

Framework for Neurosurgery Database Implementation in a Low-Resource Setting

by

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Thesis submitted in partial fulfillment of
the requirements for the degree of
Master of Science in the Duke Global Health Institute
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ABSTRACT

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Abstract

Despite significant potential for informing and driving global neurosurgery research and clinical efforts, there are significant barriers to obtaining high quality, interoperable neurosurgical data in LMICs. The aim of this paper was to initiate development of a simple, reproducible framework to guide prospective database implementation. We adapted existing established frameworks to the global neurosurgery research context and then used a case study to assess how well the framework anticipated quality issues. The proposed framework encompasses domains and key facilitators to producing high quality, interoperable neurosurgical data in low-resource settings. Future studies are needed to evaluate and further refine this framework.

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1. Introduction

Each year, more than 5 million people suffering from a treatable neurosurgical condition will never receive a therapeutic neurosurgical intervention¹. Nearly 100% of these untreated neurosurgery cases will occur in low-and middle-income countries (LMICs)^{1,2}. An estimated 23,000 neurosurgeons are needed to fill this deficit¹. In response to this magnitude, there has been an increase of global neurosurgery partnerships between institutions of high-income countries (HICs) and hospitals of LMICs³. These collaborative efforts will have the most impact if they are data-driven but to date, the availability of neurosurgery data in LMICs is lacking⁴⁻⁶. These efforts will be thwarted by the lack of quality data.

There are several challenges to obtaining quality neurosurgery data in LMICs. Hospital medical records are largely paper-based, and it requires significant time and resources to retrospectively collect data from these records^{7,8}. The information within these records tends to lack the granularity of interest to neurosurgery research^{5,6,9}. While recent advancements in technology have preceded a global shift of health sectors in LMICs moving towards electronic, standardized medical record systems, these new systems represent a longer-term solution to generating high quality neurosurgery data¹⁰. One proposed short-term solution is prospective electronic data collection systems^{3,11}. However, there are barriers to successfully developing and implementing these systems

which include securing funding, balancing multiple institutional demands across countries, and other general implementation challenges^{6,12,13}.

Surgical research databases in low-resource settings also face numerous ongoing difficulties that decrease their value. These difficulties include (1) limited human and technology resources required to maintain an electronic database system; (2) data quality issues which are largely related to how the research workflow of the database is integrated with clinical workflow; (3) and interoperability issues stemming from inconsistencies in data structures and terminology that prevent aggregation of data across multiple sources^{12,14-17}. The lack of published guidance for developing, implementing, and evaluating surgical research databases in low resource settings compounds these issues. Despite a proliferation of publications stemming from surgical research databases, the reports are largely patient-centered and epidemiology-based. Data quality issues or implementation challenges are often noted in discussion or limitation sections, but quality issues are rarely the center of focus^{18,19}.

Currently there is no consensual framework for data collection in multi-resourced settings to guide data collection and ensure quality and interoperable data for neurosurgery partnerships. In response to this gap, we aimed to create a comprehensive framework that addresses 7 domains which could impact quality data collection. In this present study, we initiated development of a framework that fills this gap and then used

case study findings to assess how well the proposed framework anticipates quality issues.

2. Methods

2.1 Study Overview

We developed our framework by adapting existing frameworks to the global neurosurgery partnership context. We conducted a case study to better understand quality-related issues of prospective data collection in low-resource settings. We chose a case study design because its flexibility captures holistic and meaningful characteristics of real-world settings. We first evaluated the quality of an existing neurosurgery database in a low resource setting and then used structured observations and interviews to explore potential causes of poor quality. We then mapped our case study findings to the proposed framework to see how well the framework anticipated the quality issues observed in the case study.

2.2 Framework Development

We developed our framework by adapting (1) World Health Organization and International telecommunication Union's eHealth components and (2) Path and Vital Wave's Theory of Change for Accelerating Data Use within a national health system context^{10,20}. Both are frameworks which prioritize areas to target by assessing causes of poor data use culture rather than focusing on deficiencies in equipment, supplies, and procedures. The Path and Vital Wave model provides an organizing framework for how the WHO eHealth components work to strengthen the production and use of data to drive data-driven decision making. This continual cycle of data production and use

eventually can lead to different outcomes. The framework illustrates that each component acts as a “lever” and with investment, each lever can sustain the cycle of data demand and information use. Similarly, a lever can act as a decelerator without investment or presence. The Path-Vital wave model primarily focuses at the national or country level and we adapted it to the global neurosurgery partnership context. To adapt this model, we identified key activities of data production and information use of global neurosurgery partnerships and then considered the specific resources, infrastructure, and capacity needed to introduce or sustain prospective data collection. To guide the latter, we also referred to the WHO Monitoring and Evaluating Digital Health Interventions Practical Guide²¹.

2.3 Case Study Methods

The purpose of undertaking a case study was to explore causes of poor data quality in a real-world context and compare these findings to our proposed framework to see if the framework was missing anything related to data quality.

2.3.1 Setting

Mbarara Regional Referral Hospital (MRRH) is located in Mbarara district in Southwest Uganda. MRRH is a 600-bed government-run hospital with a catchment area of over 3 million people and serves as the specialty referral hospital for a region of 8 million. The MRRH neurosurgery department was established in 2012 and currently employs one full-time neurosurgeon. The neurosurgery department sees nearly 700

patients and performs approximately 200-250 neurosurgeries annually. Traumatic brain injury (TBI) accounts for approximately 70% of all neurosurgery patients and neurosurgeries. In 2016, the Duke division of Global Neurosurgery and Neurology (DGNN) and the neurosurgeon at MRRH collaborated to establish a prospective electronic neurosurgery database at MRRH. The primary goal of the database was to collect neurosurgery patient care data in order to describe the neurosurgery burden at MRRH and identify current treatment patterns and potential quality improvement areas. Inclusion Criteria is defined as all patients presenting to MRRH with a neurosurgical disease or injury. Exclusion Criteria is defined as (1) patients presenting with other non-neurosurgical disease or injury and (2) patients who were suspected to have head injury or neurosurgical issue, but it was determined otherwise.

The database was designed to be very comprehensive and collects over 300 data elements. Currently, Microsoft Access is used as the database management system. The data clerk collects data by hand on paper and then manually enters data into electronic case report forms on Microsoft Access. Data is stored locally on an encrypted password protected laptop supplied by DGNN. Periodically, the research site coordinator uploads de-identified data to a firewall protected cloud server, Box, where it can be accessed by DGNN. DGNN employs a full-time data clerk to collect data and manage the database. The data clerk receives a salary equivalent to a research assistant. Additionally, DGNN

also provides a monthly stipend (approximately 50 USD per month) to the neurosurgical technician to oversee collection of specific surgery variables

2.3.2 Mixed Methods Approach

Our mixed methods approach followed a sequential explanatory approach. First, we used a quantitative analysis to examine completeness of the data within the database. We then used these findings to guide our qualitative data collection.

2.3.3 Data Collection Procedures

Using a sample dataset from the database, we collected quantitative data on completeness of 24 variables across the following domains: sociodemographics, injury-related events, assessments and examinations, treatments and interventions, and outcomes. Domains and variables were selected given their importance to quality improvement and neurotrauma research. Completeness refers to whether or not a value for a given variable for a specific patient was or was not present²². We then used these results to tailor our guides for structured observations and semi-structured interviews. We also created an additional tool to accompany our observation guide, which we designed to systematically track the generation (or lack thereof) of sociodemographic and vital sign variables on morning neurosurgery team rounds. Additionally, we explored semantic interoperability of the 24 variables. Semantic interoperability refers to the way variables are defined, coded, and stored within the database²². To assess semantic interoperability, we compared the variables with the National Institute of

Health and the National Institute of Neurological Disorders and Stroke (NIH-NINDS) recommended Core Data Elements (CDEs) for traumatic brain injury (TBI)²³. All data collection procedures for the case study took place October 2018 to December 2018 at MRRH, Mbarara, Uganda.

2.3.4 Ethical Considerations

We received ethical clearance from the Institutional Review Boards of Makerere University, Uganda and Duke University.

2.3.5 Analysis

Variables from the sample dataset were sample dataset were uploaded into R Studio for quantitative analysis. Quantitative data collected during structured observations using paper forms were manually entered in Excel and then uploaded in R Studio for quantitative analysis. Simple descriptive statistics were used to calculate frequencies and percentages. Visualization techniques were used to explore incomplete data for patterns or trends of missing data. Qualitative data collected from interviews recordings were transcribed and organized thematically. We used qualitative data to construct data flow maps. We used R Studio Language for Statistical Computing 3.4.1 for all data management and statistical analyses²⁴.

3. Results

3.1 Proposed Framework

Our proposed framework consists of 7 domains each adapted from an eHealth component and represents a required component for enabling and sustaining the data production and information-use activities of a neurosurgery database (figure 1). Within each domain is a checklist of key facilitators. This checklist, while not exhaustive, provides a mechanism for organizing what is known and present as well as what may need to be introduced or strengthened to conduct successful prospective data collection.

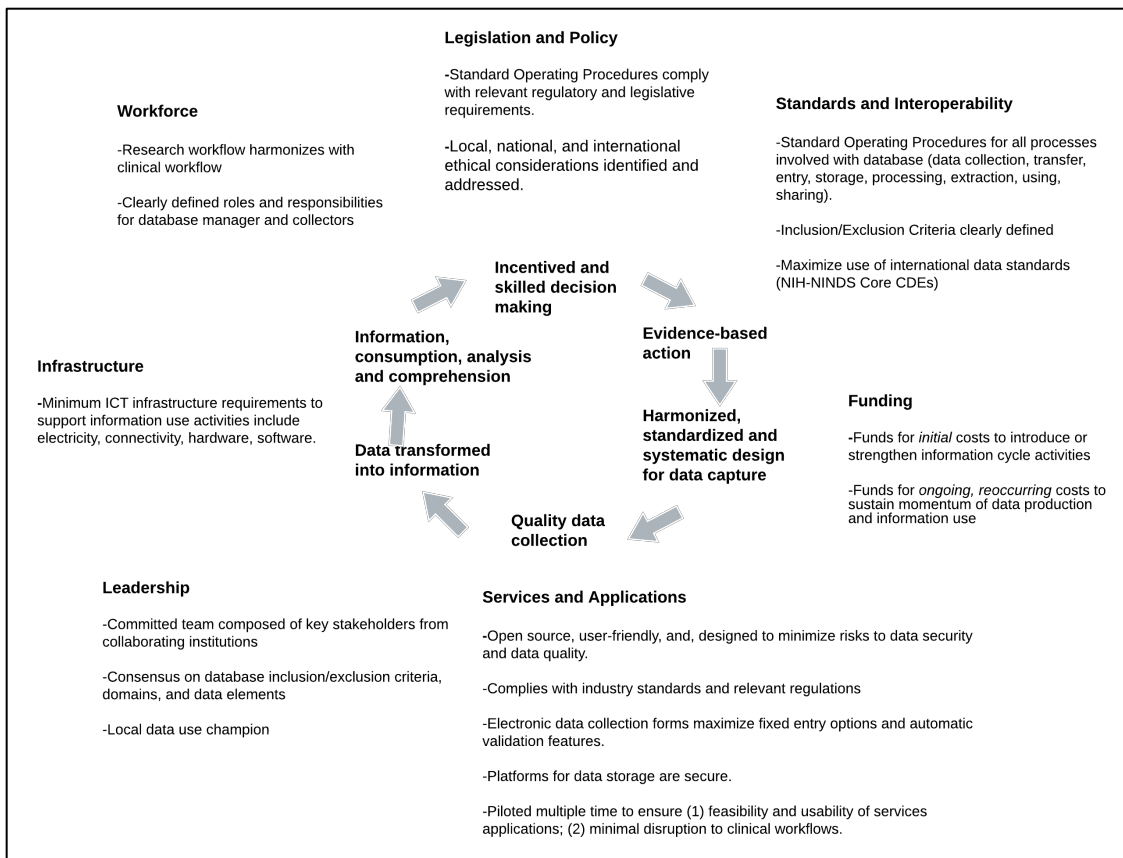


Figure 1. Proposed framework.

3.2 Case Study Findings

In our sample dataset of 627 cases, we found that completeness varied significantly across the 24 variables (table 1). Of the 4 sociodemographic variables and 5 injury-related event variables assessed, all were more than 90% complete. While outcome data were more than 95% complete, discharge Glasgow outcome scale (GOS) and discharge Glasgow coma scale (GCS) were about 70% complete. We found the assessment and examination variables to be the most incomplete. With the exception of pupil reactivity and pupil size which were both more than 97% complete, completeness varied from 64% (heart rate) to less than 4% complete (temperature). Of the 24 variables we examined completeness of, we were able to conceptually map 20 variables to NIH-NINDS CDE variables (table 1). Direct comparisons of coding standards were limited because the MRRH neurosurgery database does not have an accompanying data dictionary or operating manual.

Table 1. Completeness and semantic interoperability results.

Sample dataset of 627 cases covering Jan 2016 to Dec 2016.			Maps to CDE variable = X
Variable		Complete n (%)	(Grey fill indicates variable is coded the same as CDE variable)
Sociodemographics	<i>Patient's Age</i>	625 (99.7)	X
	<i>Gender</i>	612 (97.6)	X
	<i>District</i>	577 (92.0)	
	<i>Education</i>	598 (95.4)	X
Injury-related Events	<i>Admission Date</i>	626 (99.8)	X
	<i>Injury Type</i>	599 (95.5)	X
	<i>If Road traffic injury, type</i>	601 (95.9)	X
	<i>Injury/Symptom Date</i>	586 (93.5)	X
	<i>Polytrauma</i>	600 (95.7)	X
Assessments & Examinations	<i>GCS</i>	196 (31.3)	X
	<i>Systolic Blood Pressure</i>	325 (51.8)	X
	<i>Diastolic Blood Pressure</i>	323 (51.5)	X
	<i>Temperature</i>	21 (3.3)	X
	<i>Heart Rate/Min</i>	401 (64.0)	X
	<i>Pulse Ox</i>	114 (18.2)	X
	<i>Unequal Pupil Size</i>	617 (98.4)	X
	<i>Pupil Reactivity</i>	614 (97.9)	X
Treatments & Interventions	<i>Oxygen Supplementation with Cannula</i>	608 (97.0)	X
	<i>Management</i>	599 (95.5)	
	<i>Did patient require ICU?</i>	328 (52.3)	
Outcomes	<i>Outcome</i>	601 (95.9)	X
	<i>Outcome Date</i>	602 (96.0)	X
	<i>Discharge GCS</i>	432 (68.9)	X
	<i>Discharge GOS</i>	442 (70.5)	

Our completeness results were used to inform our qualitative data collection activities. Structured observations focused on how variables are generated, collected, and compiled before entered into the database. Our semi-structured interview guide also contained open-ended questions with key stakeholders to better understand our quantitative findings. Data collected during observations and interviews were combined

to construct a data flow map (figure 2). The flow map illustrates the flow of data through data collection activities, as well as through various stakeholders.

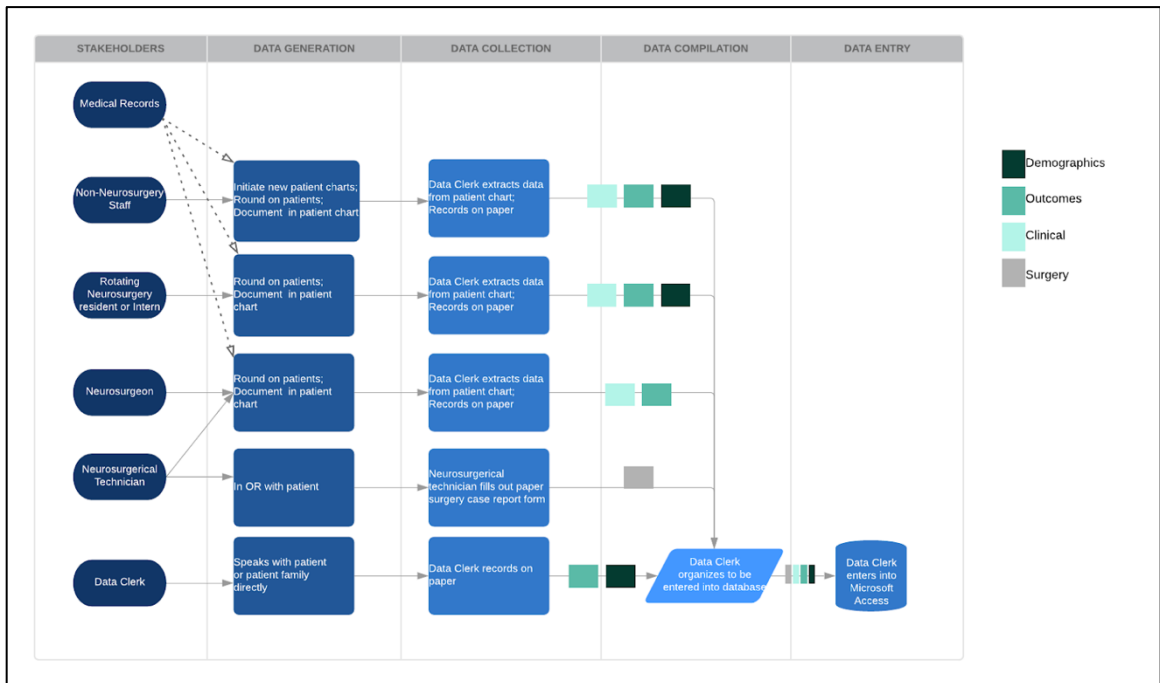


Figure 2. Data Flow Map. Visualization representation of the flow of data as it is generated, collected, compiled, and entered into the database.

Findings from our structured observations tracked variables on morning neurosurgery rounds and are presented in figure 3. Of the 75 data collection points collected over a 2-week period on morning neurosurgery rounds, demographic variables (age, gender, and address) were generated 100% of the time by non-neurosurgery staff. These can be contrasted with clinical variables (blood pressure, oxygenation saturation levels, heart rate, and temperature), which were generated less than 50% of the time. Lack of equipment was the most common reason for variables not being generated. However, for blood pressure, heart rate, and temperature, there were many events when

the necessary equipment was present, but the variable was not collected. In these cases, the apparent reason was that it was not emphasized.

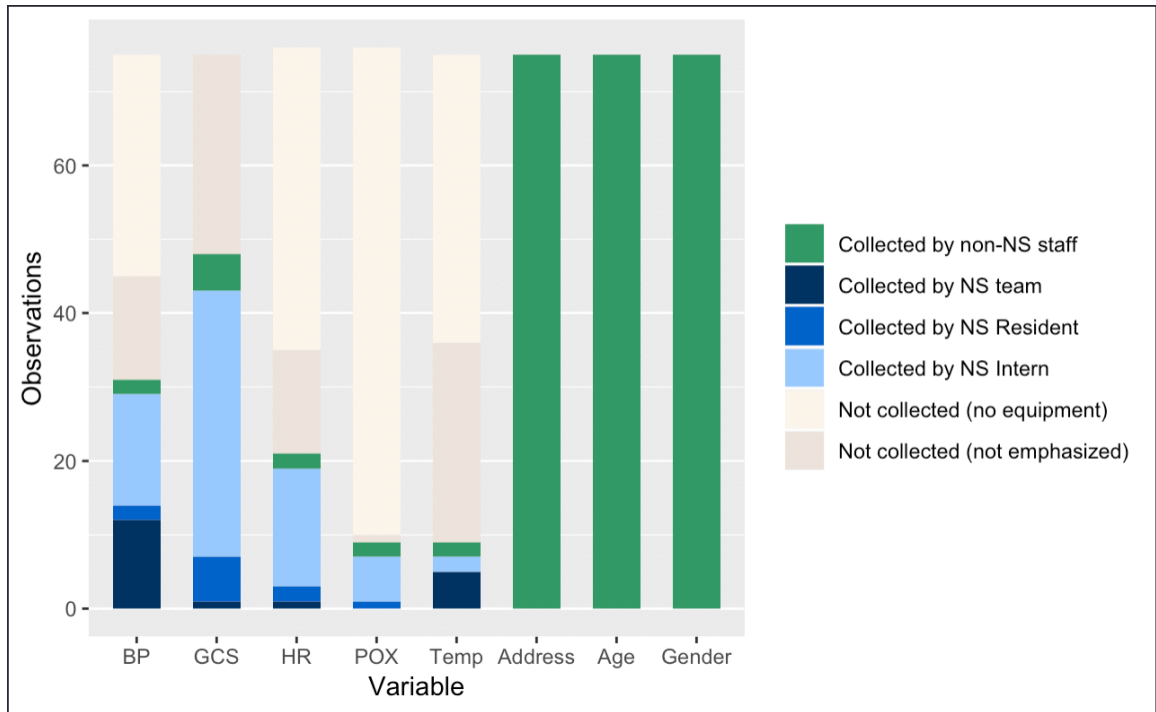


Figure 3. Bar plot presenting collection status by variable type. Total direct observation points = 75.

4. Discussion

We developed an overarching framework which could guide global neurosurgery partnerships in implementing and sustaining quality prospective data collection in low-resource settings. In the process of exploring root causes of quality, we found substantial variability in the quality and completeness of publications pertaining to implementation approaches and insufficient descriptions of methods.

The quality issues we observed in our case study were largely related to the research workflow's high dependence on clinical flow and lack of robust quality assurance systems. We observed significant variability in the completeness of variables within the database. This variability appeared to be related to data collection activities being highly dependent on existing clinical workflows to generate variables along patient care pathway. A large proportion of incompleteness of initial assessment and examination variables was reliance on the emergency department workflows to complete and document a full set of vital signs. However, during our case study period, standardized triage processes were not in place to support this. This resulted in inconsistent data collection and created an undue burden on the research workflow, which lacked capacity to make up for this. The other significant quality threat we observed stemmed from an overall lack of quality control measures in place governing database activities. Quality control measures such as automatic electronic quality

assurances, periodic quality checks of data within the database, and quality checks of data collection activities, are essential to ensuring database quality.

Even though we were able to link our case study findings back to facilitators within our framework, it became apparent in our case study that our framework was insufficient in accounting for the rapidly changing environment of developing health systems. At the end of our case study, the emergency department was reorganizing and implementing a standardized triage process. As part of the triage process, vital signs were to be collected on every patient. Standardization of patient care in the emergency department will likely improve the generation of vital signs on neurosurgery patients. While this will likely improve the completeness of the database's initial assessment and examinations variables, *any* changes to data collection activities threaten overall value and quality of the database^{19,20,22}. There is a need for continual monitoring of the environment for changes that impact database activities. In response to this, we augmented our framework to include entire feature dedicated to iterative quality improvement (figure 4).

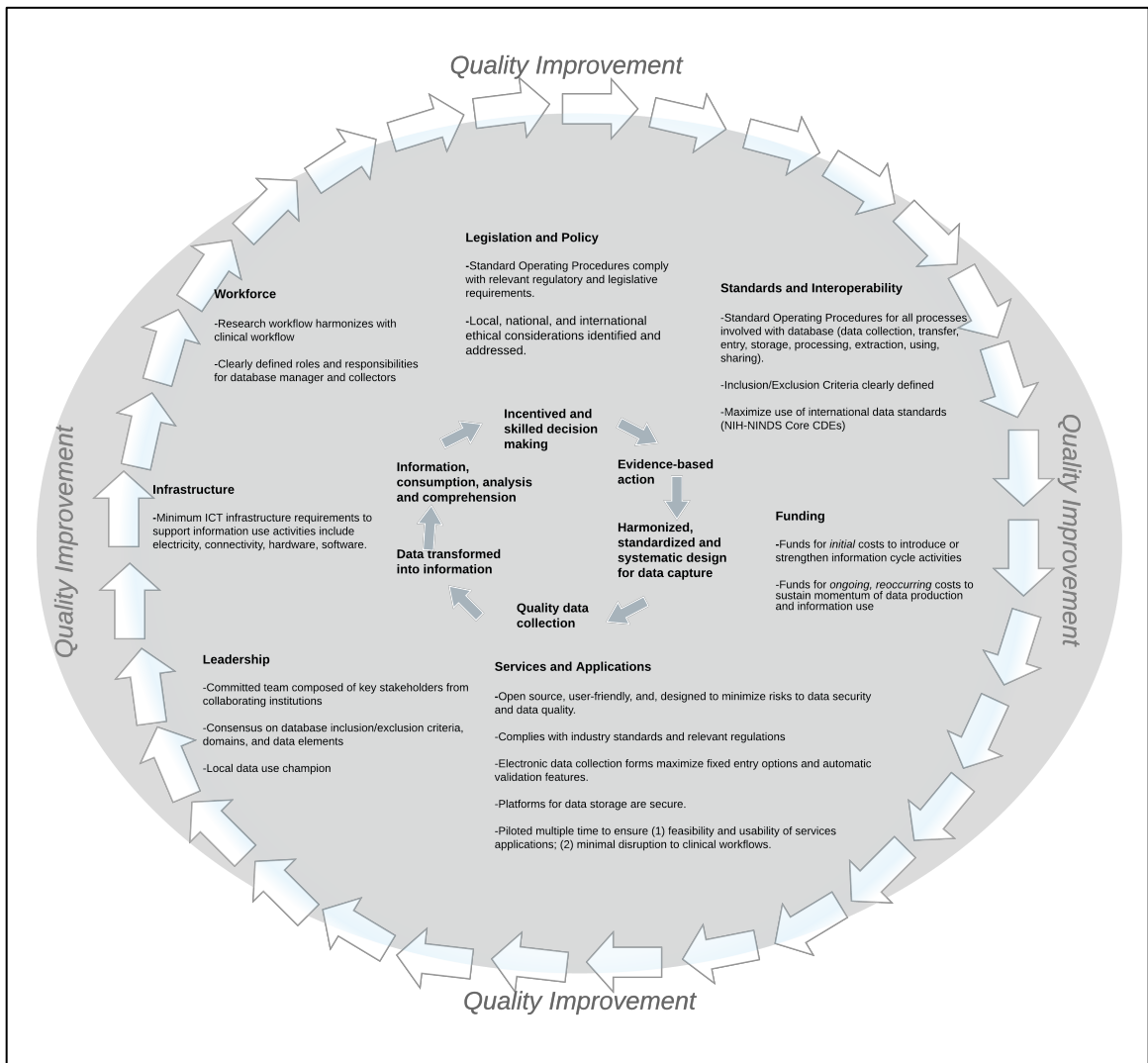


Figure 4. Updated framework.

The need for common data standards to improve data quality and allow for comparison or aggregation of data across sites has been described as a requirement to advance research and improve clinical care in both the fields of traumatic brain injury and surgery^{4,22,25,26}. While our proposed framework promoted the adoption of common data standards, the case study highlighted the fact that collecting common data elements

doesn't imply homogenous data across sites. To optimize the value of data being collected, more attention must be paid to *how* variables are collected, coded, and stored^{19,26}. Using the same core data elements across the patient care pathway and between various low-resource sites would not only allow for appropriate benchmarking of performance to support quality improvement efforts, but also accelerate filling the significant knowledge gap in the literature pertaining to neurosurgery data from low-resource settings^{4,22}.

There are some limitations to note. In this paper we only evaluated one aspect of the proposed framework: how well it anticipated quality issues. A comprehensive framework evaluation would also include assessing additional framework attributes such as validity, reproducibility, comprehensiveness. While the proposed framework presented in this paper may, in its current state, provide guidance for implementation, it needs to be developed and evaluated further. There also several limitations to our case study. A comprehensive quality assessment examines multiple data quality attributes (i.e., accuracy, completeness, validity, precision, consistency, and timeliness)¹⁹. We were only able to directly assess completeness of 24 variables in our case study. Other variables within the database may not have the same degree of completeness as the ones reported in this paper. Given the purpose of our case study was to explore causes of poor quality, we did not design nor intend to conduct to be a rigorous comprehensive quality assessment. In spite of these limitations, we believe that our use of combined

quantitative and qualitative methods to examine quality produced more robust findings than if we had only assessed quality at the database level.

Despite the increase in global neurosurgery partnerships, the lack of quality neurosurgery data in low-resource settings limits these efforts. The use of prospective databases has been a successful strategy in many HICs, but there are significant challenges to implementing and sustaining quality prospective data collection in low-resource setting. There is a need for a simple strategy for implementing prospective databases for global neurosurgery partnerships that is appropriate and feasible in low-resource settings. In this paper we initiated development of a simple framework that can be used to guide implementation of neurosurgery databases.

5. Conclusion

Given the burgeoning neurosurgical disease burden in LMICs, this paper contributes to global neurosurgery efforts by providing guidance for collecting quality, interoperable neurosurgical data in LMIC. We proposed the development of a simple, reproducible framework to guide prospective database implementation.

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