
Disease Registries-Essential for Health Professionals and Policy Makers

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Abstract

There has been evolution of disease registries over the years from sources of epidemiological information to data bases whose analysis can provide information to clinicians, patients, researchers and medical policy makers. The data can be used for developing protocols and guidelines for quality management and improvement in patient care .There is a lack of disease registries in the field of obstetrics and gynecology especially in Pakistan which reflects the lack of research oriented activities and integration of data and comparison between different health care facilities.

Keywords: disease registry, Pregnancy, Cardiac disease.

Background

A disease or patient registry is used for tracking the clinical care and outcomes of a defined patient population. Most disease registries are formulated to keep record of patients with chronic illnesses or the diseases that require long term follow up .Data included in the registry can be used by clinicians for prevention and disease management. A patient registry is defined as “an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by particular disease, condition or exposure, and that

serves one or more predetermined scientific, clinical, or policy purposes.”¹ Registries that enroll patients with specific diseases or particular treatment are an important source of data for patient-centered outcomes research (PCOR).^{2,3} Registries in addition to providing clinically relevant data are known for their ability to provide data on vulnerable populations not typically studied in clinical trials (children, elderly, minorities, pregnant women, those with multiple co-morbidities) due to limitations especially in consent taking process. Registries can offer adaptable designs and data collection strategies, in patients on long term follow up making them

particularly useful when treatments are changing due to change in disease progress. Because of their non-experimental design (i.e., non randomization), registries can also be used to examine the impact of physician practice behaviors on quality of care. Registries data however should be cautiously interpreted as these are only observational in design. This requires understanding of both the potential for bias that limits all observational studies and the tools that can be used to minimize the influence of such biases.^{4,5}

Gynecology and obstetrics is a field which works with a particular vulnerable group the pregnant woman and fetus so research in pregnancy is challenging.⁶ Even prospective observational studies are difficult to perform. In this situation these registries could be most helpful in order to maintain data and use it for future health planning and research. Similarly gynecological malignancies, screening programmes like cervical and breast cancer, ectopic pregnancy, gestational trophoblastic diseases all merit integrated national registries.

Historical Perspective: Disease registries, which contain systematic record of cases, have for nearly 100 years been valuable in exploring and understanding various aspects of medicine. Registries could be mandatory or initiated as a personal effort, prospective or retrospective in design but they have a common study population and defined outcome before initiation.⁷ In this commentary we highlight how registries have diversified to offer information on epidemiology,

risk modeling, quality assurance, improvement and original research. Registries existed much before the randomized controlled trials(RCT) gained the impact, and continue to flourish, as clinicians, researchers, healthcare companies, policymakers and patient advocacy groups recognize their importance. They are needed to complement the randomized controlled trials as their analysis fills in some of the “gaps in evidence” concerning issues for which RCTs have not been, or cannot be, performed or have not provided definitive answers. The earliest reported registries were the personal records of individual physicians. These were published as case series of particular conditions for the education of the wider medical community but were inert data only. The need for a change in registries to allow such analysis was recognized by Hugh Tustall Pedoe in 1978 .He narrated in his landmark research that the collection of information for its own sake is of doubtful value unless it is acted upon.⁸In 1926 first cancer registry at Yale, Newhaven hospital was started followed by further cancer registries like SEER(surveillance, epidemiology and end results) first ever national registry in USA in 1973.Than non cancer registries like new York city HBA1c registry and CABG registry ⁹ was formed to keep track of diabetics and all cardiac bypass surgery performed. Disease registries have helped explore various aspects of cardiology, like registry for acute myocardial infarction has provided both clinical and epidemiological information that was not available from RCT.¹⁰United Kingdom rewards physicians according to pay for performance with

chronic diseases tracked electronically.¹¹ Similarly in America, gynecology specific registries are established. These include society for Assisted reproduction technology registry in 1996, Fibroid registry in 1999 and Pelvic floor disorders registry in 2014.¹² Similarly there are many clinical studies published on the data based on registries like ROPAC registry of pregnant cardiac patients¹³ and risk of childhood cancer in hyperemesis gravidarum patients.¹⁴

New Developments: Recently, there has been general awareness that registries are not just mechanisms for the “passive” reporting of epidemiologic characteristics and treatments provision rather they can be used in an “active” process that assures and improves quality of care. Most of the registries are now computerized databases. Registries will continue to develop beyond their original functions of data collection. They are increasingly being used to assess the whole process of patient care and professional accountability, and not just looking at outcomes of interventions. Thus comparisons between clinicians, institutions and healthcare systems will be possible through similar registries at different centers in the same country or different countries. When new findings of a computerized disease registry are implemented into decision making and planning at a organization and are utilized to make meaningful changes in the system, the performance indices improve paving the way for further research and development.

Situation in Pakistan: In Pakistan the field of obstetrics and gynecology is totally lacking in

maintenance of records at national level. Even local hospital based registries do not report or integrate their findings even if they keep any records. The literature search did not reveal any local data except local registries on cancer and institution based tumor registry in Punjab¹⁵. Shaukat Khanum memorial cancer research centre’s cancer registry and clinical data management registered all cases during last twenty years. According to the data on this registry the commonest cancer amongst adult Pakistani females is breast cancer followed by ovary, uterus cervix, lip and oral cavity.¹⁶ This information can be helpful only if policy makers and people in position of authority design well conducted screening programs to target whole of population or those at risk and develop guidelines for disease management.

Types of Registry: Patient exists in one of the three states relative to the registry, on register (fits inclusion criteria), off register (now is disease free), or at risk (fits the profile that could lead to inclusion). Different types of registries are

1. Product registry including drug and devices
2. Health service registries by patients office visits, hospitalization, procedures, full episode of care
3. Referring physician’s registry.
4. Mortality registry
5. Research patient registry
6. Disease or condition registry
7. Combination

Registry Development: Any new registry should be formulated according to laid down standards of

conducting an observational study. Topics that should be addressed by the standards include:¹

1. Developing a protocol and data analysis plan,
2. Selecting and defining outcome measures and potential confounders and effect modifiers
3. Determining the length of patient follow-up,
4. Using best practices to minimize the potential for selection bias,
5. Collecting data and ensuring data quality,
6. Minimizing information bias,
7. Reducing loss to follow-up,
8. Handling missing data, controlling confounding and evaluating effect modification, assessing the potential for bias, and evaluating external and internal validity.
9. Data analysis standards should also inform standards for design and conduct of the registries

Our Initiative: Keeping the importance of disease registries in mind and in order to inculcate research oriented activities with our everyday work practice a registry has recently been formulated which enrolls all pregnant patients with cardiac disease and monitor fetal and maternal outcome at our department. This department caters primarily to cardiac patients so inclusion and follow up would be systematic. We also have a robust information technology (IT) department which is the corner stone for maintaining computerized registries.

In women with heart disease, maternal mortality is reported to be much higher than average and the risk appears to be increasing such that in western

countries heart disease is the major cause of maternal death.^{17,18} However, we do not fully understand what the impact of pregnancy is on the progression of heart disease or how heart disease affects the outcome of pregnancy.¹⁹ In 2007, the European Registry on Pregnancy and Heart disease (ROPAC) was initiated by the European Society of Cardiology.²⁰ Consecutive patients with valvular heart disease, congenital heart disease, ischaemic heart disease, or cardiomyopathy presenting with pregnancy were enrolled, with the aim of determining patterns of outcome and correlating these with management strategies to determine the areas of danger for both mother and baby and to identify the best forms of treatment. Our registry was based on this ROPAC registry model in which all consecutive patients with heart disease becoming pregnant will be included. This registry will be prospective and retrospective both. Results will be compiled every year regarding demographic characteristics, maternal and fetal morbidity and mortality, use of medical resources like caesarean section, epidural analgesia, cardiac procedures like balloon valvotomy, pacemaker insertion and comparing different type of anticoagulants. Patients will be followed up at six months after delivery. Case report form is shown in figure 1. This will help us to provide better advice to mothers and help in maintaining up to date records for further use as audit and research and continual improvement in patient care by providing reference for developing key performance indicators(KPI) for quality improvement.

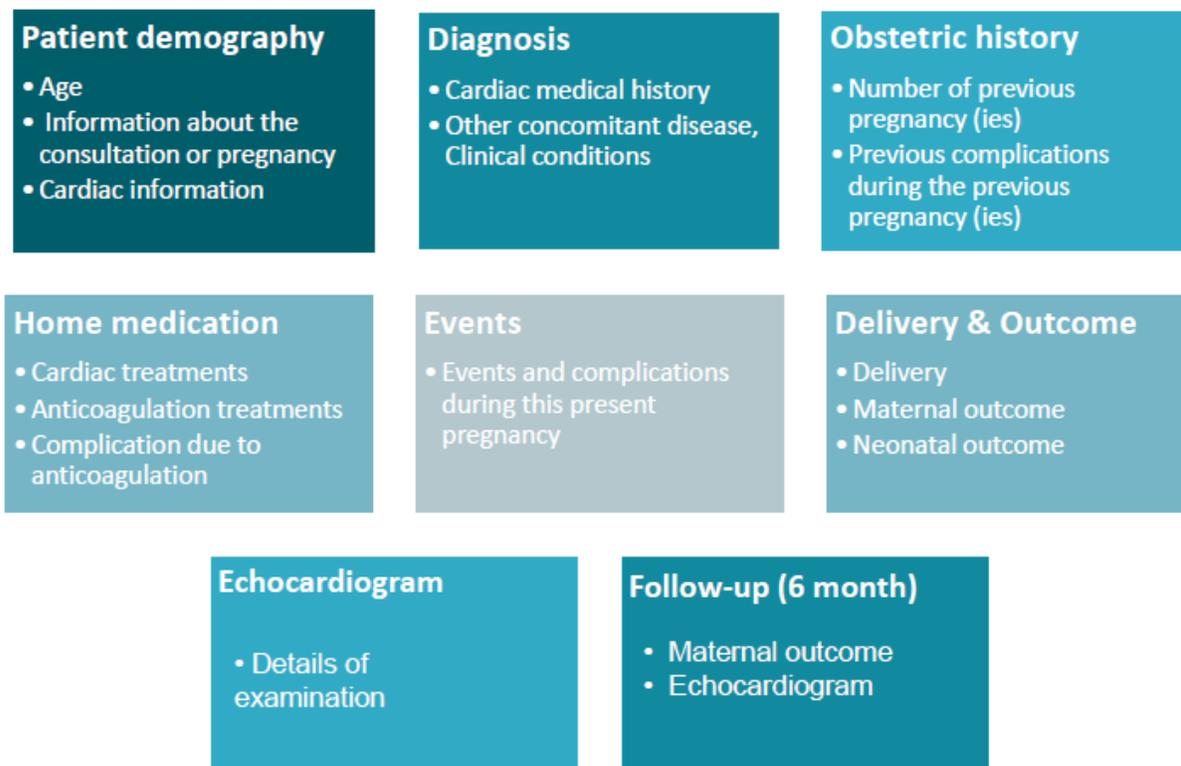


Figure 1: cardiac disease in pregnancy registry data collection form composition.

Recommendations

1. All teaching hospitals should maintain disease registries especially for diseases with a high incidence.
2. SOGP should take initiative in selecting problems with the biggest burden. Disease registries would be the first step towards data collection and identifying characteristics peculiar to our patients and than using this information to develop guidelines for our population.
3. There should be research and development department in all teaching hospitals supported by a IT department.
4. Annual meetings between different hospitals and sharing of findings to improve patient care.

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