Neurotrauma Registry Implementation in Colombia: A Qualitative Assessment

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Abstract

Objectives   Latin America is among several regions of the world that lacks robust data on injuries due to neurotrauma. This research project sought to investigate a multi-institution brain injury registry in Colombia, South America, by conducting a qualitative study to identify factors affecting the creation and implementation of a multi-institution TBI registry in Colombia before the establishment of the current registry.

Methods   Key informant interviews and participant observation identified barriers and facilitators to the creation of a TBI registry at three health care institutions in this upper-middle-income country in South America.

Results   The study identified barriers to implementation involving incomplete clinical data, limited resources, lack of information and technology (IT) support, time constraints, and difficulties with ethical approval. These barriers mirrored similar results from other studies of registry implementation in low- and middle-income countries (LMICs). Ease of use and integration of data collection into the clinical workflow, local support for the registry, personal motivation, and the potential future uses of the registry to improve care and guide research were identified as facilitators to implementation. Stakeholders identified local champions and support from the administration at each institution as essential to the success of the project.

Conclusion   Barriers for implementation of a neurotrauma registry in Colombia include incomplete clinical data, limited resources and lack of IT support. Some factors for improving the implementation process include local support, personal motivation and potential uses of the registry data to improve care locally. Information from this study may help to guide future efforts to establish neurotrauma registries in Latin America and in LMICs.

Keywords
► traumatic brain injury
► LMICS
► trauma registry
► neurotrauma

Introduction

While traumatic brain and spinal cord injuries (TBI and SCI, respectively) are a worldwide public health problem, most researches in this area have been conducted in high-income countries.

Epidemiological data on the incidence and impact of the burden of disease lack in several regions of the world.[1,2] The World Health Organization (WHO) Global Burden of Disease Study suggests that Latin American countries have the highest incidence of brain injury in the world.[3,4] One study assessing factors associated with TBI outcomes in 550 patients from nine clinical sites in Colombia, Argentina, Brazil, Bolivia, and Ecuador found that these patients had a higher rate of mortality than that which was reported in studies from higher income countries.[5] Moreover, there are regional differences in health systems that may impact the care of patients with neurotrauma in Latin America.[6] Hospitals may not have equipment for advanced neuro monitoring, leading to differences in management.[7,8] There is a need to collect regional data on neurotrauma to understand the burden of these injuries and to inform treatment protocols to fit the local context.

Patient data registries are a powerful tool for the collection of data in trauma research.[9,10] Registry data may be used for comparative effectiveness and cost-effectiveness research and may guide the development of standardized trauma protocols (STP). One retrospective cohort study investigating the use of an STP at a level-1 trauma center in Colombia found improved outcomes after STP implementation. In that study, in-hospital mortality decreased, and discharge Glasgow coma scale (GCS) increased from 10 to 14.[11] Collecting regional neurotrauma data could be a first step in developing plans to build on existing social and political alliances. Such partnerships could also facilitate collaboration with larger global health initiatives. However, there are difficulties in establishing data registries, particularly when data collection is spread across multiple facilities. Variation in local ordinances regulating data sharing and privacy and variability in treatment patterns and protocols can complicate registry administration and delay implementation.[12] Implementation science offers methods to identify barriers to these efforts and suggests possible solutions.

In this research project, we conducted a series of interviews to identify factors affecting the creation and implementation of a multi-institution TBI registry in Colombia.

Methods

We used key informant interviews to identify barriers and facilitators to the creation of a TBI registry at three participating health care institutions in Colombia. We identified stakeholders through snowball sampling and used key informant interviews to characterize current registry data collection practices. Snowball sampling is a nonprobabilistic sampling method that may be used to identify members of hidden populations.[1] This method has been used previously in qualitative global health studies to identify participants across a broad geographical area.[2,3] This group included researchers, clinicians, and trainees across different institutions in Cali, Bogota, and Neiva, in Colombia. The snowball sampling method allowed us to quickly identify and recruit participants. Interviews were used for data collection to allow participants to freely express their thoughts in this implementation effort. Interviews were audio recorded and transcribed. Observations were recorded in daily activity logs and coded for themes. The institutional review board (IRB) at the University of Pittsburgh approved this study. The research was conducted with permission from the ethics committee at Fundacion Meditech and with permission from the three participating health care institutions.

Setting

Interviews were conducted at three institutions in two metropolitan areas. One site was a large university hospital in Bogotá. Another was a large public teaching hospital in Cali with an emergency department, operating theaters, and dedicated neurotrauma intensive care unit (ICU). The third was a private clinic for the care of patients of road traffic accidents in Cali. Interviews were conducted with researchers and trainees at Fundacion Meditech, an educational and research foundation based in Neiva and Cali that serves as the coordinating center for the registry.

Key Informant Interviews

The interview questions were designed using the Theoretical Domains Framework (TDF) which is a set of 12 domains used to guide the implementation of health care initiatives.[13-16]

Our research group previously used this framework to investigate the transition from paper to electronic surgical records in a low- and middle-income country (LMIC).[15] We adapted the focus group questions used in this effort to fit the context of a multisite neurotrauma registry. Two researchers with experience in trauma systems research in Latin America reviewed this revised question set. The questions were translated. The translation was again reviewed for accuracy and relevance by the research team.

Interviews took place over a 6-week period in 2018. Participant names and other identifying information were not recorded. Interviews were conducted in either English or Spanish. A translator fluent in both languages was available to assist during interviews. Interviews were audio recorded, then transcribed for coding. Spanish interviews were translated into English and were compared with the Spanish transcripts and reviewed for accuracy by a member of the team.

Participant Observation

The ethnographic portion of this study aimed to understand the current state of implementation of the neurotrauma registry at each study site. Participant observation is a form of ethnographic research where a researcher observes and records data while engaging directly with the sample population.[17,18] This method was selected to encourage communication between the researcher and those working locally

on the registry. Observations were conducted in research and administrative offices in participating institutions, as well as in emergency departments, outpatient clinics, ICUs, and operating rooms.

Qualitative Coding

Our analysis was focused on identifying barriers and facilitators to the implementation and use of the neurotrauma registry. Qualitative findings from interviews and observation logs were organized into themes. The data were coded independently by two of the research team and were grouped into relevant themes. Any disagreements were resolved by consensus.

Results

Summary of Implementation Efforts and Identification of Stakeholders

At the time of the study, pilot data collection had been active at three study sites for approximately 6 months. Researchers had developed a targeted set of registry data domains and data elements through a process of iterative review by regional content experts, such as physicians, health care providers and researchers working in neurosurgery, trauma and emergency services in several Latin American countries, and developed to fit regional needs and differences in health care delivery and management. The study team had selected and tested an online data collection tool. Two trainees developed the online platform with the support of their university. These two trainees were also primarily responsible for the support and maintenance of the registry platform. The registry itself was maintained on servers at a large, private university in Bogotá, Colombia, and administered through a secure online data collection system. Pilot data collection had commenced at three clinics associated with a private hospital for the treatment of road traffic injuries in Cali, Colombia. Physicians working in the emergency department, outpatient clinics, surgical services, wards, and ICU of the pilot sites identified eligible patients and entered patient data into the online data collection tool. Clinicians and researchers at the two other participating health care institutions had identified personnel to perform patient identification and data entry, received training in the use of the registry tool, and worked with their local IRBs to obtain ethical approval for the project.

We identified clinicians specializing in emergency medicine, critical care, general internal medicine, and neurosurgery as stakeholders in the registry. Nonclinicians, such as researchers, hospital administrators, policymakers, patients, members of the public, and trainees, including medical students, interns, residents, fellows, and graduate students, were also identified as stakeholders.

Identification of Themes

Throughout the study, we conducted 20 interviews with key stakeholders in the neurotrauma registry. Participants identified time constraints, funding and resource limitations, information technology (IT) and software issues, challenges in obtaining ethical approvals, deficiencies in clinical data collection and lack of long-term follow-up as barriers to implementation efforts. Factors that helped with efforts to create the neurotrauma registry included the ease of use of the registry tool, the ability to integrate registry data collection into the clinical workflow, the presence of local champions, and individual engagement with the project. Support from the administration was cited as both a barrier and a facilitator, depending on the perceived level of support for the project from institutional administration.

Stakeholders frequently discussed their goals for registry data. Many participants stated that using registry data to improve the quality of patient care at their institution was a central goal of the project.

Barriers to Implementation: Incomplete Clinical Data

Most stakeholders described limited or incomplete clinical data collection as a significant barrier to the success of the project. One respondent said, "we know the importance of cranioencephalic trauma, but we do not record it in the clinic. We know it, and we see it, but we do not write it down. For example, a patient has amnesia, but they didn't record for how long, what is the time course of the amnesia." Another said, "what makes it difficult is that the data as such is not complete. What would help us to create the registry? First, to have complete data to be able to do it. To know statistically how many patients are admitted each month, what was their evolution over time, what was their treatment; I think that would be important." Occasionally, data were missing due to issues with equipment and other resources. One stakeholder mentioned, "for example, they wrote, 'pupils equal and reactive' in the electronic record, but they don't calculate pupil size, because we don't have an established method to measure the pupils." Many stakeholders were concerned with the lack of long-term follow-up in their patient population. One clinician pointed out, "the study's follow-up period is 24 months, and the patients here are vulnerable patients, and in some cases, outpatient follow-up is difficult." Another provider described loss to follow-up because of insurance issues. "When the patients come here, they come here with insurance support, but this insurance has a limit, more or less $5,000. When the patient's cost of care surpasses this amount, the patient should go on to receive medical assistance with his insurance company. And then we lose the patient."

Limited Resources

Limited resources were another frequently described barrier. One stakeholder said, "well, the Wi-Fi here does not serve us much (laughs) because it fails. Then there is the issue of the computers: there are times that using the clinic computers is problematic. Here there are only two computers, so that part is difficult." Most stakeholders described computer and IT issues. For example, one stakeholder mentioned, "The only problem is that sometimes the platform falls off. Sometimes we load some data, we record the data, and suddenly when we next open the platform, the data were lost. Suddenly, all of the data are lost." Other issues with the platform include errors in the database. One stakeholder said, "I notice a lot of

errors with the branch logic. I don't know if the other person (IT support) has much time to correct those errors." One individual remarked, "another issue is the lack of dedicated IT support staff at the university; most of these guys handle a number of different projects, not just the registry. When there are problems with the registry, we often have to wait until they have time to address them."

Time Constraints

Many stakeholders mentioned that time constraints posed a significant challenge. One said, "within the time part, it is quite difficult. We are two doctors here in the hospital part, and we have many patients. Here at (our clinic) is where there is the highest volume of hospitalized patients. Then there are 40, 50 to 60 patients, in a 2-hour shift, it is necessary to type everything, absolutely everything, then the time is quite limited." Another talked about the time to enter patient data into the registry tool: "the most difficult thing could be the number of items, but it is something that has to be evaluated. If more information is required, obviously much more time is required to fill it; that comes into play."

Finally, ethical approval at the many clinical sites was described as a significant barrier. "It is a matter of ethics, and above all, of going through all the committees of each institution in order to have the approval ...." Another researcher said, "then, there is also the issue of how to obtain IRB approval at all local sites–it can be difficult and time-consuming. Currently, we are focusing our attention on sites where approval is already in place. For other sites in general, the process is to give them the IRB applications submitted already and to act as resource if there are any questions."

Positive Factors: Ease of Use and Integration of Data Collection into Clinical Workflow

A commonly cited strength of the neurotrauma registry was the simple, easy to navigate online data collection system. One stakeholder said, "the form is something that is quite (user-) friendly. It can be filled out very easily." Others felt that the flexibility of the platform facilitated data entry. "You can enter (data) anywhere. You don't have to only use the computer. You can do it on your laptop or in your office, anywhere." According to many stakeholders, the perceived strength of the project was that the data collected for the registry was often collected during routine care, and they could easily integrate it into their workflow. One individual stated, "The other thing is that the information we collect is basic, it is data that are collected in the evaluation and tests that are done with the patient." Another said, "here in this institution, for the registry, we can work with the medical personnel, the technical personnel in nursing, who are the ones helping us with the collection of information. It is simple to integrate the information and the items that you require." He continued, "I do believe there is a way to focus all the health personnel to keep a record. At this time, we do have more administrative and billing (data collection) processes than clinical processes. You would have to start working with the clinical record ....

So, they can include data collection for the registry in what they are doing every day."

Local Support and Motivation

Several stakeholders highlighted that local support for the registry was a key facilitator of their efforts. One said, "we have a lot of support for the program, which is demonstrated by funds we have been provided from hospital leadership to support travel to conferences and meetings.

Then, we have some passionate physicians and residents who are dedicated to getting the registry up and running."

Still, others stated that motivation and engagement were critical to the success of the registry.

One participant pointed out, "you need to let people know why it is important, and then they will be motivated to do it." Another concluded, "I think that the first step is for people to be in love with idea, you know, and after that, the people will make the compromise to make it happen." Several respondents discussed the importance of engaging support by highlighting the impact of the project. One participant stated, "So, if I could understand why registries are so important, then I would like to be involved. Rather than it just being a part of my work, I would be involved." Another said, "I think that if you explain … the magnitude of the project, that there is no data (on neurotrauma) in Colombia, in Latin America, then they will be like, 'Ok, let's do it.' That is important, to explain the project. For example, in the ICU, when I presented the project to them, all the, 'Oh, I want to help … how can I get involved?'"

Future Use

The majority of stakeholders interviewed emphasized that their primary aims in working with the project were to improve the quality of care offered to their patients and improve patient outcomes. One said, "I believe that the registry may help, may serve to better treat the patient with neurotrauma. You can look for ways to generate better management than what was used initially to treat those patients." Another stated, "the information will ultimately allow institutions to evaluate themselves and to draw conclusions about how we can optimize care. So, I think the registry will do just that." One clinician said, "by knowing the information, we can start taking action, more precise measures can be taken based on the real needs we have; then we would have a record that will allow us to make a detailed analysis about how to improve our performance and what to focus on promptly."

Researchers and clinicians at participating institutions saw several other potential uses for registry data. One researcher said, "first, I would like to do an epidemiological description of neurotrauma impact and burden. Second, we could do it in our country, and then in Latin America, our whole region. That doesn't exist yet. We don't know the real burden of neurotrauma in our country." Two respondents emphasized the need to build "a culture of research" in Latin America. Three others hoped to use registry data to drive health policy. One said, "first we have to know the real burden of epidemiological data, and then work with that on public policies."

Discussion

This study is the first qualitative assessment of a multi-institution neurotrauma registry in Latin America. We found that data quality, resource and staff limitations, time constraints, and technological issues complicated implementation efforts, while a user-friendly data collection tool that was quickly integrated into clinical workflow helped to facilitate the adoption of the neurotrauma registry at pilot sites. Many stakeholders stressed the importance of local champions at participating sites to maintain project momentum and ensure progress. A majority felt that education about the goals and impact of the project was the most effective way to engage support for the project in their hospital and their community.

While few published studies have assessed the creation of traumatic brain or spinal cord registries in resource-limited settings, the barriers described in this research are like those found in implementation studies of trauma registries in other LMICs. In a 2018 literature review of 28 studies investigating trauma registry implementation in resource-limited settings, Bommakanti et al found that problems with data quality, limited resources, poor prehospital care, and administrative or organizational difficulties were commonly cited barriers in LMICs across the globe.[19] The authors also cited five studies describing limited stakeholder buy in and trauma education as barriers to trauma registry development. Similarly, St-Louis and colleagues conducted a systematic review of the literature to characterize positive and negative factors affecting the creation of trauma registries in LMICs and found that insufficient funding, incomplete data, and limited resources were the primary barriers to trauma registry implementation.[20] Most articles included in these reviews were studies of single-institution registries and few assessed multi-institutional registries.

Our results highlighted the critical role local champions played in developing the neurotrauma registry. Local support is essential to obtain funding, integrate registry activities with clinical care, and coordinate personnel to conduct research. Findings of barriers to registry implementation suggest other ways to guide future efforts. For example, issues with data quality are almost universal in registry implementation studies in resource-limited settings. Agreeing on standard process and outcome measures and training study staff in their use could decrease variability in the documentation and improve data quality. Standardized protocols for clinical data collection could also be used to improve documentation practices in study sites. Identifying roadblocks to obtaining ethical approval for research across many institutions and many cities could also help. This research demonstrates how qualitative research methods can be used to evaluate implementation efforts and guide research in resource-limited settings.

Limitations

There were several limitations to this study. The sample size for the key informant interviews was small ($n = 20$). However, our target population was also small as it was limited to individuals engaged in the implementation of the TBI registry at participating health care institutions. Additionally, qualitative coding of completed interviews demonstrated data saturation, indicating that this sample size was appropriate to answer our research question.

Another limitation of this research is that participant observation identified policy makers and members of the public, including patients and their families, as key stakeholders in this research even though the majority of respondents were administrators, researchers, and clinicians. While the interview tool used in this research was developed for researchers, clinicians, administrators, and other professionals working with the health care system, future qualitative studies could assess attitudes, knowledge, and beliefs in these other populations.

Conclusion

We were able to use key informant interviews to identify factors affecting the implementation of a national neurotrauma registry in Colombia. Like other studies of registry implementation in LMICs, barriers to the registry had to do with time constraints, issues with clinical data collection and limited resources. We found that stakeholders believe that having support from the administration at each institution was essential to the project's success. We hope that this work will inform future collaborative efforts to establish neurotrauma registries globally.

Conflict of Interest
None declared.

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