

Development of a research registry for primary care community-based research

Janine E Janosky, Susan B Laird, Jamar D Robinson and Jeannette E South-Paul

Janosky JE, Laird SB, Robinson JD and South-Paul JE. Development of a research registry for primary care community-based research. *Family Practice* 2005; **22**: 358–360.

A research registry can be of invaluable assistance to physicians and researchers by providing an available panel of patient information that could assist in understanding the patients they are serving, utilization of health care services, and the design and implementation of research studies to improve patient care. We have designed, implemented, and managed such a research registry for our Center for Primary Care Community-Based Research.

A registry has been defined as a file of documents containing uniform information about individual persons, collected in a systematic and comprehensive way, in order to serve a predetermined purpose.¹ Registry data systems are powerful tools used by researchers in a variety of health-related fields. The application of these systems in epidemiologic, clinical, and health services research are many. They are utilized to estimate disease prevalence and incidence, to estimate health care resource utilization and clinical outcomes, and to track changes in these parameters over time.² Registries may also serve as data sources for conducting comparisons of health care utilization and outcomes across different categories of patients, for example according to ethnicity, sex, age, or geographic location. Additionally, registries may serve as sampling frames for selecting patients who fulfil specific study eligibility criteria,² and for use in prevention research.

There are many disease-specific research registries that are well known, including cancer, influenza vaccinations and HIV.² Several others have been developed including cleft lip,³ trauma,⁴ pediatric neurologic disorders,⁵ vascular surgery⁶ and spinal cord dysfunction.⁷ Despite the growing utilization of disease-specific registries in

the United States, and their greater use in Canada and Europe, there is a paucity of research/experience with community-based primary care registries. Such registries may provide invaluable clinical, epidemiologic, utilization, prevention, and outcomes data that would help to improve the quality of life and clinical outcomes for patients as well as provide mechanisms for investigating ways to eliminate the disparities in health care among underserved populations. We have developed a research registry that is not disease-specific, but that encompasses the collective patient population who has consented to be contacted for possible inclusion in any applicable medical research studies.

The research registry for the Center for Primary Care Community-Based Research was developed for the purpose of:

- (1) Performing retrospective research studies on diseases that disproportionately affect minority and underserved populations. Such research involves analyses of information found in the medical records of patients enrolled in the Center for Primary Care Community-Based Research who agree to allow their medical record information to be recorded in the Research Registry.
- (2) Permitting review of medical record information contained within the Registry to identify patients who may be eligible for participation in future research studies conducted by the Center for Primary Care Community-Based Research.
- (3) Obtaining the permission of Research Registry participants to be contacted in order to ascertain their interest in participating in future research studies being conducted by the Center for Primary Care Community-Based Research for which it appears that they might be eligible (i.e. based on medical information contained within the Research Registry).

The primary recruitment for research registry participants is through primary care physician practices,

Received 7 March 2005; Accepted 21 April 2005.

University of Pittsburgh, School of Medicine, Center for Primary Care Community-Based Research, Department of Family Medicine and Clinical Epidemiology. Correspondence to Janine E Janosky, University of Pittsburgh School of Medicine, Department of Family Medicine and Clinical Epidemiology, 3518 Fifth Avenue, Pittsburgh, PA 15261, USA; Email: jej@pitt.edu

community health fairs and events, and other research endeavors.

The Center for Primary Care Community-Based Research, at the University of Pittsburgh includes FM-Pittnet, a Practice-Based Research Network (PBRN) that consists of 18 community-based medical practices, delivering services to more than 141 000 individuals. The purpose of the FM-Pittnet is to implement practice-based research in the University and community-based primary care practices offered by the University of Pittsburgh Medical Center (UPMC). Ten of these community-based ambulatory care health centers primarily serve minority, underserved groups. All patients who are receiving or seeking medical care at the community-based ambulatory care health centers are invited to participate in the Research Registry. Potential participants are approached by a member of the clinic staff or a community outreach worker and are asked to review a copy of the informed consent form prior to being seen by a clinic physician (i.e. Research Registry investigator). The center staff review the informed consent form with potential participants and address any questions or concerns prior to obtaining written informed consent for research registry participation. The clinic physicians also address any future questions or concerns of research registry participants.

In accordance with Federal regulations and the University of Pittsburgh institutional policies, research or research procedures (e.g. potential research subject identification and recruitment) involving the use of identifiable medical record information (i.e. protected health information) requires the prior written informed consent of the respective patients. Patients enrolled in the Center for Primary Care Community-Based Research are asked to provide their written informed consent to allow their identifiable medical record information related to their health status to be placed in Center's research registry for the purpose of facilitating retrospective research studies directed at their risk for and identification of diseases, and the identification and recruitment of potential, eligible subjects for participation in future research studies involving the prevention and treatment of these conditions (i.e. cancer, cardiovascular disease). The University of Pittsburgh's Institutional Review Board (IRB) is authorized to review and approve all research that is being conducted at the University, including the initial approval and continued approval of the research registry. The IRB represents diverse aspects of the University and the community and is proactive in the protection of the privacy and rights of any study participants, including compliance with the Health Insurance Portability and Accountability Act (HIPAA). Many members of the staff of the research registry serve as honest brokers, which are a system in response to HIPAA and has been approved by the IRB. Additionally, for research proposed for the use of the research registry, the Center's advisory board as well as the IRB approvals is necessary.

Given the concern for patient confidentiality and HIPAA regulations relative to health information, participation in the Center for Primary Care Community-Based Research Registry is limited to placement of the subjects' identifiable medical information related to their risk and prevention of disease in a research database (i.e., the research registry) and the use of this information for retrospective research studies directed at prevention and treatment, and/or for the identification and recruitment of potential, eligible subjects for participation in future research studies. Patients seen in the community-based ambulatory care health centers are asked to provide their written informed consent to allow their past, current, and future identifiable medical record information related to their risk and prevention of disease to be placed in the Center for Primary Care Community-Based Research Registry. The medical record information that is placed in the research registry is related directly to the patients' risk and prevention of diseases. The names, social security numbers, and medical record numbers of the research registry participants are deleted from their stored medical information and replaced with a linkage code by an honest broker, according to HIPAA regulations. Access to participant medical information contained within the research registry is restricted to The Center for Primary Care Community-Based Research investigators. Participant medical record information is stored in the Research Registry for an indefinite period of time. The Executive Director of the Center, in conjunction with the advisory board, approves all retrospective research studies being conducted by Center for Primary Care Community-Based Research investigators using medical information contained within the research registry. Such approvals are obtained prior to providing investigator access to the research registry information; are based upon considerations of scientific quality and validity; and are documented. Interested research registry participants contacted for possible participation in future research studies, being conducted by the Center for Primary Care Community-Based Research investigators undergo a separate informed consent process for each research study.

The data and safety monitoring plan for the research registry involves routine monitoring by the Executive Director of the Center and the research quality and compliance staff, and includes: (1) the removal of direct identifiers from information contained within the research registry; (2) the documentation of investigator access to the research registry; (3) the security of the database linking the research registry linkage codes with participant identifiers and the documentation of investigator access to this database; and (4) any conditions that may negatively impact the confidentiality of information contained within the research registry.

The establishment of a research registry serves in furthering the research aims of investigators and clinicians within the Center. Most importantly, it serves

as a database making it less cumbersome to identify and recruit potential patients who may be eligible for research studies conducted by the Center or other investigators. This aids in reducing recruitment efforts, costs and time expenditure of research staff. It also helps to target recruitment efforts to those patients who are interested in research and meet certain eligibility criteria. Furthermore, the registry can be of invaluable assistance to health center physicians and researchers by serving as a panel of patient information including demographic data such as age and race. Having a snapshot of this type of information readily available in electronic format could help practices understand who they are serving, enabling them to understand utilization of health care services, and design more effective research studies to improve patient care and eliminate health disparities.

Declaration

Funding: part of this work was supported by grants from Pennsylvania Department of Health, Merck Pharmaceutical, and the Health Research Service Administration.

Ethical approval: Approved by the University of Pittsburgh's Institutional Review Board (IRB) 0408083, 5 November 2004.

Conflicts of interest: none.

References

- ¹ Brooke EM. *The current and future use of registers in health information systems*. Geneva: World Health Organization; 1974.
- ² Rabeneck L, Menke T, Simberkoff MS *et al*. Using the national registry of HIV-infected veterans in research: Lessons for the development of disease registries. *J Clinical Epidemiol* 2001; **54**: 1195–1203.
- ³ Hammond M, Stassen L. Do you CARE? A national registry for cleft lip and palate patients. *Br J Plastic Surgery* 1999; **52**: 12–17.
- ⁴ Owern JL, Bolenbaucher RM, Moore ML. Trauma registry databases: A comparison of data abstraction, interpretation, and entry at two level I trauma centers. *J Trauma: Injury, Infection, and Critical Care* 1999; **46**: 1100–1104.
- ⁵ Kozinetz CA, Skender ML, MacNaughton NL *et al*. Population-based registries using multidisciplinary reporters: A method for the study of pediatric neurologic disorders. *J Clinical Epidemiol* 1995; **48**: 1069–1076.
- ⁶ Taylor SM, Robinson JG, Langan EM, Crane MM. The pitfalls of establishing a statewide vascular registry: The South Carolina experience. *Am Surgeon* 1999; **65**: 513–518.
- ⁷ Samsa G, Hoenig H, Carswell J, Sloane R *et al*. Developing a national registry of veterans with spinal cord dysfunction: Experiences and implications. *Spinal Cord* 1998; **36**: 57–62.