Creation of a Hyponatremia Registry Supported by an Industry-Derived Quality Control Methodology

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Keywords

Hyponatremia, institutional registry, control chart, process indicators

Summary

Background: A clinical registry encompasses a selective set of rigorously collected and stored clinical data focused on a specific condition. Hyponatremia has multiple, complex underlying causes and is one of the most frequent laboratory abnormalities. No systematic registries of hyponatremic patients have been reported in the medical literature. The purpose of this project was to create a registry for hyponatremia in order to obtain epidemiological data that will help to better understand this condition.
Objective: This paper describes the creation of a registry for hyponatremia within a single institution that employs industry-based approaches for quality management to optimize data accuracy and completeness.
Methods: A prospective registry of incident hyponatremia cases was created for this study. A formalized statistically based quality control methodology was developed and implemented to analyze and monitor all the process indicators that were developed to ensure data quality.
Results: Between December 2006 and April 2009, 2443 episodes of hyponatremia were included. Six process indicators that reflect the integrity of the system were evaluated monthly, looking for variation that would suggest systematic problems. The graphical representation of the process measures through control charts allowed us to identify and subsequently address problems with maintaining the registry.
Conclusion: In this project we have created a novel hyponatremia registry. To ensure the quality of the data in this registry we have implemented a quality control methodology based on industrial principles that allows us to monitor the performance of the registry over time through process indicators in order to detect systematic problems. We postulate that this approach could be reproduced for other registries.

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1. Introduction

Clinical registries comprise a set of selectively collected and stored data focusing on a specific condition. The records in a registry are generated through a process of prospective data collection that must periodically pass tests for data quality to detect errors and thus ensure data integrity. Systematic data collection is characteristic of a well designed registry [1]. The quality of a registry is directly dependent on the completeness and validity of the data it contains [2].

Hyponatremia is one of the most frequently detected laboratory abnormalities. It can arise from multiple underlying complex causes. In some clinical settings it is a marker of disease morbidity and mortality [3-6]. In most instances hyponatremia reflects the severity of an underlying chronic disease process; however, it occasionally represents a true medical emergency. In this emergent clinical scenario, there is no consensus about the diagnostic and treatment strategies that should be used [6].

We could not identify any reports describing a systematic registry of patients with alterations in sodium concentration from either the inpatient or outpatient setting in the medical literature [5].

Considering the significance of hyponatremia in Internal Medicine and the potential benefits of monitoring the course of hyponatremic patients over time, we decided to establish an Institutional Registry of Hyponatremia.

In this paper, we describe the design and implementation of a prospective registry of hyponatremia in patients admitted to a tertiary care hospital from December 2006 to April 2009. We also describe the methodology that we developed to ensure data completeness and accuracy for the Institutional Registry of Hyponatremia.

2. Objectives

The aim of this study is to describe the creation of a registry for hyponatremia within a single institution and the processes we created to ensure the systematic collection of high quality data.

3. Methods

The following is a descriptive, observational study of the performance of the Institutional Registry of Hyponatremia (IRH) within a community-based tertiary care hospital with 650 beds. The IRH is integrated into the hospital's computerized clinical record system that systematically provides specific data about the underlying pathophysiology of the hyponatremia.

We prospectively included all patients over 17 years of age with incidental hyponatremia (Na<130 mmol/L, by electrometric method ISE) who were admitted to any medical or surgical unit in the Hospital Italiano de Buenos Aires (HIBA) between December 2006 and April 2009. For each case, we collected a set of 100 specific data elements related to hyponatremia using a structured data form. We excluded laboratory errors, patients who refused informed consent, and patients with chronic renal failure undergoing hemodialysis or peritoneal dialysis.

The IRH has remained continuously active since 2006. For this paper we analyzed a three year period in order to exemplify evolution of the IRH overtime. The registry and its protocol were evaluated and approved by an independent Institutional Review Board (IRB).

Operations manual

We developed an operations manual that serves as a guide (http://www2.hospitalitaliano.org.ar/clinica/media/MPRIDv2_09.pdf) to define evaluation strategies and quality control of all the processes involved in collecting and maintaining registry cases. This document standardizes the procedures and processes of the registry to reduce inter-observer variation in data collection in order to improve the accuracy of the registry data [7].

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Process indicators

As an approach for monitoring the different activities within each process for creating and maintaining the registry, we developed specific process indicators. All of these processes are sequentially integrated to create the registry system. The indicators reflect the status of each process, allowing us to monitor how well the process is performing. Results from the process performance indicators serve to guide us regarding when and where in the system to implement improvement cycles. The indicators are quantifiable and represent critical aspects of each process. They are also comparable over time and useful for decision-making about the entire integrated system. Accordingly, the process indicators must have specific boundaries in order to detect errors and inefficient steps within a process. The monitoring information is then used to optimize the overall system based on the identification and modification of underperforming processes [8].

The process indicators for IRH are shown in the flow chart in ▶Figure 1. These indicators are calculated every month:

1. Number of reports showing hyponatremia
2. Number of patients identified with hyponatremia
3. Percentage of patients lost to follow up
4. Percentage of patients with water and electrolyte balance
5. Time to evaluation since the hyponatremia report was initially recorded (baseline)
6. Percentage of lost data

Statistical Analysis

To evaluate the behavior of the different process indicators over time, we used control charts [9-10] as statistical tools to detect nonrandom sources of variation due to systematic causes [11]. Control charts were first introduced by W. Shewart in 1920 to monitor the stability of industrial processes. The x-axis represents time and the y-axis represents the process indicator with repeated measurements over time.

All indicator limits were calculated from observed values during a relative stable period. To specify the central limit, we averaged monthly indicator measures. The superior limit was calculated as the central limit plus 3 standard deviations, and the lower limit, as the central limit minus 3 standard deviations. Nelson rules were used to detect special causes of variation for each process [9-10, 12]. Nelson rules are a method in process control of determining if some measured variable is out of control. The rules are applied to a control chart and are based around the central limit and the standard deviation of the samples [13].

4. Results

Indicators were followed over time in order to detect systematic causes of variation.

1. **Number of reported cases**: 5603 systematic causes of variation were detected by Nelson rules 1, 5 and 6 (▶Fig. 2).
2. **Included patients**: 2243 patients were included between December 2006 and April 2009 without evidence of systematic causes of variation (▶Fig. 2).
3. **Percentage of Missing cases**: there was a 6% decline in the number of missing cases during the last 3 months of the observation period due to a change in the case capture system. Many systematic causes of variation were detected by rules 1 and 6 (beginning and end of the registry) and by rule 5 in March 2008 (▶Fig. 2).
4. **Proportion of patients with water and electrolyte balance**: For most of the observation period water and electrolyte balance was maintained around 60%, except for the months of December, 2008 and January, 2009 when it rose to 85%. We also detected a systematic low cycle at the beginning of the observation period and a systematic high cycle at the end of the observation period (▶Fig. 3). These deviations are significant since they serve as an indicator of medical care.

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5. **Median Time to Evaluation (monthly median)** increased over time in parallel with the increased number of reported patients achieving a maximum of 19 hours in June, 2008, and then decreasing to 8 hours by the end of the observation period (Nelson rule 2) (▶Fig. 3).
6. **Percentage of Missing Data** was initially 14%. The measure progressively decreased to 1% by April 2008 and latter increased to 7% by January, 2009 (▶Fig. 3). This pattern reveals an unstable process at the beginning and at the end of the observation period (rules 1 and 5).

5. Discussion

All process indicators were measured monthly starting on December 1, 2006. The first two months were the implementation period during which we expected to observe high variability in processes and indicators. The evolution of the process indicators showed a favorable trend toward stability, which was probably reflects a learning curve for developing new skills for individuals participating in the project. Both the reported cases and the included cases per month increased during the observation period. In parallel with the improved stability of the process indicators, the number of missing patients decreased, reflecting the correct application of the rules defined in the operations manual [1]. As required of many longitudinal projects, we had to ensure that the steps of the registry process would not interfere with the usual hospital work flow. Median time to evaluation showed an increase with the rise in the number of included patients. Thus, we redesigned the process for identifying cases resulting in an improvement of this indicator.

While the percentage of patients with appropriate water and electrolyte balance improved during the observation period, it never attained a level higher than 60%. We suspect that this indicator might not be evaluating the process adequately (e.g., data collection may not be accomplished in a timely fashion).

We observed a clear decreasing trend in the percentage of missing data. This process indicator reflects the overall quality and reliability of the registry system and implies improvement of the other process indicators.

Systematic monitoring of the process indicators resulted in the identification of a potential compromise in the quality of the data. We propose that our monitoring approach alerted us to initiate the implementation of improvement cycles leading to the resolution of identified problems. While we recognize we have not measured all possible data quality components, we maintain that out monitoring methodology has contributed to improved data quality in the IRH. Accordingly, we recommend designing processes and monitoring systems that will ensure quality data as part of a registry design [9-10, 14].

Registries can be useful tools for tracking diseases or conditions; however, to be most useful they require defined methodologies and system processes to ensure that data collection is complete and accurate. Process indicators and control charts help with data quality management through the detection of process variations, identifying systematic causes of variation where performance improvements may be required. Even though control charts enable visual identification of specific sources of variation, they do not identify the root cause of the variation. In the ideal setting, the calculation of process indicators should be quick and simple, to avoid consumption of excessive time and resources.

6. Conclusion

We believe that the application of the real time monitoring methodology described in this paper provided a solid approach for improving and maintaining data quality in a disease/condition registry. Moreover, we suggest that registry developers collaborate closely with physicians in registry projects to ensure continuous feedback that can lead to new lines of research to address questions raised by registry data.

With regard to research, recording actual clinical practice data through registries has more external validity than interventional studies with stringent subject selection criteria; however, in order for the outcome to be valid, it is imperative to collect relevant, accurate and complete data. For this

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project, we trained the evaluators to optimize evaluation sensitivity and specificity, thus assuring data reliability as much as possible (http://www2.hospitalitaliano.org.ar/clinica/index.php?option=com_content&task=view&id=52&Itemid=34) [15-16]. Furthermore, validity can be augmented by continually improving the system through continuous monitoring and targeted quality improvements. Such improvements are most effective if based on real data resulting from process indicators and designed in collaboration with the individuals who will integrate them into practice.

Additionally, control charts, modeled after versatile tools with multiple indications [17], are useful tools for industry programs of quality management that can support quality control and management practices for producing quality data.

Implication of results for practitioners and/or patients

The methodology for monitoring data quality for disease/condition registries described in this paper supports continuous quality improvement to augment the collection of relevant, complete and accurate data.

Authorship

All listed authors have made substantial contributions to the article and have approved the version to be published.

Conflict of interest

All listed authors declare that we have no financial and personal relationships with other people or organizations that may inappropriately influence or bias the objectivity of submitted content and/or its acceptance for publication in this journal.

Protection of human subjects

The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical research Involving Human Subject and approved by an Independent Ethics Review Board.

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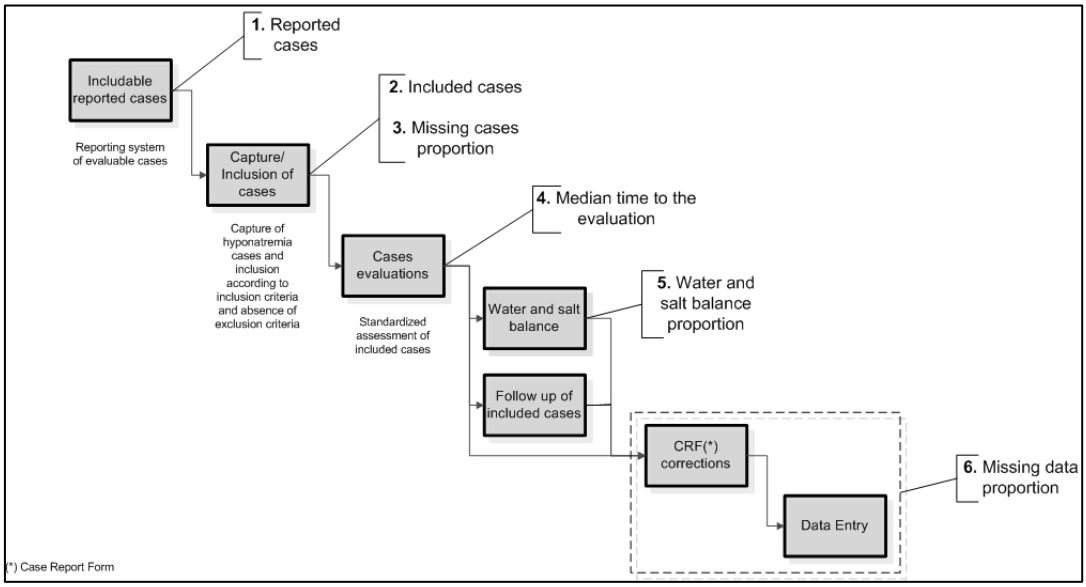

Fig. 1 Flow chart of the process indicators

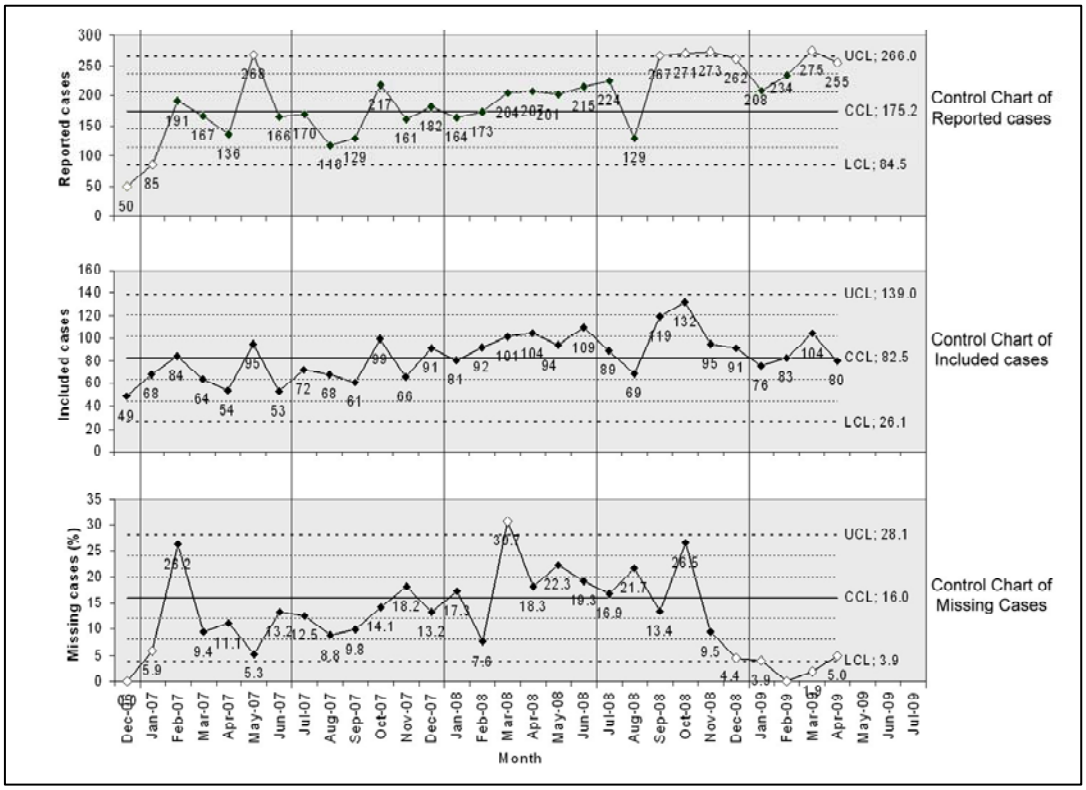

Fig. 2 Control chart of reported, included and missing cases. References: UCL = upper control limit; CCL = central control limit; LCL = lower control limit

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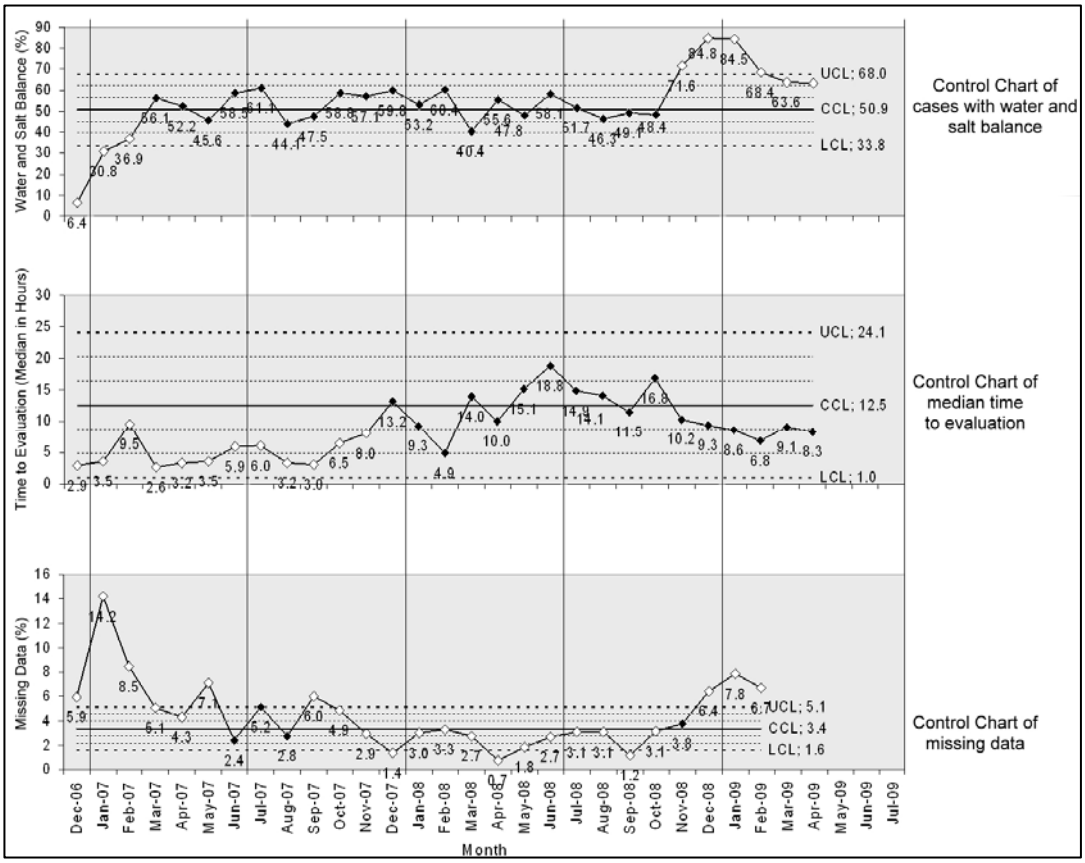

Fig. 3 Control chart of median time to the evaluation, water and salt balance proportion, missing data proportion. References: ULC = upper control limit; CCL = central control limit; LCL = lower control limit

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