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Implementation of a Registry for Acute Coronary Syndrome in Resource-Limited Settings: Barriers and Opportunities

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Abstract

Cardiovascular disease (CVD) is the leading cause of death in Egypt and worldwide, placing great strain on the world's health systems. High-quality treatment of CVD requires a valid, reliable measurement for ensuring evidence-based care. Clinical outcomes registries have been used to support quality improvement activities in some countries, but there are few examples of their implementation in resource-limited settings. A registry for acute coronary syndrome was piloted in 5 hospitals in Egypt, and observations regarding barriers and enabling factors related to implementation are summarized. Themes that emerged from daily observations include the importance of rapid cycles of change, the need to build a culture of applied research, the importance of modeling a blame-free culture, and key constraints encountered related to human resources and technical infrastructure. This pilot demonstrates that clinical registries may be a cost-effective investment in data infrastructure to support quality improvement in low- and middle-income countries.

Keywords

cardiovascular disease, Egypt, quality improvement, outcomes research, clinical registry

Introduction

Cardiovascular disease (CVD) is now the leading cause of death, both in Egypt and worldwide, placing a great strain on the world's health systems.[1] In 2001, 30% of all deaths around the world were caused by CVD and low- and middle-income countries (LMICs) accounted for nearly 80% of these deaths.[2] In Egypt, CVDs accounted for 34% of all-cause mortality.[1]

Effective treatment of acute coronary syndrome (ACS) requires a highly functioning health care delivery system, driven by valid, reliable measurement for continuous improvement. In the

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United States, cardiovascular registries are gaining popularity as the foundation for evidence-based policy, clinical guidelines, and hospital-level improvement efforts.[3] Registries have been used to identify concrete practices associated with improved patient outcomes,[1] identify prevalence of substandard or dangerous treatment patterns,[4-6] and quantifying racial and socioeconomic disparities in both treatment patterns and health outcomes.[7]

However, many low- and middle-income settings lack the most basic information about the quality of the care delivered and the outcomes achieved. Although many systems in high-income settings also suffer from this deficit, the challenges are particularly acute in LMICs, where the data infrastructure is severely lacking in terms of both technology and human capital.

To fill this gap, clinical process and outcomes registries may be a feasible, cost-effective foundation for system-wide measurement in LMICs. Hospital-based outcomes registries are detailed case report forms that capture patient-level information about (*a*) case mix, including presentation and risk factors; (*b*) processes of care including time to treatment, medication, diagnostics and procedures, and details of admission and discharge; and (*c*) health outcomes, including complications and mortality.

Systematic collection of data on health outcomes is a fundamental first step toward strengthening hospital care, and might be especially helpful in LMICs, where resource constraints are a major concern. Registries provide both evidence for the design and prioritization of improvement strategies and a means to evaluate the effects of strategies after implementation. Without an evidence-based approach to reforming care, hospitals and governments risk expending limited capital on less efficient programs with little understanding of whether their reforms have the desired impact.

Rates of CVD are rising around the world, placing increasing burden on already strained health systems. As demonstrated in the United States and Europe, registries have the potential to spark significant gains in patient care.[4-7] Is the potential as great in developing health systems? Are registries a feasible first step in the development of a data infrastructure in LMICs? This article describes the challenges and opportunities identified through the pilot of an ACS registry in 5 diverse Egyptian hospitals, with a focus on the lessons learned through the process of registry development and operationalization. The lessons learned were developed based on qualitative analysis of 3 months of daily staff journals, which were used to facilitate communication between research teams in the United States and Egypt.

Description of the Pilot Study

The pilot was conducted by the Center of Excellence (COE), collaboration between a US-based academic institution and a private sector partner in Egypt. Adapted from the American College of Cardiology's National Cardiovascular Data Registry of Acute Coronary Treatment and Intervention Outcomes Network (NCDR ACTION) registry,[8] the goals of the pilot were to (*a*) assess the technical feasibility of the implementation of an ACS registry, including both the identification of subjects and the availability of data; (*b*) assess the operational feasibility of registry implementation, including the potential to gain buy-in from clinical and administrative leadership at hospitals across Egypt's health sector (private, governmental, and university-affiliated); (*c*) develop a data collection tool and associated data management systems that were culturally and logistically appropriate, while allowing for comparisons across country settings; (*d*) develop recommendations for a long-term plan to assure sustained and effective registry operations; and (*e*) estimate and identify sources for the resources required for registry operations.

The pilot registry was launched in June 2009, with 5 sites volunteering to participate. Four of these hospitals were located in Cairo, and one was in Alexandria. They included a public hospital run by the Ministry of Health, a private hospital, and three academically affiliated hospitals.

More than 530 consecutive patients admitted between July 2009 through January 2010 were included in the study. Inclusion criteria were elevated cardiac markers and a primary diagnosis of ACS.

Observations and Lessons Learned

Lesson 1: Feasibility of Data Collection in the Context of Limited Clinical Documentation

Because a complete medical record was not consistently available at most of the pilot sites, the data collection strategy had to occur in real time. Although this proved to be a major barrier in evaluating the reliability of the data collected, the medical staff at each site engaged a team of medical residents who were able to collect complete data for most patient encounters (more than 80% completion across all variables).

Whereas the data collection form and related definitions were standardized across sites, the process for data collection was not. The registry team relied on the hospitals themselves to best understand the logistics of how to implement a system to most reliably and validly capture that information. Allowing sites to innovate in operationalization led to local problem solving and rapid troubleshooting that was then shared across hospitals.

The effort was supported by a small central office, helping registry leadership to quantify the limited investment in administrative resources required to operationalize the registry, and demonstrating the potential to support many more hospitals over time.

Lesson 2: Importance of Relationships

The willingness of physicians at local hospitals to take on the risk of participating in the registry was fundamental to its success, and the role of personal and professional relationships in identifying early adopters and gaining their buy-in was a key factor in mediating this risk. The registry was established centrally, and then the primary investigators at each hospital were identified as health care leaders who supported the belief that hospital care practices can be improved through systematic review, even though few Egyptian hospitals do this at the depth that the registry demands.

Lesson 3: Role of Rapid Cycles of Change

Rapid cycles of change were used to build trust and create an open dialogue, ensure a locally appropriate and feasible tool, and capitalize on the enthusiasm at the pilot sites. Feedback on the project operations and the data collection form was gathered on a weekly basis through a number of channels: (*a*) weekly visits to each site by registry staff; (*b*) the designation of a lead senior medical resident from each site's Cardiac Care Unit (CCU) to gathering comments, observations, and questions from colleagues; (*c*) direct contact between each hospital's primary investigator and registry leadership to relay concerns or questions; and (*d*) a space on the data collection form for anonymous suggestions or feedback. Suggestions from the pilot sites were incorporated into rapid cycles of change to improve both registry operations and the data collection tool itself. These rapid cycles, occurring weekly in the early stages of the pilot, improved clarity and local "fit" and demonstrated a commitment to responding to local feedback, grounded in a respect for the perspectives and knowledge found at each site.

Rapid cycles of change were also apparent in care processes themselves as front-line staff identified opportunities to immediately improve the quality of care. These "quick wins" emerged as the medical staff engaged in the daily testing and refinement of the data-collection tool. Simply by completing the data collection forms each day, the residents quickly became aware of potential problems in their hospital, like the delays in transferring their patients from the emergency department to the CCU. One hospital amended their transfer protocol within weeks of starting the registry to shorten time to reperfusion. Quick improvements like these helped build excitement and confidence in the purpose of the registry.

Timely cycles of data feedback helped to ensure the quality of the data collected. Because retrospective extraction from the medical record was not possible, the registry relied on real-time collection of data. As pilot sites began to receive regular summary reports that reflected both data completeness and actual summary statistics, the push for more complete data was clear. In addition, by having the medical staff drive the data collection tools and processes, they may have been more likely to trust the data and take seriously its conclusions.

Lesson 4: Culture of Applied Research and Quality Improvement

The registry was designed to capture a detailed account of treatment, with the potential to reveal variation in the care being provided across sites. It was essential that sites trusted the confidentiality of the data. Alignment with an international academic partner combined with an emphasis on collaborative research instead of regulatory mandates helped to establish this trust.

Especially given the involvement of a leading university based in the United States, many residents believed that the registry was a means to transfer American patient care practices to Egypt. By creating the time and space to learn from the pilot sites, and emphasizing the potential for collaborative research, we discovered this sentiment and were able to communicate that the registry form was not a checklist of items to be completed during a patient's care.

More fundamentally, Egypt is a country where an open scientific research community is not yet fully developed. There is little research infrastructure and few funding networks. Most research is done using a limited patient panel through the personal initiative of an attending physician, despite their already heavy workload. Many of the residents who collected data for the registry were motivated to do so because of the rare opportunity to participate in systematic, multisite research that could continue the research work through the rest of their training into their careers after graduation.

Leadership at the pilot sites also identified the opportunities to have direct measures of organizational improvement and the opportunity to benchmark against other hospitals and other national registries as key motivators for participation. Many of the medical staff felt that spending the time collecting data would detract from their ability to care for patients. As a result, much of our early work centered on conveying the potential to transform patient care at their institution using local evidence. The differentiation between the registry and a one-time study was necessary to justify the rigorous methods, many variables collected and long-term investment required.

Lesson 5: Creation of a Nonpunitive Culture

The development of a nonpunitive organizational culture is a complex process and is a recent and ongoing development in many health care systems. When external groups, such as the coordinators of this pilot study, attempt to gather data about a hospital's quality of care, it is essential to communicate that the registry enables accountability aimed at improvement, not punishment.

As in most quality improvement initiatives, we continue to navigate social desirability bias, as sites are incentivized by monthly reports to show "best practice" as opposed to actual patterns of care. In a related challenge, the study team continues to debate how to handle missing variables, balancing the desire to promote complete data with the hesitancy to take action that might promote fabrication of data.

As described above, clear consistent communication about data management strategies was important, as sites were concerned that hospital or individual performance would be shared with others.

Lesson 6: The Realities of Human Resource and Technology Constraints

We were interested in exploring the feasibility of compiling registry data in settings in which clinical documentation is limited or inconsistently recorded. Although real-time data collection proved to be possible, it is important to invest in the development and implementation of medical records systems to support both direct patient care and more sustained health services research.

In the United States, most data collection is done by nurses or technicians. However, the medical technician and allied health worker population in Egypt is very small, the level of training received by nurses is highly variable, and nurses were not generally viewed by site leadership as being able to fill detailed medical case report forms like those in the registry without additional training or orientation.

Some physicians in Egypt had experiences in which they were paid to participate in registry data collection. Monetary compensation was not sustainable for the registry over the long term. Ultimately, a major incentive was the prospect of participating in research rather early in their careers. In addition, the primary investigators at each hospital site, who served as the chief collaborators with the COE, are also the superiors to the residents who participated. Thus, there was a risk of punishment or the potential to lose face if the resident did not fulfill his or her responsibilities for the registry. Residents are expected to continue to drive the registry efforts in the near term. All of the sites emphasized the importance of resident engagement for 2 reasons: (*a*) residents are actively engaged with the patient and can understand the complex medical cases, resulting in more accurate data collection in the absence of thorough, reliable clinical documentation in the medical record and (*b*) the sites use the actual real-time experience of the pilot to thoroughly train the residents, using the data-collection tool to guide case reviews. It is unclear whether this level of resident engagement in data collection is sustainable over the long term.

Scientific researchers, data managers and analysts are also in limited supply in Egypt, a barrier for local ownership of the registry in the near future. Potential next steps include the development of collaborative training programs for scientists, leveraging of academic partnerships to develop infrastructure, and alignment with professional organizations to embed applied research into preservice and in-service training programs.

A remaining question is, What are the key opportunities in training to leverage now for sustainable operations over the long term?

Conclusion

The lessons learned from this pilot indicate that clinical outcomes registries may be a feasible, scalable investment in response to the call for data in global health, with direct links to applied quality improvement. Despite this potential, the ACS pilot in Egypt has begun to reveal the kind of challenges that exist to implementing coronary registries in resource-limited settings. Some challenges are systemic, such as a lack of reliable medical record and limited research infrastructure. Some are related to organizational culture, such as the need to build trust and a nonpunitive culture of applied research. Although hospital and health system contexts and constraints may vary, the enabling features identified through this pilot implementation may be useful to quality improvement leaders and health outcomes researchers across settings.

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