key Questions:

- How does PCORI take advantage of infrastructure at CSR but use PCORI criteria?
- Where are the gaps in peer review?
- Should there be a training system for investigators or grants writers from PCORI?

Session 5: Synthesizing the selected methods

The last session was an open discussion of the whole workshop. A lot of discussion was spent talking about the difficulty of filling in the gap between topic generation and selection and how to systematize the process.

Key Themes:

- Gap between topic generation and analysis phase
- Need for a multi-stage peer review process
- Need for a balance between programmatic development approach and investigator initiated
- Need to systematize the prioritization process
- Issue of time consumption from whole process
- Consider a two-stage process which incorporates feedback and stakeholder involvement in the peer review of research funding proposals

Attendees

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