RESEARCH NOTE

Examining the role of funders in ensuring value and reducing waste in research: An organizational case-study of the Patient-Centered Outcomes Research Institute [version 1; peer review: 1 approved]

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Abstract

International experts have recommended actions that funders can take to improve the value of research investments. They state that self-assessment and public sharing are the basis for accountability and improvement. We examined our policies and practice to determine the extent to which the Patient-Centered Outcomes Research Institute’s (PCORI) policies and practices as a research funder align with international best practice recommendations. A self-audit of current policies and practice against 17 recommendations and 35 sub-recommendations representing five major stages of research production, based on adapted methods used for self-assessment by another funder, was performed. Fit of existing PCORI policies and practices with 35 sub-recommendations, qualitative assessment of adequacy (area of strength; area of partial strength; area of growth; not applicable) for 17 recommendations for five stages of research production was assessed. Of the 17 recommendations, 15 were applicable to PCORI’s research mission and focus. PCORI has policies and practices in place for all elements of six recommendations (“area of strength”) and policies that address each element but with some still in active development for three (“area of partial strength”). PCORI is partially addressing six of the 15 relevant recommendations (“area of growth”). Areas for growth include making study protocols publicly available, improving policies on data sharing, and enhancing collaboration with other funders to reduce redundant funding. A voluntary consortium of international funders is underway to encourage further progress, including additional self-assessment and public sharing for accountability. These findings indicate PCORI has undertaken efforts to align its funding practices with international recommendations to ensure the value of public dollars invested in research. Further efforts will likely require additional coordination and collaboration between funders and stakeholders.
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Author roles: Whitlock EP: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; Selby JV: Formal Analysis, Investigation, Writing – Review & Editing; Dunham KM: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing; Fernandez A: Formal Analysis, Investigation, Writing – Review & Editing; Forsythe LP: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; Norquist G: Formal Analysis, Investigation, Writing – Review & Editing

Competing interests: Because we are employees of PCORI and this is a self-audit, it could be perceived as potentially biased. We utilized the methods used by a separate funding agency (NIHR) for a similar exercise to the extent possible. We engaged both internal staff (for knowledge and completeness of data generation) as well as Board members (for an outside informed but more objective view when rating these). For the overall self-rating, we used several rounds of feedback after independent ratings were conducted to come to a consensus. We have acknowledged this as a self-audit and that potential limitation, while also promoting the transparency and accountability it represents for a funding agency. The authors have no other relationships, circumstances, or financial activities to disclose.

Grant information: The author(s) declared that no grants were involved in supporting this work.

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Introduction
In 2014, in response to concerns about avoidable waste in research prioritization, conduct, and reporting, The Lancet published a series of articles which identified specific recommendations for the biomedical research community to ensure value and minimize inefficiency in research. Research funders were a major target for these recommendations, along with regulators, journals, academic institutions and researchers themselves. Prompted by these and related activities, the biomedical research community around the world has begun considering best practices to ensure value in publicly-funded research. As key contributors, research funders are encouraged to audit and update their own policies and practice, even as external assessments of funders are also undertaken.

In light of these trends, the Patient-Centered Outcomes Research Institute (PCORI), undertook an organizational case study of its policies and practices. PCORI was created in 2010 to address research needs of a range of healthcare stakeholders through clinical comparative effectiveness research, and ranks among the top 10 US non-commercial funders of health research (see HealthResearchFunders.org). Our goals were to examine and report how closely PCORI adheres to best practice recommendations for research funders (i.e., to foster transparency), to highlight areas of needed development for PCORI (to foster public accountability), and to consider how other research funders in the US and elsewhere can examine, report, and adopt best practices for supporting value in research (to foster enterprise-wide efficiency).

Methods
To maximize comparability, we adapted another funder’s self-assessment methods (See Adding Value to Research from the National Institute for Health Research). PCORI staff (KD, LF, EW) examined PCORI’s existing policies and initiatives against 17 recommendations for funders, using a total of 35 sub-recommendations to capture multiple dimensions within some recommendations (see PCORI site). Four authors (KD, LF, EW, GN) independently categorized fidelity to the 17 recommendations as: 1) “area of strength” – PCORI’s practices reasonably address all sub-recommendations; 2) “area of partial strength” – PCORI’s practices reasonably or partially address all sub-recommendations; 3) “area of growth” – PCORI’s practices do not address all sub-recommendations, either reasonably or partially; or 4) not applicable. We resolved discrepancies through discussion and final ratings reflect consensus.

Results
Table 1 represents a detailed summary (through November 2018) of PCORI’s policies and practices related to ensuring value in research. Across the 17 recommendations (35 sub-recommendations), two recommendations were not applicable (1, 8), and one recommendation primarily applies to non-funders (both 9a, 9b). For the 15 relevant recommendations, PCORI at least partially addresses most of the relevant sub-recommendations (28/33). Our consensus process categorized PCORI’s existing policies and practices as “areas of strength” for 6/15 applicable recommendations, “partial strength” for 3/15. PCORI’s authorizing legislation, although preceding the Lancet recommendations by several years, mandated a number of these (indicated in bold in the table).

Discussion
Our consensus process categorized PCORI’s existing policies and practices as meeting criteria for “areas of strength” or “partial strength” for many of the recommendations, and we also identified clear areas for growth. Examples of strengths include PCORI’s requirements that funded research adhere to methodology standards to minimize bias and that all study results are posted on the PCORI website to enhance public access to findings. On the other hand, PCORI has not yet fully developed its policies and practices related to rewarding research replication and reproducibility (Recommendation 7). Further development of performance metrics, standardized approaches to all study-related reporting, and enforcement of key policies (Recommendations 12, 13, 14) offer other areas ripe for growth, particularly if undertaken in coordination with others across the research enterprise. PCORI like many funders, is still actively developing its practices related to publicly sharing information, including raw data, as early as possible from funded research (Recommendations 4, 5). For example, making research protocols publicly available (Recommendation 5a) is required by PCORI’s authorizing legislation, but timing and format were not specified, and our current practices may not be ideal. PCORI now requires funded investigators to submit a study protocol and record its details in an appropriate registry but does not yet specify a standard protocol format nor require protocol publication before study completion. To our knowledge, just one funder (NIHR) clearly publishes study protocols at the time of award. Nonetheless, making study protocols available at study inception can benefit the public by providing a detailed record of the planned study, which may help avoid unwitting duplication of research underway and support detection of important study deviations and post-hoc changes.

There is also opportunity for improvement through further development of policies and practices related to research data sharing and re-use. While funders can require awardees to share data from funded research and trial participants are supportive of such sharing, many researchers remain concerned about the impact on their work. PCORI’s policy on data sharing was informed by a public comment process as well as pilot work assessing time and effort required for investigators to prepare their data for sharing and on identifying appropriate repository models. Accelerating the practice of responsible data sharing necessitates broad coordination between journals, academic institutions, and data-repository organizations, alongside consistent requirements and support from funders.

Efforts to reduce waste and increase value in research are in alignment with trials transparency, research integrity, administrative efficiency, and other similar initiatives. PCORI and other health research funders are in consortium to encourage further development and voluntary adherence to international best practice recommendations for research funders, (17; see Ensuring Value in Research (EVIR) website). The Ensuring Value in Research Funders’ Forum is exploring other initiatives, such as evaluating and sharing best practices for similar challenges that
<table>
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<tr>
<th>LANCET SERIES RECOMMENDATIONS</th>
<th>RELATED PROCESSES OR INITIATIVES AT PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI)</th>
<th>SELF-ASSESSMENT</th>
<th>AREA OF STRENGTH</th>
<th>AREA OF PARTIAL STRENGTH</th>
<th>AREA OF GROWTH</th>
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<tr>
<td>1. Research funders should make information available about how decisions are made about what research to support (2a) and ensure that this information is used by researchers (2b).</td>
<td>PCORI’s multi-stakeholder Board of Governors meetings are conducted in an open forum, allowing members of the public to listen and provide comment on the proceedings. (2a)</td>
<td>Not applicable</td>
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<td>2. Research funders should demand that proposals for additional primary research are justified by systematic reviews (3a), showing what is already known (3b), and increase funding for the syntheses of existing evidence (3c).</td>
<td>PCORI’s Methodology Standards require that any proposed study be justified by evidence gaps identified through gap analyses of systematic reviews. (3a; 3b)</td>
<td>PCORI has funded studies focused on improving the methods for systematic reviews. (3c)</td>
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<td>3. Research funders and regulators should ensure that information about in-progress research is available on PCORI’s website with links to the protocols for study inclusion and exclusion. (4a)</td>
<td>Abstracts and project statuses for all research awards are available on PCORI’s website. (4a)</td>
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<td>4. Research funders and regulators should promote collaboration and sharing of information. (4b)</td>
<td>PCORI consults with other US funders when considering new areas of research and identifies areas of collaboration for funding. (4c)</td>
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<td>LANCET SERIES RECOMMENDATIONS</td>
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| 5. Make publicly available the full protocols (5a), analysis plans or sequence of analytical choices (5b), and raw data (5c) for all designed and undertaken biomedical research | • PCORI’s authorizing legislation requires that research protocols, methods of research and analysis, and other information be made publicly available concurrent with the release of research findings. (5a; 5b)  
• PCORI’s policy on Replication and Reproducibility of Research and Data Sharing requires awardees to submit the final protocol to PCORI, requires applicants/awardees to submit a data-sharing plan, and permits PCORI to request data sharing and to share protocols upon request. (5a; 5b; 5c) | Area of growth |
| 6. Maximize the effect to bias ratio in research through: defensible design and conduct standards (6a), a well-trained methodological research workforce (6b), continuing professional development (6c), and involvement of non-conflicted stakeholders (6d) | • PCORI established a set of Methodology Standards for relevant research designs and requires that all PCORI-funded research adhere to relevant PCORI Methodology Standards. (6a)  
• PCORI offers training opportunities to develop the research workforce and support researchers in understanding and applying the Methodology Standards, including continuing medical education (CME). (6b; 6c)  
• PCORI’s requires that any conflicts of interest be disclosed for advisory panel members, individuals involved in the peer-review process, Board and Methodology Committee, and for executive staff of the Institute. PCORI’s Policy on Conflict of Interest (COI), Confidentiality, and Non-Disclosure ensures that application merit reviewers provide objective evaluations of applications for funding. (6d)  
• Individual patient data meta-analyses are set up to involve third party researchers with strict COI consideration consistent with guidance from the Institute of Medicine and the World Health Organization. (6d) | Area of strength |
<p>| 7. Reward (with funding and academic or other recognition) reproducibility practices and reproducible research and enable an efficient culture for replication of research | Not yet developed | Area of growth |</p>
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<th>RESEARCH REGULATION AND MANAGEMENT IS EFFICIENT</th>
<th>RELATED PROCESSES OR INITIATIVES AT PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI)</th>
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<td>8. People regulating research should use their influence to reduce other causes of waste and inefficiency in research. (9a)</td>
<td>• Not applicable — PCORI does not regulate research.</td>
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<td>9. Regulators and policy makers should work with researchers, patients, and health professionals to streamline and harmonize the laws, regulations, guidelines, and processes that govern whether and how research can be done. (9a, 9b)</td>
<td>• PCORI follows best practices recommended by Office for Human Research Protections, National Institutes of Health, and seeks course corrections to improve human subject protections. (9a, 9b)</td>
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<td>10. Researchers and research managers should increase the efficiency of recruitment and retention of participants, data monitoring, and data sharing in research through the use of research designs known to reduce inefficiencies. (10a)</td>
<td>• PCORI's multi-stakeholder Advisory Panel on Clinical Research and Implementation provides advice on clinical research and outcomes research. Recruitment and retention subcommittee advises on strategies for appropriate patient recruitment and retention of participants in clinical trials. (10a)</td>
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<td>11. Everyone, particularly individuals responsible for health-care systems, can help to improve the efficiency of clinical research by promoting integration of research into everyday clinical practice. (11b)</td>
<td>• PCORI promotes integration of research in everyday clinical practice through:</td>
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<td>• Demonstration: 133 healthcare sites are embedded within PCORI's network of 33 individual partner networks.</td>
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<td>• Funding: PCORI conducts many pragmatic studies in real-world settings.</td>
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<td>• Training: PCORI collaborates with the Office for Healthcare Research and Quality to provide workforce training within learning health systems.</td>
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<td>• Dissemination: PCORI works with stakeholders, including healthcare systems, to promote dissemination and implementation of key research findings.</td>
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<td>Related Processes or Initiatives at Patient-Centered Outcomes Research Institute (PCORI)</td>
<td>Self-Assessment</td>
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<td><strong>12.</strong> Institutions and funders should adopt performance metrics that recognize full dissemination of research (12a) and reuse of original datasets by external researchers (12b)</td>
<td>PCORI has developed metrics on dissemination of research findings and data sharing, and PCORI’s Board of Governors monitors high-level performance levels. PCORI’s Policy on Data Management and Sharing was approved by the PCORI Board of Governors on September 7, 2018.</td>
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<td><strong>13.</strong> Investigators, funders, sponsors, regulators, research ethics committees, and journals should systematically develop and adopt standards for the content of study protocols (13a) and full study reports (13b), and for data sharing practices (13c)</td>
<td>Awardees submit final research reports using a standard template designed to increase the quality and transparency of reporting and to follow international checklists for reporting and assessing quality (e.g., CONSORT, STROBE, PRISMA). PCORI’s Policy on Data Management and Sharing was approved by the PCORI Board of Governors on September 7, 2018.</td>
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<td><strong>14.</strong> Funders, sponsors, regulators, research ethics committees, and journals should require registration of study information in clinicaltrials.gov, PROSPERO, and Registry of Patient Registries (14a).</td>
<td>PCORI requires awardees to register awards in clinicaltrials.gov, PROSPERO, and Registry of Patient Registries (RoPR). PCORI’s Public Access to Journal Articles policy provides funds for all projects to cover open access fees and requires all publications to be deposited in PubMed Central (PMC).</td>
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<td><strong>15.</strong> Researchers and funders must shift research regulations and rewards to align with better and more complete reporting (15a).</td>
<td>PCORI findings are required to undergo a Peer Review process assessing scientific quality and level of adherence to PCORI methodology standards prior to publication. Receipt of funds dependent on completion of contract milestones, including registration of study on clinicaltrials.gov and completion of final peer-reviewed report to be posted on PCORI website.</td>
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<td><strong>16.</strong> Research funders should take responsibility for reporting infrastructure that supports good reporting and archiving (16a).</td>
<td>Lay and Clinician Abstracts that are comprehensible, useful, fully convey findings, discuss considerations specific to certain subpopulations and study limitations, and address limitations as well as research needs are required by law to be available on the PCORI website within 90 days of study completion.</td>
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<td><strong>17.</strong> Research funders should support good reporting and archiving infrastructure that recognizes full dissemination of research (17a) and reuse of original datasets by external researchers (17b).</td>
<td>PCORI, PROSPERO, and Registry of Patient Registries (RoPR) ensure adherence to reporting standards. PCORI’s Policy on Data Management and Sharing was approved by the PCORI Board of Governors on September 7, 2018.</td>
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Recommendations sourced from Lancet series on ensuring value and minimizing waste in research.

Bolded text indicates process or policy mandated by PCORI’s authorizing legislation.
funders face, and considering what avenues exist to enhance efficiency and value in the full research agenda across funders. Beyond the consortium, greater transparency and coherence between funders and key players producing health research— including journals, research institutions, sponsors, and regulators— remains vital for tangible progress in our shared efforts.

Limitations: Our methods are limited by self-assessment, but findings are consistent with audit results for PCORI from external assessors. In addition, the availability of policies or current practices represent only the first step, with actual performance measurement needed. Finally, while the Lancet series highlights areas for improvement for funders and others across the research enterprise, the impact of implementing and adhering to these recommendations on research value has yet to be demonstrated.

**Data availability**

**Underlying data**

All data underlying the results are available as part of the article and no additional source data are required.

**Acknowledgements**

The authors thank Hal Sox, MD, for comments that greatly improved the manuscript.

**References**

   PubMed Abstract | Publisher Full Text
   PubMed Abstract | Publisher Full Text | Free Full Text
   Published Abstract | Publisher Full Text
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Current Referee Status: ✔

Referee Report 25 April 2019
https://doi.org/10.5256/f1000research.20209.r47387

Hans Lund
Centre for Evidence-Based Practice, Western Norway University of Applied Sciences (HVL), Bergen, Norway

The study is a report of a self-audit done by one of the top 10 non-commercial funders in USA. The aim was to evaluate to what degree the funding agency follow international recommendations to improve the value of research investments.

This self-audit is very important for a general audience as:
1. Researchers can understand the context and environment of funding and the reason for the requirements related to application for funding
2. Other funding agencies can see how to change their policies in order to improve the value of research investments
3. Readers will understand the challenges related to improve the value of research investments

The report should include a date for when to expect an update of the self-audit. An update - for example 2 to 3 years from now - would show the improvements and identify the biggest challenges related to improve the value of research investments.

The method is only partly described as the reader is unable to see from where the 17 recommendations and 35 subrecommendations originates. None of the link leads the reader directly to the source. In addition, as the authors use another funder’s self-assessment method, the possible alterations or adjustments made in the present self-audit should be mentioned. If no alterations were done, this should also be mentioned. Using the same assessment method makes it possible to compare, and this could have been mentioned in the Discussion.

There is an * and a † in Table 1, I can’t find what these refers to.

In conclusion: this is a very important and useful report of a self-audit (see above), and with the minor adjustments mentioned is should be published the sooner the better.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: My professional content area is research within rehabilitation. Methodologically, I am using systematic reviews, meta-analyses, and meta-research. As the chair of the “Evidence-Based Research Network” I am fully occupied with issues related to promote ways of thinking and acting to improve the quality of research and to avoid waste in research.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

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