Utilization of a Voluntary Reporting System in Quantitative Risk Assessment for Medical Tasks in a Hospital Setting—with Special Reference to Tasks Done by Nurses

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Abstract: Utilization of a Voluntary Reporting System in Quantitative Risk Assessment for Medical Tasks in a Hospital Setting—with Special Reference to Tasks Done by Nurses: Kayoko Inoue, et al. Department of Health and Environmental Sciences, Kyoto University Graduate School of Medicine—Adverse events in hospitals are a worldwide concern. To develop a tool for quantitative risk assessment of medical error, human reliability analysis was applied to incident reports from a prospective cohort study in a hospital. 374 nurses in a tertiary-care hospital of 670 beds joined this study. Numbers of tasks, classified into 170 items, were actually measured by nurses during three weekdays and one weekend. The total number of tasks per year was found to be about 13.2 million. 1,030 incidents were reported over a year. The gross failure rate for tasks was estimated to be $-10^{-4}$. The relative risk for failure rates in midnight and night shifts was 2–4 times greater than in dayshifts. When the failure rate for a patient category of ages 15 and 64 yr old was taken as a standard, the relative risk of failure was about 200 times greater in a patient category of problematic behavior and 90 times greater in patient categories of clouding of consciousness and postsurgical conditions. Failure rates for individual tasks were in the range of $10^{-5}$ to $10^{-3}$; the tasks with the highest failure rate were prevention of problematic behavior ($2.32 \times 10^{-3}$), safeguards against falls ($1.47 \times 10^{-3}$), intramuscular injection ($1.30 \times 10^{-3}$) and subcutaneous injection of insulin ($9.82 \times 10^{-4}$). The present study revealed two potential risks: occasional tasks with high failure rates and patient categories with small numbers of patients with high failure rates. The present protocol enabled us to conduct quantitative risk assessment on occupational health for medical workers.

Key words: Occupational health, Failure rate, Medical error, Human reliability analysis, Incident, Voluntary reporting system

Adverse events in hospitals are a major world-wide concern. From the viewpoint of quality improvement of health care, many studies have been done, but none from the viewpoint of occupational health for medical workers. Many high-risk industries, including aviation, chemical and nuclear power industries, have focused extensively on building safety systems during the past 30 yr. The systematic reporting and analyses of these safety problems have played a central role in the quality of improvements in these industries. The need to establish an error reporting system has been addressed by the healthcare industries. The Japanese Government has encouraged hospitals to record and collect incident reports, the numbers of which are currently increasing. Until now the lack of an appropriate analyzing tool has, however, limited analyses to a small number of cases with the SHEL model or 4M–4E model. Therefore, the main body of incident reports is left entirely untouched. Our goal is not data collection but to facilitate learning from incident reports and to provide an effective method for the analysis of these reports in order to identify ways to prevent medical errors.

Modern human reliability analysis has provided tools for identifying and analyzing error or incident reports from frontline operators in many industries. It analyzes factors associated with occupational health for medical workers by using parameters such as performance shaping.
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<td>34. Education</td>
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<td>170. Continuing education and professional training inside or outside hospital</td>
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* IVH: Intravenous high calory infusion
† CT: Computed tomography
† MRI: Magnetic resonance image
factors and identifying ways to prevent accidents with the aid of probabilistic risk assessment.

But the application of human reliability analysis to the healthcare industries is not very straightforward. It cannot be assumed that all the tasks in a healthcare setting are done on a routine basis: requirements of patient care depend on conditions of patients that may change from moment to moment and may necessitate a change in the difficulty of a given task and/or may alter the number of tasks.

The major goal of the present study is to develop a method for error analysis from the viewpoint of occupational health for medical workers by means of a voluntary reporting system. A special effort was put into building a probabilistic risk assessment which would give an estimate of task failure rates. The results demonstrate that the method successfully predicted the failure rates for a given task in an explicit way under various healthcare contexts.

**Method**

**Experimental design**

An error is herein defined as the failure of a planned task to be completed as intended or the use of the wrong program to achieve an aim\(^{(1)}\). An incident is defined as an event that either caused an error or that represented a potential error which might have caused error if it had not been interrupted. A cohort study was conducted from June 2000 to May 2001. Incidents were limited to those reported by nurses on the assumption that nurses are not only frontline personnel but also the primary interceptors of medical errors made by other professionals, i.e. physicians and pharmacists\(^{(1)}\). Therefore, incident reports from nurses present not only apparent safety problems but also hidden organization problems.

The study was divided into three parts: In the first step, the total numbers of individual tasks in the task category were estimated in relation to the patient and work environmental factors. In the second step, incident reports were collected from cohort nurses over a year. Incidents were assigned to the task involved from the task table (Table 1). Finally, the failure rate was quantified for each task and modifiers were analyzed for each failure rate.

**Hospital**

The participating hospital is a tertiary-care hospital in a large city, the population of which is about 500,000. The hospital has 670 beds, 14 wards and a staff of 677 of which 374 are nurses and 114 physicians. The nursing staff works in three shifts: midnight, day and night shifts.

**Task table and recording**

Tasks were classified into two major categories, direct and indirect tasks. The former is associated with patient care and the latter is composed mainly of supportive and clerical work such as communication among nurses or between doctors and nurses. The direct tasks were categorized into 17 subclasses which were then divided into 103 individual tasks (Table 1). The indirect tasks were categorized into 17 subclasses and then into 67 individual tasks (Table 1). Since changes in patient care were expected to alter quantitatively and/or qualitatively according to the patients and their condition, the patients were classified into eleven categories (Table 2).

<table>
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<th>Tabel 2. Categories of patient factors</th>
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</table>

Patients were classified according to their most clinically critical conditions.

An example: A 30-yr-old patient entered a hospital in an emergency on the first day, underwent minor surgery on the second day and was discharged on the seventh day. He was classified as Category 7 on the first day, Category 6 on the second day and Category 1 on the other days.
The numbers and types of tasks were recorded by individual nurses during each shift over a period of a week in May 2001 comprising three weekdays and one weekend. The operation, round of wards and examination, which are scheduled weekly may change the numbers and types of tasks daily. At the weekend, the numbers and types of tasks are different from those on weekdays, but are similar on Saturday and Sunday, so that recordings were conducted for three weekdays and a weekend representing weekly medical activities in a given ward. The records were reviewed by the supervising nurse in each ward. The recording nurse was asked to answer any questions on recorded values or items. The weekly numbers of individual tasks were calculated with the following equation:

\[
\text{The number of given tasks per week} = \left(\frac{\text{The total number of given tasks during a three-weekday survey period}}{5/3} + \text{the number of given tasks on a weekend survey day} \times 2\right) - \text{Eq (1)}
\]

The annual and daily values were calculated by multiplying by 52 or dividing by seven, respectively.

**Voluntary reporting system**

A voluntary reporting system was introduced in 1997. The nurses had reported incidents in a short summary together with information on work environments with a structured form to ensure that similar types of data were obtained for all cases. The formats of the incident reports were designed to obtain details of the circumstances surrounding the incident and the nurse’s view of why it happened and how it could have been prevented. During the last nine months of this study a new version of the incident reporting format, which included patient factors, was used in place of the old version. Each incident report was sent in by the supervising nurse of the corresponding ward. Supervising nurses reviewed the report and confirmed the contents on the day that it was reported. The purpose of this review was not to blame the nurse who committed the error, but to check the message to see whether the error reported was correctly described at the scene. If the supervising nurse judged that more than one error was included in an incident report, the nurses involved were requested to file a report corresponding to each error. After completing the review of all identification, the names of the supervising nurse, reporting nurse and patient’s name and other identification were removed from the report. It was then transferred to the risk management committee (two physicians, one nurse, one pharmacist and other professional personnel for a total of eight members). The risk management committee reviewed the reports every month to determine legitimacy: whether the event should be associated with medical errors and/or should show a potential/apparent patient safety problem in the hospital. Reports were deleted when the risk management committee judged that they were outside the criteria of an incident. Having been

**Table 3.** An example of an incident report and its allocation to individual tasks

<table>
<thead>
<tr>
<th>Original incident report</th>
<th>Revised incident reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse B administered an ergometrine vial (iv) prior to delivery to a pregnant woman who was suspected of having atonic bleeding. The drug was prescribed by an obstetrician to reduce post-partum hemorrhage. She left the completed order in the nurse station without dealing with it properly (Failure in ordering, receipt and custody of medicine; Task 124). Another nurse, A, came into the nurse station, found the order on the desk and mistakenly added another ergometrine vial to the continuous drip infusion. She should have inquired why the order was left on the desk (Failure in maintenance of continuous drip infusion; Task 71). The amount of post-partum bleeding was 1.3 L. Nurse A reported the amount of bleeding to the obstetrician three hours after delivery (Failure to report on patient status; task 106).</td>
<td>Nurse B did not properly deal with the completed order (Failure in ordering, receipt and custody of medicine; Task 124). Nurse A did not check the order before she administered another vial of ergometrine (Failure in maintenance of continuous drip infusion; Task 71). Nurse A did not report the abnormal amount of post-partum bleeding immediately (Failure in reporting patient status; Task 106).</td>
</tr>
</tbody>
</table>

The original report was submitted to the supervising nurse. She reviewed it and ordered nurse A and B to submit three reports, each describing one error.
reviewed by the risk management committee, incident reports were then individually reviewed by an incident assignment group (two physicians, two nurses and one psychologist) which assigned each incident to the corresponding task.

The aim of our reporting system was to calculate the failure rate for individual tasks at the nurse level. We used a one report-one error-one task rule. This rule provided a theoretical basis for the failure rate for each task being treated as an independent variable in the probabilistic analysis. More specifically, if the supervising nurse judged that more than one error were included in an incident report, the nurses involved were requested to file a report corresponding to each error. An example of this found in the present study is shown in Table 3.

Failure rate is defined as the ratio of the total number of incidents to the total number of given tasks during a year.

Statistics
Since the quantity of tasks is distributed lognormally, the numbers of tasks were transformed into logarithms. The transformed data were analyzed with the SAS statistical package (SAS Institute Inc., Cary, NC, USA.). Values are presented as the geometric mean (GM) with geometric standard deviation (GSD).

Results
Reliability of task records
A total of 774 records were collected from the nurses. It was not necessary to delete any records from the analysis since the nurses had been involved with similar time studies that had been conducted in this hospital once a year. Possible day-by-day differences were evaluated by comparing the total numbers of tasks per ward (n=14) in three shifts for three weekdays (n=3), 42 altogether. Values collected in three shifts on three different days showed good agreement with significant correlation coefficients ($r \geq 0.83$, $p < 0.01$: data not shown). We concluded that task records were sufficiently reliable.

Numbers of tasks and extrapolation
A total of 774 nurses and 2,438 patients, over a period of three weekdays and one weekend, were involved in this study. The ratio of unclassified tasks (Task 103) was only 0.47%. All of listed tasks were recorded, including both direct and indirect tasks, suggesting that the present task table covers almost all tasks done by nurses. Taken together, these facts guaranteed the validity of task records. The GM (GSD) of the number per task annually was 22,387 (6.45) (Fig. 1A).

The number of nurses and patients per week and per year were calculated from the recorded values (Table 4) using an Eq-1.

![Fig. 1. Distribution of tasks and incidents per year, and failure rates](image)
The annual quantity of tasks amounted to 13.2 million of which two thirds (about 8.7 million) were direct tasks and the remaining one third (about 4.5 million) were indirect tasks. The numbers for the annual nurse-year and annual patient-year were about 70,000 and 220,000, respectively.

**Incident reports**

A total of 1,055 incidents were reported by nurses from June 2000 to May 2001. 25 were deleted from the

### Table 4. Summaries of observed data during a survey period and extrapolated values on weekly or annual basis

<table>
<thead>
<tr>
<th>Survey Period</th>
<th>Direct</th>
<th>Indirect</th>
<th>Total</th>
<th>Midnight</th>
<th>Day</th>
<th>Night</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observed</td>
<td>75,285</td>
<td>41,691</td>
<td>116,976</td>
<td>123</td>
<td>388</td>
<td>126</td>
<td>637</td>
</tr>
<tr>
<td>On 3 weekdays</td>
<td>21,233</td>
<td>8,384</td>
<td>29,617</td>
<td>41</td>
<td>55</td>
<td>41</td>
<td>137</td>
</tr>
<tr>
<td>On one weekend</td>
<td>168,192</td>
<td>86,392</td>
<td>254,584</td>
<td>287</td>
<td>758</td>
<td>292</td>
<td>1,338</td>
</tr>
<tr>
<td>Extrapolation</td>
<td>8,745,981</td>
<td>4,492,382</td>
<td>13,238,363</td>
<td>14,945</td>
<td>39,414</td>
<td>15,206</td>
<td>69,565</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey Period</td>
</tr>
<tr>
<td>Direct Indirect Total Midnight Day Night Total</td>
</tr>
<tr>
<td>Observed</td>
</tr>
<tr>
<td>On 3 weekdays</td>
</tr>
<tr>
<td>On one weekend</td>
</tr>
<tr>
<td>Extrapolation</td>
</tr>
</tbody>
</table>

### Table 5. Gross failure rates during 2000–2001

<table>
<thead>
<tr>
<th>Task</th>
<th>No. of Tasks</th>
<th>No. of incidents</th>
<th>Failure rate ($\times 10^{-4}$)</th>
<th>Relative risk†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midnight</td>
<td>2,656,829</td>
<td>262</td>
<td>0.986*</td>
<td>1.51</td>
</tr>
<tr>
<td>Day</td>
<td>3,406,795</td>
<td>223</td>
<td>0.655</td>
<td>1</td>
</tr>
<tr>
<td>Night</td>
<td>2,682,358</td>
<td>249</td>
<td>0.928*</td>
<td>1.42</td>
</tr>
<tr>
<td>Total</td>
<td>8,745,981</td>
<td>734</td>
<td>0.839</td>
<td>1.28</td>
</tr>
</tbody>
</table>

| Indirect                 |              |                  |                                 |               |
| Midnight                 | 857,421      | 67               | 0.781*                          | 1.19          |
| Day                      | 2,639,237    | 140              | 0.530                           | 0.81          |
| Night                    | 995,725      | 89               | 0.894*                          | 1.36          |
| Total                    | 4,492,382    | 296              | 0.659                           | 1.01          |

*: Significantly larger than either midnight or night shift by Fisher’s exact test p < 0.01.
†: Standardized with failure rate for direct task on the day shift.

2) Weekday vs weekend

<table>
<thead>
<tr>
<th>No. of tasks</th>
<th>No. of Incidents</th>
<th>Failure rates ($\times 10^{-4}$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekday</td>
<td>10,158,195</td>
<td>781</td>
</tr>
<tr>
<td>Weekend</td>
<td>3,080,168</td>
<td>249</td>
</tr>
</tbody>
</table>
analysis by the risk management committee because they were outside of the criterion of an incident, so that ultimately 1,030 reports were filed for analysis.

Among the 1,030 incident reports, physicians were involved in 108 cases (10.5%) and pharmacists were involved in 14 cases (1.4%). The 1,030 incidents were allocated to an individual task category depending on the task involved: 52 direct tasks and 33 indirect tasks. The distribution of the numbers of incidents per task is shown in Fig. 1B. GM (GSD) was 4.57 (3.46). 30 out of 85 tasks had less than three incidents. The failure rates for individual tasks (geometric mean: $1.29 \times 10^{-4}$ (GSD = 4.47)) were distributed as shown in Fig. 1C.

The gross failure rate for overall tasks was estimated to be approximately in the order of $10^{-4}$ (Table 5). The failure rates on weekdays were not different from those on weekends.

Failure rates for both direct and indirect tasks were significantly higher in midnight and night shifts than in dayshifts (Table 5). GMs of direct tasks per nurse per shift were significantly smaller during the dayshift on weekdays ($p < 0.01$, ANOVA) (Table 6). The GM of indirect tasks, however, did not change either by shift or by workday. The failure rate multiplied by the numbers of tasks per nurse per day yielded the expected number of incidents per nurse·day. The relative risk for failure rates was 3–4 times higher on midnight or night shifts (Table 6).

### Effects of patient factors

Since incident reports which carried information on patient factors were available in the most recent nine months of the study period, the numbers of tasks (denominator) was adjusted for nine months. There were significant differences in failure rates among patients in 11 categories (Table 7). When compared with the failure rate for patients in Category 1, the gross failure rates were significantly higher for those with problematic behavior (Category 10), hemodialysis (Category 9), emergency (Category 7) and postsurgical conditions (Category 6), in that order. They were moderately higher for those with disability to insure daily personal wellbeing (Category 5), younger than 15 (Category 3), critical conditions (Category 8) and clouding of consciousness (Category 4) than in patients in Category 1. Failure rates for conditions requiring hospitalization longer than one month (Category 11) and older than 64 (Category 2) were slightly higher.

GMs of numbers of tasks per patient in different patient categories are shown in Table 8. Patients in Categories 4, 5, 6, 8 and 10 accounted for consistently larger numbers of tasks than patients in Category 1 on weekdays and the weekend. Multiplying the GM of tasks with their failure rates yielded the expected numbers of incidents per patient·day (Table 8). The relative risks of failure rates for patients in Categories 10, 6 and 4 were two orders of magnitude higher than for patients in Category 1. For patients in Categories 9, 8, 7 and 5, the relative risks of

### Table 6. Relative risk of failure for three shifts

<table>
<thead>
<tr>
<th>Task</th>
<th>Shift</th>
<th>Failure rate ($\times 10^{-4}$)</th>
<th>GM: No. of Tasks per Nurse·shift</th>
<th>GSD</th>
<th>Expected No. of Incidents per Nurse·shift† ($\times 10^{-2}$)</th>
<th>Relative risk‡‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct</td>
<td>Weekday</td>
<td>Midnight</td>
<td>0.986</td>
<td>158.20</td>
<td>1.85</td>
<td>1.560</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Day</td>
<td>0.655</td>
<td>61.70*</td>
<td>2.32</td>
<td>0.404</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Night</td>
<td>0.928</td>
<td>161.23</td>
<td>1.83</td>
<td>1.500</td>
</tr>
<tr>
<td></td>
<td>Weekend</td>
<td>Midnight</td>
<td>0.986</td>
<td>159.72</td>
<td>1.76</td>
<td>1.575</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Day</td>
<td>0.655</td>
<td>129.73</td>
<td>1.48</td>
<td>0.850</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Night</td>
<td>0.928</td>
<td>144.12</td>
<td>1.68</td>
<td>1.337</td>
</tr>
<tr>
<td>Indirect</td>
<td>Weekday</td>
<td>Midnight</td>
<td>0.781</td>
<td>45.35</td>
<td>2.01</td>
<td>0.354</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Day</td>
<td>0.530</td>
<td>56.85</td>
<td>1.88</td>
<td>0.301</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Night</td>
<td>0.894</td>
<td>54.54</td>
<td>1.98</td>
<td>0.488</td>
</tr>
<tr>
<td></td>
<td>Weekend</td>
<td>Midnight</td>
<td>0.781</td>
<td>47.36</td>
<td>2.17</td>
<td>0.370</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Day</td>
<td>0.530</td>
<td>53.95</td>
<td>1.66</td>
<td>0.286</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Night</td>
<td>0.894</td>
<td>48.93</td>
<td>2.03</td>
<td>0.437</td>
</tr>
</tbody>
</table>

*: Significantly smaller than others’ direct tasks: ANOVA with Dunnett test $p < 0.01$.

†: Failure rate × GM of No.of tasks per nurse·shift.

‡‡: Standardized with expected No.of incidents per nurse·shift on the day shift.

Number of nurses per shift should be referred to Table 4.
Table 7. Patient categories and their corresponding failure rates

<table>
<thead>
<tr>
<th>Patient category</th>
<th>Total No. of tasks during 9 months</th>
<th>Total No. of incidents</th>
<th>Failure rate ($\times 10^{-5}$)</th>
<th>Relative risk†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>961,707</td>
<td>4</td>
<td>0.42</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1,104,642</td>
<td>19</td>
<td>1.72*</td>
<td>4.10</td>
</tr>
<tr>
<td>3</td>
<td>103,673</td>
<td>9</td>
<td>8.68**</td>
<td>20.67</td>
</tr>
<tr>
<td>4</td>
<td>1,151,541</td>
<td>84</td>
<td>7.29**</td>
<td>17.36</td>
</tr>
<tr>
<td>5</td>
<td>1,448,449</td>
<td>149</td>
<td>10.29**</td>
<td>24.50</td>
</tr>
<tr>
<td>6</td>
<td>704,164</td>
<td>103</td>
<td>14.63**</td>
<td>34.83</td>
</tr>
<tr>
<td>7</td>
<td>52,849</td>
<td>8</td>
<td>15.14**</td>
<td>36.05</td>
</tr>
<tr>
<td>8</td>
<td>432,804</td>
<td>34</td>
<td>7.86**</td>
<td>18.71</td>
</tr>
<tr>
<td>9</td>
<td>88,384</td>
<td>16</td>
<td>18.10**</td>
<td>43.10</td>
</tr>
<tr>
<td>10</td>
<td>259,671</td>
<td>131</td>
<td>50.45**</td>
<td>120.12</td>
</tr>
<tr>
<td>11</td>
<td>313,475</td>
<td>9</td>
<td>2.87**</td>
<td>6.83</td>
</tr>
</tbody>
</table>

*: p <0.01 different from Category 1 by Fisher’s exact test.
**: p <0.001 different from Category 1 by Fisher’s exact test.
†: Standardized with the failure rate for patients in category 1.

Table 8. Relative risks for various patient category groups

<table>
<thead>
<tr>
<th>Work day</th>
<th>Patient category</th>
<th>Failure rate ($\times 10^{-4}$)</th>
<th>GM: No. of Tasks per Patient-day</th>
<th>GSD</th>
<th>Expected No. of Incidents per Patient-day† ($\times 10^{-2}$)</th>
<th>Relative risk††</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekday</td>
<td>1</td>
<td>0.042</td>
<td>16.91</td>
<td>2.11</td>
<td>0.007</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0.172</td>
<td>20.82*</td>
<td>2.19</td>
<td>0.036</td>
<td>5.1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0.868</td>
<td>20.38</td>
<td>2.16</td>
<td>0.177</td>
<td>25.3</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>0.729</td>
<td>90.04*</td>
<td>3.14</td>
<td>0.656</td>
<td>93.7</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>1.029</td>
<td>34.48*</td>
<td>2.16</td>
<td>0.355</td>
<td>50.7</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>1.463</td>
<td>45.28*</td>
<td>2.41</td>
<td>0.662</td>
<td>94.6</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>1.514</td>
<td>24.49</td>
<td>2.39</td>
<td>0.371</td>
<td>53.0</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>0.786</td>
<td>47.97*</td>
<td>2.63</td>
<td>0.377</td>
<td>53.9</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>1.810</td>
<td>25.09</td>
<td>1.55</td>
<td>0.454</td>
<td>64.9</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>5.045</td>
<td>30.13*</td>
<td>2.19</td>
<td>1.520</td>
<td>217.1</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>0.287</td>
<td>21.29</td>
<td>1.98</td>
<td>0.061</td>
<td>8.7</td>
</tr>
<tr>
<td>Weekend</td>
<td>1</td>
<td>0.042</td>
<td>11.44</td>
<td>2.90</td>
<td>0.005</td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0.172</td>
<td>13.87</td>
<td>2.95</td>
<td>0.024</td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0.868</td>
<td>23.89</td>
<td>1.91</td>
<td>0.207</td>
<td>29.6</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>0.729</td>
<td>107.21*</td>
<td>2.86</td>
<td>0.782</td>
<td>111.7</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>1.029</td>
<td>31.81*</td>
<td>2.41</td>
<td>0.327</td>
<td>46.7</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>1.463</td>
<td>33.48*</td>
<td>1.97</td>
<td>0.490</td>
<td>70.0</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>1.514</td>
<td>36.92*</td>
<td>2.59</td>
<td>0.559</td>
<td>79.9</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>0.786</td>
<td>32.15*</td>
<td>4.35</td>
<td>0.253</td>
<td>36.1</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>1.810</td>
<td>23.11</td>
<td>1.86</td>
<td>0.418</td>
<td>59.7</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>5.045</td>
<td>28.01*</td>
<td>1.78</td>
<td>1.413</td>
<td>201.9</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>0.287</td>
<td>16.20</td>
<td>2.73</td>
<td>0.046</td>
<td>6.6</td>
</tr>
</tbody>
</table>

*: p < 0.01 Dunnett test after ANOVA, different from Category 1 on the weekday.
†: Failure rate $\times$ GM of No. of task per patient-day.
††: Standardized with expected No. of incidents per patient-day on the day shift. Number of nurses per shift should be referred to Table 4.
failure rates were 30 to 80 times higher than for patients in Category 1. These results suggest that failure rates were quite similar in all patients.

**Failure rates for individual tasks**

Since less than three incidents were too small for evaluation of failure rates for individual tasks we hereafter limit our analysis to the tasks with three or more incidents in a year.

The failure rates for individual tasks are shown in Fig. 2. The highest failure rate groups of tasks in the direct tasks category (≥ 10⁻³) were prevention of problematic behavior, safeguards against falls, intramuscular injection, subcutaneous injection of insulin and subcutaneous injection of other than insulin. The highest failure rate tasks among the indirect tasks (≥ 10⁻³.5) were record of treatments, maintenance of the medical engineering machines and emergency carts, ordering, receipt and
Fig. 3. Task utilization profiles of patients in different categories
Bars represent geometric means of individual tasks per patient day.
On the horizontal axis are task identification numbers.
custody of medicines and mixing of drugs. It is of interest that although maintenance of continuous drip infusion (243,901 times annually in the hospital) was conducted about 60 times as frequently as intramuscular injection (3,855 times annually in the hospital) the number of incidents in the former (18) was only 3.6 times greater than that of the latter (5).

The numbers of incidents were predominantly in two tasks, prevention of problematic behavior and safeguards against falls, 126 and 192, respectively, whereas the numbers of incidents for intramuscular injection, subcutaneous injection of insulin and subcutaneous injection of other than insulin were small: five, eight and three, respectively. These high-failure-rate tasks seem to be grouped into two categories: one class of tasks is routinely done with a high failure rate and another group of tasks seldom has a high failure rate. The latter high failure rate tasks might have been overlooked if incident reports had been the sole source of analysis.

**Task utilization of patients in various patient categories**

We next investigated qualitative and quantitative aspects of task utilization. As shown in Fig. 3, task profiles (GM of quantities of tasks per patient-day) were compared among patients in 11 categories. Although the profiles could not be compared statistically, task utilization patterns were quite unique to their category. For example, for patients in Category 1 the task utilization profile was simple and was composed almost exclusively of 12 tasks. In contrast, more than 40 tasks were discernible in patients in Category 4.

**Discussion**

A voluntary reporting system is the core part of an
overall program for improving patient safety. It focuses on a much broader set of errors than the mandatory reporting system and strives to detect potential system weaknesses. Error analysis of incident reports can therefore provide a rich source of information to healthcare organizations to support their quality improvement efforts.

A possible criticism of the reliance on the incident reporting system is that the limitation of analysis to incidents reported by nurses eliminated errors associated with diagnosis, treatment and other physician/pharmacist specific tasks or malpractices. We are aware of the fact that the present results obviously have limitations and could not reveal the entire spectrum of medical errors or malpractices. We would nevertheless like to believe that a similar approach would still be effective even if information on errors by other professionals were available.

The protocol of the present study enabled us to conduct a quantitative risk assessment. The gross failure rate of the tasks obtained was of the order of $10^{-4}$ (Table 5). For individual tasks, it ranged from $10^{-3}$ to $10^{-5}$ (Fig. 2). These failure rates are comparable to the human error rates in many industries, suggesting that insouciant reliance on the quality of healthcare systems is dangerous.

The quantitative risk assessment enabled us to decompose medical errors into failures at tasks. The present approach thus assigns medical errors to failure(s) in involved task(s). In addition, once the basic data are stored, it also can give a clear image of medical errors in various contexts. In one example, shown in Fig. 4, the probability of a patient in Category 10 receiving the wrong medication during his 10-d stay was calculated to have an estimated overall failure rate of 1.54%. Such a large risk may partly explain why drug-associated errors have occurred so frequently in the hospitals.

We are aware of the fact that reliance on a reporting system may underestimate the number of incidents or be confounded by a large reporting bias. Therefore, to fully utilize the advantage of qualitative risk assessment in the present approach, improvement of the quality and quantity of the voluntary reporting system is essential.

The failure rate fluctuates greatly and is greatly influenced by performance shaping factors. As expected, midnight and night shifts were shown to have increased gross failure rates: shift time increased the failure rate per task and increased the number of tasks performed (Table 5). In terms of the effect of shifts on failure rates, we have shown that hypoglycemia, which is known to reduce cognitive functions, occurs in nurses during midnight and night shifts. The association of physiological changes in the staff depending on shift with medical errors has been suspected but the evidence is still fragmentary. From the viewpoint of occupational health for medical workers more studies are needed to understand errors on the basis of physiological changes.

If should also be remembered that patient factors may be associated with high failure rates in these two shifts: patient conditions and their behavioral factors may change both the quality and quantity of tasks during midnight and night shifts. An observation (Fig. 3), although preliminary and limited, revealed that among 11 patient categories the qualitative and quantitative aspects of task utilization were quite unique. Taken together more research is needed to elucidate higher failure rates in aspects of shift works and patient factors.

Although error analysis was not performed on this study it can be easily combined with the error analysis method. We are now planning to link the present tool with the Tripot Delta Model (EDIT Model: E (error) D (direct threat) and IT (indirect threat)) (Inoue et al. in preparation). Our approach would investigate the incident error threat linkage; what kind of error is directly involved in the incident, what kind of direct threat (direct cause of error) underlies the error, and what kind of indirect threat (organization factor) is responsible for direct threat. Each error would be correlated with each task and thus could be assigned a degree of probability.

A major conclusion of the present study is that hospitals need large flexibility to cope with unpredictable perturbations. On the other hand, obviously, there should be a threshold of flexibility in any organization. Exceeding the threshold of flexibility may induce worker error by increasing the workload and/or physical stresses and/or psychological stresses, and may result in a serious accident due to the neglect of safeguards as predicted by the model of Reason. At present in hospital settings, however, no attention has been paid to the occupational health aspects of medical errors. We believe that the present approach will be an effective answer to this problem.

Acknowledgments: This study was supported by a grant-in-aid from the Japan Industrial Safety and Health Association and The Health Care Science Institute.

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