

**BIBLIOGRAPHICAL REVIEW ON COST OF
"PATIENT SAFETY FAILINGS"
IN SURGICAL PROCEDURE RELATED
PROBLEMS.
SUMMARY**



GOBIERNO
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Plan de **Calidad**
para el **Sistema Nacional**
de Salud



Bibliographical review on cost of “Patient Safety Failings” in surgical procedure related problems. Summary

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1. Introduction

Patient safety is a key element for determination of hospital quality worldwide. The rate of incidence of adverse events in hospitals is an important patient safety indicator.

In the context of healthcare organisations, adverse events are defined as non-intentional lesions or complications that result from the healthcare provided rather than from patients' clinical situation and that may extend their hospital stay or even lead to death or incapacity upon discharge.

The nationwide adverse events study (ENEAS) conducted in Spain showed that 9.3% of all patients admitted to hospital suffer from some kind of adverse event directly related to the healthcare provided, and that almost half of these adverse events are preventable (MSC, 2006).

The ENEAS study concludes that the three causes directly linked to adverse events in Spanish hospitals are, in order of importance, medication-related incidents, technical problems during procedures and nosocomial infections.

The study reveals that 25.04% of all adverse events detected originate in a problem experienced during a procedure and that 55.6% of adverse events are a consequence of a surgical intervention. These are followed by adverse events connected with administration of anaesthesia (4.1%), endoscopic procedures (4.1%), catheterization (2.9%) and bladder catheterization (2.9%), inter alia.

The ENEAS study shows that haemorrhage or bruising represents the main procedure-related adverse event in Spanish hospitals, accounting for 9.31% of the total, followed by organ lesions during procedures (3.05%), other post-surgery or post-procedure complications (2.14%) and ineffective or incomplete surgical procedures (1.68%).

Surgical wound infection is classified as a nosocomial infection and represents 7.63% of all adverse events in hospitals. In terms of procedure-related adverse events overall, 31.7% are considered avoidable.

In 1991, the Harvard Medical Practice Study (Leape, Brennan, Laird *et al*, 1991) concluded that 47.7% of all adverse events detected were connected with surgical procedures.

Accordingly, considering the statistics contained in the above mentioned studies, it would seem reasonable to conduct a study to calculate the cost of surgical procedure related problems.

The results of this study will help managers, the authorities and healthcare professionals to establish priorities and introduce improvements, with a view to reducing the incidence of these problems and hence the associated costs.

2. Objectives

This report is a bibliographical review whose key objective is to calculate the cost of adverse events relating to problems arising during surgical procedures and to determine the methods used to calculate these costs.

Specifically, this review aims to provide replies to the following questions:

- 1) What is the economic cost of surgical procedure related adverse events?
- 2) What methodology is used to analyse the economic cost of surgical procedure related adverse events?

3. Methodology

The bibliographical review comprised two separate stages: location and selection of patient safety studies, followed by detailed evaluation of these studies.

3.1 Location and selection of studies

3.1.1 Location

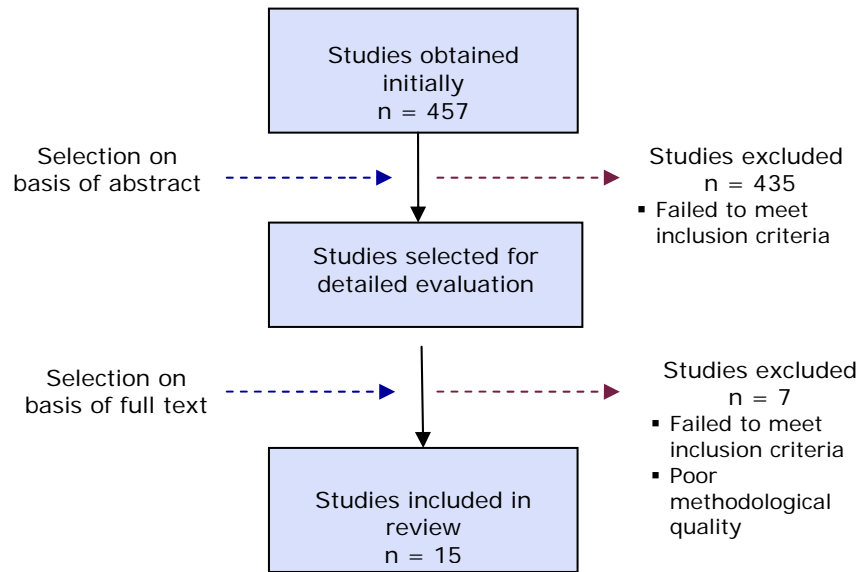
Location of articles via a search strategy in three different databases: MEDLINE, EMBASE (*Excerpta Medica Database*) and EconLit. Primarily databases of scientific articles in medicine and economics. Search limited to the period 2000 to 2007.

3.1.2 Selection

Initial selection of articles based on abstracts, incorporating those articles that met the inclusion criteria established, namely:

- *Type of study*: Economic assessment studies.
- *Context*: Healthcare organisations.
- *Independent variable*: Surgical procedure related adverse events.
- *Result measures*: Cost of surgical procedure related adverse events.

The following diagram depicts the process followed and the selection results obtained.



3.2 Evaluation of studies

The studies selected were classified according to their scientific evidence, using the classification proposed by the Agency for Healthcare Research and Quality (AHRQ). The criteria used may be summarised as follows:

- I-a. Evidence of meta-analysis of controlled and random clinical trials.
- I-b. Evidence obtained from controlled and random clinical trials.
- II-a. Evidence from well-designed non-random controlled studies.
- II-b. Evidence from well-designed quasi-experimental studies.
- III. Evidence from well-designed non-experimental descriptive studies such as comparative, correlation or case-control studies.
- IV. Evidence from expert documents or opinions and/or clinical experience of well-respected authorities.

Considering the purpose of this review and the inclusion criteria established, the studies selected meet level III of evidence in this classification.

4. Results

The results of this review are presented in three sections: description of the studies selected for review; results attributed to procedure-related adverse events; and cost analysis methods used in the different studies.

4.1 Description of studies

Table 1 shows the context and objective of each of the studies, together with the result variables analysed.

The studies selected focus on problems connected with **cardiovascular surgery** (7), **orthopaedic surgery** (4), **general surgery** (3) and **surgical procedures** (1).

All the studies include costs as a result variable; some also include length of hospital stay, mortality rate, patients' functional capacity and quality-adjusted life years (QALY).

Among the studies selected, the correlational studies aim to determine the relationship between the cost (or other result variables) and the fact of having suffered an adverse event or not, whilst the comparative studies draw a comparison between the cost of caring for patients who have / have not suffered adverse events.

In the case-control studies, each patient who has suffered an adverse event is paired with a similar control, to compare the results obtained for each one. Two of the studies selected are based on a review of the literature for calculation of costs.

Study	Context	Objective	Results	Patient sample	Type of study
Anderson <i>et al</i> , 2002	Teaching hospital, USA	Complications post cardiovascular surgery (coronary bypass)	Costs, hospital stay and functional capacity	274	Model
Callahan <i>et al</i> , 2003	Tertiary teaching hospital, USA	Renal dysfunction post coronary bypass	Cost	969	Correlational
Caprini <i>et al</i> , 2003	USA	Deep vein thrombosis after total hip replacement	Quality-adjusted life expectancy and long-term costs	Literature-based model	Review of literature
Dimick <i>et al</i> , 2004	Hospital, USA	Surgical complications (general and vascular surgery)	Costs	1,008	Correlational
Dimick <i>et al</i> , 2003	52 acute-care hospitals in one US State	Complications in adult patients post oesophagus or hepatic resection	Cost, mortality rate and hospital stay	935	Correlational
Edelsberg <i>et al</i> , 2001	USA	Venous thromboembolism post major orthopaedic surgery	Costs	---	Review and expert opinion
Ehsani <i>et al</i> , 2007	29 hospitals, Australia	Cardiac surgery complications	Costs	16,766	Correlational
Jacobson <i>et al</i> , 2007	Teaching hospital, USA	Complications post percutaneous coronary intervention	Costs	7,027	Correlational
Khasraghi <i>et al</i> , 2002	Teaching hospital, USA	Complications in patients >65 following surgery for hip fractures	Cost and hospital stay	510 (217 with complications; 293 without complications)	Comparative
Kugelmass <i>et al</i> , 2006	Hospitals, USA	Complications post percutaneous coronary intervention	Cost and hospital stay	335,477	Case-control study
Naglie <i>et al</i> , 1999	Hospital, Canada	Complications post coronary bypass	Cost	879	Correlational
Ollendorf <i>et al</i> , 2002	220 hospitals, USA	Venous thromboembolism post major orthopaedic surgery (knee or hip replacement or hip fracture reduction)	Costs	105,562	Comparative
Pronovost <i>et al</i> , 2001	52 short-stay hospitals in one US State	Complications in patients >30 following abdominal aortic surgery	Cost, mortality rate and hospital stay	2,987	Correlational
Swenson <i>et al</i> , 2002	Hospital, USA	Complications post ileoanal anastomosis	Costs	101	Correlational
Zhan & Miller, 2003	994 general acute-care hospitals in 20 US States	Surgical complications	Hospital stay, price and mortality rate	7.5 million	Case-control study

Table 1. Description of studies

4.2 Results of studies

The results obtained from the studies selected may be divided into four sections: costs attributed to problems connected with surgical procedures, cardiovascular surgery, orthopaedic surgery and general surgery.

4.2.1 Cost of surgical procedure related problems

According to the results of the Zhan & Miller study (2003), all surgical procedure related adverse events result in a significant increase in price, hospital stay and mortality rate, with two exceptions: anaesthesia complications, which result only in a significant increase in price, and obstetric trauma post caesarean delivery, which increases price and hospital stay but not mortality rate.

4.2.2 Cost of cardiovascular surgery related complications

According to the study conducted by Ehsani *et al* (2007), the presence of a **cardiac surgery** related adverse event¹ results in an increase in cost (an additional AUD5,751) and in hospital stay (an additional seven days: 10.3 days for patients who suffer post-surgery complications versus 2.9 days for patients with no complications).

In 1999 a study conducted by Naglie *et al* established that complications following a **coronary bypass** represented a cost of CAD8,200.

Similarly, Anderson *et al* (2002) concluded that in the event of post-operative complications (no details were given of the nature of these complications), the price of a coronary bypass rises by USD11,000. In addition, hospital stay increases by 3.7 days and patients' functional capacity at six months is 14 points lower (on a scale of 0 to 100).

The study conducted by Callahan *et al* (2003) showed that renal dysfunction post coronary bypass surgery led to a significant increase (+32%) in direct hospital costs, mainly as a result of patient stay in the ICU, pharmaceutical expenses and laboratory and radiology tests.

In the case of **percutaneous coronary interventions**, onset of a complication implies an increase in cost of between USD6,989 (Jacobson *et al*, 2007) and USD8,540² (Kugelmass *et al*, 2006) and an increase in hospital stay of between 3.1 days (Kugelmass *et al*, 2006) and 4.5 days (Jacobson *et al*, 2007).

According to the study conducted by Jacobson *et al* (2007), onset of complications raised the average cost: by USD5,883 in the event of haemorrhage; by USD5,086 in the event of cardiac or cerebrovascular adverse events; and by USD15,437 in the event of haemorrhage and a cardiac or cerebrovascular adverse event.

¹ Includes surgical site infection and sepsis.

² Includes septicaemia.

Kugelmass *et al* (2006) estimate that the cost of a percutaneous coronary intervention increases by USD4,278 and hospital stay by 1.8 days in the event of a vascular complication, by USD13,443 and 1.8 days in the event of acute renal failure, by USD30,430 and 11 days in the event of septicaemia, by USD25,700 and 7.8 days in the event of respiratory distress syndrome, by USD7,853 and 3.3 days in the event of post-operative icterus, by USD27,108 and 6.6 days in the event of a complication that results in an emergency coronary bypass³ and by USD4,457 in the event of a complication that results in patient death.

4.2.3 Cost of orthopaedic surgery related problems

A study conducted by Khasraghi *et al* (2002) determined that medical complications in patients over 65 undergoing **surgery for hip fractures** led to an increase in both cost and hospital stay. According to this study, costs rose significantly (an extra USD5,919) in comparison with patients free from medical complications post surgery (USD10,284 ± USD3,068, versus USD16,203 ± USD12,482).

Ollendorf *et al* (2002) focus on the cost of **venous thromboembolism after major orthopaedic surgery**. The study shows that costs, hospital stay and mortality rates all rise in the case of patients undergoing hip or knee replacements or hip fracture reduction who develop thromboembolic complications.

According to this study (Ollendorf *et al*, 2002), onset of deep vein thrombosis following a **total hip replacement** leads to a significant increase in cost (USD5,023), hospital stay (4.7 days) and mortality rate (+1.16%).

4.2.4 Cost of general surgery related complications

In accordance with the study conducted by Dimick *et al* (2004), post-operative complications following **general or vascular surgery** lead to a significant increase in both cost (USD52,466) and hospital stay (5.5 days).

They are followed, in order of importance, by: thromboembolic complications (deep vein thrombosis and pulmonary thromboembolism), which increase costs by USD18,310 and hospital stay by 2.8 days; cardiovascular complications, which increase costs by USD7,789; and infections, which increase costs by USD1,398 and hospital stay by 2.8 days.

4.3 Methodology used

All the studies selected analyse the direct costs of surgery- or procedure-related adverse events, that is, the costs directly connected with the provision of healthcare, including the cost of stay in hospital or other institution, medical and other professional fees and the cost of medication and diagnostic tests.

³ Coronary bypass surgery after a percutaneous coronary intervention in patients with no diagnosis of acute myocardial infarction upon admission.

The chief direct cost items are: cost of patient stay in ICUs, coronary units and hospital wards; cost of surgical interventions or procedures; cost of laboratory, radiology or other tests; and pharmaceutical costs.

In some studies the end result variable is the cost for the patient of the healthcare provided, which we have called "price". Owing to the characteristics of the US healthcare system, the price of healthcare is generally the most accessible variable for purposes of analysis. The majority of studies convert price into cost at a ratio of approximately 0.5, that is, assuming that cost represents approximately 50% of price.

5. Conclusions

The studies presented in this bibliographical review clearly indicate that surgical procedure related problems affect costs, hospital stay and patient mortality rates; obstetric trauma post caesarean delivery and anaesthesia-related complications are the only exception to this rule.

The studies focused on problems connected with specific surgical interventions in the areas of cardiovascular, orthopaedic and general surgery also show an increase in costs, in some cases as well as increases in hospital stay and mortality rates.

However, in light of the wide range of surgical procedures and adverse events studied, it is difficult to draw specific conclusions beyond the fact that surgery-related adverse events clearly do have an economic impact.

In addition, we note that the studies were conducted in different countries, at different times and in some cases using different methodologies, all of which makes it difficult to estimate the economic impact of these problems in Spanish hospitals.

6. Contributions

To place the results of the studies selected in a present-day context we performed two separate exercises. We converted the cost of the different surgical procedure related problems into Euros, based on the value of the Euro as of January 2005. And, based on the Zhan & Miller study (2003), we adapted the cost of the different surgical procedure related complications to Euros as of January 2005, to extrapolate the results of this study conducted in the United States to the Spanish national health system.

6.1 Estimate of cost of all surgery-related complications

To make the results obtained more uniform and estimate the economic impact in Euros, we calculated the cost of surgery-related complications as

of January 2005⁴, converting the costs contained in the studies analysed from US, Australian or Canadian dollars, as appropriate, into Euros as of January 2005.

The reference values used were the average costs recorded in the different studies. Accordingly the resultant costs must be interpreted with caution, as the costs obtained in the studies – all conducted in healthcare systems very different from our own – may not necessarily be suitable for extrapolation to the Spanish context.

Procedure	Complication	Increase in cost per patient with complication	Source
Heart surgery	Complications	EUR3,621	Ehsani <i>et al</i> , 2007
Coronary bypass	Complications	EUR8,356 – 13,702	Anderson <i>et al</i> , 2002; Naglie <i>et al</i> , 1999
	Renal dysfunction	EUR5,905	Callahan <i>et al</i> , 2003
Percutaneous coronary intervention	<ul style="list-style-type: none"> ▪ Haemorrhage or bruising ▪ Cardiac or cerebrovascular events ▪ Both 	<ul style="list-style-type: none"> ▪ EUR4,808 ▪ EUR4,157 ▪ EUR12,617 	Jacobson <i>et al</i> , 2007
	<ul style="list-style-type: none"> ▪ Vascular complication ▪ Acute renal failure ▪ Respiratory distress ▪ Post-operative ictus ▪ Emergency coronary bypass ▪ Death 	<ul style="list-style-type: none"> ▪ EUR5,298 ▪ EUR16,650 ▪ EUR31,830 ▪ EUR9,727 ▪ EUR33,574 ▪ EUR5,520 	Kugelmass <i>et al</i> , 2006
Abdominal aortic intervention	Acute renal failure ⁵	EUR17,834	Pronovost <i>et al</i> , 2001
Major orthopaedic surgery	Venous thromboembolism	EUR8,035 - 13,357	Edelsberg <i>et al</i> , 2001; Ollendorf <i>et al</i> , 2002
Hip fracture procedure	Complications	EUR6,820	Khasraghi <i>et al</i> , 2002
Total hip replacement	Deep vein thrombosis (late complications) <ul style="list-style-type: none"> ▪ First 12M ▪ Others 	<ul style="list-style-type: none"> ▪ EUR966 –4,397 per annum ▪ EUR392 –1,932 per annum 	Caprini <i>et al</i> , 2003
		Complications	EUR64,981 - 1,730
Oesophagus or hepatic resection	Complications	EUR4,494	Dimick <i>et al</i> , 2003
Ileoanal anastomosis	<ul style="list-style-type: none"> ▪ Intestinal obstruction ▪ Sepsis 	<ul style="list-style-type: none"> ▪ EUR11,131 ▪ EUR8,065 	Swenson <i>et al</i> , 2002

Table 2. Cost in Euros of cardiovascular, orthopaedic and general surgery related problems

⁴ The costs were calculated as of January 2005 as the latest data available for subsequent calculation of the overall cost for the Spanish national health system correspond to 2005.

⁵ Cost of acute renal failure *per se*, as all other complications are classed as nosocomial infections (see corresponding bibliographical review).

6.2 Estimate of cost for Spanish national health system of surgical procedure related problems in Spain

In a second exercise, we used the results obtained by Zhan & Miller (2003) to estimate the costs in Euros as of January 2005 and applied these costs to the real costs of the Spanish national health system, to estimate the overall cost for the Spanish national health system of surgical procedure related problems.

Adverse event	Increase in cost per patient with complication	% of patients	Overall cost for Spanish national health system: Euros (2005)
Haemorrhage or bruising	EUR 12,346 (SD: 728)	1.02%	EUR 445,928,771
Organ lesion	EUR 4,765 (SD: 198)	0.33%	EUR 55,682,137
Pneumothorax	EUR 9,973 (SD: 629)	0.11%	EUR 38,847,006
Wound dehiscence	EUR 23,230 (SD: 1,997)	0.08%	EUR 65,807,932

Table 3. Cost in Euros (2005) of general surgery related problems
SD: Standard deviation

For this purpose we assumed, in line with data from the ENEAS study, that adverse events connected with surgical procedure related problems affect 2.76% of all patients admitted to Spanish hospitals. Of these adverse events, 31.7% are considered avoidable.

We used these data to estimate the overall cost for the Spanish national health system of adverse events connected with surgical procedure related problems.

The results obtained are presented in summary form in Table 3 which shows the cost in Euros (2005) of adverse events connected with surgical procedure related problems and the overall cost of these problems.

As Table 3 shows, surgical procedure related problems may represent a significant expense for the Spanish national health system. Moreover, this expense may be considerably higher than is indicated in the table, which reflects only four adverse events owing to the lack of data available for calculation of the impact of all adverse events.

We also note that, according to the ENEAS study (2007), **31.7%** of adverse events connected with surgical procedure related problems are **avoidable**. Thus, if in the case of the four adverse events reflected in the table the avoidable events were in effect prevented, the Spanish national health system could achieve an annual saving of more than EUR 192 million.

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