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National Registries: Lessons Learnt from Quality Improvement Initiatives in Intensive Care

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Conflicts of Interest

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Quote:

“In God we trust, all others must bring data”

Introduction

Clinical quality registries (CQRs) are repositories of routinely collected healthcare information that are analysed and fed back with the aim of improving the safety and quality of patient care. There is substantial evidence that this system of audit and feedback can be both effective and cost effective in improving healthcare processes and patient outcomes (1-3).

Intensive care units (ICUs) are resource intensive and provide care to patients at high risk of adverse outcomes. As such, contribution to a CQRs should be considered an essential component of ICU patient care. National CQRs have a strong track record of meeting that need across a range of countries of varying income status and healthcare delivery models (4-8).

A major focus of all national ICU CQRs is to minimise selection bias. To do so, the proportion of ICU admissions within each contributing hospital, and the proportion of ICUs within each country must be high. This is essential to ensure valid data, maintain stakeholder trust, and improve the effectiveness of feedback (2). Timely, structured feedback, often classified into indicators of how patient care is organised (structure), conducted (process), or what is achieved (outcome), is essential. It is this dynamic process that transforms a CQR from a simple data repository to a cornerstone of a learning healthcare system, at the nexus of quality improvement and clinical research (9).

Rather than being one of many silos, a modern CQR is embedded into clinical care. An embedded CQR not only identifies and reduces unwarranted variations in care, but also creates a platform to generate and answer relevant clinical research questions, then informs the translation of the findings back into practice (Figure 1) (10).

In an evolving and increasingly global healthcare environment, the importance of national registries continues to grow (11). Whilst differences exist, there are also similarities in the wide range of challenges encountered and skills required to maintain a high quality CQR. Sharing common experiences and lessons learnt may help improve the development and performance of ICU CQRs, and maximise their value as a powerful tool to inform policy development and improve the outcomes of critically ill patients.

Lesson One: Make the Important Measurable, Not the Measurable Important

The aim of measurement within a CQR is to provide quantitative indicators to stakeholders with the aim of improving the structure, process, or outcomes of patient care. The Swedish Intensive Care Registry provides an example of the end result of making an important clinical indicator measurable. In 2005, night-time discharge was appointed as one of ten national quality indicators by Swedish Intensive Care Registry members, with discharge proportions and outcomes displayed publicly (12). In the subsequent ten years, the prevalence of night-time discharge and associated 30-day mortality decreased significantly. In this example, factors suggesting a process measure (night-time discharge) should be regarded as important included: 1. an observed association within the registry of an association with increased mortality, 2. consistent findings in the literature supporting a causal association, 3. unwarranted between-site variation in the indicator, and 4. a reasonable expectation that the outcome was modifiable.

The Swedish example also demonstrates how the use of a specific outcome as a performance indicator is context-dependent. Contrary to the Swedish experience, out-of-hours discharge has been demonstrate not to be an independent predictor of hospital mortality following admission to an Australian or New Zealand ICUs, with minimal between-ICU variability or change over time after its introduction as a performance indicator(13, 14). In this context, it has minimal value as a performance indicator.

In general terms, development of a clinical indicator requires input from a collaborative, multidisciplinary team with expertise in epidemiology and statistics, and broad representation from clinical, administrative and patient stakeholders. The purpose of the team is to identify indicators that are important, and to develop definitions for each indicator that are then described exhaustively and exclusively. To be meaningful, an indicator must be valid (measures what it is intended to measure), reliable (repeated measures of a stable phenomenon generate consistent results), responsive, interpretable, feasible and actionable (15). Clinical indicators should be based on the best available evidence and also be reviewed regularly under a similar collaborative, multidisciplinary framework. The purpose of review is to ensure that there is consensus that the indicator remains relevant for stakeholders, the most appropriate measure for the current healthcare environment and that the feedback process is optimal, i.e. that what is measured is important.

Lesson Two: Data Quality Is Everything

Defining a minimum data set

Datasets should comply with national and international standards. A useful general principle is that everything that is collected should be used – either as part of risk-adjustment, or reported, or both, to reduce wasted effort and ensure a natural feedback loop. There is a trade-off between the volume and quality of data collected. Every effort should be made to ease the burden of data collection by avoiding redundancy, overload and duplication. Classifying data and defining a minimum data set is a starting point. The needs of data collectors may be different to those of end-users. Data should be standardized and complete; contextualized to assess information validity (correctness); cross-checked between data sources (concordance), analyzed relationally (plausibility); and supportive of real-time entry and retrieval (16). A typical ICU minimum dataset is depicted in Table 1.

Building and reviewing a data dictionary

ICU CQRs commonly code procedures and diagnoses according to international healthcare norms, most commonly the *International Classification of Diseases* (ICD-9 or 10). However, this World Health Organization (WHO) tool was not designed to describe ICU patients. Diagnostic definitions are not provided and newer technologies such as high flow oxygen therapy are currently not coded. In systems where Electronic health record (EHR) systems are in use, normalized nomenclature such as the one provided by the Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT) may be of benefit (17).

Coding rules and data checking

Databases require checking for (non-random) missing data and flawed information (18). Coding rule can help, as can the awareness of external factors that can lead to systematic bias in the data, such as a new financial incentive (19). In the Collège des Utilisateurs de Bases de données en Réanimation (CUB-Rea) database, 40 logical consistency rules are defined between diagnosis and procedure. For example, a massive blood transfusion must be linked to a coded diagnosis of hemorrhagic shock. The Dutch National Intensive Care Evaluation (NICE) CQR uses similar automated rules at time of data upload. Data quality reports back to sites can be of substantial value in improving data quality, as can site benchmarking of data ‘missingness’.

Security and Data ownership

Safeguarding of medical data is of paramount importance. An EHR embedded in a patient data management system (PDMS) enables scheduling, billing and document management, but also clinical reporting, physician order entry and decision support —tasks that are critical to safe and efficient patient care (16). The Directory of Clinical Databases (DoCDat) Development Group and the Australian and New Zealand Intensive Care Society (ANZICS) Centre for Outcomes and Resources Evaluation (CORE) have published resources that conceptualized a framework for assessing database quality across methodological dimension including coverage and accuracy (4, 20). Additional CQR data security issues that require consideration include data ownership (versus custodianship), de-identification of data, and the impact of the European Union General Data Protection Regulation (GDPR).

Lesson Three: Mortality Benchmarking is Necessary but Not Sufficient

A variety of process and outcome indicators are commonly used to benchmark ICU performance - readmissions rate, night discharges rates, ICU length of stay or mortality. However, most are also dependent on factors external to the ICU or are difficult to modify in the short term. As a general rule, performance should not be assessed on the basis of a single indicator at a single time point, but on a combination of performance over time and in the context of other indicators.

Standardized mortality ratio

The standardized mortality ratio (SMR) is the observed mortality divided by the predicted mortality. SMR is often presented graphically, in the form of a funnel plot (Figure 2). Although widely used, it is imperfect and best interpreted alongside other quality indicators, and after time for accrual of sufficient cases and data quality checking has occurred. Indeed, a French study comparing outcomes data across 25 ICUs, found that the observed mortality varied by nearly three-fold whereas SMRs varied by about two-fold (21). When additional information was included in the mortality prediction, reordering mainly occurred in the mid and upper range, suggesting that error in the risk prediction did not occur at random. Additional considerations of SMRs include discrepancies in expected mortality computed with the different severity scores, structural differences in admission and discharge patterns that influence observed in-hospital mortality may not be captured, and that it does not reflect differences in longer-term patient-centered outcomes after hospital discharge (22, 23). Mortality prediction models are also typically less reliable at the extremes of risk and loose calibration and discrimination over time, often at different rates in different populations, compounding the loss in performance as a comparative benchmarking tool.

Financial performance

The data collected vary according to the chosen perspective (at the ICU, hospital or society level). The Cost-Block method has been shown to closely approximate a bottom-up approach across a representative range of Australian ICUs and has been compared internationally (24, 25). Staff costs were found to be the major cost components in France, Germany and UK where it can take up to 70 % of total intensive care costs. Radiology costs were the highest in France and lowest in Hungary. Hospitals in UK spent the highest on blood products and drug costs. The total cost per patient day in the UK was five times more expensive than Hungary.

A modern directional distance function approach at the patient level enables a global appraisal of financial ICU performance (26). The method estimates an efficient frontier that measure technical inefficiency of each patient by the use of relevant directional distance function. An ICU is technically inefficient in treating a patient if it does not minimize its inputs given its outputs. The measure of an ICU's performance is the sum of its' patient's inefficiencies. It is possible to produce a Chart presenting Econometric performance together with SMR. Well performing ICUs are located in the lower left part that is low adjusted SMR and low technical inefficiency (Figure 3). Given that length of stay is the most easily available surrogate for patient costs, plotting SMR versus risk-adjusted length of stay can provide similar information (27).

Lesson Four: Identifying and Managing Unwarranted Practice Variation

CQRs play an important role in monitoring disease and healthcare delivery patterns and identifying differences in outcome between ICUs, hospitals or even entire healthcare systems. Clinicians are often surprised to learn that their structure, process and outcomes are radically different from those of peers in other regions (28). This variation is considered unwarranted when it is not explained by the incidence or severity of illness, resource or scientific constraints, or the preferences of informed individuals.

Once the data has been checked for validity, the first step in understanding practice variation is to consider case-mix adjusted outcomes (e.g. SMR, disease specific length of stay, long term survival, quality of life, etc.). This makes it more likely that the difference identified is valid, and more likely to represent genuine unwarranted outcomes, perhaps driven by differences in standard clinical policies that have been shaped over time by local processes, rather than differences in case-mix. Once a difference has been identified this should be reported with the degree of statistical certainty. Sometimes differences are coincidental caused by only few excess events. The lower the sample size, the greater the effect of a small number of outliers. One way of describing the margin of uncertainty is by reporting standardised mortality ratios in funnel plots, where the borders of the confidence intervals are widest when few patients are included (Figure 2.). Control charts, such as exponentially-weighted moving average and cumulative sum charts, may also be helpful in identifying unwarranted variation not obvious through cross-sectional benchmarking with SMR, by comparing observed to predicted outcomes for each ICU over time (29). If a process changes the outcome (often mortality), this can be detected by a sudden change in the chart.

When an ICU has been identified with a statistically significantly different outcome, the structure, process and outcomes of care should be scrutinized as a whole. Where in the entire process of care are things done differently and how does that impact on outcome? This is not an easy task and this often frustrates the ambitions of the health care professionals to identify and implement quality improvement initiatives. The ICU is just one step in the entire chain of care within a hospital. Consideration of step-down units and other relevant specialties is required and should be part of any implementation strategy, otherwise difficult improvements on the ICU are equalized by flows in care on the other wards.

Lesson Five: Bridging the “Information - Intention Gap”

The primary CRQ objective of contributing to the identification and reduction in unwanted practice variation cannot be maximised without considering the influence of behaviour. The premise of audit and feedback is that it improves the accuracy with which health professionals assess their performance (30). Clinicians, whose performance is found to be significantly inferior to that of their peers are motivated to improve the differences in standard clinical policies that have been shaped over time by local capacity and practice (31). However, studies have shown repeatedly that feedback messages are rejected when recipients do not trust the data, disagree with benchmarks, consider improvement unfeasible, or do not consider the topic an important aspect of clinical quality (32, 33). This shows that feedback alone fails to change the perceptions of health care professionals or provides insufficient tools to improve the care. In other words, objective information does not automatically lead to an internally motivated incentive to change practice. This has been called the "Information–Intention Gap" (33, 34).

Clinical Performance Feedback Intervention Theory (CP-FIT) provides information about how feedback works and what factors may influence its effects (34). Feedback processes are influenced by many factors relating to the feedback itself, the recipient of the feedback, and the context in which the feedback is delivered. In part, there is a lack of correspondence between health professionals' intended improvement targets and the recommended improvement targets of feedback (35, 36). Intentions vary strongly between individual professionals, and to a lesser extent between teams, independent of the feedback. This indicates that most health care professionals have their own view on what constitutes quality of care. Moreover, professionals often overestimated their own clinical performance prior to receiving feedback and do not know how to further improve care (32).

Therefore, good feedback should be actionable! (see also Lesson One). The recipient of the feedback should immediately understand where improvements can be made, preferentially by trying to reach a target provided. Additionally, the health care worker should be intrinsically motivated to improve the quality of care. Unfortunately, in more than 50% the health care worker is not motivated (32). Once identified, a CQR may not be directly involved in addressing unwarranted outcome variation. However, bridging the information – intention gap requires that a CQR must understand these issues and incorporate CP-FIT or an alternative model into all aspects of registry development.

Lesson Six: Dynamic Registries Must Meet Evolving Needs

High quality registries must be responsive to the evolving requirements and priorities of the healthcare system under which they operate. The capacity to adapt and grow to changing technological, clinical, administrative and legal requirements is an essential component of CQR strategic planning. It is informed by a continuous dialogue with key stakeholders and an understanding of the relevant contemporary research and quality improvement literature.

Stakeholders

The need to engage consumers as healthcare partners, including in CQRs, is recognised increasingly (37). Challenges to involving consumers in ICU registries can include low awareness of ICU as a discrete specialty, shared models of care for patients admitted to the ICU involving other specialties and associated registries, and the difficulties and potential trauma associated with recollecting ICU experiences. Nevertheless, consumer involvement in the design, conduct and oversight of ICU CQRs is feasible and necessary to ensure consistency with the values and needs of critically ill patients and their next-of-kin. In particular, consumers have an essential role to play in considering the potential competing interests of data privacy and registry scope and validity, and in ensuring that the outcomes measured reflects consumer healthcare priorities.

Adapting to the needs of other key stakeholders also requires consideration. For example, clinicians, professional societies, hospital administrators and healthcare payers may be increasingly interested in improved data visualisation and real-time monitoring. Whilst these may be of substantial value, CQRs often operate under limited budgets. Data visualisation and the provision of more contemporary data may improve aesthetics and reduce the lag in response time but must be balanced against financial constraints and the time required for data checking. Although there may be technological solutions, a fundamental cost and attribute of a CQR is the expertise required to analyse and provide contextual insight to the data (38).

Research

An ICU CQR can drive a virtuous research circle to inform policy, guidelines and practice. Contemporary, generalisable epidemiological data from a CQR allows relevant research questions to be generated and accurate event rate estimates necessary to power clinical trials. Pivotal RCTs can then be embedded within the registry, and the subsequent translation into practice of the findings measured within the CQR (Figure 1) (39). In effect, rigorous quality improvement becomes indistinguishable from comparative effectiveness research.

Maximising the value of CQRs will require a greater focus on data linkage between registries and the integration of CQRs and EHRs. Technological advancement is likely to play an increasing role in ICU CQR development. Already, it has been possible to show that deviation from an Artificial Intelligence algorithm for management of sepsis is associated with a dose-dependent increase in mortality (40). Using new tools such as smart phones may also help extend the reach of data collection, perhaps for collecting patient-related outcome measures beyond hospital discharge.

Lesson seven: There are More Lessons to be Learnt

Challenges remain for national CQRs. Some are historical and some result from technological and healthcare system advances. Historically, intensive care has been at the forefront of performance benchmarking at the level of the ICU, collaborative models of care have made it difficult to assess individual performance, including academic performance. Attempts to address this for both physicians and nurses are underway, but are yet to be validated widely (41).

Risk-adjusted mortality is also imperfect. Current risk adjustment models are based on only a subset of patients from selected, generally high-income countries. Increasing contributions from within countries, from rich EHR datasets, and developing global tools would be highly informative in improving the care of critically ill patients worldwide. For low and middle income countries in particular, there is a synergy between the development of locally relevant risk prediction models and the establishment of ICU CQRs (42). Collaboration between national CQRs may help to inform international standards for quality indicators and help determine which are universally important and the standards for maintaining the performance of an indicator such as addressing drift in risk adjustment.

Lessons must also be learnt in how to incorporate other important domains of care into routinely measured and reported indicators. This is particularly true of safety culture, defined as "*the product of individual and group values, attitudes, perceptions, competencies,* *and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management*" (43). There is substantial evidence that culture, and safety culture in particular, influences both staff and patient outcomes. Comprehensive, reliable and valid measures of ICU leadership, organizational culture, communication, coordination, problem solving-conflict management and team cohesiveness exist (44). Positive caregiver interaction (coordination, communication, and conflict management abilities) is associated with lower risk-adjusted length of stay, lower nurse turnover, higher quality of care , and greater ability to meet family member needs (45). Conversely, factors such as variable and dictatorial leadership behaviour, lack of mutual respect, and fear of being stigmatized may adversely affect safety culture and harm outcomes (46, 47). Implementing an intervention across multiple ICUs with the aim of improving ICU safety culture, including teamwork and safety climate appears feasible and may be supported by incorporation within an CQR (48). Enhancing the quality of the ethical climate in the ICU may improve both the identification of patients receiving excessive care and the decision-making process at the end of life (49).

Conclusions

ICU CQRs are highly effective tools for identifying and reducing unwanted practice variation. To maximise the value of ICU CQRs in informing policy and improving outcomes for critically ill patients, clinicians, and other stakeholders, must continue to learn, and adapt the requirements and CQR capabilities to evolving healthcare needs.

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