The quality and safety of hospital care is subject to an increasing amount of attention in many countries. The famous report released by the Institute of Medicine (To Err is Human, 1999), announcing that almost 100,000 Americans die each year due to adverse events in hospitals costing an estimated 29 billion dollars per year, has created the need to better understand these events to reduce their incidence. The AE is defined as an injury related to medical management (including diagnostic, treatment, failure to diagnose or treat and equipment used to deliver care) in contrast to complications linked to the natural evolution of a patient’s illness. The AEs are not only a cause for concern in terms of patient safety and quality of care, but also in economic terms in that they represent a substantial financial burden.

In the United States, the need to gain a better understanding of the extent of this problem has led to a renewed interest in medico-administrative databases for developing measurement tools to regularly monitor AE. In order to identify AE systematically and understand their health and economic consequences, the Agency for Health Care Research and Quality has developed a series of Patient Safety Indicators (PSIs) based on routinely collected hospital data in early 2000s (Miller, 2001). These indicators, validated at international level, are tested and used increasingly in many OECD countries for monitoring preventable adverse hospital events.

Excess Costs of Adverse Events in Hospitals in France
First estimations using nine patient safety indicators

Clément Nestrigue, Zeynep Or* (Irdes)

Based on routine hospital data, this study provides the first estimations at the national level of excess costs incurred by a number of selected adverse events in hospitals. The nine patient safety indicators chosen correspond to avoidable adverse events which require attention.

The results indicate that 0.5% of hospital stays are associated with one of these nine adverse events. The excess costs generated, vary considerably ranging from a little over 500 € for obstetric traumas to almost 20,000 € for postoperative sepsis. The excess costs are closely correlated with length of hospital stay and intensity of care. In 2007, the total cost of care incurred by these nine adverse events was estimated near 700 million Euros. Four adverse events (post-operative physiologic and metabolic derangement, postoperative sepsis, decubitus ulcers and post-operative pulmonary embolism) represented 90% of the costs.

Adverse hospital events examined in this study represent a substantial burden in terms of cost and length of stay. It is necessary to invest in these areas with a perspective of improving both the quality of patient care and care cost-efficiency in hospitals.

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In France, the National survey on serious adverse events in hospitals (ENEIS) estimated that between 5.1 and 7.3 serious adverse events (SAEs) occurred per 1,000 hospital days in 2009; in other words, between 275,000 and 395,000 SAEs per year, of which between 95,000 and 180,000 could have been prevented (Michel et al., 2011). The median number of additional days of hospitalization imputable to adverse events is estimated at 6.5 days (average closer to 9 days) by the physicians treating these patients. However, the ENEIS survey does not include any other economic element and at the national level no evaluation of the costs generated by these adverse events is available.

This study provides the first national cost estimates for a selection of adverse hospital events in France exploiting routinely collected hospital data. The methodology used to detect hospital AEs by means of patient safety indicators, was developed in the United States and validated at the international level. The cost of AEs at the national level is estimated using two databases: national hospital activity database (PMSI) for the year 2007, which provide comparable cost data in a sample of volunteer public and private hospitals, to calculate AE costs; the national hospital activity database for acute hospital admissions (PMSI-MCO) to determine the number of AEs and estimate the costs at national level (Sources and Methods inserts p. 2 and 3).

### Patient safety indicators for selecting nine adverse events

The Patient Safety Indicators (PSIs) were initially developed by the Agency for Health Care Research and Quality (AHRQ) in the United States from medico-administrative data (MacDonald et al., 2002; Romano, 2003). Fifteen PSIs covering five major domains (nosocomial infections, sentinel events, operative and post-operative complications, obstetrics and other care-related AEs) were selected taking into account the feasibility and pertinence of common diagnostic codes used to identify diseases (Miller and Marrie, 2004).

PSIs focus on the notion of ‘preventable’ adverse events (MacDonald et al., 2002; Miller et al., 2001). AEs are identified using algorithms, essentially combining secondary and principal diagnoses but also medical procedures, diagnostic related groups (DRG) and length of hospital stay for defining the risk populations. For each indicator (or AE), inclusion or exclusion criteria determine the population for which the events in question would represent a patient safety problem (Quan et al., 2008; Drösler, 2008; Januel, 2011). A ‘preventable’ AE by definition excludes cases for which care outcome is determined by the patient’s inherent condition. Sepsis, for example, can be a medical complication associated with care but not all cases of sepsis can be considered preventable without first taking the patient’s clinical status into account. The PSI algorithms allow definition of the inpatient population in which the development of postoperative sepsis can be considered as a hospital-acquired AE. It is limited to surgical hospitalizations with sepsis coded as a secondary diagnosis. Patients admitted with a principal diagnosis of sepsis, infection, immunodepression syndrome or cancers are excluded (diagram opposite). As a result, the sample population at risk of developing postoperative sepsis is smaller, for example, than the total population actually concerned by PSI 5 (foreign body left during procedure), a risk that concerns all surgical hospitalizations.

These indicators are used to help hospitals identify AEs that require particular attention and to evaluate the incidence of medical complications related to hospital care. The adverse events can include problems in medical practice, incorrect use of products, problems with procedures and organisation on which it is possible to intervene for preventing the occurrence.

In France, a pilot study PSI-HCL permitted testing the majority of PSIs and demonstrated the pertinence and potential interest of using them (Januel,
0.5% of hospitalizations are associated with one of these adverse events

From the nine indicators selected, 15,107 hospital cases with an adverse event were identified in the cost database (ENCC, 2007), in other words 0.5% of the total number of stays registered in the ENCC (around 3 million cases). At national level, the hospital activity database (PMSI-MCO) records 98,288 hospital cases associated with one of these AE; equally 0.5% of the total number of hospital stays (table 1).

The relative frequency of the different PSIs is globally similar in the ENCC...
Excесs Costs of Adverse Events in Hospitals in France

**Method**

Choice of the 9 Patient Safety Indicators (PSI)

The PSIs for this study were selected in collaboration with a multidisciplinary expert group based on the results of the pilot project ‘Clarté’. The indicators were limited to the 13 PSI for which the selection algorithms are adapted to the French hospital data. Among these 13 PSI, four indicators, Complications of Anesthesia (PSI 1), Transfusion Reaction (PSI 16), Birth Trauma - Injury to Neonate (PSI 17) and Obstetric Trauma – Cesarean Delivery (PSI 20) were finally excluded from the analyses due to the low number of cases in the ENCC database (less than 10 observations). The nine indicators selected in fine are as follows:

- PSI 3 Decubitus ulcer;
- PSI 5 Foreign body left during procedure;
- PSI 7 Infections due to medical care (infections caused by intravenous lines (IV) or catheters);
- PSI 10 Postoperative physiologic and metabolic derangement;
- PSI 12 Postoperative pulmonary embolism or deep vein thrombosis;
- PSI 13 Postoperative sepsis;
- PSI 15 Technical difficulty during procedure - Laceration or accidental puncture;
- PSI 18 Obstetric trauma – vaginal delivery with instrument;
- PSI 19 Obstetric trauma – vaginal delivery without instrument.

The algorithms for each PSI (specific inclusion/exclusion criteria, list of ICD-10 codes to be assigned to the numerator or denominator) were determined at international level and are available in the 2009 OECD report (Drosler et al., 2009). The algorithms adapted to French data are detailed in a DREES working paper (Januel, 2011). By definition, ambulatory (or same-day) surgery not requiring an overnight hospital stay, and treatment sessions are excluded from the PSI field.

With the objective of producing an overall cost estimate for the medical adverse events in France, certain fields covered by PSIs were extended:

- Normally, PSIs cover the hospitalized adult population (age at least equal to 18), with an additional series of indicators for patients aged under 18. We analysed the totality of conventional hospitalizations in acute care including those for patients aged less than 18.

- For PSI 3 (Decubitus ulcer), it was impossible to exclude hospital stays for patients transferred from long-term care facilities or discharged to another acute care hospital. In effect, this information is not registered in the databases used. As our analysis involved global cost estimates rather than hospitals’ individual performance, it was not considered as being problematical for this study.

- For PSI 5 (Foreign body left during procedure), we took hospital stays for which this indicator was the primary cause of hospitalization (principal diagnosis) as well as secondary diagnosis differing from the OECD recommendations. While the exclusion of stays with primary diagnosis is justified for calculating the PSI at hospital level so as to avoid prejudice to hospitals caring for patients transferred from other hospitals, it is relevant to keep them for estimating costs at national level.

CONTEXT

To date, no economic analyses had been carried out in France regarding the cost of adverse patient safety events in hospitals. IRDES, in collaboration with the DREES, conducted a study with the objective of estimating cost of hospital adverse events using routine hospital data. These first results confirm the need to carry out this type of economic analysis in greater depth in future studies.

and PMSI databases, despite a few minor differences. The PSI with the highest frequency rate in the ENCC is PSI 10 (post-operative physiologic and metabolic derangement), with a total of 4,228 hospital admissions. At national level, decubitus ulcer (PSI 3) records the highest number of cases with a total of 29,938 hospital admissions (7.8% incidence rate), but PSI 10 records the highest incidence rate all adverse events combined (9.45‰) [table 1].

As expected, the lowest number of cases are registered for “a foreign body left during procedure” (PSI 5), classified as a sentinel event, in both the ENCC and PMSI databases; 644 hospitalizations at national level, of which 173 with a foreign body left during procedure (PSI 5) as the main reason for admission (reference to a foreign object left during procedure in the principal diagnosis).

Differences in adverse event frequency rates are mainly explained by differences in the characteristics of patients registered in the ENCC and PMSI databases. Although the two databases are globally comparable, the ENCC sample, based on volunteer hospitals, can differ from the national sample (PMSI) both in terms of patient and hospital characteristics.

The in-hospital cost of a given adverse event is the difference between the average cost of a hospital stay with and without this AE complication. As the cost of hospital stays vary considerably according to patient profile and the pathology treated, calculations of average costs need to be adjusted taking into account the characteristics of the patients treated. The excess costs generated for each AE are calculated in the ENCC database using multivariable case-matching (Methods insert above) that consists in matching each hospital stay with an AE with an equivalent hospital stay in terms of patient profile but without the AE in question, and comparing costs (Raleigh et al. 2008 ; Zhan and Miller, 2003).

The reliability of the cost estimates obtained using this method depends on the ability to identify identical case-control admissions, which presented no difficulty in the ENCC data base (99% match rate)5.

**Significant disparities in excess costs according to adverse event**

Table 2 presents the estimations of excess costs and length of stay due to adverse events from nine patient safety indicators with multivariable matching in the ENCC database.

As expected, we observe significant disparities in the costs generated by the different AEs. The (weighted) average excess cost of hospitalisation vary from 500€ for obstetric trauma during vaginal delivery with and without instrumentation (PSI 18/19) to almost 20,000 € for postoperative sepsis (PSI 13). Infections due to medical care

5 We also used generalized linear models as an alternative to test the robustness of cost estimates (Nestrigue and Or, 2011).
The excess costs incurred by adverse events are directly correlated with length of hospital stay...

The excess costs generated by adverse events are closely correlated with extra days of hospitalisation due to these events. The excess length of stay (LOS) attributable to postoperative sepsis (PSI 13) is about 20 days, while it is only 0.7 days for an obstetric trauma during delivery (PSI 19). Infections and decubitus ulcers figure among the adverse events that considerably prolong the hospital stay (respectively 14.7 days and 11.2 days).

In 2007, excess costs close to 700 million Euros for nine adverse events

The excess cost associated with these nine adverse events amounted to 682 million Euros in 2007. The total excess cost is a function of the average costs of treatment and incidence rates at national level. The PSI 19 (obstetric trauma) represents a relatively small cost at the national level (1.5 million €) since the cost of care is relatively low (525 €) despite a high incidence rate (4 in 1 000). Whereas technical difficulties during the course of a medical intervention (lacerations or accidental punctures) lead to catheter-related infections (PSI 7) and postoperative physiologic and metabolic derangement (PSI 10) record respectively 14.7 days and 11.2 days).

The excess LOS is not the only factor determining excess costs in hospital; intensity of care delivered also has an impact on costs. For example, the excess cost associated to catheter related infections (PSI 7) and physiologic and metabolic derangement (PSI 10) are relatively close despite the fact that excess LOS for infections is twice as long since PSI 10 often requires intensive, complex care over a shorter time period.

Table 1: Number of adverse patient safety events identified in the ENCC and PMSI 2007

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>ENCC</th>
<th>PMSI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of hospital stays</td>
<td>Number of hospital stays</td>
</tr>
<tr>
<td>PSI 3 Decubitus ulcer</td>
<td>3,456</td>
<td>29,938</td>
</tr>
<tr>
<td>PSI 5 (DP) Foreign body left</td>
<td>75</td>
<td>173</td>
</tr>
<tr>
<td>PSI 5 (DA) Foreign body left</td>
<td>14</td>
<td>471</td>
</tr>
<tr>
<td>PSI 7 Infections</td>
<td>915</td>
<td>4,274</td>
</tr>
<tr>
<td>PSI 10 Postoperative derangements</td>
<td>4,228</td>
<td>26,276</td>
</tr>
<tr>
<td>PSI 12 Pulmonary embolism</td>
<td>3,003</td>
<td>18,968</td>
</tr>
<tr>
<td>PSI 13 Postoperative sepsis</td>
<td>1,852</td>
<td>8,368</td>
</tr>
<tr>
<td>PSI 15 Laceration or accidental puncture</td>
<td>1,149</td>
<td>6,887</td>
</tr>
<tr>
<td>PSI 18/19 Obstetric trauma</td>
<td>415</td>
<td>2,933</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>15,107</td>
<td>98,288</td>
</tr>
</tbody>
</table>

The table presents the number of hospital cases with one of the nine adverse patient safety events in the ENCC and national PMSI databases. The size of the risk population is defined by the PSI algorithms. The prevalence rates are calculated at national level (PMSI) for one thousand at-risk hospitalizations.

Sources: National hospital costs study (ENCC), National hospital database (PMSI) 2007.

Download data: [www.irdes.fr/Donnees/Qes171_SurcoutEvenementsIndesirables.xls](http://www.irdes.fr/Donnees/Qes171_SurcoutEvenementsIndesirables.xls)

... and intensity of care

The excess cost associated to catheter related infections (PSI 7) and physiologic and metabolic derangement (PSI 10) record respectively 14.7 days and 11.2 days)

Numbers Prolongation of average length of stay Confidence interval at 95% Excess costs Confidence interval at 95%

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>ENCC</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Numbers</td>
<td>Prolongation of average length of stay</td>
<td>Confidence interval at 95%</td>
<td>Excess costs</td>
<td>Confidence interval at 95%</td>
</tr>
<tr>
<td>PSI 3 Decubitus ulcer</td>
<td>3,456</td>
<td>11.2</td>
<td>±0.83</td>
<td>5,612 €</td>
<td>±656 €</td>
</tr>
<tr>
<td>PSI 5 Foreign body left</td>
<td>89</td>
<td>2.5</td>
<td>±3.05</td>
<td>2,156 €</td>
<td>±2,879 €</td>
</tr>
<tr>
<td>PSI 7 Infections</td>
<td>915</td>
<td>14.7</td>
<td>±1.84</td>
<td>10,950 €</td>
<td>±1,690 €</td>
</tr>
<tr>
<td>PSI 10 Postoperative derangements</td>
<td>4,228</td>
<td>7.3</td>
<td>±0.59</td>
<td>10,273 €</td>
<td>±629 €</td>
</tr>
<tr>
<td>PSI 12 Pulmonary embolism</td>
<td>3,003</td>
<td>5.0</td>
<td>±0.59</td>
<td>4,300 €</td>
<td>±578 €</td>
</tr>
<tr>
<td>PSI 13 Postoperative sepsis</td>
<td>1,852</td>
<td>19.7</td>
<td>±1.44</td>
<td>20,838 €</td>
<td>±1,317 €</td>
</tr>
<tr>
<td>PSI 15 Laceration or accidental puncture</td>
<td>1,220</td>
<td>1.2</td>
<td>±0.88</td>
<td>1,723 €</td>
<td>±902 €</td>
</tr>
<tr>
<td>PSI 18/19 Obstetric trauma</td>
<td>415</td>
<td>0.7</td>
<td>±0.11</td>
<td>529 €</td>
<td>±32 €</td>
</tr>
</tbody>
</table>


Download data: [www.irdes.fr/Donnees/Qes171_SurcoutEvenementsIndesirables.xls](http://www.irdes.fr/Donnees/Qes171_SurcoutEvenementsIndesirables.xls)
tion or accidental puncture), a much rarer event (0.89 in 1000), represents a cost of over 9 million Euros.

Four adverse events represent 90% of total excess costs

Postoperative physiologic and metabolic derangement (PSI 10) generates the highest excess costs. Average cost is estimated at 9,910€ generating a total cost of 260 million Euros; almost 40% of the total excess costs associated with the nine AEs combined. Postoperative sepsis (PSI 13) and decubitus ulcer (PSI 3) are among the AEs generating the highest costs at respectively 155 million Euros (22% of the total costs) and 136 million Euros, followed by postoperative pulmonary embolism (PSI 12) costing over 70 million Euros. These four events alone represent over 90% of excess hospital costs generated by adverse events in 2007.

Robust statistical results coherent with estimations carried out in other countries

The results obtained by multivariable matching are confirmed by the generalised linear models: the total cost of medical care for the nine AEs amounts to 733 million Euros. The difference in cost estimates observed between the matching method and the linear model is due to the fact that models take into account all hospital stays whereas it is not possible to match 100% of cases in the PMSI with cost database (ENCC) which is a smaller sample.

In any case, the adverse events examined in this study are associated with a substantial increase in the cost and length of hospital stays. Our results are in accordance with those of other studies exploring PSIs. Only results concerning excess LOS can be compared directly across countries. It is difficult to compare excess cost estimates related to PSI due to differences in the prices of production factors, cost accounting methods and healthcare organization across countries.

Estimations concerning excess length of stay for different patient safety indicators used in this study compared with those carried out in England (Rivard et al., 2008) and the United States (Zhan and Miller, 2003; Rivard et al. 2008). The relative impact of each PSI on length of hospital stay is relatively coherent. These results suggest that the PSIs calculated from routine hospital data are of interest in monitoring and comparing adverse events associated with medical care and for evaluating their economic and medical consequences.

Our study shows that shortcomings in the organization and process of care in hospitals that can give rise to adverse patient safety events represent a considerable economic cost. In the current context of budgetary constraints facing hospitals, it is vital to examine ways of improving the quality of care whilst at the same time strengthening cost-efficiency in hospitals. It is clear that interventions aimed at preventing adverse events can incur additional costs. While we have not examined the cost of different strategies to improve the safety of medical care in this study, our results nevertheless permits identifying priority action areas to target the resources for improving patient safety.

It is possible that some of the adverse events identified with PSI are unavoidable (false positives). Several factors nevertheless suggest that our calculations unde-
restimate the overall costs associated with adverse events: first, only hospital adverse events for which the definition and identification are agreed at the international level and validated in France were retained. Certain adverse events, the importance of which are emphasized in national and international surveys such as adverse drug events, are not taken into account due to lack of standardized measurements. It is necessary to extend this study to a wider range of patient safety indicators for a global picture.

Furthermore, the reliability of patient safety indicators largely depends on the quality of diagnostic coding in hospitals. While there has been some improvement in the coding of primary and secondary diagnoses in the PMSI database since the introduction of the DRG (Diagnosis-Related Groups) based payment, all adverse events are not systematically coded. The diagnostics and medical procedures related to adverse events are more likely to be coded if they have a financial impact on the determination of DRG payment. Therefore, the risk of under-estimating the rate of adverse events due to medical care is not negligible. In addition, in PMSI 2007 data, it is possible that a case with an adverse event is reclassified in a DRG with complication and/or comorbidity. The matching analyses comparing the cost of patients with the same profiles (age, gender and DRG) can artificially increase the cost of ‘reference’ hospital stays (without AE) and thus may lead to an under-estimation of certain additional costs.

Finally, the cost estimations provided by this study concern only direct costs of treating adverse events from the hospital point of view. A complete economic evaluation would require taking into account the direct and indirect costs incurred for the patient after discharge, including out-of-pocket expenses, productivity loss due to work absence and the financial consequences of a deterioration in the quality of life, in addition to the direct hospital costs.

FURTHER INFORMATION