Unplanned Endotracheal Extubations in the Intensive Care Unit: Systematic Review, Critical Appraisal, and Evidence-Based Recommendations

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BACKGROUND: In this study, we updated the state of knowledge on unplanned tracheal extubations in the intensive care unit. We focused on the following topics: incidence, risk factors, reintubation after unplanned extubation, outcomes, and prevention. Based on this review, recommendations were made for preventing unplanned extubations.

METHODS: Electronic databases were searched for relevant publications from January 1, 1950 through June 30, 2011 on the MEDLINE, EMBASE, CINAHL, Scielo, LILACS, and Cochrane systems. Fifty articles were eligible for data abstraction. Study quality was assessed using the Newcastle-Ottawa Scale. Grades of recommendation were assessed according to the Oxford Centre for Evidence-Based Medicine.

RESULTS: Unplanned extubations occur at a rate of 0.1 to 3.6 events per 100 intubation days. Risk factors associated with unplanned extubations included male gender (odds ratio [OR] 4.8), APACHE score ≥17 (OR 9.0), chronic obstructive pulmonary disease, restlessness/agitation (OR 3.3–30.6), lower sedation level (OR 2.0–5.4), higher consciousness level (OR 1.4–2.0), and use of physical restraints (OR 3.1). Reintubation rates ranged from 1.6% to 88% of unplanned extubations. Thirteen studies assessed preventive measures for avoiding unplanned extubations. These studies focused on data collection tools, standardization of procedures, staff education, staff surveillance, and identification and management of high-risk patients. These studies reported reductions in unplanned extubation rate from 22% to 53%. The best methods of securing the endotracheal tube and use of physical restraints remain controversial issues.

CONCLUSIONS: Despite numerous publications on unplanned extubation, few studies assess preventive strategies for adverse events, and few clinical trials have assessed unplanned extubations. Recommendations are proposed based on the currently available literature. (Anesth Analg 2012;114:1003–14)

The intensive care unit (ICU) setting poses safety risks to patients, including an increased risk of medical errors. A large proportion of patients admitted to the ICU require tracheal intubation and/or mechanical ventilation, both posing additional risks of adverse events. Unplanned extubation is a widely cited example of a potentially catastrophic and costly adverse event leading to complications including bronchospasm, aspiration pneumonia, hypotension, arrhythmias, cardiorespiratory arrest, and death. Unplanned extubation is defined as premature removal of the endotracheal tube by a patient receiving mechanical ventilation support (deliberate unplanned extubations) or by staff during nursing and medical care (accidental extubation).

An unplanned extubation is a marker of poor quality of care. There is no consensus on strategies for the prevention of this event. The majority of studies assess the risk factors associated with unplanned extubations. With the present emphasis on improving the quality of health care and patient safety, there is a demand for tracking and reducing unplanned extubations in health care accreditation. Quality improvement programs can reduce the incidence of unplanned extubations. Different approaches and methods in the published studies have resulted in widely differing outcomes. Standardizing procedures and goals may reduce outcome variability.

This review assesses the incidence and risk factors for unplanned extubations, the factors associated with reintubation after unplanned extubation, and the outcomes of unplanned extubations. We conclude with recommendations based on the available evidence.

METHODS

Search Strategy

The United States National Library of Medicine and National Institutes of Health (PubMed), the Excerpta Medica database (EMBASE), the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Library, the Scientific Electronic Library Online (SciELO), and the
Latin American and Caribbean Literature on Health Sciences (LILACS) databases were searched for the period January 1950 to May 2011. The search strategy included the following key words: “unplanned extubation,” “accidental extubation,” “self extubation,” “unintentional extubation,” “unexpected extubation,” “inadvertent extubation,” “unintended extubation,” “spontaneous extubation,” “treatment interference,” and “airway accident.” In addition, the reference lists contained in the articles retrieved were checked and review articles were also included in the search to identify other potentially relevant articles. The search was limited to articles written in English, Portuguese, Spanish, and French. Articles dealing with neonatal or pediatric intensive care were excluded.

**Study Selection**

Both authors independently and sequentially reviewed citations, abstracts, and full-text articles to select eligible studies (Fig. 1). The titles or abstracts, or both, selected by either author were included in the subsequent step of the selection process. At each step, the authors calculated interobserver agreement using percent agreement and the $\kappa$ statistical measure. Differences between the 2 reviewers were discussed and agreement was reached by consensus. Duplicate publications, abstracts, case reports, letters to the editor, surveys, and review articles were excluded.

Criteria for initial inclusion of studies were study populations of mechanically ventilated adult patients with unplanned extubations, outcomes that included unplanned extubations rate, risk factors associated with unplanned extubations, reintubation after unplanned extubation, and strategies to prevent unplanned extubation. Study designs were cohort, case control, or cross-sectional.

Study quality was evaluated using the Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies (e.g., case-control and cohort studies). The NOS comprises 9 items categorized into 3 groups: selection, comparability, and outcome or exposure for cohort or case-control studies, respectively.

The assessment of cohort studies included:

1. Selection (4 points)
   a. Exposed cohort representativeness
   b. Nonexposed cohort selection
   c. Ascertainment of exposure
   d. Demonstration that the outcome of interest was not present at the beginning of the study

2. Comparability (2 points)
   a. Cohort comparability based on design
   b. Cohort comparability based on analysis

3. Outcome (3 points)
   a. Outcome assessment
   b. Adequacy of the length of follow-up
   c. Appropriate cohort follow-up

The assessment of case-control studies included:

1. Selection (4 points)
   a. Representativeness of the cases
   b. Case definition adequacy
   c. Controls definition
   d. Controls selection

2. Comparability (2 points)
   a. Cases and controls comparability based on design
   b. Cases and controls comparability based on analysis

3. Exposure (3 points)
   a. Exposure ascertainment
b. Same method of ascertainment for cases and controls
c. Nonresponse rate

Points were awarded to each study based on the above criteria. The highest quality study would receive 4 points for selection, 2 points for comparability, and 3 points for outcome. Studies with a NOS score \( \geq 5 \) with appropriate statistical analysis (e.g., risk-adjusted or multivariate) were deemed of high methodological quality. Multivariate analysis or other acceptable methods of adjusting for risk were required to reduce the influence of confounding variables. Both reviewers independently rated each study. Variations in ratings were reconciled via discussion. An independent statistician calculated the level of agreement between the 2 reviewers.

Grades of recommendation were assessed according to the Oxford Centre for Evidence-Based Medicine’s Levels of Evidence.  

- **Grade A**
  - Evidence from consistent level 1 studies (systematic review of randomized controlled trials [RCTs] or a well-designed and executed RCT)
- **Grade B**
  - Evidence from consistent level 2 studies (systematic review of cohort studies or well-designed and executed cohort studies)
- **Evidence from consistent level 3 studies** (systematic review of case-control studies, an individual case-control)
- **Extrapolations from level 1 studies**
- **Grade C**
  - Evidence from level 4 studies (case series or poor-quality cohort and case-control studies)
- **Extrapolations from level 2 or 3 studies**
- **Grade D**
  - Level 5 evidence (expert opinion)
- Troublingly, inconsistent, or inconclusive studies of any level

**Statistical Analysis**

The medians and 25th to 75th interquartile ranges (IQRs) are presented for continuous variables. Interrater reliability was assessed using the overall percentage of agreement and the \( \kappa \) statistic during the literature abstraction. Using the methods of Landis and Koch, \( \kappa \) values were categorized for agreement between reviewers as follows: \( \geq 0.80 \) (excellent), 0.61 to 0.80 (substantial), 0.41 to 0.61 (moderate), and \( \leq 0.40 \) (poor).

**RESULTS**

The combined computerized and bibliographic literature search yielded 44,766 potentially relevant studies, of which 103 articles were identified for more detailed review (Fig. 1). Fifty of these studies met the inclusion criteria. The percent agreement (\( \kappa \) statistic) for each stage of study selection and data abstraction process was as follows: citation review, 89% (\( \kappa = 0.52 \)); abstract review, 95% (\( \kappa = 0.83 \)); full-text review, 98% (\( \kappa = 0.87 \)); and data abstraction, 96% (\( \kappa = 0.96 \)). Of the 50 studies reviewed, 29 were prospective cohort studies, 1,5,6,11–15,17–20,24–26,28,30–32,34,37,39–42,44,45,48,50 eight were retrospective cohort studies, 7,16,22,27,33,36,38,47 one was a retrospective and prospective cohort study, 49 eleven were case-control studies, 2,21,23,29,35,46,51–53,55 and one was cross-sectional. 54 Three studies were not in English. 36,49,50

Thirty-six studies were of low methodological quality and 14 were of high methodological quality. 1,2,6,13,20,23,25,39,46,54,52,55

The overall median NOS score was 4 (IQR 3–6) and the initial level of agreement between reviewers was 75%. All selected studies were classified as level 4 of evidence. A summary of the studies assessed in this review is provided in Table 1.

**Incidence**

In the literature, the incidence of unplanned extubations is expressed as the number of unplanned extubations per 100 ventilated patients or as the number of unplanned extubations per 100 days of mechanical ventilation. The latter measure incorporates the concept of duration as an exposure factor for event occurrence. Studies conducted over the last 10 years reported unplanned extubation rates ranging from 0.5 to 35.8 (median 7.3, IQR 4.0–11) unplanned extubations per 100 ventilated patients, or from 0.1 to 4.2 unplanned extubations per 100 intubation days (median 0.9, IQR 0.6–1.7). This incidence has not significantly changed over the last 5 years, with reported rates ranging from 2.1 to 18.5 (median 6.4, IQR 3.8–9.6) unplanned extubations per 100 ventilated patients or from 0.1 to 3.6 unplanned extubations per 100 intubation days (median 0.6, IQR 0.4–1.2). Self-extubations accounted for the majority of unplanned extubations, occurring at a rate of 50 to 100 unplanned extubations per 100 ventilated patients (median 85, IQR 76%–93%).

**Risk Factors Associated with Unplanned Extubation**

Increased level of consciousness was a risk factor for unplanned extubation in 20 studies. 2,6,7,11–13,15,18,21,23–26,33,34,35,41,47,53,55 Among these studies, multivariate analyses identified the presence of restlessness/agitation (odds ratio [OR] 3.3–31, 95% confidence interval [CI] 1.3–294) 21,53,55 and a higher level of consciousness (OR 1.4–2.0, 95% CI 1.0–3.8) 2,21,46 or inadequate sedation (OR 2.0–5.4, 95% CI 1.16–9.9) 2,25 as the main risk factors for unplanned extubation. Tung et al. 35 reported that fewer patients who self-extubated were alert and oriented compared with control subjects. Other studies described patients as agitated 31,21,55 or having recently received sedation before unplanned extubations. 31 Unplanned extubations occurred more often during weaning from controlled ventilation. 1 Approximately half of the patients in whom unplanned extubation occurred, independent of whether the patient was aware of it, were sedated at the time of the event (range 20%–69%; median 56.5%, IQR 37%–69%). 7,11,13,34

In one study, patients receiving midazolam had a greater risk for unplanned extubations (OR 2.3, 95% CI 1.01–5.18) compared with mechanically ventilated patients who did not receive midazolam. 35 Another study reported...
<table>
<thead>
<tr>
<th>Author (year) and reference</th>
<th>NOS</th>
<th>Design</th>
<th>Type of population</th>
<th>Study duration (d)</th>
<th>Patients (n)</th>
<th>UE (n)</th>
<th>UE (%)</th>
<th>UE/100 intubation days</th>
<th>Reintubation (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coppolo and May (1990)</td>
<td>2 1 2 5</td>
<td>PC</td>
<td>Mixed</td>
<td>365</td>
<td>112</td>
<td>13</td>
<td>11.6</td>
<td>2.8</td>
<td>30.8</td>
<td>Self-extubation is a common and well tolerated occurrence.</td>
</tr>
<tr>
<td>Pesiri (1994)</td>
<td>1 0 1 2</td>
<td>PC</td>
<td>NA</td>
<td>365</td>
<td>288</td>
<td>35</td>
<td>12</td>
<td>NA</td>
<td>NA</td>
<td>Reduction of UE based on an 8-step protocol.</td>
</tr>
<tr>
<td>Vassal et al. (1993)</td>
<td>2 1 2 5</td>
<td>PC</td>
<td>Medical</td>
<td>240</td>
<td>197</td>
<td>27</td>
<td>12</td>
<td>NA</td>
<td>74</td>
<td>Deliberate extubation is the most frequent UE type.</td>
</tr>
<tr>
<td>Whelan et al. (1994)</td>
<td>2 1 2 5</td>
<td>PC</td>
<td>Mixed</td>
<td>730</td>
<td>319</td>
<td>23</td>
<td>7.2</td>
<td>NA</td>
<td>78.3</td>
<td>Reintubation after UE is not mandatory. Reintubated patients received higher ventilatory parameters before event.</td>
</tr>
<tr>
<td>Maguire et al. (1994)</td>
<td>1 0 2 3</td>
<td>PC</td>
<td>Mixed</td>
<td>30</td>
<td>121</td>
<td>7</td>
<td>5.8</td>
<td>0.94</td>
<td>57.1</td>
<td>UE incidence can be substantially reduced, but not eliminated, by an education program and greater attention to risk factors.</td>
</tr>
<tr>
<td>Listello and Sessler (1994)</td>
<td>2 1 3 6</td>
<td>RC</td>
<td>Mixed</td>
<td>540</td>
<td>NA</td>
<td>81</td>
<td>NA</td>
<td>NA</td>
<td>39</td>
<td>UE can lead to serious complications. Half of UE patients do not require reintubation.</td>
</tr>
<tr>
<td>Tindol et al. (1994)</td>
<td>2 1 2 5</td>
<td>PC</td>
<td>Mixed</td>
<td>120</td>
<td>460</td>
<td>13</td>
<td>3</td>
<td>NA</td>
<td>46.2</td>
<td>UE was relatively rare. Vigilance and weaning contribute to a low UE incidence.</td>
</tr>
<tr>
<td>Grap et al. (1995)</td>
<td>1 0 2 3</td>
<td>PC</td>
<td>Mixed</td>
<td>540</td>
<td>4100</td>
<td>122</td>
<td>2.9</td>
<td>NA</td>
<td>46</td>
<td>—</td>
</tr>
<tr>
<td>Tominaga et al. (1995)</td>
<td>2 0 2 4</td>
<td>PC</td>
<td>Surgical</td>
<td>8640</td>
<td>687</td>
<td>31</td>
<td>4.5</td>
<td>1.08</td>
<td>22.6</td>
<td>The use of hand restraints and tube securement using water-resistant material are effective measures for reducing UE.</td>
</tr>
<tr>
<td>Christie et al. (1996)</td>
<td>1 0 3 4</td>
<td>PC</td>
<td>Mixed</td>
<td>365</td>
<td>NA</td>
<td>96</td>
<td>NA</td>
<td>1.62</td>
<td>1.23</td>
<td>58</td>
</tr>
<tr>
<td>Chiang et al. (1996)</td>
<td>1 0 3 4</td>
<td>PC</td>
<td>Mixed</td>
<td>270</td>
<td>831</td>
<td>76</td>
<td>9.1</td>
<td>NA</td>
<td>NA</td>
<td>Implementation of CQI program is effective in reducing UE.</td>
</tr>
<tr>
<td>Atkins et al. (1997)</td>
<td>2 2 2 6</td>
<td>CC</td>
<td>Mixed</td>
<td>360</td>
<td>150</td>
<td>50</td>
<td>NA</td>
<td>NA</td>
<td>74.0</td>
<td>Standardization is required for weaning and monitoring of high-risk patients for UE.</td>
</tr>
<tr>
<td>Achauer et al. (1997)</td>
<td>0 0 2 2</td>
<td>RC</td>
<td>Surgical burns</td>
<td>180</td>
<td>276</td>
<td>21</td>
<td>7.7</td>
<td>1.7</td>
<td>28.5</td>
<td>UE rates are higher in burn patients than surgical patients. UE occurred more frequently during painful procedures.</td>
</tr>
<tr>
<td>Chevron et al. (1998)</td>
<td>3 1 2 6</td>
<td>CC</td>
<td>Mixed</td>
<td>300</td>
<td>281</td>
<td>40</td>
<td>14</td>
<td>NA</td>
<td>NA</td>
<td>UE was associated with oral intubation and inadequate sedation. Predictive factors for reintubation: Glasgow score &lt;11, accidental UE, and PaO2/FiO2 &lt;200.</td>
</tr>
<tr>
<td>Betbese et al. (1998)</td>
<td>2 1 3 6</td>
<td>PC</td>
<td>Mixed</td>
<td>960</td>
<td>750</td>
<td>59</td>
<td>7.3</td>
<td>NA</td>
<td>45.8</td>
<td>Reintubation after UE depends on mode of ventilatory support.</td>
</tr>
<tr>
<td>Boulin (1998)</td>
<td>2 1 3 6</td>
<td>PC</td>
<td>Mixed</td>
<td>60</td>
<td>426</td>
<td>46</td>
<td>10.8</td>
<td>1.38</td>
<td>60.9</td>
<td>Vigilance, adequate sedation, tube securement, and weaning from MV must be emphasized to reduce UE. (Continued)</td>
</tr>
<tr>
<td>Author (year) and reference</td>
<td>NOS</td>
<td>Design</td>
<td>Type of population</td>
<td>Study duration (d)</td>
<td>Patients (n)</td>
<td>UE (n)</td>
<td>UE (%)</td>
<td>UE/100 intubation days (%)</td>
<td>Reintubation (%)</td>
<td>Comments</td>
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<td>----------------------------</td>
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</tr>
<tr>
<td>Powers (1999)²⁶</td>
<td>1 0 3 4 PC</td>
<td>NA</td>
<td>Medical</td>
<td>365</td>
<td>NA</td>
<td>7</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>A sedation protocol allowed critical care nurses to effectively manage agitation, prevent self-extubation, and improve patient outcomes. Numerous hemodynamic and airway complications are associated with reintubation after UE. Twill tape and adhesive tape are comparable in preventing UE, maintaining facial integrity and oral mucosa.</td>
</tr>
<tr>
<td>Mort (1998)²⁷</td>
<td>0 0 2 2 RC</td>
<td>Mixed</td>
<td>Medical</td>
<td>930</td>
<td>1247</td>
<td>57</td>
<td>3</td>
<td>NA</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Barnason et al. (1998)²⁸</td>
<td>1 1 2 4 PC</td>
<td>Medical</td>
<td></td>
<td>180</td>
<td>52</td>
<td>10</td>
<td>19.2</td>
<td>NA</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Epstein et al. (2000)²⁹</td>
<td>2 1 2 5 CC</td>
<td>Mixed</td>
<td>Medical</td>
<td>1320</td>
<td>225</td>
<td>75</td>
<td>11</td>
<td>NA</td>
<td>56</td>
<td>UE was associated with longer MV times and ICU and hospital stays. Eighty-five percent of patients with UE during weaning did not require reintubation. UE can be reduced by a protocol that includes education of the team and close observation of patients.</td>
</tr>
<tr>
<td>Razek et al. (2000)³⁰</td>
<td>1 1 3 5 PC</td>
<td>Surgical</td>
<td>Medical</td>
<td>540</td>
<td>1178</td>
<td>61</td>
<td>4.9</td>
<td>NA</td>
<td>36.1</td>
<td></td>
</tr>
<tr>
<td>Frezza et al. (2000)⁷</td>
<td>1 0 2 3 RC</td>
<td>Surgical</td>
<td>Medical</td>
<td>1440</td>
<td>2528</td>
<td>162</td>
<td>6.4</td>
<td>2.46</td>
<td>88</td>
<td>Education of medical personnel and upper-extremity restraint resulted in a significant reduction of patient-related removal of tubes and catheters.</td>
</tr>
<tr>
<td>Carrion et al. (2000)³¹</td>
<td>1 1 3 5 PC</td>
<td>Surgical</td>
<td>Medical</td>
<td>180</td>
<td>289</td>
<td>38</td>
<td>13.1</td>
<td>2.46</td>
<td>88</td>
<td></td>
</tr>
<tr>
<td>Kapadia et al. (2000)³²</td>
<td>1 1 2 4 PC</td>
<td>Mixed</td>
<td></td>
<td>1460</td>
<td>5043</td>
<td>26</td>
<td>0.5</td>
<td>0.30</td>
<td>NA</td>
<td>Adherence to established protocols is associated with a lower rate of upper airway accidents. Approximately half of self-extubated patients may not require reintubation. Pre-extubation PaO₂/FIO₂ and ventilator mode, as well as gender, may be useful in determining the likelihood of self-extubated patients requiring reintubation.</td>
</tr>
<tr>
<td>Jiang et al. (2000)³³</td>
<td>2 1 3 6 RC</td>
<td>Medical</td>
<td></td>
<td>720</td>
<td>NA</td>
<td>69</td>
<td>NA</td>
<td>NA</td>
<td>45</td>
<td>Use of sedation “as needed” was a common factor for UE. Benzodiazepines can be ineffective for treating agitation or prevent UE. Intervention led to a 45% (albeit nonsignificant) reduction in UE. Higher severity scores and worse oxygenation indexes predicted reintubation after UE. Reintubation after UE is not mandatory.</td>
</tr>
<tr>
<td>Balon (2001)³⁴</td>
<td>1 0 3 4 PC</td>
<td>Mixed</td>
<td></td>
<td>420</td>
<td>NA</td>
<td>75</td>
<td>35.8</td>
<td>NA</td>
<td>59</td>
<td></td>
</tr>
<tr>
<td>Tung et al. (2001)³⁵</td>
<td>2 2 1 5 CC</td>
<td>Mixed</td>
<td></td>
<td>365</td>
<td>150</td>
<td>50</td>
<td>33.3</td>
<td>NA</td>
<td>74</td>
<td></td>
</tr>
<tr>
<td>Moraga (2001)³⁶</td>
<td>0 2 1 3 RC</td>
<td>Medical</td>
<td>Medical</td>
<td>180</td>
<td>117</td>
<td>7</td>
<td>5.98</td>
<td>NA</td>
<td>3.42</td>
<td></td>
</tr>
<tr>
<td>Phoa et al. (2002)³⁷</td>
<td>0 1 3 4 PC</td>
<td>Mixed</td>
<td></td>
<td>360</td>
<td>312</td>
<td>27</td>
<td>8.7</td>
<td>NA</td>
<td>58.3</td>
<td></td>
</tr>
<tr>
<td>Pandey et al. (2002)³⁸</td>
<td>0 1 2 3 RC</td>
<td>Mixed</td>
<td></td>
<td>8640</td>
<td>350</td>
<td>12</td>
<td>3.4</td>
<td>NA</td>
<td>58.3</td>
<td>(Continued)</td>
</tr>
<tr>
<td>Author (year) and reference</td>
<td>NOS</td>
<td>Design</td>
<td>Type of population</td>
<td>Study duration (d)</td>
<td>Patients (n)</td>
<td>UE (n)</td>
<td>UE (%)</td>
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<td>Comments</td>
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</tr>
<tr>
<td>(Continued) de Lassence et al. (2002)</td>
<td>3</td>
<td>PC</td>
<td>Medical</td>
<td>720</td>
<td>750</td>
<td>75</td>
<td>10</td>
<td>0.94</td>
<td>NA</td>
<td>Accidental extubation but not self-extubation increased risk of VAP. Reintubation after UE may not be required, particularly in patients with heart disease.</td>
</tr>
<tr>
<td>Chen et al. (2002)</td>
<td>3</td>
<td>PC</td>
<td>Medical</td>
<td>420</td>
<td>590</td>
<td>50</td>
<td>8.5</td>
<td>NA</td>
<td>50.6</td>
<td>The use of the Bloomsbury Sedation Score and Glasgow Coma Scale enabled identification of patients at risk of UE.</td>
</tr>
<tr>
<td>Yeh et al. (2004)</td>
<td>3</td>
<td>PC</td>
<td>Medical</td>
<td>540</td>
<td>1176</td>
<td>225</td>
<td>22.5</td>
<td>NA</td>
<td>44.7</td>
<td>Accidental extubation occurred more frequently during routine nursing care and was associated with more complications.</td>
</tr>
<tr>
<td>Moons et al. (2004)</td>
<td>3</td>
<td>CC</td>
<td>Mixed</td>
<td>90</td>
<td>74</td>
<td>50</td>
<td>4.2</td>
<td>0.68</td>
<td>57.7</td>
<td>No difference in the incidence of airway accidents was detected among patients submitted to long-term and short-term intubation or between endotracheal tube and tracheostomy.</td>
</tr>
<tr>
<td>Chatterjee et al. (2004)</td>
<td>3</td>
<td>PC</td>
<td>NA</td>
<td>225</td>
<td>665</td>
<td>40</td>
<td>6.02</td>
<td>4.21</td>
<td>NA</td>
<td>A tool was used to collect data on UE and then to clarify perceptions and assumptions, steps that led to a change in practice.</td>
</tr>
<tr>
<td>Richmond et al. (2004)</td>
<td>3</td>
<td>PC</td>
<td>Mixed</td>
<td>180</td>
<td>495</td>
<td>9</td>
<td>1.8</td>
<td>2.14</td>
<td>NA</td>
<td>The use of the self-extubation risk assessment tool (SERAT) is not advocated.</td>
</tr>
<tr>
<td>Krinsley and Barone (2005)</td>
<td>3</td>
<td>CC</td>
<td>Mixed</td>
<td>2430</td>
<td>1515</td>
<td>100</td>
<td>6.6</td>
<td>NA</td>
<td>44</td>
<td>UE was associated with longer ICU stay but lower mortality.</td>
</tr>
<tr>
<td>Bouza et al. (2007)</td>
<td>3</td>
<td>PC</td>
<td>Medical</td>
<td>360</td>
<td>353</td>
<td>34</td>
<td>10</td>
<td>0.92</td>
<td>41</td>
<td>UE was associated with longer MV time and need for ICU care.</td>
</tr>
<tr>
<td>Bhattacharya et al. (2007)</td>
<td>3</td>
<td>PC</td>
<td>NA</td>
<td>365</td>
<td>556</td>
<td>32</td>
<td>5.21</td>
<td>1.42</td>
<td>43.7</td>
<td>Self-extubating patients had better outcomes than those with accidental extubation.</td>
</tr>
<tr>
<td>Moons et al. (2008)</td>
<td>3</td>
<td>PC</td>
<td>Mixed</td>
<td>90</td>
<td>256</td>
<td>8</td>
<td>4.47</td>
<td>0.56</td>
<td>NA</td>
<td>The use of the self-extubation risk assessment tool (SERAT) is not advocated.</td>
</tr>
<tr>
<td>Chang et al. (2008)</td>
<td>3</td>
<td>CC</td>
<td>Mixed</td>
<td>630</td>
<td>1455</td>
<td>126</td>
<td>8.7</td>
<td>NA</td>
<td>54</td>
<td>Neurological impairment and nosocomial pneumonia increased UE risk. Sedation levels and restraint use are associated with UE and reintubation.</td>
</tr>
<tr>
<td>Curry et al. (2008)</td>
<td>3</td>
<td>RC</td>
<td>Surgical</td>
<td>280</td>
<td>NA</td>
<td>31</td>
<td>NA</td>
<td>NA</td>
<td>48.3</td>
<td>Patients with UE before weaning must be reintubated immediately. NPPV represents an alternative after UE during weaning.</td>
</tr>
<tr>
<td>Eryüksel et al. (2009)</td>
<td>3</td>
<td>PC</td>
<td>Medical</td>
<td>365</td>
<td>130</td>
<td>15</td>
<td>11</td>
<td>NA</td>
<td>45.5</td>
<td>Reduction in UE incidence after guide implementation.</td>
</tr>
<tr>
<td>Castellões and da Silva (2009)</td>
<td>3</td>
<td>RC</td>
<td>Cardiological</td>
<td>180</td>
<td>72</td>
<td>70</td>
<td>2</td>
<td>8.3</td>
<td>0.32</td>
<td>0.10</td>
</tr>
</tbody>
</table>
that patients in the self-extubation group were more likely to have received benzodiazepines (midazolam, lorazepam, or diazepam) compared with control patients who did not receive benzodiazepines (59% vs 35%, P < 0.05). Multivariate analyses identified that APACHE II (Acute Physiology and Chronic Health Evaluation II) score was a risk factor for unplanned extubations (APACHE score ≥17; OR 9.01, 95% CI 1.02–80.5). Chronic obstructive pulmonary disease (COPD) was a risk factor for unplanned extubation in 2 studies (OR 2.3–2.4, 95% CI 1.0–5.3) but not in a third study. Interpretation of these data is compromised by the small number of patients and differences in the sedation level between groups. Boulain reported that COPD patients were prone to self-extubation because they frequently received prolonged mechanical ventilation on partial ventilation mode without sedation because of their longer weaning process. COPD was not a risk factor when intubation days were included in the model, although the lack of sedation remained a significant risk factor.

Nursing care was a risk factor. Unplanned extubations occurred more frequently during the night shift and with less-experienced nurses (<5 years of experience). In one study, 89% of the unplanned extubations occurred while the nurse was not at the patient’s bedside. In several studies, control patients were matched for age and sex. Three studies found age to be a risk factor whereas 11 studies evaluated age and did not find it to be a risk factor. Sex was found to be a risk factor in one study but not in 3 other studies that examined sex as a risk factor.

Six studies assessed the type of admittance (medical versus surgical) and none of them found that it was a risk factor for unplanned extubations. The frequency of unplanned extubations during weaning from mechanical ventilation ranged from 16% to 77% (median 54%, IQR 44%–60%) whereas this frequency for full ventilatory support ranged from 23% to 84% (median 46%, IQR 40%–56%). Seventeen studies examined the incidence of unplanned extubation in physically restrained patients. The percentage of restrained patients under physical restraint at the time of unplanned extubations ranged from 25% to 87% (median 67%, IQR 42%–74%). Only one study identified the use of physical restraints as a risk factor for unplanned extubations on multivariate analysis (OR 3.1, 95% CI 1.71–5.7).

Complications of Unplanned Extubations

Exubation Complications

Atkins et al. reported complications immediately after unplanned extubations, such as laryngeal or vocal trauma, prolonged respiratory distress, respiratory arrest, ventricular tachycardia, hypotension, and emesis with possible

### Table 1. (Continued)

<table>
<thead>
<tr>
<th>Author (year) and reference</th>
<th>NOS</th>
<th>Type of population</th>
<th>Study duration (d)</th>
<th>Patients (n)</th>
<th>UE (%)</th>
<th>UE/100 intubation days</th>
<th>Reintubation (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aylón Garrido et al. (2009)</td>
<td>0</td>
<td>PC</td>
<td>180</td>
<td>79</td>
<td>15</td>
<td>18.9</td>
<td>3.62</td>
<td>13.3</td>
</tr>
<tr>
<td>Huang (2009)</td>
<td>1</td>
<td>CC</td>
<td>360</td>
<td>708</td>
<td>44</td>
<td>6.4</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Chang et al. (2011)</td>
<td>2</td>
<td>CC</td>
<td>1095</td>
<td>NA</td>
<td>21</td>
<td>NA</td>
<td>NA</td>
<td>Most self-extubation occurs at night or during shifts with less-experienced nurses on duty. Eighty percent of self-extubations occur in restrained patients.</td>
</tr>
<tr>
<td>Elmetwally et al. (2010)</td>
<td>0</td>
<td>CC</td>
<td>730</td>
<td>80</td>
<td>40</td>
<td>NA</td>
<td>NA</td>
<td>Age is a risk factor for failed UE and adverse events. First and second category of the Ramsay scale associated with UE. Male gender and use of midazolam were risk factors. Mortality the same as controls.</td>
</tr>
<tr>
<td>Chen et al. (2010)</td>
<td>0</td>
<td>CC</td>
<td>1080</td>
<td>539</td>
<td>3.6</td>
<td>0.63</td>
<td>48.2</td>
<td></td>
</tr>
<tr>
<td>de Groot et al. (2011)</td>
<td>2</td>
<td>CC</td>
<td>900</td>
<td>74</td>
<td>2.12</td>
<td>0.42</td>
<td>47.3</td>
<td></td>
</tr>
</tbody>
</table>

CC = case-control; ICU = intensive care unit; MV = mechanical ventilation; NA = not available; NOS = Newcastle-Ottawa Scale (S = selection; C = comparability; E = exposure; O = outcome); NPPV = noninvasive positive-pressure ventilation; PC = prospective cohort; RC = retrospective cohort; UE = unplanned extubation; VAP = ventilator-associated pneumonia.
aspiration in 22% of this patient group. Hemodynamic or airway complications were found in 72% of patients. Complications included hypotension (35%), tachycardia (30%), hypertension (14%), multiple laryngoscopy attempts (22%), difficult laryngoscopy (16%), difficult intubation (14%), hypoxemia (14%), and esophageal intubation (14%). Coppolo and May\textsuperscript{11} reported 2 patients with respiratory failure and 2 episodes of arrhythmias in 4 of 12 patients.

**Reintubation Complications**

Reintubation rates ranged from 1.8%\textsuperscript{36} to 88%\textsuperscript{31} (median 45.8%, IQR 37.5–58.1). Mort\textsuperscript{27} reported a similar rate for emergency intubation (30%) and found that reintubation was associated with a high rate of difficult intubation and hypoxemia. Reintubation rates after unplanned extubation varied according to the population studied (surgical versus medical), type of unplanned extubation (deliberate versus accidental), and level of ventilatory support (weaning versus full mechanical ventilation). Most patients (62%–74%) were reintubated within 1 hour of unintentional extubation.\textsuperscript{21,22} Reintubation rates were slightly higher in medical patients than surgical patients, with rates between 3.4%\textsuperscript{46} and 74%\textsuperscript{13} (median 44.8%, IQR 40.5–48%), compared with surgical patients with rates ranging from 22.6%\textsuperscript{19} to 88%\textsuperscript{31} (median 42%, IQR 32.7–58.2%).

Reintubation was less frequent during weaning from mechanical ventilation,\textsuperscript{24,29,30} with rates between 15%\textsuperscript{30} and 30%\textsuperscript{29} (median 15.6%, IQR 15.1–26.4%) compared with patients on continued ventilatory support\textsuperscript{24,29,30} whose reintubation rates ranged from 61% to 81% (median 76%, IQR 64.7–80.1%). Patients who extubated themselves had reintubation rates between 0%\textsuperscript{50} and 63%\textsuperscript{39} (median 39%, IQR 25.3–51.0%), whereas patients with accidental extubation had rates of 7%\textsuperscript{24} to 100%\textsuperscript{2,39} (median 100%, IQR 30.2–100%).

Of the 16 studies that reported factors associated with reintubation after unplanned extubation,\textsuperscript{11,14,16,17,19,20,23,25,30,33,37,40,47,53,55} only 4 used multivariate analysis to assess risk factors for reintubation.\textsuperscript{16,23,33,54} These studies showed that the likelihood of reintubation was associated with age, type of unplanned extubation, ventilatory mode, prior ventilatory variables, and level of consciousness. Specific risk factors were age older than 65 years (OR 2.0, 95% CI 1.20–3.4),\textsuperscript{23} accidental extubation (OR 2.2–6.3, 95% CI 1.1–37.4),\textsuperscript{23,54} full ventilatory support (OR 2.7, 95% CI 1.6–4.6),\textsuperscript{54} assisted/control ventilatory mode (OR 3.8, 95% CI 1.1–13.6),\textsuperscript{33} volume-controlled ventilation with rate >6/minute (OR 12.8, 95% CI 2.5–65.3),\textsuperscript{16} arterial pH ≥7.45 before unplanned extubation (OR 11.2, 95% CI 2.4–52.1),\textsuperscript{16} PaO\textsubscript{2}/FiO\textsubscript{2} <200 to 250 mm Hg before unplanned extubation (OR 8.3–9.6, 95% CI 0.7–44.3),\textsuperscript{23,33} Glasgow coma scale score <11 (OR 5.5–49.7, 95% CI 1.3–607),\textsuperscript{16,23} nonsurgical patients (OR 5.5, 95% CI 1.3–241),\textsuperscript{16} diagnosis of pneumonia (OR 1.95–5.0, 95% CI 1.19–19.9),\textsuperscript{40,54} and presence of ≥3 comorbidities (OR 6.1, 95% CI 1.5–25.9).\textsuperscript{16}

**Outcomes**

Five studies reported prolonged mechanical ventilation and longer ICU stay and hospital stay in patients experiencing unplanned extubations,\textsuperscript{1,29,43,46,53} whereas one study reported shorter time on mechanical ventilation in patients with unplanned extubations.\textsuperscript{55} Prolonged mechanical ventilation and longer ICU stay and hospital stay were attributed to patients who required reintubation after unplanned extubation.\textsuperscript{23,37,43,54} A case-control study conducted by de Groot et al.\textsuperscript{55} showed that patients who did not need reintubation after an unplanned extubation had shorter length of ICU stay and hospital stay, shorter duration of total intubation time, and less ICU and hospital mortality compared with mechanically ventilated controls and unplanned extubation patients who required reintubation. Reintubated patients incurred higher hospital costs,\textsuperscript{33,54} demanded more chronic care,\textsuperscript{29} and had a greater incidence of ventilator-associated pneumonia (relative risk 1.8), which in turn was associated with accidental-type unplanned extubation events (relative risk 5.3)\textsuperscript{39} than non-reintubated patients. Another case-control study showed that the ICU length of stay and hospital costs were similar between unplanned extubation patients who did not require reintubation and control subjects.\textsuperscript{42} Study results on mortality were inconsistent, with unplanned extubation patients having greater mortality.\textsuperscript{23,31,54} lower mortality,\textsuperscript{1,43,59} or unchanged mortality\textsuperscript{28,29} compared with patients who did not have an unplanned extubation. Reintubation was associated with increased mortality in unplanned extubation patients.\textsuperscript{23,31,43,54}

**Preventive Measures**

Although numerous studies have been published over the last 20 years on unplanned extubation, only a few studies assessed the efficacy of preventive measures at reducing the incidence of unplanned extubation.\textsuperscript{5,7,12,15,19,20,22,26,28,31,36,49} Seven studies used a before and after design\textsuperscript{5,6,15,26,31,36,47} to assess the effectiveness of interventions on the incidence of unplanned extubation. The following preventive measures have been assessed: continuous education for nurses,\textsuperscript{52} agitation avoidance,\textsuperscript{95} 24-hour bedside supervision,\textsuperscript{54} regular surveillance,\textsuperscript{54} protocols for patient transport, securing the endotracheal tube before adjusting patient positioning or bathing the patient and changing the method for securing the endotracheal tube,\textsuperscript{55} implementation of a sedation protocol,\textsuperscript{47} staff ability for weaning patients,\textsuperscript{54} protocols for identifying patients ready for withdrawal from mechanical ventilation,\textsuperscript{43} and appropriate nurse to patient ratio.\textsuperscript{41}

Continuous quality improvement (CQI) programs have reduced unplanned extubation by 22%,\textsuperscript{15} to 53%,\textsuperscript{36} (median 42%, IQR 31%–46%). The incidence of unplanned extubation after implementation of CQI programs ranged from 0.10% to 2.72\textsuperscript{36} unplanned extubations per 100 intubation days (median 0.87, IQR 0.18–1.51)\textsuperscript{5,15,31,36,49} CQI programs involved multiple interventions and focused mainly on data collection tools, standardization of procedures, staff education, staff surveillance, and identification and management of high-risk patients.

**Physical Restraints**

Although many studies\textsuperscript{7,11,17,19,20,23,25,28,35,46,47,51} reported a higher incidence in the use of physical restraints at the time of unplanned extubation, few studies\textsuperscript{19,31,46} assessed
the influence of physical restraints on the occurrence of unplanned extubation. Physical restraints were used by nurses after consultation with the physician based primarily on the subjective assessment of level of patient agitation or persistent failure to obey instructions," when deemed necessary by the nursing staff, or in agitated patients. These studies had inconsistent results. A case-control study by Chang et al. found increased use of physical restraints in the unplanned extubation group compared with the control group (82% vs 54.5%, P < 0.001). A prospective study by Tominaga et al. assessing 2 time periods found that decreased use of hand restraints increased the incidence of unplanned extubations (2% vs 6%, P < 0.001). Unplanned extubations usually occur when patients physically remove the endotracheal tube with their hands. Carion et al. suggested keeping patients’ hands at least 20 cm away from endotracheal tubes to prevent unplanned extubation. However, only a few studies described the type of physical restraint used. The most common type of restraint was the wrist belt, but use of chest, 4-point, arm, and hand restraints were also described.

Securing the Endotracheal Tube

Three of the 48 studies assessed the impact of the method of securing the endotracheal tube on unplanned extubation. Tominaga et al. found fewer unplanned extubations when tubes were secured with waterproof tape around the tube, upper lip, and face compared with an endotracheal tube secured via a cloth or Velcro tie around the back of the head (15% vs 4%, P < 0.001). Barnason et al. showed that securing the endotracheal tube using twill or adhesive tape was comparable in preventing unplanned extubations and maintaining oral mucosa and facial skin integrity. In fact, standardizing the method for securing the endotracheal tube (twill tape method) in studies involving quality improvement programs reduced the incidence of endotracheal tube displacement, which also included unintended extubation. Richmond et al. found that securing endotracheal tubes with a Comfit or Holister holder reduced the incidence of unplanned extubations. The use of wire to anchor the tube to the oral cavity or mandible has proven effective in securing and maintaining the airway in patients with facial burns.

Sedation

The role of sedatives in preventing unplanned extubation remains unclear. Studies have shown that more than half of patients were sedated at the time of unplanned extubation, suggesting inadequate sedation. Two studies associated the use of benzodiazepines, particularly midazolam, with an increased occurrence of unplanned extubations. Although a paradoxical excitatory effect or delirium associated with midazolam has been identified as a probable explanation for this finding, the dose and schedule of administration of this sedative were not defined in these studies. No studies evaluated the role of other short-acting drugs such as propofol or remifentanil in decreasing the number of patients experiencing unplanned extubations. A prospective study by Balon demonstrated that IV boluses of morphine sulfate, benzodiazepines (diazepam, midazolam, or lorazepam), and haloperidol given “as needed” were found to increase the incidence of unplanned extubations. Powers reported that the introduction of a sedation protocol linked to the Ramsay Scale reduced the incidence of unplanned extubation from 7% to 3% in 1 year.

Weaning

Thirteen studies recommended prompt identification of patients ready for weaning from mechanical ventilation as a strategy to reduce unplanned extubation. This recommendation was based on the finding that most patients successfully tolerated unplanned extubation, suggesting they were eligible for elective extubation within the ensuing few hours.

Nurse/Patient Ratio

Six studies found a correlation between higher unplanned extubation rate and increased nursing workload, nurse experience of <5 years, or nurse absence from the room. The health care provider was not at the bedside at the time of unplanned extubations in 71% to 89% of cases. The majority of unplanned extubations that occurred during nursing care took place in the presence of nurses with ≤4 years of experience. However, a study by Chevron et al. did not find any influence of increased nursing workload on the incidence of unplanned extubation.

DISCUSSION

Our literature review identified a large number of studies on unplanned extubations. Unfortunately, we found very few high-quality studies. We also found very few studies that assessed the effectiveness of strategies for reducing the incidence of unplanned extubations. The majority of studies assessed the risk factors associated with unplanned extubation and/or outcomes of patients after unplanned extubation. We found no systematic reviews or clinical RCTs.

The incidence of events varied widely from 0.49 to 3.60 unplanned extubations per 100 ventilation days. The majority of studies expressed unplanned extubations as a percentage, hampering comparison among studies because an unplanned extubation can occur more than once in the same patient. Reporting a percentage of patients is also confounded by ventilated patient turnover, because ICUs with many patients requiring brief mechanical ventilation will have a larger denominator, and hence a lower incidence of unplanned extubation. Nevertheless, the overall unplanned extubation rate seems to have decreased over the last 5 years, largely as a result of quality improvement programs.

The use of physical or chemical restraints has shown inconsistent results. The majority of patients (85%) self-extubate. This occurs more frequently in patients receiving sedation (55%) or in patients who are physically restrained (60%), suggesting inadequate management of sedation in these patients. It may also indicate a false sense of security on the part of health care providers as a result of the measures in use. Agitation and anxiety occur in inadequately sedated patients, which may increase the risk of...
unplanned extubation. The American College of Critical Care Medicine of the Society of Critical Care Medicine has developed clinical practice guidelines for the sustained use of sedatives and analgesics in critically ill adults. Assessment of the degree of sedation facilitates titration of sedatives to appropriate and predetermined end points. Several assessment tools are available, but there is no universally applicable and prospectively validated ICU standard. Consistent application of such scales in conjunction with prospectively designed sedation protocols have been shown to improve outcomes in critically ill patients by reducing the number of patients with excessive sedation.

The use of physical restraints in acute and critical care settings has been restricted significantly in recent years. These changes are the result of the detection of adverse outcomes caused by restraint use, as well as the fact that restraint-free care has been provided effectively in many countries. The clinical practice guidelines produced by the American College of Critical Care Medicine Task Force contain 9 recommendations for limiting the use of physical restraints to “clinically appropriate” situations and emphasize the need to consider alternative methods in the ICU. “Clinically appropriate” is defined as avoiding a routine use component therapy and when alternative measures have been unsuccessful or cannot be used without jeopardizing patient safety or care. The situations involve all those required to ensure patient safety, which, in turn, include the most common indication: risk of deliberate or inadvertent removal of an essential medical device. The present literature review shows that the use of physical restraints for preventing unplanned extubation yields inconsistent results.

Failure to identify patients ready for liberation from ventilatory support is another important factor contributing to increased unplanned extubation incidence. Although it seems that many patients are kept on mechanical ventilation longer than necessary, there is a high rate of reintubation of mechanically ventilated patients in those with an unplanned extubation. Formal weaning protocols may reduce the incidence of unplanned extubations, although they may still occur because of the usually low sedation level during weaning.

The majority of studies identified lack of health care professionals at bedside and inexperienced nursing staff as factors contributing to higher unplanned extubation rates. Although only a single study reported no association between nursing workload and unplanned extubations, an appropriate nurse/patient ratio would likely result in fewer adverse events, including unplanned extubations. The literature search identified nursing care as a key component of several quality outcomes including shorter lengths of stay, lower complication rates, and less mortality due to complications. The presence of nursing teams and the ability to influence the quality of care hinge on the ability of each nurse to adequately assess the patient and to remain at bedside.

Unplanned extubation is a quality measure. We previously developed a quality improvement model based on the “Plan-Do-Check-Act” cycle in a pediatric ICU. We were able to quantify and compare the incidence of unplanned extubation, and conduct a root-cause analysis of associated factors and develop action plans to address the issues identified. We implemented a care bundle consisting of educational courses, standardization of selected procedures such as tracheal tube fixation, tube suctioning, patient hygiene and transport, identification of high-risk patients, and standardization of sedation practices by implementing a protocol. Our CQI program decreased the incidence of unplanned extubation from 2.9 to 0.6 unplanned extubations per 100 intubation days. In the current review, we found a decrease between 22% and 53% in unplanned extubations rates reported by CQI studies.

**Recommendations**

**Incidence (Benchmarking)**
To allow comparison of different quality improvement interventions and programs, we recommend that studies report incidence in terms of number of unplanned extubations per 100 mechanical ventilation days (recommendation grade C). Given that the quality improvement studies reported lower unplanned extubations rates, and that the median unplanned extubation incidence among these studies was 0.85 unplanned extubations per 100 ventilation days, we suggest that a reduction in unplanned extubations is an appropriate benchmark for quality improvement targets. Despite limitations in establishing this objective, this rate proved to be the most suitable for use as a benchmark (recommendation grade D).

**Sedation and Analgesia**
We recommend incorporating the identification of delirium as a cause of agitation into sedation/analgesia protocols. Improvements in sedation practice by patient assessment with corresponding sedative dose minimization may be associated with improvements in outcomes but not an increased risk of self-extubation (recommendation grade C). We also recommend teaching health care professionals that the level of consciousness of critically ill patients can fluctuate rapidly. Constant vigilance is essential, and the effectiveness of measures implemented should not be overestimated (recommendation grade D).

**Physical Restraints**
We recommend that restraining therapies should be used only in clinically appropriate situations and not as a routine component of therapy. Inadequate patient sedation and a lack of health care professionals at bedside may lead to greater use of physical restraints.

**Endotracheal Tube Securement and Stabilization**
No studies identifying an ideal method for securing endotracheal tubes are currently available. We recommend standardizing endotracheal tube securement procedures as well as maintaining safe and constant vigilance to be key components for stabilizing endotracheal tubes (recommendation grade C).

**Weaning**
Although only one study has shown the positive impact on unplanned extubations of implementing a weaning protocol, we recommend developing protocols to identify patients ready for extubation (recommendation grade C).
Nursing Staff
We recommend maintaining an adequate nurse/patient ratio, continuing education, training, and updating standard procedures for the care of intubated patients to help prevent unplanned extubations (recommendation grade C).

DISCLOSURES
Name: Paulo Sergio Lucas da Silva, MD, MSc.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Attestation: Paulo Sergio Lucas da Silva approved the final manuscript.
Name: Marcelo Cunio Machado Fonseca, MD, MSc.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Attestation: Marcelo Cunio Machado Fonseca approved the final manuscript.
This manuscript was handled by: Steven L. Shafer, MD.

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