Patient comfort in the intensive care unit: a multicentre, binational point prevalence study of analgesia sedation and delirium management

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Patient comfort in ICU: A multicentre, binational point prevalence study of analgesia, sedation and delirium management

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Abstract

Purpose: To measure the prevalence of assessment and management practices for analgesia, sedation and delirium in patients admitted to Australian and New Zealand intensive care units.

Materials and Methods: Survey items were developed from a modified Delphi Panel, and included in a bi-national, point prevalence study using a standard case report form (CRF). The CRF captured retrospective patient data on management of analgesia, sedation and delirium prior to the census point of the point prevalence study day. Other data were collected during independent assessment of patient analgesic and sedative requirements, and delirium scoring.

Results: Data were collected on 569 patients in 41 ICUs. Pain assessment was documented in the 4 hours prior to study observation in 46% of patients. Of 319 assessable patients, 16% and 6% had moderate and severe pain respectively. Routine sedation assessment using a scale was recorded in 64% of intubated/ventilated patients. When assessed, 38% were alert/calm or drowsy/rousable, 22% were lightly-moderately sedated, 31% were deeply sedated (66% of these had a documented indication), while 9% were agitated/restless. Sedatives were titrated to a target level in 42%. Routine assessment of delirium occurred in only 3%, and at study assessment 9% had delirium. Wrist/arm restraints were used for 8% of patients.

Conclusions: Only two-thirds of sedated patients had their sedation levels formally assessed, half had pain assessed and very few had formal assessment of delirium. This description of current practices, along with other observational data may assist in planning further research in this important area of ICU practice.

Key Words

Analgesia, Sedation, Delirium, Intensive care, Point prevalence
Background
The importance of effective assessment and management of pain, sedation needs, and delirium in critically ill patients has been highlighted in the last decade. Significantly, two-thirds of critically ill patients received sedatives and opioids for a median of 3 days while receiving mechanical ventilation; this proportion increased to 92% for a subgroup of patients with Acute Lung Injury or Acute Respiratory Distress Syndrome required the same medications.\(^1\) Incidences of delirium range from 20 – 80%.\(^2,3\)

It is essential that adequate pain relief and anxiolysis be provided to all critically ill patients, and one approach may be to manage the three elements of pain, agitation and delirium separately (Riker R, personal communication). Appropriate sedation helps to ensure comfort for patients with invasive and difficult-to-tolerate procedures and treatments.\(^4\) The detrimental impact of poor analgesia and sedation practices, including both under- and over-sedation has both short- and long-term consequences. These include anxiety, agitation, accidental removal of tubes and catheters, ineffective pain management, and, increased intensive care and hospital lengths of stay in the short term.\(^5,6\) Compromised long-term psychological recovery has been reported in review and original research papers, particularly for cognitive function and delusional memories,\(^6-9\) and post-traumatic stress disorder.\(^10,11\)

Strategies proposed to improve critical care practice in this area include effective assessment of analgesic and sedative needs using validated instruments, timely delivery of effective analgesia, use of lighter levels of sedation and protocols involving nurse-directed sedation or daily sedation interruption.\(^4,12-17\)

Although multiple surveys have explored sedation practices in various countries, a major limitation associated with all reports is that they commonly relied on clinicians’ perceptions of practice; e.g.\(^18-22\) Actual care delivered to patients often differs significantly from that documented in policies or guidelines, and varies between individual clinicians. While these previously cited studies and review papers have provided important information on baseline practice, we proposed a detailed assessment of patient needs for sedative and analgesic medications, and delirium assessment in routine practice, supplemented by contemporaneous assessment of the same components by a specifically trained individual. This point prevalence study
was therefore designed to audit actual practices in the areas of sedation, pain and delirium management across ICUs in Australia and New Zealand. This information may provide baseline data for future studies of interventions to potentially improve patients’ experiences and outcomes of ICU treatment.

Methods
Design / Sampling
This two-phase dual methods design incorporated a modified Delphi Panel to develop the item statements, followed by inclusion of the survey in an observational point prevalence study conducted within the bi-national Point Prevalence Program coordinated by the Australian and New Zealand Intensive Care Society Clinical Trials Group (CTG) and the George Institute for Global Health. The study was approved by the Human Research Ethics Committees of each participating institution, with the need for individual informed patient consent being waived.

Item development
Using a modified Delphi Panel approach, 5 members of the research team participated as the expert panel in reaching consensus on the statements for identifying assessment and management practices related to analgesia, sedation, and delirium. Preliminary statements were based on recent and earlier practice surveys and suggestions by our content experts (Delphi Panel). Consensus on the content and format of a practice statement was defined as an arithmetic average of group response scores of >3 on a 4-point scale (Strongly Agree = 4 to Strongly Disagree = 1). Two Delphi rounds were completed to reach consensus for the patient-level items – analgesia (3 items); sedation (7 items); delirium (4 items) (See Appendix 1).

These final 14 items were formatted into a Case Report Form (CRF), and then tested for clarity and feasibility using a sample of volunteer ICU Research Coordinators and clinicians, prior to inclusion in the point prevalence study.

Point Prevalence Study
Data were collected locally at the sites by designated ICU clinical or research staff who had received training and/or were experienced in completing patient-level CRFs. Data collectors completed a CRF for each patient in the ICU at 10am on the
point prevalence day, using a prepared data dictionary which precisely defined the items, listed the range of acceptable responses and how those responses were to be derived. The two temporal components for CRF completion at the census point were: 1) a retrospective note and chart review of the previous 4 hours, including discussions with the patient’s nurse for any issues requiring clarification; and 2) contemporaneous independent assessment for analgesic, sedative needs and delirium scoring using the Intensive Care Delirium Screening Checklist (ICDSC)\textsuperscript{26} at or shortly after the census point. Additional clinical (Acute Physiology and Chronic Health Evaluation [APACHE] II score, APACHE diagnostic category, hospital admission date, ICU admission date) and demographic (age, gender) data were also collected. Vital status was then assessed at hospital discharge, censored 28 days after the study day with patients categorised as alive, dead, or still admitted to hospital.

**Data Analysis**

Descriptive statistics were used for all clinical and demographic data and for all items in the CRF. Distributions of the variables were examined and guided the use of parametric or non-parametric tests. Non-normally distributed data are described using median and interquartile ranges (IQR) or percentages. Mean and standard deviations (SD) describe normal data distributions. No assumptions were made about missing data.

**Results**

The CTG Point Prevalence Day was conducted on one of three assigned days in late 2009 and early 2010, with 41 units participating (36 from Australia, 5 from New Zealand). Each site collected data on a single day. Of these ICUs, 31 were tertiary, 6 metropolitan, 3 regional / rural, and 1 was located in a private hospital. The sample represented 89% (31/35) of all tertiary units in Australia and New Zealand, 15% (6/39) of metropolitan units, 6% (3/49) of rural/regional, and 2% (1/59) of private ICUs. A total of 569 patients were studied (see Table 1 for patient characteristics). Patients were predominantly male (63%) with a mean APACHE II score of 18.5. Half of the patients were intubated and ventilated, and just over half had a non-operative diagnosis.

**Pain assessment**
Almost one-half of the patients had documentation of being assessed for pain, during routine clinical care, at any time in the 4 hours prior to assessment on the study day (n=253, 46%). For those patients able to interact (n=319/546, 58%), a numerical rating (0-10) for pain “now” was available for 91% (n=290/319). The median pain score was 0 (IQR: 0-3). Over half (n=157, 54%) had a pain score of 0 (no pain), 25% (n=71) had pain scores from 1-3 (mild), 16% (n=46) from 4-6 (moderate), and 6% (n=16) had scores from 7-10 (severe pain).

**Sedation assessment**
Of the 569 patients studied, 293 had an artificial airway on the study day. Of these 293, 185 (64%) had a sedation score recorded, during routine clinical care, at any time in the 4 hours prior to observation. A variety of scales were in use at different study hospitals: the most common instruments were the Richmond Agitation and Sedation Scale (RASS) (38%), Sedation and Agitation Scale (SAS) (28%), Motor Activity Assessment Scale (MAAS) (10%). One quarter of patients (24%) were assessed using modified scales (RASS or Ramsay), or other scales.

Of the 293 patients assessed at the time of the survey using the RASS, 38% were alert and calm or drowsy but rousable (n = 111; RASS 0 to -1), 22% were lightly to moderately sedated (n = 64; RASS -2 to -3), 31% were deeply sedated or unrousable (n = 90; RASS -4 to -5), while 9% were restless or agitated (n = 26; RASS +2 to +4).

**Analgesic and sedative management**
A majority of patients (n=340; 60%) of patients were receiving either analgesic or sedative agents or both on the study day. Specifically, 295 (52%) were receiving analgesic agents by either infusion or bolus doses and 201 (35%) were receiving sedative agents by either infusion or bolus doses. For those patients receiving analgesia and / or sedative by intravenous infusions or bolus doses, the common medications are listed in Table 2.

When considering only those patients who were intubated and mechanically ventilated (n=293), 227 (78%) of patients were receiving either a sedative or analgesic or both, with 186 (64%) receiving an analgesic agent and 188 (64%) receiving a sedative agent. Sedation medication was prescribed to be titrated to a documented
specific level of sedation in 115 (42%) intubated and mechanically ventilated patients while 68 of 263 (26%) of these patients received a planned cessation of sedation on the study day.

Two-thirds of the 90 patients with a RASS of -4 to -5 (n=59; 66%) had a perceived specific indication for deep sedation; management of hemodynamic instability (23%), intracranial pressure (14%), uncontrollable agitation (14%) and ventilator dysynchrony (10%). In 39% of instances deep sedation was for unspecified ‘other’ reasons.

**Delirium assessment**

Formal assessment of delirium was performed on the study day in 3% of patients (19 of 569); of these, the ICDSC was used in 8 (42%), clinical assessment was used in 7 (37%), and two patients were assessed with other scales. No patients were assessed using the Confusion Assessment Method for ICU (CAM-ICU), the Delirium Rating Scale, or the Mini Mental State Examination (MMSE). For those 428 patients with a RASS of -2 or higher (lightly sedated to very agitated) at the time of observation on the study day, delirium assessment identified 40 patients (9.3%) as being delirious. Of these, 23 were intubated and ventilated, while 17 were spontaneously breathing.

Specific characteristics related to delirium included that 77% were normally wakeful and 21% were responsive to mild stimuli. Eight patients (2%) were hypervigilant. The most common behavioural manifestations observed for delirium were sleep/wake cycle disturbances (28%); inattention (15%); disorientation (13%); and psychomotor agitation or retardation (9%). Less common behaviours were symptom fluctuation (7%); inappropriate speech or mood (5%) and hallucinations / delusions (3%).

**Physical restraints**

During the study day, 7% of patients (40 of 569) were being restrained; all were wrist/arm restraints, while one patient also had ankle restraints.

**Discussion**

**Key findings**
In this point prevalence study of 569 patients from Australian and New Zealand ICUs, only half of the patients had been assessed for pain, two-thirds receiving sedatives had formal assessment using a sedation score and a minority of patients had been formally assessed for delirium. Half of all study patients were receiving analgesics and over one-third were receiving sedatives. For those patients mechanically ventilated, two-thirds were receiving analgesics and sedatives, with sedatives titrated for almost half of this sub-sample. The most common analgesics/sedatives used to promote patient comfort were morphine, fentanyl, propofol and midazolam, although prescribing patterns varied. For patients appropriate for prospective assessment of delirium, one in ten were identified as delirious.

Comparison with previous studies
Despite the close practice relationship between sedation and analgesia assessment and management, pain assessment processes have been inconsistently examined in previous surveys of practice, with no Australian surveys including this aspect of care.3, 18, 25, 27 Internationally, two reports of pain assessment practices were identified; the first from Germany21 reported practice changes from 2002 to 2006, with 21% of units reporting introduction of pain scoring during the four year period. No details of the actual number of units was included in the paper, with only numeric rating or visual analogue scales used to assess pain. The second report detailed pain assessment in 43 ICUs in France (and one unit in Luxembourg) where it was noted that despite 90% of patients receiving opioids, only 42% of patients were assessed for pain, with the Behavioural Pain Scale being the most common instrument used.28 Systematic assessment of pain and sedation have been demonstrated to reduce length of mechanical ventilation and incidence of nosocomial infections in one ICU in France29.

At the time of the point prevalence assessment in the current study the majority of interacting patients reported no or mild pain, with only one-fifth reporting moderate to severe pain (i.e. 4 – 10 on a 10-point NRS), suggesting that pain was reasonably well managed in the study units. This is consistent with ‘at rest’ pain scores reported in a single Australian ICU30 as well as single centre studies elsewhere.31, 32 This low occurrence of pain self-report is in contrast to the reports by patients in other studies that pain is one of the most common recollections from their time in ICU; e.g.33, 34
However, this may reflect ineffective peri-procedural management of pain at the time of interventions or activity rather than pain being a continuously under-treated entity over the entire intensive care/hospital stay.

Similar to previous survey findings, sedation assessment occurred in approximately two-thirds of patients who had an artificial airway in place. The most common instruments used were the RASS and the SAS; in contrast to most of the European and North American studies that report higher use of the Ramsay Scale. O’Connor et al had earlier found that more than 50% patients were assessed using the Glasgow Coma Scale (even though it is not a true sedation scale), 25% used the SAS, 15% Ramsay and 8% RASS. The use of scales and the transition to specific measures of ICU sedation highlights increased awareness and practice changes. Of note, one-quarter of patients were assessed using a modified version of an instrument which raises questions about the validity and reliability of these modified versions.

Of note, delirium assessment was not a routine practice in our ICUs, and the CAM-ICU was not used as a delirium screening tool. This is consistent with an earlier Australasian report. More recently Shehabi and colleagues reported 51% of patients as delirious for at least one day, with the incidence increasing to more than 70% for patients with ICU stays of longer than 14 days, highlighting the need for closer monitoring. There is evidence, mainly from North America, that both the CAM-ICU and the ICDSC have good reliability and utility in practice, although the evidence in an Australian practice setting is somewhat less convincing. Adoption of an effective instrument would enable application of research evidence to practice, and also enable more comparisons between countries, given the current global focus on assessing and intervening in the nexus between sedation, delirium and symptoms of post-traumatic stress.

Morphine, fentanyl, propofol and midazolam were the most common medications used for patient comfort, both as infusion and bolus doses, although prescribing patterns differed slightly. Given the high proportion of patients managed with light sedation levels, there was limited use of ‘daily wake-up’ or daily interruption of sedation, with this practice reported to be used in about one-quarter of cases. This use of daily interruption of sedation was at the lower end of the range reported in a review.
where sedation interruption was used in 20-78% of patients in 8 of 12 studies. Shehabi \(^{36}\) also reported that only 3% of study days from a total of 2678 had routine sedation interruption. As identified, if patients are managed with light sedation there should be no need for daily interruption of sedation and results of this point prevalence and another recent study \(^{38}\) support this position.

Also similar to Shehabi, \(^{36}\) approximately 2/3 of patients who were deeply sedated (RASS -4 to -5) had a specific clinical indication for deep sedation, with approximately one-tenth of the intubated and ventilated patients assessed on the study day being deeply sedated without a clinical indication. Shehabi also reported that about 25% of patients with RASS assessments had prescribed targets for sedation despite finding that early sedation depth was predictive of time to extubation. \(^{36}\)

The low prevalence of physical restraints observed here differed significantly from a recent survey of 121 French ICUs. In almost one-third of units, physical restraint was used in over half of awake, calm and cooperative patients, and in two-thirds of ICUs, restraints when used were applied for more than half of mechanical ventilation duration. \(^{39}\)

**Implications for practice**

This study identified that only two-thirds of sedated patients had their levels of sedation of formally assessed, half had their pain assessed and very few had a formal assessment of delirium. This baseline description of current practices can inform development and testing of specific strategies to improve assessment and management of discomfort and delirium for intensive care patients in Australia and New Zealand.

**Strengths and Limitations**

The key strength of the study is that it provides a binational, multicentre evaluation of sedation, analgaesia and delirium practices providing a detailed description of practice over a period of four hours with an independent assessment at each site of pain, sedation and analgaesia by a trained assessor.
Limitations inherent in a point prevalence design are however noted. Assessment of patients occurred at a single 4 hour time point during their ICU stay and, because prevalent patients may be systematically different to incident patients, the study may not accurately reflect management during the patient’s entire ICU admission. In addition the intensity of management may differ depending on the phase of the patients illness (illness severity) and the particular type of primary pathology, and, there may be competing priorities in patient management (priority being given for the need to reduce sedation/analgesia to facilitate neurological evaluation or observation of respiratory status against patient comfort).

A high representation of tertiary units precluded meaningful comparisons between type and level of unit in our analyses. We were therefore unable to identify any practice differences between type and level of ICU because of the low proportion of rural / regional and private units, and to a lesser extent non-tertiary metropolitan units. Further work could focus on identifying any important practice differences across type and level of unit.

**Conclusions**

This point prevalence study details current practices for assessing and managing pain, sedation and delirium in a sample of ICUs across Australasia; two-thirds of sedated patients had their sedation levels formally assessed, half had their pain assessed and very few had a formal delirium assessment. These results suggest that current practices in many ICUs in Australia and New Zealand are not fully compliant with guidelines or expected practices.

This baseline description of current practices is however consistent with previous Australian and International observational data and may provide justification for randomised, interventional studies and also provide information that may be useful in defining usual care. 

**Acknowledgements**

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the thoughtful comments and suggestions received during the peer review process, which improved the clarity and quality of the manuscript.
References


<table>
<thead>
<tr>
<th>Demographic and clinical characteristics of sample</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (n = 568): median (IQR), years</strong></td>
</tr>
<tr>
<td><strong>Gender (n = 569): n (%), male</strong></td>
</tr>
<tr>
<td><strong>APACHE II score (n = 534): mean (SD)</strong></td>
</tr>
<tr>
<td><strong>Days in ICU (up to and including study day) (%)</strong></td>
</tr>
<tr>
<td>Day 1</td>
</tr>
<tr>
<td>Days 2 – 4</td>
</tr>
<tr>
<td>Days 5 – 7</td>
</tr>
<tr>
<td>&gt; 7 Days</td>
</tr>
<tr>
<td><strong>Diagnostic category on admission (n = 569): n (%)</strong></td>
</tr>
<tr>
<td>Cardiovascular Surgery</td>
</tr>
<tr>
<td>Gastrointestinal Surgery</td>
</tr>
<tr>
<td>Neurological Surgery</td>
</tr>
<tr>
<td>Respiratory (thoracic) Surgery</td>
</tr>
<tr>
<td>Trauma</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td><strong>TOTAL Post-operative diagnostic categories</strong></td>
</tr>
<tr>
<td>Respiratory</td>
</tr>
<tr>
<td>Sepsis</td>
</tr>
<tr>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Trauma</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td><strong>TOTAL Non-operative diagnostic categories</strong></td>
</tr>
<tr>
<td>Artificial airway requiring positive pressure ventilatory support on study day (n = 569)</td>
</tr>
</tbody>
</table>
Table 2  Common medications used for analgesia and / or sedation

<table>
<thead>
<tr>
<th>Medication</th>
<th>Infusion n (%)</th>
<th>Bolus n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl</td>
<td>113 (27)</td>
<td>55 (29)</td>
</tr>
<tr>
<td>Midazolam</td>
<td>73 (18)</td>
<td>22 (11)</td>
</tr>
<tr>
<td>Morphine</td>
<td>78 (19)</td>
<td>61 (32)</td>
</tr>
<tr>
<td>Propofol</td>
<td>114 (27)</td>
<td>31 (16)</td>
</tr>
</tbody>
</table>

Note: % is of total medications prescribed (n=417 for infusions; n=192 for bolus doses); additional medication prescribed not included in table because of small numbers
## Appendix 1

### Sedation

<table>
<thead>
<tr>
<th>#</th>
<th>Item</th>
<th>Response levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Does the patient have an artificial airway (ETT or tracheostomy) and require positive pressure for some part of the study day (includes CPAP or Pressure Support)?</td>
<td>Y / N</td>
</tr>
<tr>
<td>2</td>
<td>Has the patient been assessed within the last 4 hours using a sedation scoring scale?</td>
<td>Y / N</td>
</tr>
<tr>
<td>2.1</td>
<td>What specific sedation scoring scale was used? (RASS, Ramsay, Riker SAS, MAAS, Other - specify)</td>
<td>Y</td>
</tr>
<tr>
<td>2.2</td>
<td>What was the documented score using your scale?</td>
<td>numerical score or range</td>
</tr>
<tr>
<td>3</td>
<td>Using the RASS what is the actual sedation score now</td>
<td>numerical score</td>
</tr>
<tr>
<td>4</td>
<td>Is sedation medication being titrated to a specific level of sedation?</td>
<td>Y / N</td>
</tr>
<tr>
<td>5</td>
<td>Does the patient have an indication for deep sedation? (Management of ICP, Ventilator dys-synchrony, Haemodynamic instability, Uncontrolled agitation, Other [please indicate])</td>
<td>Y / N</td>
</tr>
<tr>
<td>6</td>
<td>Please list the sedatives and analgesics the patient is receiving, by continuous infusion, bolus or both, and the total dose administered (Morphine, Fentanyl, Midazolam, Propofol, Dexmedetomidine, Other [please specify])</td>
<td>Y</td>
</tr>
<tr>
<td>7</td>
<td>Did the patient have a planned cessation of sedation at any time in the study day?</td>
<td>Y / N</td>
</tr>
<tr>
<td>7.1</td>
<td>At what time was the drug ceased and restarted? Three episodes; time started and stopped, or tick if not restarted</td>
<td></td>
</tr>
<tr>
<td>7.2</td>
<td>What was the reasons for re-starting the infusions? [tick all that apply (Time due according to daily interruption of sedation protocol, Intolerance of ventilation, Pain, Agitation, Haemodynamic instability, To perform a procedure, Other [please specify])]</td>
<td>Y</td>
</tr>
</tbody>
</table>

### Analgesia

<table>
<thead>
<tr>
<th>#</th>
<th>Item</th>
<th>Response levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Has the patient been assessed within the last 4 hours using a pain scoring instrument?</td>
<td>Y / N</td>
</tr>
<tr>
<td>8.1</td>
<td>What was the documented pain score using your scale?</td>
<td>Numerical score</td>
</tr>
<tr>
<td>9</td>
<td>Using a Numerical Rating Scale from 0 (no pain) to 10 (worst imaginable pain), what is the patient’s pain score now?</td>
<td>Numerical score</td>
</tr>
<tr>
<td>10</td>
<td>Has the patient received any analgesics today, aside from those listed in question 6?</td>
<td>Y Drug, total dose</td>
</tr>
</tbody>
</table>

### Delirium

<table>
<thead>
<tr>
<th>#</th>
<th>Item</th>
<th>Response levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Has the patient been assessed for delirium today using a delirium scoring tool?</td>
<td>Y / N</td>
</tr>
<tr>
<td>11.1</td>
<td>What specific delirium scoring tool was used? (CAM-ICU, Delirium Rating Scale, Delirium Screening Checklist, MMSE, General clinical assessment, Other)</td>
<td>Y</td>
</tr>
<tr>
<td>11.2</td>
<td>What was the documented score using your scale?</td>
<td>Numerical score</td>
</tr>
<tr>
<td></td>
<td>Question</td>
<td>Y / N</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>12</td>
<td>Did the patient have a RASS of –3, -4 or –5 in question 3?</td>
<td>Y</td>
</tr>
<tr>
<td>13</td>
<td>On assessing the patient now, is the patient (Bedside nurse can assist)?</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>(Normally wakeful or easily roused, Responsive to mild stimuli [e.g. touch, calling name], Hypervigilant or making exaggerated responses to normal stimuli)</td>
<td></td>
</tr>
<tr>
<td>13.1</td>
<td>Inattention: Difficulty following a conversation or instructions; easily distracted by external stimuli; difficulty in shifting focus</td>
<td>Y / N</td>
</tr>
<tr>
<td>13.2</td>
<td>Disorientation: Any obvious mistake in time, place or person</td>
<td></td>
</tr>
<tr>
<td>13.3</td>
<td>Hallucination-delusion-psychosis: Any manifestations of hallucination (eg seeing or trying to catch nonexistent objects) or delusions</td>
<td></td>
</tr>
<tr>
<td>13.4</td>
<td>Psychomotor agitation or retardation: Hyperactivity requiring additional drugs or physical restraints for patient or staff safety; or hypoactivity which is clinically noticeable psychomotor slowing</td>
<td></td>
</tr>
<tr>
<td>13.5</td>
<td>Inappropriate speech or mood: inappropriate, disorganised or incoherent speech, inappropriate display of emotion related to event or situation?</td>
<td></td>
</tr>
<tr>
<td>13.6</td>
<td>Sleep/wake cycle disturbance: sleeping less than 4 hours or waking frequently at night; sleeping during most of the day</td>
<td></td>
</tr>
<tr>
<td>13.7</td>
<td>Symptom fluctuation: significant fluctuations in the manifestations of 13.1-13.6</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Did the patient require physical restraints during the study day?</td>
<td>Y / N</td>
</tr>
<tr>
<td>14.1</td>
<td>If yes, please specify type of restraints</td>
<td></td>
</tr>
</tbody>
</table>