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## Unique Review Criteria and Patient and Stakeholder Reviewers: Analysis of PCORI's Approach to Research Funding

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### ABSTRACT

**Objective:** The Patient-Centered Outcomes Research Institute (PCORI) uses a unique approach to Merit Review that includes patients and stakeholders as reviewers with scientists, and includes unique review criteria (patient-centeredness and active engagement of end users in the research).

This study assessed the extent to which different reviewer types influence review scores and funding outcomes, the emphasis placed on technical merit compared to other criteria by a multistakeholder panel, and the impact of the in-person discussion on agreement among different reviewer types. **Methods:** Cross-sectional analysis of administrative data from PCORI online and in-person Merit Review (N = 1312 applications from the five funding cycles from November 2013 to August 2015). Linear and logistic regression models were used to analyze the data. **Results:** For all reviewer types, final review scores were associated with at least one review criterion score from each of the three reviewer types. The strongest predictor of final overall scores for all reviewer types was scientists' prediscussion ratings of technical merit. All reviewers' prediscussion ratings of the potential to

improve health care and outcomes, and scientists' ratings of technical merit and patient-centeredness, were associated with funding success. For each reviewer type, overall impact scores from the online scoring were changed on at least half of the applications at the in-person panel discussion. Score agreement across reviewer types was greater after panel discussion. **Conclusions:** Scientist, patient, and stakeholder views all contribute to PCORI Merit Review of applications for research funding. Technical merit is critical to funding success but patient and stakeholder ratings of other criteria also influence application disposition.

**Keywords:** comparative effectiveness research, Patient-Centered Outcomes Research Institute, patient/stakeholder engagement, peer review, research proposal review.

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### Introduction

Clinical research funders rely heavily on external review of applications for funding to identify methodologically rigorous, high-impact research. Yet, experts have questioned the ability of traditional scientific review processes to identify novel, important research [1,2], and examinations of associations between review scores, and bibliometric indicators are mixed such that some studies find associations [3–7] and others fail to demonstrate relationships [8–13]. The existing evidence should be interpreted in light of a recognition that correlations between review scores and bibliometric indicators may not be valid tests of peer review for a variety of reasons [14] and calls for evaluation of review processes using metrics of impact beyond bibliometrics [10,15]. Nevertheless, finding ways to ensure optimal selection of promising research via peer review of funding applications is critical to effective allocation of limited research funds.

Inclusion of nonscientists such as patients and other health care stakeholders (e.g., clinicians, health systems administrators, policy-makers, caregivers) who are poised to apply research findings in their decision making on review panels has been proposed as a way to improve identification of high-impact projects. Specifically, by bringing to the review process expertise that complements that of researchers, patients and health care stakeholders are expected to identify research that is both feasible and relevant to those who would use the findings in their decision making [16,17]. However, research examining the impact of patient and stakeholder reviewers on review process and outcomes is sparse [18,19], and concerns have been raised about the rigor of review with nonscientists included and the assessment of scientific methods in inclusive reviews [16,18,20].

The Patient-Centered Outcomes Research Institute (PCORI) was established to fund patient-centered comparative clinical

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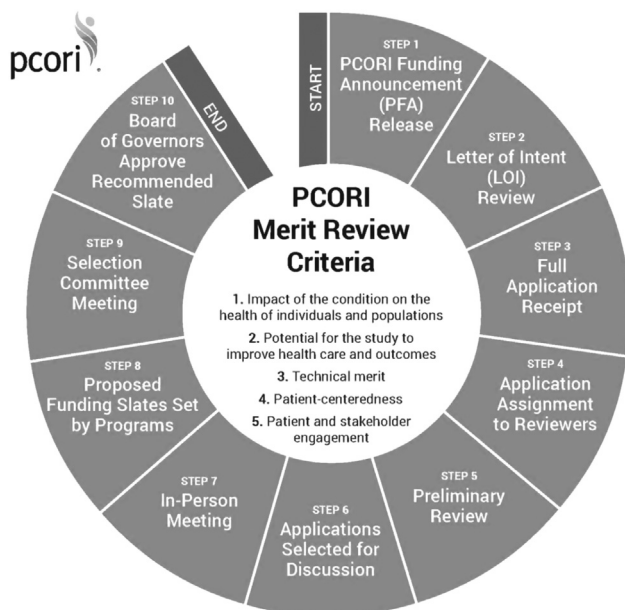
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<https://doi.org/10.1016/j.jval.2018.03.017>

effectiveness research (CER) [21] relevant to patients and other health care decision makers and that can be quickly applied in health decision making. Although much of PCORI's competitive review process, begun in 2012, is similar to those of other major clinical research funders (Fig. 1), PCORI also added unique elements for its Merit Review to meet imperatives of patient-centered outcomes research. PCORI includes patient-centeredness and engagement of patients and other stakeholders as distinct review criteria, along with technical merit, impact of the condition, and likelihood to improve health care and outcomes. Another unique feature is inclusion of patients and stakeholders as primary reviewers for every application. Although other funders have incorporated patients, consumers, or the public in their reviews [20,22–25], the extent to which PCORI involves nonscientists in application review is unprecedented.

PCORI has examined its Merit Review since the inaugural cycle [16] and early findings demonstrated that scientists, patient, and stakeholder reviewers' final review scores converged through in-person discussion of applications. This examination of a limited sample indicated that PCORI funded a different set of projects after a second review that involved scientists, patients, and stakeholders together, than would have been funded by the first review including only scientists. Results suggest that patient and other stakeholders influence merit review results, but more evidence from more review cycles is needed to understand the influence more clearly as well as to permit future investigation of the relationship between this review model and success in funding high-impact research. Thus, this study examined review scores from multiple subsequent PCORI Merit Review cycles to assess the extent to which views from different types of reviewers influence review scores and funding outcomes. This study also assessed the relative emphasis placed on technical (scientific) merit compared to other criteria by a multistakeholder panel. Finally, to assess the effect of the in-person panel discussion on subsequent application scoring as one indicator of influence of reviewers, we examined the effect of the in-person discussion on reviewer scores and on agreement among different reviewer types.



**Figure 1. PCORI Merit Review Overview (pertains to review of applications to the Broad funding announcements).**

## PCORI Review Process

Applications to Broad PCORI Funding Announcements (PFAs; aligned with the 5 National Priorities for Research [26]) undergo preliminary review by two scientists, one patient, and one stakeholder based on the PCORI Merit Review criteria and Methodology Standards [27,28] (Fig. 1). Reviewers are recruited into mutually exclusive groups based on the following definitions: “Patients” include those with or at risk of a condition, unpaid caregivers to someone affected by illness, and those serving in a patient advocacy role. “Stakeholder” reviewers include clinicians, purchasers, payers, representatives from industry, representatives from health systems, policymakers, or staff from clinical training institutions [29].

Over time, PCORI has implemented multiple process improvements to enhance process quality and reduce burden for applicants and reviewers. For the current study sample, the process was as follows: Reviewers first independently evaluate applications to provide written critiques of strengths and weaknesses, and assign criterion scores from 1 (Exceptional) to 9 (Poor) and preliminary overall scores. Scientists are required to score all five criteria; patient and stakeholder reviewers are required to score three criteria: potential to improve care, patient-centeredness, and engagement. The top scoring applications (approx. 50%, based on average preliminary overall scores) are discussed at in-person panel meetings comprising approximately 50% scientists, 25% patients, and 25% stakeholders. After in-person discussion, all panel members provide a final overall score. Funding recommendations were made by PCORI staff and finalized by the PCORI Board of Governors based on Merit Review feedback, portfolio balance, and programmatic fit.

## Methods

### Design

This is an observational study using administrative data from PCORI Merit Review approved by the Chesapeake Institutional Review Board (IRB; formerly MaGil IRB, at the time of this work). This article follows reporting guidelines for observational studies [30].

### Sample and Data Collection

This study includes applications submitted to PCORI funding announcements for PCORI's scientific priority programs, excluding applications to the program with sole emphasis on methods research (Accelerating Patient-Centered Outcomes Research and Methodological Research). Applications submitted for special one-time funding opportunities, were excluded because they use different review criteria. Score data were obtained for the five recent review cycles (November 2013–August 2015 cycle) using the same review criteria and processes (see [Supplemental Digital Content 1 for cycle timing](#)).

### Analysis

Statistical analyses were conducted using SAS/STAT software and R.

### Descriptive Statistics and Correlations

Criterion scores means and variances were examined by review cycle and reviewer type for the pre-panel reviews. To use comparable variances between the reviewer types (given the reviewer type ratio of 2 scientists: 1 patient: 1 stakeholder) one of the two scientists reviewers' scores was randomly selected for each application for each review criterion in the descriptive

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