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Process Improvement Methods Increase the Efficiency, Accuracy and Utility of a Neurocritical Care Research Repository

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Abstract

Background—Reliable and efficient data repositories are essential for the advancement of research in Neurocritical care. Various factors, such as the large volume of patients treated within the Neuro ICU, their differing length and complexity of hospital stay and the substantial amount of desired information can complicate the process of data collection.

Methods—We adapted the tools of process improvement to the data collection and database design of a research repository for a Neuroscience intensive care unit. Using the Shewhart-Deming method, we implemented an iterative approach to improve the process of data collection for each element. After an initial design phase, we re-evaluated all data fields that were challenging or time-consuming to collect. We then applied root-cause analysis to optimize the accuracy and ease of collection, and to determine the most efficient manner of collecting the maximal amount of data.

Results—During a six month period, we iteratively analyzed the process of data collection for various data elements. For example, the pre-admission medications were found to contain numerous inaccuracies after comparison with a gold standard (sensitivity 71% and specificity 94%). Also, our first method of tracking patient admissions and discharges contained higher than expected errors (sensitivity 94% and specificity 93%). In addition to increasing accuracy, we focused on improving efficiency. Through repeated incremental improvements, we reduced the number of subject records that required daily monitoring from 40 to 6 per day, and decreased daily effort from 4.5 to 1.5 hours per day.

Conclusions—By applying process improvement methods to the design of a Neuroscience ICU data repository, we achieved a three-fold improvement in efficiency and increased accuracy. Although individual barriers to data collection will vary from institution to institution, a focus on process improvement is critical to overcoming these barriers.

INTRODUCTION

Despite the recognition that Neurocritical care specialists can improve outcome in acutely brain-injured patients^{1,2}, there is a great need to advance the understanding of this patient population. An approach that enables the systematic study of Neurocritical care patients³ would greatly facilitate this goal. However, one challenge is that patients with Neurocritical illness are heterogeneous and treatment modalities are equally varied. Therefore, strategies that facilitate research within Neurocritical care units are an important cornerstone in achieving this goal.

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Clinical research repositories serve as an important foundation in patient-oriented research. Although not class I evidence, a systematically collected cohort may have a particularly important role in the Neuroscience intensive care unit (Neuro ICU) where randomized controlled trials may be difficult to implement or may lack generalizability⁴. A carefully designed research repository could facilitate many Neuro ICU research priorities⁵, supporting observational and hypothesis-generating studies, multimodal monitoring and biomarker research. Implementation at individual sites is also necessary for multi-center collaborative initiatives³. A major challenge however, is that the potential breadth of data collection is significantly limited by resource availability.

The application of process improvement methodology is one potential solution to resource limitation. Process improvement has been successfully applied in fields as varied as automobile production and healthcare quality improvement^{6,7}. A guiding principle is that myriad small barriers impair overall quality and efficiency. Improvement therefore entails iterative evaluation of each step that together yields a more efficient and reliable result. The Shewhart-Deming cycle of plan-do-study-act (PDSA) codifies this approach to process improvement⁶. In the design of a research repository, we sought to apply the PDSA method. Our goal was to create an efficient, accurate, and feasible method of data capture and storage in order to maximize the utility and sustainability of research data collection. Although some of the specific barriers encountered may be unique to our institution, we describe a general approach that may facilitate Neurocritical care research in any Neuro ICU.

METHODS

Data Collection and Database Design

We generated a list of variables, aiming to be comprehensive but also pertinent across the diseases routinely cared for in the Neuro ICU. Data points included diagnoses, demographics, social history, past medical history, medication history, admission clinical scales, length of stay in the ICU and hospital, procedures performed in the ICU and OR, as well as discharge clinical scales and location (see Supplemental Material for a complete list of data variables and case report forms). After generating the list of variables, we organized them by method of collection, source and timing of collection, and method of consent required. We then ordered the variables to match the flow of data collection and custom-designed a relational database (MS Access) to match that order. All data was abstracted from electronic medical records, which are available from any hospital workstation. This permitted access to the data without interfering with clinical care. Moreover, the use of templated progress notes provided a potential opportunity to adapt them to capture data elements that arose in the context of routine clinical care. Standard data management principles were applied to minimize erroneous or missing data⁸, such as the use of drop-down selections, the development of a data dictionary and data consistency checks.

We used the Plan-Do-Study-Act (PDSA) method⁶ to iteratively improve our approach to data collection and database design. This method defines an approach where a plan is established (Plan) and carried out (Do), and then the efficiency is studied (Study) and any potential barriers are investigated using root cause analysis. A new solution is proposed (Act) and the cycle is repeated.

Accuracy Analysis: Medication list

In the process of carrying out PDSA cycles, we conducted both formal and informal analyses. For example, the pre-admission medication list (PAML) was identified as a data field with potential for variability, depending on the source. We determined the accuracy of two types of admission notes (pre-admission and acute emergency department admission),

defining the gold standard as a hospital-based PAML source. The hospital PAML is created within 3 days of each patient's admission, and is an electronic medication list populated by the admitting physician. It is then confirmed by the nurse with the patient or family member, and signed-off on by the pharmacist.

In 24 consecutive patients, we evaluated the number of inaccuracies in the admission or pre-admission notes, whichever was applicable. We conducted sensitivity and specificity analyses, and calculated the false positive and false negative rates. A false negative was defined as a medication omitted on the admission note but present in the gold standard PAML list. A false positive occurred when a medication was included in the admission note but was not present in the PAML list. More than one false positive and/or negative was possible for any given subject. We focused our analysis on drug classes where inaccuracies would have clinical importance (anti-seizure, anticoagulant or anti-platelet, anti-hypertensive, diabetic and hyperlipidemia medications).

Accuracy Analysis: Patient Census

We also applied the PDSA method to tracking the patient census. With an estimated ~1500 admissions and discharges annually, and given the vital importance of being able to accurately track them, we evaluated several strategies to track subjects. The POPS list is a handwritten tally of daily admissions and discharges maintained by the operations assistants in the Neuro ICU. When a patient arrives or leaves the unit, the operations assistant records the date and destination of the patient. The ICU list is a daily printout of the electronic unit census, which provides a cross-sectional list of patients at a specific time of day. We defined the gold standard as PATCOM, which is the hospital's electronic census that is used for billing purposes. Each admitted patient is entered into PATCOM in real-time, along with their unit and bed location. The date and location of any subsequent transfers or discharge is also reported.

Over a two week period of study, we collected patient admissions and discharges using the POPS and ICU lists. We also obtained a single report from PATCOM containing all neurological and neurosurgical admissions and discharges from the hospital during the same time period. We then performed sensitivity and specificity analysis for admissions and discharges using PATCOM as the gold standard.

Time Efficiency Analysis

To calculate the number of records that required active monitoring on a daily basis, we simulated three methods of data entry. All subjects were enrolled on admission into the Neuro ICU. Data abstraction occurred at three possible time points. If data were first abstracted on admission into the Neuro ICU, intermittent monitoring of the record was needed to update any empty data fields and to determine the date of transfer and discharge. If data abstraction occurred at the point of transfer, the subject's record still needed monitoring until the date of discharge. All data could be entered at one time when data abstraction occurred at the time of discharge.

We also estimated the amount of time per day that was required to maintain the database during the course of the improvement process, averaged over one-month blocks of time. In order to estimate the overall time reduction, we calculated the amount of time spent for each task, which included monitoring the census for newly eligible subjects, entering data into the database, monitoring incomplete records, and conducting database updates and alterations.

Statistics

Descriptive statistics are presented as mean and standard deviation or median and interquartile range, as appropriate. For accuracy analysis of the medication list and patient tracking method, sensitivity and specificity analyses were performed. The gold standard used for each analysis is defined above. False positive and false negative rates were calculated.

Institutional Review Board

Given the varied modes of data collection, we created two separate IRB protocols. A waived consent protocol allowed data extraction from the medical record, and all patients admitted into the Neuro ICU are eligible and enrolled. A second protocol delineates the biospecimen collection and follow-up outcome data collection, which requires informed consent of each subject or his/her surrogate. Any subject who had recovered mental capacity at the 3 month follow-up phone call was verbally re-consented.

RESULTS

We first assembled and categorized potential data variables based on source, reliability and timing of collection (Supplemental Table). From this analysis, we developed a tiered organizational structure to data collection based on the timing of data collection and consenting methodology (Figure 1). We focused our initial efforts on developing a comprehensive database that enrolled every Neuro ICU admission. This necessarily resulted in a balance between the breadth of data collection for each subject versus inclusion of the entire subject population. Table 1 shows the demographics of the patient population enrolled during the design phase of the database. With an estimated volume of 1500 subjects per year and limited success of prior efforts at our institution, we devoted substantial time developing a method of data collection that was both accurate and efficient.

Accuracy

After the initial design, we re-evaluated all data fields that were challenging or time-consuming to collect. One data variable with low initial reliability was the medication list, which was originally abstracted from admission notes. During the initial trial period, we suspected a high error rate from the admission notes. We therefore obtained access to an electronic pre-admission medication list (PAML) that is available for each inpatient at our institution. The electronic PAML is initially created by the admitting physician based on the admission note, but then verbally re-confirmed with the patient and family by the nurse and double-checked against outpatient medication lists by the pharmacist.

Defining the electronic PAML as the gold standard, we evaluated the number of inaccuracies in the admission note or pre-operative note (when applicable). Although the sensitivity and specificity were high for pre-operative admission notes (91% and 98%, respectively; Table 2), the accuracy of acute admission notes was substantially worse (71% sensitivity, 94% specificity). Corresponding false positive and false negative rates were approximately three-fold higher in acute admission notes compared to pre-operative notes (Table 2). Because almost two thirds of Neuro ICU subjects are admitted acutely, these error rates would limit the reliability of this data field. As a result, we abandoned the admission notes as the source of medications and used the electronic PAML once we obtained access. This also necessitated a change in the timing of data collection for this variable to hospital day 3 or later.

We also evaluated the accuracy and reliability of admission and discharge dates for Neuro ICU subjects. In our initial pilot phase, we used a written list of daily admissions and

transfers that is maintained by the operations assistant in the ICU (POPS list). We reasoned that this method would be both accurate and efficient, since it tracked both admission and transfers on the same document. However, during its implementation we discovered this approach was both tedious and suspected it was prone to error. We therefore sought to formally determine the accuracy of this method and consider potential alternatives, including the ICU list and the PATCOM list.

For the handwritten POPS list, we found that it had 97% sensitivity and 97% specificity for accurately tracking admissions into the ICU (Table 3). For discharges, the POPS list was less accurate (94% sensitivity and 93% specificity). Of 71 admissions and 72 discharges during the two-week study period, there were a total of 24 errors. For the ICU list, the sensitivity was 96% and specificity of 100% for identifying both admissions and discharges. However, in one quarter of patients, the exact date of admission or discharge was could not be distinguished between one of two consecutive days. Because the list is a cross-sectional census of the ICU, a patient admitted or discharged in the previous 24 hours could be assigned either of two dates. Resolving the date required an additional step looking in the chart to confirm the exact date. Confronted with limitations of these sources, we explored the option of directly generating a list of admissions and discharges from the PATCOM hospital census. After several weeks of discussion with an information technology representative, we developed an automated search algorithm that generated a daily report listing the previous day's admissions, transfers and discharges from the Neuro ICU.

Efficiency

In addition to evaluating the data variables as described above, we also sought to improve the overall process of data collection and database entry. Initially, data abstraction was started on the date of a patient's admission into the Neuro ICU and enrollment into the data repository. Following the analyses above, we recognized that certain sections of the electronic medical record contained more accurate data, but these were not available for several days after admission. We therefore evaluated the number of steps and time required to complete a subject's record, based on three potential timepoints: on admission, on transfer out of the Neuro ICU and at discharge from the hospital (Figure 2).

We then monitored the average number of open records per day that would require daily data abstraction. When data entry began on the date of admission to the ICU, there were 40 ± 5 patient records that needed active monitoring on a daily basis (Figure 3). When data was entered at the time of transfer out of the Neuro ICU, there were 17 ± 2 open records. When data was abstracted on date of discharge from the hospital, then the entire entry could be completed at once, and only 4 ± 2 patient records were actively monitored each day. Selecting a later time point for data abstraction not only allowed us to use the most reliable data sources, but it led to significant improvements in efficiency. Given the progressive improvements that resulted from applying PDSA cycles to the data repository, we next estimated the amount of time devoted to data entry each day over the five month development period (Figure 4). Continued incremental improvements resulted in a reduction of 3 hours per day, from 4.5 to 1.5 hours required per day.

Prospective Data Collection

Recognizing that some data elements were inherently less reliable when abstracted from the medical record, we next developed a prospective tier to the repository, which required an informed consent process (see Figure 1). This allowed us to approach subjects or their surrogates and obtain data in a subset of data fields that were unreliable or unavailable to collect from abstraction from the medical record. These included more detailed social history, independent confirmation of the past medical history and assessments of premorbid

functional status. We also included follow-up telephone calls for structured outcome assessments at standardized time intervals. Finally, plasma and DNA collection was included for future biomarker and genomic analyses. Given the improvements in the efficiency of the database described above, there was available time to approach subjects to consent for participation in this prospective portion of the research repository.

DISCUSSION

Despite innovations in the field of Neurocritical care, there is a continued need to advance our understanding of these diseases³. A research repository can help facilitate that effort and promote a variety of Neuro ICU research priorities⁵. However, there is a tension between comprehensiveness and feasibility, which prompted us to systematically evaluate the design and data collection process. Using the tools of process improvement, we dramatically increased our capability to collect information and ensure that it was the highest quality available. Process improvement methods used in other arenas (i.e., Toyota automobile production) has demonstrated that quality and efficiency require consistent and iterative attention to detail⁶. Potential barriers are identified and studied using root-cause analysis and solutions are implemented and studied again for improvement. We found that applying these tools were instrumental to successfully establishing our research repository.

Electronic medical records have facilitated the process of data collection, and have allowed us to collect data without interfering with clinical care. A variety of electronic quality initiatives inspired by the Institute of Medicine's report *To Err is Human*⁹ and formalized by accrediting organizations such as the Joint Commission (JCAHO) have resulted in efforts to reduce medical errors in inpatient care. At our institution, the electronic PAML which is vetted through three separate healthcare professionals is one example of such efforts. These efforts designed to improve patient safety can also be leveraged for clinical research. However, our experience is that electronic systems—even within a single institution—are not necessarily well integrated. Leveraging the available electronic resources for clinical research may require investigation and the assistance of information technology specialists, as we discovered in tracking admissions and discharges.

There are limitations to our study. Our database is largely retrospective. However, we have discovered that the reliability of some data fields (e.g., PAML) can be higher quality when collected retrospectively. We were also limited in the breadth of data variables that we were able to collect. Because our goal was to enroll every subject admitted to the Neuro ICU, we could not collect all potentially relevant data fields, particularly ones that were unique to specific diagnoses. However, we reasoned that the database could be used for a variety of hypothesis-generating studies, and that those individual studies could subsequently acquire disease-specific data fields.

Once the framework for data repository was established, we were able to superimpose a second tier of prospective data collection. Based on our PDSA analysis, we focused prospective data collection only on items that were unreliable or unavailable through the electronic medical record (see Supplemental Table). This tier of the database required separate IRB approval and consenting structure, and is limited to consenting subjects or their surrogates. However, this has also allowed us to build additional research initiatives, including bio-specimen collection and structured telephone outcome assessments.

We estimate that the data entry for the repository requires 0.5 FTE and the the inclusion of systematic informed consent, blood draw, and outcomes assessment requires an additional 1.0 to 1.5 FTE, depending on the scope of collection. This effort would be complimentary to emerging efforts by the field to acquire bedside physiological data beyond the standard of

care. Although we have not added physiological data collection to the repository at our institution, we believe that the PDSA process would be complimentary to the streamlining of this process.

The approach of process improvement can yield significant efficiencies in data collection, thereby promoting clinical research at an institutional level and as well as at a multi-site collaborative level³. Our method of database process improvement can be applied to research repository design at other institutions. Although individual barriers to data collection will vary from institution to institution, a focus on the methods of process improvement is critical to overcoming these barriers.

CONCLUSION

Through the application of process improvement methods, we have created a Neurocritical care research repository that is accurate and efficient, and serves as a foundation for research studies in our Neuroscience ICU. Although the precise methods and available resources may vary between institutions, a process improvement approach can be essential to successfully advancing clinical research in Neurocritical care.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Suarez JJ, Zaidat OO, Suri MF, et al. Length of stay and mortality in neurocritically ill patients: impact of a specialized neurocritical care team. *Crit Care Med.* 2004; 32:2311–7. [PubMed: 15640647]
2. Josephson SA, Douglas VC, Lawton MT, English JD, Smith WS, Ko NU. Improvement in intensive care unit outcomes in patients with subarachnoid hemorrhage after initiation of neurointensivist co-management. *J Neurosurg.* 2010; 112:626–30. [PubMed: 19731990]
3. Suarez JJ, Geocadin R, Hall C, et al. The Neurocritical Care Research Network: NCRN. *Neurocrit Care.* 2011 DOI 10.1007/s12028-011-9612-x.
4. Geocadin RG, Bleck TP, Koroshetz WJ, et al. Research Priorities in Neurocritical Care. *Neurocrit Care.* 2011 DOI 10.1007/s12028-011-99611-y.
5. Wijman CA, Smirnakis SM, Vespa P, et al. Research and Technology in Neurocritical Care. *Neurocrit Care.* 2011 DOI 10.1007/s12028-011-9609-5.
6. Deming, WE. *The new economics : for industry, government, education.* 2nd ed. MIT Press; Cambridge, Mass.: 2000.
7. Langlely, GJ. *The improvement guide : a practical approach to enhancing organizational performance.* 2nd ed. Jossey-Bass; San Francisco: 2009.
8. Kruse RL, Mehr DR. Data management for prospective research studies using SAS software. *BMC Med Res Methodol.* 2008; 8:61. [PubMed: 18786262]
9. Kohn, LT.; Corrigan, JM.; Donaldson, MS., editors. *To Err is Human: Building a Safer Health System.* National Academy Press; Washington, D.C.: 2000.

Figure 1. A conceptual organization of patient-oriented research in the Neuroscience ICU
 No single solution equally addresses generalizability and scientific reliability. A combination of approaches is needed, and a research repository that enrolls all patients in the Neuro ICU can serve as the foundation.

Figure 2. Increasing efficiency by reducing the number of steps required for complete data entry
 We mapped the overall enrollment and data collection process, based on the start time of enrollment. Row A shows the number of steps when data is abstracted upon admission to the ICU. Row B shows the number of steps when subjects' data are abstracted upon transfer from the Neuro ICU. In row C, the most streamlined process occurred when data was abstracted upon discharge from the hospital.

Figure 3. Selecting the time to begin data abstraction can influence the efficiency of data entry in a high volume repository

We evaluated the number of subject records that would require active daily monitoring for data abstraction, depending on the timing of when the data abstraction was begun. Filled circles indicate the number of subjects with incomplete data repository entries, if data abstraction were begun on admission to the Neuro ICU. Filled squares are the number of incomplete entries if data abstraction is started at the time of transfer from the Neuro ICU. The least number of open records occurred when data was started and completed at the time of discharge from the hospital (filled triangles).

Figure 4. The iterations of process improvement incrementally decreases the time spent maintaining a research repository
The amount of time per day (in minutes) spent on data entry is represented based on the average workload during one month epochs.

Table 1

Demographics of patients admitted during a six month period.

Total, N	806
Age, mean $\pm$ SD	58 $\pm$ 18
Female, N (%)	403 (50%)
ICU LOS (days), median [IQR]	2 [1, 4]
Hospital LOS (days), median [IQR]	6 [3, 12]
Elective Post-Op, N (%)	297 (37%)
Acute Admissions, N (%)	509 (63%)
Acute ischemic stroke	104 (20%)
Intracerebral hemorrhage	94 (18%)
Traumatic brain injury	78 (15%)
Brain tumor	60 (12%)
Subarachnoid hemorrhage	62 (12%)
Seizures/Status epilepticus	22 (4%)
CNS Infection	16 (3%)
Altered Mental Status	16 (3%)
Spinal cord disease	12 (2%)
Other	45 (9%)
In-Hospital Mortality, N (%)	77 (10%)

ICU, intensive care unit. LOS, length of stay.

Table 2

Accuracy of sources for the pre-admission medication list.

Admission Note Type	False Positive Rate Specificity	False Negative Rate	Sensitivity	
Elective Post-Operative	2%	9%	91%	98%
Acute Admissions	6%	29%	71%	94%

Table 3

Accuracy of sources for tracking patient admissions and discharges.

Source of Admissions	False Positive Rate Specificity	False Negative Rate	Sensitivity	
POPS list *	3%	3%	97%	97%
ICU list **	0%	4%	96%	100%
<u>Source of Discharges</u>				
POPS list	7%	6%	94%	93%
ICU list	0%	4%	96%	100%

* POPS list is a written tally of admission and discharges that is maintained by the ICU operations assistant.

** ICU list is cross-sectional, electronic census of the ICU.