Research article

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The case of Patient Safety Indicator 12 (PSI12): use of administrative data to estimate the incidence of "Postoperative Pulmonary Embolism or Deep Vein Thrombosis". A pilot study in a General Hospital

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Abstract

Introduction. The AHRQ Quality Indicators (QIs) were created in order to both identify the performance and to track the improvement of patient safety. Patient Safety Indicator 12 (PSI12) is relative to the risk of Post Operatory Pulmonary Embolism or Deep Venous Thrombosis (PO DVT/PE). This pilot study has three main objectives. Firstly, to perform an analysis of the performance of different hospital wards by using administrative data; secondly, to analyze defects in the process that led to the occurrence of the adverse event; thirdly, reviewing the single PO DVT/PE.

Methods. Data were extracted from a Hospital Information data flow (SIO) and compared to Clinical Discharge Record. PSI12 estimates were computed before and after the screening. Control Charts allowed the static analysis of performance between different hospital wards in 2014. The Ishikawa diagram was drawn for the analysis of the underlying causal process.

Results. The number of PSI12 cases provided by DRGs through SIO data flow decreased from 45 to six after the comparison with the correspondent clinical records. Four clinical records provided full information allowing the analysis of process. The Ishikawa Diagram identified the defects in the process of prophylaxis that resulted into a PO DVT/PE.

Discussion. The clinical records screening revealed a lower incidence of PO DVT/PE with respect to the DRGs statistics. Overall the PO DVT/PE occurrence in 2014 fell into the control limits, although the result could be undermined by the low quality of clinical records compilation. The failure in the prophylaxis procedure was imputable to pitfalls in the health care management and to the individual attitude towards patient safety procedures. In conclusion, the reliability and validity of administrative data in monitoring quality and safety are worthy to be explored in the context of further validation studies. ***Clin Ter 2019; 170(1):e27-35. doi: 10.7417/CT.2019.2104***

Key words: *Patient Safety Indicator, administrative data, Postoperative, Pulmonary Embolism, Deep Vein Thrombosis, Hospital*

Introduction

The Agency for Healthcare Research and Quality's (AHRQ) is an operating division of the US Department of Health and Human Services (HHS), designated to improve quality, safety, efficiency, and effectiveness of American health care and health care delivery system. As part of this mission, AHRQ developed a tool for health care decision making that can be used by managers and researchers within institutes at both national and local levels, to measure the performance of patient safety. The AHRQ PSIs are a set of administrative data based indicators used to identify potential in-hospital patient safety events (1-5).

The AHRQ PSI indicators were created in order to both identify the performance and to track the progress in patient safety. The theory underlying these indicators is based on strong evidence suggesting that public reporting performance is a key element that promotes enhanced patient care. Consequently, they were designed with the goal of creating tools for quality tracking and improvement. The PSIs were developed after a comprehensive literature review, the analysis of ICD-9-CM codes, the implementation of a risk adjustment from a clinical panel data, and further rigorous empirical analyses. They can be employed to detect potential quality problems, to identify areas that need further studies and surveys, and to track changes over time. (6) Moreover they can allow preventive interventions, at "system" or "provider" level (6, 7).

The set of QIs requires the use of Hospital administrative data in order to provide information on potential hospital complications and adverse events following surgeries, procedures, and childbirth. They are measured as ratio (percentage of complications or adverse events and hospitalizations for a given condition or procedure, in a specified period of time). Eight of these are related to surgical adverse events, eight to other different medical and surgical events, and four to obstetric events (7, 8).

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The PSI module contains in its entirety 24 indicators that identify "potential risks for the quality of care." They are divided into two groups according to the type of hospitalization. Seventeen "Provider-based Patient Safety Indicators" are specific for medical conditions and surgical procedures, and they have been proven to be associated with deficient quality of care. Seven "Area-based Patient Safety Indicators" are identical to the indicators 'Provider-based', except for the fact that the numerator also incorporates the primary diagnosis, in order to comprise all cases of complication, not only those occurred during hospitalization are considered (7, 8).

The aims of the present study are:

a) To conduct an analysis of performance of departments through Control Chart by using administrative data;
b) To analyze defects in the process, through a cause-effect diagram that led to the occurrence of the adverse event, reviewing the single clinical charts of events related to PSI 12.
c) To focus the health decision maker policy on the weak points of process in order to improve the quality and safety of procedure accordingly (2).

Methods

This descriptive study was carried out in a General Hospital located in Rome, Italy. It focused on either perioperative pulmonary embolism (PE) or deep vein thrombosis (DVT) (in secondary diagnosis) cases occurred after surgical interventions in 2014. The hospital administrative data system (SIO) provided the DRGs corresponding to the AHRQ PSI12 indicator. By definition, PSI12 includes perioperative pulmonary embolism or deep vein thrombosis (secondary diagnosis) per 1,000 surgical discharges for patients aged 18 years and older. The PSI12 exclusion criteria include:

- Cases with principal diagnosis for pulmonary embolism or deep vein thrombosis;
- Cases with secondary diagnosis for pulmonary embolism or deep vein thrombosis present on admission;
- Cases in which interruption of vena cava is the only operating room procedure or in which interruption of vena cava occurs before or on the same day as the first operating room procedure;
- Obstetric discharges (6-8).

Data drawn up from Electronic Medical Records (SIO) were compared with the information reported in the correspondent Clinical Records. The Office of Quality and Safety handled the SIO flow, conversely the access to the archive of Clinical Records was issued by the Hospital General Management. Patient personal information was not disclosed by law, furthermore it was beyond the purposes of this study.

Data extraction

PO DVT/PE data were extracted from SDO (Schede di Dimissione Ospedaliera, Hospital Discharge Records) Records through the Hospital Information System Data (SIO) and collected in an Excel spreadsheet. Cases were either reported for any single ward or aggregated at Department level; for instance, four Wards pertained to General Surgery Department, hence, data for the whole Department were provided summing up the cases recorded in each General Surgery Ward. Either the crude number of PO DVT/PE cases occurred in each ward or the number of cases weighted for discharges were furnished. The Clinical Records for data extraction were provided by the Health Hospital Authority. Data were drawn up from Clinical Records by two authors and each conflict of information has been solved with the intervention of all authors. In order to obtain a reliable patient-measure, the individual PO DVT/PE standardized risk was assessed by employing the Tuscany Guidelines for PO DVT/PE prevention, available at (http://www.snlg-iss.it/lgr_toscana_TEV). The standardized PO DVT/PE risk was weighted for the main categories of Surgery, for type of surgical procedure, for individual baseline risk and prophylaxis. (9) Two types of prophylaxis were included, mechanical and pharmacological (Appendix). Further standardized risk factors for Neurosurgery and Cardiac Surgery specialties were extracted from the scientific literature cited by the Tuscany Guidelines. (10-13) The risk factors were graded into high degree and mild/moderate degree of risk (Appendix).

Data were collected in Excel tables.

The analysis of performance

Computing PSI12

By definition, the PSI12 is a 'Provider Level' of safety evaluation. The numerator refers to the number of discharges among cases meeting the inclusion and exclusion rules for the denominator: with ICD-9-CM codes for PO DVT/PE in any secondary diagnosis field. (8) The denominator figure includes surgical discharges for patients aged 18 years and older with any-listed ICD-9-CM procedure codes for an operating room procedure. Surgical discharges provided by SIO, are defined by specific DRG or MS-DRG codes. Exclusion criteria include:

- Observations with a principal ICD-9-CM diagnosis code (or secondary diagnosis present on admission) for deep vein thrombosis (DVT)
- Observations with a principal ICD-9-CM diagnosis code (or secondary diagnosis present on admission) for pulmonary embolism (PE)
- Observations where the only operating room procedure is interruption of vena cava
- Observations where a procedure for interruption of vena cava occurs before or on the same day as the first operating room procedure
- DRG associated with pregnancy, childbirth, and puerperium (8).

Postoperative PE or DVT generally performs well on different dimensions, including reliability, bias, relatedness of indicators, and persistence over time. In particular The signal ratio measure of thetotal variation across hospitals that is truly related to systematic differences (signal) in hospital performance rather than random variation (noise) is moderately high, relative to other indicators, at 72.6%, suggesting that observed differences in risk-adjusted rates likely reflect true differences across hospitals (6-8).

Control Chart

Theoretically, the Control Chart describes the trend of a variable and it is considered significant to represent the quality of a process over time. (14) In this study, the graph was adapted such that the X-axes corresponds to the total number of non-cases among the wards discharges over one year (2014) and the Y-axes represents the measure of outcome under 'control', in other words, the number of PO DVT/PE cases. The resulting 'static' analysis of performance was relative to one year's worth of data analysis (2014) (Fig.1). Defectives are counts of dichotomized outcomes (cases or non-cases) and each spikes represents the number of cases plotted against non-cases for each hospital ward in 2014.

The Central Line (CL) of the graph represents the gold standard value for the controlled process. In addition, the Control Chart establishes the 'monitoring limits', in order to report any anomalous trends of the process, before reaching the threshold of 'error':

- UWL = Upper Warning Limit (mean +2 standard deviation, SD)
- LWL = Lower Warning Limit (mean – 2 standard deviation, SD).

The average and the control limits (LCL and UCL) were computed and displayed for each ward over one year. If the peak's shard (or point) falls outside the lowest or highest limits, it means that the process is out of control. This statistical tool was realized by using Stats Direct (14, 15).

The analysis of Process: Cause-Effect Diagram

Measurement error may be decomposed according to various sources, Ishikawa diagram, also known as a 'fishbone' diagram of 'cause-effect', represents an useful qualitative tool to visualize how different sources of measurement error and uncertainty may contribute to the overall measurement result. Such as diagram is drawn with one 'principal bone' and several 'secondary bones' for each source of measurement error and uncertainty detected. The 'fish head' represents the main problem; the secondary bones were built by holding constant one or several categories of problems (16).

Results

Data and PSI12

This pilot study focuses on PO DVT/PE cases occurred in 2014. Overall, 27 Wards over 56 presented an adverse event and the SIO flow identified 45 SDO (Hospital Discharge Records) reporting a code for PO DVT/PE, in secondary diagnosis (Table1).

Concerning the single ward, the highest number of cases were recorded in Thoracic Surgery (5) followed by General Surgery and Cardiovascular Diseases (4), and finally Gastroenterology (3).

Regarding the performance of wards grouped by Specialty, General Surgery ranked at the top with eight cases overall, followed by Internal Medicine with six cases, Thoracic Surgery, already mentioned (five events), and the Cardiovascular Diseases Unit with four cases.

Using the original algorithm for the PSI12 and applying it to 2014 inpatient discharges, we identified six numerator events and 13,088 patients in the denominator after the clinical records check. 45 cases were detected in 2014 by the SDO data. The PSI12 rate relative to SDO data was 3.438 and 0.458 after the Clinical Records' screening.

The ratio ranking (number of cases over the total discharges) reported at the top position Gastroenterology (375.00) followed by Stroke Unit (71.43), Internal Medicine (Metabolic Disorders) (58.82) and Respiratory diseases (58.82); at the bottom Neurosurgery and Gynecological Oncology.

The screening of the Clinical Records provided six true positive cases out of 45 that met the PSI12 inclusion criteria. In four cases, it was possible to draw up full information in order to rebuild the entire process that led to the adverse event and to compute the individual risk for PO TVP/PE (Table2). The SDO data documented that the highest PSI12 rate pertained to Gastroenterology ward, showing a PSI=375.00; followed by Stroke Unit with PSI=71.43 and Internal Medicine together with Respiratory Diseases Unit with PSI=58.82.

Control Chart

Figure1 shows the Control Chart relative to the average number of PO DVT/PE in 2014, according to the data provided by SDO. The mean of PO DVT/PE cases in 2014 was 0.804±3.073 (±2 SD). The three peaks of the broken line outside two SD from the mean pertained to Thoracic Surgery and General Surgery reported the two highest peaks, Urology the lowest one (Fig. 1).

After the screening of Clinical Records only four cases met the inclusion criteria for the PSI12 and went through further analysis to detect errors in the process. Two cases were Italian, 1 South American and one from the Eastern Europe. The age ranged between 43 and 83 years. Two cases occurred in the General Surgery ward and two in the Gynecology ward but the latter were not associated with pregnancy, childbirth, and puerperium. None underwent internal or external transfers towards or by different Departments.

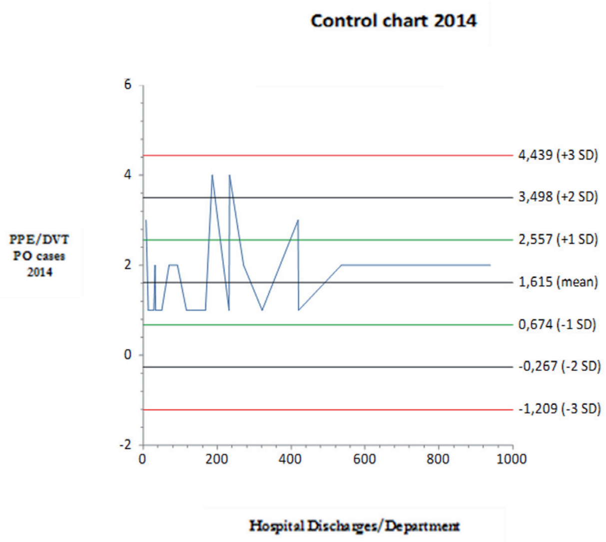

Fig. 1) Control Chart 2011: PSI 12 cases extracted by administrative data (first and second SDO diagnosis).

Table1. SDO data on PO TVP/PE cases, year 2014 (Ward's letters assigned purely random).

Ward	N Cases	N Non-Cases	N Discharges	Cases/ Non Cases*1000	Cases/ Discharges*1000
Anesthesia_Cardiac Surgery	0	19	19	0.000	0.000
Anesthesia_OrganTransplantation	1	30	31	33.333	32.258
TOT Anesthesia Specialty	1	49	50	20.408	20.000
Angiology Unit A	0	86	86	0.000	0.000
Angiology Unit B	1	117	118	8.547	8.475
TOT Angiology Specialty	1	203	204	4.926	4.902
Cardiovascular Diseases Unit	4	426	430	9.390	9.302
Cardiovascular Diseases_Physiopathology Unit	0	124	124	0.000	0.000
TOT Cardiovascular Diseases Specialty	4	550	554	7.273	7.220
Day Surgery A	1	127	128	7.874	7.813
Day Surgery B	0	136	136	0.000	0.000
DaySurgery C	1	118	119	8.475	8.403
TOT DaySurgery Specialty	2	381	383	5.249	5.222
Ematology	1	36	37	27.778	27.027
Emergency Department	1	46	47	21.739	21.277
Emergency Surgery	2	93	95	21.505	21.053
Endocrine Surgery	0	110	110	0.000	0.000
Gastroenterology	3	5	8	600.000	375.000
General Surgery A	1	53	54	18.868	18.519
General Surgery B	1	387	388	2.584	2.577
General Surgery C	2	321	323	6.231	6.192
General Surgery D	4	251	255	15.936	15.686
General Surgery_ Frail Patient	0	66	66	0.000	0.000
General Surgery_OrganTransplantation	0	149	149	0.000	0.000
General Surgery_Reconstructive Surgery	0	356	356	0.000	0.000
General Surgery_Gastro Hepatobiliary	0	38	38	0.000	0.000
General Surgery_Endoscopy	0	87	87	0.000	0.000
TOT General Surgery Specialty	8	1708	1716	4.684	4.662
Geriatrics	1	37	38	27.027	26.316
Geriatrics_Riabilitation	0	0	0	0.000	0.000
TOT Geriatrics Specialty	1	37	38	27.027	26.316
Gynecological Oncology	2	940	942	2.128	2.123
Infectious Diseases A	0	23	23	0.000	0.000
Infectious Diseases B	0	33	33	0.000	0.000
Infectious Diseases C	0	12	12	0.000	0.000
Infectious Diseases D	0	0	0	0.000	0.000
TOT Infectious Diseases Specialty	0	68	68	0.000	0.000
Intensive Care Unit	0	17	17	0.000	0.000
Internal Medicine A	1	23	24	43.478	41.667
Internal Medicine B	2	70	72	28.571	27.778
Internal Medicine C	1	45	46	22.222	21.739
Internal Medicine D	0	27	27	0.000	0.000
Internal Medicine _Metabolic Disorders	2	32	34	62.500	58.824
Internal Medicine_Therapy of Neck Diseases	0	76	76	0.000	0.000
TOT Internal Medicine Specialty	6	273	279	21.978	21.505
Jaw Surgery	0	526	526	0.000	0.000
Laparoscopic Surgery	0	0	0	0.000	0.000
Nephrology	0	6	6	0.000	0.000
Neurosurgery	1	443	444	2.257	2.252
Orthopedics A	2	543	545	3.683	3.670
Orthopedics B	0	536	536	0.000	0.000
Orthopedics C	1	173	174	5.780	5.747
TOT Orthopedics Specialty	3	1252	1255	2.396	9.417

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Otolaryngology	0	299	299	0.000	0.000
Polytrauma Surgery	1	44	45	22.727	22.222
Respiratory Diseases	1	16	17	62.500	58.824
Stroke Unit A	1	13	14	76.923	71.429
Stroke Unit B	0	29	29	0.000	0.000
TOT Stroke Unit Specialty	1	42	43	23.810	23.256
Thoracic Surgery	5	205	210	24.390	23.810
Tracheobronchial Laserterapy	0	30	30	0.000	0.000
TOT Thoracic Surgery Specialty	5	235	240	21.277	20.833
Traumatology	0	278	278	0.000	0.000
Urology	0	267	267	0.000	0.000
Urology_Mini-invasive surgery technology	0	257	257	0.000	0.000
TOT Urology Specialty	0	524	524	0.000	0.000
Vascular Surgery A	1	242	243	4.132	4.115
Vascular Surgery B	0	292	292	0.000	0.000
TOT Vascular Surgery Specialty	1	534	535	1.873	1.869
TOTAL	45	14571	13088	3.088	3.438

Table 2. Complete Clinical Discharge Records of PSI12 cases in 2014.

DATA OF FOUR PO DVT/PE PSI12 DISCHARGE RECORDS PROVIDING FULL INFORMATION		DISCHARGE RECORDS YEAR 2014			
		201406----	201403----	201403----	201402----
AGE		47	83	66	43
GENDER		FEMALE	FEMALE	FEMALE	FEMALE
COUNTRY		ROMANIA	ITALY	ITALY	VENEZUELA
COD DIAGNOSIS ICD-9	PRINCIPAL	1809	1522	1830	14583
	SECONDARY	591. 4019. 5849. 7895. 41511. 1976	4539	41511	4539
TRANSFER		NO	NO	NO	NO
WARD		GINECOLOGY	GENERAL SURGERY	GINECOLOGY	GENERAL SURGERY
DATE OF INTERVENTION		MISSING	04.08.2014	23.06.2014	14.04.2014
PO DVT/PE PROPHYLAXIS	THERAPY	YES	YES	YES	NO
	DRUG	NADROPARIN	ENOXAPARIN	NADROPARIN	FONDAPARINUX
	THERAPY AT ADMISSION	NO	NO	NO	NO
	DOSAGE (UNITS)	4000	6000	12000	7500
	START DATE	MISSING	MISSING	23.06.2014	19.04.2014
	LENGHT OF THERAPY ADMINISTRATION (DAYS)	MISSING	5	3	-5
RISK DVT/PE	ANAGRAPHIC	0.5	1.5	1	0.5
	INDIVIDUAL	2	2	2	0
	OTHER	3	2	2	1
	TOTAL	5.5	5.5	5	1.5
APPROPIATENESS OF THERAPY	DRUG	MISSING	YES	NO	NO
	POSOLOGY	MISSING	YES	NO	NO
	LENGHT OF THERAPY ADMINISTRATION	MISSING	YES	NO	NO
	SUT* INCOMPLETE	YES	YES	YES	YES
	TOTAL	1+	1	1	1

*SUT: therapy record form for nurses and health care staff.

The PO DVT/PE event (where certainly diagnosed and documented) arose on average 5 days after the surgical procedure; the principal diagnoses in the Gynecology ward were relative to ovarian and cervical cancer, and the principal diagnoses of cases occurred in the General Surgery ward were ileum cancer and oral cancer.

In any case, PO DVT/PE was present in secondary diagnosis. ICD-9 4539 (OTHER VENOUS EMBOLISM AND THROMBOSIS OF UNSPECIFIED SITE) was reported in two cases and ICD-9 41511 (IAGTROGENIC PULMONARY EMBOLISM AND INFARCTION) in the remaining two events.

PE occurred only in Gynecology ward; conversely, DVT arose among patient who underwent General Surgery. In both PE cases occurring in the Gynecology ward, NADROPARIN was adopted for prophylaxis, contrariwise ENOXAPARIN and FONDAPARINUX were employed in the General Surgery wards. In three cases, the risk of PO DVT/PE (Appendix) scored over five. Overall, the main characteristics of the adverse events showed:

- High individual baseline risk of PO DVT/PE according to Tuscany Guidelines
- Use of LMWH anticoagulant for pharmacological prophylaxis according to the Hospital Internal Procedure and Tuscany Guidelines (9)
- Failure of mechanical prophylaxis: mobilization, use of elastic stockings, plantar venous pump adopted in three cases.
- Nurse treatment sheet was not available in one case.

Ishikawa Diagram

The Ishikawa Diagram is shown in Figure 2. We appraised that the main cause of PO DVT/PE lied in the substantial failure of the PO DVT/PE prophylaxis. The lateral spikes identified the flawed steps of the process contributing to the main cause occurrence and entailed who was involved, what the problem was related to, or at which point of process the PO DVT/PE occurred (Fig.2).

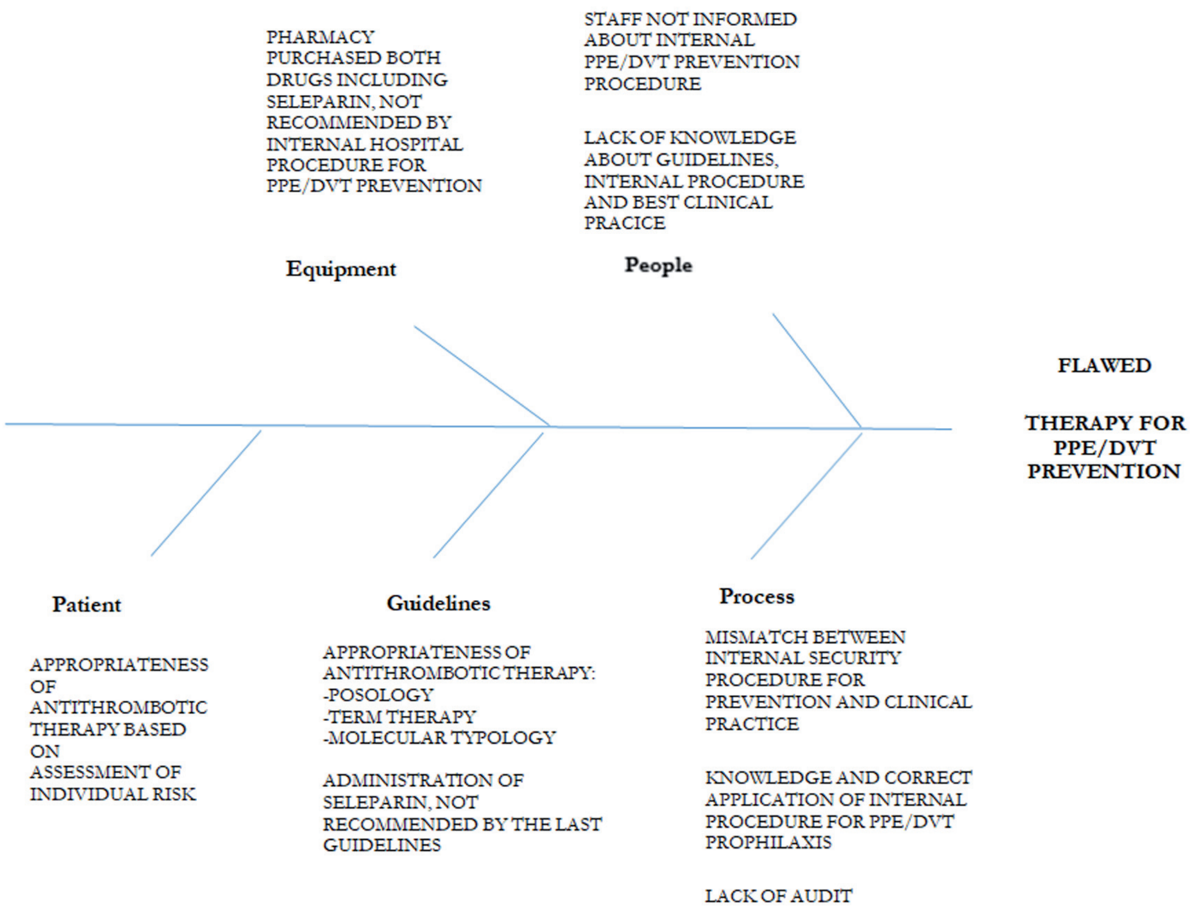

Fig.2. 'Fish Bone' ISHIKAWA flow-chart. Copyright JCAHO 2001.

Four principal categories of causes were included in the 'cause-effect' diagram resulting in a failure of PO DVT/PE prophylaxis therapy. The spines heading the causes alongside the central line were grouped in four categories:

Organization: the incomplete filling of the Clinical Records turned out to be the main cause involved in the chain of causation, because it did not allow a full and consistent brainstorming of the entire health care process.

Method: the improper Internal Procedure implementation involves either the Health Care Staff or The Hospital Management. An inadequate personnel auditing and monitoring, together with a weak Health Patient Safety Policy contributed to the final effect occurrence.

Scientific evidence: the Internal Hospital procedure broadly recommended the use of Low Molecular Weight Heparin (LMWH) for the prophylaxis. In all cases, a LMWH anticoagulant was adopted as preventive therapy. In one case the prophylaxis was postponed to 5 days after the surgical intervention, apparently without explicated reason.

Environment: both the presence of communication barriers among the stakeholders and a weak "patient safety culture" were advocated as causes.

Discussion

The growing international interest in patient safety has led individuals and organizations to develop methods and systems of detecting, reporting and preventing potentially adverse events (17). Developed after a comprehensive literature review, the PSIs can be used to identify potential adverse events that might need further study. They can also be used to provide the incidence rate of adverse events and in-hospital complications by using administrative data drawn from the Discharge Records (6-7, 18-21). Deep vein thrombosis (DVT) and perioperative pulmonary embolism (PE) are a common postoperative complication and an important cause of morbidity and mortality, with 300,000 to 600,000 new cases each year and 100,000 to 300,000 deaths per year (21-22).

The need to provide Decision Makers with reliable information on which basing their portfolio of patient-security methodology is considered a priority for the development of a risk management system composition tool.

The analysis of performance

According to the AHRQ, the Empirical Performance of PSI12 reported a value of 9.830 x 1,000 population at risk in 2003 (population rate). The substantial bias was attributable to the effect of the heterogeneity in the risk-adjustment factors considered, either individual (age, gender, comorbidity) or system related (DRG, single hospital characteristics and performance). Apparently the General Hospital involved in this study performed well concerning the PSI12 rate, reporting a ratio of 0.803. However, several limitations must be taken into account. Essentially the low frequency of PO DVT/PE occurrence would require a larger sample of observations, hence, a multicentric study might be a desirable option. This might allow understanding the extent to which the variability and heterogeneity surrounding the result was related to the aforementioned risk–adjustment factors (i.e individual or systemic). Accordingly, any endeavor to achieve a marginal improvement in quality and safety of healthcare would be oriented towards Provider or rather Patient level. Finally the 'stability' of the result must be checked by measuring the trend of the performance over time, therefore the follow up period should be extended (6-8).

Overall, the Hospital performance this study established the potential value of administrative data based measures to screen for patient safety events. So far, despite their approachability, availability and low-cost, administrative PSIs data sources have not been proven a viable screening tool in order to provide data on the quality of care related to patient safety. However, the validity and the reliability of administrative data as source of safety and quality patient's indicators is still controversial (18, 23-26).

Iezzoni et al. performed the first systematic exploration of the value of administrative data in quality and patient safety research in the early 1990s (27-28). They identified 27 potentially preventable in-hospital complications and they found that patients with complications were significantly older, increasingly likely to have comorbid conditions, more likely to die, and were higher in charges and lengths of stay than other patients (27-28). The accuracy of administrative data, such as SDO/DRG, in detecting the 'true positive cases', was assessed by Quan et al. in a series of validation studies (25-26). They concluded that administrative data alone could not accurately distinguish between medical conditions present on admission and those developing during hospitalization. A central issue might probably lie in the low sensitivity and positive predictive values (PPV) for many of the conditions studied due to their low prevalence (25). In connection with the validity of AHRQ PSI derived from ICD-10 hospital discharge, Quan et al. calculated PPV(positive predictive value) statistics: the proportion of positives in the administrative data representing 'true positives' were determined through Chart Reviews (CR) for several PSIs. They proved that administrative data had high PPV and are thus powerful tools for true positive case finding. In contrast, their sensitivity has not been well characterized, because under-coded data would generate falsely low PSI rates (26).

Furthermore, in a cross sectional study applying the CR, Maas et al. concluded that Indicators based on German administrative data deviate broadly from indicators based on clinical data. Therefore, hospitals should be cautious to use indicators based on administrative data for quality assessment (29). The reasons of a disproportionate rate of 'false positive' in SDO/Discharge Clinical records should be better assessed and understood, especially for the economic implications behind. In fact, a DVT may add a cost of $7769 and a pulmonary embolism (PE) $9176, to a hospital stay. Mean short- and long-term disability claims for DVT were estimated between $7400 and $58,000, respectively. For the PE, these were estimated to be approximately $7600 and $48,800 for short- and long-term, respectively (22).

The analysis of process

In the present pilot study, the application of PSI12 to Surgical Wards of a General Hospital raised several aftermaths and duties for the Health Care Provider:

- To encourage a proper filling of Medical Records and SDO among the health care staff.

- To promote the monitoring system through Audit in order to check the adherence of Health Care Staff to the Hospital Internal Procedure.

- To empower the 'safety culture' among the Health Care Workers

- To extend the assessment of quality and safety standards by computing all PSIs provided by the AHRQ.

The reliability and validity of administrative data are worth to be explored in the context of further validation studies that utilize data from other sources. Moreover, according to the 2014-15 HCQI (Health Care Quality Indicators) data collection revision, the PSI12 numerator was decomposed into two separate indicators, one for PE and one for DVT, therefore, countries are requested to calculate these indicators using the revised specifications and algorithms (30) and further studies will be required.

In conclusion, looking at the objectives of this study, one could argue that the use of administrative data is far from being perfect in a context of patient safety management, and this could be important from the medico-legal point of view (31-34). The revision of single PO DVT/PE through the clinical chart is still an option to consider for fully understand the process.

COMPETING INTEREST

The authors have not competing interest.

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DATA SHARING

The final manuscript does not contain unpublished data. Any further information not provided by this article is protected by privacy. No repository or data retrieval system applied.

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