Application of Information Technology ■

Integrating Incident Reporting into an Electronic Patient Record System

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Abstract Developments in information technology offer new opportunities to design electronic patient record systems (EPR) which integrate a broad range of functions such as clinical decision support, order entry, or electronic alerts. It has been recently suggested that EPR could support new applications for disease surveillance and patient safety. We describe the integration of a voluntary incident reporting system into an EPR used in operating theatres, to allow the reporting of accidents and preventable complications. We assessed system's reliability and users' acceptance. During the 4-years observation period (2002-2006), 48,983 interventional procedures were performed. Clinicians documented 85.1% of procedures on the incident reporting form. Agreement between chart review and electronically reported incidents was 80.6%. The integration of an incident reporting system into an EPR is reliable and well supported by health care professionals.

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Introduction

Electronic patient record systems (EPR) integrate an increasing number of functions. It has been recently suggested that EPR could support new applications for disease surveillance and patient safety.[1,2] We integrated a voluntary incident reporting system into an EPR used in operating theatres and assessed both its reliability and acceptance by health care professionals.

Background

EPR are widely used across countries and health care systems. In the United States, for example, 31% of hospital emergency departments have fully implemented EPR.[3] In the United Kingdom, 58% of primary care physicians use EPR.[4] In Norway, 77% of hospitals have purchased an EPR. Initially developed to collect, store, and retrieve clinical information into a digital format,[5] EPR have evolved and include clinical guidelines,[6,7] order entry,[8,9] clinical decision support[10,11] and electronic alerts.[12] By integrating information into comprehensive systems and allowing easy access to patient information, test results, drug information, published guidelines, and decision support algorithms, these systems provide greater accuracy, accessibility, and completeness of clinical information than their paper-based counterparts.[13]

It has been recently suggested that EPR could also be used for reporting purposes, including those that support disease surveillance and patient safety.[1,2] Currently, patient safety is largely monitored by mandatory or voluntary reporting systems. Incidents are reported on specific computerized or paper-based forms.[14,15] These are not integrated into EPR and require health care professionals to spend extra time and effort to complete forms or to log on to specific computer-based systems to report incidents. Furthermore, most declaration forms require users to fill in extensive sections of narrative free text and are therefore relatively cumbersome to use. This largely impairs the effectiveness of existing reporting systems. Currently, only 4.3% to 23% of the total number of incidents occurring in clinical settings are reported.[16–18]

These limitations could be potentially addressed by designing a standardized electronic incident reporting system which would be fully integrated into an EPR and include a large selection of predefined categories of incidents together with narrative fields. Incident reporting would be made easier, quicker, and more accessible.

Study Hypothesis

We hypothesized that an integrated reporting system designed with such characteristics, would provide an improved infrastructure for documenting critical incidents during surgical procedures and that it would lead to higher user acceptance rates. We describe the design, implementa-

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tion, and evaluation of an intraoperative incident reporting system integrated into an EPR used for the management of surgical inpatients.

Methods

System Description

The Alfred Hospital (Melbourne, Australia) is an adult university-affiliated hospital, with all types of medical and specialized surgical services, including neurosurgery, cardio-thoracic surgery (inc. heart and lung transplantation), and a level 1 trauma center. About 12,000 surgical inpatients are admitted every year for an interventional procedure. Before the procedure, the anesthetist in charge performs a full examination and preoperative assessment of the patient. The EPR is used to capture patient information such as patient demographics, past medical history, current health status, main diagnosis, co-morbidities, medication usage, and the American Society of Anesthesiologists (ASA) physical status score.[19] During the operation, information such as emergency status, surgical and anesthetic techniques, administered medications, duration of procedure, and postoperative complications are recorded. Until 1993, information was exclusively recorded on a paper-based form and integrated into patients' medical records. The form included several open free text fields for reporters to describe incidents and circumstances of events. At any time, anaesthesiologists could fill in these forms which were available in the department. Completed forms were collected by a senior staff member, secured in a drawer, and discussed during the weekly Mortality-Morbidity conference. On average, staff members filled in seven forms a week.

As part of an ongoing quality assurance (QA) program, the department of anesthesia developed an EPR for the management of surgical inpatients. It integrated all information relating to patient characteristics including past and current condition, medication usage, and preoperative risk factors; details on the anesthetic technique used, medication administered during the procedure, and postoperative complications were also incorporated. To enhance usability and accessibility, the EPR was integrated into a computerized network implemented in the operating and ambulatory suites as well as in the department of anesthesia.

Each computer was linked to a central database management system (MS-Access™, Microsoft Corporation, Seattle, WA) where data were checked, stored, and regularly saved on portable and hard drives. All medical and QA staff were instructed in the collection of data and also received a booklet of instructions and item definitions for the completion of the EPR and postoperative assessment. Data consistency and completeness was ensured by automatic checks implemented in the system to ensure comprehensiveness, plausibility, and integrity of all fields. For instance, the system did not allow an ASA score >6 to be entered or another gender than male or female to be recorded. Since 2002, blood tests results, x-rays, and other investigation results have been made available in all computerized workstations of the hospital. Future developments should see the addition of investigation and test results directly into the EPR to enhance its effectiveness as an integrated perioperative information management tool.

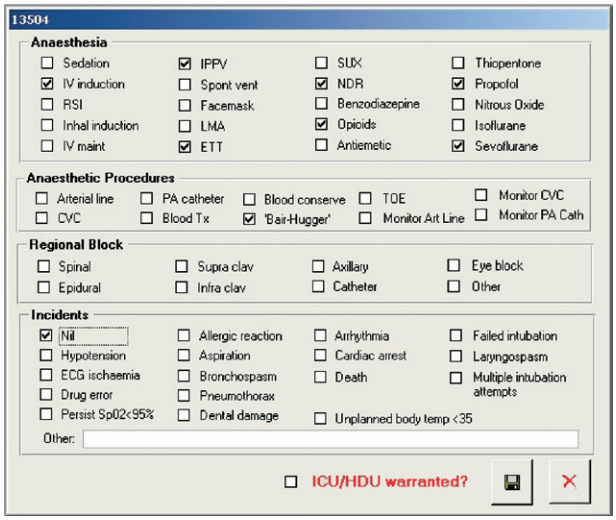

Figure 1. Integrated Incident Reporting Form

The incident reporting was implemented in the system in 1995. Following a consensus conference five board-certified anesthesiologists, one QA officer, an informatics officer, and a technician agreed on a list of incidents, defined as *unintended events or outcomes which could have, or did reduce the safety margin for the patient*.[20]

Prior to the system's implementation, we piloted the content with scannable forms. As a result, the initial list of incidents was reduced to 16 incident categories, deemed most frequent in anesthesia. A "no incident" category and a free text data entry field to record incidents that did not fit a predefined incident category were added. Staff members were requested to systematically use the "no incident" category if no adverse event had occurred during the intraoperative period.

We considered that the use of check boxes for pre-defined categories of incidents and a text box for narratives were the most appropriate user interface to ensure usability and accessibility.

The incident form allowed several incidents to be recorded at the same time. The reporting form was placed immediately below the intraoperative procedure form so that the graphical user interface would make the reporting form apparent each time the anesthetist would access the EPR to look up or record information (Figure 1). To encourage the use of the system, a computer workstation was installed in each operating theatre and office in the department of anesthesia. The fully implemented perioperative EPR integrated three different sections. One for the preoperative period with details on patient characteristics, past medical history, current health status, main diagnosis, co-morbidities, medication usage, and the American Society of Anesthesiologists (ASA) physical status score; one for the intraoperative period which included details on the anesthetic technique used, medication administered, and the incidents reporting form; and one for the postoperative period. The latter included mainly details on postoperative complications and patient satisfaction.

The anesthesiologist completes each section of the EPR for each patient, while in charge. For instance, information

regarding the preoperative period is completed during the preoperative visit (the day or week before) or before the beginning of the procedure, during the first encounter with the patient. The intraoperative section is filled in during or at the end of the surgical procedure. This also includes the completion of the incident reporting form. Staff members are, however, allowed to access the system at any time to complete missing information on the reporting form or any other section of the EPR. The recovery room and 24 hour follow-up section is completed after the procedure, during the postoperative follow-up visit. Any additional adverse event occurring during this period is recorded into the postoperative section of the EPR.

Access to computers is secured. EPR access requires a login and password and users need to enter a patient's unique identification number in order to record or review clinical information. All sections of the EPR can be accessed by both consultants and registrars of the department of anesthesia from the main access window. Once entered into the EPR, users can move from one section to another by choosing from a menu list the wanted section. Or they can select the "record" icon, at the bottom of the page (Figure 1). This will automatically open the next section of the EPR, in a new window.

For every procedure staff members are required to complete the pre-and intraoperative section of the EPR. The QA officer or anesthesiologists completing the daily postoperative follow-up visit are responsible for filling in the postoperative section. Staff members are encouraged to provide comments and suggestions for improvement. Regular feedback is provided to staff members regarding the overall use of the system.

Incidents are discussed during the weekly mortality-morbidity meeting on Friday afternoon. Staff members involved in the process usually describe the sequence of events and suggest a number of corrective strategies to avoid incidents occurring again. Incidents are also analyzed outside the mortality-morbidity meeting, as part of the departmental QA program.

System Evaluation

Following hospital ethics approval, we analyzed surgical inpatient data for the period between April 2002 and June 2006. First, we assessed the acceptance of the system by quantifying the overall usage of the incident reporting system. We measured the proportion of incident reporting forms filled (forms filled out with or without incidents reported) for all procedures performed on all patients, from the early introduction of the fully computerized system in 2002 to its latest update in 2006. Unfilled forms were identified as those where none of the incident categories were completed (predefined, free text, or "no incident" category).

Secondly, we assessed the relevance of combining both predefined categories and free text. We measured the specific utilization of each approach and analyzed the content of the free text section. The latter was examined for relevance with patient safety issues according to the definition of an incident used in the department[20] and for potential duplicates with predefined categories of incidents.

Table 1 ■ Characteristics of All Patients Recorded in the System

Patient Characteristics N=48,983	Number (%)
Age	
<41	15,956 (32.6)
41 to 64	15,946 (32.5)
>64	17,081 (34.9)
Gender	
Female	21,013 (42.9)
Male	27,970 (57.1)
ASA score*	
ASA 1	12,785 (26.1)
ASA 2	17,378 (35.4)
ASA 3	13,801 (28.2)
ASA 4	4,714 (9.6)
ASA 5-6	305 (0.7)
Surgical procedures	
Procedures on digestive system	14,182 (28.9)
Procedures on musculoskeletal system	10,367 (21.1)
Dermatologic and plastic procedures	5,521 (11.3)
Procedures on cardio-vascular and respiratory system	5,056 (10.3)
Procedures on nervous system	3,784 (7.7)
Procedures on urinary system and male genital organs	2,594 (5.3)
Procedures on ear, nose, mouth, pharynx	2,158 (4.4)
Procedures on female genital organs and breast	2,041 (4.2)
Miscellaneous procedures	1,383 (2.8)
Procedures on eye and adnexa	865 (1.8)
Procedures on mastoid process and dental services	616 (1.3)
Procedures on blood and blood forming organs	416 (0.9)
Timing and planning of procedures	
In- hours (7h–19h)	45,055 (92.0)
After-hours (19–7h)	3,928 (8.0)
Emergency	9,306 (19.0)

*Co-morbidity score used as a predictor of postoperative complications (ASA 1-low risk to ASA 5–6-major risk of death).

Finally, we assessed the reliability of predefined categories in our reporting system by measuring their level of agreement with incidents identified in medical charts by experts. This was done because the use of predefined categories of incidents compared to the narrative format of traditional incident reporting forms could potentially limit the number of events reported or even distort events by forcing classification into a predefined category and lead to reporting inaccuracies. An incident was considered to agree with the electronic system if it could also be identified in medical charts. It was defined as a disagreement with the electronic system if a) the incident recorded in the reporting system could not be identified in medical charts; or if b) the category "no incident" was selected on the reporting form but an incident could be identified in medical charts.

To limit biases associated with the assessment of narrative fields by unblinded reviewers, more likely to reinterpret free text according to study purpose, an early version of the reporting form with only predefined categories of incidents was used. Incidents reported into the EPR were compared to those identified following a peer review process of handwritten medical records. Two board-certified anesthesiologists who had previously participated in audits of clinical

Table 2 ■ Completion of Incident Reporting Forms for Surgical Procedures

Year*	Completed Forms N (% per year)	Empty Forms N (% per year)	OR for Non Filling Forms (95% Confidence Interval)	p-value
2002 to 2003	9,675 (87%)	1,443 (13%)	1.0 (reference)	1.00 (reference)
2003 to 2004	10,163 (83.4%)	2,028 (16.6%)	1.33 (1.24-1.43)	<0.001
2004 to 2005	9,805 (83.7%)	1,906 (16.3%)	1.30 (1.21-1.40)	<0.001
2005 to 2006	10,301 (86.6%)	1,588 (13.4%)	1.03 (0.95-1.11)	0.39
2006 . . .	1,734 (83.6%)	340 (16.4%)	1.31 (1.15-1.49)	<0.001

*From April to April, except 2006 from April to June.

practice, independently compared information from the patient's medical chart with incident reports from the EPR. Reviewers used a structured implicit review protocol that was specifically developed for the assessment of perioperative adverse outcomes by the Victorian Consultative Council on Anesthetic Mortality and Morbidity.[21]

Reviewers determined whether or not an incident had occurred intraoperatively, and classified incidents according to cause and preventability. An incident was defined as an *unintended events or outcome which could have, or did reduce the safety margin for the patient*.[20] Because there was some disagreement between reviewers [exact agreement 59.5%, kappa score 0.44 (0.39–0.48)], only incidents identified by both reviewers were considered. Reviewers were also blinded to the content of the computerized incident reporting form.

We analysed all patients with an unplanned admission to the Intensive Care Unit (UIA), a screening indicator developed to signal patients most likely to have suffered an incident and first used in the Harvard Medical Practice study.[22] This was done to avoid assessing the level of agreement of both systems on cases where no incident had happened.

UIA patients were all extracted from the EPR. This information was easily available as all patients are systematically seen within 24 hours following the end of their anesthetic procedure and any UIA occurring, systematically recorded.

Analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS Version 12.0.1, SPSS Inc, Chicago, IL). For descriptive statistics we used numbers and percents. For univariate analyses, we used chi-square, binary logistic regression, and odds ratio (OR) with 95% confidence interval (CI). The level of agreement, corrected for chance, was assessed by the Cohen Kappa score.[23]

Results

Acceptance

During the study period 48,983 patients having an interventional procedure under anesthesia were recorded into the system. The majority of patients (67.4%) were 41 years or older. The most frequent types of procedures were performed on the digestive (28.9%) and musculo-skeletal system (21.1%). There were 9,306 (19%) emergency procedures and 3,928 (8%) of these were performed after hours (Table 1).

System users, senior staff anesthesiologists, and trainees completed 41,678 (85.1%) computerized incident forms over the period of observation, from April 2002 to June 2006. Most of these forms (86.3%) reported no incident occurring. In the remaining forms (13.7%) one or several intraoperative incidents per procedure were reported. The proportion of uncompleted forms, following an initial increase, remained relatively constant throughout the period of observation, between 13% to 16.6% (Table 2).

Relevance

Predefined categories were most often preferred over free text. Among the 6,512 incidents occurring during the 217-week study, users selected a predefined category in 86.1% and documented events in free text in 13.9% of cases (Table 3). This represented altogether approximately 30 incidents per week. The relevance of the free text content for safety issues was very good. Only 19.8% of events reported in the free text section were not associated with patient safety. These related most often to organizational issues such as delay in transfers, unavailability of surgeons, or unscheduled procedures. Reporters also used this section to describe a special anesthetic or surgical technique used (e.g., fiber optic endo-tracheal intubations). All descriptions were very short, on average three to five words.

There were also a number of duplicates. 14.7% of incidents described in the free text section had also been selected in the predefined categories section. Most of the time this was done to provide more details on the circumstances of the incident selected in the predefined categories.

Reliability

The level of agreement between predefined categories and true events occurring was performed on the 201 patients with an unplanned admission to the intensive care unit. Their medical charts were assessed by the two reviewers. Thirteen (6.5%) charts had to be excluded from the analysis because of missing data that prevented any reliable assessment of medical charts. In the remainder, reviewers found 106 (56.4%) patients having an intraoperative incident. Of these, 68 (64.1%) patients had one incident; 29 (27.3%) patients had two incidents; 7 (6.6%) and 2 (2%) patients had four incidents and more, respectively. Incidents are described in Table 4.

There was a good level of agreement between incidents reported and those identified following the chart review process. 80.6% of incidents reported into the computerized

Table 3 ■ Content Analysis of Narrative Fields

Category	Incidents N=6,512 N (%)	Relevance with Definition	Duplicates
Predefined	5,603 (86.1%)	100% (reference)	0% (reference)
Narrative field	909 (13.9%)	80.2%	14.7%

Table 4 ■ Type of Incidents Reported

Type of Event	No. of Events
Hypotension (uncontrolled)	4,289
Other (mainly technical failures and complications of regional block techniques, fiber optic intubation, arterial or venous line insertion+ material defects)	909
Persistent oxygen saturation <95%	278
Difficult intubation with multiple attempts	215
Arrythmia (ventricular or supraventricular)	211
Body temperature below 35°C	145
Laryngospasm	142
ECG–Cardiac ischemia	62
Bronchospasm	62
Cardiac arrest	40
Death	36
Failed intubation	28
Aspiration	27
Allergic reaction	23
Dental damage	17
Iatrogenic pneumothorax	14
Drug error	14
Total	6,512

integrated form matched those events detected by reviewers in medical charts.

Disagreement between the reporting system and medical charts occurred in 19 patients (19.4%). In 14 patients (14.2%) an incident was recorded in the reporting system but no incident could be identified in medical charts by reviewers. In five patients (5.2%), incidents recorded did not correspond to those identified by reviewers. These discrepancies corresponded most often to cases of severe complications such as hypoxemia, shock, or hemorrhage which were reported as technical issues with intravenous lines or arterial catheters by staff members. The level of exact agreement between both systems was 75.5%, kappa 0.50 (95% CI 0.44–0.56) (Table 5).

Discussion

We found that the use of an incident reporting system that is integrated into an EPR was very high among health care professionals; 85.1% of the procedures performed had an incident reporting form filled. Most of these forms (84.5%) reported "no incident" occurring. In 15.5% of the remaining forms one or several intraoperative incidents were reported.

This level of reporting is significantly higher than the level usually reported in the literature, on average between 4.1% to 23%.[16-18] There are several reasons which can explain these differences. First, authors[16,17] find a low level of reporting for systems that use handwritten forms or verbal communication. This implies that reporters have to spend extra time completing forms or contacting the risk manager or quality assurance administrator to report incidents. A recent hypothesis emerging from qualitative investigations suggests that time constraints could play a major role in the level of incident reporting, particularly by physicians.[24,25] An incident reporting form integrated into the EPR which is used on a day-to-day basis by health care professionals does not require extra time to be completed. Incident reporting is largely facilitated. This may partly explain why we found a significantly higher level of reporting than other authors.[16,17]

Secondly, even when authors report the use of Web-based systems[18,26] which also include predefined categories of events and should be theoretically more convenient to use than paper-based forms, the level of reporting is still low (4.3% to 30.7%). This could be due to specific characteristics of the user interface design. Benson et al.[26] implemented a computerized incident reporting form with 89 different types of predefined categories of events. However, it has been demonstrated that the human short term memory processing has limitations and often obeys the "seven plus or minus two rule."[27] A list of incidents which does not exceed seven lines and seven incidents by line is much more likely to be processed effectively and appropriately than a long list of categories of events, displayed over several pages. In our system, we limited the different categories of incidents to 16 with two additional categories for "no incident" occurring and others not listed (narrative field) respectively. Predefined categories could be easily selected from a short list of events with a single mouse-click. Furthermore, the positioning of the reporting form in the EPR, immediately below the section for the recording of the anesthetic technique used and medication administered may have acted as a constant reminder for users that the reporting form should be completed. This may explain why Sanborn et al.,[18] despite the use of a short and computerized incident reporting form found only 4.1% of adverse events reported, as their form was located on another Web page.

The third reason for a higher level of reporting in our system when compared to current figures reported in the literature could be the strict control of the reporting system within professional boundaries. Our system was developed, implemented, and controlled by physician staff members of the department of anesthesia.

Although the system did not guarantee anonymity to reporters, almost none of the incidents reported were disclosed outside the department. Events were strictly managed within departmental boundaries by the anesthesia quality assurance officer and all staff members involved. Only

Table 5 ■ Level of Agreement between the Reporting System and Chart Review

	Incidents Identified in Medical Charts N=106			
Incident in reporting system N=98	Yes	No	Exact Agreement (Positive/Negative) (%)	Kappa (95% CI)
Yes	79	19	75.5	0.50 (0.44–0.56)
No	27	63	(77/73)	

exceptional sentinel events such as wrong side procedures or death in operating theatre required notification to hospital administrators and risk managers.[28] This may decrease fear of litigation, a barrier to incident reporting.[14]

The fourth reason could be the regular feedback provided to staff members on the use of the system and the weekly discussions on some of the incidents during the weekly departmental mortality-morbidity conferences. This may increase staff members' recognition of the utility and efficiency of the reporting system.

Finally, the impact of a positive reporting culture has also to be discussed. If staff members reporting incidents know that their report will be used as a quality improvement tool and not as a punitive method, the level of voluntary reporting will significantly increase.[29] In our department, reported incidents are used on a regular basis to stimulate discussions during the weekly mortality-morbidity conferences and are considered as a helpful tool to improve practice and to learn from mistakes. This certainly contributes to enhance the reporting culture in the department and the use of our system. However the major benefits seemed to result from the reporting system design itself. Before its implementation the number of incidents reported on traditional paper-based forms was, on average, seven per week. After 2002 and during all the years following its full implementation, the level of reporting was four times higher, on average 30 incidents a week.

We also found that the integrated reporting system had a good level of relevance and reliability. Only 19.8% of events reported in the free text section were not related to patient safety. Also, 80.6% of the predefined categories of incidents reported matched those identified by reviewers in medical charts. This shows that allowing part of the reporting to be performed on preselected categories of events does not impact on the reliability of the information provided. There are several reasons to explain this phenomenon. First, major incidents occurring during anesthesia were defined following a large comprehensive consensus process which involved a large number of staff members of the department. This resulted in a large number of potential incidents occurring to be discussed and the most pertinent to be carefully selected. The end result was a comprehensive catalogue of anesthetic incidents made available for discussion and the most relevant ones to be listed. Secondly the use of an open-ended field, allowed the remaining non-listed events to be reported. Finally, regular feedback provided to staff members allowed categories to be modified and others to be added or deleted, as required.

There are a number of limitations to this study. First, the EPR and its integrated reporting form were mainly used by anesthesiologists for patient management during the perioperative period. Because of confidentiality, interoperability, and portability issues, its use was limited to departmental boundaries. Its effectiveness and reliability at a hospital level is therefore unclear. However there is no reason to suspect that the four-fold increase in the level of reporting we observed in our department, after the implementation of the new system, could not be observed in other hospital settings.

Secondly, to assess the level of adherence, we used all categories of incidents, including the "no incident" category. However, for various reasons anesthesiologists may have chosen to tick the category "no incident" while an incident had actually occurred. This may have led to an ambiguous interpretation of the true level of adherence to reporting practices. This is why we assessed the level of agreement between the reporting system and medical charts. We found that a large amount of incidents documented in the medical record were actually reported on the EPR.

Thirdly, to assess the level of agreement between events notified in the reporting system and medical charts, we used a screening method to select charts most likely to include undesirable events. We chose patients with an unplanned admission to the ICU. While increasing the efficiency of the chart review process this may have introduced a selection bias of charts likely to include those adverse events classified within the predefined categories of incidents of the reporting system. This may have falsely increased the level of matching between both measurement methods, as the presence of one incident in the reporting system which would match one of those found by reviewers would be considered as a proof of agreement. To account for this potential bias, we restricted the definition of incident in medical charts to those events identified by both reviewers.

Fourth, 19.4% of incidents reported did not match those identified by reviewers in medical charts with a level of agreement beyond chance (the kappa score) of 0.50 (95%CI 0.44–0.56). This may be due to the use of chart review as a reference or gold standard to assess reliability of the reporting system. Limitations of this method are well known,[30] particularly the low level of agreement between reviewers regarding the presence of adverse events and suboptimal care.[31,32] As we considered incidents which were only identified by both reviewers in medical charts (full agreement), a number of events truly occurring and identified by only one of the two reviewers were excluded. This resulted in a number of incidents measured in medical charts not to be considered for the analysis and leading to a lower level of agreement between both systems than could have been expected.

Conclusions

The integration of an incident reporting system into an EPR used on a day-to-day basis by clinicians significantly increases the number of incidents reported compared to figures reported in the literature. The use of both predefined categories of incidents and free text provides a flexible and accurate solution for incident reporting by busy clinicians.

This report opens new perspectives on the design of incident reporting systems to which health care professionals are more likely to adhere than the ones currently used. Future development should consider more often the use of fully integrated systems.

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