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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.

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. An 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.

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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 costs study (ENCC) for 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 events¹, 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 Mattke, 2004).

PSIs focus on the notion of 'preventable' adverse events (McDonald *et al.*, 2002; Miller *et al.*, 2001). AEs are identified using algorithms², 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-HCL³ permitted testing the majority of PSIs and demonstrated the pertinence and potential interest of using them (Januel,

SOURCES

National hospital costs study database (ENCC, Étude nationale de coûts méthodologie commune)

The cost of adverse events is calculated using data from hospital costs study for 2007 (ENCC). The ENCC 2007 sample is composed of 99 volunteer hospitals made up of 42 public hospitals, 13 private non-profit and 44 private for-profit hospitals. In total, it represents about 3 million hospital stays of which 2.1 million in the public sector and 0.8 million in the private sector (see table below). The ENCC provides the total cost of hospital stays as they were reported by the hospitals. The costs include all expenditures related to clinical activities, monitoring, intensive care, life support, logistic and management costs and overheads directly imputable to hospital stays. Structural costs, that is to say financing (interest, loans and debts...) and real estate expenditures are not included in the total costs. The fees and salaries of medical and non-medical personnel are taken into account in the total costs in both public and private for-profit hospitals.

National hospital activity database, PMSI (Programme de médicalisation des systèmes d'information)

Adverse events are recorded in the Hospital activity database (PMSI-MCO) for the year 2007. This database covers all acute care cases in public and private hospitals in France and provides medical (primary and secondary diagnoses, surgical acts, homogeneous patient groups, etc.) and individual patient level information (age, gender etc.). The PMSI includes a total of 21 million hospital stays in 2007 (table below). The ENCC database can be matched with PMSI data so as to acquire the totality of medical and individual data concerning a hospital stay.

Number of hospitals and cases recorded in the 2007 ENCC and PMSI databases

	ENCC		PMSI	
	Number of hospitals	Number of stays	Number of hospitals	Number of stays
Private for-profit	44	800,000	655	6,819,335
Public	42	1,944,000	693	12,006,284
Private non-profit	13	225,825	208	2,370,436
Total	99	2,969,825	1,556	21,196,055

¹ A sentinel event is defined as an unexpected accident, incident or dysfunction that must give rise to an enquiry (root cause analysis). It concerns unacceptable medical errors that could generally have been avoided and that present a high risk for the patient (mortality, invalidity). For example, a foreign body left during a surgical intervention or wrong-site surgery.

² A finite set of rules that specify a sequential series of operations to be applied to input data producing a finite amount of output data providing a solution technique for similar problem categories.

³ In France, the PSI development program is conjointly carried out by the Hospices Civils de Lyon (a pool of Lyon's general hospitals), the High Authority for Health (HAS) and the Department of Research, Studies, Evaluation and Statistics (DREES) and involved different French and international institutional partners. Another project (Clarté) has the mission of adopting a series of PSIs in version 11 of the French DRGs.

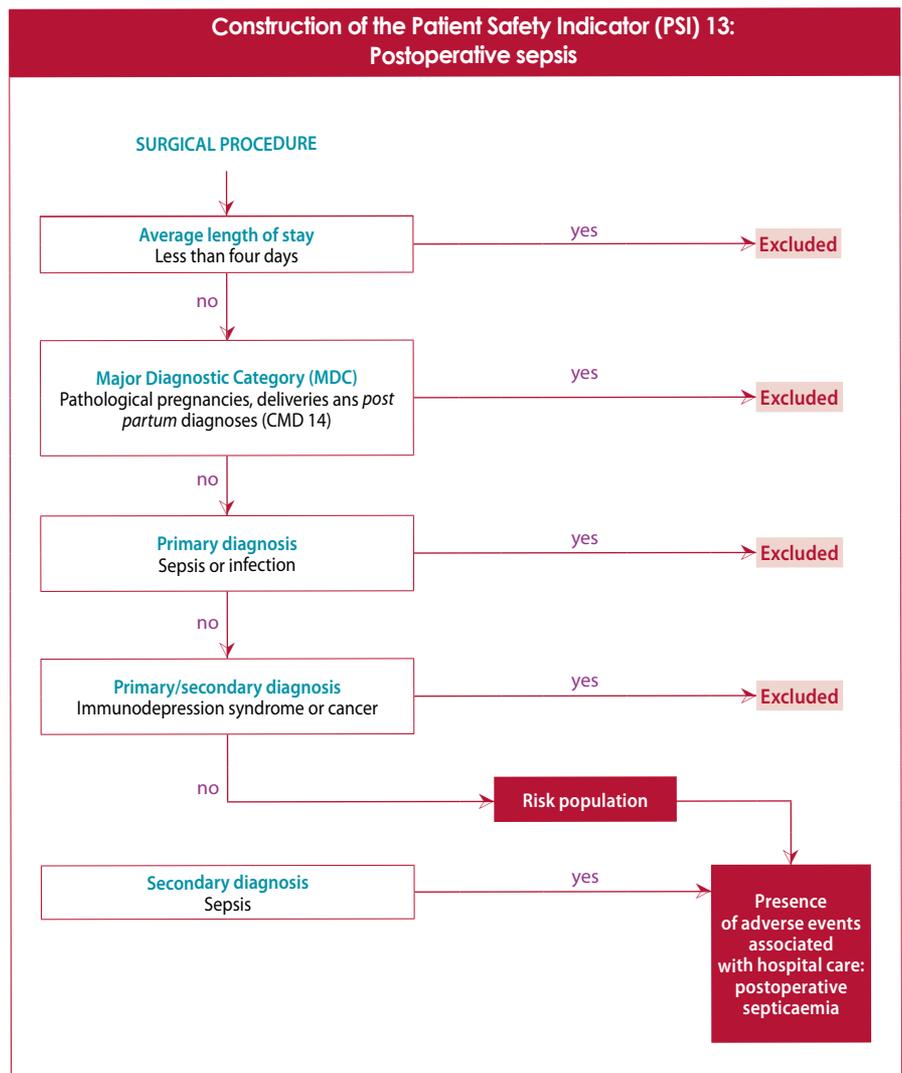
2011). The study is being continued within the framework of the *Clarté* project⁴ whose aim is notably to refine these indicators in order to use them to compare the quality of care in hospitals. Among the 13 indicators studied on in this project, nine were retained for our cost analysis (see Methods insert below).

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

⁴ Consortium for the production of health indicators 2011- 2013, involving several regions of France (Loire-Atlantique, Aquitaine and Rhône-Alpes).



METHOD

Cost estimates

Multivariate case matching involves grouping hospital cases into relatively fine comparable groups (strata) so as to reduce the differences between the groups being compared. In order to establish the excess cost of an adverse event for a given strata, we compare the cost of a hospital stay associated with the adverse event in question against one without the adverse event. The characteristics of the hospital stays included in each stratum are identical on four control variables:

- Homogeneous patient group HPG (DRG);
- Patient's age in 6 categories: 0-17 / 18-49 / 50-64 / 65-74 / 75-84 / 85 and over;
- Patient's gender;
- Ownership of the hospital in three categories: public / private not for profit / private for profit.

Thus, for each patient safety indicator (PSI), and for each stratum (cross between HPG, age gender and type of establishment) observed in the ENCC database, the cost and average length of hospital stay are calculated for cases with and without an adverse event. By comparing the two, we established the additional cost of care and the prolongation of the hospital stay imputable to adverse events. Regarding PSI 5, foreign body left during procedure as the cause of hospitalization (principal diagnosis), we

considered that the cost of excess care corresponded to the total cost of the hospital stay since it would not have occurred if the surgery was done properly in the first place.

Almost all the hospital stays (almost 100%) with an adverse event, on the basis of the four control variables, were able to be matched with a hospital stay without adverse event in the ENCC database.

To produce cost estimates for the hospital stays observed at national level, the costs of additional treatment calculated per stratum from the ENCC database are applied to the national PMSI datasets using the same strata (age, gender, HPG, type of establishment) for each PSI. However, certain strata observed in the national database (PMSI) were not observed in the ENCC database in which the number of hospital stays registered is seven times lower than PMSI. We affected the average cost calculated on the basis of strata for which information was available. This can be problematic if match rates are low for certain strata. In this study, this was the case only for PSI 5 (20% match rate). Therefore we also estimated linear models to confirm robustness of the result. Details of the models are presented in an IRDES working paper: Nestrigue, Or (2012), *Estimated Cost of Adverse Events Associated with Hospital Care*. no. 44, 2012/02.

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 compa-

ring 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).

T1

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

Adverse events	ENCC	PMSI		
	Number of hospital stays	Number of hospital stays	Risk population	Prevalence rate (%)
PSI 3 Decubitus ulcer	3,456	29,938	3,832,011	7.81
PSI 5 (DP) Foreign body left	75	173	7,639,056	0.08
PSI 5 (DA) Foreign body left	14	471	-	-
PSI 7 Infections	915	4,274	6,248,132	0.68
PSI 10 Postoperative derangements	4,228	26,276	2,781,628	9.45
PSI 12 Pulmonary embolism	3,003	18,968	2,829,610	6.70
PSI 13 Postoperative sepsis	1,852	8,368	1,190,606	7.03
PSI 15 Laceration or accidental puncture	1,149	6,887	7,725,975	0.89
PSI 18/19 Obstetric trauma	415	2,933	640,967	4.58
Total	15,107	98,288	-	-

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.

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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.

Estimations of total excess costs and LOS attributable to adverse events at national level are presented in table 3. Average cost estimates (Methods insert p. 3) from ENCC data are used to estimate the cost for each PSI taking into account the incidence rate and adjusting for patient and hospital profiles at national level. The overall costs of care for adverse events thus reflect the structure of hospital stays observed in the PMSI database.

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 (lacera-

(PSI 7) and postoperative physiologic and metabolic derangement (PSI 10) record the highest costs after PSI 13 at around 10,000€.

These averages hide however strong variation across patients within each AE. For example, the excess cost of treating hospital acquired infections can vary from less than 6,000€ to over 20,000€.

... and intensity of care

But the excess LOS is not the only factor determining excess costs in hospital; intensity of care delivered also has an impact on

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).

T2

Excess cost and length of stay per PSI in ENCC 2007

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

Source: National hospital costs study (ENCC) 2007.

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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 (PSI13) 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 general-

ised 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-

T3

Estimates of excess costs and length of stay by PSI (stratification method)

Adverse events	PMSI					
	Numbers	Excess length of stay	Confidence interval at 95%	Additional costs	Confidence interval at 95%	Total cost
PSI 3 Decubitus ulcer	29,937	9.8	± 0.14	4,568 €	± 101	136,765,563 €
PSI 5 Foreign body left	644	2.2	± 0.42	1,639 €	± 392	1,055,399 €
PSI 7 Infections	4,273	14.7	± 0.59	10,821 €	± 537	46,238,384 €
PSI 10 Physiologic derangements	26,275	7.4	± 0.16	9,911 €	± 173	260,409,993 €
PSI 12 Pulmonary embolism	18,968	4.6	± 0.16	3,740 €	± 146	70,945,028 €
PSI 13 Postoperative sepsis	8,368	18.5	± 0.56	18,578 €	± 478	155,457,100 €
PSI 15 Laceration or accidental puncture	6,887	1.1	± 0.23	1,356 €	± 239	9,337,096 €
PSI 18/19 Obstetric trauma	2,933	0.7	± 0.02	525 €	± 5	1,540,334 €
						681,748,897 €

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

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reestimate 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. ♦

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