Automated detection of harm in healthcare with information technology: a systematic review

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ABSTRACT

Context To improve patient safety, healthcare facilities are focussing on reducing patient harm. Automated harm-detection methods using information technology show promise for efficiently measuring harm. However, there have been few systematic reviews of their effectiveness.

Objective To perform a systematic literature review to identify, describe and evaluate effectiveness of automated inpatient harm-detection methods.

Methods Data sources included MEDLINE and CINAHL databases indexed through August 2008, extended by bibliographic review and search of citing articles. The authors included articles reporting effectiveness of automated inpatient harm-detection methods, as compared with other detection methods. Two independent reviewers used a standardised abstraction sheet to extract data about automated and comparison harm-detection methods, patient samples and events identified. Differences were resolved by discussion.

Results From 176 articles, 43 articles met inclusion criteria: 39 describing field-defined methods, two using natural language processing and two using both methods. Twenty-one studies used automated methods to detect adverse drug events, 10 detected general adverse events, eight detected nosocomial infections, and four detected other specific adverse events. Compared with gold standard chart review, sensitivity and specificity of automated harm-detection methods ranged from 0.10 to 0.94 and 0.23 to 0.98, respectively. Studies used heterogeneous methods that often were flawed.

Conclusion Automated methods of harm detection are feasible and some can potentially detect patient harm efficiently. However, effectiveness varied widely, and most studies had methodological weaknesses. More work is needed to develop and assess these tools before they can yield accurate estimates of harm that can be reliably interpreted and compared.

INTRODUCTION

It is widely recognised that harm caused by the healthcare system is a major source of morbidity and mortality in hospitalised patients.[1] An estimated 15 million instances of medical harm occur in the USA every year.[2] However, the lack of simple, practical and accurate methods to identify adverse events in hospitals has hampered efforts to develop routine monitoring systems, assess the impact of interventions to prevent harm and compare interhospital performance.

Detecting incidence and types of patient harm are prerequisites for implementing strategies to prevent harm. Manual, comprehensive chart review by trained professionals has been used in key studies and can be considered the gold-standard harm-detection method.[3–6] However, this approach requires time and trained abstractors, thereby decreasing its feasibility as a pragmatic method for routine measurement of adverse events.

Several organisations are currently using the Institute for Healthcare Improvement's Global Trigger Tool, which is based on manual chart review, and allows targeted chart review to identify harm more efficiently than comprehensive chart review and more extensively than voluntary reporting of harm.

Automated strategies of harm detection that use computerised methods to scan patient records may require fewer time and personnel resources than traditional methods, and can potentially provide real-time surveillance alerts. We performed this review to: (1) identify types of automated methods of inpatient harm detection described in published literature, (2) describe types of events identified by these methods and (3) evaluate accuracy of these methods in identifying harm. We also independently evaluated the quality and validity of key studies.

METHODS

Definitions

In this review, we used the terms harm, automated harm detection and gold standard chart review as defined in Box 1.

Data sources/study selection

We (MG and AVC) identified articles for this review through a literature search of MEDLINE (start date 1950) and CINAHL (start date 1982) using the following search terms: (harm OR adverse event OR adverse drug event OR nosocomial infection) AND (automated OR computerised OR electronic) AND (identify OR detect OR detection OR recognise OR recognition). We identified additional articles using bibliographic review of key articles, the 'related articles' feature of Medline, and the 'find similar' and 'find citing articles' feature of CINAHL. We reviewed the title and abstract of each article, and obtained the full text of relevant articles. We limited our search to English language articles indexed through 31 August 2008.

We included studies that: (a) occurred in an inpatient setting, (b) described an automated harm-detection method, (c) measured actual harm and (d) compared the automated method to an alternative method of harm detection.

Box 1 Definitions

Harm
Poor patient outcome resulting from medical care rather than the natural history of the disease, whether or not it was preventable. This term includes adverse medical events (ie, falls, nosocomial infections), adverse drug events and adverse surgical events (ie, postoperative infections, surgical complications). It excludes medical errors that did not result in injury to patients.

Automated harm-detection method
A method of rapidly searching a large number of patient medical records with a computerised tool to identify actual harm, or indicators (associations) of harm. Records and events identified through computerised screening may then be subjected to further scrutiny by electronic or manual means to verify harm. We defined two degrees of automation: (1) fully automated methods, in which identification of harm was not followed by further chart review, and (2) partially automated methods, in which identified patient records were manually reviewed to verify harm.

Gold standard chart review
Manual review of the medical record initially by trained personnel, with subsequent review by either a physician or clinical pharmacist to confirm the presence or absence of harm and characteristics of such harm.

Data extraction and analysis

We developed and tested a standardised data form and extracted the following variables from included articles: details of patient sample, methodology used for automated harm detection, nature of events identified, description of alternative method of harm detection and comparisons of events detected by automated and alternative methods. Data were extracted by MG and AVC, with uncertainties resolved by discussion and consensus.

We critically appraised each study that compared the automated method of harm detection to a gold standard chart review using published criteria for validity of diagnostic test studies.[7] We assessed each study for: (a) independent, blind comparison of the automated method with a gold standard method, (b) performance of the gold standard assessment regardless of the automated method's results and (c) validation of the assessment in a second, independent set of patients.

If studies provided adequate data, we independently calculated the sensitivity, specificity and positive and negative predictive values of the automated harm-detection method.

RESULTS

Selection of articles

One hundred and seventy-six articles were reviewed for potential inclusion, of which 43 provided information on validity of automated methods of harm detection.[8–50] The remaining articles were excluded because they: were review articles on harm-detection methodologies (n=9)[51–59]; did not focus on detection of harm (n=26) or automated methods (n=22); did not include a comparison group (n=17); were not limited to inpatients (n=13); were descriptive papers of a program, incident reporting system, algorithm or computer simulation (n=33); were commentaries or editorials (n=11); or were repeat publications (n=2).

The methodologies and results from the 43 included studies are described in online appendix 1. Of these, 14 studies compared the automated harm-detection methodology to a gold standard chart review, and their methods and results are summarised in tables 1, 2.

As shown in online appendix 1, 20 studies were conducted among adult populations, three in paediatric patients, two among all age groups, one in geriatric patients, one among Medicare beneficiaries and one among patients 14 years and older. The most common hospital settings were general medical units (n=14), followed by general surgical units (n=8), medical, surgical or general intensive care units (n=8), medical subspecialties (n=3), neonatal and paediatric intensive care units (n=3) and obstetric units (n=2). The target population and setting were unstated in 15 studies.

Data sources for automated harm-detection methods

Automated harm-detection methods were classified into field-defined and natural language-processing systems. Field-defined systems relied on computerised detection using pre-existing numeric or coded data stored in medical records. Natural language processing relied on computerised analysis of free text within a medical record to detect language indicative of harm. Field-defined and natural language-processing systems are described in table 3.

Forty-one of 43 studies used field-defined systems for automated harm detection. The nature of the programs, databases used, data fields used and types of harm detected within this category were source-specific. Typical sources of data for field-defined programs included laboratory, radiology, microbiology, pharmacy, and administrative and billing databases. Five of 43 studies used natural language-processing systems. The most common source of data was discharge summaries. Radiology reports, chart text, daily progress notes, consultation notes, nursing records, and procedure or operative reports also were used.

Degree of automation

Twenty-five studies (58%) reported on detection tools that were partially automated,[8–14 21–25 31 32 34–38 40 45–48 50] 14 studies (33%) described fully automated tools,[15–17 19 26–30 33 41 42 44 49] and one study (2%) reported both fully and partially automated systems.[20] The degree of automation was unclear in three reports (7%).[18 39 43]

Types of events identified

Automated methods for detecting harm predominantly focused on identification of adverse drug events (ADEs) (n=21, 49%).[11 12 18 21–26 29–32 35–38 43 45 50] Ten automated methods (23%) focused on general adverse events,[8–10 19 33 34 40 46–48] eight (19%) focused on nosocomial infection,[14 20 28 39 41 42 44 49] and four (9%) focused on other specific adverse events (eg, decubitus ulcers, surgical complications).[13 15 17 27]

Accuracy of automated harm-detection methods

Only 14 studies[15 17 18 20 22 23 26 30 32–34 44 47 48] compared an automated harm-detection method with 'gold-standard' adverse event detection and were eligible for critical appraisal of validity (table 2). Methodologies used to evaluate these automated systems were heterogeneous. Seven studies (50%) applied the gold standard using independent, blind evaluators. Eight studies (57%) applied the gold standard independently of the outcome from the automated method. One study (7%) validated the results of the automated method in an independent, second set of patients.

Table 4 shows the sensitivity, specificity, and positive and negative predictive values of the automated methods that were

Table 1 Summary of studies comparing automated harm-detection methods with gold standard chart review

Reference	Patient sample and time frame	Sampling strategy*	Specialty	Events identified	Automated event dataset sample size	Comparison event dataset sample size
Field-defined						
Nebeker *et al*[18]	Adults 2001 and 2003	Random	Unknown	Adverse drug events	3987 admissions	3987 admissions
Zhan *et al*[17]	Medicare benefic. 2002 to 2004	Random	General Surgery	Adverse event: specifically postoperative deep venous thrombosis and/or pulmonary embolism	20 868 hospital discharges identified as surgical patients	20 868 hospital discharges identified as surgical patients
Brossette *et al*[44]	Unknown 1–3 Dec 2003 and 26–29 Apr 2004	Sequential	Unknown	Infection	907 admissions	907 admissions
Hougland *et al*[30]	Adults 1 Jan 2001 to 31 Dec 2001	Random, Flagged sample (from records with at least one flagged adverse drug event code)	Unknown	Adverse drug events	3103 inpatients: 1961 random, 1142 flagged	Unknown
Polancich *et al*[15]	Unknown	Unknown	Unknown	Hospital acquired decubitus ulcers	Unknown	123 charts from patients with PSI-identified decubitus ulcers
Dormann *et al*[26]	Adults 1 Sept 2000 to 28 Feb 2001	Sequential	Gastroenterology	Adverse drug events	474 admissions of 377 patients; 109 ADEs	474 admissions of 377 patients; 109 adverse drug events
Trick *et al*[20]	Adults 1 Sept 2001 to 28 Feb 2002	Sequential	Unknown	Infection	135 positive blood cultures	144 positive blood cultures
Levy *et al*[23]	All age groups 1 Apr 1997 to 31 May 1997	Sequential	General Medical	Adverse drug events	199 admissions (192 patients)	199 admissions
Azaz-Livshits *et al*[22]	All age groups 1 Apr 1995 to 31 May 1995	Sequential	General Medical	Adverse drug events	153 admissions	153 admissions
Jha *et al*[32]	Adults 1 Oct 1994 to 31 May 1995	Sequential	MICU, SICU, General Medical, General Surgical	Adverse drug events	21 964 patient-days	21 964 patient-days
NLP						
Penz *et al*[47]	Adults 1 Jun 1999 to 31 Dec 2004	Sequential	MICU, SICU and other (placement of CVC)	Adverse events related to central venous catheter placement	316 patient records	40 patients records (10 very low probability† records, 30 high probability)
Forster *et al*[34]	Adults FY 2002	Random	General Medical, General Surgical	Adverse event	245 patients	245 patients
Melton and Hripcsak[48]	Unknown 1996–2000	Random (charts), Sequential (electronic discharge summaries)	Unknown	Adverse events: specifically 45 NYPORTS event types	1000 charts, 57 422 electronic discharge summaries	1000 charts
Murff *et al*[33]	Adults 1 Jan 2000 to 30 Jun 2000	Random (Cohort 1), Sequential (Cohort 2)	General Medical, Medicine subspecialties	Adverse drug events, adverse events, diagnostic errors, operative complications, falls	Cohort 1: 424 admissions. Cohort 2: 2826 admissions	Cohort 1: 295 Cohort 2: 145 Complex sampling/ subsampling and manual review process

*Sampling strategy refers to the method by which charts were chosen to be screened by the automated tool. Unless specifically noted, the same sampling strategy also applies to the gold standard method.
†A scoring system was developed by the authors to reflect the probability of the adverse event in question relating to the central venous catheter placement. This system is described in the text and in table 1 of the paper.
CVC, central venous catheter; MICU, Medical Intensive Care Unit; NYPORTS, New York Patient Occurrence Reporting and Tracking System; PSI, patient safety indicators; SICU, Surgical Intensive Care Unit.

Table 2 Evaluation of validity of studies comparing automated method to gold standard chart review

Reference	Strategy of event identification	Degree of automation*	Automated method source of data	Comparison method source of data	Gold standard applied by independent, blind reviewer?	Gold standard applied regardless of automated outcome?	Study method applied to independent patient set?	Comments
Field-defined								
Nebeker *et al*[18]	Computer algorithms	Chart review for study, unclear if strategy aims to be Full or Partial	ICD-9 CM codes	Medical record	Yes	Yes	No	Study used Hougland *et al*[30] methodology to specifically apply HOCTA (hierarchically optimal classification tree analysis) to administrative data to develop surveillance rules for the identification of ADEs manifesting as either bleeding or delirium. Requires expert computer programming.
Zhan *et al*[17]	Patient Safety Indicators	Full	ICD-9 CM codes	Medical record	Unknown	Unknown	No	DVT/PE events flagged by ICD-9 CM codes were compared with those discovered by gold standard chart review. The sample studied was a random sample abstracted by the Medicare Patient Safety Monitoring System.
Brossette *et al*[44]	Nosocomial Infection Marker	Full	Medical record and Lab database	Medical record	Yes	Yes	No	Nosocomial Infection Marker (NIM) program by Med Mined, Birmingham, Alabama. Took about 10 min/week to maintain. Total time for NIM: 2 h/10 000 admissions, compared with medical record review at 1.5 full time employees per 10 000 admissions.
Hougland *et al*[30]	Automated ICD-9 code strategy	Full: Review of flagged charts here for study purposes	ICD-9 CM codes	Medical record	Yes	Yes	No	Expert panel identified 416 ICD-9 CM codes to represent ADEs (flagged ADEs). Then chart review performed to ascertain codes' ability to detect/identify ADE.
Polancich *et al*[15]	Patient Safety Indicators	Full	Administrative data, Billing data, ICD-9 CM diagnosis and procedure codes	Medical Record	No	No	No	Designed to test validity of Agency for Healthcare Research and Quality (AHRQ) PSIs for detecting hospital acquired decubitus ulcers. Only a sample of cases was manually reviewed.
Dormann *et al*[26]	Automated laboratory signal detection	Full	Demographics, History, Lab findings, Drugs, & Diagnosis	Medical record	Unknown	Unknown	No	Used automated lab signals (ALS) and changes in ALS to identify ADEs. Automated system used to flag potential ADEs, which were then sent as an alert to physicians. Use of delta ALS (change) resulted in improvement over Dormann *et al*'s[25] methodology.
Trick *et al*[20]	Computer algorithm	Full and Partial	Medical record; Lab, pharmacy, & radiology database; Microbiology	Medical record; Lab, pharmacy, & radiology database; Microbiology	Yes	Yes	No	Comparison of manual and computer assisted bloodstream central venous catheter infection surveillance using data from two hospitals. Different computer algorithms developed for full or partial automation were tested.
Levy *et al*[23]	Automated laboratory signal detection	Partial	Lab database	Lab database and clinical data	Unknown	Yes	No	Implementation of the pilot program described in Azaz-Livshits *et al*.[22] Computerised lab data monitored to detect ADEs using the same signals as the pilot study.
Azaz-Livshits *et al*[22]	Automated laboratory signal detection	Partial	Lab database	Lab database and clinical data	Unknown	Yes	No	Pilot program to develop and assess computerised laboratory data as a detection tool for ADE in 34-bed medical ward in Jerusalem, Israel. Lab signals generated by computer, then verified by team. Limited computerised patient data at this hospital; however lab data were fully electronic. Cost of this system reasonable compared with costs of ADEs.

Continued

Table 2 Continued

Reference	Strategy of event identification	Degree of automation*	Automated method source of data	Comparison method source of data	Gold standard applied by independent, blind reviewer?	Gold standard applied regardless of automated outcome?	Study method applied to independent patient set?	Comments
Jha *et al*[32]	Automated triggers	Partial	Medical record	Medical record	Yes	Unknown	No	Study of computer-based ADE identification using modified Classen 1991[8] rules to create automated triggers with which the electronic record was screened. Rules modified during the study to increase PPV, and new rules created. Trained reviewer and physician were blinded to detection method. 11 person-hours per week for automated method versus 55 for chart review and 5 for voluntary reporting.
NLP								
Penz *et al*[47]	Computer algorithms & Natural Language Processing	Partial	Text records: Daily progress notes; Consultation, Nursing, and Procedure notes; Operative reports; Discharge summaries	Text records: Daily progress notes; Consultation, Nursing, and Procedure notes; Operative reports; Discharge summaries	No	No	No	Compared two methods for semiautomated review of text records within the VA database using NLP (MedLEE) and a phrase matching algorithm (PMA). Limited by incomplete or inaccurate documentation, incomplete coding, spelling errors, and sentence structure abbreviations. Time/technology intensive.
Forster *et al*[34]	Computerised screen for trigger words in free text	Partial	Discharge summaries	Discharge summaries	Yes	Yes	No	Automated adverse event lexicon made up of 104 terms used by Murff *et al*.[33] Computerised search engine scanned discharge summaries (dtsearch desktop) to detect potential harm. Specificity higher for non-elective admissions and discharge summaries dictated by residents/staff versus medical students. Automated detection reduced physician time by one-fifth.
Melton and Hripcsak[48]	Natural Language Processing	Partial	Discharge summaries	Full electronic chart; combined electronic chart and paper chart for a subset of 100 patients	No	No	No	Natural Language Processing system (MedLEE) to identify 45 NY Patient Occurrence Reporting and Tracking System event types. Chart review by physician and independent informatician of random sample of 1000 charts to assess performance of NLP program. Results biased towards patients with electronic discharge summaries. This method is technologically intensive.
Murff *et al*[33]	Computerised screen for trigger words in free text	Full (goal is a fully automated system, manual review of subsamples performed for study)	Discharge summaries	Medical record (not otherwise specified)	Yes	Yes†	Yes	Brigham and Women's Hospital, using Brigham Integrated Computer system. Computerised screening tool searched free text discharge summaries for trigger words indicating possible adverse events. List of automated trigger words compiled using Harvard Medical Practice Study definitions as base. Electronic method alone versus electronic plus manual review compared for two cohorts. Reviewers blinded to whether screening tool had identified the admission.

ADE, adverse drug event; AE, adverse event; DVT, deep venous thrombosis; NLP, natural language processing; PE, pulmonary embolism; PPV, positive predictive value; PSI, patient safety indicators; VA, Veterans Administration.
*We define fully automated methods as those where the identification of harm was not followed by further chart review, and partially automated methods where patient records flagged by the automated detection of potential harm (eg, 'trigger') were manually reviewed to verify harm.
†Authors manually reviewed a random 25% sample of screened-negative charts, then used this random sample to estimate the number of adverse events occurring in entire set of screened-negative charts.

Table 3 Description and classification of field-defined and natural language processing systems for automated detection of harm*

Automated method	Data source used	Events identified	Comments
Complications Screening Program (CSP)[8–10 46]	ICD-9 CM codes	Adverse drug events, adverse surgical outcomes, infections, and miscellaneous complications such as falls	A computerised method for identifying potentially preventable complications of hospital care.
Health Evaluation through Logical Processing (HELP)[11–14]	Electronic Medical Record: specifically including pharmacy, laboratory, radiology and surgery records	Adverse drug events, adverse medical device events, infection	Integrated electronic medical record of the LDS Hospital in Salt Lake City, Utah, which contains an interactive modular knowledge base that continually analyses information
Patient Safety Indicators (PSI)[15–17 46]	Administrative data: billing information, ICD-9 CM diagnosis codes and procedure codes	Adverse events	A fully automated method developed by the Agency for Healthcare Research and Quality
Computer algorithms[18–21]	Electronic Medical Record: components specific to the particular program: see online appendix 1	Adverse events, adverse drug events, infection	Specific, named computer programs
Lab signal detection tools[22–26]	Laboratory Database	Adverse drug events	Automated tools search for key words or word combinations that signal potential or actual harm—for example, detection of elevated potassium levels
ICD-9 CM or billing code detection tools[27–30]	Administrative data: ICD-9 CM or billing codes	Adverse drug events, infections, surgical complications	Automated tools scan for diagnosis, discharge, or billing codes that signal potential or actual harm—for example, evidence of antibiotic exposure following a postoperative infection
Tools using computerised triggers[31–45 50]	Electronic Medical Record: multiple sources such as pharmacy, laboratory, and microbiology databases	Adverse events, adverse drug events infection	Automated tools using multiple triggers to signal actual or potential harm—for example, detection of elevated potassium levels (laboratory database) combined with certain medication administration (pharmacy database). Among the various tools included in this category, there are four named systems: Dynamic Pharmaco-Monitoring System, Nosocomial Infection Marker, Event Detector, New York Antimicrobial Resistance Project.
Natural language processing systems[33 34 47–49]	Free text in the Electronic Medical Record: discharge summaries, radiology reports, chart notes	Adverse events, infection	Sophisticated programs that 'read' free text via the application of computer logic

*Multiple detection strategies were used in several studies, including those that combined two or more field-defined systems,[46] two natural language-processing systems,[47] and both a field-defined and natural language-processing system.[33 34]

Table 4 Accuracy of automated methods for event identification*

Reference	Events identified by automated harm-detection method	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
Field-defined					
Nebeker *et al*[18]	Calculated separately for bleeding/ anticoagulation ADEs and delirium ADEs	Bleeding: 0.86† Delirium: 0.94†	Bleeding: 0.89† Delirium: 0.71†	Bleeding: 0.12† Delirium: 0.03†	NA
Zhan *et al*[17]	DVT Cases	0.67 (0.58 to 0.76)	NA†	0.31 (0.25 to 0.37)	NA†
	PE cases	0.74 (0.59 to 0.90)	NA†	0.24 (0.16 to 0.33)	NA†
	DVT/PE Cases	0.68 (0.60 to 0.76)	NA†	0.29 (0.24 to 0.34)	NA†
Brossette *et al*[44]	Hospital-wide nosocomial infection	0.88†¶	NA†¶	0.78	NA
Hougland *et al*[30]	Codes for inpatient ADE	0.10 (0.63 to 0.14)	0.97 (0.96 to 0.98)	0.32 (0.22 to 0.43)	0.89 (0.88 to 0.91)
Polancich *et al*[15]	Patients with decubitus ulcers	NA†	NA†	0.50 (0.42 to 0.59)	NA†
Dormann *et al*[26]	ADR positive admissions using NEW ALS	0.91	0.23	0.18‡	0.93
	ADR positive admissions using DELTA ALS	0.41	0.76	0.25‡	0.87
Trick *et al*[20]	Hospital-acquired episodes of primary CVC associated bloodstream infections	0.81†	0.72†	0.62†	0.87†
Levy *et al*[23]	Admissions	0.63 (0.51 to 0.74)	0.42 (0.34 to 0.51)	0.34 (0.25 to 0.42)	0.70 (0.60 to 0.80)
Azaz-Livshits *et al*[22]	Admissions	0.66 (0.51 to 0.81)	0.51 (0.42 to 0.60)	0.31 (0.21 to 0.41)	0.82 (0.73 to 0.91)
Jha *et al*[32]	ADE	NA†	NA†	0.16§ (0.16 to 0.19)	NA†
NLP					
Penz *et al*[47]	Cases	PMA: 0.70 † NLP: 0.50 † Combination: 0.72†	PMA: 0.55 † NLP: 0.91 † Combination: 0.80†	PMA: 0.41† NLP: 0.71† Combination: 0.64†	PMA: 0.8† NLP: 0.8† Combination: 0.85†
Forster *et al*[34]	Patients	0.23 (0.11 to 0.35)	0.92 (0.88 to 0.96)	0.41 (0.22 to 0.59)	0.83 (0.78 to 0.88)
Melton *et al*[48]	Cases	0.28 (0.16 to 0.40)	0.98 (0.97 to 0.99)	0.47 (0.30 to 0.64)	0.96 (0.95 to 0.97)
Murff *et al*[33]	AE	Fully automated: 0.69 (0.62 to 0.75) Partially automated: 0.64 (0.56 to 0.70)	Fully automated 0.48 (0.42 to 0.55) Partially automated: 0.85 (0.80 to 0.90)	Fully automated: 0.52 (0.46—0.58) Partially automated: 0.78 (0.72—0.85) (cohort 1), 0.84 † (cohort 2)	Fully automated: 0.65 (0.58—0.72) Partially automated: 0.74 (0.69—0.79)

*95% CIs for independently verified values reported in parentheses.
†Denotes figures that we could not independently verify.
‡Dormann *et al*[26] defined the positive predictive value (PPV) as the number of alerts associated with adverse drug reactions (ADRs) out of the total number of alerts. Using this criteria, they found the following PPVs: New automatic laboratory signals (ALS) (574/2328) 25%; Delta ALS (189/580) 32%.
§Jha *et al*[32] report a range of PPVs based on the first and final 8 weeks of data collection (0.16 and 0.23, respectively). We were able to independently verify the PPV for the first 8 weeks of the study only.
¶Brossette *et al*[44] reported a sensitivity of 0.86 and a specificity of 0.98. It is unclear how they identified true negative screens.
ADE, adverse drug event; AE, adverse event; CVC, central venous catheter; DVT, deep venous thrombosis; NLP, natural language processing; PE, pulmonary embolism; PMA, phrase matching algorithm.

compared against a gold standard chart review. Sensitivities of different methods ranged from 0.10 to 0.94, and specificities ranged from 0.23 to 0.98. Positive predictive values ranged from 0.03 to 0.84, and negative predictive values ranged from 0.70 to 0.96. Our independent assessment of validity allowed us to verify all published values for nine of the 14 studies that reported validity data.[15 17 22 23 30 33 34 48] Figure 1 displays the sensitivity and 1-specificity intersection points of methods used in these studies in a format similar to that of a receiver-operating characteristic curve.

DISCUSSION

Strategies to improve patient safety require efficient and accurate detection of patient harm. Automated methods of harm detection have been used for this purpose because they offer the potential to rapidly scan patient records with minimal human effort. This systematic review describes types of automated methods of harm detection used in inpatient settings, events identified by these methods and their accuracy.

We found two categories of automated harm detection described in the literature: field-defined systems (used in most studies) and natural language-processing systems. Most frequently laboratory, pharmacy and administrative databases were used to identify adverse drug events, general adverse events and nosocomial infections.

We found that the validity of studies describing automated harm-detection methods was variable. Of these studies, those attempting to identify ADEs [18 30] and nosocomial infections[20 44] using field-defined methods, and one attempting to identify multiple types of adverse events[33] using natural language processing satisfied more validity criteria than others. We believe that automated harm-detection methods will have more validity if they attempt to identify events that are discrete, easily and reliably detected, and consistently documented in the chart, such as adverse drug events, nosocomial infections, pressure ulcers and postoperative complications.

Automated harm detection has the potential to positively impact clinical practice. While most automated methods retrospectively identified harm, eight were paired with real-time surveillance alerts that informed physicians or pharmacists of an adverse event. Such prospective surveillance systems can alert the clinical team of impending or ongoing harm, thus allowing early intervention to limit harm. Real-time alerts were present within methods for detecting adverse drug events,[11 21 23 26 35 45] general adverse events[40] and nosocomial infection.[14] Automated alerts were a component of the Health Evaluation through Logical Processing system[11 14] and were incorporated within methods using automated lab signal detection,[23 26 45] computer algorithms[21] and other automated triggers.[35 40]

Another potential benefit of automated detection is the reduction of person-hours required for harm surveillance. Few studies[14 21 22 32 34 38 40 44] provided information on financial or human resource requirements for implementing and maintaining automated detection tools. In general, the automated methods reviewed here require fewer person-hours than manual

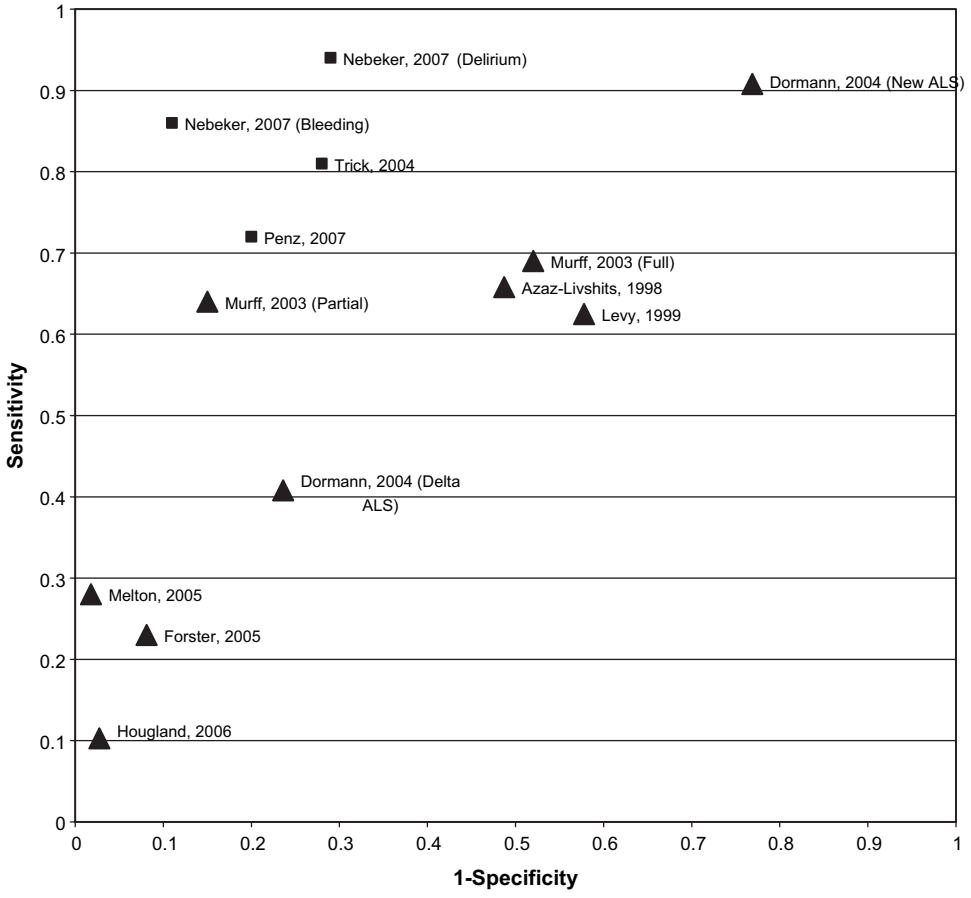

Figure 1 Sensitivity by 1-specificity for automated methods compared with gold standard methods of harm detection.

[a] Only the aggregated values for the harm detection method from each paper are shown. Individual components of an automated method are not shown.

[b] Triangles represent sensitivity and specificity values that could be independently verified.

chart review. Field-defined strategies appear to be less technologically demanding than natural language-processing strategies. Sophisticated computer algorithms and natural language-processing programs require specialised subject knowledge, skill and time to develop, and require installation and instruction by experts.[18 48] Whether costs to implement such programs are offset by savings from eliminating manual chart review and decreased patient harm is unknown and should be studied. Future studies also should quantify differences in time and personnel resources needed for the automated detection method, relative to other detection strategies.

To our knowledge, four of the 43 unique articles report on commercially available automated harm-detection systems (MedLEE,[48] dtsearch desktop,[34] Nosocomial Infection Marker (NIM)[44] and Dynamic Pharmaco-Monitoring System[45]). Other articles report on systems that employ data elements common across medical institutions (ie, ICD-9 codes used in the Complications Screening Program[8–10]) use software available to the VA or specific states (ie, RADARx, NY Antimicrobial Resistance Project[21 42]) or are available through the Agency for Healthcare Research and Quality (ie, Patient Safety Indicators[15–17]). The availability of the remaining detection systems is either institution-specific or not made clear by their developers.

While automated tools offer promise for efficient and accurate harm detection, there are important limitations that currently make them unsuitable for widespread application, particularly for interhospital comparisons. The reported sensitivity and specificity are variable and often low, suggesting that many episodes of harm may go undetected, and that many events identified will be false positives. Low accuracy may result from limited capability of the tool to detect events, or from flawed sources of data used for automated harm detection. For example, the reliability of field-defined systems can be affected by data entry errors or limited availability and accuracy of administrative codes, while natural language processing is sensitive to spelling and grammatical errors in free text. Both systems may include irrelevant or erroneous information, or exclude necessary information. For example, perhaps driven by medical-legal concerns, health professionals often do not include information about medical errors and resulting adverse events in their progress notes, problem lists and discharge summaries. Thus, an electronic medical record containing accurate, complete and easily accessible information can enhance the performance of an automated detection tool. Understanding these factors is important when evaluating the technological requirements, feasibility and inherent limitations of automated detection methods.

The variety of distinct automated methodologies makes comparisons between studies and between automated tools difficult and unreliable. Differences in the quality and content of data sources, as well as other unknowns such as accuracy of hospital documentation and coding practices, also complicate comparisons. The performance and methods of automated tools also may be institution-specific, making it difficult to generalise to other organisations or patient populations. For example, the Health Evaluation through Logical Processing system used by LDS Hospital in Salt Lake City, Utah relies on an advanced, highly integrated and dynamic information system that is not widely available.[11–14]

We speculate that field-defined methods of automated harm detection will prove superior to natural language-processing methods, particularly if information about harm is accurately documented in electronic medical record systems in prespecified fields, thus allowing rapid and reliable detection of harm events.

The methodological rigour of studies was variable. Only two-thirds of the 14 studies that compared an automated method with a gold standard chart review had verifiable validity results. Moreover, most studies compared automated harm-detection methods with other sources of data on patient harm (eg, voluntary reporting,[11–13 24 25 29 31 37 38 50] unstandardised chart reviews,[8 10 14 28 36 41 43 45] and prospective surveillance records[42 49]). The validity of data from studies without chart review comparison is questionable given the absence of a defined denominator of events against which to measure the performance of the automated tool. The use of different methods, statistical analyses, denominator values and outcomes precludes a comparison of one automated method with another, as well as any attempt to statistically pool their results in a meta-analysis.

Other authors have summarised the literature on automated harm-detection methods, but most have focused on automated methods specific to a type of harm (ie, adverse drug events[51 54] or nosocomial infections),[59] patient population (ie, paediatrics),[52] source of data (ie, administrative data)[57] or automated technology (ie, natural language processing).[58] Our systematic review included all types of automated methods, harm events and sources of data evaluated in an inpatient setting. Furthermore, we provide an additional level of critical appraisal compared with other systematic reviews.[55 56] For example, while Bates *et al*[55] address differences between study methodologies by noting the presence or absence of gold standard comparison, they do not assess validity of studies or independently verify reported data. To our knowledge, this is the first systematic review to critically assess methodological rigour and study validity.

While our review has several strengths, it also has limitations. First, the search strategy was limited to published English language articles. Second, we did not evaluate scientific meeting abstracts, nor did we contact investigators to identify unpublished studies. Third, publication bias must be considered in which studies with negative findings may not have reached dissemination venues. Fourth, most of the articles evaluated automated methods of harm detection among adults in general medical or surgical units, which may limit application to other populations and settings. Finally, our independent appraisal of the methodology and validity of key studies relied on information available within published articles. Our inability to verify the rigour and validity of all studies highlights the variation among even the most rigorous evaluations.

In conclusion, our review identified numerous automated methods of harm detection in two broad categories—field-defined methods and natural language processing—that identified a broad range of harm events, but particularly adverse drug events and nosocomial infections. Although many of these studies described the accuracy (sensitivity and specificity) of automated harm detection when compared with chart review, these results may not be valid due to methodological flaws in the conduct of many of these studies. Future studies assessing the performance of automated harm-detection methods should ensure that the gold-standard assessment (usually chart review) is performed by a blinded assessor, the gold-standard is applied independently of the results of the automated method (ie, charts not flagged by the automated method are reviewed for false negatives), and the automated method is tested in a set of patients that is independent of the set used to develop the automated method. Finally, efforts should be made to improve documentation of harm episodes in the patient record, in problem lists and when generating diagnosis codes, in order to

improve automated harm detection. Future research should also focus on developing methods for real-time harm detection. In this way, automated harm-detection tools will realise their potential to describe accurately the incidence of harm in hospitalised patients, monitor changes from preventive interventions, and compare institutions and individual health professionals. Establishing universal standards and guidelines for the development, testing and utilisation of automated harm-detection methods, perhaps through a centralised agency, would allow data to be collected and compared in a rigorous, systematic fashion.

Summary

Automated methods of harm detection are feasible, allow rapid scanning of a large number of patient records with minimal effort and have the potential to identify events as they occur or soon thereafter. However, the heterogeneity of automated methodologies, the spectrum of study rigour and the widely varying accuracy data suggest that currently available automated methods poorly measure the true incidence of harm. These methods cannot replace chart review as the gold standard but can provide estimates of the frequency of harm that can allow hospitals to identify priorities for action, make decisions about safety interventions and potentially monitor change over time. As automated harm-detection tools and scientific methods to test them evolve, there exists a great potential to positively impact patient safety.

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Reference	Patient Sample and Time Frame	Sampling Strategy	Specialty	Events Identified	Automated Event Dataset Sample Size	Comparison Event Dataset Sample Size	Strategy of Event Identification	Method of Automated Event Identification	Degree of Automation	Source of Automated Event Data	Source of Comparison Event Data	Method of Comparison Event Identification	Comments
Complications Screening Program													
Lawthers, 2000 [10]	Adults 1994	Combination of random sample and risk stratification sampling	Major surgical and medical risk groups	Adverse events: "complications of hospital care"	1298 cases: 634 California, 664 Connecticut	1298 cases	Complications Screening Program	Field Defined	Partial	ICD-9 CM codes	Medical record and ICD -9 CM codes	Chart review, not otherwise specified	Used ICD-9 CM codes to screen for complications. When code was triggered, computer algorithm tested for specific qualifications to categorize the complication further. This study used Medicare 1994 MEDPRO database claim codes and a 2 stage review to compare the codes to manual review. Study designed with chart review after computerized detection. Number of cases per screen were relatively small. Reviewers unblinded to trigger codes.
Weingart, 2000 [9]	Geriatrics 1994	Random	Unknown	Adverse Event: complications of care including surgical compli-cations, infections, falls, ADE etc	1025 Medicare beneficiaries	NA	Complications Screening Program	Field Defined	Partial	Administrative Data	NA	NA	Used administrative data from Medicare patients in California and Connecticut in 1994. Hospitals stratified by expected complication rates, then randomly selected cases flagged with surgical and medical complications as well as unflagged controls were collected. Cases subjected to peer review physician judgments to attempt to validate the CSP.
Iezzoni, 1992 [8]	Adults 1988	Unknown	Gen Med and Gen Surg (excluded obstetric patients)	Adverse events	100 discharge abstracts. Original sample size unknown.	100 standard hospital discharge abstracts	Appears to be Complications Screening Program (CSP) or a precursor to CSP.	Field Defined	Partial	Discharge summary; ICD-9 diagnosis and procedure codes	Discharge summary and administrative data	Chart review, not otherwise specified	Computerized screening based on patient age, sex, ICD-9-CM diagnosis and procedure codes, DRG, and number of days from admission to principal major surgeries or procedures. 27 quality screens used to identify potential adverse events. Physician reviewers only had access to administrative data and had poor inter-rater reliability.
Computer Algorithms													
Nebeker, 2007 [18]	Adults 2001 and 2003	Random	Unknown	Adverse drug events	3987 admissions	3987 admissions	Computer algorithms	Field Defined	Chart review for study, however unclear whether strategy aims to be fully or partially automated.	ICD-9 CM codes	Medical record	Gold standard chart review	Study used Hougland, 2006 [28] methodology to specifically apply HOCTA (hierarchically optimal classification tree analysis) to administrative data to develop surveillance rules for the identification of ADEs manifesting as either bleeding or delirium. Specifically interested in creating models using this type of nonlinear statistical method for 2 particular ADEs. Model's validation was limited and may be overfit. Requires expert computer programming.
Trick, 2004 [20]	Adults 9/1/01-2/28/02	Sequential	Unknown	Infection	135 positive blood cultures	144 positive blood cultures	Computer algorithm	Field Defined	Full and Partial	Medical record, lab database, pharmacy database, radiology database, microbiology	Medical record, lab database, pharmacy, radiology, microbiology	Gold standard chart review	Comparison of manual and computer assisted bloodstream central venous catheter infection surveillance using data from two hospitals. Different computer algorithms developed for full or partial automation were tested. Findings may not generalize to other institutions.
Benson, 2000 [19]	Patients aged 14 years and older 1998	Sequential	Patients under anesthesia	Adverse Event	16,019 surgical procedures	16,019 surgical procedures	Computer algorithm: structure query language	Field Defined	Full	Online anesthesia documenting software (Anesthesia Information Management System, or AIMS)	Anesthesia record	Other: manually recorded information during perioperative period by anesthesiologist	AIMS database queried for 9 common perioperative adverse events with structured query language (SQL) queries.

Brown, 2000 [21]	Unknown 7/1/99 to 9/30/99	Sequential	Unknown	Adverse drug events	1643 RADARx alerts over study period	Unknown	Computer Algorithms: RADARx	Field Defined	Partial	Lab database, pharmacy database, demographics, diagnoses and procedures	Unknown	Other: "traditional methods", not otherwise specified	RADARx (Recognizing, Assessing, and Documenting Adverse Rx events) is a VA software program integrating computerized adverse drug event (ADE) screening, probability assessment, documentation and reporting capabilities. Study evaluated patient data every four hours for possible ADEs, generated and stored alerts. Clinical pharmacists reviewed alerts daily, documented findings, and contacted clinicians in real-time. Used Naranjo algorithm to assess causality. Major source of algorithm rules from Jha, 1998 [30]. Manual review of 8-20 alerts daily costed 10-30 minutes daily. RADARx used 12 seconds of CPU time every 4 hours. Initially involved 30 minutes installation time and 1-2 hours to run mapping tools. RADARx rules designed as screens and meant to be sensitive and not specific.
HELP: Health Evaluation through Logical Processing													
Samore, 2004 [13]	Adults 1/00 -9/00	Sequential	Other: all "regular and short stay" pts except obstetrics and neonates.	Adverse medical device events	20,441 pts	20,441 pts	HELP and computer based flags	Field Defined	Partial	Medical record, lab database, pharmacy database, radiology database, billing data, ICD-9 CM codes - HELP integrates multiple interfaces	Voluntary reporting and ICD-9 CM codes	Voluntary reporting and ICD-9 discharge codes	Automated surveillance designed to detect device related patient harm (AMDE) based on existing HELP adverse drug event detection methods. 7 categories of automated flags based on common complications and availability of electronic data, then flagged charts reviewed manually. AMDE definition includes all definitions of harm such as infection, bleeding, dropping oxygen saturations etc.
Classen, 1991 [11]	Adults 5/1/89 to 10/31/90	Sequential	Obstetrics, ICU, Gen Med and Gen Surg	Adverse drug events	36,653 patients	NA	HELP	Field Defined	Partial	Medical record, lab database, pharmacy database	Voluntary reporting	voluntary reporting and stimulated voluntary reporting	Results from the HELP system at the LDS Hospital, Utah using highly integrated electronic medical record. Daily computerized ADE report generated from automated surveillance of the medical record for defined signals, followed by clinical pharmacist review.
Evans, 1991 [12]	Unknown 5/89-5/90	Sequential	Unknown	Adverse drug events	23,297 patients	25,142 patients from 5/1/88-5/1/89	HELP	Field Defined	Partial	Medical record, lab database, pharmacy database, demographics	Voluntary reporting	voluntary reporting	Results from HELP information system at LDS hospital in Utah. ADE monitor program generated daily list of alerts using automated signals. Signaled charts were reviewed by trained nurse and pharmacist to verify ADE. Based on Classen 1991 [8] rules/program.
Evans, 1986 [14]	Unknown 2/84 to 3/84	Sequential	Unknown	Infection	4,679 patients; 217 with suspected NI	217 patients with suspected NI	HELP and other	Field Defined	Partial	Medical record, lab database, microbiology test results	Medical record	Chart review, not otherwise specified	Study evaluated computer screening versus infection control practitioner screening, both followed by chart review. The overall computerized system looked at patients with 1) hospital-acquired infections, 2) who were not receiving antibiotics to which their pathogens were susceptible, 3) who could be receiving less expensive antibiotics, or 4) who were receiving prophylactic antibiotics for too long. Time required: 8.6 hours to complete computerized report of unverified alerts, compared to 138 hours for infection control practitioners. Physician review took 15 minutes per chart to verify alerts.
Natural Language Processing													
Haas, 2005 [49]	Children 3/1/01-1/31/03	Sequential	NICU	Pneumonia	1692 patients	1692 patients	Natural Language Processing	Natural Language Processing	Full	Radiology database: specifically chest x-rays	Radiology database, medical record, microbiology, interviews with caregivers	Prospective infection surveillance by experienced infection control professional.	Designed to use chest x-rays from two neonatal intensive care units to detect nosocomial pneumonia in neonates. NLP program screened chest x ray reports and flagged reports indicative of pneumonia according to rules derived from National Nosocomial Infection Surveillance System.

Melton, 2005 [48]	Unknown 1996-2000	Random sampling and Sequential (all electronic discharge summaries during study years)	Unknown	Adverse events: specifically 45 NYPORTS event types.	1000 charts randomly sampled and then 57,422 electronic discharge summaries	1000 charts (random sample during study period)	Natural Language Processing	Natural Language Processing	Partial	Discharge summaries	Full electronic chart and combined electronic chart and paper chart for a subset of 100 pts.	Gold standard chart review	Natural Language Processing system (MedLEE) to identify 45 NY Patient Occurrence Reporting and Tracking System event types. Discharge summaries converted to coded form then tested. Chart review by physician and independant informatician of random sample of 1000 charts to assess performance of NLP program. Results biased towards patients with electronic discharge summaries. This method is technologically intensive.
Patient Safety Indicators													
Zhan, 2007 [17]	Medicare beneficiaries 2002 to 2004	Random	Gen Surg	Post-operative Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE)	20,868 hospital discharges identified as surgical patients	20,868 hospital discharges identified as surgical patients	Patient Safety Indicators	Field Defined	Full	ICD-9 CM codes	Medical record	Gold standard chart review	DVT/PE events flagged by ICD-9 CM codes were compared to those discovered by gold standard chart review. The sample studied was a random sample abstracted by the Medicare Patient Safety Monitory System.
Polancich 2006 [15]	Unknown	Unknown	Unknown	Hospital acquired decubitus ulcers	not reported	123 charts from list of patients identified through PSI as having decubitus ulcers	Patient Safety Indicators	Field Defined	Full	Administrative data, billing data, ICD-9 CM diagnosis codes, procedure codes	Medical Record	Gold Standard Chart Review	Study designed to test validity of Agency for Healthcare Reseach and Quality (AHRQ) PSIs for detecting hospital acquired decubitus ulcers. Only a sample of cases were manually reviewed.
McDonald, 2002 [16]	NA	NA	NA	Adverse events	NA	NA	Patient Safety Indicators	Field Defined	Full	Discharge summaries; ICD-9 codes	NA	NA	Technical report providing detailed coding manual, including numerator, denominator, and ICD-9 codes for defining accepted, experimental, and rejected Patient Safety Indicators (PSIs). Several of the PSIs were derived from other harm detection methods. Report summarized validity information on PSIs, when this information was available from other studies.
Multiple Detection Methods													
Penz, 2007 [47]	Adults 99 - 12/04	Sequential	MICU, SICU and other (placement of Central Venous Catheters)	Adverse events related to central venous catheter placement	316 pt records	40 patient records: 10 very low probability records and 30 high probability	Computer algorithms and Natural Language Processing	Natural Language Processing	Partial	Text records, daily progress notes, consultation notes, nursing notes, procedure notes, operative reports, discharge summaries	Text records, daily progress notes, consultation notes, nursing notes, procedure notes, operative reports, discharge summaries	Gold standard chart review	Study compared two methods for semi-automated review of text records within the VA database using NLP (MedLEE) and a phrase matching algorithm (PMA). Reviewers instructed to use only the language of notes to determine if adverse event occurred. Methods limited by incomplete or inaccurate documentation, incomplete coding, spelling errors, sentence structure abbreviations. Time/technology intensive.
Weissman, 2007 [46]	Adults 10/1/00 to 9/30/01	Random	Acute medical and surgical	Adverse event	24,676; includes 6,841 pos. screens and 17,835 neg. screens	NA	Complications Screening Program, Patient Safety Indicators, and Bates 1995 methodology	Field Defined	Partial	Medical record; billing data; ICD-9 codes	NA	NA	Screens identified by a combination of Complications Screening Program, Patient Safety Indicators, and Bates 1995 [26] methods. Gold standard full chart review done on all positive screens and on 1990 negative screens (of 17,835 negative screens). Article focused on the relationship between adverse events and hospital workload. Compared adverse events across hospitals.
Other Automated Methodologies: Lab Signal Detection													
Dormann, 2004 [26]	Adults 6/97 - 12/97	Sequential	Gastroenterology	Adverse drug events	474 admissions of 377 patients; 109 ADEs	474 admissions of 377 patients; 109 ADEs	Automated lab signal detection	Field Defined	Full	Demographics, history, lab findings, diagnosis, and drugs	Medical record	Gold standard chart review	Used automated lab signals (ALS) and changes in ALS to identify ADEs. Automated system used to flag potential ADEs which were then sent as an alert to physicians. Use of delta ALS (change) resulted in improvement over Dormann, 2000 methodology.

Bagheri, 2000 [24]	Adults 6/97 - 10/97	Sequential	Gen med and other medical subspecialties	Adverse drug event: specifically drug induced liver injury.	147 patients (156 ALT values, 159 AP)	Unknown	Detection based on serum enzyme values	Field Defined	Partial	Medical record, lab database, pharmacy database, demographics, social history (i.e. drug/alcohol use)	Voluntary reporting	voluntary reporting and stimulated voluntary reporting	Prospective study from Tolouse, France to assess incidence/detection of drug induced biochemical liver abnormalities. Patients selected by automated computer screening of alanine aminotransferase (ALT) and alkaline phosphatas (AP) values in electronic lab database. Medical charts then reviewed to determine if this was ADE. Computerized detection compared to voluntary reporting from the same time period. Relatively easy, technologically simple method.
Dormann, 2000 [25]	Unknown	Sequential	Gen Med	Adverse drug events	379 pts	Unknown	Computer based monitoring of automatically generted lab signals and reports	Field Defined	Partial	Lab database	Voluntary reporting	Stimulated voluntary report	Automated identification of cases in a German hospital, followed by manual evaluation by clinical pharmacist and clinicians. Verified ADE matched to controls to assess costs and length of hospital stay issues.
Levy, 1999 [23]	All age groups 4/97 - 5/97	Sequential	Gen Med	Adverse drug events	199 admissions (192 patients)	199 admissions	Automated lab signal detection	Field Defined	Partial	Lab database	Lab database and clinical data	Gold standard chart review	Implementation of the pilot program described in Azaz-Livshits 1998 [19]. Computerized lab data monitored to detect ADEs using the same signals as the pilot study.
Azaz-Livshits, 1998 [22]	All age groups 4/95-5/95	Sequential	Gen Med	Adverse drug events	153 admissions	153 admissions	Automated lab signal detection	Field Defined	Partial	Lab database	Lab database and clinical data	Gold standard chart review	Pilot program to develop and assess computerized laboratory data as a detection tool for ADE in 34 bed medical ward in Jerusalem, Israel. Lab signals generated by computer, then verified by team. Limited computerized patient data at this hospital, however lab data was fully electronic. Generalizable to other institutions with limited electronic data (lab only). Cost of this system reasonable compared to costs of ADEs.
Other Automated Methodologies: ICD-9 or Billing Code Detection													
Hougland, 2006 [30]	Adults 2001 calendar year	Random and Flagged sample (from records with at least one flagged ADE code)	Unknown	Adverse drug events	3103 inpatients: 1961 random sample, 1142 flagged sample	Unknown	Automated ICD-9 code strategy	Field Defined	Full: however review of flagged charts here for study purposes	ICD-9 CM codes	Medical record	Gold standard chart review	Expert panel identified 416 ICD-9 CM codes to represent ADEs (flagged ADEs). Then chart review performed to ascertain codes' ability to detect/identify ADE.
Seeger, 1996 [29]	Unknown 7/91-6/94	Sequential	Unknown	Adverse drug events	52,695 admissions	52,695 admissions	Capture-recapture method applied to automatic surveillance via medical record coding	Field Defined	Full	ICD-9 CM codes	Voluntary reporting	Voluntary reporting	ICD-9 CM codes indicative of 7 categories of ADRs used to scan patient database at University of Illinois at Chicago Medical Center to identify ADRs (electronic sample). Capture-recapture assumed all subgroups within population have equal chance of being captured each time.
Hirschhorn, 1993 [28]	Adults 4/15/87 to 10/1/89	Sequential	Obstetrics (Women with nonrepeat, nonelective cesarean sections and perioperative prophylaxis with cefazolin or cefoxitin alone.)	Infection	2,197 women	457 records (Randomly selected from full sample)	Screen for infection based on ICD-9 codes and antibiotic exposure	Field Defined	Full	Pharmacy database and ICD-9 codes	Medical record and anesthesia records	Chart review, not otherwise specified	Tool specifically detected cases of cesarean section infection using ICD-9-CM codes and parenteral postoperative antibiotic (PPA) exposure. Performance of indicators depended on accuracy of coded discharge diagnoses and automated pharmacy records. ICD-9 and infection codes listed in the appendix.
Roos, 1985 [27]	Adults 1976	Sequential	Readmissions following hysterectomy, cholecystectomy, and prostatectomy	Surgical complications	Hyst: 387; Chol: 695; Prost: 488	Hyst: 387; Chol: 695; Prost: 488	Claims review	Field Defined	Full	ICD-9 and ICDA-8 diagnostic codes	Claims data (service use) and diagnoses. Additional information provided on about 20 cases per procedure.	2 independent physician specialists rated data; met to resolve discrepancies. Only those events with agreement were included	Computer algorithm developed on 1974 Manitoba surgical claims database, revised on 1975 data, and tested on 1976 data. Used 3 or 4 digit ICDA-8 codes in first readmission after surgery for up to a 2 year period. Focused only on readmissions following hysterectomy, cholecystectomy, prostatectomy. Appendix lists of ICD-9 and ICDA-8 codes with appropriate timeframe of reference for different complications.
Other Automated Methodologies: Other Automated Triggers													

Ferranti, 2008 [50]	Pediatric 12/1/04-1/31/06	Sequential	PICU, Gen Med, Transitional Care	Adverse drug events	4,711 admissions (51,046 patient-service days)	4,711 admissions (51,046 patient-service days)	Automated triggers: abnormal lab values, antidote administration, drug-lab combination triggers.	Field Defined	Partial	Lab database, pharmacy database.	Voluntary reporting	Voluntary reporting	Duke University Hospital evaluation of ADE detected by computerized surveillance versus voluntary reporting system. Voluntary reporting ADE rate = 1.8 events per 1000 patient days versus 1.6 events per 1000 patient days for automated method. (No statistical difference between methods). Authors postulate the reason automated surveillance fails to outperform voluntary reporting in this specific pediatric population is that the automated triggers need to be refined and tailored to better match pediatric situations.
Bellini, 2007 [41]	Adults 2 year period. Date not stated	Sequential	MICU, SICU, Gen Med, Gen Surg	Infection	669 cases of a positive blood culture	669 cases of a positive blood culture	Unnamed system with similarities to the CDC's NISS method	Field Defined	Full	Microbiological data, administrative data (patient ID, ward, and date of admission)	Medical record	Chart review, not otherwise specified	Identified new bacteremia cases as community-acquired or nosocomial (catheter related and other origins). Lausanne, Switzerland. Automated method similar to Center for Disease Control's Nosocomial Infection Surveillance System (NISS), but differed in two ways: a) did not separate blood stream infections (BSIs) that were documented microbiologically versus clinical sepsis without microbiological documentation, b) focused on catheter related infection versus other sites, instead of excluding bacteremia related to other (non-catheter) sites. Method used data available in most health care electronic record systems.
Kilbridge, 2006 [37]	Unknown 3/1/05 - 10/31/05	Sequential	Unknown	Adverse drug events	25,177 patients at univ hospital, 8029 pts at community hosp	Unknown	Automated triggers	Field Defined	Partial	Lab database, pharmacy database, demographic data	Voluntary reporting	voluntary reporting	Comparison of ADE rates and nature between academic center and community setting using methods reported in Kilbridge, 2006 [36]. Pharmacist and physician chart reviewers.
Kilbridge, 2006 [38]	Unknown 3/05-4/05	Sequential	Unknown	Adverse drug events	6940 pts	Unknown	Automated triggers	Field Defined	Partial	Lab database, pharmacy database, demographic data	Voluntary reporting	voluntary reporting	Duke University Hospital. Detection of ADEs by automated trigger signals derived from various lab abnormalities, physician orders etc. Daily list of triggers evaluated by 2 pharmacists and weekly reviewed by physician. Automated rules derived and modified from HELP studies. Specialized resources involved, and 30 person hours per week. Programming resources considerable, perhaps not widely available.
Pokorny 2006 [39]	Adults 4/15/99-6/30/02	Sequential	ICU - general	Infection	1043 patients	194 pts in ENVIN-UCI project from 99-02 (see methods)	Computer surveillance	Field Defined	Unknown	Lab database, pharmacy database, administrative data, diagnoses data	Medical record, bedside clinical data.	Other: "bedside data collection"	Retrospective analysis comparing computer based surveillance using three nosocomial infection (NI) suspicion criteria (positive microbiology, antibiotic administration, clinical diagnosis infection) with rates of infection obtained from prospective incidence study done over the same period (ENVIN - UCI) which consisted of bedside collection of data on ICU infections. NI classified according to international definitions, onset > 48 hrs after admission.
Szekendi, 2006 [40]	Adults 6/03 to 9/03	Sequential	All units, except pediatric and NICU	Adverse event	327 medical records; 493 trigger events	NA	Automated trigger tools	Field Defined	Partial	Lab database and pharmacy database	NA	NA	Automated identification of charts with trigger tool (using 21 electronic triggers), followed by a manual review by a nurse and pharmacist (followed by additional physician review if no agreement). All records with 2 or more triggers were selected, followed by cases with triggers from medical list, abnormal lab list, and positive blood culture selected on a sequential rotating basis. Time: 35 minutes/chart not requiring physician review; 45 minutes/chart if physician review required.

Forster, 2005 [34]	Adults fiscal 2002	Random	Gen Med, Gen Surg	Adverse event	245 patients	245 patients	Computerized screen for trigger words in free text	Natural Language Processing	Partial	Discharge summaries	Discharge summaries	Gold standard chart review	Substudy of Ottawa Hospital Patient Safety study. Automated adverse event lexicon made up of 104 terms used by Murff 2003 [31]. Computerized search engine scanned discharge summaries (dtsearch desktop) and detected charts with potential harm, which were then reviewed by MD. Specificity found to be higher for nonelective admissions and discharge summaries dictated by residents and staff versus medical students. Automated detection reduced physician time by one-fifth.
Hartis, 2005 [35]	Unknown 7/02 - 12/03	Sequential	Unknown	Adverse drug event: specifically warfarin associated.	1,952 inpatient beds from 6 community hospitals	NA	Automated triggers	Field Defined	Partial	Lab database, pharmacy database	NA	NA	Automated triggers developed to detect warfarin associated ADE. Automated triggers are INR > 3.0 and pharmacy orders for Vitamin K. Pharmacist reviewed triggers monthly. Interventions made when trigger confirmed, (i.e. education and therapy change). Goal of study is to assess ADE rates pre and post interventions.
McIntosh, 2005 [36]	Unknown 2003 January	Sequential: all tracer drugs dispensed during time period	Unknown	Adverse drug events	775 tracer drugs ordered from Automatic Dispensing Units (ADU)	Unknown	Computerized data from automated dispensing units	Field Defined	Partial	other: ADU	not specified	Chart review, not otherwise specified, and voluntary reporting	Miami Veterans Affairs Medical Center study to determine if monitoring the removal of tracer drugs (such as naloxone) from ADU improves ADE reporting. Investigator reviews charts from ADU generated list. Upon removal of tracer drug, ADU prompts reply to the question "is medication ordered due to ADR/allergy". If the answer is yes, then chart reviewed to determine ADE. Automated surveillance data as reliable as answers to questions prompted by ADU - thus education of nurses and other staff is key.
Murff, 2003 [33]	Adults 1/1/00-7/00	Random (424) and sequential (all remaining admissions during study pd)	Gen Med and Medicine subspecialties	Adverse drug events, adverse events, other: diagnostic errors, operative complications, falls	Cohort 1: 424 randomly selected admissions Cohort 2: 2826 remaining admissions over study period	295 of cohort 1 and 145 of cohort 2 via complex sampling/sub sampling and manual review process (see Reference for details)	Computerized screen for trigger words in free text	Natural Language Processing (Keyword triggers within free text).	Full (goal is a fully automated system, manual review of subsamples performed for study.	Discharge summaries	Medical record (not otherwise specified)	Gold standard chart review	Brigham and Women's Hospital, using Brigham Integrated Computer system. Computerized screening tool searched free text discharge summaries for trigger words indicating possible adverse events. List of automated trigger words compiled using Harvard Medical Practice Study definitions as base. Electronic method alone versus electronic plus manual review compared for 2 cohorts. Computerized screen searches for programmed key words (not as sophisticated as natural language processing programs that "read" free text). Reviewers blinded to whether screening tool had identified the admission. Complex sampling/subsampling methods plus manual review process for each cohort.
Jha, 1998 [32]	Adults 10/94-5/95	Sequential	MICU, SICU, Gen Med, Gen Surg	Adverse drug events	21,964 patient-days	21,964 patient-days	Automated triggers	Field Defined	Partial	Medical record	Medical record	Gold standard chart review and stimulated voluntary report	Study of computer based ADE identification using modified Classen 1991 [8] (HELP) rules to create automated triggers with which the electronic record was screened. Rules modified during the study to increase PPV, and new rules created. Trained reviewer and physician were blinded to detection method. 11 person-hours per week for automated method versus 55 for chart review and 5 for voluntary reporting.
Whipple, 1994 [31]	Unknown	Sequential	Unknown	Adverse drug events - specifically Patient Controlled Anesthesia (PCA) related overdose	4669 patients who received PCA	4669 patients who received PCA	Computerized search strategy	Field Defined	Partial	Billing data, clinical admission data, transfer, discharge and death databases	Voluntary reporting	voluntary reporting	Retrospective computerized data retrieval study to identify ADE related to PCA use. First identified applicable billing codes for overdose, plus patients who had other evidence for overdose (i.e. ICU transfer etc). Charts with possible overdose then reviewed manually. Study used hospital's current computer system as they did not have funds for a new computer or computer programs, thus this technology could be generalizable.

Other Automated Methodologies: Specific Named Programs													
Seger, 2007 [45]	Adults 7/1/02 to 12/31/02	Sequential	Gen Med and Gen Surg	Adverse drug events	3,428 patients, of which 215 had high or critical alerts	56 charts; 48 unique patients	Dynamic Pharmaco-Monitoring System	Field Defined	Partial	Lab database, pharmacy database, and demographics	Medical record	Chart review, not otherwise specified	Dynamic Pharmaco-monitoring system identified critical, high, medium, and low alerts. This method focused on the critical and high alerts only. Separately identified preventable and non-preventable ADE. Provides a rough estimate of cost and time required (1.5 hours/day of pharmacist time - results in expected cost savings of $49,000 in first year).
Brossette, 2006 [44]	Unknown 12/1/03 to 12/3/03 and 4/26/04 to 4/29/04	Sequential	Unknown	Infection	907	907	Nosocomial Infection Marker (NIM)	Field Defined	Full	Multiple sources: Medical record; Lab database	Medical record	Gold standard chart review	Nosocomial Infection Marker (NIM) program by Med Mined, Birmingham, AL. Took about 10 minutes/week to maintain.Total time for NIM: 2 hours/10,000 admissions, compared to medical record review at 1.5 full time employees per 10,000 admissions)
Huang, 2005 [43]	Unknown 1/1/04-12/41/04	Sequential	Unknown	Adverse drug event: specifically hyperkalemia on spironolactone	3995 pts on spironolactone	662 pts on spironolactone sequentially from 1/1/04 - 9/30/05	Event Detector automated event detecting computer program	Field Defined	Unknown	Lab database, pharmacy database (none others specified)	Lab database, pharmacy database, none others specified	Chart review, not otherwise specified	Implementation of a new rule in an established automated event detection system (EventDetector) to monitor serum potassium in patients receiving spironolactone. Study encompassed 3 separate hospitals.
Graham, 2004 [42]	Children 1/00 - 12/02	Unknown	NICU	Infection	Unknown	Unknown	NYARP (New York Antimicrobial Resistance Project) electronic monitoring of bloodstream infections	Field Defined	Full	Microbiology data for positive blood cultures	Medical record, prospective evaluation by ICP	Other: Prospective surveillance study "Staff hand hygiene and nosocomial infections in neonates" by infection control professional (see methods)	Study designed to validate NYARP data by comparing with prospective surveillance by infection control professional (independent study over the time period march 2001 - Jan 2002.) The NYARP electronically monitors trends in nosocomial infections in 14 acute care hospitals via monitoring positive blood cultures. Not validated to other institutions or patient populations. NYARP limited to bacterial infections. Relatively low cost to maintain database.