INTEGRATIVE REVIEW

Quality and safety in intensive care—A means to an end is critical

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KEYWORDS
Quality; Safety; Intensive care; Process measures; Evidence-based medicine; Clinical practice improvement

Summary
Background: To achieve improvement in healthcare quality and safety, all four domains (outcome, process, structure and culture) must be considered in conjunction with the best available clinical evidence to improve patient care and reduce harm. A range of improvement initiatives have targeted processes of care in recognition of: (1) complexities of patient care and (2) evidence that a large portion of adverse events are preventable, occur during ongoing care, and result in poorer patient outcomes.

Purpose: The aims of this paper are to: (1) outline national and international quality and safety initiatives; (2) identify evidence-based processes of care applicable to the general adult ICU patient population; (3) summarise the literature on relevant quality improvement strategies.

Methods: An integrative literature review was conducted by: (1) database search of Ovid Medline, CINAHL, EMBASE and Cochrane for articles published between 1996 and October 2009; (2) identification of additional studies from articles obtained; (3) purposive internet search identifying relevant quality and safety initiatives.

Findings: Quality improvement initiatives across the globe were identified, with ensuing focus on how the development, implementation and evaluation of evidence-based processes of care can lead to improvements in the delivery and outcomes of intensive care practice. Variation in practice and methodological limitations of existing studies were also noted, highlighting the need for innovative approaches to improving processes in the ICU.

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Conclusion: This integrative review has outlined potential for achieving practice improvements in intensive care and highlighted the need for further evaluative research to improve patient care at the bedside.

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Introduction

Improving quality and safety in healthcare is an important issue for health systems worldwide. Two landmark reports from the United States' Institute of Medicine (IoM) in 1999 and 2001 highlighted deficiencies in quality of care and patient safety and outlined strategies for redesign, respectively. A number of agencies and projects across the globe have since been established, exploring issues designed to improve the quality and efficiency of health services. The discipline of 'safety science' has also evolved, with specific application to health care delivery and more recently, critical care medicine, particularly with the Declaration of Vienna.

For any discussion on healthcare quality, it is important to define the term 'quality of care'. From a contemporary perspective, the IoM considered health care quality as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge'. Quality and safety in healthcare is commonly described in terms of Donabedian's approach, with three major domains:

1. Patient outcomes—the results of care in terms of recovery, restoration of function and/or survival.
2. Process—the practices involved in the delivery of care.
3. Structure—the way the healthcare setting and/or system is organised to deliver care.

More recently, a fourth domain of culture or context has been suggested specifically for patient safety models to evaluate the context in which care is delivered. The contemporary model for healthcare improvement recognises that the resources (structure) and activities carried out (processes) must be addressed within a given context (culture) to improve the quality of care (outcome). Quality improvement (QI) activities identify and address gaps between knowledge and practice. Importantly, these activities need to reflect the most recent and robust clinical evidence to improve patient care and reduce harm.

The complexity of patient care creates a human factors environment where errors are potentially common and safety systems are required to minimise adverse events for patients. To quantify deficiencies in healthcare delivery one U.S. study assessed compliance with specific recommended processes of medical care for a wide range of conditions. Overall, participants received recommended care only 55% of the time across preventive, acute, and chronic care settings. In Australia, national reporting of omissions in care or adverse events is in its infancy. The first, and so far only national report for Australia focused on sentinel events (i.e. a specific set of adverse events considered to be serious) in public hospitals, served to pilot a national reporting framework resulting in recommendations for improving data collection and reporting methods. However, earlier work conducted in 28 hospitals across two States (New South Wales and South Australia) clearly demonstrated the need for improved care—17% of admissions were associated with an adverse event, with 51% of adverse events considered preventable and over half (52%) deemed errors of omission. This study also demonstrated the impact of adverse events on patient outcome, with 18.5% of events resulting in permanent disability or death. A more recent study conducted in a tertiary ICU over a 2-month period found 84% of 211 incidents were preventable, with 53% occurring during ongoing care.

Since this time, there has been increasing international attention on the quality and safety of intensive care practice with a range of initiatives targeting improvement in a number of identified areas. The translation of clinical evidence into practice is the key underlying principle to achieving improvements in healthcare delivery and outcomes, with numerous models, methods and strategies proposed. Arguably, intensive care practice has a substantial body of good clinical evidence that should be integrated into everyday practice, and there appears to be an increasing number of QI initiatives to achieve that aim. There has also been a range of recent clinical trials examining elements of practice (e.g. glucose control, nutrition, sedation and deep venous thrombosis prophylaxis), and subsequent work evaluating...
implementation of best practice and QI initiatives at local ICU levels.

It is therefore timely to investigate these various improvement efforts that have been implemented using an integrative review approach. Within the context of intensive care unit (ICU) practice, the aims of this paper are to: (1) outline national and international quality and safety initiatives; (2) identify evidence-based processes of care that are broadly applicable to the general adult ICU patient population; (3) summarise the literature on relevant quality improvement strategies.

Methods

To address these aims, a search of the literature was conducted using Ovid Medline, CINAHL, EMBASE and Cochrane databases for articles published between 1996 and October 2009. The single and combined search terms used were: 'intensive care', 'intensive care units', 'critical care', 'quality assurance (health care)', 'quality of health care', 'safety', 'culture', 'organisational culture', 'outcome and process assessment (health care)', 'outcomes', 'process assessment (health care)', 'clinical process', 'quality indicators (health care)', 'evidence-based medicine', 'patient care management', clinical practice and improvement. Terms were combined to search for relevant research articles and reviews. Reference lists from identified articles were used to identify additional studies. A purposive internet search was also conducted to identify relevant quality and safety initiatives using broad key terms similar to the above to identify projects, and a search of websites of known relevant organisations. Publications were included if they were in English-language, the full text articles were accessible, and were directly related to the stated aims. A total of 37 papers met the criteria for inclusion and were reviewed. The studies are discussed below using the following themes: quality and safety agencies and projects; evidence-based processes of care; and quality improvement strategies.

Quality and safety agencies and projects

Internationally, agencies promoting healthcare quality and safety have started to gain the support of governments and funding bodies and obtain media attention. Although there is still much to achieve, these agencies are committed to implementing changes to healthcare systems to improve the quality of care and safety of patients. To promote patient safety issues across the globe, the World Health Organization (WHO) launched the World Alliance for Patient Safety in 2007 to ‘initiate and coordinate the work of developing and disseminating solutions for patient safety’. An international collaborative project was then established to achieve significant reductions in five highly prevalent patient safety problems: (1) patient care hand-over errors; (2) wrong site/wrong procedure/wrong person surgical errors; (3) medication errors; (4) high concentration drug errors; (5) hand hygiene practices. The World Alliance has developed a classification system for patient safety, including identification of 48 major concepts and definition of key terms. Other groups are also conducting similar concept mapping work. Most recently, the ‘Declaration of Vienna’, with a focus on intensive care medicine, outlined key points noting the importance of patient and clinical team safety, and translation of knowledge to improve quality of care.5

The ‘100,000 Lives Campaign’ was widely implemented throughout the U.S. by the Institute of Healthcare Improvement (IHI) in 2006 using six evidence-based interventions demonstrated to improve patient outcomes:

1. deploy rapid response teams to patients at risk of cardiac or respiratory arrest;
2. deliver reliable, evidence-based care for acute myocardial infarction;
3. prevent adverse drug events through reliable documentation of changes in medication orders;
4. prevent central line infections;
5. prevent surgical-site infections;
6. prevent ventilator-associated pneumonia.

The majority of these interventions relate to critical care practice. While the claim of reportedly saving 122,000 unnecessary deaths over an 18-month period was criticised for being unverifiable due to the lack of supporting hospital data, the campaign was successful in promoting actions that had the potential to save patient lives and eliciting widespread stakeholder engagement.

In Australia, a number of national and state-based agencies are now focused on healthcare improvement in a range of areas. The Australian Commission for Safety and Quality in Health Care (ACSQHC) facilitates national collaboration on quality and safety improvement, including the development of a national strategic framework and associated work program to guide efforts in improving quality and safety across the health care system. Recent initiatives include a Clinical Han-
Evidence-based processes of care

One of the three domains of quality proposed by Donabedian,7 and arguably one that has been unjustly overshadowed by outcomes,33 is the measurement of clinical process. Process measures assess the extent to which health care providers perform certain processes that lead to appropriate patient outcomes.34 These measures offer important insights into quality by providing a direct measure of care. To be valid, process measures need to: be supported by good clinical evidence, logic or experience; based on either established clinical standards or agreed criteria; and include identifiable actions.33 Table 2 describes studies that examined process of care delivery in intensive care.

Contemporary process measures of health care quality exhibit both advantages and disadvantages. Advantages include: data collection can be embedded into the daily routine; relates directly to clinical practice; are easy to benchmark; and when compared with risk-adjusted outcomes—have lower costs, take less time to collect, and require a smaller sample size (as all eligible patients experience the process). Importantly, these types of measures facilitate acceptance from clinicians because of the direct relationship with care activities, and offer clear and interpretable feedback for quality improvement.34 Disadvantages include having to: specify eligible populations for a process given there can be exclusions and contraindications and many are specific to a single disease; create valid summary measures given they are rarely comprehensive; and regularly update and maintain the relevance and appropriateness of measures.34 Although these limitations pose challenges to the implementation of process measures, they can be addressed by proper design, planning and close monitoring during implementation.

The role of evidence in improving the quality of healthcare is crucial. Evidence-based medicine (EBM) integrates individual clinical expertise with the best available external clinical evidence from systematic research.35 Good quality clinical care is achieved by implementing practices that work according to the current knowledge base, and avoiding those that do not. Over the past decade, increasing attention has been directed towards the development, implementation and evaluation of evidence-based process of care measures. For example, a review prepared for the Agency for Healthcare Research and Quality (AHRQ) in the U.S.,36 identified 79 evidence-based practices that were most likely to improve patient safety. Eleven received the highest rating, with three of these related to ICU process measures:

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Table 1  Examples of state-based organisations that have implemented quality and safety projects.

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Project</th>
<th>Year</th>
<th>Description</th>
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<tbody>
<tr>
<td>NSW Clinical Excellence Commission (CEC)</td>
<td>Safer Systems-Saving Lives (SSSL)</td>
<td>2006–2007</td>
<td>Based on the IHI’s 100K Lives Campaign, six interventions (prevention of adverse drug events, ventilator-associated complication, central venous catheter-related blood stream infections, surgical-site infections, and implementing a rapid response system) were implemented at 48 regional and metropolitan sites across Australia (7 states and territories).</td>
</tr>
<tr>
<td>CEC</td>
<td>CLAB in ICUs</td>
<td>2007–present</td>
<td>Involves a modified collaborative methodology to implement a consensus guideline to reduce CLAB in Intensive Care, building on the work commenced through the SSSL project.</td>
</tr>
<tr>
<td>CEC &amp; National Institute of Clinical Studies</td>
<td>Venous Thromboembolism Prevention Program</td>
<td>2005–2009</td>
<td>Developed to improve the assessment of all patients at risk, improve the use of preventive measures and integrate effective thromboprophylaxis systems into Australian hospitals.</td>
</tr>
<tr>
<td>CEC &amp; NSW Therapeutic Advisory Group</td>
<td>PIMS Project</td>
<td>2004</td>
<td>Focused on improving medication safety systems and monitoring performance in QUM in Australian hospitals by: (1) adapting U.S. developed risk assessment tools specifically for hospitals to take a proactive and system-based approach to medication safety and (2) producing a revised manual of ‘Indicators for Quality Use of Medicines in Australian Hospitals’ to enable hospital managers and clinicians to guide improvements in medication management.</td>
</tr>
<tr>
<td>Victorian Quality Council</td>
<td>Pressure Ulcer Point Prevalence Surveys (PUPPS) project</td>
<td>2003, 2004 &amp; 2006</td>
<td>Conducted three state-wide surveys on the prevalence of pressure ulcers within acute and subacute health services. The level of improvement in pressure ulcer prevalence, prevention and management was tracked over time. In 2006, mean prevalence was 17.6% (a 33% reduction since 2003), there was a 25% increase in the use of a risk assessment tool, and 22% increase in the proportion of patients with a pressure reducing/relieving device in situ.</td>
</tr>
<tr>
<td>Victorian Quality Council</td>
<td>Pressure Ulcer Basics (PUBS) education program</td>
<td>2004</td>
<td>In responding to recommendation from the PUPPS project, developed two online education programs aimed at providing basic information on pressure ulcer development, assessment, management and prevention, for all clinical staff.</td>
</tr>
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appropriate deep venous thromboembolism (DVT) prophylaxis; appropriate provision of nutrition; and pressure ulcer prevention. ‘Prevention of ventilator-associated pneumonia (VAP) via semi-recumbent positioning’ was also rated highly on strength of evidence, while inadequate pain relief was rated with a ‘medium’ strength of evidence category.

To specifically develop ICU process measures, Berenholtz et al. conducted a systematic review.
### Table 2: Studies describing process of care delivery in critical care units.

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample</th>
<th>Setting</th>
<th>Method</th>
<th>Critique</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papadimos et al., 2008. (USA)</td>
<td>Before–after study using historical control in a single centre</td>
<td>115 (over 2 yrs pre-intervention); 165 (over 3 yrs post-intervention)</td>
<td>10-Bed surgical ICU</td>
<td>Medical records</td>
<td>Historical control (1 yr pre-intervention) and year 1 combined were compared to extended post FastHUG period Year 1—procedural...</td>
<td>No difference in VAP rate b/w historical control year (19.3/1000 ventilator days) and Intervention year 1 (16.6/1000 ventilator days), ( p = 0.62 )</td>
</tr>
<tr>
<td>Ilan et al., 2007. (Canada)</td>
<td>Retrospective observational study academic medical-surgical ICU</td>
<td>100 randomly selected pts admitted over 1 yr</td>
<td></td>
<td>Medical records</td>
<td>Multiple regression analysis tested the association between compliance (%) and severity of illness</td>
<td>Variability in eligibility for (median 36.5%, range 10–100%) and actual prescription (56.5%, range 8–95%) of best practices</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Setting</td>
<td>Sample Size</td>
<td>Data Collection</td>
<td>Methods</td>
<td>Outcomes</td>
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<tr>
<td>Keroack et al., 2006. (USA)</td>
<td>Point prevalence; retrospective chart review</td>
<td>38 academic medical centers—114 ICUs of 15 types (65% medical, surgical, cardiac, cardiothoracic)</td>
<td>1463 cases, mech. vent &gt;96 h</td>
<td>Data extracted from clinical database &amp; supplemented by chart review</td>
<td>Correlations between pairs of interventions and logistic regression model for mortality included each intervention as an independent variable (also incorporated severity of illness, age, gender, race &amp; 21 specific comorbidities)</td>
<td>Audit sampled a single day as a proxy for practice throughout the ICU stay</td>
</tr>
<tr>
<td>Hatler et al., 2006. (USA)</td>
<td>Prospective, before–after</td>
<td>8-Bed medical ICU over 12 months</td>
<td>Not stated</td>
<td>Multi-faceted intervention included clinician engagement, daily rounds &amp; pt goals forms, data feedback, range of communication strategies &amp; rewards using rapid-cycle approach ‘HOTSPUD’ mnemonic reminder: HOB &gt; 30°, oral care, turning pt, sedation vacation, peptic ulcer and DVT prophylaxis Impact of individual components of multi-faceted intervention not reported Compliance with individual care components not detailed Tools not formally evaluated Uncontrolled study design Statistical analysis not detailed</td>
<td>Adherence to ventilator bundle increased from 73% to 98.6%; DVT prophylaxis greatest variability in implementation VAP rate reduced 54% from 11.4/1000 ventilator days to 5.3/1000 resulting in 22.5 fewer VAP occurrences Rate of CR-BSIs reduced 78% from 12.8 to 2.88 Mean LOS reduced 18% from 3.59 to 4.4 days Annual cost savings = $97,700—$267,700 for reduction in VAP; $220,000—$1,309,000 for reduction in CR-BSIs; $726,600 for reduced mean length of stay</td>
<td></td>
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<tr>
<td>Study</td>
<td>Design</td>
<td>Sample</td>
<td>Method/Critique</td>
<td>Findings</td>
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</table>
| Resar et al., 2005. (USA)\(^{58}\) | Before—after                     | 35 ICUs    | Weighted averages of 6 monthly measures (1st 6 months = "before", 2nd 6 months = "after")
No baseline data collected prior to implementation of strategies (ventilator bundle, multidisciplinary rounds and daily pt goals)
Voluntary data submission led to incomplete & inconsistent data
Reporting bias as outcomes assessment not standardised or blinded
Other relevant outcomes not measured, e.g. VTE, gastro-intestinal bleeding | 57% of teams reported data required for analysis
Units with the highest compliance rates with bundle had highest rates of VAP reduction
In 21 units with ≥95% compliance, VAP rates decreased 59% from 6.6 to 2.7 per 1000 vent days (p < 0.001)
VAP rate decreased 45% in all units that provided required data and a minimum 20% improvement in adherence to ventilator bundle |
| Wall et al., 2005. (USA)\(^{61}\) | Before—after using real-time process measurement | 14-Bed adult medical ICU | Baseline: approx. 2 yrs, 9 months; Intervention: approx. 2 yrs (630 CVCs inserted)
CQI methodology including provider education, continuous audit, performance feedback & checklist developed as a measurement tool/reminder
SPC charts used—measured process of CVC care in real-time
Extraneous variables that may have impacted on CR-BSI rate not controlled for, e.g. case-mix, catheter duration
Contribution of each component of multi-faceted intervention to improvements not determined | CR-BSI rate reduced from 7/1000 catheter days to 3.8/1000
No. days between infections increased post-intervention (depicted graphically using process control chart) |
<table>
<thead>
<tr>
<th>Study</th>
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<th>Sample Size</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crunden et al., 2005. (UK)&lt;sup&gt;57&lt;/sup&gt;</td>
<td>Retrospective</td>
<td>6-Bed general ICU/HDU</td>
<td>Baseline audit $n = 21$ (pt obs.); post-implementation audit $n = 24$ Pt outcomes &amp; unit activity: pre-test: 286; post-test: 372</td>
<td>Evaluated impact of a ventilator care bundle (PUD &amp; DVT prophylaxis, sedation stop, HOB &gt; 30°) on outcomes</td>
<td>Measure outcomes over 2 yr study period</td>
</tr>
<tr>
<td>Pronovost et al., 2003. (USA)&lt;sup&gt;38&lt;/sup&gt;</td>
<td>Prospective, cross-sectional, observational</td>
<td>13 adult medical &amp; surgical ICUs in urban teaching &amp; community hospitals.</td>
<td>Not stated</td>
<td>Compliance of process measures</td>
<td>Performance varied widely among &amp; within 13 ICUs</td>
</tr>
<tr>
<td>Clemmer et al., 1999. (USA)&lt;sup&gt;63&lt;/sup&gt;</td>
<td>Before/after quasi-experimental with historical controls</td>
<td>12-Bed tertiary shock/trauma/respiratory ICU</td>
<td>2,764 (range: 512–602 per yr) over 5 yrs</td>
<td>Formal staff training, create &amp; implement computerised standard practice protocols</td>
<td>Sig improvement in glucose control (mean of all glucose measurement reduced from 9.9 ± 4.4 to 8.2 ± 2.7 mmol/L), use of enteral feeding (reduction of pts on TPN from 15% to 8%, reduction in days starting enteral feeding from 2.95 to 1.6 days), and appropriate use of</td>
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and an extensive evaluation of several potential measures including appropriate sedation, prevention of VAP via semi-recumbent positioning, appropriate peptic ulcer disease (PUD) prophylaxis, appropriate DVT prophylaxis and effective assessment of pain. Most measures were rated highly on strength of evidence and recommendation for use, while pain was the only measure to be selected on face validity alone. These indicators were later used to measure quality of care in 13 ICUs (see Pronovost et al. 2003 in Table 2).

Importantly, process measures of care have been linked with better health outcomes. For example, in an Australian and New Zealand sample of intensive care patients, conventional glucose control (i.e. maintenance of glucose concentrations below 10.0 mmol/L) was associated with lower mortality and a lower rate of hypoglycaemia when compared with tight glycaemic control (4.5—6.0 mmol/L). Some processes have also been shown in randomised controlled trials (RCTs) to improve surrogate end-points; e.g. interruption of sedative infusions, spontaneous breathing trials, and protocol-directed weaning have been associated with a reduction in duration of mechanical ventilation hours. Semi-recumbent body position has been associated with lower nosocomial pneumonia rates. In a systematic review of RCTs, early enteral nutrition was associated with a lower incidence of infections and reduced hospital length of stay.

### Quality improvement strategies

The widespread translation of evidence into practice is the necessary next step from the identification of best practice. A recent model for improving care in 100 ICUs in the U.S. demonstrated that implementing a series of targeted interventions can improve healthcare processes and unit safety culture and reduce adverse events. Essentially, changes to the healthcare delivery system must be made if healthcare organisations are to achieve higher levels of performance.

In a paper discussing evidence-based practices in the ICU, Vincent proposed that to achieve effective bedside rounds, a series of evidence-based statements needs to be raised systematically for each patient. With further reference to relevant clinical literature, he later introduced the ‘FASTHUG’ mnemonic (Feeding, Analgesia, Sedation, Thromboembolism prophylaxis, Head-of-bed elevation, stress Ulcer prevention and Glucose control). Although ‘FASTHUG’ does not cover all

<table>
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</tr>
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<tbody>
<tr>
<td>Sedation (95% reduction in sedation costs), among others</td>
<td>A severity-adjusted total hosp cost reduction of $2,580,981 with 87% of the reduction in cost centers directly influenced by the intervention</td>
<td>Study Design Sample Method/Critique</td>
<td>Table 2 (Continued)</td>
</tr>
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</table>

**Table 2**

Abbreviations: ICU = intensive care unit; HDU = high dependency unit; QI = quality improvement; no. = number; b/w = between; yr = year; pts = patients; grp = group; hosp = hospital; sig = significant; mx = management; mech vent = mechanical ventilation; VAP = ventilator-associated pneumonia; PUD = peptic ulcer disease; DVT = deep vein thrombosis; VTE = venous thromboembolism; TPN = total parenteral nutrition; LOS = length of stay; SPC = statistical process control.
aspects of every patient’s care and will not apply to all patients at all times, it does highlight seven key areas to be considered daily by the entire clinical team for each patient during their ICU stay.48

An IHI collaborative project developed a set of quality indicators for the evaluation of care, resulting in a comprehensive guide to measuring performance in ICUs that included evidence-based measures, strategies for change, and a range of implementation tools.49 A number of other initiatives have since been implemented to improve care delivered both within and outside ICUs, including the implementation of process tools such as daily goals,50 morning briefings, and safety scorecards,52 as well as a unit-based safety program.53,54

The daily goals form was devised to improve communication between ICU clinicians and to assist in developing explicit patient-centred goals. The form contained standard processes of care including semi-recumbent patient positioning, sedation cessation, peptic ulcer prophylaxis and DVT prophylaxis, and was to be completed during patient ward rounds. Clinical staff reviewed the goals throughout the day and updated them if a change occurred. Form use increased the proportion of resident doctors and nurses who understood what the patient daily goals and tasks to be completed were, from less than 10% to over 95% over an 8-week period.50 Similarly, the morning briefing tool was introduced to direct attention to safety issues during clinical handover. Briefings covered: an update of issues that occurred overnight (e.g. adverse events, near misses, admissions and discharges); prioritised the order in which patients were seen; and identified current problems or defects (e.g. equipment availability, staffing, patient scheduling and testing).51

The comprehensive unit-based safety program (CUSP) identified defects in care using a structured 8-step approach designed to: encourage staff to identify and eliminate potential errors in patient care settings; engage senior hospital executives to work with staff on identifying patient safety issues; and empower unit staff to address identified issues. The program required 6 months for implementation and consisted of the following steps: (1) conduct a culture survey with staff; (2) educate staff on patient safety; (3) identify specific safety concerns through a separate staff survey; (4) implement the ‘Senior Executive Adopt-a-Work Unit Program which involved assigning an executive to a unit who worked collaboratively with staff to identify potential areas for improvement and develop strategies to address them; (5) implement improvements using a plan-do-study-act (PDSA) cycle; (6) document the results and share stories on project successes and failures; (7) disseminate results within the organisation; (8) repeat the cultural survey with staff after 6 months to compare with baseline data.55 While the CUSP intervention improved median ‘teamwork climate’ from 47% to 51% (in the 72 ICUS with before—after safety attitudes questionnaire data), adherence to evidence-based practices ranged from 25% to 89%, and the before—after design limited any causal inference.55

Bundles of care

Leading from the development of the above process initiatives, evidence-based ‘bundles of care’ were developed by the IHI.56 Table 2 outlines studies examining process of care delivery in critical care units, including those where care bundles were implemented and evaluated. One bundle directed towards reducing the incidence of ventilator-associated pneumonia (VAP) in critically ill patients included the following elements:

- elevating the head of the patient’s bed to 30–45 degrees;
- daily ‘sedation vacations’ or gradually lightening sedative use each day;
- daily assessment of the patient’s readiness to extubate or wean from the ventilator;
- delivering both PUD and DVT prophylaxis.

Increased bundle compliance was associated with decreased ICU length of stay (LOS), reduced ventilator days and increased ICU patient throughput,57 and decreased rates of ventilator-associated pneumonia.58 Other quality improvement studies targeted similar processes of care without taking the bundled approach (Table 2). A range of measures demonstrated improved outcomes:

- decreased VAP,59,60 catheter-related bloodstream infection (CR-BSI) rates and LOS60;
- increased days between CR-BSIs61;
- decreased hospital mortality as the number of process interventions increased62;
- reduction in severity-adjusted total hospital costs related to improvements in process measures of care, including glucose control, use of enteral feeding and appropriate sedation.63

Although studies revealed improvements in both processes and outcomes, variation in levels of compliance with process measures were also reported. Substantial variations in practice were identified, including the prescription and delivery of PUD and DVT prophylaxis, enteral nutrition, gly-
caemic control, prevention and management of pressure ulcers, sedation management practices, semi-recumbent positioning, spontaneous breathing trials, and pain assessment (see Table 2 for detail). Three studies reported variation in compliance of processes between units. Interestingly, one study reported an inverse relationship between the prescription of best practices and severity of illness (coefficient $\beta = -0.93$, $p = 0.001$). That is, the sicker the patient was, the less likely they were to have received practices they were eligible for.

These studies were not without their limitations in both design and measurement. Measurement poses the greatest challenge for examining the effect of implementing care bundles. Common limitations included practicalities of data collection, establishing consistent definitions (e.g. not all units use the Centers for Disease Control and Prevention criteria for VAP), using appropriate process measures, and/or outcome measures, not controlling for extraneous variables that could impact on outcomes, and lack of baseline data for comparisons. Low inference study designs were common, e.g. uncontrolled and retrospective. Other methodological limitations included: small or unknown sample sizes, limited representation of ICU population due to single centre studies, failure to evaluate tools developed and used as part of the intervention, and not evaluating the impact of individual components of multi-faceted interventions on outcomes. Improving rigour and quality of study methods can be improved with attention at the design and data collection, management and analysis phases; including standardised data collection forms, training, auditing for data quality, and management of missing data.

Checklists

The use of checklists in healthcare, particularly surgical, anaesthetic, and intensive care settings has increased markedly over the past 5 years. The most prominent study to date developed as part of the World Health Organization’s ‘Safe Surgery Saves Lives’ program—a multi-centre study (8 hospitals in 8 cities across the globe) evaluating the impact of a 19-item surgical safety checklist on patient outcomes. Results demonstrated improvement in all 6 process measures (from 34% to 57%, $p < 0.001$) and a reduction in both the rate of death (from 1.5% to 0.8%, $p = 0.003$) and complications (from 11% to 7%, $p < 0.001$).

In intensive care settings, checklists have been used to facilitate staff training, detect errors, check compliance with safety standards and evidence-based processes of care (such as those outlined previously), increase knowledge of patient-centred goals and prompt clinicians to review certain practices on morning rounds in the ICU. Findings from studies (see Table 3) noted that checklists:

- assisted in improving the understanding patient therapy goals;
- improved compliance with safety standards;
- detected patient safety errors and omissions in care;
- improved compliance with evidence-based care;
- proved useful in preparing for a procedure;
- were not time consuming or labour intensive;
- when developed in conjunction with clinicians produce a valid and reliable tool that is consistently used;
- enabled collection of real-time process measures to assist in the immediate identification of anomalies.

Three studies suggested that checklists also contributed to improved outcomes: (1) reduced LOS, ventilator days, unit mortality; (2) catheter-related bloodstream infections; (3) reduced mean monthly rates of VAP. However, the current evidence base is scant and lacking in methodological rigour. Limitations of all the studies evaluating checklists included:

- study designs that lack comparison with other methods and/or control of extraneous variables therefore preventing inference of causal links between checklist use and improved outcomes;
- outcomes closely related to practices in the checklists not measured;
- impact on care not evaluated;
- utility of a checklist in detecting and correcting omissions or errors not evaluated;
- not determining the contribution of multi-faceted interventions to reported improvements;
- lack of baseline data or statistical process control limited inferences of measured improvements;
- lack of formal validity and reliability testing;
- extensive lists imposed additional burden on busy clinical staff;

Table 3: Studies evaluating the implementation of checklists.

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<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Sample</th>
<th>Method/Critique</th>
<th>Findings</th>
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<tr>
<td>Byrnes et al., 2009.</td>
<td>Prospective, before-after</td>
<td>(USA) 72</td>
<td>24-Bed surgical ICU/trauma ICU</td>
<td>Before—after observational (prospective), retrospective (prospective)</td>
<td>Consideration of checklist domains improved from 91% (530/583 assessments) to 99.7% (669/671) (p &lt; 0.0001). Variation between checklist domains improved from range = 77—100% to range = 98—100% (p &lt; 0.0001). Surgical site infection (89 vs. 100, p = 0.003), DVT prophylaxis (92 vs. 100, p = 0.007), electrolyte repletion (89 vs. 100, p &lt; 0.0001), oral care for ventilated patients (81 vs. 98, p = 0.002), physical therapy use (81 vs. 98, p = 0.002), documentation of restraint orders (77 vs. 100, p &lt; 0.0001), trend towards more rapid initiation of pharmacologic DVT prophylaxis (16.1 vs. 8.6 days, p = 0.01), time in CVC in ICU (75 vs. 33 days, p = 0.001), number of days spent in ICU (23.4 vs. 12.4 days, p = 0.001), number of in-hospital days (10.3 vs. 7.7 days, p = 0.002).</td>
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<tr>
<td>Haynes et al., 2009.</td>
<td>Prospective, before-after</td>
<td>Multi-national 66</td>
<td>8 hospitals in 37 countries in 8 countries, 160 operating rooms</td>
<td>Evaluate impact of 19-item WHO checklist used at 3 different points in time for each pt on complications including death up to 30 days post-op.</td>
<td>Complication rates dropped from 11% to 7% (p = 0.001). Total in-hospital rate of death dropped significantly from 1.5% to 0.8% (p = 0.03). Overall rates of surgical-site infection and unplanned reoperation declined significantly (p &lt; 0.01 and p = 0.047, respectively).</td>
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### Table 3 (Continued)

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<td>Du Bose et al., 2008 (USA)</td>
<td>Prospective, before–after</td>
<td>Level 1 trauma ICU</td>
<td>Quality Rounds Checklist (QRC) tool developed &amp; used to measure compliance with 16 prevention measures, e.g. VAP, CL infection QRC used to collect baseline data for 1 month (clinical staff blinded) Implementation included monthly process improvement activities, i.e. reminders, prompts, education, revising protocol Contribution of each component of multi-faceted intervention to improvements not determined No formal reliability or validity tests on checklist Not controlled for extraneous variables that may have impacted on outcome measures Relevance of all outcome measures to process measures reported unclear Relationship between process measures and outcomes not tested Statistical analyses conducted not detailed Before/after analysis included 3 months of intervention as ‘after’ measure</td>
<td>Neither presence nor absence of direct observers nor changes in case-mix affected the significance of changes in complication rates ($p &lt; 0.001$ for both) or the rate of death ($p = 0.003$ and $p = 0.002$, respectively) No single site was responsible for overall effect and effect not confined to either high or low-income sites Compliance with all 6 process measures increased from 34.2% to 56.7% ($p &lt; 0.001$) Compliance with following cares increased significantly ($p &lt; 0.05$): HOB elevation (35.2–84.5%); sedation holiday (78–86%); stress ulcer prophylaxis (76.2–92.3%) Decrease in CL duration &gt;72 h (62% vs. 53%) and ventilator duration &gt;72 h (74% vs. 62%) Decrease in mean monthly rates per 1,000 device days of VAP (16.3 vs. 8.9), CL infection (11.3 vs. 5.8) &amp; self-extubation (7.8 vs. 2.2)</td>
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Develop implement & review a checklist 

Hewson et al., 2006. (Australia) 

Prospective, observational, 16-Bed tertiary adult ICU (114 pts) 

Evaluation: 10 medical staff at baseline, 15 post-implementation 

Before—after real-time process measurement 

16-item EB process of care checklist

Checklists completed daily as a direct ‘challenge and answer’ on morning ward rounds by medical staff for 1 month. Checklists served as data collection toolBaseline and evaluation surveys conducted with ICU staff 

Wall et al., 2005. 

81% compliance in completing the checklist 

Certain cares not delivered when appropriate (e.g. 21% of pts were in pain, 31% of invasively ventilated pts could not respond appropriately ventilated pts could not respond appropriately ventilated pts could not

No baseline data = no quantification of improvement in completion of checklist 

Psychometric properties of checklist not evaluated 

Non-compliance data not measured 

McDonald et al., 2008. (USA) 

61 14-Bed adult medical ICU 

Not stated Baseline: approx. 2 yrs, 9 months; Intervention: approx. 2 yrs (630 CVCs inserted) 

Multi-faceted intervention included implementation of a nursing checklist for CVC insertion developed as a measurement tool/reminder 

SPC charts used — measured process of CVC care in real-time 

No validity or reliability tests on checklist 

Extraneous variables that may have impacted on CR-BSI rate not controlled for, e.g. case mix, catheter duration

Implementation collection tool collection not evaluating contribution of each component of multi-faceted intervention to improvements not determined 

CR-BSI rate reduced from 7/1000 catheter days to 3.8/1000 

No. days between infections increased post-intervention (depicted graphically using process control chart) 

CR-BSI rate reduced from 7/1000 catheter days to 3.8/1000 

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<td>Ursprung et al., 2005. (USA)</td>
<td>Prospective, observational</td>
<td>20-bed tertiary care medical-surgical neonatal ICU</td>
<td>Average daily census of 19.5 infants</td>
<td>36-item pt safety checklist developed via modified Delphi technique. Safety process audits performed using checklist during and after morning ward rounds for 5 weeks (13 days). Errors reported to appropriate staff upon detection. Auditing process was time consuming and occasionally disrupted the flow of ward rounds. Reliability of checklist not tested. Impact of detecting errors on quality of care not measured.</td>
<td>Utility: 338 errors detected representing a range of systems problems. Errors detected on all days of auditing—35 errors detected during multidisciplinary rounds, 303 via observation at pts bedside including medical record review. Feasibility: Auditing was completed all 13 days attempted. Errors reported on more than 17 occasions. Clinical staff disclosed errors on all days of auditing. Reliability of checklist not tested. Impact of detecting errors on quality of care not measured. Median no. of items not checked was 13 (range = 7–23). On average, participants didn’t check approx. 1/3 of items when relying on memory alone. 19/20 (95%) felt the checklist was about the right length. 12/20 (60%) preferred a written checklist and 8 (40%) preferred the verbal checklist.</td>
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<td>Hart &amp; Owen, 2005. (Australia)</td>
<td>Prospective, observational</td>
<td>20-experienced anaesthesia registrars and consultants</td>
<td>Anaesthesia Department at a tertiary hospital</td>
<td>Modified Delphi technique used to generate checklist items. Checklist programmed into an electronic device that displayed several lines of text and had a speech facility. Participants were audited via checklist during preparation for a given scenario.</td>
<td>Median no. of items not checked was 13 (range = 7–23). On average, participants didn’t check approx. 1/3 of items when relying on memory alone. 19/20 (95%) wanted to use the checklist when practicing simulated scenarios. 8 (40%) wanted to use it in clinical settings. 16/20 (80%) wanted to use the checklist right length. 17/20 (85%) preferred a written checklist and 8 (40%) preferred the verbal checklist.</td>
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<td>Study</td>
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<td>Pronovost et al., 2003. (USA)</td>
<td>Prospective, cross-sectional, observational</td>
<td>13 adult medical &amp; surgical ICUs in urban teaching &amp; community hospitals</td>
<td>Not stated</td>
<td>A scannable daily rounding form was completed on morning ward rounds &amp; collected data on process measures. Tests for reliability (inter-rater) and validity (construct and content). Sustainability of data collection for the measures tenuous without additional resources due to data processing external to the unit. Impact of data collection form on care delivered not measured. No baseline data = no quantification of improvement.</td>
<td>Performance varied widely among &amp; within 13 ICUs. Interviews: the form was easy to understand and could be completed in &lt;2 min per pt. Focus group: burden of data collection was low, process measures collected via the form much less onerous than collecting outcome data. Validity: ICU physicians and quality experts agreed process measures addressed important aspects of ICU quality &amp; all were supported by clinical evidence. Reliability: high reliability for each of the process measures ($K = 0.9$ for appropriate sedation and $1.0$ for the 5 other measures).</td>
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<td>Dobkin, 2003. (USA)</td>
<td>Observational</td>
<td>Surgical ICU</td>
<td>Not stated</td>
<td>Implement &amp; evaluate a pt daily goals check-off form. The form comprised pt safety goals &amp; EB process measures &amp; used twice daily by multidisciplinary team on ward rounds. Measured accuracy of nurse's knowledge of pt goals. Improvement in medical staff knowledge of daily goals not measured. Extraneous variables that may have impacted on outcome measures not controlled for. Outcomes that some practices were designed to prevent not measured.</td>
<td>Improvement in nurse's understanding of the goals of therapy (from approx. 50% of the goals planned to 98–100%). Reduction in LOS by an average of 1.5 days. Reduction of ventilators days by an average of 1 day. Decreased overall unit mortality from 11.5% to 8.3%.</td>
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| Piotrowski & Hinshaw, 2002. (USA)<sup>68</sup> | Prospective, observational   | Medical, surgical and thoracic ICUs at one medical centre              | Pt safety checklists to be completed by nurses, respiratory therapists and maintenance staff | Improvements made over 2 yr period included  
60% increase in physician restraint assessments completed  
50% increase in completion of restraint safety flow sheets  
42% increase in delivery of mouth care every 4 h  
31% increase in documentation of sedation scale |

*Abbreviations: ICU = intensive care unit; EB = evidence-based; no. = number; pts = patients; sig = significant; yr = year; mins = minutes; approx = approximately; HOB = head of bed; CL = central line; CVC = central venous catheter; CR-BSI = catheter-related bloodstream infection; VAP = ventilator-associated pneumonia; SUP = stress ulcer prophylaxis; DVT = deep vein thrombosis LOS = length of stay; SPC = statistical process control; WHO = World Health Organisation.  

<sup>a</sup> The checklist was not the sole intervention in this study.
• sustainability issues, particularly where data collection was resource intensive.38

Additional studies that address these methodological limitations are required to demonstrate the benefits of checklists in different healthcare settings, including intensive care. However, in response to early promising results and their proven ability to reduce error in industries such as aviation,74 checklists are being promoted widely75,76 and an increasing number of healthcare settings are integrating them into clinical practice.

Conclusion

This integrative review has explored contemporary initiatives that aim to improve the quality and safety of intensive care both nationally and internationally. Importantly, these initiatives have achieved a significant amount of clinician engagement in the implementation of local strategies. Several evidence-based processes of care that are broadly applicable to the general ICU patient population have been discussed including: appropriate provision of nutrition, DVT and stress ulcer prophylaxis; effective pain assessment and adequate pain relief; appropriate management of sedation; semi-recumbent body positioning; and pressure ulcer prevention. Lastly, a number of relevant QI strategies, including the use of checklists, were examined. Both the methodological limitations and the overall variation in practice reported in these studies demonstrate the need for innovative approaches to improve processes in the ICU that are rigorously developed and implemented and empirically evaluated.

The potential for achieving practice improvements and the importance of implementing strategies that ensure comprehensive and individual patient assessment by the clinical team on a daily basis have been highlighted. However, consideration must also be given to the sustainability of interventions including availability of resources and associated costs. Further evaluation research is required to determine the utility of implementing targeted, multi-faceted QI projects to improve the delivery of care to intensive care patients at the bedside. This includes testing methods for translating evidence into practice and evaluating their effectiveness and sustainability over time.

References


42. Vincent J-L. Evidence-based medicine in the ICU. Chest 2004;126:592–600.


Quality and safety in intensive care

75. Gawande A. The checklist. If something so simple can transform intensive care, what else can it do? New Yorker 2007; (December).