PCORI Pilot Projects Selection Committee

Recommendation to Board

April 25, 2012

pcori

Selection Committee Members

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Sherine Gabriel, MD, MSc

Christine Goertz, DC, PhD (Ex-Officio Committee Member)

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Grayson Norquist, MD, MSPH (Selection Committee Chair)

Joe Selby, MD, MPH (Ex-Officio Committee Member)

Clyde Yancy, MD, MSc

Background and Updates

Activities to Date:

- Members of a workgroup made up of BOG members met on a conference call January 25th and arrived at eight potential balancing criteria
- Selection Committee was appointed and met initially on March 6th at which time they refined the balancing criteria and proposed options for selecting applications to be funded
- Applications in potential fundable range were checked for accuracy of balancing criteria
- The Committee held a conference call on March 19th at which time they further refined the balancing criteria and decided on two options for selecting a slate of awards to be funded
- The Committee held a conference call on April 2nd and developed a final recommendation for the Board.

The Process

Step One: Determine Universe	The decision was made to eliminate all applications with a score above 3.0 from consideration for further funding. This yielded a potential fundable pool of 80 applications.
Step Two: Determine Approach	The criteria to be used for balancing were refined and two options for selecting a base slate of applications were proposed.
Step Three: Develop Core Slates	Staff applied the two selection process options to the top 80 applications, yielding two possible sets of fundable applications (one with 37 selected; the other with 50).
Step Four: Analyze Balance	Using the balancing criteria staff analyzed the balance of each of the two possible sets to determine if balance was achieved or if additional balancing activities would be required.
Step Five: Make Final Recommendation	The Selection Committee reviewed the two possible sets of fundable applications to determine if balancing was needed. The group decided on two options for the Board and selected one for recommendation.
Step Six: Approve	The Board of Governors will vote on the recommendation.

This process was completed using only generalized information regarding the applicant. No Selection

Rationale for Selection Method

The selection comm. considered all potential options for selecting the slate of fundable applications and decided to go with an option that would use priority score first and then ensure the top two applications were selected in each review group. All selection committee members were blinded as to the names and affiliations of the applicants.

- Percentiles (as noted on the NIH web site) are calculated usually for study sections that have had at least three meetings – traditionally, the last three rounds during a year. Thus, percentiles for the Pilot Projects Program do not have the same meaning as NIH percentiles. They reflect the application's ranking within a single study section meeting.

- Priority scoring is likely to be the most reliable measure across all groups since all reviewers had the same training regarding how to score.

- We don't know (since there is no history to the review group) if a "poor" score is due to a review group that just scores "harsher" or the grants they had were just not very "good".

Rationale (cont'd)

- NIH attempted to assign applications to reviewers based on areas of interest, though it was difficult given the large number of applicants and PI's did not necessarily self-assign correctly as well as listing more than more area.
- However, we did want to take into consideration the potential that some groups could be harsher and give some weight to ranking within the review group – so, we decided to also pick up the top two applications in each review group.

Balancing Criteria

Eight potential criteria were discussed and refined. The top four were proposed as the most appropriate for balancing.

Balancing Criteria	Definition	Operationalization	Source
Area of Interest*	The eight areas of interest listed in the PFA	At least 2 unique applications but no more than 50% in any one area	At least two members of the Selection Committee read each application abstract and determined the primary areas of interest.
Population*	Defined as addressing 1) Specific ethnic or cultural group, 2) disabled populations, 3) children, and 4) elderly populations.	At least 1 application in each of the four categories	PCORI staff reviewed abstracts to determine if the application had a clear focus on one or more of the four populations.
Condition*	The disease or condition used to demonstrate the approach	No more than 25% in any major category within the final slate.	Staff reviewed the abstracts to categorize conditions addressed, if any
Stakeholder/Patient Involvement*	The average score given by the three reviewers for this criterion in the initial merit review group	Any application added to the core slate will have a score of 1 or 2 (except methods focused applications)	The average score from the IRG review was used.
Geography	Geographic location of institutional affiliation	Will be reported but not used for balance.	The state or country on the application face page for the PI.
Method	The innovation of the research method	Only to be used if balance is needed within the area of interest related to methodologies (8).	The methodology committee would make the determination, if needed.
PI Discipline	Categorization of PI qualifications based on primary area of expertise	Insufficient data to use	
PI Seniority	Whether the PI has received federal funding	Insufficient data to use	

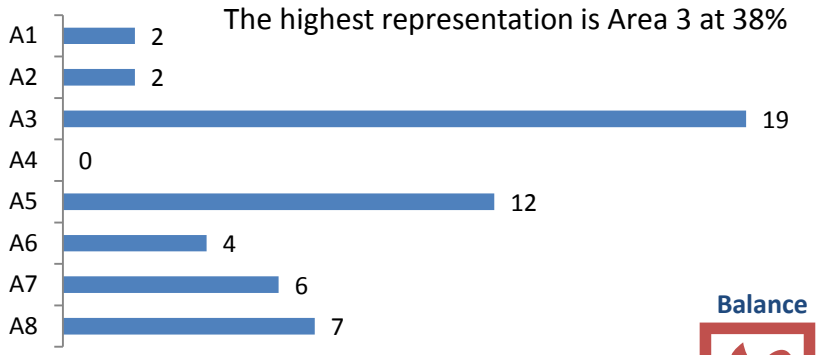
Areas of Interest (summary)

1. Developing, testing, refining, and/or evaluating new or existing methods and approaches that can inform the PCORI national priorities.
2. Developing, testing, and/or refining existing methods for bringing together patients, caregivers, and other stakeholders in all stages of a research process.
3. Developing, refining, testing, and/or evaluating patient-centered approaches, including decision-support tools, for translating evidence-based care into health care practice in ways that account for individual patient preferences for various outcomes.
4. Developing, refining, testing, and/or evaluating methods to identify gaps in CE knowledge such as tools collecting and assessing patient- and provider-perceived gaps.
5. Identifying, testing, and/or evaluating patient-centered outcomes instruments.
6. Identifying, testing, and evaluating methods that can be used to assess the patient perspective when researching behaviors, lifestyles, and choices.
7. Identifying, testing, refining and/or evaluating methods for studying the patient care team interaction in situations where multiple options exist.
8. Advancing analytical methods for CER

Option 1: Qualities of Proposed Slate

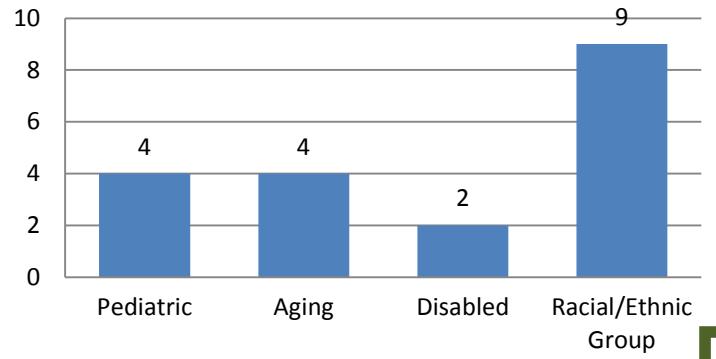
Applications with a priority score of 25 or better and ensured the inclusion of all applications in the top two of each review panel. This resulted in 50 applications.

Costs: Year 1--$15,843,724; Year 2--$15,005,483



Balance

Areas of Interest*



Balance

Underserved Populations

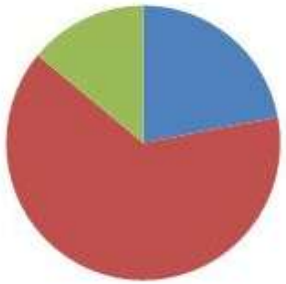
Chronic Condition	7	14%
Mental Health	5	10%
Cardiac	4	8%
Cancer	3	6%

These conditions and focuses are those with the highest representation.

Balance

Conditions Categories

Score = 1	11	22%
Score = 2	32	64%
Score = 3+	7	14%



alance

Stakeholder Engagement Scores

Option 1: Balancing

Option 1 takes the applications with a priority score of 25 or better and ensures at least the top two applications from each panel are included. This option yields 50 applications and has only one balancing issue:

- **Issue**: Area of Interest 4--There are no applications within this slate with that designation as a primary area of interest.

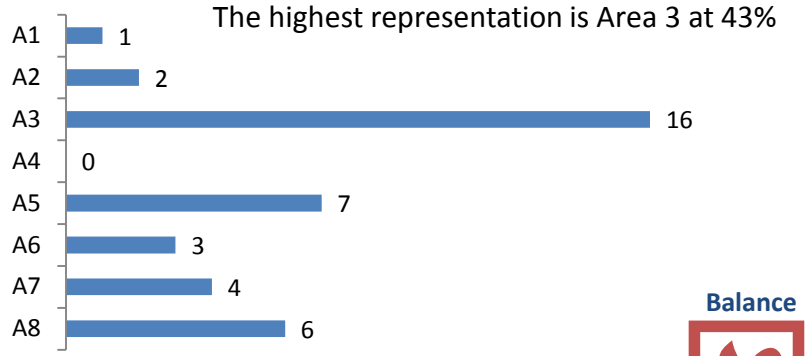
  Developing, refining, testing, and/or evaluating methods to identify gaps in CE knowledge such as tools for the ongoing collection and assessment of gaps as perceived by patients and providers. Of special interest are gaps that are particularly relevant to vulnerable populations, including but not limited to, low-income populations; underserved minorities; children; the elderly; women; and people with disabilities, chronic, rare, and/or multiple medical conditions.

- **Balancing Recommendation:** There are no applications within the top 80 that have this designation as a primary area of interest. The committee recommends we not balance on this area and propose it be a focus in one of the new PFA's or use a contract mechanism to address.

Option 2: Qualities of Proposed Slate

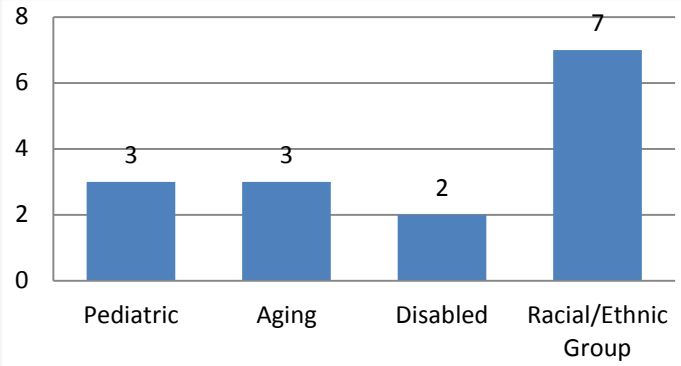
To remain as close to 40 grants (the number approved by the BoG), applications with a priority score of 24 or better were selected and ensured the inclusion of the top application in each review panel. This resulted in 37 applications.

Costs: Year 1--$11,803,263; Year 2--$10,944,425



Areas of Interest*

Balance



Underserved populations

Balance

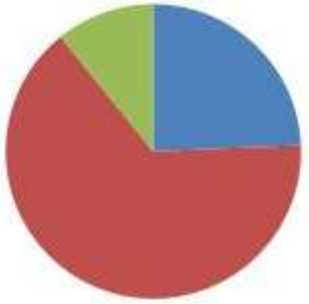
Mental Health	5	13.51%
Chronic Condition	4	10.81%
Cancer	3	8.11%

These conditions and focuses are those with the highest representation.

Balance

Conditions and Focus Categories

Score 1	9	24%
Score 2	24	65%
Score 3+	4	11%



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Stakeholder Engagement Scores

Option 2: Balancing

To remain as close to 40 grants (number approved by the BoG), option 2 takes applications with a priority score of 24 or better and ensured the inclusion of the top application in each review panel. This resulted in 37 applications.

1. **Issue**: Area of interest 4— This is the same issue encountered under Option 1.

   Recommendation: This issue should be handled in the same way as in Option 1.

2. **Issue:** Area of interest 1—There is only 1 application within the slate that addresses this area.

   Developing, testing, refining, and/or evaluating new or existing methods (qualitative and quantitative) and approaches that can inform the process of establishing and updating national priorities for the conduct of patient-centered outcomes research (PCOR). This may include research prioritization approaches (such as Value of Information (VOI), burden of illness, peer review/expert opinion/Delphi approaches) or methods for incorporating the perspectives of patients or other stakeholders into the development of national priorities.

   Recommendation: To add an additional application with a primary area of interest of 1, the committee looked within those applications with a priority score of 25. Within that group there is one application with a primary area of interest of 1.

Geographic Distribution

Option 1

AK	1
AR	1
AZ	1
CA	8
CO	3
CT	1
DC	1
FL	1
GA	1
IA	1
IL	1
MA	8
MD	3

MI	2
MN	1
MO	1
NC	3
NY	1
OH	2
PA	4
RI	1
SC	1
TN	1
VA	1
WA	1

Option 2

AK	1
AR	1
AZ	1
CA	6
CO	2
CT	1
DC	1
FL	1
IA	1
IL	1
MA	5
MD	1

MD	1
MI	1
MN	1
MO	1
NC	3
OH	2
PA	3
RI	1
TN	1
VA	1
WA	1

Discussion and Voting

Selection Committee Recommendation

- The committee recommends the Board vote for Option 1 and that we not try to balance on Area 4.