

Effective Health Care Program Research Reports

Number 41

Registry of Patient Registries (RoPR) Policies and Procedures

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Research from the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network



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Registry of Patient Registries (RoPR) Policies and Procedures

Structured Abstract

Objectives. The primary purpose of the Registry of Patient Registries (RoPR) is to provide a searchable, central listing of registries. A fundamental step in creating the RoPR is the development of clearly articulated policies and procedures regarding the program's scope, operations, and governance. The purpose of this document is to describe the policies and procedures for the RoPR.

Data Sources. Not applicable.

Methods. An iterative stakeholder engagement process was employed to develop, review, and refine the policies and procedures. Stakeholders included representatives from eight major groups: patients/consumers; physicians, hospitals, other health care providers, and physician associations; payers, including private and public insurance programs; funding agencies; government regulatory and public health agencies; researchers; journal editors; and industry. Key questions were formulated and expanded based on a series of three stakeholder meetings, and a final stakeholder meeting was held to discuss the key questions and to develop consensus around difficult topics.

Results. The major issues include (1) the policies on the scope of the registries database, access to the system, methods to ensure accuracy of information, and governance, and (2) the procedures for listing a new registry, updating an existing registry, and contacting registry holders. Because the RoPR is a voluntary system, burden of use is a major consideration. The policies and procedures strive to achieve an appropriate balance between minimizing burden and providing sufficiently complete and accurate information to users of the RoPR.

Conclusions. The policies and procedures described here support the RoPR's goals of providing a searchable central listing of patient registries to promote collaboration, reduce redundancy, and improve transparency in clinical research.

Contents

Introduction.....	1
Methods.....	2
ROPR Policies	3
Scope of the Database	3
Ensuring the Accuracy of Information in the RoPR System	4
Ensuring Consistency of Terminology Within the RoPR System	4
Access to the RoPR.....	4
Motivations for Listing a Registry	4
Additional Incentives for Consideration	5
Potential Outreach Activities	5
Use of Information	6
Governance	6
Procedures for Using the ROPR	7
Submission of a New Registry Listing	7
Responsible Party.....	7
When To Submit a New Registry Listing	7
Required Information for New Registry Listings	7
Updates to an Existing Registry Listing	8
When To Update a Registry Listing	8
Updating Existing Registries	8
Non-Updated Registries.....	8
Deletion of Registry Listings	8
Contacting Registry Record Holders	9
References	10

Effective Health Care Program Research Report Number 41

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Introduction

The primary purpose of the Registry of Patient Registries (RoPR) is to provide a searchable, central listing of registries. As envisioned, the RoPR will contain information for each listed patient registry that would enable a user of the RoPR to understand a registry's purpose, design, clinical focus, goals, targeted outcomes (if applicable), and progress towards its goals. Participation in the RoPR is voluntary, and it will include information on the data being collected in patient registries, particularly with respect to standardized elements and outcomes. Search capabilities will allow users to locate specific registries, such as those in a disease area or with particular classifications or purposes. This information will be useful to many stakeholder groups. For example, researchers seeking to develop a registry may find other researchers with similar registries with whom they could collaborate or discuss best practices. This may reduce duplication of effort and result in knowledge sharing across disease areas, ultimately optimizing the use of limited health care research resources. In addition, similar to the goal of ClinicalTrials.gov, a searchable listing of registries will improve transparency in the field. Even registries that do not publish their data will be identifiable, and information on the scope and use of the registry may potentially be estimated.

A fundamental step in creating the RoPR is the development of clearly articulated policies and procedures regarding the program's scope, operations, and governance. The major issues to be addressed include (1) the policies on the scope of the registries database, access to the system, methods to ensure accuracy of information, and governance, and (2) the procedures for listing a new registry, updating an existing registry, and contacting registry holders. Registry holders can enter patient registry profiles in the RoPR after logging into ClinicalTrials.gov Protocol Registration System (PRS), creating a patient registry record there, and then navigating to the RoPR. ClinicalTrials.gov has agreed to create a new study type: "patient registry." ClinicalTrials.gov currently supports patient registries, but that information must be submitted within an observational study "shell"; this new initiative will allow for the submission of patient registry information within a distinct patient registry study type. The purpose of this document is to describe the policies and procedures for the RoPR, which are distinct from those of ClinicalTrials.gov. As the RoPR is developed, some design features or implementation decisions may change based on public comments or user acceptance testing results. This document will be revised to reflect the public comments and the final implementation of the RoPR.

Methods

An iterative stakeholder engagement process was employed to develop, review, and refine these policies and procedures. Stakeholders included representatives from eight major groups: patients/consumers; physicians, hospitals, other health care providers, and physician associations; payers, including private and public insurance programs; funding agencies; government regulatory and public health agencies; researchers; journal editors; and industry. Key questions were formulated and expanded based on a series of three stakeholder meetings (held on November 18, 23, and 30, 2010), which introduced the RoPR project to approximately 112 unique participants, and provided a review of the policies and procedures for ClinicalTrials.gov and other similar projects (e.g., HSRProj, DocDAT, and the National Institute of Diabetes and Digestive and Kidney Diseases Central Data Repository). A large, in-person meeting was held on January 13, 2011 at the Agency for Healthcare Research and Quality (AHRQ) to discuss the key questions and to develop consensus around difficult topics. This meeting involved a diverse group of stakeholders who interact with registries at various levels and for different purposes; participants included representatives from patient organizations (4); medical and surgical associations (12); academic researchers (4); journal editors (5); industry (7); payer organizations (3); independent research organizations (4); health information technology vendors (2); and government agencies (8). The findings from this meeting were reviewed and refined at a second in-person stakeholder meeting (held on January 18, 2011, at AHRQ) involving 16 additional stakeholders.

ROPR Policies

Scope of the Database

Defining the scope of the database, specifically which patient registries should be included or excluded from the RoPR, is an important first step in describing the RoPR policies and procedures. The scope of the database influences other aspects of the policies and procedures, such as the motivations for listing registries and procedures for listing and updating registries. To describe the scope, a definition of a patient registry appropriate for inclusion in the RoPR was developed as:

An organized system that uses observational methods to collect uniform data (clinical and other) for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including to products, health care services, and procedures) and that serves a predetermined scientific, clinical, or policy purpose.

This was adapted from the definition provided in the AHRQ publication, “Registries for Evaluating Patient Outcomes: A User’s Guide,” to be inclusive of registries that are not used to evaluate patient outcomes.¹

Similarly, it is important to identify what registries (if any) will be excluded from the RoPR. The consensus view of the stakeholders is that the RoPR should be highly inclusive to encourage participation and should not limit registration based on criteria such as the number of participants, number of centers, practices or institutions participating, or the specific purpose (e.g., quality improvement). For example, a large number of registries are managed within single institutions for non-research purposes, and yet these registries may be important to particular registry seekers using the RoPR.

While registration of registries would ideally be limited to those characterized by having ‘high-quality’ data or research practices, it is not feasible for the RoPR to perform such evaluations as the effort required would be resource-intensive for each registration and would therefore limit the number of registries that could be registered and maintained. Rather, alternative approaches to enabling the RoPR users to discern basic levels of quality through the content of the registration itself are more practical. These are described in the next section.

Another final scope question relates to how both registries and studies generated from registry data should be registered and maintained in the RoPR. This is an area where registries may differ significantly from interventional trials. Some registries, such as those used to fulfill a post-marketing commitment, are narrowly defined data collection efforts designed to support a single observational study. Other registries are ongoing data collection programs that may provide data for multiple studies or may link with other data sources to facilitate new investigations. While the former case closely mimics the challenges for posting an interventional trial in a trials registry like ClinicalTrials.gov, the latter case raises new questions about how to distinguish the registry (i.e., the collection of uniform data as described above) from the registry studies (i.e., studies performed on data collected through the registry). Examples of registry studies range from studies that rely directly on data from the registry to those that utilize the registry data and other data as well.

It is the consensus view that both the registry and the registry studies should be listed. Details of the registry should be listed in the RoPR, and studies performed on registry data should be listed in ClinicalTrials.gov. Each registry should have a unique identifier within the RoPR, and it should be possible to link to and from the registry and registry studies. This linkage would allow

study reviewers to access the registry listing, thus serving as a reference to provide additional information about the registry or registries from which the study is derived. Similarly, the RoPR identifier could be maintained in other searchable places such as PubMed citations.

Ensuring the Accuracy of Information in the RoPR System

Ensuring the accuracy of information in the registry listings is critical to developing a useful RoPR system, but this requirement introduces a number of issues. First, duplicate registry listings must be identified and managed. Automated, real-time checks based on duplication algorithms and the display of warnings to the registrant are part of the solution, but because a registry can be described in more than one way, these will not be completely effective. Therefore, there will be a periodic (e.g., monthly) review of all RoPR records to manage duplicates. This is especially important given the goal of having a unique identifier for each RoPR listing. In addition, other checks will be established to validate internal consistency between required fields, check spelling, and so forth.

While validation of submitted information to the RoPR by RoPR staff would be the ideal, such curation is not feasible given the likely number of registry entries. As an indicator of quality for some purposes, the RoPR will provide a listing of key procedures or processes that are associated with quality and will allow registry record holders to self-report their use or adherence to such procedures. Examples of quality assurance procedures that a particular registry may have undertaken include creation of a quality plan and the comparison of data in the registry to source documents.

Ensuring Consistency of Terminology Within the RoPR System

Ensuring the consistency of terminology used within the RoPR system is a priority for providing valuable and understandable content from multiple sources. Guidance will be provided to RoPR users regarding commonly used terminology for free-text entries, and the Medical Subject Headings (MeSH) controlled terminology will be utilized within the RoPR search portal.

Access to the RoPR

The RoPR will be available to the public. User accounts will not be required for general searching and review of the RoPR listings. Individuals wishing to submit a new registration or update an existing listing will need to set up a user account on the ClinicalTrials.gov system.

Motivations for Listing a Registry

Beyond inclusion and exclusion criteria, a key question is which registries (if any) will be required to be listed in the RoPR. For this question, there are several important perspectives. First, from a regulatory and legal perspective, the RoPR does not currently have the authority to require any registry to 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, the issue was 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.^{2,3} While it is a clear advantage to both reviewers and publishers of peer-reviewed journals to have patient registries listed in the RoPR, the predominant view of the editors participating in the development of these policies and procedures is that the compelling moral rationale that justified requiring 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. Some of the specific motivations cited by stakeholders include:

- To contribute to the common good.
- To increase general awareness about the existence of the registry, which may support the registry's goals or the goals of the sponsoring organizations.
- To 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.
- To find other groups with whom to collaborate.
- To facilitate research.
- To meet requirements that may exist as a condition of funding.

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, listing will be increasingly important for a registry to have an impact on evidence development.

Additional Incentives for Consideration

In discussions with stakeholders, it became clear that there are several explicit incentives that could be established to motivate registry holders to list their registries in the RoPR. For example, the RoPR could provide tools that give direct benefit to listed registries, such as notifications when the listed registry is included in a publication posted on PubMed; updates about other similar registries as they are posted on the RoPR; or tools that enable and facilitate collaboration opportunities between interested organizations and the listed registries. The RoPR could also offer a 'community of practice' program (e.g., a learning network) to support registry holders in improving the registries listed in the RoPR and/or developing new registries. As described earlier, funding organizations, both public and private, might require registration as part of their funding agreements. This might be justified by the likelihood that visibility in the RoPR may improve the overall evidentiary impact of the funded registry. Negative incentives might also be established by journals, institutional review boards, Congress, or others. Such negative incentives are viewed as less likely to be enacted given the reasons described in the "Scope of the Database" section.

Potential Outreach Activities

The RoPR would benefit from a targeted campaign after launch to generate awareness of the system and urgency to register. The utility of the system for registry seekers will depend on the number of registries that are listed. Therefore, the initial campaign would need to reach a broad set of current and future registry holders and secondarily, likely users of the RoPR system.

Stakeholders suggested a number of activities that could be undertaken, such as:

- Soliciting organizations with likely registry holders as members, including the Council of Medical Specialty Societies; International Society for Pharmacoeconomics and Outcomes

Research; International Society for Pharmacoepidemiology; manufacturer trade associations (e.g., Pharmaceutical Research and Manufacturers of America, AdvaMed, Drug Information Association); associations of patient organizations; academic institutions; public health agencies; and government agencies (e.g., National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention).

- Performing research on existing registries through standard sources and soliciting those registry holders to participate.
- Presenting the RoPR at conferences attended by registry developers and sponsors and researchers who may be interested in using the RoPR.
- Adding a section on the RoPR to the AHRQ publication, “Registries for Evaluating Patient Outcomes: A User’s Guide,” since it is already widely used in the community of registry developers and owners.
- Targeting journal advertisements to the community likely to use or list on the RoPR.
- Publishing a scholarly article about the RoPR purpose, development, content, and oversight.
- Publishing a journal supplement to announce the initial registrants in the RoPR within the first year or so to provide an incentive for early registration.

Stakeholders recommended that the RoPR maintain the outreach and dissemination activities described above for some time after the initial campaign. The visibility of the RoPR in the registry holder and seeker communities needs to be high. Ultimately, the RoPR needs to become the “norm” in the registry community; at that point, registration would become self-perpetuating.

Use of Information

Since information will be linked between the RoPR and ClinicalTrials.gov, the RoPR will adopt the same policies as ClinicalTrials.gov with respect to the use of submitted information.⁴

Governance

The RoPR should maintain representative and transparent governance in the form of an advisory board to the agency that houses it. While the stakeholder group participates in active advising during the development and testing of the RoPR, eventually a more permanent advisory function should be established for the agency that will house RoPR. The advisory board should be composed of individuals with sufficient expertise to extend or revise the policies and procedures over time. Specifically, the advisory board should include individuals with expertise in registry science and methodology and research ethics. One or more registry holder representatives should be included, along with one or more patient/consumer representatives. An external nomination process may be used to nominate candidates for the advisory board. Advisors should serve on the board for a defined period (e.g., 1 to 2 years), during which time they will attend in-person meetings (at least one per year), attend regularly scheduled remote meetings (e.g., one per quarter), and review documents or discuss issues on an ad-hoc basis. Some agencies, including AHRQ, maintain external advisory committees that could also potentially be used for this purpose.

The policies and procedures will be readily available to all users of the system and to the public in general. A mechanism should be available to allow users to submit suggestions for improvement or other comments to the advisory board and government agency housing the RoPR.

Procedures for Using the ROPR

Submission of a New Registry Listing

Responsible Party

Registry holders or their designees will be responsible for submitting new RoPR entries and updates. Typically, the registry holder is the organization or individual with control of the patient registry and with any rights that exist with respect to the aggregate data contained within the registry. Because a RoPR registration includes data elements for describing the registry purpose, design, and outcomes, the person responsible for entering information into the RoPR should be an individual with sufficient operational knowledge of the registry to provide complete, accurate, and timely information. As noted above, individuals wishing to submit a new registration will need to set up a user account on the ClinicalTrials.gov PRS and register a patient registry record.

When To Submit a New Registry Listing

Many patient registries will exist at the time of the RoPR launch, and some new registry holders may have concerns about the timing of their registration, especially if there is proprietary information that may be revealed through registering. Therefore, the timing of posting is provided as a recommendation and not as a requirement. Ideally, detailed information about patient registries will be posted on the RoPR at registry inception, prior to the first participant being enrolled, as is typically the case for trials registered in ClinicalTrials.gov.⁵ This is consistent with the standard held by the International Committee of Medical Journal Editors, which has established a requirement that all interventional clinical studies be entered in a public registry before the onset of patient enrollment, as a condition of consideration for publication.⁶

Required Information for New Registry Listings

What information should be required at a minimum for those listing information in the RoPR is an important consideration in striving to achieve an appropriate balance between minimizing burden and providing sufficiently complete information. The consistent perspective from the stakeholder group is that required data elements for the RoPR record should be limited to make it easy to register both new and existing registries with limited burden on the registry holders.

Under the planned model, patient registries will first be registered through ClinicalTrials.gov and then an additional set of data elements may be completed through the RoPR data entry system (the “RoPR record”). The RoPR record will require data elements such as registry classification, purpose, a brief description of data elements (e.g., are common data elements collected?), contact information, and a registry progress update. (See the RoPR Executive Summary document for more information.) Many other data elements in the RoPR are important but, if required, may dissuade certain registry holders from completing the initial registration. Therefore, the RoPR will make the full set of data elements available, with the expectation that only some registry holders will complete the optional elements. Over time, it is anticipated that more of these data elements may be required as the number of RoPR registrations and its visibility amongst stakeholders grows, and registration of registries in the RoPR becomes the norm.

While not required, it would be helpful for published studies to provide the RoPR unique identifier for the registry so that readers and reviewers can readily obtain background information on the registry.

Updates to an Existing Registry Listing

When To Update a Registry Listing

Because participation in the RoPR is voluntary, the timing of updates is provided as a recommendation and not as a requirement. Data updates should occur at least annually, and preferably within 30 days of any major change in status. While different automated intervals for requesting updates could be created based on the particular registry classification, this is likely to be infeasible due to the wide variation in registry designs and purposes. Rather, updates should be made to the RoPR record whenever updates are made to the corresponding ClinicalTrials.gov patient registry record. In addition, the RoPR will track changes to registry listings over time. A change log listing all modifications to posted RoPR information will be provided in the system for each registry entry.

As part of the update process, the RoPR will facilitate the posting of links to progress reports or summary results. Progress reports may include descriptive information on the population(s) enrolled and the numbers achieved. Many registries will be ongoing, and updated links to progress reports should be posted on a regular basis (e.g., annually) with the updating of the registration.

Updating Existing Registries

Existing RoPR registry listings can be updated by any responsible party with access to the corresponding ClinicalTrials.gov record.

Non-Updated Registries

Since the RoPR is a voluntary system, even registry holders that list their registry may not continuously update their information. Registries that are not updated at the expected time will be flagged as non-updated (e.g., “Last updated on MM/DD/YYYY”). Non-updated registries will be moved to an archive after 4 years. Archived registries will be marked in the RoPR as such. A RoPR user will be able to select whether searches include results from archived registries. An archived registry will become an active registry again if the registry holder provides updated information.

Deletion of Registry Listings

Generally, registries that are listed in the RoPR will not be deleted from the system. Registry holders can contact the RoPR administrators if they feel that a registry listing should be deleted. The RoPR will adopt the same policies as ClinicalTrials.gov with respect to deletion of listed registries.^a

^aThe deletion policy for ClinicalTrials.gov is described in an FAQ document within the Protocol Registration System at <https://register.clinicaltrials.gov/prs/app/template/FAQ.vm>. Because this site requires login credentials, the policy is summarized here: ClinicalTrials.gov is intended to serve as a long-term public registry. Once a protocol record has been published on ClinicalTrials.gov, it remains in the system even after a trial has closed. Under rare circumstances, such as the discovery of duplicate records, a sponsor may request that a record be removed from ClinicalTrials.gov.

Contacting Registry Record Holders

A major goal of the RoPR system is to encourage collaboration among researchers and reduce duplication of effort. To achieve that goal, the RoPR must facilitate communication among researchers by providing contact information. Contact information will be made available for those interested in contacting the registry sponsor/owner to inquire about accessing registry data, collaboration opportunities, or other matters. However, contact information is difficult to maintain accurately and is often non-specific to the particular needs of the person who may initiate the contact (i.e., there may be different reasons to contact the registry holder, and these may require different contacts within the registry organization). The RoPR will strive to obtain limited but specific information (e.g., an email address, telephone number or Web site) for the contact person. Further, the registrant will be able to provide, from a list, the purposes for which they are amenable to being contacted. Contact information listed in the RoPR should be confirmed or updated whenever updates are made to the patient registry record at ClinicalTrials.gov.

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