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# A Pilot Study to Test the Use of a Checklist in a Tertiary Intensive Care Unit as a Method of Ensuring Quality Processes of Care

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SUMMARY

*This pilot study aimed to test the use of a checklist as a method of ensuring that certain processes of care are performed routinely and systematically in a tertiary intensive care unit. The pilot involved the development of a process indicator checklist, its implementation and review. The checklist contained 16 items sourced from the literature or deemed important by local clinicians. Checklists were completed on the morning round for all adult patients admitted to the unit for approximately one month. Baseline and evaluation surveys were conducted with medical staff to assess both the benefits and shortcomings of using the checklist. Results demonstrated good compliance in completing the checklist (81%) and that when checked, certain aspects of care were not always delivered when appropriate. At the conclusion of the study the majority of medical staff believed that care in the intensive care unit actually improved with the use of the checklist, and all thought that it assisted in ensuring that good quality care was delivered. The checklist is a useful tool that can be readily applied to facilitate best practice and quality in everyday clinical care, ultimately leading to better health outcomes for patients.*

Key Words: checklist, quality, process of care, indicators, intensive care, tertiary

The intensive care unit (ICU) is a high-risk clinical environment where attention to detail is essential in achieving optimal patient outcomes. The quality of care delivered can be assessed in a number of ways, including risk-adjusted outcomes, incident monitoring, access indicators and process indicators. Arguably, when emphasis is placed largely on measuring outcomes, omissions in important processes of care will not be apparent. As a result, a significant amount of work has gone into the development of process indicators as a part of the ICU quality agenda. Process-of-care measures assess 'the degree to which providers perform health care processes demonstrated to achieve the desired aims and the degree to which they avoid processes that avert the desired aims'[1]. A number of these measures have been identified as variables that are associated with improved health outcomes[2] and have therefore been proposed as strategies to improve current performance and quality of care in the ICU[3].

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One pilot study used process indicators that were supported by evidence from randomized clinical trials to measure the quality of care in 13 ICUs[4]. Performance varied widely both among and within the ICUs studied but more importantly, the study revealed that many patients were not receiving indicated therapies or interventions. The authors also calculated how improving performance on these measures may lead to reduced mortality, morbidity, and ICU length of stay.

Obviously, a comprehensive patient management plan requires the interpretation of many variables. Given the limited power of the human brain to process information and the potential for miscommunication in the average ward round, there are times when basic care, particularly in large busy units, is overlooked[5,6]. The same risk applies in aviation, where checklists are used routinely to avoid reliance on memory alone.

In a paper on evidence-based medicine (EBM) in the ICU, Vincent[7] proposes that 'for effective bedside rounds, a battery of questions should be raised systematically in front of each patient'. More recently, he has introduced the concept of the 'Fast Hug' mnemonic (feeding, analgesia, sedation, thromboembolism prophylaxis, head-of-bed elevation, stress ulcer prevention, and glucose control) that he says highlights seven of the key areas that must be considered regularly by the entire team for each

patient during their ICU stay[8]. A range of specialized checklists have also been proposed for intensive care including delirium screening[9], weaning from ventilation[10], and preparation for transport[11]. Several daily goals forms/checklists have recently been posted on the discussion forum of the Society of Critical Care Medicine Protocols Group[12].

The aim of this pilot study was to test the use of a checklist in a tertiary ICU as a method of ensuring that processes of care were performed routinely and systematically, as well as a means of collecting data on compliance for quality improvement.

## METHOD

The pilot study involved the implementation and review of a checklist at a tertiary Intensive Care/ High Dependency Unit (ICU/HDU) for a period of approximately one month. The objective was to have the list completed at the bedside for each patient on the morning ward round and that it be carried out as a direct 'challenge and answer' at a senior medical level, i.e. intensivist or senior registrar. The expectation was that when appropriate care had not been given, the omission would be corrected immediately.

The checklist was introduced and championed by an ICU staff specialist, who demonstrated its use and promoted the perceived benefits to co-workers. The key to engaging ICU staff was to encourage the duty intensivist to involve the whole team in the use of the checklist. Each item on the checklist was to be verbalized and assessed by the team. Education on the use of the checklist was therefore an informal, on-the-job process involving initiation, implementation and review.

The checklist allowed for recording of demographic data, some information regarding the clinical condition (to give context to some of the responses) and the actual process indicator questions. It was a paper-based form that contained the checklist items on the front page and the protocols for use on the back. Definitions of items on the list were provided, along with the checklists, in a folder that the ward clerk collected at the end of each day.

The process indicators used in the checklist (see Table 1) were mostly evidence-based, with some locally developed items that were deemed by the ICU team as important. Each process indicator required a 'Yes', 'No' or 'Not applicable (N/A)' response. 'Yes' meant the item on the checklist had been indicated and done. 'No' meant the item had been indicated and not done. 'N/A' meant the item was not appropriate to the patient at the time, but it did not preclude the patient from receiving that treatment/care at a later date if indicated.

TABLE 1
*Process indicators used as checklist items*

| Indicator | Version of checklist |
|---|---|
| Is the patient in pain at rest? | A & B |
| Is the patient in pain with relevant movement? | A & B |
| If there is pain, has it been addressed? | A & B |
| Sedation—is the patient able to respond appropriately? | A & B |
| If ventilated, is the head of the bed raised 30 degrees? | A & B |
| Is the patient being weaned? | A & B |
| If not ventilated, is the patient sitting out of bed daily? | A & B |
| Has the age of all lines been checked? | B |
| Is the patient being fed (enteral, parenteral, oral)? | A & B |
| Is the patient receiving thromboprophylaxis? | A & B |
| Is the patient receiving stress ulcer prophylaxis? | A & B |
| Is there an antibiotic strategy in place? | A |
| Have the antibiotics been reviewed? | B |
| Was the blood sugar recorded in the last 12 hours? | A & B |
| If yes, was the last recorded blood sugar <8.3 mmol/l? | A |
| If yes, was the last recorded blood sugar <10.0 mmol/l? | B |
| Has the microbiology been checked? | A & B |
| Have the bowels been opened in the last 24 hours? | A & B |

There were two versions of the checklist. The first version (A) was implemented and then reviewed after nine days of use. During the initial period, medical staff were introduced to the concept, familiarized with the process and then gave feedback on the list's practicality. Evidence of inconsistencies and errors in completing the checklist along with the feedback received, made it apparent that some changes were needed. The checklist was revised and the final content was validated by senior medical staff at the pilot site. The second version of the form (B) was implemented for the remaining 24 days.

Data were collected for a four-week period during November-December 2004. The projected sample size (n=528) was calculated by multiplying the number of funded beds (16) by the number of days (33) the checklist was piloted. The total sample consists of two separate sub-sets. The first sample size (n=144) was calculated for the nine-day initial trial period. The second sample size (n=384) was calculated for the remainder of the study period.

Checklist data were entered manually into SPSS statistical software and descriptive statistics were employed. The first ("A" data) and second ("B" data) data sets were combined for overall analysis. Separate analyses were conducted where appropriate, i.e. where different questions were asked.

Self-report baseline and evaluation surveys were conducted with ICU medical staff members who were directly responsible for patient care. The intention of the baseline survey (see Table 2) was to obtain

an initial assessment of the checklist as a tool and whether the medical staff believed that the current daily processes of care could be improved.

TABLE 2
*Baseline survey tool*

| Question | Measure |
|---|---|
| How well do the items on the checklist relate to current daily delivery of care processes within this ICU? | 5 point Likert scale: Very well—Not well at all (including unsure) |
| Do you believe that the current daily processes of care could be improved in this ICU? | Yes/No/Unsure |
| Do you think this checklist may assist in ensuring daily processes of care are delivered? | Yes/No/Unsure |
| Comments | Open response |

At the end of the pilot period the checklist was evaluated using a survey (see Table 3) that assessed the benefits and shortcomings of its use and the reported effects it had on the process of patient care.

Data from the surveys were analysed quantitatively and qualitatively. Thematic analyses were utilized for open-ended questions and comments. Descriptive statistics were used for quantifiable responses.

This study was recognised as a quality assurance project by the relevant Human Research Ethics Committee.

## RESULTS

The size of the sample (i.e. the number of patient assessments) that was achieved was 426 (81% of predicted sample size). This sample consisted of 114 patients in total. The remaining 19% of the predicted sample size was made up of unoccupied beds at the time of the round and missing or not completed checklists. The achieved sample size, split by the two subsets of data (A & B) were similarly comparable (A=83%, B=80%).

The frequency of responses to the process indicators (shown in Table 4) exclude non-responses where not required, e.g. if there is no pain then the follow-on question 'If there is pain, has it been addressed?' obviously does not need to be indicated and should not be classified as either 'N/A' or 'missing'.

Some indicators were only relevant to either the first ("A" data) or the second ("B" data) versions of the checklist, and are indicated as such in the table. The data obtained from the indicators used consistently across both versions of the checklist were combined for overall analysis. This results in different population sizes amongst the indicators, i.e. 'A' data only=119, 'B' data only=307, 'A+B' data=426.

The collection of certain items pertaining to the current clinical state of the patient assisted with the analysis of some checklist data. The useful clinical states were 'Invasive ventilation', 'Septic', and 'Post-elective surgery'. These items were cross-tabulated with relevant process indicators to provide context to the omissions detected. For example, of all applicable assessments, data showed that on 35/112 (31%)

TABLE 3
*Evaluation survey tool*

| Question | Measure |
|---|---|
| How well did the items on the checklist relate to the existing daily delivery of care processes within this ICU? | 5 point Likert scale: Very well—Not well at all (including unsure) |
| Do you believe that the current daily processes of care improved with the use of the checklist? | Yes/No/Unsure |
| Do you think the checklist assisted in ensuring daily processes of care were delivered? | Yes/No/Unsure |
| Was the use of the checklist supported by team members including senior staff? | Yes/No/Unsure |
| On average, how long did it take to complete the checklist? (in minutes) | Visual analogue scale 1-10+ |
| Please rate the following elements of the checklist:<br>Appropriateness of items on checklist<br>Clarity of items i.e. are they easily understood?<br>Checklist design/ layout<br>Ease of use<br>Having the checklist protocols on back of form | 5 point Likert scale: Very good—Very poor (including unsure) |
| Please rate the following elements of the checklist protocols:<br>To be completed during daily ward rounds for each patient<br>To be completed at end of patient visit as a direct 'challenge & answer'<br>Only 1 person to complete the checklist<br>Clarity of definitions | 5 point Likert scale: Very good—Very poor (including unsure) |
| Overall, do you believe the checklist is useful and worth continuing its use in the ICU? | Yes/No/Unsure |
| What do you believe were the benefits of using the checklist? | Open response |
| What do you believe were the barriers or shortcomings of using the checklist? | Open response |
| Additional comments? | Open response |

TABLE 4
*Frequency of responses to process indicators*

| Process Indicators | Yes | % Yes | No | % No | N/A | % N/A | Missing | % Missing |
|---|---|---|---|---|---|---|---|---|
| Is the patient in pain at rest? | 46 | 10.8 | 284 | 66.7 | 93 | 21.8 | 3 | 0.7 |
| Is the patient in pain with relevant movement? | 74 | 17.4 | 226 | 53.1 | 122 | 28.6 | 4 | 0.9 |
| If there is pain, has it been addressed? | 90 | 21.1 | 9 | 2.1 | 275 | 64.6 | 6 | 1.4 |
| Sedation—is the patient able to respond appropriately? | 114 | 26.8 | 40 | 9.4 | 259 | 60.8 | 13 | 3.1 |
| If ventilated, is the head of the bed raised 30 degrees? | 181 | 42.5 | 27 | 6.3 | 206 | 48.4 | 11 | 2.6 |
| Is the patient being weaned? | 107 | 25.1 | 77 | 18.1 | 231 | 54.2 | 10 | 2.3 |
| If not ventilated, is the patient sitting out of bed daily? | 112 | 26.3 | 66 | 15.5 | 225 | 52.8 | 12 | 2.8 |
| Has the age of all lines been checked? (B) | 299 | 97.4 | 0 | – | 4 | 1.3 | 4 | 1.3 |
| Is the patient being fed (enteral, parenteral, oral)? | 349 | 81.9 | 50 | 11.7 | 23 | 5.4 | 4 | 0.9 |
| Is the patient receiving thromboprophylaxis? | 346 | 81.2 | 40 | 9.4 | 32 | 7.5 | 8 | 1.9 |
| Is the patient receiving stress ulcer prophylaxis? | 298 | 70.0 | 56 | 13.1 | 65 | 15.3 | 7 | 1.6 |
| Is there an antibiotic strategy in place? (A) | 67 | 56.3 | 16 | 13.4 | 32 | 26.9 | 4 | 3.4 |
| Have the antibiotics been reviewed? (B) | 189 | 61.6 | 6 | 2.0 | 95 | 30.9 | 17 | 5.5 |
| Was the blood sugar recorded in the last 12 hours? | 403 | 94.6 | 18 | 4.2 | 0 | – | 5 | 1.2 |
| If yes, was the last recorded blood sugar <8.3 mmol/l? (A) | 97 | 81.5 | 16 | 13.4 | 2 | 1.7 | 1 | 0.8 |
| If yes, was the last recorded blood sugar <10.0 mmol/l? (B) | 261 | 85.0 | 29 | 9.4 | 7 | 2.3 | 4 | 1.3 |
| Has the microbiology been checked? | 303 | 71.1 | 38 | 8.9 | 77 | 18.1 | 8 | 1.9 |
| Have the bowels been opened in the last 24 hours? | 150 | 35.2 | 244 | 57.3 | 19 | 4.5 | 13 | 3.1 |

A=relates to "A" data (from version 1 of the checklist) only, n=119.
B=relates to "B" data (from version 2 of the checklist) only, n=307.

occasions, invasively ventilated patients were not able to respond appropriately, and of all those that were post-surgical, 7 (18%) were in pain at rest and 18 (49%) were in pain with relevant movement. There were four assessments that indicated that the pain for a post-surgical patient was not addressed. Furthermore, of all 426 assessments, 89 (21%) demonstrated that the patient had pain of some description.

After the initial introduction to the checklist concept, ten staff members responded to the baseline survey. All respondents thought that the items on the checklist related well to the current daily delivery of care processes within their ICU. With one exception, all respondents believed that care in general could be improved in their ICU and all thought that the checklist might assist in ensuring that care was delivered.

An impact evaluation survey was completed by fifteen staff at the end of the trial. All respondents indicated that the checklist assisted in ensuring that the daily processes of care were delivered. It reportedly took an average of 2.5 minutes (SD= 0.72, range=1.5–4.0) to complete the checklist, which was not considered onerous. The majority believed that care in the ICU actually improved with the use of the checklist (only three were unsure). Sixty per cent of respondents indicated that the checklist was supported by other team members, though some comments made indicated that not all senior medical staff were as supportive of the process as others. For some of the more experienced ICU staff members it was felt that this process was merely reiterating what they did routinely anyway.

The assessment of elements of both the checklist and the checklist protocols were rated favourably overall (see Table 5). However, two (13%) respondents indicated that the clarity of items on the checklist were "poor" and six (40%) respondents were "unsure" about the clarity of definitions that were provided in the protocols. This might be reflective of the lack of formal or structured education on the checklist.

According to medical staff, some of the benefits of the checklist included improving the quality of care; ensuring that important care was delivered routinely and systematically; identifying gaps in the delivery of care; serving as a reminder and a prompt to pay attention to detail; and that it was a useful tool for reinforcing the notion of carrying out daily processes of care.

The reported barriers/shortcomings of the checklist were the extra amount of administrative work added to the ward rounds; a disruption to ward rounds on busy days; variation in completion of checklist; some definitions/terms seemed unclear; and not a structured head-to-toe or organ system checklist.

Overall, 87% of respondents indicated that the checklist was useful and worth continuing its use in the ICU (2 were unsure).

## DISCUSSION

This pilot study suggests that omissions of care do occur in the ICU and the routine use of a

TABLE 5

*Rating the elements of the checklist and checklist protocols*

| Question | Responses, n (%) | | | | |
|---|---|---|---|---|---|
| | Very good | Good | Unsure | Poor | Very poor |
| **Elements of the checklist:** | | | | | |
| Appropriateness of items on checklist | 4 (27) | 10 (67) | 1 (7) | – | – |
| Clarity of items i.e. are they easily understood? | 1 (7) | 11 (73) | 1 (7) | 2 (13) | – |
| Checklist design/layout | 2 (13) | 10 (67) | 3 (20) | – | – |
| Ease of use | 4 (27) | 10 (67) | 1 (7) | – | – |
| Having the checklist protocols on back of form | 3 (21) | 10 (71) | 1 (7) | – | – |
| **Elements of the checklist protocols:** | | | | | |
| To be completed during daily ward rounds for each patient | 1 (7) | 13 (87) | 1 (7) | | |
| To be completed at end of patient visit as a direct 'challenge & answer' | – | 11 (73) | 3 (20) | 1 (7) | – |
| Only 1 person to complete the checklist | 2 (13) | 7 (47) | 4 (27) | 2 (13) | – |
| Clarity of definitions | – | 9 (60) | 6 (40) | – | – |

Note: Missing variables are excluded.

checklist at the bedside is valuable in detecting and correcting those omissions. For example, only 298 of 354 (84%) patient assessments indicated that stress ulcer prophylaxis was delivered. In other words, on assessment during the morning ward rounds, a number of patients had not received appropriate treatment to prevent stress ulcers. Anecdotally, once the omissions were identified they were remedied as soon as practicable.

There are many potential benefits of the checklist methodology. The checklist can serve as a prompt or reminder, as in Vincent's use of the 'Fast Hug' mnemonic, and/or as a tool to collect data that allows for performance review. The advantages of using this methodology to collect process indicators include simple real-time monitoring and feedback; data collection embedded into the daily routine; smaller sample size and less time required to collect (when compared with risk-adjusted outcomes); and the low costs incurred. Importantly, this method has face validity with clinicians as it relates directly to what the clinician is trying to achieve and offers clear and interpretable feedback on what they are actually doing for the purpose of quality improvement[13].

Checklists are certainly becoming popular in patient safety audits. One surgical ICU used a daily goals form as a checklist or 'check-off', rather than a 'to do' list[14]. Deliberately modelled on a pilot's take-off checklist, the form was developed around patient safety goals. The results showed a marked improvement in the understanding of the goals of therapy, a reduction in length of stay (LOS) by an average of 1.5 days and a reduction of ventilator days by an average of one day. Furthermore, a decrease in overall unit mortality from 11.5% to 8.3% was claimed. Ursprung and others[15] also used a checklist to conduct thrice weekly patient safety audits during and after morning rounds in a neonatal ICU. During a five-week study period they detected 338 errors. In a more extensive but less clinically focused program, the Veterans Administration Ann Arbor Healthcare System in Michigan introduced a 'Safety Checklist Program' into their intensive care units[16]. Their intention was to instil a culture of safety in the intensive care unit by requiring nurses, respiratory therapists, and maintenance staff to monitor compliance with an extensive list of safety standards that are regularly audited.

Another advantage could be in facilitating staff training. Hart and Owen[17] recently reported the use of a checklist when training staff for caesarean section under general anaesthesia. While some anaesthetists in their study were not enthusiastic about using the checklist in the actual clinical situation, the advantage of reinforcement would ensure that the preparation was done properly each time. Similarly, in a busy ICU, the constant repetition arising from the use of a checklist at the bedside would assist greatly in informing clinical staff of new policies and treatments.

There were some difficulties in the interpretation of data from the pilot. Of the items on the checklist, only a few, i.e. thromboembolism prophylaxis[18], stress ulcer prophylaxis Data Linkage in Long-Term Survival After ICU[19] and raised head-of-bed[20], are well accepted as best practice and could be considered to require 100% compliance. Other items, such as daily wake-up[21] and aggressive blood sugar management[22], could require 100% compliance but are not universally accepted and subject to ongoing investigation. Indicators that would also elicit useful and measurable data if a scale allowing precise assessment were used, include level of sedation and pain assessment using a visual analogue score (VAS), neither of which

is used routinely in the study unit. Some questions may actually serve better as prompts, though could still be measured to ensure compliance with unit policy. For example, 'Has the age of all lines been checked?'.

A further limitation of this study was that the actual correction of omissions was not quantified. For the purposes of this pilot it was confidently assumed that the omissions were corrected. However, in a larger formal study this would need to be measured.

As with most pilot studies, logistical problems were encountered. First, it became apparent that more formal education on the use of the checklist was required, with ICU clinicians unclear on some of the definitions and indeed on how to complete the checklist itself. Second, the support of senior ICU clinicians was seen as important to the successful implementation of the checklist. A significant amount of time was put into engaging intensivists and senior registrars in particular, with considerable success. However, resistance to change is inevitable and there were some concerns expressed by senior medical staff that the checklist was interfering somewhat with the flow of the daily rounds.

Third, there were a few difficulties noted with data collection. The manual collection of information via a paper-based form added to the daily work of not only the clinicians, but also to administrative staff on the ward. Despite the fact that compliance was good, there were also some issues with incomplete and missing forms. The data then had to be hand-entered into a spreadsheet. In all, the process was reasonably labour intensive considering there is existing technology that could have assisted in this process. If data collection can be integrated into existing processes (e.g. daily care plans) and supported by technology (e.g. computer assisted, use of a Personal Digital Assistant (PDA), electronic transfer of data) a new and effective method of collecting and recording clinical indicators may evolve. This approach would require the clinicians on the round to collect the relevant information routinely and not as a separate 'quality process'.

Whilst it is clear that the use of a checklist in the ICU is of value, and past studies have demonstrated the potential of process indicators to improve quality of care, future studies could endeavour to investigate the actual extent of improvement following implementation of the checklist. In further developing the assessment of the checklist's psychometric properties, there may also be benefit in evaluating both its test-retest and inter-rater reliability.

Future studies might also look to incorporate essential daily processes via checklists, prompts and reminders into existing and/or new technology. The growing emphasis and increasing importance of putting evidence into practice has given rise to an influx of clinical practice guidelines, unit protocols and procedures and so on. However, there are not necessarily any systematic processes in place that ensure their adherence. Indeed, it has been suggested that increased use of information systems has the potential to improve performance of ICUs in a number of different ways[23].

Importantly, the checklist ties in well with some of the important work being done in the field of quality improvement in medicine, both nationally[24] and internationally[25-27]. For example, the Institute of Healthcare Improvement's 100k Lives Campaign has engaged over 3,000 hospitals in the U.S. to implement changes in care demonstrated to improve patient outcomes, e.g. applying a "ventilator bundle" to prevent ventilator-associated complications. A generic checklist could comprise a core set of process measures that draw from these experiences and can be tailored to an individual unit's needs by adding and/or subtracting items depending on case-mix and other local issues. The checklist could then be integrated into the daily process of delivering good quality care to patients regardless of their physical location.

In conclusion, there is potential for the routine use of a process indicator checklist in the ICU setting. The present checklist was a useful tool that, at the very least, reminded medical staff to deliver the daily processes of care that are overlooked or forgotten. It provided a means of collecting formative information that has the potential to improve the quality of care and safety of patients. The checklist can be used to readily implement evidence-based or 'best' practice. The key to successfully doing this in individual ICUs will involve a process of trial and error, of continuing review and development, and the ongoing support and engagement of ICU clinical staff.

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