SUPPORTING STATEMENT

Part B

American Recovery and Reinvestment Act
"Developing a Registry of Registries"

Version: 15 October 2015

Agency of Healthcare Research and Quality (AHRQ)

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1. Respondent universe and sampling methods

The Registry of Patient Registries (RoPR) was created to provide a central point of collection for information about all patient registries in the United States. The site helps to further the Agency of Healthcare Research and Quality's (AHRQ) goals by making information regarding quality, appropriateness, and effectiveness of health services (and patient registries in particular) more readily available and centralized.

The RoPR database system, PatientRegistry.AHRQ.gov, is compatible with ClinicalTrials.gov and meets the following objectives:

1) Provides a searchable database of patient registries in the United States (to promote collaboration, reduce redundancy, and improve transparency);
2) Facilitates the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage);
3) Provides a public repository of searchable summary results (including results from registries that have not yet been published in the peer-reviewed literature);
4) Offers a search tool to locate existing data that researchers can request for use in new studies; and
5) Serves as a recruitment tool for researchers and patients interested in participating in patient registries.

To achieve the goals of this database system, the following data collections are implemented:

1) Collect patient registry information from users to populate the RoPR database system, achieving all of the above goals.

This study is being conducted by AHRQ through its contractor, L&M Policy Research and partner Quintiles, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Statistics	**Cumulative Traffic**
Total # Visits to RoPR website (since inception 2011)	11,674
# Registries available on RoPR Search (as of June 2015)	136
Registry Purpose	
Clinical Practice Assessment	57
Effectiveness	53
Natural History of Disease	48
Payment / Certification	5
Post Marketing Commitment	13
Public Health Surveillance	17
Quality Improvement	40
Safety or Harm	31

The purpose of the RoPR is to create a readily available public resource, based upon the model of ClinicalTrials.gov, to allow for the increased availability and efficacy of various types of observational research (e.g., patient registries, comparative effectiveness studies, and post-approval studies). These types of research have become more prevalent, and are not adequately served by ClinicalTrials.gov. The information being collected in the RoPR Record is visible to the public visiting the RoPR website, and is available for public use in this capacity.

At this time there is no plan for the data to be used by AHRQ or any other Federal agency for purposes outside of the RoPR and the patient registries represented.

The RoPR is an existing data collection initiative.

There is no outreach towards a particular "sample size" of respondents to solicit data spurring analysis focused on answering a particular scientific research question, (e.g., surveys).

2. Information Collection Procedures

The RoPR integrates with ClinicalTrials.gov to present a seamless user interface and provide a low response burden. Users who define a record as "Patient Registry" when managing data in ClinicalTrials.gov are directed to access the RoPR website with a blank RoPR record to complete. The RoPR record is comprised of 11 required data elements and 34 optional data elements (of which 11 may be required conditionally). Respondents are not be able to submit their record until all required data elements are completed. Once a respondent completes and releases a RoPR record, after 24 hours that record is available for the public to view via RoPR search.

RoPR records, which are either missing required data elements or have invalid entries (e.g. an email address in a non-standard format), are not able to be released for viewing on the RoPR search site. The RoPR clearly displays errors for any such missing, or invalid data elements. Additional prompts for incomplete records will display for the respondent on attempting to release a record with errors.

If a RoPR registry record has not been updated over one year, the registry point(s) of contact are sent a reminder via email (contact address is required). The RoPR system will send them an automated email message informing them that it has been one year since their registry record was updated, and prompting them to return to the RoPR website, review their registry record, and update it if necessary.

The text of this email follows. It is estimated that the time burden for reviewing and updating a registry record is approximately 15 minutes.

Automated email message text:

> To: [Registry Holder]
> From: [RoPR@tbd]
> Subject: RoPR Record [Registry Title]
>
> *Body:*
> To Whom It May Concern:
>
> The record [Registry Title], currently posted on RoPR (The Registry of Patient Registries] has not been updated in one year.
>
> Please log into PRS at https://prs.nlm.nih.gov/ to make any updates to the ClinicalTrials.gov record as necessary. From the links present on either the Study Design section or the Release page of PRS, please navigate to the RoPR Registration System and make any updates to your RoPR record.
>
> If no updates are made to the record after four years, it will be set to an Archived status. Archived records will still be available on the RoPR search site, but the public may choose to filter them out of search results.
>
> Thank you for your support,
> The RoPR team

The RoPR support team does not input any missing data for any optional data elements left incomplete.

The nature of the RoPR site is that of an optional, publicly-available, central point of collection for information about patient registries within the United States.

3. Methods to Maximize Response Rates

As described above, the RoPR is not a data collection effort aimed at answering a specific research question. There is no need for a particular sample size of respondents to power analysis of respondent data. Nonetheless, AHRQ is committed to maximizing response rates by lowering respondent burden and raising industry awareness of the RoPR site as a resource for patient registry holders and seekers of information about patient registries.

AHRQ's efforts to lower the response burden have been discussed in Part A of this supporting statement. AHRQ attempts to raise public awareness of the RoPR by affiliating it with ClinicalTrials.gov, which has a similar (although not identical) user base as the RoPR. The National Library of Medicine adds new data elements to ClinicalTrials.gov to support Patient Registry records and their data element definitions serve as means to boost their community's awareness of the RoPR.

Additional awareness may be achieved via actions described below under *"Potential Outreach Activities"*.

Another factor possibly affecting response rates is whether any registries are required to provide data beyond the inclusion and exclusion criteria, and be listed in the RoPR. There are several important perspectives in answering this question.

First, from a regulatory and legal perspective, the RoPR does not currently have the authority to require that any registry be listed in the RoPR system. However, other groups could require listing of registries in the RoPR system. For example, it is recommended that certain funding sources, such as government agencies, strongly consider requiring the listing of registries that they fund in the RoPR through their contract terms. Such a requirement would benefit the funding agency by increasing the transparency of the registries that they fund.

Second, factors impacting response rates can also be considered from a health care journal perspective, since the decision by the International Committee of Medical Journal Editors to require ClinicalTrials.gov listing of interventional studies for publication as part of their Uniform Requirements for Manuscripts policy was critical to the rapid growth of ClinicalTrials.gov as a trials registry. [1,2] While it is a clear advantage to both reviewers and publishers of peer-reviewed journals alike to have patient registries listed in the RoPR, the predominant view of the editors participating in the development of these the RoPR policies and procedures is that the compelling moral rationale that justified requiring the registration of interventional trials does not exist for observational studies.

Despite the lack of requirements, there are very strong motivations for registry holders to list their registries in RoPR.

Some of the specific motivations cited by stakeholders include:

1) Contribute to the common good;
2) Increase general awareness about the existence of the registry, which may support the registry's goals or the goals of the sponsoring organizations;
3) Increase awareness of the registry in order to improve investigator and, in some cases, participant enrollment, which could reduce time to completion for time-sensitive registries;
4) Find other groups with whom to collaborate;
5) Facilitate research; and
6) To meet requirements that may exist as a condition of funding.

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[1] Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors, (September 2004); http://www.icmje.org/clin_trial.pdf.

[2] Update on Trials Registration: Clinical Trial Registration: Looking Back and Moving Ahead, (June 2007); http://www.icmje.org/update_june07.html.

Stakeholders also noted that, as more patient registries are listed over time, the RoPR will likely become the key source for identifying registries for systematic reviews and meta analyses. Therefore, listings will be increasingly important in order for a registry to have an impact on evidence development.

4. Tests of Procedures

As part of the RoPR development process, done by Quintiles under contract with AHRQ, in 2011, usability testing was conducted on a prototype of the data collection system. At the time, nine individuals took part in 8 separate sessions that were a minimum of 1 hour long. Based on feedback obtained from these sessions, changes were made to the RoPR system to improve navigation and ease of use. Several changes were made to the wording of the data elements, to clarify intent and improve user understanding.

All subsequent development and modifications to the live RoPR system are subject to a test plan submission and approval and software quality assurance testing. . The documentation associated with these testing efforts are shared with AHRQ.

5. Statistical Consultants

The RoPR is designed and built by Quintiles, under contract to the Agency for Healthcare Research and Quality (AHRQ). Quintiles is sub-contractor to L&M as the prime contractor. Quintiles, as sub-contractor, is to maintain the RoPR system through to 30 April 2016. Contract renewal for optional year two (2) is available for extension beyond 30 April 2016. Quintile's point of contact for the RoPR system is Monica Sarmiento, the Senior Researcher at L&M Policy Research; and Jason Colquitt, the Vice President of Information Technology at Quintiles.