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Validation of adverse events after hip arthroplasty: a multicentre cohort study

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Validation of adverse events after hip arthroplasty: a multicentre cohort study

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ABSTRACT

Objectives

Preventing adverse events (AEs) after orthopaedic surgery is a field with great room for improvement. There are two major instruments for measuring AEs after hip arthroplasty surgery. Both are based on administrative data, and neither is validated. The aim of this study is to validate the sensitivity and specificity of the two instruments and to calculate the adjusted cumulative incidence and incidence rate of AEs following hip arthroplasty.

Design

Retrospective cohort study using retrospective record review (RRR) (Global Trigger Tool) in combination with register data.

Setting

Twenty-four different hospitals in 4 major regions of Sweden.

Participants

Two thousand patients with either total or hemi hip arthroplasty were recruited from the Swedish Hip Arthroplasty Register. We included acute patients with hip fractures and elective patients with degenerative joint disease.

Primary and secondary outcome measures

The sensitivity and specificity of the instruments. Adjusted cumulative incidence and incidence rate.

Results

The sensitivity for all identified AEs was 6% (95% CI: 5 - 7) for 30 days and 15% (95% CI: 8 - 25) for 90 days, and the specificity was 95% (95% CI: 94 – 97 for 30 days and 92% (95% CI: 90 – 94) for 90 days. The adjusted cumulative incidence for all AEs was 28% (95% CI: 25 - 33) for

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30 days and 30% (95% CI: 26 - 34) for 90 days. The incidence rate was 0.43 AEs per personmonth (95% CI: 0.39 - 0.47).

Conclusions

The AE incidence was high, and most AEs occurred within the first 30 days. The instrument sensitivity for AEs was very low for both 30 and 90 days, but the specificity was high for both 30 and 90 days. The studied instruments are insufficient for valid measurements of AEs after hip arthroplasty.

ARTICLE SUMMARY

Strengths and limitations of this study

- The use of retrospective record review and the Global Trigger Tool for data collection is the method that identifies the most adverse events (AEs).
- This is a multicentre study that includes a large sample size comprising both acute and elective patients.
- The use of the Swedish personal number in combination with the national register ensured that no admissions were missed.
- Our results are only generalisable to healthcare systems where International Classification of Disease codes are used to measure AEs.

KEYWORDS

Orthopaedics, Adverse events, Hip arthroplasty, Validation, Global Trigger Tool

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BACKGROUND

Adverse events (AEs) following surgery are a major challenge in the field of orthopaedics. Hip arthroplasty is one of the most successful procedures in modern medicine, and the technical improvements since Charnley arthroplasty have been minor.[1]

Complication rates after hip arthroplasty are between 3.4% - 57%[2-5] and preventing AEs is a field with great room for improvement. AEs after hip arthroplasty, including dislocation or periprosthetic joint infection, are typically connected to the implant, but patients also sustain more general AEs, such as pulmonary embolism and pneumonia.[6, 7]

There are many different methods for identifying AEs. The method that has been proven to be most sensitive compared to others is retrospective record review (RRR) by trained reviewers.[8–10] Another method for identifying and measuring AEs is by using administrative data and International Classification of Diseases (ICD) codes.[11]

Sweden has a rich history of quality registers and today, there are 96 publicly founded quality registers in Sweden. The Swedish Hip Arthroplasty Register (SHAR) issues a yearly report that includes the AE rate after hip arthroplasty. The AE rate is generated from administrative data with selected ICD-10 codes indicating AEs. The codes are found in the Swedish National Patient Register (NPR).[12] The SHAR instrument only uses codes that are registered during discharge from readmissions. AEs that occur during the index admission are not included. The instrument algorithm used by SHAR is also used by the Swedish Association of Local Authorities and Regions in a public access web application named the healthcare in numbers (HIN). The SHAR and HIN are both used for comparing the performances of different caregivers in Sweden. None of these instruments have been validated, and their sensitivity and specificity are unknown.

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The aim of this study was to validate the SHAR and HIN by studying their sensitivity and specificity, and to calculate the adjusted cumulative incidence and incidence rate of AEs following hip arthroplasty in patients with both planned and acute surgery.

METHODS

Study design

This is a retrospective multicentre cohort study on prospectively collected data from medical records and register data from SHAR and NPR.

Study size

The calculated sample size was estimated to be 2000 patients, assuming 5-10% inconclusive records, using an alpha level of 0.05 and a power minimum of 80%. The main assumptions regarding the HIN and SHAR's rate of failure to register a correct ICD-10 code for an AE was set to 15% (the sensitivity), and the rate for incorrectly coded non-event was set to 5% (the specificity).

Setting

The study comprises hip arthroplasty patients from four major county councils in Sweden (Stockholm, Skåne, Västra Götaland and Västra Norrland) in 24 different hospitals (six university hospitals, five central county council hospitals, seven county council hospitals and six private hospitals who have agreements/contracts with the county councils). Patients underwent surgery between January 2009 and December 2011.

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Participants

All patients 18 years of age or older whose data were recorded in the SHAR for either a hemi or total hip arthroplasty were eligible for inclusion. Both acute surgery for hip fractures and elective surgery for degenerative joint disease were included.

To increase the probability of selecting medical records with an AE and avoiding excess RRR on records without AEs, we used a weighted sample. Ten different selection groups were created as follows.

1. We constructed three groups with lengths of primary stay in percentiles divided as 0-50%, 51-80% and 81-100%. The three groups were further divided based on whether there was an ICD-10 code indicating an AE in the NPR. Overall, six groups were generated.

2. A selection was made for patients who had readmissions in the NPR. The readmission groups were divided in readmission within 2-30 days and within 31-90 days after surgery. The two groups were further divided based on whether there was an ICD-10 code indicating an AE in the NPR, generating a total of four groups.

The weighted samples, the ten selection groups and the ICD-10 codes are shown in Table A.1, Appendix.

Patient involvement

This is a register and record-based retrospective study with no patient involvement.

Data sources

Data on the primary procedures were received from the SHAR and cross-linked with data from the NPR, using the Swedish personal identity numbers. The coverage for total hip arthroplasties and for hemi arthroplasties in the SHAR was 98.3% and 97.5%, respectively, in 2015.[13]

All admissions and readmissions were received from cross-linking SHAR data with data from NPR. Medical records were obtained as paper copies or were reviewed on location at the hospital. Death data were available from the national death register.

Review teams and the RRR method

The review team consisted of ten reviewers (registered nurses, medical students and physicians) with a record review experience ranging from novice to expert. All reviewers received obligatory one-day training by two of the senior researchers (MG and MU).

We used the Swedish adaptation of the Global Trigger Tool (GTT),[14] named Markörbaserad journalgranskning,[15] as the RRR method for collecting all AE data. A studyspecific manual was created and included definitions, inclusion criteria, exclusion criteria, and all alterations and clarifications from the GTT.

Definitions

An AE was defined as suffering, physical harm or disease as well as death related to the index admission and as a condition that was not an inevitable consequence of the patient's disease or treatment.

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Based on the terminology in the Swedish Patient Safety Act,[16] a preventable AE was defined as an event that could have been prevented if adequate actions had been taken during the patient's contact with healthcare.

The index admission was defined as the orthopaedic admission when the patient had hip arthroplasty surgery. If the patient was discharged directly to a geriatric or rehabilitation clinic, this admission was also considered to be a part of the index.

AEs related to acts of either omission or commission were included.

Inclusion and exclusion criteria

We included and performed RRR on all inpatient care and all unplanned outpatient care in all Swedish hospitals from the index admission date up to 90 days after surgery. We included AEs that occurred during index admission and AEs that occurred during readmissions that originated from the index admission. AEs that were identified during unplanned outpatient visits at a hospital (accidents and emergencies visits) and originated from the index admission were also included.

We excluded AEs that were unrelated to the index admission and AEs that originated from the care of another AE. For example, if a patient was admitted because of a periprosthetic joint infection and sustained a fracture from falling in the ward, the infection was included as an AE, and the fracture was not included. We did not include planned outpatient visits at hospitals or planned or unplanned outpatient visits outside of hospitals, such as with a general practitioner.

The review process

The GTT consisted of a two-stage review process.

Review stage 1

All medical records, including notes from different professionals, were reviewed. The reviewers screened the record, searching for any of the 38 predefined triggers that indicated a potential AE. The triggers were divided into 5 modules: general triggers (n=18), laboratory triggers (n=5), surgical triggers (n=7), medication triggers (n=3) and intensive care triggers (n=5).

A summary of the RRR and all identified triggers with a free text description of the trigger/event were documented in a database (Microsoft Access 2007). All records with a potential AE went forward to review stage 2.

Review stage 2

All identified triggers deemed as positive for a potential AE were assessed in stage 2. Each potential AE was then assessed if it was caused by the healthcare service using a 4-point Likert scale graded as follows: 1) the AE was not caused by the index admission, 2) the AE was probably not caused by the index admission, 3) the AE was probably caused by the index admission, and 4) the AE was caused by the index admission. AEs graded as 1 or 2 were excluded and AEs graded as 3 or 4 were included, and the reviewer made a full assessment that included evaluations of preventability, severity, and whether or not the AE was ICD-10 coded. Preventability was assessed using a similar 4-point Likert scale as follows: 1) the AE was not preventable, 2) the AE was probably not preventable, 3) the AE was probably preventable, and 4) the AE was preventable. AEs that were graded 3 or 4 were classified as preventable AEs.

The severity of the AEs was evaluated using a slightly modified version of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index.[17] NCC MERP index categories E–I were included, and the categories indicated the following: E) contributed to or resulted in temporary harm, F) contributed to or resulted in temporary harm that required outpatient or inpatient care or prolonged hospitalization, G) contributed to or resulted in permanent harm, H) required intervention necessary to sustain life within 60 minutes and I) contributed or resulted in the patient's death.

Reliability and validity

Inter-rater reliability was evaluated through the double review of 6 percent of the records to assess agreement between the primary reviewers' judgements concerning whether at least one trigger or potential AE was identified in the record, whether the record was to be forwarded to secondary review, whether the reviewer identified the same specific event and whether this event was a potential AE.

The review process was monitored by an RRR expert (MU) who also was available for questions from the reviewers. The completeness and adherence to the study manual in stages 1 and 2 were monitored closely. All questions or discrepancies were given as written feedback to the reviewers for resolution. If needed, clarifying discussions were held with the respective reviewer.

Validation

To validate the SHAR and HIN, we used data from the NPR as test data that were validated with the AE data from the from the RRR. The SHAR and HIN use a set of selected

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ICD-10 codes as definitions of AEs (Table A.2, Appendix). All admissions from the NPR that had one of the selected primary codes as the main diagnosis or one of the selected general codes as the primary or secondary diagnosis, or had a death date after the index admission within 90 days after surgery were considered to be test positive in the sensitivity and specificity analysis. We analysed the sensitivity and We excluded the index admissions (i.e., the admission for the primary surgery) and all admissions over 90 days after surgery, and we only analysed the readmissions.

Statistical methods

Adjusted sensitivity and specificity were calculated for both 30 days and 90 days. We compared the test positive results from the NPR with both the results from all identified AEs from the RRR and from the AEs identified during readmissions. We also compared the results with preventable AEs in the RRR and major AEs (NCC MERP F and above).

The sensitivity and specificity were calculated in each sample group and multiplied by the group proportion (population group/total population). The products of all groups were summed, and the result was the adjusted sensitivity and specificity for the population. Bootstrap samples (n=2000) were used to calculate the 95% confidence intervals.

The adjusted cumulative incidence for 30 and 90 days was calculated by dividing the number of patients with an AE in each group with the group sample size, generating a rate for that group. This rate was multiplied by the group proportion (population group/total population). The products of all ten groups were summed to provide the adjusted cumulative incidence. The same method was used to calculate the adjusted cumulative incidence of preventable AEs and

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serious AEs. Bootstrap samples (n=3000 for all AEs and preventable AEs and n=1500 for serious AEs) were used to calculate the 95% confidence intervals.

The incidence rate was calculated by taking the total sum of the identified AEs within 30 days after surgery for each selection group and dividing it with the sample group size and then multiplying it with the group proportion. The sum was the incidence rate in AEs/person-month.

Cohen's kappa was calculated for inter-rater reliability between the primary

reviewers.[18]

We used R (v 3.4.2) and packages dplyr, boot, irr and Gmisc.

RESULTS

Participants

The study population consisted of 21 774 patients. We included 2000 patients weighted according to the selection group table (Table A.1, Appendix). Two patients were excluded. The first patient had no available medical record, a short primary admission, no readmissions and was unlikely to have sustained an AE. The second patient had a hip fracture treated with internal fixation, with an assumingly faulty registration in the SHAR. After exclusion, 1998 patients with a total of 5422 inpatient admissions and outpatient visits in 69 hospitals were reviewed and included in the analysis.

The study cohort comprised 667 acute hip fracture patients and 1331 elective patients, and 63% of the patients were female. The hip fracture group comprised more women, contained older patients, and had a longer length of stay during the index admission. Demographic baseline data are shown in Table 1.

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Table 1 Baseline data on patients

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	Total n=1998	Yes n=667	No n=1331
Age*, median	77 (68 – 84)	84 (79 – 89)	73 (64 – 80)
Female, n (%)	1 250 (62.6)	444 (66.6)	806 (60.6)
Length of stay*, days	7 (4 – 11)	11 (6 – 15)	6 (4 - 8)

*Interquartile range

Identified AEs and rate of correct ICD-10 codes

In total, we found 2116 AEs in 1171 (58.6%) patients. Of these, 1604 AEs (75.8%) in 975 (48.8%) patients were classified as preventable AEs, and 1378 AEs (65.1%) in 935 (46.8%) patients were classified as major AEs (NCC MERP F or higher).

Of the 2116 AEs, a correct ICD-10 code was found in 1145 (54.1%) records, in 879

(54.8%) of the 1604 preventable AEs and in 1004 (72.9%) of the 1378 major AEs.

The majority of AEs occurred during the index admission (n=1260, 59.5%), and 443 (35.2%) of them had correct ICD-10 codes. The number of AEs that occurred during readmission within 30 days after surgery was 590 (27.9%), and 476 (80.7%) had correct ICD-10 codes. The number of AEs that occurred during readmission within 90 days after surgery was 856 (40.5%), and 702 (82.0%) had correct codes.

The group of AEs that had the highest rate of correct ICD-10 codes was thrombosis and embolism, at 91.4%. AEs related to the surgical procedure, such as dislocation, had the second highest rate (76.1%), and bleeding that did not occur during the operation had the third highest rate (75.7%).

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The group of AEs that had the lowest rate of correct coding was pressure ulcers (5.3%),

followed by skin and superficial vessel damage (6.3%) and neurological AEs (14.6%). All

groups of AEs and their rates of correct ICD coding are displayed in Table 2.

Table 2 Groups of adverse events (AEs) and rates of correct International Classification of

Diseases (ICD) codes
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AE group	N of correct ICD codes	N of incorrect ICD codes	Total n of ICD codes	% of correct ICD codes
Thrombosis/embolus	106	11	116	91.4%
AEs related to the surgical procedure	353	111	464	76.1%
Haemorrhage, not during surgery	28	9	37	75.7%
Hospital-acquired infections	430	228	658	65.3%
Falls	53	30	83	63.9%
Miscellaneous	55	65	120	45.8%
Deterioration in vital signs	57	69	126	45.2%
Pain	9	19	28	32.1%
Allergic reactions	8	19	27	29.6%
Late detection of urine retention	19	63	82	23.2%
AEs related to anaesthesia care	2	7	9	22.2%
Neurological AEs	7	41	48	14.6%
Skin and superficial vessel AEs	8	119	127	6.3%
Pressure ulcers	10	180	190	5.3%
Total	1145	971	2116	

The single individual AE that had the highest rate of correct coding was acute myocardial infarction with 100% of the ICD-10 codes being correct, followed by the next top four correctly coded AEs, which were dislocation, (98.5%), periprosthetic joint infection (96.0%), pulmonary embolism (95.3%) and fracture caused by falling (90.2%). Ten different individual types of AEs

were not correctly coded at all and had rates of 0%. Among them were AEs caused during anaesthesia care (awareness and laryngospasm), thrombophlebitis, small blood vessel damage, soft tissue damage, muscle weakness, respiratory arrest, genital infection and pressure ulcers of unknown category or category 4.

Adjusted cumulative incidence and incidence rate

The adjusted cumulative incidence for patients sustaining at least one AE was 28.4% for 30 days and 29.5% for 90 days. The cumulative incidences for preventable AEs and major AEs are displayed in Table 3.

Table 3 Cumulative incidence (95% confidence interval) for all, preventable and major adverse events (AEs)

Cumulative incidence	All AEs	Preventable AEs	Major AEs
30 days	28.4 (24.7 – 32.5)	22.2 (19.2 – 25.7)	17.5 (15.0 – 20.4)
90 days	29.5 (25.8 – 33.6)	23.4 (20.3 – 27.1)	18.9 (16.2 – 21.9)

The incidence rate for all AEs was 0.43 AEs per person-month (95% CI: 0.39 - 0.47). For preventable AEs, the incidence rate was 0.32 (95% CI: 0.29 - 0.35), and for major AEs, the incidence rate was 0.22 (0.20 - 0.25).

Adjusted sensitivity and specificity

Adjusted sensitivity and specificity for all AEs were 5.7% and 95.2%, respectively, at 30 days and 14.8% and 92.1%, respectively, at 90 days. This was the comparison of the test positive readmissions from the NPR data versus all identified AEs in the RRR that included both index admissions and readmissions and represented the true performance of the SHAR and HIN. Table

4 shows the comparisons of these instruments versus all identified preventable and major AEs and of the instruments versus AEs identified only during readmissions.

Table 4 Sensitivity and specificity with 95% confidence intervals for all adverse events (AEs),

preventable AEs and major AEs.

All admissions <i>vs</i> readmissions	All AEs	Preventable AEs	Major AEs
Sensitivity 30 days	5.7 (5.0 – 6.7)	5.9 (5.0 – 7.0)	6.2 (5.1 – 7.6)
Specificity 30 days	95.2 (93.6 – 96.6)	95.0 (93.3 - 96.2)	95.1 (93.4 – 96.3)
Sensitivity 90 days	14.8 (8.2 – 24.5)	18.0 (8.6 – 30.9)	15.4 (8.0 – 31.2)
Specificity 90 days	92.1 (90.0 – 93.7)	92.0 (90.0 - 93.5)	91.5 (89.5 – 93.3)
Readmissions <i>vs</i> readmission	All AEs	Preventable AEs	Major AEs
Sensitivity 30 days	4.2 (2.9 – 5.5)	3.0 (2.9 – 3.1)	3.0 (2.9 – 3.1)
Specificity 30 days	93.8 (92.4 – 94.9)	93.9 (92.4 – 95.1)	93.8 (92.4 – 95.0)
Sensitivity 90 days	21.6 (6.4 – 64.4)	22.1 (5.1 – 65.5)	22.0 (5.1 – 65.5)
Specificity 90 days	90.4 (88.3 – 92.1)	90.5 (88.3 - 92.2)	90.4 (88.3 - 92.0)

Inter-rater reliability

Ez on The inter-rater reliability values of the primary reviewers' judgements concerning whether at least one trigger or potential AE was identified in the record were κ =0.828 and 0.965, respectively. The inter-rater reliability for whether the record was to be forwarded to secondary review was κ =0.965. The inter-rater reliability values for the identification of a specific event or whether that event was a potential AE were κ =0.65 and 0.873, respectively.

DISCUSSION

In this retrospective multicentre cohort study using RRR on 1998 patients who had undergone hip arthroplasty surgery, we validated two instruments based on administrative data for measuring AEs (the SHAR and HIN). We found a low overall rate of correct ICD-10 codes for all and preventable AEs (55%) and a higher rate for major AEs (73%).

The incidence of AEs was high, and more than every fourth patient sustained an AE, more than every fifth patient sustained a preventable AE, and slightly less than every fifth patient sustained a major AE within 30 days. The difference in incidences between 30 and 90 days was below 2% for all AEs, preventable AEs and major AEs. In the validation of the existing instruments, we found the sensitivity to be very low for both 30 and 90 days after surgery.

The specificity was very high for all AEs, preventable AEs and serious AEs, both 30 days and 90 days after surgery. We conclude that the two instruments have a low capacity for detecting AEs but are reliable when an AE has not yet occurred.

Huddleston et al.[3] found a 5.8% rate of AEs after total hip arthroplasty within 30 days. Our study found a much higher adjusted rate, and this was probably because we found more AEs with the RRR method than with the data abstraction from Medicare records. Studies on AEs in mixed orthopaedic patients have shown rates of 15–30%.[19, 20] The use of administrative data for measuring AEs after orthopaedic surgery has been studied by Sebastien et al.[21] The authors compared the Agency for Healthcare Quality and Research's Patient Safety Indicators (AHRQ-PSI), an ICD code-based instrument, with the Agency for Healthcare Quality and Research National Surgical Quality Improvement Program (ACS-NSQIP), a system that uses trained surgical clinical reviewers and well-defined criteria to identify AEs. In their study on mixed orthopaedic patients, the AHQR-PSI revealed an AE rate of 1%, and the ACS-NSQIP revealed

an AE rate of 22%. The authors concluded that the instruments were unable to adequately assess AEs in orthopaedic surgery. Best et al.[22] compared the ACS-NSQIP with administrative data for AEs after surgery and found similar results to those of our study. The authors found that the sensitivity was > 50% in only 23% of the selected AEs. Classen et al.[9] also compared the AHQR-PSI with the GTT and found that the AHQR-PSI fared very poorly.

These two examined instruments are used to compare hospitals in Sweden related to the Orthopaedic departments' quality of care. With regards to their low sensitivity to detect AEs, their validity is questionable. The low overall rate of correct ICD-10 codes in only half of the cases is the largest obstacle for using administrative data with ICD-10 codes for measuring all AEs after hip arthroplasty. The perfect rates (100%) - for coding specific AEs, such as acute myocardial infarction indicate that the method can be used as a powerful instrument for measuring some specific AEs. In our study, we found that the majority of the AEs, including one fifth of the dislocations, occurred during the index admission, so excluding the index admissions in an instrument will decrease the sensitivity. A plausible explanation for the low rate of correct ICD-10 codes is that the ICD-10 codes are not only used for medical purposes but also for economic ends. This can lead to Diagnosis Related Groups (DRG) creep, when hospitals choose codes with a higher reimbursement for economic purposes.[23]

Strengths and limitations

To our knowledge, this is the largest study on AEs after hip arthroplasty that uses RRR and the only study that includes both acute hip fracture patients and elective surgery patients, thereby including both total and hemi hip arthroplasties. The study contains a large study population and a multicentre design with a wide range of patients of all ages and types of

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hospitals. The 90-day follow-up is long enough to detect all acute and subacute AEs. The Swedish personal identity numbers and the NPR enabled us to review admissions, and this in combination with the RRR method decreased the risk of missing an AE to approximately zero and resulted in high quality data on the AEs. All kappa values were classified as near perfect agreement except for one that was classified as good agreement, indicating the good quality of the RRR.

The study period of 90 days after surgery in this study makes this analysis a study on short-term AEs and does not address late-onset AEs, such as aseptic loosening, one of the most common causes of revision surgery.[24] The baseline data on the patients are from the registers, and information on patient factors, such as comorbidities and physical status, is lacking. Therefore, this study cannot identify risk factors for AEs. In addition, our results are only generalisable to healthcare systems where ICD codes are used to measure AEs.

4.8

Conclusion

The conclusions from this study are that the incidence of AEs after hip arthroplasty is high and that the tested instruments cannot measure this correctly. Furthermore, because of the low reliability of the ICD-10 codes, an improved instrument needs to be based on robust variables, possibly in combination with ICD-10 codes, and also include AEs identified during index admission and a wider range of AE types.

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Competing interests

None declared.

Author contributions

MM collected, analysed and interpreted the data and contributed to the drafting of the work.

MU contributed to the design of the study, collected data, contributed to the drafting of the work and revised the manuscript critically.

CR contributed to the design of the study and the drafting of the work and revised the manuscript critically.

OR contributed to the design of the study and to critically revising the work.

AH collected data and critically revised the work.

BS collected data and critically revised the work.

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KS collected data and critically revised the work.

DS collected data and critically revised the work.

MG contributed to the design of the study; collected, analysed and interpreted the data;

contributed to the drafting of the work; and revised the manuscript critically.

OS contributed to the design of the study, collected data, contributed to the drafting of the work and revised the manuscript critically.

All authors have approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Ethical approval

Ethical approval was provided by the Regional Ethics Committee of Gothenburg (516-13 and T732-13). Permission for data access for the reviewers was granted by the head of each respective unit. The patients did not provide an informed consent to the record review.

Data-sharing statement

No additional data are available.

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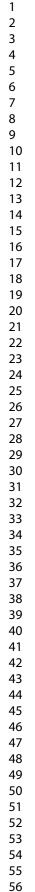
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the study process. Figure 1. Flow chart of the study process.

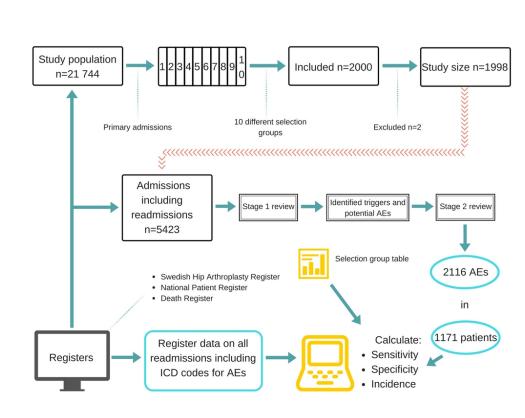
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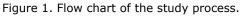
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Table A1: Selection groups						
	With AE code			No AE code		
		Population	Sample	Population	Sample	
Percentiles	0 - 55 %	289	33	12 628	130	
(lenght of stay)						
	56 - 80 %	206	49	3237	195	
	81 - 100 %	537	74	2547	294	
Readmission	20 - 30 days	630	294	631	442	
	31 - 90 days	403	293	666	194	

With AE code = Patients that had a recorded international classification of diseases (ICD) code indicating an AE. The following codes were used: as main diagnose: all I codes, J819, J13, J15, J18 and R33. As secondary diagnose I803, I269, L899, M243, M244, S730, T810, T813, T814, T840, T845 and T933.

Table A2: ICD-10 codes

ICD-10 code	As main code
I	Diseases of the circulatory system (All I codes)
J819	Pulmonary oedema
J15	Bacterial pneumonia
J18	Pneumonia, organism unspecified

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J13	Pneumonia due to Streptococcus pneumoniae
R33	Urine retention
ICD-10 code	As secondary code
T810	Haemorrage and haematoma complication a procedure
T813	Disruption of operation wound
T814	Infection following a procedure
L899	Decubitus ulcer and pressure area, unspecified
T840	Mechanical complication of internal joint prosthesis
T845	Infection and inflammatory reaction due to internal joint
	prosthesis
S730	Dislocation of hip
Т933	Sequele of dislocation, sprain and strain of lower limb
International classifi	ication of diseases (ICD) tenth revision codes used by the instrument for defining adverse
events.	
Table A.3: The 38	triggers with its five modules used in the study
Care module	Transfusion In-hospital stroke Cardiac arrest or deterioration in vital signs Unplanned dialysis Deep venous thrombosis or pulmonary embolus Fall Pressure ulcer Distended urinary bladder Thrombophlebitis or skin impairment Neurological impairment Abnormal temperature Positive blood culture Healthcare-associated infection Transfer to higher level of care Acute visit within 2 days after discharge from in-hospital care

Readmission within 90 days Documentation of mistake Other
Low haemoglobin value Low glucose value Increased creatinine value Abnormal potassium value Abnormal sodium value
 Reoperation Change in procedure/organ harm Unplanned ventilation treatment Intra- or Post-Operative Death Postoperative increase of troponin Postoperative complication Anesthesia related impairment/harm
Increased risk for haemorrhage Anaphylactic reaction Adverse drug event/adverse drug reaction
Ventilator-associated pneumonia Readmission to the intensive care unit or other higher level of care Treatment within intensive care Intubation, reintubation, tracheotomy or coniotomy Intensive care unit syndrome

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STROBE Statement—Checklist of items that should be included in reports of cohort studies

	 (a) Indicate the study design with a commonly used term in the title or abstract. (b) In the abstract, provide an informative and balanced summary of what was done and what was found. 	1-4
	abstract. (<i>b</i>) In the abstract, provide an informative and balanced summary of what was done	
	(<i>b</i>) In the abstract, provide an informative and balanced summary of what was done	
	and balanced summary of what was done	
	and what was found.	
	Explain the scientific background and	6
	rationale for the investigation being	
	reported.	
3	State specific objectives, including any	7
	prespecified hypotheses.	
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ŀ	Present key elements of the study design	7
	early in the paper.	
5	Describe the setting, locations, and	7
	relevant dates, including periods of	
	recruitment, exposure, follow-up, and data	
	collection.	
6	(a) Provide the eligibility criteria and the	8
	sources and methods of the selection of	
	participants. Describe the methods of	
	follow-up.	
	(b) For matched studies, provide	
		 State specific objectives, including any prespecified hypotheses. Present key elements of the study design early in the paper. Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection. (a) Provide the eligibility criteria and the sources and methods of the selection of participants. Describe the methods of follow-up.

Variables	7	Clearly define all outcomes, exposures,	9-
		predictors, potential confounders, and	
		effect modifiers. Provide diagnostic	
		criteria, if applicable.	
Data sources/	8*	For each variable of interest, provide the	9
measurement		sources of the data and details of the	
		methods of assessment (measurement).	
		Describe the comparability of the	
		assessment methods if there is more than	
		one group.	
Bias	9	Describe any efforts to address potential	
		sources of bias.	
Study size	10	Explain how the study size was	7
		determined.	
Quantitative variables	11	Explain how quantitative variables were	
		handled in the analyses. If applicable,	
		describe which groupings were chosen	
		and why.	
Statistical methods	12	(a) Describe all statistical methods,	13
		including those used to control for	14
		confounding.	
		(b) Describe any methods used to	
		examine subgroups and interactions.	
		(c) Explain how missing data were	
		addressed.	

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		follow-up was addressed.	
		(<u>e</u>) Describe any sensitivity analyses.	
Results			
Participants	13*	(a) Report the number of individuals at	14
		each stage of the study, such as the	
		number of potentially eligible individuals,	
		of those examined for eligibility, of those	
		confirmed as eligible, of those included in	
		the study, of those completing follow-up,	
		and of those analysed.	
		and of those analysed.	
		(b) Provide reasons for non-participation	
		at each stage.	
		(c) Consider the use of a flow diagram.	
Descriptive data	14*	(a) Provide the characteristics of the study	14
		participants (e.g., demographic, clinical,	1
		social) and information on exposures and	
		potential confounders.	
		(b) Indicate the number of participants	
		with missing data for each variable of	
		interest.	
		(c) Summarise the follow-up time (e.g.,	
		average and total duration).	
Outcome data	15*	Report numbers of outcome events or	13
		summary measures over time.	14
Main results	16	(a) Provide unadjusted estimates and, if	15
		applicable, confounder-adjusted	

		estimates and their precision (e.g., 95%
		confidence interval). Make clear which
		confounders were adjusted for and why
		they were included.
		(b) Report category boundaries when
		continuous variables were categorized.
		(c) If relevant, consider translating
		estimates of relative risk into absolute risk
		for a meaningful time period.
Other analyses	17	Report other analyses performed, such as
		analyses of subgroups and interactions as
		well as sensitivity analyses.
Discussion		
Key results	18	Summarise key results with reference to
		the study objectives.
Limitations	19	Discuss the limitations of the study, taking
		into account sources of potential bias or
		imprecision. Discuss both the direction
		and magnitude of any potential bias.
Interpretation	20	Provide a cautious overall interpretation of
		the results considering the objectives,
		limitations, multiplicity of analyses, results
		from similar studies, and other relevant
		evidence.
Generalisability	21	Discuss the generalisability (external
		validity) of the study results.
Other information		

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Funding	22	Provide the source of funding and the role	22
		of the funders for the present study and, if	
		applicable, for the original study on which	
		the present article is based.	
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*Provide informat	ion separately	for exposed and unexposed groups.	

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Validation of adverse events after hip arthroplasty: a multicentre cohort study

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SCHOLARONE[™] Manuscripts

Validation of adverse events after hip arthroplasty: a multicentre cohort study
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3 4	1	ABSTRACT
5 6	2	Objectives
7 8 9	3	Preventing adverse events (AEs) after orthopaedic surgery is a field with great room for
9 10 11	4	improvement. A Swedish instrument for measuring AEs after hip arthroplasty that is based on
12 13	5	administrative data from the national patient register (NPR), is used by both the Swedish hip
14 15	6	Arthroplasty register (SHAR) and the Swedish Association of Local Authorities and Regions. It
16 17 18	7	has never been validated and its accuracy is unknown. The aim of this study was to validate the
19 20	8	instrument's ability to detect AEs, and to calculate the incidence of AEs following primary hip
21 22	9	arthroplasties.
23 24 25	10	Design
25 26 27	11	Retrospective cohort study using retrospective record review (RRR) with Global Trigger Tool
28 29	12	methodology in combination with register data.
30 31	13	Setting
32 33 34	14	Twenty-four different hospitals in four major regions of Sweden.
35 36	15	Participants
37 38	16	Two thousand patients with either total or hemi hip arthroplasty were recruited from the SHAR.
39 40 41	17	We included acute patients with hip fractures and elective patients with degenerative joint
42 43	18	disease.
44 45	19	Primary and secondary outcome measures
46 47 48	20	The sensitivity and specificity of the instrument. Adjusted cumulative incidence and incidence
49 50	21	rate.
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1 Results

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> 2 The sensitivity for all identified AEs was 5.7% (95% CI: 4.9-6.7%) for 30 days and 14.8% (95%

- 3 CI: 8.2-24.3) for 90 days, and the specificity was 95.2% (95% CI: 93.5-96.6%) for 30 days and
- 4 92.1% (95% CI: 89.9-93.8%) for 90 days. The adjusted cumulative incidence for all AEs was
- 5 28.4% (95% CI: 25.0 – 32.3%) for 30 days and 39.5% (95% CI: 26.0 – 33.8%) for 90 days. The
- 6 incidence rate was 0.43 AEs per person-month (95% CI: 0.39 - 0.47).

7 **Conclusions**

8 The AE incidence was high, and most AEs occurred within the first 30 days. The instrument 9 sensitivity for AEs was very low for both 30 and 90 days, but the specificity was high for both 30 10 and 90 days. The studied instrument is insufficient for valid measurements of AEs after hip 11 arthroplasty. review

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13 **ARTICLE SUMMARY**

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15 Strengths and limitations of this study

The use of one of the most sensitive method for identifying AEs (retrospective record • review with Global Trigger Tool methodology).

The multicentre study design, that includes a large sample size comprising both acute and elective patients.

- 20 The use of the Swedish personal number in combination with the national register 21 ensured that no admissions were missed.
 - Our results are only generalizable to healthcare systems where International

Classification of Disease codes are used to measure AEs.

1	
2 3 4 5	KEYWORDS
6	Orthopaedics, Adverse events, Hip arthroplasty, Validation, Global Trigger Tool
7	
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BACKGROUND

1	DACKOROUND
2	Adverse events (AEs) following surgery are a major challenge in the field of
3	orthopaedics. Hip arthroplasty is one of the most successful procedures in modern medicine, and
4	the technical improvements since Charnley arthroplasty have been minor.[1]
5	Preventing AEs is a field with great room for improvement. Complication rates after hip
6	arthroplasty are between 3.4% – 27%.[2–4] However, comparison of AE rates should be done
7	with caution.[5] Two reasons for this is 1) there are no globally accepted definitions of AEs after
8	hip arthroplasty[6] and 2) there are many different methods for identifying AEs which
9	complicates comparisons.[7]
10	The method that has been proven to be most sensitive compared to others is retrospective
11	record review (RRR) by trained reviewers.[8–10] Another method for identifying and measuring
12	AEs is by using administrative data and International Classification of Diseases (ICD) codes.[11]
13	The Swedish Hip Arthroplasty Register (SHAR) issues a yearly report that includes the
14	AE rate after hip arthroplasty.[12] This AE rate is generated from an instrument that uses
15	administrative data with a set of selected AE ICD-10 codes (Table A1, appendix), that are found
16	in the Swedish National Patient Register (NPR).[13] Thus this report is not based on SHAR data
17	but on NPR data, and the same instrument is used by the Swedish Association of Local
18	Authorities and Regions in a public accessible web application named Healthcare in Numbers
19	(HIN).[14] The major difference about HIN and SHAR concerns the definition of the population.
20	HIN is based on NPR procedure codes and SHAR is based on hospitals recording of
21	interventions into the register.
22	The instrument only uses codes that are registered during discharge from readmissions.
23	AEs that occur during the index admission are not included.

1	Despite this widespread usage, we know nothing of its sensitivity and specificity. While
2	NPR's primary ICD-codes are known to be accurate (but with some variation between
3	diagnoses)[15], we do not know the accuracy for secondary codes. We also do not know how
4	well this set of codes and their selection are suited for detecting AEs.
5	The aim of this study was to validate the instrument's ability to detect AEs, and to
6 7	calculate the incidence of AEs following primary hip arthroplasties.

METHODS

2	
3	Study design
4	This is a retrospective multicentre cohort study on prospectively collected data from
5	medical records and register data from SHAR and NPR.
6	
7	Study size
8	The calculated sample size was estimated to be 2 000 patients, assuming 5-10%
9	inconclusive records, using an alpha level of 0.05 and a power minimum of 80%. The main
10	assumptions regarding the instrument's rate of failure to register a correct ICD-10 code for an
11	AE was set to 15% (the sensitivity), and the rate for incorrectly coded non-event was set to 5%
12	(the specificity).
13	
14	Setting
15	The study comprises hip arthroplasty patients from four major county councils in Sweden
16	(Stockholm, Skåne, Västra Götaland and Västernorrland) in 24 different hospitals (six university
17	hospitals, five central county council hospitals, seven county council hospitals and six private
18	hospitals who have agreements/contracts with the county councils, one private hospital treats
19	both acute and elective patients. Patients underwent surgery between January 2009 and
20	December 2011.

1		
2 3 4	1	
5 6	2	Participants
7 8 9	3	All patients 18 years of age or older whose data were recorded in the SHAR for either a
9 10 11	4	hemi or total hip arthroplasty were eligible for inclusion. Both acute surgery for hip fractures and
12 13	5	elective surgery for degenerative joint disease were included.
14 15 16	6	To increase the probability of selecting medical records with an AE and avoiding excess
17 18	7	RRR on records without AEs, we used a weighted sample. Twenty different selection groups for
19 20 21 22	8	acute and elective arthroplasties were created as follows (Table A2, appendix).
22	9	1. We constructed three groups with lengths of primary stay in percentiles divided as 0-
23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39	10	50%, 51-80% and 81-100%. The three groups were further divided based on whether
	11	there was an ICD-10 code indicating an AE in the NPR (Table A3, appendix). Overall,
	12	six groups were generated.
	13	2. A selection was made for patients who had readmissions in the NPR. The readmission
	14	groups were divided in readmission within 2-30 days and within 31-90 days after surgery.
	15	The two groups were further divided based on whether there was an ICD-10 code
	16	indicating an AE in the NPR, generating a total of four groups.
39 40 41	17	
42 43	18	This created a total of ten selection groups and we sampled according to the table (Table A2,
44 45	19	appendix) both from acute and elective patients yielding a total of 20 groups.
46 47 48	20	
49 50	21	Patient and public involvement
51 52	22	This is a register and record-based retrospective study with no patient involvement.
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2 Data sources

From the SHAR we collected data on the primary procedures that were cross-linked with data from the NPR, using the Swedish personal identity numbers. From the NPR we collected data on all admissions from the primary procedure and 90 days postoperatively. With the NPR data we could create a timeline with all admissions for each patient. This timeline was used as a template to know which admissions to review with the RRR. The NPR data also contained ICD-codes that were used in the validation of the instrument. Death data that was used in the validation of the instrument were available from the national death register (NDR). Medical records were obtained as paper copies or were reviewed on location at the hospital. **Review teams and the RRR method** The review team consisted of ten reviewers with a record review experience ranging from novice to expert (Table A4, appendix). The more experienced reviewers performed both stage one and two of the review. All reviewers received obligatory one-day training by two of the senior researchers (MG and MU).

We used the Swedish adaptation of the Global Trigger Tool (GTT), [16] named Marker
based record review[17], as the RRR method for collecting AE data. A study-specific manual
was created and included definitions, inclusion criteria, exclusion criteria, and all alterations and
clarifications from the GTT.

1		
2 3 4	1	
5 6	2	Definitions
7 8 9 10 11	3	An AE was defined as suffering, physical harm or disease as well as death related to the
	4	index admission and as a condition that was not an inevitable consequence of the patient's
12 13	5	disease or treatment.
14 15 16	6	Based on the terminology in the Swedish Patient Safety Act[18], a preventable AE was
16 17 18	7	defined as an event that could have been prevented if adequate actions had been taken during the
19 20	8	patient's contact with healthcare.
21 22	9	The index admission was defined as the orthopaedic admission when the patient had hip
23 24 25	10	arthroplasty surgery. If the patient was discharged directly to a geriatric or rehabilitation clinic,
26 27 28 29	11	this admission was also considered to be a part of the index admission.
	12	AEs related to acts of either omission or commission were included.
30 31 32	13	
33 34	14	Inclusion and exclusion criteria
35 36	15	We included and performed RRR on all inpatient care and all unplanned outpatient care
37 38 39 40 41	16	in all Swedish hospitals from the index admission date up to 90 days after surgery. We included
	17	AEs that occurred during index admission and AEs that occurred during readmissions that
42 43	18	originated from the index admission. AEs that were identified during unplanned outpatient visits
44 45 46	19	at a hospital (accidents and emergencies visits) and originated from the index admission were
46 47 48	20	also included.
49 50	21	We excluded AEs that were unrelated to the index admission and AEs that originated
51 52	22	from the care of another AE. For example, if a patient was admitted because of a periprosthetic
53 54 55	23	joint infection and sustained a fracture from falling in the ward, the infection was included as an
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AE, and the fracture was not included. We did not include planned outpatient visits at hospitals or planned or unplanned outpatient visits outside of hospitals, such as with a general practitioner. The review process The GTT consisted of a two-stage review process. Review stage 1 All medical records, including notes from different professionals, were reviewed. The reviewers screened the record, searching for any of the 38 predefined triggers that indicated a potential AE. The triggers were divided into five modules: general triggers (n=18), laboratory triggers (n=5), surgical triggers (n=7), medication triggers (n=3) and intensive care triggers (n=5). A summary of the RRR and all identified triggers with a free text description of the trigger/event were documented in a database (Microsoft Access 2007). All records with a potential AE went forward to review stage 2. Review stage 2 All identified triggers deemed as positive for a potential AE were assessed in stage 2. Each potential AE was then assessed if it was caused by the healthcare service using a 4-point

- 20 Likert scale graded as follows: 1) the AE was not caused by the index admission, 2) the AE was
- 21 probably not caused by the index admission, 3) the AE was probably caused by the index
- 22 admission, and 4) the AE was caused by the index admission.

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1	AEs graded as 1 or 2 were excluded and AEs graded as 3 or 4 were included, and the
2	reviewer made a full assessment that included evaluations of preventability, type of AE (71
3	different types in 15 different categories, Table A5, appendix), severity, and whether or not the
4	AE was ICD-10 coded.
5	Preventability was assessed using a similar 4-point Likert scale as follows: 1) the AE was
6	not preventable, 2) the AE was probably not preventable, 3) the AE was probably preventable,
7	and 4) the AE was preventable. AEs that were graded 3 or 4 were classified as preventable.
8	The severity of the AEs was evaluated using a slightly modified version of the National
9	Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index [19].
10	NCC MERP index categories E-I were included, and the categories indicated the following: E)
11	contributed to or resulted in temporary harm, F) contributed to or resulted in temporary harm that
12	required outpatient or inpatient care or prolonged hospitalization, G) contributed to or resulted in
13	permanent harm, H) required intervention necessary to sustain life within 60 minutes and I)
14	contributed or resulted in the patient's death.
15	Preventable AEs that were classed as NCC MERP F or higher were classified as major
16	AEs.
17	
18	Reliability and validity
19	Inter-rater reliability was evaluated through the double review of six percent of the
20	records to assess agreement between the primary reviewers' judgements concerning whether at
21	least one trigger or potential AE was identified in the record, whether the record was to be
22	forwarded to secondary review, whether the reviewer identified the same specific event and
23	whether this event was a potential AE.

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The review process was monitored by an RRR expert (MU) who also was available for questions from the reviewers. The completeness and adherence to the study manual in stages 1 and 2 were monitored closely. All questions or discrepancies were given as written feedback to the reviewers for resolution. If needed, clarifying discussions were held with the respective reviewer.

7 Validation

The instrument is based on a set of 13 specific ICD-codes and one code category (I-codes: diseases of the circulatory system) defining AEs (Table A1, Appendix). Five of the specific codes and the code category has to be as primary diagnose and the remaining eight can be either as primary or secondary code. In the validation of the instrument, test positive for an AE was defined as if the patient had: 1. Any of these code criteria in any readmission within 90 days after surgery (data source = NPR). or 2. A death date after discharge from the primary admission and within 90 days after surgery (data source = NDR). We used the results from the RRR as gold standard when we performed the sensitivity and specificity analysis. To give a nuanced study of the performance of the instrument we divided the AEs found with RRR into four categories. 1. All AEs (all found AEs with causality Likert scale \geq 3). 2. Preventable AEs (all AEs with preventability Likert scale \geq 3). 3. Major AEs (preventable AEs with NCC MERP \geq F)

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- 3 4	1	4. Selected AEs (AEs types that correspond to the set of "AE" ICD-codes).
5 6	2	We did two different validations for the four AE categories:
7 8	3	1. AEs found (with RRR) during both index and readmissions versus the instrument (only
9 10 11	4	readmissions.
12 13	5	2. AEs found (with RRR) during only readmissions versus the instrument.
14 15	6	We performed the two separate validations for all AE categories for all patients and with the
16 17	7	subsets of acute and elective patients. The rationale for the multiple validations was to test
18 19 20	8	different nuances of the instrument.
20 21 22	9	
23 24	10	Statistical methods
25 26 27	11	Adjusted sensitivity and specificity were calculated for both 30 days and 90 days. The
27 28 29	12	sensitivity and specificity were calculated in each sample group and multiplied by the group
30 31	13	proportion (population group/total population). The products of all groups were summed, and the
32 33	14	result was the adjusted sensitivity and specificity for the population.
34 35 36	15	The adjusted cumulative incidence for 30 and 90 days was calculated by dividing the
37 38	16	number of patients with an AE in each group with the group sample size, generating a rate for
39 40	17	that group. This rate was multiplied by the group proportion (population group/total population).
41 42 43	18	The products of all ten groups were summed to provide the adjusted cumulative incidence. The
43 44 45	19	same method was used to calculate the adjusted cumulative incidence of preventable AEs and
46 47	20	serious AEs.
48 49	21	We used the selection group tables for acute and elective patients separated for the
50 51 52	22	analysis of sensitivity and specificity for acute and elective patients and the two tables pooled
52 53 54	23	together for the analysis of all patients.
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The incidence rate was calculated by taking the total sum of the identified AEs within 30 days after surgery for each selection group and dividing it with the sample group size and then multiplying it with the group proportion. The sum was the incidence rate in AEs/person-month. Cohen's kappa was calculated for inter-rater reliability between the primary reviewers.[20] Bootstrap samples (n=2 000) were used to calculate the 95% confidence intervals. We used R (v 3.5.2) and packages dplyr, boot, irr, htmlTable and Gmisc. to beet terien only

Participants

The study population consisted of 21 774 patients. We included 2 000 patients weighted according to the selection group table (Table A2, Appendix). Two patients were excluded. The first patient had no available medical record, a short primary admission, no readmissions and was unlikely to have sustained an AE. The second patient had a hip fracture treated with internal fixation, with an assumingly faulty registration in the SHAR. After exclusion, 1 998 patients with a total of 5 422 inpatient admissions and outpatient visits in 69 hospitals were reviewed and included in the analysis (Figure 1). The study cohort comprised of 667 acute hip fracture patients and 1 331 elective patients, and 63% of the patients were female. The hip fracture group comprised more women, contained older patients, and had a longer length of stay during the index admission (Table1). FIGURE LEGENDS Figure 1, flowchart of the study process. AEs, adverse events; NPR, National Patient Register; SHAR, Swedish Hip Arthroplasty Register; RRR, retrospective record review.

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Table 1. Demographics

	Total n= 1 998	Acute n= 667	Elective n= 1 331
Female n=	1 250 (62.6%)	444 (66.6%)	806 (60.6%)
Male n=	748 (37.4%)	223 (33.4%)	525 (39.4%)
Age, median†	77.0 (68.0 - 84.0)	84.0 (79.0 - 89.0)	73.0 (64.0 - 80.0)
LOS, median†	7.0 (4.0 - 13.0)	14.0 (9.0 - 20.0)	5.0 (4.0 - 8.0)
Type of Hospital n=			
University	630 (31.5%)	295 (44.2%)	335 (25.2%)
County	556 (27.8%)	180 (27.0%)	376 (28.2%)
Rural	531 (26.6%)	109 (16.3%)	422 (31.7%)
Private	281 (14.1%)	83 (12.4%)	198 (14.9%)

†, Interquartile range

Identified AEs and rate of ICD-10 codes

In total, we found 2 116 AEs in 1 171 (58.6%) patients. Of these, 1 604 AEs (75.8%) in
975 (48.8%) patients were classified as preventable AEs, 1 066 AEs (50.4%) in 744 (37.2%)
patients were classified as major AEs and 1206 (57.0%) in 829 (41.5%) patients were classified
as selected AEs. The 667 acute patients sustained 981 (46.4%) of these and the elective patients
sustained 1 135 (53.6%). The acute patients sustained 758 (47.3%) of the preventable AEs and
431 (40.4%) of the major AEs.

Of the 2 116 found AEs, an ICD-10 code for the AE was found in 1 145 (54.1%) records,
in 879 (54.8%) of the 1 604 preventable AEs, in 787 (71.1%) of the 1 066 major AEs and in 758
(62.9%) of the 1 206 selected AEs.

The majority of AEs occurred during the index admission (n=1 260, 59.5%), and 443 (35.2%) of them had an ICD-10 code. The number of AEs that occurred during readmission within 30 days after surgery was 590 (27.9%), and 476 (80.7%) had an ICD-10 code. The

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number of AEs that occurred during readmission within 90 days after surgery was 856 (40.5%),
and 702 (82.0%) had an ICD-10 code.
The group of AEs that had the highest rate of ICD-10 codes was thrombosis and
embolism, at 91.6%. AEs related to the surgical procedure, such as dislocation, had the second
highest rate (76.1%), and bleeding that did not occur during the operation had the third highest
rate (75.7%). The group of AEs that had the lowest rate of codes was pressure ulcers (5.3%),
followed by skin and superficial vessel damage (6.3%) and neurological AEs (14.6%) (Table 2).
The single AE type that had the highest rate of available ICD-codes were acute myocardial
infarction and stroke with 100% available codes, followed by the next top four, which were
dislocation (98.5%), periprosthetic joint infection (96.0%), pulmonary embolism (95.3%) and
fracture caused by falling (90.2%). Ten different individual types of AEs were not coded at all
(Table A6, appendix).
(Table A6, appendix).

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Table 2. Groups of adverse event types and frequency of ICD-codes

	<u>Available</u>	ICD-code		
	Yes n=	No n=	Total n=	Rate %
Thrombosis or embolus	106	11	117	90.6
AEs related to the surgical procedure	353	111	464	76.1
Dislocation of prosthesis†	(270)	(4)	(274)	(98.5)
Tissue damage†	(11)	(7)	(18)	(61.1)
Bleeding, reoperation	(3)	(2)	(5)	(60.0)
Bleeding, no reoperation†	(47)	(62)	(109)	(43.1)
Other AEs related to the surgical procedure†	(22)	(36)	(58)	(37.9)
Bleeding (not related to surgery)	28	9	37	75.7
latrogenic infections	430	228	658	65.3
Falls	53	30	83	63.9
Other AEs	112	134	246	45.5
Abnormal pain	9	19	28	32.1
Allergic reaction	8	19	27	29.6
Distended bladder	19	63	82	23.2
AE cause by anaesthesia	2	7	9	22.2
Neurological AEs	7	41	48	14.6
Skin and superficial vessel AEs	8	119	127	6.3
Pressure ulcer	10	180	190	5.3
Total n=	1145	971	2116	54.1%

ICD-10, the 10th revision of the International Classification of Diseases

†, sub-group, numbers in brackets are not included in total

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- Adjusted cumulative incidence and incidence rate
- The adjusted cumulative incidence for patients sustaining at least one AE was 28.4% for 30 days and 29.5% for 90 days (Table 3). The acute patients had higher incidence than the

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elective patients with 51.4% compared to 17.2% for 30 days and 52.1% compared to 18.6% for
 90 days. The incidence of preventable AEs and major AEs were also higher for the acute patients
 compared with the elective, both for 30 and 90 days.

Table 3, adjusted cumulative incidence of adverse events (AEs)

	All patients	Acute patients	Elective patients
All AEs	0,		
Incidence 30 days	28.4 (25.0-32.3)	51.4 (44.0-59.5)	17.2 (14.0-21.1)
Incidence 90 days	29.5 (26.0-33.8)	52.1 (45.0-60.2)	18.6 (15-22.7)
Preventable AEs			
Incidence 30 days	22.2 (19.0-25.6)	40.6 (35-47.2)	13.9 (11.0-17.5)
Incidence 90 days	23.4 (20.0-26.8)	41.1 (36.0-48.1)	15.3 (12.0-19.2)
Major AEs			
Incidence 30 days	13.4 (11.0-15.6)	21.4 (18.0-25.7)	10.1 (8.0-13.1)
Incidence 90 days	14.7 (12.0-17.2)	22.1 (19.0-26.2)	11.6 (9.0-14.9)

All results are in %, 95% confidence interval in brackets.

The incidence rate for all AEs was 0.43 AEs per person-month (95% CI: 0.39 - 0.47).

6 For preventable AEs, the incidence rate was 0.32 (95% CI: 0.29 - 0.35), and for major AEs, the

7 incidence rate was 0.22 (0.20 - 0.25).

9 Adjusted sensitivity and specificity

Adjusted sensitivity and specificity for all AEs were 5.7% and 95.2%, respectively,
at 30 days, and 14.8% and 92.1%, respectively, at 90 days (Table 4). This was the comparison
that used the widest definition of AEs that were found from surgery until 90 days

1	postoperatively. The sensitivity and specificity for the narrowest definition of AE that only
2	compared readmissions were 3.0 % and 93.5%, respectively, at 30 days, 26.6% and 90.5%,
3	respectively, at 90 days.
4	The acute patients had higher sensitivity but lower specificity compared with the
5	elective patients, for all classes of AEs, for both 30 and 90 days.
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	All patients	Acute patients	Elective patients
	Sensitivity Specificity	Sensitivity Specificity	Sensitivity Specificity
All AEs			
Standard 30†	5.7 (4.9-6.7) 95.2 (93.5-96.6)	11.5 (9.4-13.8) 89 (82.0-93.4)	3.2 (2.9-3.5) 97.4 (97.1-97.7)
Standard 90†	14.8 (8.2-24.3) 92.1 (89.9-93.8)	20.6 (15.6-28.1) 82.6 (75.0-87.3)	15.5 (4.5-37.3) 95.1 (93.1-96.2)
Readmission 30‡	4.2 (2.9-5.5) 93.8 (92.3-94.9)	4.5 (4.2-4.8) 86.6 (83-89.5)	3.1 (2.3-3.9) 96.8 (96.6-97)
Readmission 90‡	21.6 (6.4-64.4) 90.4 (88.4-92.0)	12.9 (8.2-13.3) 80.1 (76.0-83.6)	20.8 (3.8-68.4) 94.7 (92.8-95.7)
Preventable AE	s		
Standard 30†	5.9 (5-7) 94.9 (93.3-96.2)	11.8 (9.5-14.4) 89.6 (84.4-93.4)	3.1 (2.9-3.6) 97.3 (96.9-97.6)
Standard 90†	18.0 (8.6-31.4) 91.9 (89.9-93.6)	23.2 (15.8-36.1) 83.5 (77.7-87.7)	17.7 (4.6-69.0) 95.1 (93.1-96.2)
Readmission 30‡	3.0 (2.9-3.1) 93.9 (92.4-95.1)	4.5 (4.2-4.9) 86.9 (83.4-89.9)	2.4 (2.3-2.5) 96.9 (96.7-97.2)
Readmission 90‡	22.1 (5.1-65.5) 90.5 (88.4-92.2)	12.9 (8.0-13.4) 80.1 (76.1-83.5)	19.9 (3.8-57.3) 94.8 (92.9-95.8)
Major AEs			
Standard 30†	6.2 (5-7.8) 94.8 (93.2-96)	12.8 (9.2-17.5) 89.1 (85.0-92.3)	3.2 (2.9-3.6) 97.3 (96.9-97.6)
Standard 90†	18.9 (8.1-39.1) 91.2 (89-92.9)	18.2 (14.4-23.4) 81.9 (77.2-85.8)	21.2 (4.7-68.4) 95.1 (93.2-96.1)
Readmission 30‡	3.0 (2.9-3.1) 93.9 (92.4-95.1)	4.5 (4.2-5) 87.0 (83.6-90.0)	2.4 (2.3-2.5) 96.9 (96.7-97.2)
Readmission 90‡	19.6 (5.1-65.5) 90.5 (88.4-92.2)	8.4 (7.7-9) 80.1 (76.0-83.6)	19.9 (3.8-67.9) 87.2 (92.9-95.8)
Selected AEs			
Standard 30†	6.5 (5.3-8.1) 95.1 (93.4-96.2)	13.0 (10.1-16.2) 90.0 (85-93.7)	3.3 (3-3.6) 97.2 (96.9-97.5)
Standard 90†	14.3 (8.8-25.3) 91.6 (89.2-93.3)	19.5 (16.3-23.1) 83.4 (77.5-88.0)	17.9 (4.7-48.2) 95.0 (93.2-96.1)
Readmission 30‡	3.0 (2.8-3.1) 93.9 (92.5-95.0)	4.5 (4.2-5.2) 87.0 (83.5-89.8)	2.3 (2.3-2.5) 96.9 (96.6-97.1)
Readmission 90‡	26.6 (6.5-65.6) 90.5 (88.5-92.1)	13.3 (8.7-14.2) 80.4 (75.8-84.0)	26.2 (3.9-69.4) 87.3 (92.9-95.7)

AEs, adverse events

†, AEs found (with RRR) during index and readmissions versus instrument (readmissions only)

AEs found (with RRR) during readmissions versus instrument (readmissions only)
 95% confidence interval in brackets

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Inter-rater reliability

The inter-rater reliability values of the primary reviewers' judgements concerning whether at least one trigger or potential AE was identified in the record were κ =0.828 and 0.965, respectively. The inter-rater reliability for whether the record was to be forwarded to secondary review was κ =0.965. The inter-rater reliability values for the identification of a specific event or whether that event was a potential AE were κ =0.65 and 0.873, respectively.

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DISCUSSION

In this retrospective multicentre cohort study using RRR on 1 998 patients who had
undergone hip arthroplasty surgery, we validated an instrument based on ICD-codes from NPR.
We found a high incidence for AEs and more than every fourth patient sustained an AE. The
incidence was higher for the acute patients and every other acute patient sustained an AE,
compared with almost every fifth elective patient. Almost two thirds of the AEs occurred during
the index admission and the difference between AEs within 30 days and 90 days was below 2
percentage.

We found a low overall rate of coded AEs for all and preventable AEs (55%) and a
higher rate for major AEs (73%).

We validated different nuances of the instrument and found that sensitivity was low, and at best every fourth patient with an AE is detected. We found that for all different nuances the specificity was high with the best result of 97%. Maas et al. compared ICD-codes with record review and also found low sensitivity and high specificity.[21] When we compared found AEs (with RRR) during readmissions to the instrument the sensitivity was lower for all AEs within 30

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days. This was due to the fewer total number of true positives and their distribution in fewer
selection groups for the readmissions versus instrument.
The definition of AEs in this study is wide and can by some be considered as excessive.
The rationale behind the choice of GTT as the method for identifying AEs was not that we
wanted the instrument to fail or to imply that hip arthroplasty is a dangerous procedure. When
we decided to do a record review validation, we wanted to use the method that has proven to
identify the most AEs to ensure that we had the highest quality data possible. The range of
severity of the found AEs is wide and it is easier to remove irrelevant AEs from a data-set than
the opposite.
As expected, our definition and method for measuring AEs yielded higher rates than for
example Huddleston et al.[3], who used data abstraction from Medicare records and found a 30-
day AE rate of 5.8% after total hip arthroplasty. Studies on AEs in mixed orthopaedic patients
using the GTT have shown rates of 15–30%.[22,23]
The preventability can be a hard to assess in RRR. To ensure concordant assessments
some AEs, as falls, prosthetic dislocation and pressure ulcers were always classed as preventable
in the study. The combination of our inclusive definition of preventability and structured RRR
might be an explanation that the rate of preventable AEs in elective patients were more than
double than Jorgensen et al. found in their study on total knee and hip replacements.[24]
However, our incidence of preventability is in accordance with another national GTT study in
orthopaedic care.[23]
The use of administrative data for measuring AEs after orthopaedic surgery has been
studied by Sebastien et al.[25] The authors compared the Agency for Healthcare Quality and

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Research's Patient Safety Indicators (AHRO-PSI), an ICD code-based instrument, with the Agency for Healthcare Quality and Research National Surgical Quality Improvement Program (ACS-NSQIP), a system that uses trained surgical clinical reviewers and well-defined criteria to identify AEs. In their study on mixed orthopaedic patients, the AHQR-PSI revealed an AE rate of 1%, and the ACS-NSQIP revealed an AE rate of 22%. The authors concluded that the instruments were unable to adequately assess AEs in orthopaedic surgery. Best et al.[26] compared the ACS-NSQIP with administrative data for AEs after surgery and found similar results to this study, a sensitivity of more than 50% in only 23% of the selected AEs. Classen et al.[9] also compared the AHQR-PSI with the GTT and found that the AHQR-PSI fared very poorly. The examined instrument is used to compare the quality of care in different Swedish hospitals, and this is one of the quality indicators that determines economic reimbursement to the hospitals. With regards to the low sensitivity to detect AEs, their validity is questionable. The instrument algorithm is also used by the Healthcare in Numbers, and by the Swedish Knee Arthroplasty register to measure AEs following total knee arthroplasty.[27] The use of the ICDinstrument for knee arthroplasties have not yet been validated, but our results from the elective hip patients implies that the use of the instrument might be questionable. The low overall rate of correct ICD-10 codes in only half of the cases is the largest obstacle for using administrative data with ICD-10 codes for measuring all AEs after hip arthroplasty. Furthermore, we found that the majority of the AEs, including one fifth of the dislocations, occurred during the index admission, so excluding the index admissions in an instrument will decrease the sensitivity.

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5 6	2	Strengths and limitations
7 8 9	3	To our knowledge, this is the largest study on AEs after hip arthroplasty that uses RRR
9 10 11	4	and the only study that includes both acute hip fracture patients and elective surgery patients,
12 13	5	thereby including both total and hemi hip arthroplasties. The study contains a large study
14 15 16	6	population and a multicentre design with a wide range of patients of all ages and types of
17 18	7	hospitals. The 90-day follow-up is long enough to detect all acute and subacute AEs. The
19 20	8	Swedish personal identity numbers and the NPR enabled us to review admissions, and this in
21 22	9	combination with the RRR method decreased the risk of missing an AE to approximately zero
23 24 25	10	and resulted in high quality data on the AEs. All kappa values were classified as near perfect
26 27	11	agreement except for one that was classified as good agreement, indicating the good quality of
28 29	12	the RRR.
30 31 32	13	The study period of 90 days after surgery in this study makes this analysis a study on
33 34	14	short-term AEs and does not address late-onset AEs, such as aseptic loosening, one of the most
35 36	15	common causes of revision surgery.[28] The baseline data on the patients are from the registers,
37 38 30	16	and information on patient factors, such as comorbidities and physical status, is lacking.
39 40 41	17	Therefore, this study cannot identify risk factors for AEs. In addition, our results are only
42 43	18	generalisable to healthcare systems where ICD codes are used to measure AEs. The weighted
44 45	19	sample did not include type of hospital and we can therefore not calculate incidence for the
46 47 48 49 50 51	20	different types of hospitals.

Conclusion The conclusions from this study are that the incidence of AEs after hip arthroplasty is high and that the tested instrument cannot measure this correctly. Furthermore, because of the low reliability of the ICD-10 codes, an improved instrument needs to be based on robust variables, possibly in combination with ICD-10 codes, and also include AEs identified during index admission and a wider range of AE types. Acknowledgments The authors thank Marie Ax, Susanne Hansson, Ammar Jobory, Zara Hedlund, Mirta Stupin, Tim Hansson, Lovisa Hult-Ericson and Christina Jansson for valuable help in carrying out the study. We would also like to thank all department managers for access to the medical records and Per Nydert for help with the study database. Finally we would like to thank Christoffer C Jørgensen, who performed a splendid review of the manuscript which improved this article tremendesly. Funding This study was funded by institutional grants from the Karolinska Institutet, Department of Clinical Sciences, Danderyd Hospital, from the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and Karolinska Institutet, and from LÖF, the Swedish patient insurance programme. The grant providers were not involved in any

1 2						
3 4	1	part of the study, in the writing of the manuscript or in the decision to submit the manuscript for				
5 6	2	publication.				
7 8 9	3					
10 11	4	Competing interests				
12 13	5	None declared.				
14 15	6					
16 17 18	7	Author contributions				
19 20	8	MM collected, analysed and interpreted the data and contributed to the drafting of the				
21 22	9	work.				
23 24 25	10	MU contributed to the design of the study, collected data, contributed to the drafting of				
25 26 27	11	the work and revised the manuscript critically.				
28 29	12	CR contributed to the design of the study and the drafting of the work and revised the				
30 31 32	13	manuscript critically.				
33 34	14	OR contributed to the design of the study and to critically revising the work.				
35 36	15	AH collected data and critically revised the work.				
37 38 39	16	BS collected data and critically revised the work.				
40 41	0 17 KS collected data and critically revised the work.					
42 43	18	DS collected data and critically revised the work.				
44 45 46	19	MG contributed to the design of the study; collected, analysed and interpreted the data;				
40 47 48	20	contributed to the drafting of the work; and revised the manuscript critically.				
49 50	21	OS contributed to the design of the study, collected data, contributed to the drafting of the				
51 52	22	work and revised the manuscript critically.				
53 54 55						
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All authors have approved the final version of the manuscript and agree to be accountable for all aspects of the work. **Ethical approval** Ethical approval was provided by the Regional Ethics Committee of Gothenburg (516-13 and .or th. . provide an in. able. T732-13). Permission for data access for the reviewers was granted by the head of each respective unit. The patients did not provide an informed consent to the record review. **Data-sharing statement** No additional data are available.

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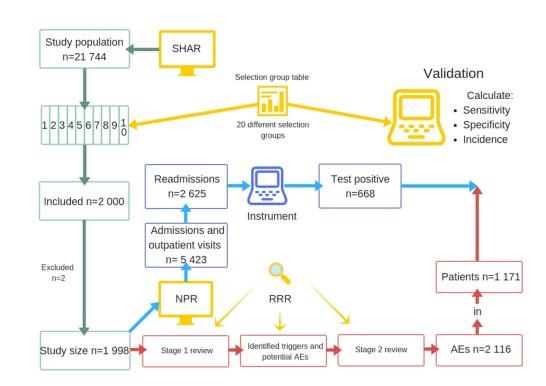
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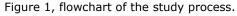
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AEs, adverse events; NPR, National Patient Register; SHAR, Swedish Hip Arthroplasty Register; RRR, retrospective record review.

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APPENDIX

Table A1, the set of ICD-10 codes for the defining an adverse event by the instrument

As main dia	agnosis
All I codes	Diseases of the circulatory system
J819	Pulmonary oedema
J13	Pneumonia due to Streptococcus pneumoniae
J15	Bacterial pneumonia, not elsewhere classified
J18	Pneumonia, organism unspecified
R33	Retention of urine
As main or	secondary diagnosis
L899	Decubitus ulcer and pressure area, unspecified
S730	Dislocation, sprain and strain of joint and ligaments of hip
T810	Haemorrhage and haematoma complicating a procedure, not elsewhere classified
T813	Disruption of operation wound, not elsewhere classified
T814	Infection following a procedure, not elsewhere classified
T840	Mechanical complication of internal joint prosthesis
T845	Infection and inflammatory reaction due to internal joint prosthesis
Т933	Sequelae of dislocation, sprain and strain of lower limb
ICD-10, the	10th revision of the International Classification of Diseases

Table A2, selection groups used for the weighted sample

With a predefine	d ICD-10 code indic	cating an AE in the	e NPR		
		Acute Elective			
		Population	Sample	Population	Sample
Percentiles of	0 - 55 %	194	11	95	22
length of stay	56 - 80 %	148	16	58	33
	81 - 100 %	302	25	235	49
Readmission	2 - 30 days	274	98	356	196
	31 - 90 days	199	98	204	195

Without a predefined ICD-10 code indicating an AE in the NPR

		<u>Acı</u>	<u>ute</u>	<u>Elec</u>	<u>tive</u>
		Population	Sample	Population	Sample
Percentiles of	0 - 55 %	2859	44	9769	86
length of stay	56 - 80 %	1167	65	2070	131
	81 - 100 %	766	97	1781	197
Readmission	2 - 30 days	294	147	337	295
	31 - 90 days	341	66	325	129
	Total	6544	667	15230	838

ICD-10, the 10th revision of the International Classification of Diseases

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Table A3, set of ICD-10 codes used in the selection of patients

As main diagnosis	
All I codes	Diseases of the circulatory system
J819	Pulmonary oedema
J13	Pneumonia due to Streptococcus pneumoniae
J15	Bacterial pneumonia, not elsewhere classified
J18	Pneumonia, organism unspecified
R33	Retention of urine

As main or secondary diagnosis

1803	Phlebitis and thrombophlebitis of lower extremities, unspecified
1269	Pulmonary embolism without mention of acute cor pulmonale
L899	Decubitus ulcer and pressure area, unspecified
M243	Pathological dislocation and subluxation of joint, not elsewhere classified
M244	Recurrent dislocation and subluxation of joint
S730	Dislocation, sprain and strain of joint and ligaments of hip
T810	Haemorrhage and haematoma complicating a procedure, not elsewhere classified
T813	Disruption of operation wound, not elsewhere classified
T814	Infection following a procedure, not elsewhere classified
T840	Mechanical complication of internal joint prosthesis
T845	Infection and inflammatory reaction due to internal joint prosthesis
Т933	Sequelae of dislocation, sprain and strain of lower limb

ICD-10, the 10th revision of the International Classification of Diseases

Table A4, characteristics of the reviewers and panel of specialists available for consultation during the review process.

Type of profession	Experience in RRR
Registered nurse	Expert in using different RRR methods including GTT
Registered nurse	Expert in using GTT
Registered nurse	Skilled in using GTT
Registered nurse	Skilled in using GTT
Registered nurse	Skilled in using GTT
Operating room nurse	Unfamiliar with GTT
Medical student	Unfamiliar with GTT
Medical student	Unfamiliar with GTT
Resident orthopedic surgeron	Used to structured review records but unfamiliar with GTT
Senior consultant orthopedic surgeon	Used to structured review records but unfamiliar with GTT
Senior consultant orthopedic surgeon	Specialist available for consultation
Senior consultant orthopedic surgeon	Specialist available for consultation
Senior consultant in internal medicine	Specialist available for consultation

GTT, Global Trigger tool; RRR, Retrospective record review

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Care module	Transfusion
	In-hospital stroke
	Cardiac arrest or deterioration in vital signs
	Unplanned dialysis
	Deep venous thrombosis or pulmonary embolus
	Fall
	Pressure ulcer
	Distended urinary bladder
	Thrombophlebitis or skin impairment
	Neurological impairment
	Abnormal temperature
	Positive blood culture
	Healthcare-associated infection
	Transfer to higher level of care
	Acute visit within 2 days after discharge from in-hospital care
	Readmission within 90 days
	Documentation of mistake
	Other
Laboratory module	Low haemoglobin value
	Low glucose value
	Increased creatinine value
	Abnormal potassium value
	Abnormal sodium value
Surgical and other invasive	Reoperation
procedure module	Change in procedure/organ harm
	Unplanned ventilation treatment
	Intra- or Post-Operative Death
	Postoperative increase of troponin
	Postoperative complication
	Anesthesia related impairment/harm
Medication module	Increased risk for haemorrhage
	Anaphylactic reaction
	Adverse drug event/adverse drug reaction
Intensive care module	Ventilator-associated pneumonia
	Readmission to the intensive care unit or other higher level of care
	Treatment within intensive care
	Intubation, reintubation, tracheotomy or coniotomy
	Intensive care unit syndrome

Type of AE	Found n=
Thrombophlebitis	7
Pressure ulcer unknown category	7
Other AEs caused by anaesthesia	4
Respiratory arrest	3
Awareness during anaesthesia	2
Pressure ulcer category 4	2
Superficial vessel damage	1
Genital infection (vaginal candidiasis)	1
Neurological AE: Muscle weakness	1

ICD-10, the 10th revision of the International Classification of Diseases

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STROBE Statement—Checklist of items that should be included in reports of cohort studies

1		
1	(a) Indicate the study design with a	1-4
	commonly used term in the title or	
	abstract.	
	(b) In the abstract, provide an informative	
	and balanced summary of what was done	
	and what was found.	
2	Explain the scientific background and	6
	rationale for the investigation being	
	reported.	
3	State specific objectives, including any	7
	prespecified hypotheses.	
	0	
4	Present key elements of the study design	7
	early in the paper.	
5	Describe the setting, locations, and	7
	relevant dates, including periods of	
	recruitment, exposure, follow-up, and data	
	collection.	
6	(a) Provide the eligibility criteria and the	8
	sources and methods of the selection of	
	participants. Describe the methods of	
	follow-up.	
	(b) For matched studies, provide	
	3 4 5	 abstract. (b) In the abstract, provide an informative and balanced summary of what was done and what was found. 2 Explain the scientific background and rationale for the investigation being reported. 3 State specific objectives, including any prespecified hypotheses. 4 Present key elements of the study design early in the paper. 5 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection. 6 (a) Provide the eligibility criteria and the sources and methods of the selection of participants. Describe the methods of follow-up.

		exposed and unexposed groups.	
Variables	7	Clearly define all outcomes, exposures,	9-
		predictors, potential confounders, and	
		effect modifiers. Provide diagnostic	
		criteria, if applicable.	
Data sources/	8*	For each variable of interest, provide the	9
measurement		sources of the data and details of the	
		methods of assessment (measurement).	
		Describe the comparability of the	
		assessment methods if there is more than	
		one group.	
Bias	9	Describe any efforts to address potential	
		sources of bias.	
01 1 1	10		
Study size	10	Explain how the study size was	7
		determined.	
Quantitative variables	11	Explain how quantitative variables were	
		handled in the analyses. If applicable,	
		describe which groupings were chosen	
		and why.	
Statistical methods	12	(a) Describe all statistical methods,	13
		including those used to control for	14
		confounding.	
		(b) Describe any methods used to	
		examine subgroups and interactions.	
		(c) Explain how missing data were	
		addressed.	

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		follow-up was addressed.	
		(<u>e</u>) Describe any sensitivity analyses.	
Results			
Participants	13*	(a) Report the number of individuals at	14
		each stage of the study, such as the	
		number of potentially eligible individuals,	
		of those examined for eligibility, of those	
		confirmed as eligible, of those included in	
		the study, of those completing follow-up,	
		and of those analysed.	
		(b) Provide reasons for non-participation	
		at each stage.	
		(c) Consider the use of a flow diagram.	
Descriptive data	14*	(a) Provide the characteristics of the study	14
		participants (e.g., demographic, clinical,	15
		social) and information on exposures and	
		potential confounders.	
		(b) Indicate the number of participants	
		with missing data for each variable of	
		interest.	
		(c) Summarise the follow-up time (e.g.,	
		average and total duration).	
Outcome data	15*	Report numbers of outcome events or	13
		summary measures over time.	14
Main results	16	(a) Provide unadjusted estimates and, if	15
		applicable, confounder-adjusted	

confidence interval). Make clear which confounders were adjusted for and we they were included.(b) Report category boundaries where continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolut for a meaningful time period.Other analyses17Report other analyses performed, su analyses of subgroups and interaction well as sensitivity analyses.	rhy n ed. e risk
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well as sensitivity analyses.	ns as
Discussion	
Key results 18 Summarise key results with reference	e to
the study objectives.	
Limitations 19 Discuss the limitations of the study, t	aking
into account sources of potential bias	or
imprecision. Discuss both the direction	n
and magnitude of any potential bias.	
Interpretation 20 Provide a cautious overall interpretation	on of
the results considering the objectives	,
limitations, multiplicity of analyses, re	sults
from similar studies, and other releva	nt
evidence.	
Generalisability 21 Discuss the generalisability (external	
validity) of the study results.	
Other information	

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Funding	22	Provide the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.	22
		for exposed and unexposed groups.	

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Validation of adverse events after hip arthroplasty: a Swedish multicentre cohort study

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3 4	1	Validation of adverse events after hip arthroplasty: a Swedish multicentre cohort study
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7 8	3	Martin Magnéli ^{1,2} , Maria Unbeck ^{3,4} , Cecilia Rogmark ^{5,6,7} , Ola Rolfson ^{7,8} , Ami Hommel ^{9,10,11} ,
9 10 11	4	Bodil Samuelsson ² , Kristina Schildmeijer ¹² , Desirée Sjöstrand ¹³ , Max Gordon ^{1,2} , Olof
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21 22 23	9	Word count: 4153 Number of figures: 1 Number of tables: 4 Number of references: 28 Tables in appendix: 6
23 24 25	10	Number of figures: 1
26 27	11	Number of tables: 4
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2 3	1	
4	1	ABSTRACT
5 6	2	Objectives
7 8 9	3	Preventing adverse events (AEs) after orthopaedic surgery is a field with great room for
10 11	4	improvement. A Swedish instrument for measuring AEs after hip arthroplasty based on
12 13	5	administrative data from the national patient register (NPR), is used by both the Swedish hip
14 15 16	6	Arthroplasty register (SHAR) and the Swedish Association of Local Authorities and Regions. It
17 18	7	has never been validated and its accuracy is unknown. The aim of this study was to validate the
19 20 21	8	instrument's ability to detect AEs, and to calculate the incidence of AEs following primary hip
21 22 23	9	arthroplasties.
24 25	10	Design
26 27	11	Retrospective cohort study using retrospective record review (RRR) with Global Trigger Tool
28 29 30	12	methodology in combination with register data.
31 32	13	Setting
33 34	14	Twenty-four different hospitals in four major regions of Sweden.
35 36 37	15	Participants
38 39	16	Two thousand patients with either total or hemi hip arthroplasty were recruited from the SHAR.
40 41	17	We included both acute and elective patients.
42 43 44	18	Primary and secondary outcome measures
45 46	19	The sensitivity and specificity of the instrument. Adjusted cumulative incidence and incidence
47 48	20	rate.
49 50 51	21	Results
52 53	22	The sensitivity for all identified AEs was 5.7% (95% CI: 4.9-6.7%) for 30 days and 14.8% (95%
54 55 56 57 58	23	CI: 8.2-24.3) for 90 days, and the specificity was 95.2% (95% CI: 93.5-96.6%) for 30 days and

1 2		
2 3 4	1	92.1% (95% CI: 89.9-93.8%) for 90 days. The adjusted cumulative incidence for all AEs was
5 6	2	28.4% (95% CI: 25.0 – 32.3%) for 30 days and 39.5% (95% CI: 26.0 – 33.8%) for 90 days. The
7 8 9	3	incidence rate was 0.43 AEs per person-month (95% CI: $0.39 - 0.47$).
9 10 11	4	Conclusions
12 13	5	The AE incidence was high, and most AEs occurred within the first 30 days. The instrument
14 15	6	sensitivity for AEs was very low for both 30 and 90 days, but the specificity was high for both 30
16 17 18	7	and 90 days. The studied instrument is insufficient for valid measurements of AEs after hip
19 20	8	arthroplasty.
21 22	9	
23 24 25	10	ARTICLE SUMMARY
25 26 27	11	
28 29	12	Strengths and limitations of this study
30 31	13	• The use of one of the most sensitive method for identifying AEs (retrospective record
32 33 34	14	review with Global Trigger Tool methodology).
35 36	15	• The multicentre study design, that includes a large sample size comprising both acute and
37 38	16	elective patients.
39 40 41	17	• The use of the Swedish personal number in combination with the national register
42 43	18	ensured that no admissions were missed.
44 45	19	• Our results are only generalizable to healthcare systems where International
46 47 48	20	Classification of Disease codes are used to measure AEs.
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1 2		
2 3 4	1	KEYWORDS
5 6	2	Orthopaedics, Adverse events, Hip arthroplasty, Validation, Global Trigger Tool
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BACKGROUND

2	Adverse events (AEs) following surgery are a major challenge in the field of
3	orthopaedics. Hip arthroplasty is one of the most successful procedures in modern medicine, and
4	the technical improvements since Charnley arthroplasty have been minor.[1]
5	Preventing AEs is a field with great room for improvement. Complication rates after hip
6	arthroplasty are between $3.4\% - 27\%$.[2–4] However, comparison of AE rates should be done
7	with caution.[5] Two reasons for this is 1) there are no globally accepted definitions of AEs after
8	hip arthroplasty[6] and 2) there are many different methods for identifying AEs which
9	complicates comparisons.[7]
10	The method that has been proven to be most sensitive compared to others is retrospective
11	record review (RRR) by trained reviewers.[8–10] Another method for identifying and measuring
12	AEs is by using administrative data and International Classification of Diseases (ICD) codes.[11]
13	The Swedish Hip Arthroplasty Register (SHAR) issues a yearly report that includes the
14	AE rate after hip arthroplasty.[12] This AE rate is generated from an instrument that uses
15	administrative data with a set of selected AE ICD-10 codes (Table A1, appendix), that are found
16	in the Swedish National Patient Register (NPR).[13] Thus this report is not based on SHAR data
17	but on NPR data, and the same instrument is used by the Swedish Association of Local
18	Authorities and Regions in a public accessible web application named Healthcare in Numbers
19	(HIN).[14] The major difference about HIN and SHAR concerns the definition of the population.
20	HIN is based on NPR procedure codes and SHAR is based on hospitals recording of
21	interventions into the register.
22	The instrument only uses codes that are registered during discharge from readmissions.
23	AEs that occur during the index admission are not included.

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1 2		
2 3 4	1	Despite this widespread usage, we know nothing of its sensitivity and specificity. While
5 6	2	NPR's primary ICD-codes are known to be accurate (but with some variation between
7 8	3	diagnoses)[15], we do not know the accuracy for secondary codes. We also do not know how
9 10 11	4	well this set of codes and their selection are suited for detecting AEs.
12 13	5	The aim of this study was to validate the instrument's ability to detect AEs, and to
14 15	6	calculate the incidence of AEs following primary hip arthroplasties.
16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 23 34 35 36 37 38 9 40 41 42 34 45 46 47 48 9 50 51 52 53 54 55 55 57	7	caculate the incidence of AEs following primary hip arthropiasues.
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METHODS

Study design

This is a retrospective multicentre cohort study on prospectively collected data from medical records and register data from SHAR and NPR.

Study size

The calculated sample size was estimated to be 2 000 patients, assuming 5-10%inconclusive records, using an alpha level of 0.05 and a power minimum of 80%. The main assumptions regarding the instrument's rate of failure to register a correct ICD-10 code for an AE was set to 15% (the sensitivity), and the rate for incorrectly coded non-event was set to 5% Jie4 (the specificity).

Setting

The study comprises hip arthroplasty patients from four major county councils in Sweden (Stockholm, Skåne, Västra Götaland and Västernorrland) in 24 different hospitals (six university hospitals, five central county council hospitals, seven county council hospitals and six private hospitals who have agreements/contracts with the county councils, one private hospital treats both acute and elective patients. Patients underwent surgery between January 2009 and December 2011.

1 2						
3 4	1					
5 6	2	Participants				
7 8 9	3	All patients 18 years of age or older whose data were recorded in the SHAR for either a				
10 11	4	hemi or total hip arthroplasty were eligible for inclusion. Both acute surgery for hip fractures and				
12 13	5	elective surgery for degenerative joint disease were included.				
14 15	6	To increase the probability of selecting medical records with an AE and avoiding excess				
16 17 18	7	RRR on records without AEs, we used a weighted sample. Twenty different selection groups for				
19 20	8	acute and elective arthroplasties were created as follows (Table A2, appendix).				
21 22	9	1. We constructed three groups with lengths of primary stay in percentiles divided as 0-				
23 24 25	10	50%, 51-80% and 81-100%. The three groups were further divided based on whether				
26 27	11	there was an ICD-10 code indicating an AE in the NPR (Table A3, appendix). Overall,				
28 29	12	six groups were generated.				
30 31 32	13	2. A selection was made for patients who had readmissions in the NPR. The readmission				
33 34	14	groups were divided in readmission within 2-30 days and within 31-90 days after surgery.				
35 36	15	The two groups were further divided based on whether there was an ICD-10 code				
37 38	16	indicating an AE in the NPR, generating a total of four groups.				
39 40 41	17					
42 43	18	This created a total of ten selection groups and we sampled according to the table (Table A2,				
44 45	19	appendix) both from acute and elective patients yielding a total of 20 groups.				
46 47 48	20					
49 50	21	Patient and public involvement				
51 52	22	This is a register and record-based retrospective study with no patient involvement.				
53 54 55						
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2 Data sources

From the SHAR we collected data on the primary procedures that were cross-linked with data from the NPR, using the Swedish personal identity numbers. From the NPR we collected data on all admissions from the primary procedure and 90 days postoperatively. With the NPR data we could create a timeline with all admissions for each patient. This timeline was used as a template to know which admissions to review with the RRR. The NPR data also contained ICD-codes that were used in the validation of the instrument. Death data that was used in the validation of the instrument were available from the national death register (NDR). Medical records were obtained as paper copies or were reviewed on location at the hospital. Review teams and the RRR method The review team consisted of ten reviewers with a record review experience ranging from novice to expert (Table A4, appendix). The more experienced reviewers performed both stage one and two of the review. All reviewers received obligatory one-day training by two of the senior researchers (MG and MU).

We used the Swedish adaptation of the Global Trigger Tool (GTT), [16] named Marker
based record review[17], as the RRR method for collecting AE data. A study-specific manual
was created and included definitions, inclusion criteria, exclusion criteria, and all alterations and
clarifications from the GTT.

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5 6	2	Definitions
7 8	3	An AE was defined as suffering, physical harm or disease as well as death related to the
9 10 11	4	index admission and as a condition that was not an inevitable consequence of the patient's
12 13	5	disease or treatment.
14 15	6	Based on the terminology in the Swedish Patient Safety Act[18], a preventable AE was
16 17 18	7	defined as an event that could have been prevented if adequate actions had been taken during the
19 20	8	patient's contact with healthcare.
21 22	9	The index admission was defined as the orthopaedic admission when the patient had hip
23 24 25	10	arthroplasty surgery. If the patient was discharged directly to a geriatric or rehabilitation clinic,
26 27	11	this admission was also considered to be a part of the index admission.
28 29	12	AEs related to acts of either omission or commission were included.
30 31 32	13	
33 34	14	Inclusion and exclusion criteria
35 36	15	We included and performed RRR on all inpatient care and all unplanned outpatient care
37 38 39	16	in all Swedish hospitals from the index admission date up to 90 days after surgery. We included
40 41	17	AEs that occurred during index admission and AEs that occurred during readmissions that
42 43	18	originated from the index admission. AEs that were identified during unplanned outpatient visits
44 45	19	at a hospital (accidents and emergencies visits) and originated from the index admission were
46 47 48	20	also included.
49 50	21	We excluded AEs that were unrelated to the index admission and AEs that originated
51 52	22	from the care of another AE. For example, if a patient was admitted because of a periprosthetic
53 54 55	23	joint infection and sustained a fracture from falling in the ward, the infection was included as an
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AE, and the fracture was not included. We did not include planned outpatient visits at hospitals or planned or unplanned outpatient visits outside of hospitals, such as with a general practitioner. The review process The GTT consisted of a two-stage review process. Review stage 1 All medical records, including notes from different professionals, were reviewed. The reviewers screened the record, searching for any of the 38 predefined triggers that indicated a potential AE. The triggers were divided into five modules: general triggers (n=18), laboratory triggers (n=5), surgical triggers (n=7), medication triggers (n=3) and intensive care triggers (n=5)(Table A5, Appendix). A summary of the RRR and all identified triggers with a free text description of the trigger/event were documented in a database (Microsoft Access 2007). All records with a potential AE went forward to review stage 2. Review stage 2 All identified triggers deemed as positive for a potential AE were assessed in stage 2. Each potential AE was then assessed if it was caused by the healthcare service using a 4-point Likert scale graded as follows: 1) the AE was not caused by the index admission, 2) the AE was probably not caused by the index admission, 3) the AE was probably caused by the index

22 admission, and 4) the AE was caused by the index admission.

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1	AEs graded as 1 or 2 were excluded and AEs graded as 3 or 4 were included, and the
2	reviewer made a full assessment that included evaluations of preventability, type of AE (71
3	different types in 15 different categories), severity, and whether or not the AE was ICD-10
4	coded.
5	Preventability was assessed using a similar 4-point Likert scale as follows: 1) the AE was
6	not preventable, 2) the AE was probably not preventable, 3) the AE was probably preventable,
7	and 4) the AE was preventable. AEs that were graded 3 or 4 were classified as preventable.
8	The severity of the AEs was evaluated using a slightly modified version of the National
9	Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index [19].
10	NCC MERP index categories E-I were included, and the categories indicated the following: E)
11	contributed to or resulted in temporary harm, F) contributed to or resulted in temporary harm that
12	required outpatient or inpatient care or prolonged hospitalization, G) contributed to or resulted in
13	permanent harm, H) required intervention necessary to sustain life within 60 minutes and I)
14	contributed or resulted in the patient's death.
15	
16	Reliability and validity
17	Inter-rater reliability was evaluated through the double review of six percent of the
18	records to assess agreement between the primary reviewers' judgements concerning whether at
19	least one trigger or potential AE was identified in the record, whether the record was to be
20	forwarded to secondary review, whether the reviewer identified the same specific event and
21	whether this event was a potential AE.
22	The review process was monitored by an RRR expert (MU) who also was available for
23	questions from the reviewers. The completeness and adherence to the study manual in stages 1

1 2		
3 4	1	and 2 were monitored closely. All questions or discrepancies were given as written feedback to
5 6 7	2	the reviewers for resolution. If needed, clarifying discussions were held with the respective
7 8 9	3	reviewer.
10 11	4	
12 13	5	Validation
14 15 16	6	The instrument is based on a set of 13 specific ICD-codes and one code category (I-
17 18	7	codes: diseases of the circulatory system) defining AEs (Table A1, Appendix). Five of the
19 20	8	specific codes and the code category has to be as primary diagnose and the remaining eight can
21 22 23	9	be either as primary or secondary code. In the validation of the instrument, test positive for an
23 24 25	10	AE was defined as if the patient had:
26 27	11	1. Any of these code criteria in any readmission within 90 days after surgery (data
28 29	12	source = NPR).
30 31 32	13	or
33 34	14	2. A death date after discharge from the primary admission and within 90 days after
35 36 27	15	surgery (data source = NDR).
37 38 39	16	We used the results from the RRR as gold standard when we performed the sensitivity and
40 41	17	specificity analysis. To give a nuanced study of the performance of the instrument we divided the
42 43	18	AEs found with RRR into four categories.
44 45 46	19	1. All AEs (all found AEs with causality Likert scale \geq 3).
47 48	20	2. Preventable AEs (all AEs with preventability Likert scale \geq 3).
49 50	21	3. Major AEs (preventable AEs with NCC MERP \geq F)
51 52 53	22	4. Selected AEs (AEs types that correspond to the set of "AE" ICD-codes).
55 54 55 56	23	We did two different validations for the four AE categories:
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2 3 4	1	1. AEs found (with RRR) during both index and readmissions versus the instrument (only
5 6	2	readmissions.
7 8 9	3	2. AEs found (with RRR) during only readmissions versus the instrument.
9 10 11	4	We performed the two separate validations for all AE categories for all patients and with the
12 13	5	subsets of acute and elective patients. The rationale for the multiple validations was to test
14 15 16	6	different nuances of the instrument.
16 17 18	7	
19 20	8	Statistical methods
21 22	9	Adjusted sensitivity and specificity were calculated for both 30 days and 90 days. The
23 24 25	10	sensitivity and specificity were calculated in each sample group and multiplied by the group
26 27	11	proportion (population group/total population). The products of all groups were summed, and the
28 29	12	result was the adjusted sensitivity and specificity for the population.
30 31 32	13	The adjusted cumulative incidence for 30 and 90 days was calculated by dividing the
33 34	14	number of patients with an AE in each group with the group sample size, generating a rate for
35 36	15	that group. This rate was multiplied by the group proportion (population group/total population).
37 38 39	16	The products of all ten groups were summed to provide the adjusted cumulative incidence. The
40 41	17	same method was used to calculate the adjusted cumulative incidence of preventable AEs and
42 43	18	serious AEs.
44 45 46	19	We used the selection group tables for acute and elective patients separated for the
47 48	20	analysis of sensitivity and specificity for acute and elective patients and the two tables pooled
49 50	21	together for the analysis of all patients.
51 52		
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The incidence rate was calculated by taking the total sum of the identified AEs within 30 days after surgery for each selection group and dividing it with the sample group size and then multiplying it with the group proportion. The sum was the incidence rate in AEs/person-month. Cohen's kappa was calculated for inter-rater reliability between the primary reviewers.[20] Bootstrap samples (n=2 000) were used to calculate the 95% confidence intervals. We used R (v 3.5.2) and packages dplyr, boot, irr, htmlTable and Gmisc. to beet teries only

Participants The study population consisted of 21 774 patients. We included 2 000 patients weighted according to the selection group table (Table A2, Appendix). Two patients were excluded. The first patient had no available medical record, a short primary admission, no readmissions and was unlikely to have sustained an AE. The second patient had a hip fracture treated with internal fixation, with an assumingly faulty registration in the SHAR. After exclusion, 1 998 patients with a total of 5 422 inpatient admissions and outpatient visits in 69 hospitals were reviewed and included in the analysis (Figure 1). The study cohort comprised of 667 acute hip fracture patients and 1 331 elective patients, and 63% of the patients were female. The hip fracture group comprised more women, contained older patients, and had a longer length of stay during the index admission (Table1). **FIGURE LEGENDS** Figure 1, flowchart of the study process. AEs, adverse events; NPR, National Patient Register; SHAR, Swedish Hip Arthroplasty Register; RRR, retrospective record review.

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Table 1. Demographics

Total n= 1 998	Acute n= 667	Elective n= 1 331
1 250 (62.6%)	444 (66.6%)	806 (60.6%)
748 (37.4%)	223 (33.4%)	525 (39.4%)
77.0 (68.0 - 84.0)	84.0 (79.0 - 89.0)	73.0 (64.0 - 80.0)
7.0 (4.0 - 13.0)	14.0 (9.0 - 20.0)	5.0 (4.0 - 8.0)
630 (31.5%)	295 (44.2%)	335 (25.2%)
556 (27.8%)	180 (27.0%)	376 (28.2%)
531 (26.6%)	109 (16.3%)	422 (31.7%)
281 (14.1%)	83 (12.4%)	198 (14.9%)
	n= 1 998 1 250 (62.6%) 748 (37.4%) 77.0 (68.0 - 84.0) 7.0 (4.0 - 13.0) 630 (31.5%) 556 (27.8%) 531 (26.6%)	n= 1 998 n= 667 1 250 (62.6%) 444 (66.6%) 748 (37.4%) 223 (33.4%) 77.0 (68.0 - 84.0) 84.0 (79.0 - 89.0) 7.0 (4.0 - 13.0) 14.0 (9.0 - 20.0) 630 (31.5%) 295 (44.2%) 556 (27.8%) 180 (27.0%) 531 (26.6%) 109 (16.3%)

†, Interquartile range

Identified AEs and rate of ICD-10 codes

In total, we found 2 116 AEs in 1 171 (58.6%) patients. Of these, 1 605 AEs (75.9%) in
975 (48.8%) patients were classified as preventable AEs, 1 066 AEs (50.4%) in 744 (37.2%)
patients were classified as major AEs and 1206 (57.0%) in 829 (41.5%) patients were classified
as selected AEs. The 667 acute patients sustained 981 (46.4%) of these and the elective patients
sustained 1 135 (53.6%). The acute patients sustained 758 (47.3%) of the preventable AEs and
431 (40.4%) of the major AEs.
Of the 2 116 found AEs, an ICD-10 code for the AE was found in 1 145 (54.1%) records,

in 879 (54.8%) of the 1 605 preventable AEs, in 787 (71.1%) of the 1 066 major AEs and in 758
(62.9%) of the 1 206 selected AEs.

The majority of AEs occurred during the index admission (n=1 260, 59.5%), and 443 (35.2%) of them had an ICD-10 code. The number of AEs that occurred during readmission within 30 days after surgery was 590 (27.9%), and 476 (80.7%) had an ICD-10 code. The

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number of AEs that occurred during readmission within 90 days after surgery was 856 (40.5%), and 702 (82.0%) had an ICD-10 code. The group of AEs that had the highest rate of ICD-10 codes was thrombosis and embolism, at 91.6%. AEs related to the surgical procedure, such as dislocation, had the second highest rate (76.1%), and bleeding that did not occur during the operation had the third highest rate (75.7%). The group of AEs that had the lowest rate of codes was pressure ulcers (5.3%), followed by skin and superficial vessel damage (6.3%) and neurological AEs (14.6%) (Table 2). The single AE type that had the highest rate of available ICD-codes were acute myocardial infarction and stroke with 100% available codes, followed by the next top four, which were dislocation (98.5%), periprosthetic joint infection (96.0%), pulmonary embolism (95.3%) and fracture caused by falling (90.2%). Ten different individual types of AEs were not coded at all (Table A6, appendix).

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Available ICD-code					
	Yes n=	No n=	Total n=	Rate %	
Thrombosis or embolus	106	11	117	90.6	
AEs related to the surgical procedure	353	111	464	76.1	
Dislocation of prosthesis†	(270)	(4)	(274)	(98.5)	
Tissue damage†	(11)	(7)	(18)	(61.1)	
Bleeding, reoperation†	(3)	(2)	(5)	(60.0)	
Bleeding, no reoperation†	(47)	(62)	(109)	(43.1)	
Other AEs related to the surgical procedure†	(22)	(36)	(58)	(37.9)	
Bleeding (not related to surgery)	28	9	37	75.7	
latrogenic infections	430	228	658	65.3	
Falls	53	30	83	63.9	
Other AEs	112	134	246	45.5	
Abnormal pain	9	19	28	32.1	
Allergic reaction	8	19	27	29.6	
Distended bladder	19	63	82	23.2	
AE cause by anaesthesia	2	7	9	22.2	
Neurological AEs	7	41	48	14.6	
Skin and superficial vessel AEs	8	119	127	6.3	
Pressure ulcer	10	180	190	5.3	
Total n=	1145	971	2116	54.1%	

ICD-10, the 10th revision of the International Classification of Diseases

†, sub-group, numbers in brackets are not included in total

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2 Adjusted cumulative incidence and incidence rate

The adjusted cumulative incidence for patients sustaining at least one AE was 28.4% for 30 days and 29.5% for 90 days (Table 3). The acute patients had higher incidence than the

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elective patients with 51.4% compared to 17.2% for 30 days and 52.1% compared to 18.6% for
 90 days. The incidence of preventable AEs and major AEs were also higher for the acute patients
 compared with the elective, both for 30 and 90 days.

Table 3, adjusted cumulative incidence of adverse events (AEs)

	All patients	Acute patients	Elective patients
All AEs	0.		
Incidence 30 days	28.4 (25.0-32.3)	51.4 (44.0-59.5)	17.2 (14.0-21.1)
Incidence 90 days	29.5 (26.0-33.8)	52.1 (45.0-60.2)	18.6 (15-22.7)
Preventable AEs			
Incidence 30 days	22.2 (19.0-25.6)	40.6 (35-47.2)	13.9 (11.0-17.5)
Incidence 90 days	23.4 (20.0-26.8)	41.1 (36.0-48.1)	15.3 (12.0-19.2)
Major AEs			
Incidence 30 days	13.4 (11.0-15.6)	21.4 (18.0-25.7)	10.1 (8.0-13.1)
Incidence 90 days	14.7 (12.0-17.2)	22.1 (19.0-26.2)	11.6 (9.0-14.9)

All results are in %, 95% confidence interval in brackets.

The incidence rate for all AEs was 0.43 AEs per person-month (95% CI: 0.39 - 0.47).

For preventable AEs, the incidence rate was 0.32 (95% CI: 0.29 - 0.35), and for major AEs, the

incidence rate was 0.22 (0.20 - 0.25).

9 Adjusted sensitivity and specificity

Adjusted sensitivity and specificity for all AEs were 5.7% and 95.2%, respectively,
at 30 days, and 14.8% and 92.1%, respectively, at 90 days (Table 4). This was the comparison
that used the widest definition of AEs that were found from surgery until 90 days

1 2		
3 4	1	postoperatively. The sensitivity and specificity for the narrowest definition of AE that only
5 6	2	compared readmissions were 3.0 % and 93.5%, respectively, at 30 days, 26.6% and 90.5%,
7 8	3	respectively, at 90 days.
9 10 11	4	The acute patients had higher sensitivity but lower specificity compared with the
12 13	5	elective patients, for all classes of AEs, for both 30 and 90 days.
14 15 16 17 18 19 20 21 22 32 42 52 62 72 82 93 31 22 33 34 35 36 37 38 940 41 42 43 44 50 51 52 53 54 55 55 57 85 960	6	
00		

	All patients	Acute patients	Elective patients
	Sensitivity Specificity	Sensitivity Specificity	Sensitivity Specificity
All AEs			
Standard 30†	5.7 (4.9-6.7) 95.2 (93.5-96.6)	11.5 (9.4-13.8) 89 (82.0-93.4)	3.2 (2.9-3.5) 97.4 (97.1-97.
Standard 90†	14.8 (8.2-24.3) 92.1 (89.9-93.8)	20.6 (15.6-28.1) 82.6 (75.0-87.3)	15.5 (4.5-37.3) 95.1 (93.1-96.
Readmission 30‡	4.2 (2.9-5.5) 93.8 (92.3-94.9)	4.5 (4.2-4.8) 86.6 (83-89.5)	3.1 (2.3-3.9) 96.8 (96.6-97)
Readmission 90‡	21.6 (6.4-64.4) 90.4 (88.4-92.0)	12.9 (8.2-13.3) 80.1 (76.0-83.6)	20.8 (3.8-68.4) 94.7 (92.8-95.
Preventable AE	s		
Standard 30†	5.9 (5-7) 94.9 (93.3-96.2)	11.8 (9.5-14.4) 89.6 (84.4-93.4)	3.1 (2.9-3.6) 97.3 (96.9-97.
Standard 90†	18.0 (8.6-31.4) 91.9 (89.9-93.6)	23.2 (15.8-36.1) 83.5 (77.7-87.7)	17.7 (4.6-69.0) 95.1 (93.1-96.
Readmission 30‡	3.0 (2.9-3.1) 93.9 (92.4-95.1)	4.5 (4.2-4.9) 86.9 (83.4-89.9)	2.4 (2.3-2.5) 96.9 (96.7-97
Readmission 90‡	22.1 (5.1-65.5) 90.5 (88.4-92.2)	12.9 (8.0-13.4) 80.1 (76.1-83.5)	19.9 (3.8-57.3) 94.8 (92.9-95
Major AEs			
Standard 30†	6.2 (5-7.8) 94.8 (93.2-96)	12.8 (9.2-17.5) 89.1 (85.0-92.3)	3.2 (2.9-3.6) 97.3 (96.9-97.
Standard 90†	18.9 (8.1-39.1) 91.2 (89-92.9)	18.2 (14.4-23.4) 81.9 (77.2-85.8)	21.2 (4.7-68.4) 95.1 (93.2-96.
Readmission 30‡	3.0 (2.9-3.1) 93.9 (92.4-95.1)	4.5 (4.2-5) 87.0 (83.6-90.0)	2.4 (2.3-2.5) 96.9 (96.7-97.
Readmission 90‡	19.6 (5.1-65.5) 90.5 (88.4-92.2)	8.4 (7.7-9) 80.1 (76.0-83.6)	19.9 (3.8-67.9) 87.2 (92.9-95.
Selected AEs			
Standard 30†	6.5 (5.3-8.1) 95.1 (93.4-96.2)	13.0 (10.1-16.2) 90.0 (85-93.7)	3.3 (3-3.6) 97.2 (96.9-97.
Standard 90†	14.3 (8.8-25.3) 91.6 (89.2-93.3)	19.5 (16.3-23.1) 83.4 (77.5-88.0)	17.9 (4.7-48.2) 95.0 (93.2-96.
Readmission 30‡	3.0 (2.8-3.1) 93.9 (92.5-95.0)	4.5 (4.2-5.2) 87.0 (83.5-89.8)	2.3 (2.3-2.5) 96.9 (96.6-97
Readmission 90‡	26.6 (6.5-65.6) 90.5 (88.5-92.1)	13.3 (8.7-14.2) 80.4 (75.8-84.0)	26.2 (3.9-69.4) 87.3 (92.9-95.

 a construct (with RRR) during index and readmissions versus instrument (readmissions only)
 4, AEs found (with RRR) during readmissions versus instrument (readmissions only)
 95% confidence interval in brackets iy)

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Inter-rater reliability

The inter-rater reliability values of the primary reviewers' judgements concerning whether at least one trigger or potential AE was identified in the record were κ =0.828 and 0.965, respectively. The inter-rater reliability for whether the record was to be forwarded to secondary review was κ =0.965. The inter-rater reliability values for the identification of a specific event or whether that event was a potential AE were κ =0.65 and 0.873, respectively.

DISCUSSION

In this retrospective multicentre cohort study using RRR on 1 998 patients who had
undergone hip arthroplasty surgery, we validated an instrument based on ICD-codes from NPR.
We found a high incidence for AEs and more than every fourth patient sustained an AE. The
incidence was higher for the acute patients and every other acute patient sustained an AE,
compared with almost every fifth elective patient. Almost two thirds of the AEs occurred during
the index admission and the difference between AEs within 30 days and 90 days was below 2
percentage.

We found a low overall rate of coded AEs for all and preventable AEs (55%) and a
higher rate for major AEs (73%).

We validated different nuances of the instrument and found that sensitivity was low, and at best every fourth patient with an AE is detected. We found that for all different nuances the specificity was high with the best result of 97%. Maas et al. compared ICD-codes with record review and also found low sensitivity and high specificity.[21] When we compared found AEs (with RRR) during readmissions to the instrument the sensitivity was lower for all AEs within 30

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1	days. This was due to the fewer total number of true positives and their distribution in fewer
2	selection groups for the readmissions versus instrument.
3	
4	The definition of AEs in this study is wide and can by some be considered as excessive.
5	The rationale behind the choice of GTT as the method for identifying AEs was not that we
6	wanted the instrument to fail or to imply that hip arthroplasty is a dangerous procedure. When
7	we decided to do a record review validation, we wanted to use the method that has proven to
8	identify the most AEs to ensure that we had the highest quality data possible. The range of
9	severity of the found AEs is wide and it is easier to remove irrelevant AEs from a data-set than
10	the opposite.
11	As expected, our definition and method for measuring AEs yielded higher rates than for
12	example Huddleston et al.[3], who used data abstraction from Medicare records and found a 30-
13	day AE rate of 5.8% after total hip arthroplasty. Studies on AEs in mixed orthopaedic patients
14	using the GTT have shown rates of 15–30%.[22,23]
15	The preventability can be a hard to assess in RRR. To ensure concordant assessments
16	some AEs, as falls, prosthetic dislocation and pressure ulcers were always classed as preventable
17	in the study. The combination of our inclusive definition of preventability and structured RRR
18	might be an explanation that the rate of preventable AEs in elective patients were more than
19	double than Jorgensen et al. found in their study on total knee and hip replacements.[24]
20	However, our incidence of preventability is in accordance with another national GTT study in
21	orthopaedic care.[23]
22	The use of administrative data for measuring AEs after orthopaedic surgery has been
23	studied by Sebastien et al.[25] The authors compared the Agency for Healthcare Quality and

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Research's Patient Safety Indicators (AHRQ-PSI), an ICD code-based instrument, with the Agency for Healthcare Quality and Research National Surgical Quality Improvement Program (ACS-NSOIP), a system that uses trained surgical clinical reviewers and well-defined criteria to identify AEs. In their study on mixed orthopaedic patients, the AHQR-PSI revealed an AE rate of 1%, and the ACS-NSQIP revealed an AE rate of 22%. The authors concluded that the instruments were unable to adequately assess AEs in orthopaedic surgery. Best et al.[26] compared the ACS-NSQIP with administrative data for AEs after surgery and found similar results to this study, a sensitivity of more than 50% in only 23% of the selected AEs. Classen et al.[9] also compared the AHQR-PSI with the GTT and found that the AHQR-PSI fared very poorly. The examined instrument is used to compare the quality of care in different Swedish hospitals, and this is one of the quality indicators that determines economic reimbursement to the hospitals. With regards to the low sensitivity to detect AEs, their validity is questionable. The instrument algorithm is also used by the Healthcare in Numbers, and by the Swedish Knee Arthroplasty register to measure AEs following total knee arthroplasty.[27] The use of the ICDinstrument for knee arthroplasties have not yet been validated, but our results from the elective hip patients implies that the use of the instrument might be questionable. The low overall rate of correct ICD-10 codes in only half of the cases is the largest

obstacle for using administrative data with ICD-10 codes for measuring all AEs after hip
arthroplasty. Furthermore, we found that the majority of the AEs, including one fifth of the
dislocations, occurred during the index admission, so excluding the index admissions in an
instrument will decrease the sensitivity.

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1	
2	Strengths and limitations
3	To our knowledge, this is the largest study on AEs after hip arthroplasty that uses RRR
4	and the only study that includes both acute hip fracture patients and elective surgery patients,
5	thereby including both total and hemi hip arthroplasties. The study contains a large study
6	population and a multicentre design with a wide range of patients of all ages and types of
7	hospitals. The 90-day follow-up is long enough to detect all acute and subacute AEs. The
	Swedish personal identity numbers and the NPR enabled us to review admissions, and this in
	combination with the RRR method decreased the risk of missing an AE to approximately zero
	and resulted in high quality data on the AEs. All kappa values were classified as near perfect
	agreement except for one that was classified as good agreement, indicating the good quality of
	the RRR.
12	
13	The study period of 90 days after surgery in this study makes this analysis a study on
14	short-term AEs and does not address late-onset AEs, such as aseptic loosening, one of the most
15	common causes of revision surgery.[28] The baseline data on the patients are from the registers,
16	and information on patient factors, such as comorbidities and physical status, is lacking.
17	Therefore, this study cannot identify risk factors for AEs. In addition, our results are only
18	generalisable to healthcare systems where ICD codes are used to measure AEs. The weighted
19	sample did not include type of hospital and we can therefore not calculate incidence for the
20	different types of hospitals.
	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19

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2 3 4	1	
5 6	2	Conclusion
7 8	3	The conclusions from this study are that the incidence of AEs after hip arthroplasty is
9 10 11	4	high and that the tested instrument cannot measure this correctly. Furthermore, because of the
12 13	5	low reliability of the ICD-10 codes, an improved instrument needs to be based on robust
14 15	6	variables, possibly in combination with ICD-10 codes, and also include AEs identified during
16 17 18	7	index admission and a wider range of AE types.
19 20	8	
21 22	9	Acknowledgments
23 24 25	10	The authors thank Marie Ax, Susanne Hansson, Ammar Jobory, Zara
25 26 27	11	Hedlund, Mirta Stupin, Tim Hansson, Lovisa Hult-Ericson and
28 29	12	Christina Jansson for valuable help in carrying out the study.
30 31	13	We would also like to thank all department managers for access
32 33 34	14	to the medical records and Per Nydert for help with the study
35 36	15	database. Finally we would like to thank Christoffer C
37 38	16	Jørgensen, who performed a splendid review of the manuscript
39 40	17	which improved this article tremendously.
41 42 43	18	
44 45	19	
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48 49 50	21	This study was funded by institutional grants from the Karolinska Institutet, Department of
50 51 52	22	Clinical Sciences, Danderyd Hospital, from the regional agreement on medical training and
53 54	23	clinical research (ALF) between Stockholm County Council and Karolinska Institutet, and from
55 56 57	24	LÖF, the Swedish patient insurance programme. The grant providers were not involved in any
57 58 59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml 28

1 2		
2 3 4	1	part of the study, in the writing of the manuscript or in the decision to submit the manuscript for
5 6	2	publication.
7 8 9	3	
9 10 11	4	Competing interests
12 13	5	None declared.
14 15 16	6	
17 18	7	Author contributions
19 20	8	MM collected, analysed and interpreted the data and contributed to the drafting of the work.
21 22 23	9	MU contributed to the design of the study, collected data, contributed to the drafting of the work
24 25	10	and revised the manuscript critically.
26 27	11	CR contributed to the design of the study and the drafting of the work and revised the manuscript
28 29 30	12	critically.
31 32	13	OR contributed to the design of the study and to critically revising the work.
33 34 25	14	AH collected data and critically revised the work.
35 36 37	15	BS collected data and critically revised the work.
38 39	16	KS collected data and critically revised the work.
40 41 42	17	DS collected data and critically revised the work.
42 43 44	18	MG contributed to the design of the study; collected, analysed and interpreted the data;
45 46	19	contributed to the drafting of the work; and revised the manuscript critically.
47 48	20	OS contributed to the design of the study, collected data, contributed to the drafting of the work
49 50 51	21	and revised the manuscript critically.
52 53	22	All authors have approved the final version of the manuscript and agree to be accountable
54 55 56 57 58	23	for all aspects of the work.

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2 3 4	1	
5 6	2	Ethical approval
7 8	3	Ethical approval was provided by the Regional Ethics Committee of Gothenburg (516-13 and
9 10 11	4	T732-13). Permission for data access for the reviewers was granted by the head of each
12 13	5	respective unit. The patients did not provide an informed consent to the record review.
14 15	6	
16 17	7	Data-sharing statement
18 19 20	8	No additional data are available.
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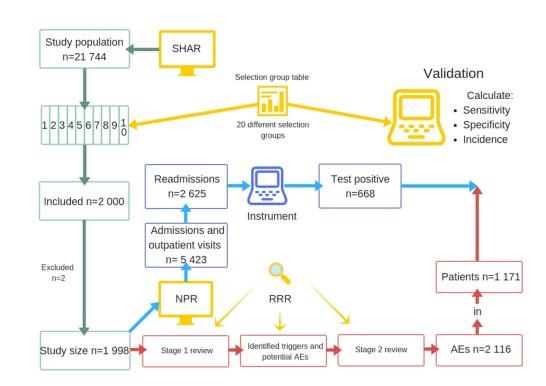
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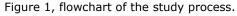
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AEs, adverse events; NPR, National Patient Register; SHAR, Swedish Hip Arthroplasty Register; RRR, retrospective record review.

203x152mm (300 x 300 DPI)

APPENDIX

Table A1, the set of ICD-10 codes for the defining an adverse event by the instrument

As main dia	agnosis				
All I codes Diseases of the circulatory system					
J819	Pulmonary oedema				
J13	Pneumonia due to Streptococcus pneumoniae				
J15	Bacterial pneumonia, not elsewhere classified				
J18	Pneumonia, organism unspecified				
R33	Retention of urine				
As main or	secondary diagnosis				
L899	Decubitus ulcer and pressure area, unspecified				
S730	Dislocation, sprain and strain of joint and ligaments of hip				
T810	Haemorrhage and haematoma complicating a procedure, not elsewhere classified				
T813	Disruption of operation wound, not elsewhere classified				
T814	Infection following a procedure, not elsewhere classified				
T840	Mechanical complication of internal joint prosthesis				
T845	1845 Infection and inflammatory reaction due to internal joint prosthesis				
Т933	Sequelae of dislocation, sprain and strain of lower limb				
ICD-10, the	10th revision of the International Classification of Diseases				

Table A2, selection groups used for the weighted sample

With a predefined ICD-10 code indicating an AE in the NPR						
		<u>Acute</u>		Elective		
		Population	Sample	Population	Sample	
Percentiles of	0 - 55 %	194	11	95	22	
length of stay	56 - 80 %	148	16	58	33	
	81 - 100 %	302	25	235	49	
Readmission	2 - 30 days	274	98	356	196	
	31 - 90 days	199	98	204	195	

Without a predefined ICD-10 code indicating an AE in the NPR

		<u>Acı</u>	<u>ute</u>	<u>Elec</u>	<u>tive</u>
		Population	Sample	Population	Sample
Percentiles of	0 - 55 %	2859	44	9769	86
length of stay	56 - 80 %	1167	65	2070	131
	81 - 100 %	766	97	1781	197
Readmission	2 - 30 days	294	147	337	295
	31 - 90 days	341	66	325	129
	Total	6544	667	15230	838

ICD-10, the 10th revision of the International Classification of Diseases

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Table A3, set of ICD-10 codes used in the selection of patients

As main dia	ignosis
All I codes	Diseases of the circulatory system
J819	Pulmonary oedema
J13	Pneumonia due to Streptococcus pneumoniae
J15	Bacterial pneumonia, not elsewhere classified
J18	Pneumonia, organism unspecified
R33	Retention of urine

As main or secondary diagnosis

1803	Phlebitis and thrombophlebitis of lower extremities, unspecified
1269	Pulmonary embolism without mention of acute cor pulmonale
L899	Decubitus ulcer and pressure area, unspecified
M243	Pathological dislocation and subluxation of joint, not elsewhere classified
M244	Recurrent dislocation and subluxation of joint
S730	Dislocation, sprain and strain of joint and ligaments of hip
T810	Haemorrhage and haematoma complicating a procedure, not elsewhere classified
T813	Disruption of operation wound, not elsewhere classified
T814	Infection following a procedure, not elsewhere classified
T840	Mechanical complication of internal joint prosthesis
T845	Infection and inflammatory reaction due to internal joint prosthesis
Т933	Sequelae of dislocation, sprain and strain of lower limb

ICD-10, the 10th revision of the International Classification of Diseases

Table A4, characteristics of the reviewers and panel of specialists available for consultation during the review process.

Type of profession	Experience in RRR
Registered nurse	Expert in using different RRR methods including GTT
Registered nurse	Expert in using GTT
Registered nurse	Skilled in using GTT
Registered nurse	Skilled in using GTT
Registered nurse	Skilled in using GTT
Operating room nurse	Unfamiliar with GTT
Medical student	Unfamiliar with GTT
Medical student	Unfamiliar with GTT
Resident orthopedic surgeron	Used to structured review records but unfamiliar with GTT
Senior consultant orthopedic surgeon	Used to structured review records but unfamiliar with GTT
Senior consultant orthopedic surgeon	Specialist available for consultation
Senior consultant orthopedic surgeon	Specialist available for consultation
Senior consultant in internal medicine	Specialist available for consultation

GTT, Global Trigger tool; RRR, Retrospective record review

Care module	Transfusion
	In-hospital stroke
	Cardiac arrest or deterioration in vital signs
	Unplanned dialysis
	Deep venous thrombosis or pulmonary embolus
	Fall
	Pressure ulcer
	Distended urinary bladder
	Thrombophlebitis or skin impairment
	Neurological impairment
	Abnormal temperature
	Positive blood culture
	Healthcare-associated infection
	Transfer to higher level of care
	Acute visit within 2 days after discharge from in-hospital care
	Readmission within 90 days
	Documentation of mistake
	Other
Laboratory module	Low haemoglobin value
	Low glucose value
	Increased creatinine value
	Abnormal potassium value
	Abnormal sodium value
Surgical and other invasive	Reoperation
procedure module	Change in procedure/organ harm
	Unplanned ventilation treatment
	Intra- or Post-Operative Death
	Postoperative increase of troponin
	Postoperative complication
	Anesthesia related impairment/harm
Medication module	Increased risk for haemorrhage
	Anaphylactic reaction
	Adverse drug event/adverse drug reaction
Intensive care module	Ventilator-associated pneumonia
	Readmission to the intensive care unit or other higher level of care
	Treatment within intensive care
	Intubation, reintubation, tracheotomy or coniotomy
	Intensive care unit syndrome

Type of AE	Found n=
Thrombophlebitis	7
Pressure ulcer unknown category	7
Other AEs caused by anaesthesia	4
Respiratory arrest	3
Awareness during anaesthesia	2
Pressure ulcer category 4	2
Superficial vessel damage	1
Genital infection (vaginal candidiasis)	1
Neurological AE: Muscle weakness	1

ICD-10, the 10th revision of the International Classification of Diseases

STROBE Statement—Checklist of items that should be included in reports of cohort studies

1		
1	(a) Indicate the study design with a	1-4
	commonly used term in the title or	
	abstract.	
	(b) In the abstract, provide an informative	
	and balanced summary of what was done	
	and what was found.	
2	Explain the scientific background and	6
	rationale for the investigation being	
	reported.	
3	State specific objectives, including any	7
	prespecified hypotheses.	
	0	
4	Present key elements of the study design	7
	early in the paper.	
5	Describe the setting, locations, and	7
	relevant dates, including periods of	
	recruitment, exposure, follow-up, and data	
	collection.	
6	(a) Provide the eligibility criteria and the	8
	sources and methods of the selection of	
	participants. Describe the methods of	
	follow-up.	
	(b) For matched studies, provide	
	3 4 5	 abstract. (b) In the abstract, provide an informative and balanced summary of what was done and what was found. 2 Explain the scientific background and rationale for the investigation being reported. 3 State specific objectives, including any prespecified hypotheses. 4 Present key elements of the study design early in the paper. 5 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection. 6 (a) Provide the eligibility criteria and the sources and methods of the selection of participants. Describe the methods of follow-up.

		exposed and unexposed groups.	
Variables	7	Clearly define all outcomes, exposures,	9-
		predictors, potential confounders, and	
		effect modifiers. Provide diagnostic	
		criteria, if applicable.	
Data sources/	8*	For each variable of interest, provide the	9
measurement		sources of the data and details of the	
		methods of assessment (measurement).	
		Describe the comparability of the	
		assessment methods if there is more than	
		one group.	
Bias	9	Describe any efforts to address potential	
		sources of bias.	
01 1 1	10		
Study size	10	Explain how the study size was	7
		determined.	
Quantitative variables	11	Explain how quantitative variables were	
		handled in the analyses. If applicable,	
		describe which groupings were chosen	
		and why.	
Statistical methods	12	(a) Describe all statistical methods,	13
		including those used to control for	14
		confounding.	
		(b) Describe any methods used to	
		examine subgroups and interactions.	
		(c) Explain how missing data were	
		addressed.	

		follow-up was addressed.	
		(<u>e</u>) Describe any sensitivity analyses.	
Results			
Participants	13*	(a) Report the number of individuals at	14
		each stage of the study, such as the	
		number of potentially eligible individuals,	
		of those examined for eligibility, of those	
		confirmed as eligible, of those included in	
		the study, of those completing follow-up,	
		and of those analysed.	
		(b) Provide reasons for non-participation	
		at each stage.	
		(c) Consider the use of a flow diagram.	
Descriptive data	14*	(a) Provide the characteristics of the study	14
		participants (e.g., demographic, clinical,	15
		social) and information on exposures and	
		potential confounders.	
		(b) Indicate the number of participants	
		with missing data for each variable of	
		interest.	
		(c) Summarise the follow-up time (e.g.,	
		average and total duration).	
Outcome data	15*	Report numbers of outcome events or	13
		summary measures over time.	14
Main results	16	(a) Provide unadjusted estimates and, if	15
		applicable, confounder-adjusted	

confidence interval). Make clear which confounders were adjusted for and we they were included.(b) Report category boundaries where continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolut for a meaningful time period.Other analyses17Report other analyses performed, su analyses of subgroups and interaction well as sensitivity analyses.	rhy n ed. e risk
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well as sensitivity analyses.	ns as
Discussion	
Key results 18 Summarise key results with reference	e to
the study objectives.	
Limitations 19 Discuss the limitations of the study, t	aking
into account sources of potential bias	or
imprecision. Discuss both the direction	n
and magnitude of any potential bias.	
Interpretation 20 Provide a cautious overall interpretation	on of
the results considering the objectives	,
limitations, multiplicity of analyses, re	sults
from similar studies, and other releva	nt
evidence.	
Generalisability 21 Discuss the generalisability (external	
validity) of the study results.	
Other information	

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Funding	22	Provide the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.	22
		for exposed and unexposed groups.	