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DETECTING MEDICAL ERRORS IN A TERTIARY HOSPITAL: COMPARING CASE NOTE REVIEW AND ADMINISTRATIVE DATABASE

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ABSTRACT

Aim: Medical error is common problem in health care, lead to different kind of harm to patients and also additional cost for health care system. The purpose of this research was to assess the reliability of International classification of disease 10th version (ICD 10) administrative data in identifying health care medical errors.
Materials and methods: Case Note Review (CNR) was conducted on 1316 patients' medical file to extract hospital incidents. Standard forms was used to extract the data through random stratified sampling method in a period of 1 year in a 1000 beds specialty and subspecialty hospital in Tehran, Iran to extract patient safety problems. Patient Safety Indicators (PSIs) derived from ICD10 hospital database are also extracted from the same sample size. Two methods were compared using kappa factor.
Results: According to the outcomes of patient record review, 5.4% of the hospital's inpatients, exposed to at least one incidence related to one of AHRQ[1] PSIs, while ICD 10 administrative data only showed 1.35% of inpatients exposed to at least one incidence.
Conclusions: This study results shown that use of ICD 10 administrative database to extract medical errors needs major considerations.

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Introduction

Health systems, worldwide, are faced to the challenge of addressing adverse medical events and their associated consequences [1-6]. Estimates by the World Health Organization [WHO] show that as many as one in 10 patients are harmed while receiving hospital care in developed countries [7]. In the United States, hospital-based errors are among the top eight leading causes of death, ahead of breast cancer, AIDS, and motor-vehicle accidents [8]. Recent study in Iran also showed 10.9% of patients admitted to the hospitals experienced some type of adverse events including admission with AEs [1]. Establishment of a low cost, efficient monitoring system is an essential part of any effort to reduce or to abate the medical error(s). Such a monitoring system needs measures and indicators to be able to identify medical errors. Patient safety indicators (PSIs), a set of measures introduced by many nationally and internationally distinguished organizations

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such as Agency for Healthcare Research and Quality (AHRQ), WHO, etc., may be used with hospital inpatient discharge data to provide a perspective of patient safety [7, 9].

Today, varieties of methods are available to detect, measure, and monitor hospital adverse events (AEs); each one has strengths and weaknesses. In a study that was conducted in 2003 [10], eight morbidity and mortality conferences and autopsy, malpractice claims analysis, error reporting systems, administrative data analysis, chart review, electronic medical record review, observation of patient care and clinical surveillance methods performance in extracting data about patient safety problems were studied. Another method, which despite its limitations, is still considered as a "gold-standard" method and is widely used is Case Note Review (CNR) method. The method is being used to assess the nature, frequency and root cause of medical errors and to estimate the rate, consequences and preventability of adverse events and also for monitoring safety improvement strategies efficacy, until a cheaper and more reliable method is designed [2,11]. The main limitations of this method are being time consuming and expensive. It may, however, be used to examine the performance of other available methods in assessing the nature and frequency of AEs [2].

International classification of diseases (ICD) introduced by WHO and intended to be used in all healthcare systems to monitor the incidence and prevalence of diseases and other health problems, providing a picture of the general health situation of countries and populations [12], worldwide. Now many developed countries utilized ICD9 or ICD10 in their hospitals' databases, which are being used as a low cost and routinely available means for monitoring hospital performance in quality of the care and patient safety.

Since in our study site ICD10 is being used as part of recording procedure of patients' files data and information records in hospital information system (HIS) and considering its dynamic nature it was observed as main candidate for the development of a low cost and efficient patient safety monitoring system. Accordingly, a study was designed to validate its performance in identification of medical errors and hospital incidents utilising CNR method.

Methods

The site of study was a public sector 1000 beds specialty and subspecialty hospital. To identify Medical errors and hospital incidents, 1,316 patients' medical files that were selected from 57,633 cases belonging to those patients, who were hospitalized for more than 24 hours, using stratified sampling method, were reviewed using Case Note Review (CNR) method.

Sample size was calculated using $n = \frac{Z^2(P)(1-P)}{C^2}$ formula, where 'n' is Sample size, 'Z' is standard normal variation, which is taken equal to 1.96 for 5% type 1 error, 'P' is expected proportion in population based on previous or pilot studies, which was taken to be 0.11 following [2,7], and 'C' is absolute error or precision, which was decided to be 0.02 in our study. To avoid the reduction of sample size due to the elimination of duplicated records, the number of sampled cases was increased by 10%. Also, to assure that our statistical analysis was meaningful the minimum number of selected cases from each ward was set at 25.

CNR is a retrospective two stages method uses two review forms [7, 13] to identify incidents from patients' files. We modified those review forms screening criteria to include 20 AHRQ PSIs (Table 1). Death in low mortality DRGs (PSI 2), which is not recorded in Iran health care system, was deleted from the forms and the rest were left intact.

At first stage, two trained nurses examined the sampled records for incidents and malpractices without any further judgment. At second stage, medical doctors (MDs) made the final decision about the occurrence of incidents and their nature. They also examined the level of the involvement of hospital in the occurrence of identified incidents. Then HIS database was searched for the same 1316 sampled cases, writing a query according to the definition of PSIs and their equivalent ICD10 codes, to extract data and information related to them, if any.

CNR and ICD10 data entered into excel and SPSS spread sheets. Then, the Rate of each incident calculated in 1000 admitted patients. Cohen's Kappa factor (κ) was used to measure the agreement between two methods' outcomes.

Results

From 1316 sampled cases 83.3% were surgical and 18.9% non-surgical, 41.4% of patients were male and 58.6% were female and average age of sampled patients were 44 (SD=18.9). 5.4% of patients were exposed to a problem defined by AHRQ PSIs. Results are shown in table2. Postoperative hemorrhage or hematoma with 13.61 in 1000 cases was the most prevalence incident identified by CNR method. Postoperative Sepsis was in second place with 10.89 in 1000 and pressure Ulcer and infection due to medical care were in third place with 7.60 in 1000 cases. For some incidents like Complication of anesthesia, Foreign body left during procedure, Postoperative pulmonary embolism or deep vein thrombosis, Birth trauma, Obstetric trauma vaginal delivery (with and without instrument), no evidence of occurrence was found from CNR method(table2, Fig. 1).

There were ICD10 codes equivalent to 15 AHRQ PSIs. Those ICD codes were available from administrative database. Those indicators and their equivalent ICD10 codes are shown in table 2. A programme was written to find ICD10 codes related data and information from those 1,316 sampled cases. Accordingly, 20 cases (1.5%) were found inclusive of some

type of incidents. The most frequent identified incident from administrative database was postoperative hemorrhage or hematoma, by 4.54 per1000.

No data on 8 of 15 PSIs with ICD10 codes, i.e., complication of anesthesia, foreign body left during procedure, infection due to medical care, postoperative physiologic and metabolic derangement, postoperative wound dehiscence, birth trauma and obstetric trauma (with and without instrument), were found in administrative database. As the table 2 shows there were some incidents that no cases were identified from both methods.

Differences were also observed between the numbers of the identified incidents for some specific PSIs by the two methods. In contrast, data on infection due to medical care and postoperative physiologic and metabolic derangement, and postoperative wound dehiscence were found by CNR method while no data was found in administrative database. According to CNR method 10, 9 and 2 patients experienced infection due to medical care, postoperative physiologic and metabolic derangement, and postoperative wound dehiscence, respectively. 4 cases were found exposed to postoperative pulmonary embolism or deep vein thrombosis from ICD10 codes where no data was found from CNR method.

According to the calculated kappa factor significant agreement between two methods only observed in postoperative hemorrhage or hematoma, postoperative pulmonary embolism or deep vein thrombosis, pressure (decubitus) ulcer, and postoperative sepsis. The most significant agreement was observed for postoperative hemorrhage or hematoma, where the kappa factor was 0.5. Results are shown in table 3.

Discussion

Based on review of literature this is the first study about the credibility of International Classification of Diseases version 10 (ICD10) in identifying health care incidents in Iran health care system. The most recent study in identification of medical errors in Iran using ICD10 codes were conducted in Al-Zahra hospital [15] in the city of Esfahan. In that study 8 AHRQ PSIs were used. They compared their results by [14] but no validity study was carried out in their study.

Case note review was adopted as the basic method in this study to evaluate the administrative database performance as the main source of data and information of occurred incidents that may threaten patients' safety. However, it must be pointed out that both methods suffer from some common problems, most importantly making correct and detailed record of occurred incidents by medical team during patients' hospitalisation and after that by medical documentation department staff that enter them in the form of ICD10 codes in hospital information system. Another problem that may affect the creditability of both methods, more specifically CNR, is their dependence on reviewers' judgment and medical documentation staff, especially when complications are not recorded in patients' files properly. Then human factor plays crucial role in the level of accuracy of the outcome of the both methods. Therefore, when the results for some events related to some of the AHRQ PSIs are zero, the meaning could be: no incident happened, incident happened but has not been recorded, is not recorded properly therefore has not been recognized by CNR reviewers or by medical documentation staff.

Comparison between the two methods showed that the number of incidents identified from recorded ICD10 codes were 3.5 times lower than those identified with CNR method.

Comparison with [14] that utilized ICD10 codes to identify the occurred incidents showed that the rate of identified complications was significantly less than [14]. Comparison with [16] also showed the same problem as [14].

The observed differences with studies carried out in developed countries may be attributed to the making better record of medical complications using ICD10 codes. Another reason for observation of those differences may be related to modifications that were done to ICD codes to improve the system performance considering their national standards and interests.

In this study concordance was poor for postoperative sepsis (κ=0.15), and good for pressure ulcer (κ=0.43), postoperative hemorrhage or hematoma (κ=0.50) and moderate for postoperative pulmonary Embolism or Deep Vein Thrombosis (κ=0.46). The same conditions were observed in [17]. Results for postoperative pulmonary Embolism or Deep Vein Thrombosis and postoperative sepsis in our study were comparable with [18] (PPV=9.8%) and contradictory to [19] (PPV=43%)

Studies have not shown a good positive predictive value (PPV) as the result of AHRQ PSIs validation [20-24]. It is believed that ICD10 administrative data should be used as primary tool for screening and case-finding [18] and as the routine for data collection. We may agree with [18], but more work is needed to make administrative database a reliable source of data and information about medical errors utilizing ICD10 codes.

Conclusion

Since, ICD coding system is designed to be flexible enough to be fitted to the health systems worldwide, and having the capability of being expanded to meet the users' needs, it has a great potential to be utilized as an efficient and low cost monitoring tool of patients safety and hospital performance in this regard. Therefore, administrative database utilising ICD (despite coding irregularities and limited clinical details) supplemented by AHRQ PSIs, offer valuable insight into the impact and risks of medical errors [25]. This conclusion seems valid because there are ICD codes attributable to AHRQ patient safety indicators. Also, all Iranian hospitals required to record all admitted patients data and information in their HIS utilising ICD9 or ICD10 codes, by the ministry of Health and Medical Education. Consequently, it is expected that all

Iranian hospitals to be able to provide data and information about any problem that may put patients' wellbeing at risk. Consequently, investment on the establishment of a patient safety monitoring system based on ICD codes is justifiable. The CNR method may be utilised occasionally to evaluate the established ICD based monitoring system performance.

This study was the first of its kind in Iran and the selected hospital for this study is a good example of public sector hospitals in Iran from both variety of medical services that it provides and the diversity of its customer. However, still some differences could be expected to be observed if carry out the same study in educational and private sector hospitals. Consequently, care should be taken in extending this study results to the other Iranian healthcare systems.

Ethical Considerations

Ethical issues (Including plagiarism, informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors. Accordingly, all patient information as well as names of the hospital was kept confidential.

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Conflict of interest

All authors declare that they have no conflicts of interest regarding this paper.

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Table 1: Screening criteria defined according to AHRQ PSIs

Criteria
1. Complications of anesthesia
2. Death in low mortality DRGs
3. Pressure (Decubitus) Ulcer
4. Failure to rescue
5. Foreign Body Left during Procedure
6. Iatrogenic Pneumothorax
7. Infection due to medical care
8. Postoperative hip fracture
9. Postoperative Hemorrhage or Hematoma
10. Postoperative Physiologic and Metabolic Derangement
11. Postoperative Respiratory Failure
12. Postoperative Pulmonary Embolism or Deep Vein Thrombosis
13. Postoperative Sepsis
14. Postoperative Wound Dehiscence

15. Accidental Puncture or Laceration
16. Transfusion reaction
17. Birth Trauma
18. Obstetric Trauma -Vaginal Delivery with Instrument
19. Obstetric Trauma -Vaginal Delivery without Instrument
20. Obstetric trauma-cesarean delivery

Table 2: Rate of incidents identified by the two methods and their rate in 1000 patients

PSI's number	**PSI's title**	**Corresponding ICD10 code(s)**	**No. of incidents according to CNR method**	**Rate of incidents in1000 medical & surgical patients (CNR)**	**No. of incidents according to ICD10 in sample size**	**Rate of incidents in1000 medical & surgical patients (ICD10)**
PSI 1	Complications of anesthesia	T88.5	0	0.00	0	0.00
PSI 3	Pressure (Decubitus) Ulcer	L89.	10	7.60	4	3.04
PSI 5	Foreign Body Left during Procedure	T81.5	0	0.00	0	0.00
PSI 6	Iatrogenic Pneumothorax	J93.9,J95.8	2	1.52	2	1.52
PSI 7	Infection due to medical care	T85.7	10	7.60	0	0.00
PSI 9	Postoperative Hemorrhage or Hematoma	T81.0	15	13.61	5	4.54
PSI 10	Postoperative Physiologic and Metabolic Derangement	T81.8	9	8.17	0	0.00
PSI 11	Postoperative Respiratory Failure	T81.7	9	8.17	1	0.91
PSI 12	Postoperative Pulmonary Embolism or Deep Vein Thrombosis	I26.9+T81.7	0	0.00	4	3.63
PSI 13	Postoperative Sepsis	T81.4	12	10.89	3	2.72
PSI 14	Postoperative Wound Dehiscence	T81.3	2	1.81	0	0.00
PSI 15	Accidental Puncture or Laceration	T81.2	2	1.52	1	0.76
PSI 17	Birth Trauma (2008)	P14,P15	0	0.00	0	0.00
PSI 18	Obstetric Trauma - Vaginal Delivery with Instrument	P14,P15	0	0.00	0	0.00
PSI 19	Obstetric Trauma - Vaginal Delivery without Instrument	P14,P15	0	0.00	0	0.00
			71		20	

Table 3: agreement test results between CNR findings and ICD10 Administrative data.

PSI No.	**Adverse Event**	**Kappa**	**SE**	**Pv**
1	Complications of anesthesia	-	-	**-**
3	Pressure (Decubitus) Ulcer	**0.432**	0.174	**<0.001**
5	Foreign Body Left during Procedure	-	-	**-**
6	Iatrogenic Pneumothorax	-	-	**-**
7	Infection due to medical care	-	-	**-**
9	Postoperative Hemorrhage or Hematoma	**0.504**	0.137	**<0.001**
10	Postoperative Physiologic and Metabolic Derangement	-	-	**-**
11	Postoperative Respiratory Failure	-0.017	0.015	**0.790**
12	Postoperative Pulmonary Embolism or Deep Vein Thrombosis	**0.462**	0.316	**<0.001**
13	Postoperative Sepsis	**0.152**	0.130	**0.003**
14	Postoperative Wound Dehiscence	-	-	**-**
15	Accidental Puncture or Laceration	-	-	**-**
17	Birth Trauma	-	-	**-**
18	Obstetric Trauma—Vaginal Delivery with Instrument	-	-	**-**
19	Obstetric Trauma—Vaginal Delivery without Instrumentation	-	-	**-**

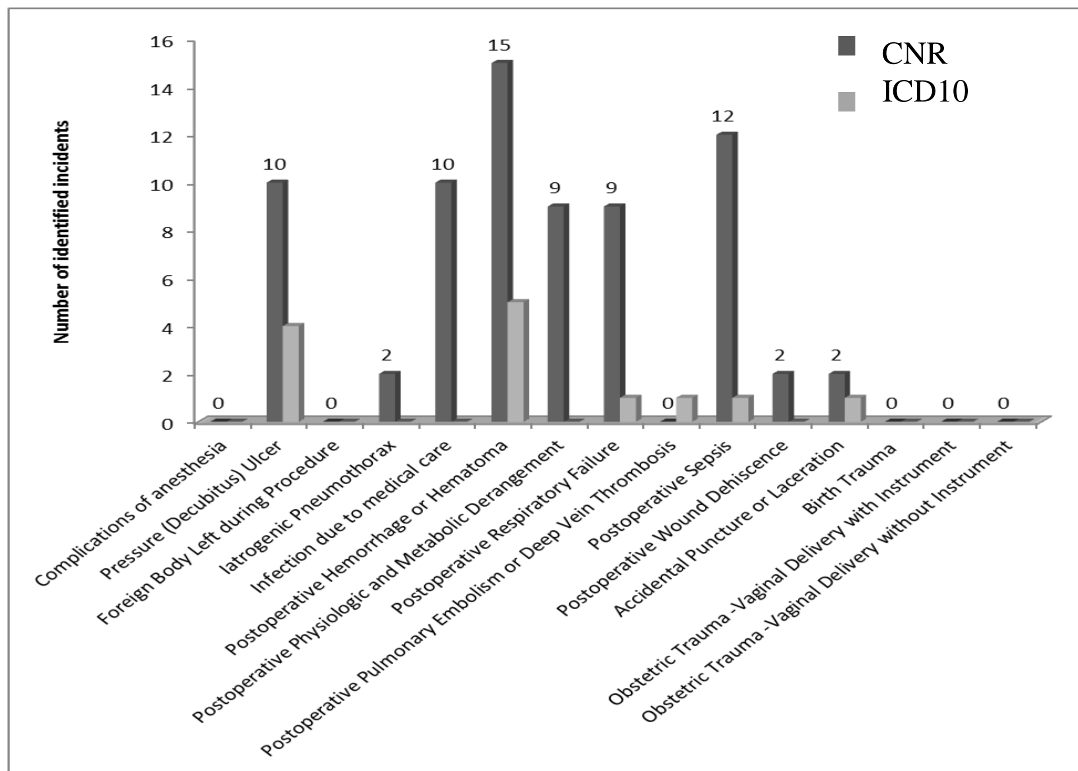

Chart1: Comparison between the two incident identification methods.