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# Registration Of Surgical Adverse Events: As Reliable As Its Underlying Resources. A Reliability Study

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# Registration of surgical adverse events: As reliable as its underlying resources. A reliability study

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**Short title:** What are the best resources for registration of surgical adverse events?

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## ARTICLE SUMMARY

**Article focus:**

- How complete is the national surgical complication registry as applied in a university hospital?
- Should we use more or other resources for this purpose?

**Key messages:**

- Surgical complication registration largely depends on the reliability of the underlying resources.
- Better hand-off and additional consultation of the patient's dossier will increase the reliability.
- This extra effort can help avoid "mild" adverse events patients perceive as important and undesirable.

**Strengths and limitations:**

- Representative data set from a consistently used registry.
- Only in-hospital complications were taken into account.

## ABSTRACT

**Objective:** Accurate registration of adverse surgical events is essential to detect areas for improvement of surgical care quality. One reason for inaccurate adverse event registration may be the method to collect these outcomes. We compared the completeness of the national complication registry database (LHCR) as used in our hospital with relevant information from other available resources.

**Design:** Retrospective reliability analysis.

**Setting:** University hospital.

**Participants:** From the 3252 patients admitted to the surgical wards in 2010 we randomly selected a cohort of 180 cases, oversampling those with adverse events. The LHCR contains adverse outcomes as reported during morning hand-offs or in discharge letters. We checked whether the number and severity of adverse outcomes recorded in the LHCR agreed with those reported in morning hand-offs, discharge letters, and medical and nursing files.

**Results:** In 135 out of 180 patients all resources could be retrieved completely. Fourteen percent of the patients with adverse events were not recorded in the LHCR. Missing adverse events were all reversible without the need for (re)operation, e.g., postoperative pain, delirium, or urinary tract complications. Only 38% of these adverse events were reported in the morning hand-offs and discharge letters, but were best reported in the medical and nursing files.

**Conclusions:** Surgical complication registration appears largely depending on the reliability of the underlying sources. For a more complete adverse outcome registration we advocate a better hand-off and additional consultation of the patient's dossier. This extra effort allows for improvement actions to eventually avoid "mild" adverse events patients perceive as important and undesirable.

**BACKGROUND**

Of the patients admitted to a clinical department of surgery, approximately 10% is at risk of suffering a treatment-related complication and for some extensive gastrointestinal procedures even up to 50%.[1] A substantial part of these complications is preventable and thus epitomizes suboptimal care.[2] Accurate and routine registration of these adverse events is an important starting point from which to take action,[3-5] in order to reduce or even prevent these events and lower hospital mortality due to diminishing flaws in the care system.[6] Hence, professional societies and governmental institutions have urged to accurately record postoperative complications and to use this as a quality indicator. In the Netherlands, the Dutch Society of Surgeons already introduced a national surgical complication registry (LHCR) for this purpose in 2003.[7, 8]

However, information is needed on the performance of hospitals' adverse-event reporting systems.[9] Inaccurate registration and thus underreporting of complications or adverse events, as shown in previous studies,[10, 11] seems to be rewarded with an erroneously high score for quality of care. Part of the explanation might be a reluctance or negligence among doctors to report adverse events. Particularly strong disincentives for reporting are shame, fear of liability, loss of reputation, and peer disapproval.[12] The awareness that medical errors – but also surgical complications – are frequently system errors rather than an individual liability has helped abandoning a shame-and-blame culture and has harnessed the medical professional to report errors and complications.[13] Furthermore, increasing societal demands as to safety and transparency in healthcare have created more awareness of the importance of, and willingness to contribute to, and a better quality of care.[14, 15]

Another reason for an inaccurate complication registration could be the method chosen to collect and record these adverse events. The events entered into the registration database may be as complete as the resources from which these events are drawn. These resources can be daily verbal hand-offs, regular (multidisciplinary) meetings, medical and nursing dossiers, or the discharge letter. A previous comparison between daily reported adverse events with those documented in medical dossiers showed considerable discrepancy.[11] Hence, even a uniform, structural complication registration may have flaws to be improved. However, the effort to achieve a (nearly) complete registration should be weighed against its surplus value.

The aim of this study was to assess the accuracy of the postoperative complication registration database we are using routinely and a comparison with the source documents in order to detect areas for improvement of the complication registration in clinical surgical care.

## METHODS

### Patients

This survey was undertaken in the Department of Surgery of a tertiary referral university hospital in Amsterdam. From the admissions to any of the surgical wards during the year 2010, we randomly selected a sample of 180 patients (5.5%) from the LHCR database, while ensuring that at least half of the patients had suffered at least one postoperative adverse event according to the LHCR information. Thus, we ensured a sufficient number of admissions with adverse events to analyse. Patients admitted more than once during that year were included only once. We excluded patients whose resources could not be retrieved

completely. The resulting sample was considered valid, because we compared the various resources rather than the true incidence of adverse outcomes.

The definition of a surgical adverse event used in this study was "*an unintended and unwanted outcome or state occurring during or following medical care that is so harmful to the patients' health that it requires (adjustment of) treatment or leads to permanent damage*", according to the Dutch Society of Surgery.[16] These could include adverse events due to medical management errors, [17] as defined in the WHO reporting guidelines, but the recording of events took place before a conclusion regarding its causality (i.e. medical management error or disease complication) could be given. The definition, its interpretation, and the method of registration did not change during the study period.

Patients without adverse events according to the LHCR were used to check whether the absence of events was in agreement with the other resources. The patient set with complications was used to check whether the events as recorded in the LHCR were complete when compared with the other resources.

**Resources**

For each patient included, we retrieved and studied the medical and nursing files, the discharge letters relevant to that admission period, the documented morning hand-offs, and the complication database (LHCR). Adverse events entered into the LHCR were derived from the daily surgical morning hand-offs and the discharge letters. During these hand-offs every discharged patient was reported. Adverse events documented were those reported by the surgical residents or attending surgeons.[Goslings] The discharge letters were screened to find any additional events. The content of the discharge letters used during the study period

was predefined in a local protocol, in which the reporting of adverse events that had occurred during the patient's admission was compulsory.

As reference standard for the true number and type of adverse events occurring during the hospital admission period of each patient we used the combination of all resources consulted, i.e., LHCR, morning hand-off, discharge letter, medical file and nursing file. The discharge letter, medical and nursing files were judged separately within the patient's dossier as they were being kept separately and produced by different caregivers. At the time of the study, the medical and nursing files were not yet digitalised, but contained daily reports of the patient's condition and well-being.

**Study procedure**

From each of the resources, except the morning hand-offs, two investigators independently extracted the documented adverse events that had occurred in the selected patients and entered these in a database. Any discrepancies were resolved by discussion.

The various types of adverse events were first categorized based on the national classification as used by the Dutch Surgical Society. Because these categories in our sample were too fragmented, we regrouped the events by similarity (type) and number of appearance (Table 1). The grading of the severity of each event was based on the classification of Clavien et al.,[18] and was divided into four classes: 1) temporary health disadvantage recovering without (re)operation, e.g. wound infection; 2) recovery after (re)operation, e.g. anastomotic leakage; 3) (probably) permanent damage or function loss, e.g. stroke; and 4) death during admission. In retrospect, we also categorized recorded events that had no adverse health effects, e.g. a cancelled operation, as "class 0".

**Data analysis**

Data were transferred from the various resources into Excel 2003 (Microsoft Corp. Seattle, WA, USA) for further analysis. Descriptive statistics were expressed as means including standard deviations or medians with interquartile ranges whenever appropriate. Agreements between the adverse events recorded in the LHCR and in other resources were expressed as percentages. Similarly, we calculated the agreements for each event severity group.

**RESULTS**

During 2010, a total of 4196 admissions (of 3252 patients) to the gastro-intestinal, vascular, or trauma surgery wards were recorded. In 705 (16.8%) of these, one or more adverse events were documented in the LHCR. Of the 180 selected admissions, the resources of 135 different patients admitted could be analyzed. Forty-five admissions were excluded because these concerned readmissions of the same patients (n=3) or the data from one of the resources could not be retrieved (n=42). These reasons for exclusion were not likely to be related to the completeness of the adverse events as stated in the various resources. Hence, we considered the remaining set of 135 patients as valid for our purpose.

Of the 135 patients included, 60.7% were male with a mean age of 59.3 years. Median length of stay was 8 days. As shown in Table 2, their characteristics did not differ significantly from the whole group of patients admitted in 2010, except for a significantly longer length of stay and higher number of ASA-2 patients, obviously because we oversampled patients with complications. In 70% of the 135 patients one or more surgical procedures were performed, resulting in a total of 208 procedures in these patients. Based

on the summary of all events from all resources, 275 adverse events were recorded in total. A total of 98 out of 135 patients had suffered one or more adverse events.

The proportions of patients with one or more adverse events as recorded in the different resources as well as in the official LHCR are summarized in Table 3. In 86% of the cases the LHCR was in agreement with the reference standard as to the total number of patients with one or more events. In other words, 14% of admissions with adverse events were not recorded in our official registry. Table 4 shows the severity categorization of the events as recorded in the various resources. The events missing in the LHCR were all mild (class 1) events that could be treated with non-surgical interventions, like pain, delirium, or bladder complications.

Adverse events related to medical management errors ("class 0") occurred rarely but were poorly registered, particularly in the morning hand-offs and discharge letters. This is mainly due to the fact that these events mainly concerned "cancelled operations". Although these were recorded during the morning hand-offs, they were considered to be of limited information to include in the discharge letters.

The vast majority (80.4%) of the adverse events in the reference standard was reversible and mild (class 1). The morning hand-offs and discharge letters omitted most of these events. Only 38% of these mild events were registered in these resources. Also the LHCR missed most of the mild events, which were best reported in the nursing and medical files.

Surgical complications requiring a re-intervention (class 2) seemed to be under-recorded in most resources. However, this may be influenced by the fact that in some patients more than one class-2 event had led to a single re-intervention, but only one of

these events was recorded as reason for the re-intervention. Unfortunately, there was no consensus on how this should have been recorded.

The more serious adverse events (classes 3 and 4) occurred less frequently. The medical and nursing files did not state class-3 events, probably because at that time the permanent effects of such events could not yet be assessed. Strikingly, even the discharge letter did not mention many of the events leading to permanent damage or function loss. A few deaths were not documented in the nursing and medical files because the patient died on the ICU unit, which was documented in a separate discharge letter not included in this study.

To discover which types of adverse events in particular might be under-recorded, we investigated which events had a documentation rate of less than 50% as compared with the reference standard. These were the following: abscess, shock, pressure ulcers, delirium, fluid collections, pain, pulmonary complications, over-infusion, urinary tract-related complications, fistulas and vascular complications.

## DISCUSSION

Registration of surgical adverse events appears valuable, but is largely depending on the reliability of the underlying sources. In many hospitals a complication registration system, such as the LHCR in the Netherlands, heavily depends on the accuracy of the reporting and documentation of adverse events through various resources. The usage of the available resources might be different in the various Dutch hospitals using the LHCR and is not well defined.

The present study showed that adverse events are under-reported with the LHCR system but also during the morning report. The less severe events tended to be reported

less frequently, except in the nursing file, which was not designed to serve as input for the LHCR. Nevertheless, all likely resources should be incorporated for an optimum registration of adverse events. The medical rather than the nursing file seems the most appropriate additional resource for this purpose.

The completeness of the complication registration may also vary with the types of adverse events a hospital decides to record. Should adverse events with a low severity, for example such as delay of surgery, be omitted, i.e. a “light” version of complication registration, a higher accuracy would be achievable. A drawback of this would be that other - but common – events, such as wound infections or pressure ulcers, are not monitored properly and cannot be acted upon. Moreover, particularly for relatively minor surgical interventions, patients will still perceive “mild” adverse events as important and undesirable.

Conversely, registration of all possible adverse events requires more effort to extract these from the various complementary resources. When pursuing this policy, the nursing file may be included as an important source of more “mild” events, such as pressure ulcers, insufficiently controlled pain, or urinary tract infections. Besides, recording the number of postponed or cancelled surgical interventions can be useful as indicator for a change in the organization process of care and thereby an improvement of the quality of care.

The low number of adverse events included in the discharge letter may be due to selection of items considered relevant to the general practitioner or follow-up institution. However, any permanent damage or function loss acquired during admission surely needs more attention than it appears to receive, based on this study, in particular in the early phase after discharge and management of the adverse events by the general practitioner. A predefined format and content of these letters, including for example a computer-generated

summary, can improve quality and safety of hand-off communication and subsequent care.[19]

A limitation of this study could be that even the reference standard may have been an underestimation of the true number of adverse events that had actually occurred. If so, the various sources leave even more events untracked. However, this does not seem likely, as all possible sources were studied in retrospect. We did not study the events that might have occurred (shortly) after discharge, which was beyond the scope of this research. Secondly, the random sample of admissions investigated may have been relatively small. Nevertheless, the trends we found are quite conspicuous and seem reliable since two investigators independently reviewed the resources for events.

In conclusion, the registration, management and prevention of surgical adverse events is serious business. It may also impact the selection of patients to be treated and procedures to be performed. Therefore, hospitals and clinicians should be willing to put effort in a structural and reliable means to register not only the beneficial, but also the harmful effects of their professional activities to improve the quality of care for their patients.

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**Table 1.** Categories used to group the recorded adverse events.

| | |
|---|---|
| **1:** Abscess | **13:** Fluid collections<br>• Seroma |
| **2:** Surgical procedure cancelled | **14:** Pain<br>• Correction of epidural analgesia |
| **3:** Cardiac complications<br>• Atrial or ventricular tachycardia<br>• Brady/tachycardia<br>• Asthma of cardiac origin<br>• Myocardial infarction<br>• Heart failure<br>• Arrhythmias | **15:** pulmonary complications<br>• Pneumothorax<br>• Respiratory Insufficiency<br>• Atelectasis<br>• Respiratory depression |
| **4:** Pneumonia | **16:** Over-infusion |
| **5:** Bleeding<br>• Aneurysm<br>• Hematoma<br>• Dissection | **17:** Wound or fascia dehiscence |
| **6:** Shock | **18:** Thrombosis |
| **7:** Anastomotic dehiscence | **19:** (Wound) Infection<br>• Sepsis<br>• Poor wound healing<br>• Wound infection |
| **8:** Miscellaneous leakages<br>• Chylus<br>• Gall<br>• Wound | **20:** Bladder complications<br>• Retention<br>• Urinary tract infection<br>• Urethritis |
| **9:** Pressure ulcer | **21:** Fistula |
| **10:** Delirium | **22:** Vascular complications<br>• Phlebitis<br>• Cellulitis |
| **11:** Electrolyte derailment<br>• Hemodynamic instability<br>• Anaemia<br>• Hyperglycaemia<br>• INR derailment | **23:** Cerebral complications<br>• CVA<br>• Infarction<br>• Neuropraxia<br>• Neural compression |
| **12:** Gut complications<br>• Gastroparesis<br>• Ileus<br>• Derailed stoma output<br>• Ischemia of sigmoid | **24:** Other complications<br>• Kidney infarction<br>• Allergy<br>• Ascites<br>• Contractures<br>• Disturbed liver function<br>• Paresis<br>• Wrong K-wire<br>• Increased dislocation<br>• Rhabdomyolysis<br>• Addison's crisis<br>• Hernia<br>• Temporary hoarseness<br>• Small intestinal perforation<br>• Shunt occlusion |

**Table 2.** Patient characteristics in the 135 selected patients vs. all patients admitted in 2010.

| Characteristic | Included patients N=135 | Patients admitted in 2010 N=3252 |
|---|---|---|
| Male (%) | 82 (60.7%) | 1808 (55.6%) |
| Age (years): | | |
| Mean (SD[1]) | 59.3 (17.0) | 55.1 (18.0) |
| Median (IQR[2]) | 62.0 (47.5-71.8) | 57.6 (42.7-68.1) |
| Length of stay (days): | | |
| Mean (SD[1]) | 14.9 (27.6) | 7.9 (13.9) |
| Median (IQR[2]) | 8.0 (3.0–16.5) | 4.0 (1.0-9.0) |
| Underwent surgery: | 104 (70%) | 2276 (70%) |
| General | 22.4% | 26.2% |
| Oesophago-gastro-intestinal | 34.5% | 30.4% |
| Hepato-pancreato-biliary | 14.3% | 8.9% |
| Trauma | 11.3% | 20.6% |
| Vascular | 17.5% | 13.9% |
| ASA-classification[3]: | | |
| 1 | 6.8% | 24.2% |
| 2 | 72.7% | 45.6% |
| 3 | 13.6% | 26.0% |
| 4 | 6.8% | 3.3% |
| 5 | 0.0% | 1.0% |

1: Standard deviation

2: Interquartile range

3: ASA-class at admission of patients who underwent surgery

**Table 3.** Percentage and absolute numbers of patients with one or more adverse event as recorded in each resource, as compared with the reference standard.

| Resource | Patients with adverse event(s) |
|---|---|
| Reference standard | 98 (100%) |
| LHCR* | 84 (86%) |
| Morning hand-offs | 78 (80%) |
| Discharge letter | 76 (78%) |
| Medical file | 76 (78%) |
| Nursing file | 75 (77%) |

*: Dutch national surgical complication registry.

**Table 4.** Percentages and absolute numbers of adverse events as recorded in each resource, categorized per severity class.

| Severity class* | Reference standard | LHCR** | Morning hand-offs | Discharge letter | Medical file | Nursing file |
|---|---|---|---|---|---|---|
| **0** | 100% (11) | 73% (8) | 9% (1) | 18% (2) | 55% (6) | 64% (7) |
| **1** | 100% (221) | 44% (97) | 32% (71) | 38% (85) | 60% (132) | 67% (148) |
| **2** | 100% (31) | 81% (25) | 66% (20) | 77% (24) | 68% (21) | 58% (18) |
| **3** | 100% (9) | 89% (8) | 56% (5) | 22% (2) | 0% (0) | 0% (0) |
| **4** | 100% (3) | 100% (3) | 100% (3) | 67% (2) | 67% (2) | 33% (1) |
| **Total** | **100% (275)** | **51% (141)** | **36% (100)** | **42 % (115)** | **59% (161)** | **63% (174)** |

*: Severity classes:
0: event without adverse effect on health;
1: temporary health disadvantage recovering without (re)operation;
2: recovery after (re)operation;
3: (probably) permanent damage or function loss;
4: death.

**: Dutch national surgical complication registry.

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|---|---|---|
| **Results** | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed |
| | | (b) Give reasons for non-participation at each stage |
| | | (c) Consider use of a flow diagram |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders |
| | | (b) Indicate number of participants with missing data for each variable of interest |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) |
| Outcome data | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time |
| | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure |
| | | *Cross-sectional study*—Report numbers of outcome events or summary measures |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 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 done—eg analyses of subgroups and interactions, and sensitivity analyses |
| **Discussion** | | |
| Key results | 18 | Summarise key results with reference to study objectives |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |
| Interpretation | 20 | Give a cautious overall interpretation of results considering 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** | | |
| Funding | 22 | Give 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 |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

STROBE Statement—checklist of items that should be included in reports of observational studies

| | Item No | Recommendation |
|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found |
| **Introduction** | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses |
| **Methods** | | |
| Study design | 4 | Present key elements of study design early in the paper |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br>*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants |
| | | (*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study*—For matched studies, give matching criteria and the number of controls per case |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of 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 arrived at |
| 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, including those used to control for confounding |
| | | (*b*) Describe any methods used to examine subgroups and interactions |
| | | (*c*) Explain how missing data were addressed |
| | | (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed<br>*Case-control study*—If applicable, explain how matching of cases and controls was addressed<br>*Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy |
| | | (*e*) Describe any sensitivity analyses |

Continued on next page

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| Primary Subject Heading: | Surgery |
| Secondary Subject Heading: | Health services research |
| Keywords: | SURGERY, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Clinical audit < HEALTH SERVICES ADMINISTRATION & MANAGEMENT |
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|---|---|---|
| **Results** | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed |
| | | (b) Give reasons for non-participation at each stage |
| | | (c) Consider use of a flow diagram |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders |
| | | (b) Indicate number of participants with missing data for each variable of interest |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) |
| Outcome data | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time |
| | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure |
| | | *Cross-sectional study*—Report numbers of outcome events or summary measures |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 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 done—eg analyses of subgroups and interactions, and sensitivity analyses |
| **Discussion** | | |
| Key results | 18 | Summarise key results with reference to study objectives |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |
| Interpretation | 20 | Give a cautious overall interpretation of results considering 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** | | |
| Funding | 22 | Give 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 |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

STROBE Statement—checklist of items that should be included in reports of observational studies

| | Item No | Recommendation |
|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found |
| **Introduction** | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses |
| **Methods** | | |
| Study design | 4 | Present key elements of study design early in the paper |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br>*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants |
| | | (*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study*—For matched studies, give matching criteria and the number of controls per case |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of 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 arrived at |
| 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, including those used to control for confounding |
| | | (*b*) Describe any methods used to examine subgroups and interactions |
| | | (*c*) Explain how missing data were addressed |
| | | (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed<br>*Case-control study*—If applicable, explain how matching of cases and controls was addressed<br>*Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy |
| | | (*e*) Describe any sensitivity analyses |

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