



eRegistries
Initiative

learning package

research

core principles

An eRegistry is designed to facilitate the use of maternal and child health data by health care providers, policy makers, and women and families as well as encourage research studies using eRegistry data in order to advance scientific inquiry in maternal and child health.

There are endless opportunities for conducting research using eRegistry data. Given the prospective, 'real world' nature of the data collection, registry-based research has been called "a gold mine" for epidemiologic research. The richness of eRegistry maternal and child health data supports many different types of study methodologies including cohort, cross-sectional, and case control research designs.

An eRegistry provides unique individual level data on pregnant women captured at the point of care extending through the postpartum phase thereby facilitating analyses that take into account continuity of care across the span of a pregnancy.

This repository of data provides an ideal starting point for investigating many different research questions concerning surveillance, trends, health outcomes, quality of care, service provision, to name a few. Moreover, research can also focus on registry implementation issues or overall effectiveness of a registry system.

Registry studies provide high external validity given that data are collected in the setting of standard clinical practice with typically large sample size enabling better estimation of event rates and outcomes. **Before conducting registry-based research, the following topics should be considered:**

- **Research planning**
- **Research methods**
- **Ethical considerations**
- **Data quality and analysis**
- **Data governance**
- **Dissemination**
- **Research priorities**

step by step guide

This step by step guide provides general guidance on conducting research studies using data from an eRegistry.

STEP I: DEVELOP A RESEARCH PLAN

The first step for conducting studies using registry data is to develop a research plan that identifies the specific goals of the research. Define your research question and priorities by specifying the scope, target population, core data set, and outcomes of interest. In addition, identify a research team that includes expertise in the content areas of interest as well as quantitative and statistical analysis.

The following core questions should be addressed:

- What is the primary research question?
- What are the main priorities of the study?
- Will research be linked with national priorities?
- What are the primary and secondary objectives of the study?
- How is the population of interest defined, i.e., inclusion and exclusion criteria?

Another issue that merits early attention in the planning process is the ethical review process that is described below.



STEP 2: ETHICAL CONSIDERATIONS

Given the sensitivity of reproductive, maternal and child health data, particular attention should be accorded to ethical protocols. Researchers must obtain ethical approval (IRB, ethics board, etc.) and adhere to all national data privacy, confidentiality, security, and storage requirements for the eRegistry to ensure the privacy of individual data. (See The eRegistry Governance Toolkit for more information.) This process can be lengthy and time-consuming so it is advisable to prioritize this work early in the planning phase.

In particular, it is important to take note of the following:

- Complete all necessary applications pertaining to registry data access for research purposes
- Confirm compliance with the data safety monitoring board, as applicable
- Ensure the dataset contains only de-identified data
- Establish rules for reporting data that contains very small sample sizes within cells
- Consider potential conflicts of interest and address appropriately
- Establish a publication policy, including who are the key authors and the author order
- Aim to publish results in peer-reviewed literature to share information in the public domain.

STEP 3: RESEARCH DESIGN

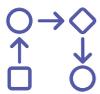
The research design phase involves identifying what type of study design is most suited to answering your research question. There are numerous types of research designs that can be used with an eRegistry. The other aspect of this phase is developing a formal study protocol that defines the

study objectives, population, data elements, and outcomes, to name a few. Careful consideration must be made to the data format. Specifically, longitudinal data should be analyzed using methods that takes into account the time perspective in contrast to cross-sectional analyses.

Table I below lists examples of research designs that are likely to be possible with registry data.

TABLE I

<i>Study Design</i>	<i>Description</i>
Case-control	This design focuses on 'cases' that share a specific trait of interest compared to 'controls', or those that do not. This design is most suited to rare events given that it looks for associations between exposure and outcomes.
Cohort	This design follows individuals sharing a common trait over time and may focus on a specific exposure, health condition or disease occurrence, health outcome, or service care utilization.
Cross-sectional	This design is used to assess a situation at a specific point in time.
Ecological	This design examines the frequency of an outcome of interest in relation to the exposure levels among groups or over time.
Economic	This design examines the financial implications (i.e., cost-effectiveness) of services or treatments in relation to health outcomes.
Implementation	This design is intended to examine the process and issues that impact how an eRegistry is implemented in the field
Randomized controlled trial	This design, often referred to as the gold standard, uses random assignment of intervention and control, to test a hypothesis and has recently emerged as a design approach with registry infrastructure.



STEP 4: DATA MANAGEMENT AND ANALYSIS PLAN

An important component of a research project is to develop a data management and analysis plan. The following issues should be addressed:

- Data analysis: What analytic approaches are relevant for the research question and what type of statistical methods will be used?
- Data quality: What strategies will be used to assess data quality?
- Data completeness: How will missing data be handled and reported?
- Internal and external validity: Consider, explore and report potential threats to internal and external validity.
- Data security and storage: How will data be securely stored to protect data privacy?

Comprehensive documentation of the selection of data elements that will be used to answer the research question should be recorded. In other words, a clear protocol for extracting a predefined dataset from the eRegistry must be documented and limited to correspond to the scope of the research question and objectives.

To ensure the scientific integrity of the research, it is important to limit data analyses to the research question and avoid data fishing and/or mining. Secondly, patient selection parameters delimiting the study population should be clearly defined with inclusion and exclusion criteria.

A data analysis plan describes the statistical approach and techniques that to be used to evaluate the primary and secondary objectives specified in the study plan. The data analysis plan should define the key variables that will be included in descriptive analyses along with all potential subgroups that will be investigated. It should also mention the statistical software and methods that will be used. The data

analysis plan should address potential confounding, including sensitivity analyses, and describe all strategies for handling missing data.

Descriptors of data quality such as data completeness, data ranges or interquartile ranges, or missing data proportions should be identified and documented. To ensure data quality of the research, it is vital to appropriately address these issues to maximize the validity of the results of the study and its value to decision makers.



STEP 5 : CONDUCT THE RESEARCH

Allocate adequate time and resources for conducting the research. It is easy to underestimate the time required to conduct research so it is advisable to buffer your timeline to accommodate unexpected delays. It is also important during this phase to strictly adhere to the ethical obligations concerning data security and storage.



STEP 6: COMMUNICATE AND DISSEMINATE RESEARCH FINDINGS

Sharing and disseminating research findings is important to the general public, policy makers, and the scientific community. Tailoring the findings to these different audiences, however, requires appropriate language (avoiding jargon whenever possible) and clear visual display of findings is important so that the results are clearly understood. It is advisable to use multiple communication channels to convey research findings including press releases, local or international scientific journals, and/or websites.

There are many guidelines and resources (see Resource section) that provide comprehensive checklists on items that should be included in research articles or reports. A brief summary of reporting requirements is noted in the Table

2. In addition, it is important to address and clearly assign authorship roles and responsibilities prior to publication. In sum, at a minimum, the following issues should be addressed:

TABLE 2

research reporting recommendations

review of the literature

methods: study design, setting

participants, selection criteria

variables of interest

sample size calculation

statistical methods

missing data

key findings

generalizability

limitations, bias

funding source

conflict of interest

- Describe the research method, including target population, selection of study subjects, compliance with applicable rules and regulations, data collection methods, statistical data analytic methods, and any issues that may have affected data quality
- Report results for both descriptive statistics and the main objectives
- Mention and fully describe limitations as this can increase confidence in the findings among readers and researchers
- Don't overstate the generalizability of your study findings
- Ensure that authors who are acknowledged have had a meaningful role in the design, conduct, analysis, or interpretation of results
- Remember that publishing negative findings can be as important to the literature as positive findings.

From the research summary, the following should be clear to the reader:

- the research aim
- appropriateness of the research design
- appropriateness of recruitment strategy
- ethical considerations relevant to data protection
- rigor of data analysis
- clearly stated findings
- overall value of the research

FINAL NOTE: CONSIDER UNINTENDED CONSEQUENCES

Although an eRegistry provides an excellent source of data for research studies, it is important to keep in mind the potential of unintended consequences of poorly executed statistical analyses that can result in misleading results that could adversely affect program planning and impact policy. Inadequate preparation of datasets can also result in misleading findings.

RESOURCES

- [*Registries for Evaluating Patient Outcomes: A User's Guide.*](#) This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. Registries for Evaluating Patient Outcomes: A User's Guide, 3rd edition.
- [*Registry-based randomized controlled trials- what are the advantages, challenges, and areas for future research?*](#) (2016) Lia and colleagues examine and the pros and cons of using registries as a platform for implementing registry-based randomized controlled trials investigating effectiveness research questions.
- [*Standards in the Conduct of Registry Studies for Patient-Centered Outcomes Research.*](#) This document reviews existing guidelines and literature to develop methodological standards for the design of registries and the analysis of studies using registry data. This report summarizes the methods used to identify relevant guidelines and recommends minimum standards for registries designed to support PCOR.
- [*The CONSORT Statement*](#) . The CONSORT Statement is a minimum set of evidence-based recommendations designed for researchers reporting on randomized trials. CONSORT standardizes the reporting process of trial findings thereby facilitating a comprehensive and transparent reporting in order to facilitate interpretation and assessment.
- [*The Spirit statement.*](#) The SPIRIT statement provides recommendations on scientific, ethical, and administrative elements that should be addressed in a clinical trial protocol and can be found in a 33-item checklist.
- [*Strobe guidelines.*](#) The Strobe statement offers guidance in the form of checklists that itemize what should be reported in journal articles when using observational research designs such as cohort, case-control, and cross-sectional studies. The Strobe statement does not provide advice on designing or conducting studies but the checklists are useful in highlighting information and details that should be described when reporting on a research study that can ultimately assist readers in accurately assessing study findings.

field notes



The eRegQual trial began recruitment in January 2017 and is expected to conclude in June 2018. During this trial period, we have planned sub-studies that will inform the process of use of eRegistry, care providers' and patients' perspectives of use and satisfaction.

The eRegTime is one such sub-study that aims to evaluate time efficiency of the eRegistry. In February and March 2017, we undertook an exercise to systematically map the workflow of clinics with and without the eRegistry. We visited clinics and interviewed nurses and midwives.

We also made cue cards with the activities listed on them and asked health workers to arrange them

in a meaningful order to describe their workflow. We then conducted simulations of workflow in the clinics during model consultations and filmed these simulations for training. Observing care providers in the clinics helped us understand how the eRegistry fits into the everyday workflow of the clinics.

Care providers were enthusiastic about using the eRegistry! Since care providers still spend a lot of time maintaining record books and papers in the clinics, we will continue to monitor the clinics as more functionalities are added to the eRegistry.