Comparative Study – Retrospective Cohort

INTERNATIONAL JOURNAL OF SURGERY

OPEN

The impact of patient safety incidents during hip and knee replacements on patients' health related quality of life: a before and after study using longitudinal data linked to patient-reported outcome measures

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Background: The burden of patient safety incidents (PSIs) is often characterized by their impact on mortality, morbidity, and treatment costs. Few studies have attempted to estimate the impact of PSIs on patients' health-related quality of life (HRQoL) and the studies that have made such estimates primarily focus on a narrow set of incidents. The aim of this paper is to estimate the impact of PSIs on HRQoL of patients undergoing elective hip and knee surgery in England.

Patients and methods: A unique linked longitudinal data set consisting of patient-reported outcome measures for patients with hip and knee replacements linked to Hospital Episode Statistics (HES) collected between 2013/14 and 2016/17 was examined. Patients with any of nine US Agency for Healthcare Research and Quality (AHRQ) PSI indicators were identified. HRQoL was measured using the general EuroQol five dimensions questionnaire (EQ-5D) before and after surgery. Exploiting the longitudinal structure of the data, exact matching was combined with difference in differences to estimate the impact of experiencing a PSI on HRQoL and its individual dimensions, comparing HRQoL improvements after surgery in similar patients with and without a PSI in a retrospective cohort study. This design compares the change in HRQoL before and after surgery in patients who experience a PSI to those who do not.

Results: The sample comprised 190 697 and 204 649 observations for patients undergoing hip replacement and knee replacement respectively. For six out of nine PSIs, patients who experienced a PSI reported improvements in HRQoL that were 14–23% lower than those who did not experience a PSI during surgery. Those who experienced a PSI were also more likely to report worse health states after surgery than those without a PSI on all five dimensions of HRQoL.

Conclusion: PSIs are associated with a substantial negative impact on patients' HRQoL.

Keywords: difference in difference, patient-reported outcome measures, patient safety incidents

Introduction

Over the last two decades, the case for improving patient safety in England has been increasingly emphasized. Patient harm is estimated to be the 14th leading cause of morbidity and mortality, responsible for the loss of 33 million disability-adjusted life-years per year globally[1], and half of this burden is potentially preventable[2].

In secondary care, patient harm includes adverse events such as hospital acquired infections, pressure ulcers and falls. Specifically, we define PSIs according to the PSIs developed by the US Agency for Healthcare Research and Quality (AHRQ) for the detection of PSIs in administrative data. These are complications of anesthesia, pressure ulcer, retained surgical item, postoperative hip fracture, perioperative hemorrhage, postoperative respiratory

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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International Journal of Surgery (2023) 109:1085–1093

Received 22 August 2022; Accepted 30 January 2023

Supplemental Digital Content is available for this article. Direct URL citations are provided in the HTML and PDF versions of this article on the journal's website, www.journal-surgery.net.

Published online 10 April 2023

http://dx.doi.org/10.1097/JS9.0000000000000275

failure, perioperative pulmonary embolism, postoperative sepsis, accidental puncture. Patients that experience these events can face longer hospital stays, higher treatment costs and an increased risk of death[3,4]. For a typical developed country, the cost of treating patient harm is thought to represent around 15% of acute care expenditure[5].

While the literature on the impact of PSIs on mortality, morbidity and costs, is maturing, the evidence on the impacts of PSIs on patients' HRQoL is much weaker. A review of 31 studies focusing on the impact of adverse surgical events found that these occurrences significantly decrease patients' self-reported HRQoL[6]. The authors suggested that a ranking of adverse events in terms of their impact on patients' quality of life would be an important objective for future research. However, the studies included in the review used different definitions of safety incidents, used a variety of HRQoL instruments and did not all take preoperative quality of life into account which limited comparability. In particular, they highlighted generic HRQoL instruments such as the EuroQual 5 Dimensions (EQ-5D) as attractive because it would allow assessment of severity of PSIs in terms of quality-adjusted life-years.

A study by Hauck *et al.*[7] was able to do the ranking previously called for, by calculating healthy life-years lost due to different safety incidents, and found that for the UK, the burden caused by six patient incidents alone is comparable to the burden caused by multiple sclerosis, HIV/AIDS, and tuberculosis or cervical cancer. However, due to data limitations, the study could only assess the impact on healthy life-years for incidents associated with excess mortality. The impact of relatively common adverse events such as central line infections on HRQoL was thus not included in the estimates by Hauck and colleagues, which could have led to a substantial underestimate of the societal impact of adverse events. If the impact of safety incidents on HRQoL goes unmeasured, there is risk that safety-improving interventions that are cost-effective from a societal perspective are either not invested in, or are displaced by investments which may be cost-effective from a narrow healthcare sector perspective but fail to account for the benefits gained from improving patients' HRQoL[8].

This paper takes a novel approach to estimating the impact of PSIs on HRQoL for patients undergoing elective surgery in the English NHS. Individual-level longitudinal data from nearly 400 000 patients in the English patient-reported outcome measures (PROMs) programme linked with detailed admissions records from the English Hospital Episode Statistics (HES) enables us to identify the impact of nine specific PSIs on patients' HRQoL measured using EQ-5D. The longitudinal nature of the data allows us to compare improvements in quality of life between patients that do and do not experience PSIs and to assess how each type of incident affects the change in patients' HRQoL. In addition, we can examine changes to the individual dimensions of quality of life, while controlling for observed and unobserved patient characteristics including existing comorbidities and preoperative quality of life.

Our approach allows us to estimate the HRQoL losses the experience of specific PSI is associated with. Therefore, our findings can inform healthcare and policy decision-makers on the potential gains from avoiding safety incidents, which in turn can demonstrate the value of investments in improving the quality and safety of healthcare.

HIGHLIGHTS

- For six out of nine patient safety incidents (PSIs) (complications of anesthesia, pressure ulcer, retained surgical item, postoperative hip fracture, perioperative hemorrhage, postoperative respiratory failure, perioperative pulmonary embolism, postoperative sepsis, accidental puncture), patients who experience a PSI report improvements in health-related quality of life (HRQoL) that are 14–23% lower than those who do not experience a PSI during surgery.
- The HRQoL loss associated with experiencing a PSI is similar for patients undergoing hip replacement and knee replacement.
- Patients who experience a PSI are more likely to report worse health states after surgery than those without a PSI on all five dimensions of HRQoL, namely self-care, mobility, anxiety, activity, and discomfort.

Patients and methods

This was a retrospective cohort study. This study was performed in accordance with the Declaration of Helsinki. The research was retrospectively registered on ClinicalTrials.gov, Unique Identifying Number (UIN) is 'NCT05464771.' The hyperlink to the specific registration is: 'https://clinicaltrials.gov/ct2/show/NCT05464771.' This work has been reported in line with the STROCSS criteria[19,20] (Supplemental Digital Content 1, http://links.lww.com/JS9/A271). According to the English National Health Service Health Research Authority tool for determining research ethics need, this study did not require ethics approval because it was a retrospective study using secondary data.

Data sources

Measuring HRQoL

In 2009, the English Department of Health launched a large-scale programme to routinely collect PROMs before and after surgery for all patients undergoing hip replacement, knee replacement, hernia repair and varicose veins surgery[9,10]. Under this programme, a patient's HRQoL is measured via a questionnaire sent to all patients before surgery which uses both generic and condition-specific health status instruments. The questionnaire on the HRQoL measurement was sent out before the surgery with a follow-up measurement 6 months after surgery.

The difference in self-reported health state between the two questionnaires can then be used to assess the outcome of surgery[9] and can help compare hospital performance over time and between providers[11]. The overall response rate of the first questionnaire on patient-reported outcome measures is 98.17%, 98.18% for patients with PSI, and 98.17% for those without PSIs. The response rate of the second questionnaire is 76.3% for all the patients, 68.8% for patients with PSIs, and 76.4% for those without PSIs. This addresses the concern on the selection that the response rate of patients with PSIs might be higher than those without PSIs. To assess improvements in HRQoL presurgery and postsurgery, we rely on the EQ-5D-3L instrument developed by the EuroQoL group[12]. This is a generic measure of health status focusing on five dimensions: mobility, self-care,

usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems (coded as 1), some problems (2), and extreme problems (3). By combining these five dimensions, a patient's health profile can be expressed as a single string. For example, the health profile 11111 expresses a state of full health. Each health state can be converted to a utility score by attaching social preference weights to the health state elicited from the general population[13].In addition to the utility score, we also analyze the individual components of the EQ-5D instrument to gain a better understanding of which dimensions of exposure to a safety incident most impact health[14].

Measuring patient safety incidents

To identify patients who experienced a PSI, we link PROMs data to detailed records of hospital admissions from the English HES (The datasets generated and/or analyzed during the current study are not publicly available due to the agreement between NHS digital and Imperial College London). HES data comes from the routine submissions of data from providers to NHS Digital for the purposes of payment for and commissioning of healthcare in England. HES contains records of all admissions, appointments and attendances for patients admitted to NHS hospitals in England. For each admission, we observe the patient's age and sex as well as the primary diagnosis and up to 19 co-diagnoses coded in the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10). We requested and obtained the HES and PROMs data by applying via Data Access Request Service (DARS) from NHS Digital with assistance from the Imperial College Big Data Analytical Unit (BDAU).

This detailed information allows us to identify patients that have experienced a PSI according to the PSIs developed by the AHRQ. These indicators have previously been validated for use in the English HES data[15,16]. In this work, we focus only on the numerator of the indicators.

The names and descriptions of AHRQ PSIs are reported in Table 1. In addition to the nine PSIs presented in the table, AHRQ has defined 11 other PSIs. Of these, two (PSI 7 and PSI 10) are not included in the study as they appear too infrequently to allow for reliable identification of their impact on HRQoL (three or fewer incidences per condition in our data). The remaining indicators were related to birth and obstetric trauma (which were irrelevant for the conditions studied in this paper) and death in low-mortality DRGs or among surgical inpatients with serious treatable conditions (which would not give us a postsurgical measurement of quality of life).

Sample definition

The data available for our study was collected between 2013 and 2017. The PSIs we study are relatively rare, and to yield enough observations to reliably estimate the impact of different incidents, we limit our sample to patients undergoing hip or knee replacements because these have more observations than do varicose veins and groin hernia. There are 267 477 and 288 967 observations for patients undergoing hip replacement and knee replacement respectively. We further limit our sample to patients for which we have observations of health status both before and after surgery. This leaves us with 190,697 and 204,649 observations for patients undergoing hip replacement and knee replacement respectively. As shown in Table D1 (Supplemental Digital Content 3, http:// links.lww.com/JS9/A389) we do not see systematic differences between patients with complete pre-HRQoL and post-HRQoL information.

To assure the concern that there might be marked difference in the characteristics between patients who are observed only before surgery and those who are observed both before and after ;surgery, we present the descriptive statistics in Table D1 (Supplemental

Table 1

Agency for Healthcare Research and Quality PSI indicators

Short name	Description	PSI number	ICD codes
Complications of anesthesia	Complications of anesthesia	PSI 01	diag_Y653,Y480,Y481,Y482,Y483, T410,T411,T412,T413,X440,X447, X446, X445,X443,X444,X442,X441, X448,X449
Pressure ulcer	Pressure ulcer	PSI 03	diag_L89
Retained surgical item	Retained surgical item or unretrieved device fragment count	PSI 05	diag_T815, T816, Y610,Y611, Y612, Y613, Y614, Y616, Y615,Y617, Y618, Y619
Postoperative hip fracture	Postoperative hip fracture	PSI 08	diag_S7201,S7202,S7204, S7205, S7208, S7210, S7211,S722,S7200
Perioperative hemorrhage	Perioperative hemorrhage or hematoma	PSI 09	diag_T810,T811 op9_h1_L933, op9_h2_Y443,op9_h3_ F365, op9_h4_P131 op9_h1Z394,Z396,Z397,D041,Z404,Z931,Z981,Z982,Z983,Z984,Z393, Z402 op9_h2H568,L798,L588,M418,M708 op9_h3E203 op9_h4Y221 opertn_L703,L933,L663,L995,L333,L302,L382,L255,L126,L691,L423,L463, L623,L628,T309,T301,N032,N131,P292, P149,P093,P271,S471,S472
Postoperative respiratory failure	Postoperative respiratory failure rate	PSI 11	diag_ J969, opertn_E411, E851
Perioperative pulmonary embolism	Perioperative pulmonary embolism or deep vein thrombosis	PSI 12	diag_I260, I269, I801, I802, I803, I808,I809,I828,I829
Postoperative sepsis	Postoperative sepsis	PSI 13	diag_A40, A41,T826,T827, T835,T836,T845,T846,T847,T857,T811
Accidental puncture	Unrecognized abdominopelvic accidental puncture/laceration rate	PSI 15	diag_Y600,Y601,Y602,Y603,Y604, Y606, Y605,Y607,Y608, Y609,T812

ICD, International Statistical Classification of Diseases and Related Health Problems; PSI, patient safety incident.

Digital Content 3, http://links.lww.com/JS9/A389). It suggests that there is not a systematic difference between the characteristics of these two groups, this lends confidence to our study using the sample on patients who are observed both before and after the surgery.

Statistical analysis

To estimate the impact of experiencing a PSI on HRQoL, we employ a difference-in-differences (DiD) design to compare the change in HRQoL before and after surgery in patients who experience a PSI and in those who do not. By comparing those who are exposed and those who are unexposed to a safety event, we can thus attribute the difference in the change of HRQoL presurgery and postsurgery to the PSI.

The DiD setup allows us to control for time-invariant unobserved differences between patients, under the assumption that the probability of being exposed to a PSI is not related to the ability to experience HRQoL improvement.

We estimate ordinary least squares models for each condition and each PSI individually. In addition, we define the binary variable 'Any PSI' which indicates that a patient has experienced any of the nine PSIs. To assess the impact of PSIs on each of the five health dimensions, we estimate ordered logit models using the individual dimensions of EQ-5D as dependent variables. The models we estimate can be written as follows:

$$\mathrm{HQoL}_{it} = \beta_0 + \beta_1 \mathrm{PSI}_i + \beta_2 \mathrm{post}_t + \beta_3 \mathrm{PSI}_i \times \mathrm{post}_t + \alpha_i + \varepsilon_{it},$$

where HRQoL_{it} represents either the utility score or level of the individual dimension of EQ-5D for patient i at time t, PSI_i is a binary variable equal to 1 when patient i was exposed to a PSI during admission, and 0 otherwise. The variable post_t indicates that the HRQoL measurement was taken after surgery and is thus the common change in HRQoL across all patients. α_i denotes individual fixed effects, and ε_{it} is the residual term. The coefficient of the interaction term, β_3, is our variable of primary interest. It represents the difference in improvement in health state after surgery between patients that did and did not experience a PSI and can thus be interpreted as the loss in quality of life attributable to experiencing a PSI.

It is an assumption of the DiD method that the HRQoL improvement for patients exposed to a safety event would have been the same as those not exposed if the exposed patients did not experience PSIs. This is fundamentally unobservable, but commonly tested by comparing the trend in the outcome variable between the two groups. However, since we do not have measurements of patients' HRQoL multiple times before surgery, we cannot perform this test of the assumption of 'parallel trends.' To ensure that patients who do and those who do not experience a PSI are comparable, we conduct coarsened exact matching[17] to identify a group of patients as the comparison that are as similar as possible to the patients exposed to a PSI before surgery. For each condition and PSI, we match patients on age in 5-year age bands, sex, Charlson Comorbidity Index, and the levels on each of the five dimensions of the EQ-5D health profile in the presurgery survey. As mentioned earlier, different from the previous studies, the longitudinal nature of the data allows us to account for the presurgery HRQoL measures. More details on this method can be found in Appendix B (Supplemental Digital Content 3, http://links.lww.com/JS9/A389).

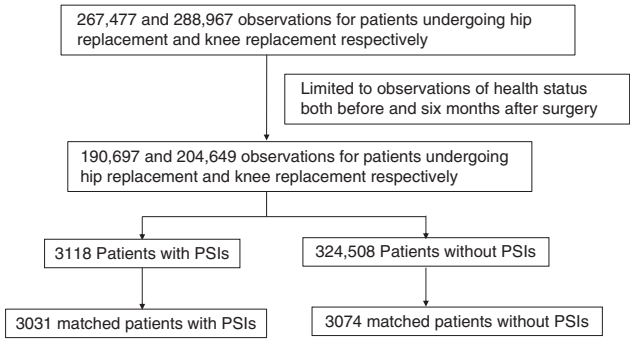

Figure 1. Chart of patients with regard to the study. PSI, patient safety incident.

All analysis was done in Stata, version 16.

The work has been reported in line with the STROCSS criteria[18,19] (Supplemental Digital Content 1, http://links.lww.com/JS9/A271).

Results

Descriptive analysis

A flowchart of the patients included in this study is shown in Figure 1. Table 2 shows the descriptive statistics of our dependent and control variables before and after matching. Before matching, for patients with hip replacement, the average age of patients with PSIs was 73 years, while the average age of patients without PSIs was lower (69 years). Similarly, for patients with knee replacement, on average patients experiencing PSIs were older (72 years) than patients who did not experience PSIs (70 years). For patients undergoing hip replacement surgery, males accounted for a slightly smaller proportion of patients with PSIs (0.39) than those without PSIs (0.41). But in the case of knee replacement, the proportion of males was slightly larger for patients with PSIs (0.46) than for those without PSIs (0.44). After matching, the differences between patients that did and did not experience a PSI were minimal and statistically insignificant. Table 2 presents the frequency of PSIs per 1000 patients. We see that pressure ulcer was the most frequently occurring PSI (0.392 PSIs per 1000 patients), and pulmonary embolism and sepsis were the second and third most frequent PSIs. For both hip and knee replacement patients, the average improvement in health state utility after surgery was lower for patients with PSIs than for those without PSIs.

The Impact of PSIs on HRQoL

Table 3 presents the estimates of the impact of patient safety events on health state utility values. Section 1 of the table reports the estimates for patients undergoing either hip or knee replacement. Column (1) suggests that experiencing any PSI had a statistically significant negative effect on the utility score. While on average patients who underwent hip or knee replacement experienced an improvement in their utility score of 0.42 points (95% CI 0.406 to 0.431), the improvement for patients that

Table 2

Descriptive statistics of the sample before and after surgery

	Hip replacement						Knee replacement					
	Before matching			After matching			Before matching			After matching		
Variables	With PSI	Without PSI	*t*-stat	With PSI	Without PSI	*t*-stat	With PSI	Without PSI	*t*-stat	With PSI	Without PSI	*t*-stat
Change in EQ-5D	0.40	0.43		0.40	0.48		0.29	0.32		0.29	0.35	
Age	73.05	68.72	−16.34	73	72.92	−0.20	71.92	69.64	−10.3	71.93	71.83	−0.30
Sex (male = 1)	0.38	0.41	1.85	0.38	0.38	−0.15	0.46	0.44	−1.79	0.46	0.46	−0.11
Charlson Comorbidity Index	0.91	0.49	−18.21	0.86	0.84	−0.38	0.90	0.56	−15.37	0.85	0.85	0.06
EQ-5D before surgery	0.26	0.36	11.79	0.27	0.27	−0.10	0.35	0.42	8.54	0.35	0.35	0.01
Self-care before surgery	1.68	1.55	−10.07	1.67	1.67	−0.00	1.42	1.31	−9.76	1.41	1.41	0.00
Mobility before surgery	1.98	1.93	−6.82	1.97	1.97	−0.30	1.96	1.93	−5.44	1.96	1.96	0.16
Anxiety before surgery	1.56	1.45	−7.55	1.55	1.56	0.33	1.48	1.39	−6.08	1.47	1.47	0.11
Activity before surgery	2.27	2.11	−12.30	2.26	2.25	−0.16	2.11	2.03	−7.08	2.11	2.11	−0.01
Discomfort before surgery	2.50	2.40	−7.33	2.50	2.50	0.05	2.44	2.37	−5.29	2.44	2.44	0.01
PSIs per 1000												
Complications of anesthesia	0.364						0.196					
Pressure ulcer	2.46						1.58					
Retained surgical Item	0.126						0.113					
Postoperative hip fracture	1.500						0					
Perioperative pulmonary embolism	1.97						4.28					
Postoperative sepsis	1.79						1.37					
Accidental puncture	0.659						0.779					
Observation	1526	157 829		1476	1497		1592	166 679		1555	1577	

EQ-5D, EuroQual 5 Dimensions; PSI, patient safety incident.

experienced a PSI was about 17% lower (– 0.07 points, – 0.091 to – 0.055) after surgery.

Columns (2–10) present the effects of each individual PSI on the EQ-5D index change. They show that in all cases, the coefficient on the PSI variable had the expected negative sign. For six out of the nine PSIs, the impact was statistically significant with magnitudes ranging from 0.06 points (– 0.106 to – 0.026) for patients experiencing a pressure ulcer to 0.20 points (– 0.344 to – 0.057) for those with perioperative hemorrhage.

Sections 2 and 3 of Table 3 present the estimates of the effect of PSIs for patients who underwent hip or knee replacement separately. For all but one PSI, the coefficients still had the expected signs and the statistical significance was similar to that in Section 1 with a few exceptions: for patients with hip replacement, the impact of respiratory failure was not statistically significant; for patients with knee replacement, the impact of retained surgical item did not have the expected sign and was not statistically significant. The results in Table 4 show the impact of experiencing a PSI on the individual dimensions of the EQ-5D health profile. Recall that a higher value on the individual dimension indicates a worse health outcome. The positive coefficient on the PSI variable in column (1) thus suggests that patients who experienced any PSIs were more likely to report a worse health state on each of the five dimensions of EQ-5D after surgery than those without a PSI. Comparing across PSIs, we see that except for retained surgical items, complication of anesthesia and accidental puncture, experiencing a PSI was associated with worse reported health in five dimensions. Activity was the dimension where the effect was statistically significant for most (six) PSIs. Respiratory failure, pulmonary embolism and sepsis had statistically significant negative impacts on each of the five dimensions. Separate estimates of PSI effects for patients with hip replacement and those with knee replacement, are presented in the Appendix Table A1 (Supplemental Digital Content 2, http://links.lww.com/JS9/A272). They reveal a similar pattern as Table 4: patients with any PSI were more likely to have worse health states for all five dimensions, and again, respiratory failure, pulmonary embolism and sepsis were the PSIs where the impact was statistically significant across all five dimensions of EQ-5D. There was no substantial difference across the five dimensions in terms of the number of PSIs they were negatively affected.

Discussion

This study examined the impact of PSIs on patients' quality of life. We found consistent evidence that experiencing a PSI was associated with a loss of HRQoL. First, we examined the impact of PSIs on EQ-5D utility scores. We found that patients who experienced any PSI had 14%-23% lower improvements in EQ-5D health utility score after surgery than patients without a PSI did. When examining the impact of individual PSIs on the utility score, we found that for six out of nine PSIs, the detrimental impact on HRQoL of experiencing a PSI was statistically significant. When we employed the model to obtain separate estimates for patients who underwent hip replacement compared with those who underwent knee replacement, the results were similar for the two groups. In addition, we estimated the impact of PSIs on different dimensions of EQ-5D. We found that, on average, patients exposed to a PSI were more likely to report worse health after surgery on every dimension of the health profile: anxiety, self-care, mobility, activity, and discomfort. In particular, we found that patients experiencing postoperative respiratory failure, pulmonary embolism and sepsis were more likely to have statistically significantly worse health states across

Table 3

The impact of patient safety events on EQ-5D after surgery

	Dependent variable: EQ-5D index									
	(1) Any PSI	(2) Complications of anesthesia	(3) Pressure ulcer	(4) Retained surgical item	(5) Postoperative hip fracture	(6) Perioperative hemorrhage	(7) Postoperative respiratory failure	(8) Perioperative pulmonary embolism	(9) Postoperative sepsis	(10) Accidental puncture
Section 1: Hip replacement and knee replacement										
PSI	– 0.0732***	– 0.0248	– 0.0659**	– 0.0511	– 0.0825*	– 0.201**	– 0.0990***	– 0.0637***	– 0.101***	– 0.0267
	(– 0.091, – 0.055)	(– 0.133, 0.084)	(– 0.106, – 0.026)	(– 0.235, 0.133)	(– 0.149, – 0.016)	(– 0.344, – 0.057)	(– 0.152, – 0.046)	(– 0.094, – 0.033)	(– 0.146, – 0.056)	(– 0.094, 0.040)
Post	0.418***	0.444***	0.459***	0.329***	0.462***	0.468***	0.430***	0.371***	0.445***	0.392***
	(0.406, 0.431)	(0.367, 0.520)	(0.430, 0.488)	(0.197, 0.460)	(0.414, 0.509)	(0.365, 0.570)	(0.392, 0.468)	(0.349, 0.392)	(0.413, 0.477)	(0.344, 0.439)
N	12 210	360	2504	156	932	220	1348	4080	1996	928
Section 2: Hip replacement										
PSI	– 0.0834***	– 0.0143	– 0.0746**	– 0.112	– 0.0825*	– 0.194*	– 0.0732	– 0.0960**	– 0.0997**	– 0.0232
	(– 0.11, – 0.057)	(– 0.158, 0.13)	(– 0.126, 0.023)	(– 0.377, 0.15)	(– 0.149, – 0.016)	(– 0.370, – 0.018)	(– 0.159, 0.013)	(– 0.155, – 0.037)	(– 0.162, – 0.037)	(– 0.129, 0.082)
Post	0.485***	0.455***	0.518***	0.432***	0.462***	0.536***	0.495***	0.481***	0.471***	0.463***
	(– 0.088, – 0.040)	(– 0.211, 0.125)	(– 0.115, 0.009)	(– 0.254, 0.265)	(– 0.149, – 0.016)	(– 0.446, 0.020)	(– 0.184, – 0.053)	(– 0.086, – 0.016)	(– 0.168, – 0.038)	(– 0.113, 0.056)
Section 3: Knee replacement										
PSI	– 0.0635***	– 0.0428	– 0.0530	0.00537	– 0.0825*	– 0.213	– 0.119***	– 0.0510**	– 0.103**	– 0.0286
	(– 0.088, – 0.040)	(– 0.211, 0.125)	(– 0.115, 0.009)	(– 0.254, 0.265)	(– 0.149, – 0.0156)	(– 0.446, 0.019)	(– 0.184, 0.053)	(– 0.086, – 0.016)	(– 0.168, – 0.038)	(– 0.113, 0.056)
Post	0.355***	0.424***	0.372***	0.225*	0.462***	0.394***	0.387***	0.324***	0.413***	0.334***
	(0.338, 0.372)	(0.305, 0.543)	(0.328, 0.416)	(0.0417, 0.40)	(0.414, 0.509)	(0.229, 0.558)	(0.340, 0.434)	0.299, 0.348)	(0.367, 0.459)	(0.274, 0.394)

95% CIs are shown in parentheses.
*$P < 0.05$.
**$P < 0.01$.
***$P < 0.001$.

Table 4

Impact of patient safety events on the indices of individual dimensions of EQ-5D

	Dependent variable: the level of individual dimension of EQ-5D									
	(1) Any PSI	(2) Complications of anesthesia	(3) Pressure ulcer	(4) Retained surgical item	(5) Postoperative hip fracture	(6) Perioperative hemorrhage	(7) Postoperative respiratory failure	(8) Perioperative pulmonary embolism	(9) Postoperative sepsis	(10) Accidental puncture
Section: Hip replacement and knee replacement										
Anxiety	0.577*** (0.416, 0.738)	0.705 (– 0.250, 1.66)	0.394* (0.0439, 0.744)	0.351 (– 1.025, 1.726)	0.912** (0.287, 1.537)	1.014 (– 0.091, 2.118)	0.666** (0.188, 1.144)	0.528*** (0.245, 0.811)	0.659** (0.265, 1.053)	0.472 (– 0.116, 1.060)
Self-care	0.721*** (0.552, 0.891)	0.0719 (– 0.874, 1.018)	0.830*** (0.458, 1.201)	– 0.0384 (– 1.548, 1.472)	0.509 (– 0.0561, 1.074)	1.681* (0.329, 3.033)	0.916*** (0.394, 1.438)	0.679*** (0.376, 0.981)	1.089*** (0.673, 1.505)	0.0314 (– 0.571, 0.634)
Mobility	0.646*** (0.498, 0.795)	3.629 [a]	0.767*** (0.432, 1.103)	0.277 (– 0.966, 1.520)	0.513 (– 0.067, 1.092)	1.042 (– 0.111, 2.195)	0.895*** (0.384, 1.405)	0.533*** (0.281, 0.784)	1.014*** (0.657, 1.371)	0.0515 (– 0.522, 0.625)
Activity	0.715*** (0.587, 0.842)	0.231 (– 0.449, 0.912)	0.787*** (0.503, 1.071)	0.715 (– 0.306, 1.74)	0.654** (0.184, 1.124)	1.597** (0.494, 2.699)	0.970*** (0.565, 1.376)	0.638*** (0.423, 0.853)	0.963*** (0.646, 1.279)	0.275 (– 0.162, 0.711)
Discomfort	0.395*** (0.279, 0.511)	0.576 (– 0.030, 1.182)	0.16 (– 0.0924, 0.413)	– 0.0824 (– 1.084, 0.919)	0.574** (0.159, 0.989)	1.289** (0.350, 2.228)	0.455* (0.0898, 0.819)	0.470*** (0.264, 0.676)	0.576*** (0.284, 0.868)	0.0537 (– 0.333, 0.440)

95% CIs are shown in parentheses.

EQ-5D, EuroQual 5 Dimensions; PSI, patient safety incident.

[a]The estimated model did not converge.

*$P < 0.05$.

**$P < 0.01$.

***$P < 0.001$.

all five dimensions of EQ-5D. This suggests that these PSIs are detrimental to all observed aspects of patients' HRQoL. While this finding may be partly explained by sample size and the fact that these PSIs were relatively more frequent, pressure ulcers and post operative hip fractures which had similar prevalence levels, were not associated with a statistically significant impact on discomfort and self-care, respectively.

The availability of health state measures before and after surgery linked to administrative data on patient safety events is a significant strength of this study. This allows us to use a DiD design which, combined with coarsened exact matching, suggests that the estimates presented here are likely to be causal. Our findings advance the work by Hauck *et al.*[7] who used population average values of disability-adjusted life-years to estimate the burden of PSIs. We are able to estimate the direct impact on quality of life, which is in addition to the impact on longevity previously estimated by Hauck and colleagues. The size of the estimates suggests that the impact of experiencing PSIs is substantial: some patients with PSIs experience a loss of improvement in HRQoL of up to one-fifth compared with patients without PSIs.

Our study findings on the impact of PSIs on quality of life could be limited by confounding. Patients who are more likely to experience a PSI may be less capable of improving their health status after surgery. However, our matching procedure combined with the longitudinal structure of the data allows us to employ a DiD approach to alleviate the potential impact of confounding. As there might be concerns on the predictive value of AHRQ PSI, studies suggest that only one PSI (Accidental Puncture and Laceration) met the proposed threshold for validity of a positive predictive value of at least 80%[20], McIsaac *et al.*[21] find that the accuracy of the ICD-10 PSIs might be insufficient to identify individual-level complications.

A key limitation of this study is that we rely on hospitals' accurate recording of PSIs in administrative data and are not able to account for the impact of PSIs that are not recorded. Although the PSI have been frequently used to detect safety events in administrative data, a recent study using Korean data highlighted the potential limitation of this approach compared with a checklist approach[22]. In addition, unlike other data sources, such as the US Medicare claims data, the English HES data used in this study does not contain a 'present on admission' (POA) indicator which means that we are not able to distinguish between PSIs that were and were not present on admission. However, with the exception of pressure ulcers (PSI 03), the PSIs studied in this paper by definition relate to events occurring during or after surgery, and we, therefore, find it most likely that the PSIs we study measure events occurring during the admission. To address these concerns, we also conducted the analysis using patient-reported PSIs on urine, wound, bleed, and allergy. The results are presented in Table C1 of Appendix (Supplemental Digital Content 3, http://links.lww.com/JS9/A389)). We compared the results with those using AHRQ PSIs (hospital reported PSIs) and find that they are consistent. These results lend credibility to the predictive value of AHRQ PSIs we adopt in this study. Our findings are also in line with a previous study[23] which used patient-reported complications in four categories as an indicator of a PSI occurrence. Even if we failed to capture all events, as long as patients for whom incidents are recorded are representative of exposed patients, our findings still hold, since our aim is to estimate the impact of PSIs on individual patients' HRQoL rather than the total impact in the English NHS. In addition, it may be questioned whether the experience of a PSI can have measurable impact on quality of life 6 months after surgery. However, the use of DiD on a matched sample that takes pre-surgery health status into account ensures that the most plausible explanation in the difference in HRQoL between patients that were and were not exposed to PSI is the incidence itself. This result is in line with the literature where Grosse Frie *et al.*[24] found that patient-reported complications are associated with a 4–7% reduction in improvement of HRQoL (EQ-5D) from hip, knee, varicose veins and hernia operations 3/6 months after the surgery.

Our results have implications for policy makers considering investing in interventions that can reduce medical error. Cost-effectiveness evaluations of new practices or technologies which only consider the cost of patient harm in terms of additional treatment costs underestimate the potential benefit of reducing harm. Even studies that estimate the number of healthy life-years lost due to medical error do not include the full societal cost of PSIs because they, by definition, only include the costs of safety events associated with increased mortality. In addition, our results demonstrate to practitioners that the impact of PSI goes beyond the additional costs associated with treating the complication, but in fact reduces patients' HRQoL gains from surgery. Initiatives that can reduce PSIs can therefore generate value for both patients and payers.

Finally, our findings suggest that, although beyond the scope of this paper, it is possible to estimate the monetary value of quality of life losses associated with PSIs. Such research will bring additional information to decision-makers wishing to understand the full societal impact of safety incidents, and the potential benefits of avoiding them.

Ethical approval

Not required.

Sources of funding

This work was funded and supported by the National Institute for Health Research (NIHR) Imperial Patient Safety Translational Research Centre (grant number PSTRC-2016-004], the Humanities and Social Sciences Research Project of Chongqing Education Commission (No. 22SKGH068), Development Research Center of Medical Science & Society-Chongqing Key Research Base of Humanities and Social Sciences.

Author contribution

M.X., S.R.K., and E.M. conceptualized and designed this project. M.X. did the literature search and review for evidence on the study. M.X. and S.R.K. contributed to data collection and data analysis of the economic modeling, and had full access to the data. The manuscript was written by M.X. with contributions and comments from S.R.K., J.M., and E.M.

Conflicts of interest disclosure

None.

Research registration unique identifying number (UIN)

1. Name of the registry: https://www.clinicaltrials.gov/
2. Unique Identifying number or registration ID: NCT05464771
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://clinicaltrials.gov/ct2/show/NCT05464771

Guarantor

Elias Mossialos.

Data availability statement

The datasets generated and/or analyzed during the current study are not publicly available due to the agreement between NHS digital and Imperial College London.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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