Examining adverse events after intensive care unit discharge: Outcomes from a pilot questionnaire

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Adverse events are common in acute clinical settings but little is known about these events occurring after Intensive Care discharge. This study aimed to develop a reliable and valid tool for exploring clinicians’ opinions of factors associated with post-Intensive Care adverse events. A convenience sample of Australian Intensive Care Liaison Nurses was invited to complete and appraise a questionnaire using structured guidelines. Content validity and internal consistency were assessed.

Twelve Intensive Care Liaison Nurses completed the questionnaire. Cronbach’s alpha coefficient showed high internal consistency for the questionnaire; all 24 items on the questionnaire had coefficients greater than 0.852. The content validity index of the questionnaire overall was 0.76.

The post-Intensive Care adverse events questionnaire demonstrated reliability and validity. It is a tool that can be used to explore clinicians’ opinions of factors associated with these events. The tool is important as it facilitates further insight into the causes of post-Intensive Care adverse events.

Key words: adverse events, Intensive Care, patient safety.

INTRODUCTION
An adverse event is any unintended harm or injury to a patient, including temporary or permanent disability, which is caused by the health care provided rather than the patient’s disease or illness. These events are not
uncommon, with nearly a quarter of patients experiencing an adverse event during their hospital admission. Of these patients, one fifth die as a result and another 13% suffer permanent disability; half of these events could be preventable with better standards of care.

Adverse events occur in many clinical settings including intensive care units (ICUs). These units provide a vital service for critically ill patients but at a high cost; as much as $81.7 billion US dollars is spent each year funding critical care services in North America. In Australia, the annual cost of ICU services is $850 million US dollars, whereas in the United Kingdom the estimated cost is $872 million US dollars. In order to justify this expense, it is essential that continuity of care occurs after ICU discharge, as preventable deaths in the post-ICU population represent, among other things, a high human cost and a significant investment of expensive health-care resources.

The high demand for ICU beds often results in patients being discharged prematurely from ICU, before they are ready for ward level care. Ward staff can find it challenging to care for these patients as their care needs are often complex. This places vulnerable post-ICU patients at high risk for an adverse event as they might not continue to receive the care required. Research has therefore found that up to a third of patients will experience an adverse event soon after ICU discharge. Consistent with adverse events in other patient populations, half or more of adverse events occurring after ICU discharge could be preventable with better standards of care.

To date, most research on short-term adverse outcomes after ICU discharge has focussed on mortality, as it is an outcome which is easy to define and measure clinically. Seminal research found that up to 20% of patients who died on a ward after ICU discharge were expected to survive; these patients tended to be older, have longer ICU lengths of stay and higher illness acuity scores. Research also concluded that some deaths might have been avoided with better standards of ward care. However, various changes to contemporary clinical practice mean that the findings of these studies, though seminal, are less applicable today.

Two recent Australian studies identified factors contributing to adverse events in the post-ICU population. Patients who experienced an adverse event were older and required a high level of nursing care at the time of ICU discharge. Delays in taking action for abnormal physiological signs and infrequent charting were evident in post-ICU patients. Data collection in these studies occurred via medical chart review which, although a common method, has limitations. Documentation in medical records is often subjective and ad hoc and could therefore provide limited insight into care processes.

Other research designs are therefore needed to further the understanding of adverse events occurring post-ICU discharge.

Limited data are currently available on the incidence, characteristics and outcomes of adverse events in the post-ICU population. A contemporary understanding of the factors contributing to these events is lacking. The clinicians best positioned to fill this knowledge gap are ICU Liaison Nurses. These Nurses represent a new clinical service role in Australia which evolved due to the increasing number of critically ill patients on hospital wards. Important tasks performed by these Nurses include facilitating patient transition from ICU and assisting ward staff with the management of patients with complex care needs. ICU Liaison Nurses are very similar to Patient-At-Risk and Critical Care Outreach Teams in the United Kingdom. These teams were developed to improve the care and outcomes of critically ill ward patients, support ICU discharges and ensure timely ICU admission.

As the ICU Liaison Nurse is a new clinical role in Australia, to date no research has capitalized on these Nurses’ knowledge of adverse events in the post-ICU population. To capitalize on these Nurses’ unique experience and to help fill the knowledge gap on factors contributing to adverse events following ICU discharge, a valid and reliable data collection tool was developed.

**AIM**

This pilot study informs the second phase of a larger programme of research which aims to improve post-ICU patient outcomes through the identification of key factors associated with adverse events in this unique patient cohort. The research programme aims to promote the development of corrective action to reduce the risk and severity of future adverse events in these high-risk patients.

The aim of the second phase of the programme was to explore ICU Liaison Nurses’ opinions of adverse events occurring after ICU discharge. This paper reports the development and testing of the post-ICU adverse events questionnaire, to be used for exploring ICU Liaison Nurses’ opinions.
ETHICS
Approval for this study was obtained from a university Human Research Ethics Committee and deemed negligible risk. Consent was implied through completion of the questionnaire. All data were stored on security protected hardware. The ethical principles of the Declaration of Helsinki were adhered to.

METHODS
Reason’s accident causation model was used as the framework to guide questionnaire development. The model proposes that accidents such as adverse events are the end point of failures in the system or environment in which humans work. When exploring the causes of accidents, Reason’s model encourages a proactive approach by focussing on the conditions in which the individual was working, rather than blaming the individual for the error.

Item development
Guidelines for questionnaire development were followed. These guidelines described the essential steps for questionnaire development, including formulating conceptual definitions of the variables to be measured, deciding whether variables are categorical or continuous, and pilot testing the preliminary questionnaire. In the absence of any survey tool for exploring clinicians’ opinions of factors contributing to adverse events after ICU discharge, the research team developed the preliminary questionnaire draft.

The preliminary draft was informed by an extensive review of the literature and the findings of an earlier qualitative study of ICU readmissions undertaken by the research team. The literature suggested three key domains of factors contributing to adverse events in acute care settings: factors relating to the system or environment in which care is delivered, the person delivering care (i.e. human factors) and the care recipient (i.e. patient factors).

The qualitative study of ICU readmissions which informed the questionnaire was one of few which have attempted to describe clinicians’ opinions and experiences of ICU readmission. As ICU readmission is a common adverse event following ICU discharge, it was hypothesized that factors contributing to readmissions would be common to most adverse events after ICU discharge. These factors were therefore included in the preliminary questionnaire draft. Although some of these factors were similar, they were not identical. For example, staff skill mix referred to the experience of staff whereas nurse to patient ratios reflect numbers not skill base.

Response format
The questionnaire contained five-point Likert scales which measured the respondent’s level of agreement with the questionnaire items (never, seldom, sometimes, often, always). A Likert scale was used because of its sensitivity and ability to produce interval level data. A five-point scale was chosen as reliability increases when the number of rating points increases, with the maximum benefit achieved with five or seven points. Respondents were asked to use the Likert scale to rate the extent to which they believed each of the questionnaire’s items contributes to adverse events in patients discharged from ICU.

The preliminary questionnaire draft contained two sections:
1. A demographics section with 17 questions. This included questions on the number of hours worked by the respondent, their qualifications, the number of hospital beds where they work, including ICU and high-dependency beds, and the type of nursing care delivery on their hospital’s wards (e.g. team nursing).
2. A 24-item questionnaire of causal factors contributing to adverse events after ICU discharge. These factors were divided into three domains: system, human and patient factors, based on the conceptual framework.

Validity
Once the items were generated, three nurses were asked to assess the face and content validities of the preliminary draft. These nurses were experienced critical care nurses with at least 6 years experience in senior clinical roles. Their opinions were therefore important as the goal of the preliminary draft was to capture key factors associated with adverse events.

Although face validity has limitations, it is a useful procedure in the early phase of instrument development as the readability and clarity of content are examined. Minor changes to the wording of some items were made based on face validity assessment by the nurses. Clarifying examples were also added to each of the 24 items.

Expert panel
Questionnaire development involves tool validation by a panel of experts. Experts in the content area are often called on to analyse a tool’s adequacy in representing the
concept being measured. A convenience sample of Australian ICU Liaison Nurses was therefore invited to participate in the study. These nurses had an existing professional relationship with the Chief Investigator (ME) through common membership of the Australian College of Critical Care Nurses Liaison Nurse Interest Group. The nurses were invited to participate in the study at a quarterly meeting of this Group.

Fifteen ICU Liaison Nurses volunteered to participate. These Nurses were emailed an electronic copy of the questionnaire. They were asked to complete the questionnaire and then comment on the comprehensiveness and readability of the questionnaire and the relevance of the questionnaire’s items to adverse events after ICU discharge. A list of instructions for providing this feedback was provided based on De Vellis (see Table 1). They were then asked to email their feedback to the Chief Investigator.

**Statistical analyses**

Data were analysed in PASW Statistics 18. All data were cleaned and checked before analysis. Analyses included determining the reliability and content validity of the questionnaire. For reliability analysis (i.e. internal consistency), Cronbach’s alpha coefficient for the questionnaire overall and item-total correlation were calculated. To establish content validity, the expert panel of nurses was asked to rate each item in terms of its relevance to adverse events following ICU discharge. A four-point Likert scale was provided: 1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant. This allowed calculation of the content validity index (CVI). The CVI indicates the extent to which a panel of experts agree that instrument items relate to or measure the desired construct (i.e. adverse events).

Two types of CVI can be calculated; one for each individual item and one for the instrument overall. An instrument has good content validity if its overall CVI is 0.8 or higher. The CVI for the questionnaire overall was calculated by averaging the CVIs for the 24 items. For individual items, a CVI between 0.7 and 0.9 is optimal. The CVI for each item was determined by calculating the proportion of experts giving a rating of either 3 or 4 for that item.

**RESULTS**

Of the 15 nurses invited to participate, complete data were provided by 12 nurses. Incomplete data were not analysed. The 12 nurses were employed in eight tertiary referral hospitals across three Australian states. These hospitals had between 140 and 470 beds (mean 372) and between 6 and 45 ICU beds (mean 16). The ICU Liaison Nurse services were available between 8 and 23 h per day within these hospitals (mean 11 h). All the Liaison Nurses were experienced ICU nurses and had between 1 and 10 years experience (mean 3) in their Liaison Nurse role. All but one had a postgraduate intensive care qualification.

The alpha coefficient for the questionnaire overall was 0.872 (an alpha between 0.7 and 0.8 is considered acceptable). The mean, standard deviation of each item and correct item-total correlation are provided in Table 2. Floor and ceiling effects were not observed for any of the 24 items.

The CVI for the questionnaire overall was 0.76, suggesting that the expert panel felt that the questionnaire is relevant to adverse events following ICU discharge. However, 8 of the 24 items (see Table 2) had individual CVIs of less than 0.7. Four of these eight items were removed from the final questionnaire due to their low CVI (equipment problems; care omission; the patient’s age; impaired ability to communicate). Four were retained as they were deemed by the researchers to be clinically relevant to adverse events based on the literature. Removing

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**Table 1** Guiding instructions for expert panel

- The 24 items are grouped under three headings (system/human/patient factors). Please comment on whether the items listed under each heading fit appropriately under that heading.
- Please comment on the clarity and conciseness (i.e. wording) of each item. Is it clear? Could it be better worded? If so, please make a suggestion.
- Are any of the items awkward or confusing? If so, please suggest alternate wording.
- Are there other items (i.e. factors which contribute to adverse events in patients discharged from ICU) not listed which should be in the questionnaire? Please feel free to make a suggestion.
the four items with a low CVI increased the CVI of the questionnaire overall to 0.825.

Qualitative feedback from the expert panel also resulted in changes to the questionnaire. The changes are summarized in Table 3.

### DISCUSSION

Many factors contribute to adverse events in acute care settings. These include factors unique to the patient (e.g. co-morbidities), the environment in which care is delivered (e.g. staffing levels) and to the staff delivering care (e.g. qualifications). In unique patient populations such as those recently discharged from ICU, these and other factors might contribute to the development of adverse events. The post-ICU adverse events questionnaire was developed to obtain a better understanding of those factors and is the first questionnaire designed to do so. It was felt that a questionnaire was optimal as it offered a mechanism to collect the unique opinions of ICU Liaison Nurses in a validated, timely and cost-effective manner. It could therefore be superior to other data collection techniques such as chart review.

The content validity of the questionnaire is sound as its content was informed by a literature review of adverse events following ICU discharge and a qualitative study of ICU readmission. The questionnaire’s items were validated by an expert panel of 12 experienced ICU Liaison Nurses, employed in eight tertiary referral hospitals across Australia. The pilot study also indicates that the post-ICU adverse events questionnaire is a reliable and valid tool for identifying areas for improvement in ICU care.
Table 3 Changes to questionnaire based on qualitative feedback

- System Factor ‘lack of/inadequate supervision of medical/nursing staff’ split into two factors; one for medical staff and one for nursing staff
- System Factor ‘lack of experienced staff’ split into two factors; one for medical staff and one for nursing staff
- System Factor ‘patient discharged from ICU before they are ready’ split into two factors—premature ICU discharge and after hours discharge
- System Factor added: ‘fragmentation of patient management due to multiple medical teams’
- Human Factor added: ‘lack of recognition of (or response to) patient deterioration’
- Human Factor added: ‘Inadequate patient handover from ICU to ward staff (e.g. patient care needs not obvious from ICU documentation or verbal handover)’
- Clarifying example (‘omitting observations’) added to Human Factor ‘inadequate patient monitoring or assessment’

Internally consistent tool as evidenced by a high Cronbach’s alpha score.

Four factors were retained in the questionnaire despite having a low CVI. These factors were deemed by the researchers to be clinically relevant to adverse events following ICU discharge. Based on quantitative analysis and qualitative feedback from the expert panel, the final version of the post-ICU adverse events questionnaire contained 25 items: 14 items in the System Factors domain; 8 items in the Human Factors domain; and 3 items in the Patient Factors domain.

Limited data are currently available on adverse events in patients discharged from ICU. Plans for future research therefore include using the questionnaire to determine Australian ICU Liaison Nurses’ perceptions of factors contributing to adverse events in post-ICU patients. Identifying factors associated with adverse events in this high-risk population has the potential to improve outcomes by streamlining care processes. Although the ICU Liaison Nurse’s role is unique to the Australian health-care setting, the questionnaire could also be used to explore opinions of clinicians who perform a similar role in other comparable health-care settings. Examples include Patient-At-Risk Teams and Critical Care Outreach Teams in the United Kingdom.

Limitations
This study has some limitations. ICU Liaison Nurses are unique to the Australian health-care system. If the expert panel had consisted of clinicians from other health-care systems, the results of the study might have differed. The United Kingdom, for example, has a health-care system comparable with Australia, but North America does not. A further limitation is that the pilot data reflect collective expert opinion. Although the first-hand experience of experts is valuable, it is only opinion and thus subjective and reliant upon memory.

Little formal guidance exists in the literature on the sample size for a pilot study; few epidemiology or research textbooks cover the topic with the necessary detail. Seminal research texts offer no guidance; other advice is that no set number is needed for a pilot study. Others state that usually a small group of colleagues can be an appropriate sample to perform a pilot study. For a pilot clinical trial, a minimum of 12 subjects per group is recommended, based on feasibility and the precision around estimates to be used to design future studies.

For pilot samples of 24 to 40 members, the observed Cronbach’s alpha should be at least 0.75, in order to have confidence that the population value is at least 0.70; samples having fewer than 25 participants need the observed alpha to be close to 0.80 to achieve this. The observed alpha for the post-ICU adverse events questionnaire overall was 0.872.

As with any statistical test, CVI has limitations. It has been said that expert judgements about the relevance of an instrument’s content should not be construed as validity and that expert opinion is merely a mechanism for obtaining an estimate of an item’s relevance. Furthermore, an expert panel might agree on an item’s relevance purely by chance. Content validity is based mainly on the judgement, logic and reasoning of the researcher, with validation from a panel of judges holding expertise in the domain of content. Content validity is thus a subjective entity even though attempts are made to quantify it. Recommendations to overcome this limitation include using an expert panel of at least five members and four-level
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Contributed data to this study.

The authors thank the Australian ICU Liaison Nurses who contributed data to this study.

The accuracy of pilot study results becomes questionable when unrepresentative samples are used. As this pilot captured one out of every three Australian ICU Liaison Nurses, it would not truly be representative; however, the homogeneity of the responses suggests good representation.

A final limitation is that panel members were recruited through the Australian College of Critical Care Nurses ICU Liaison Special Interest Group. One of the researchers (ME) is also a member of the Group. This could have influenced panel members’ responses to the questionnaire due to the lack of confidentiality. Although a valid concern, the researchers felt that this would not impact significantly, given that this group of clinicians are very autonomous.

CONCLUSION

The post-ICU adverse events questionnaire is a structured measure of factors contributing to adverse events following ICU discharge. The findings of this pilot study demonstrate that the questionnaire is a reliable and valid tool. It could therefore be a useful tool for better understanding adverse events following ICU discharge.

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