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Consistency of safety monitoring using routine national databases: results using a quality of care interpretative model

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Background: In the framework of targeted action for continuous safety monitoring, we aimed to evaluate the consistency of indicators derived from available databases for regular reporting. **Methods:** We used a quality of care interpretative model to select characteristics from five national databases, aggregated and linked by homogeneous groups of providers. The target population included all subjects admitted to public hospitals for acute care in four regions of Italy between 2011 and 2013. The association between structures, processes and safety-related outcomes was investigated using odds ratios from generalized estimating equations logistic regression. Outcome measures included claims of malpractice and five patient safety indicators calculated from discharge abstracts using standardized algorithms. **Results:** Over 3 years, claims of malpractice and sepsis increased, whereas deep vein thrombosis and pulmonary embolism decreased. Hospitals with high vs. low volume of discharges were associated with −16% lower rates of claims, but +12% increased risk of sepsis. Compared with research institutes, university clinics had −17% lower rates of claims and −41% cases of dehiscence, with a +32% increased risk of deep vein thrombosis. Local health care authorities recorded −49% deep vein thrombosis, −26% pulmonary embolism, −40% sepsis and +37% risk of claims. Hospitals submitting cases of safe practices and implementing safety recommendations showed significantly higher rates for most outcome measures. **Conclusions:** Indicators from regular databases can be conveniently used to develop a national safety monitoring system for hospital care. Although deeper analysis is needed, institutions with a higher propensity to implement safe practices and recommendations consistently showed higher rates of adverse events.

Introduction

The continuous monitoring of patient safety is a key element of quality improvement strategies that need standardized actionable indicators to be implemented.[1]

Routine data may offer a sustainable solution to compute patient safety indicators automatically.[2] However, their reliability can be hampered by systematic under-reporting of adverse events.[3,4]

Various methods have been proposed to overcome these limitations: integrated use of multiple databases (e.g. incident reporting, retrospective reviews, malpractice claims, patient complaints, etc.); structured recording or data extraction from clinical activity (text mining from clinical records, data gathering from direct observation and trigger tools, safety walkarounds, etc.); and advanced statistical techniques (e.g. longitudinal algorithms using hospital records, process/injury analysis and morbidity/mortality assessment).[2,5–11]

Barriers to the applicability of these methods include the fragmentation of safety-related data and the lack of coordination between different stakeholders holding relevant information.[2,12–16]

During the past decade, the Italian Ministry of Health (MoH) applied some of the above methods systematically, in strong collaboration with the Regions and Autonomous Provinces (R&APs) and the National Agency for Regional Health Services (AGENAS).[17,18,19]

Targeted actions included the creation of a central database of mandatory declarations of malpractice claims,[20] the release of MoH recommendations to prevent adverse events,[21] the data collection of safe practices[18] from R&APs and the regular calculation of patient safety indicators using the national hospital discharge database (SDO).

In 2013, the OECD review of quality of care in the Italian National Health Service (SSN) advised to strengthen the production of usable and reliable data for the continuous audit and systematic benchmarking of patient safety.[22] A subsequent report presented Italy as a relevant case study.[23] Consequently, the MoH addressed the use of available databases by financing the project 'Supporting Regions in the Implementation and Improvement of Monitoring Systems for Clinical Risk Management' (Linkage).[24]

This article aims to respond to the following research questions posed by the Linkage project:

- How can the available data sources be combined to compare practices at regional, district and provider level through proper patient safety indicators?
- To what extent the resulting indicators can be interpreted consistently to promote their use as crucial information to make healthcare organizations learn and to inform policies on patient safety? What are the strengths and weaknesses of the overall model and how to improve it for continuous safety monitoring?

Methods

The study was conducted by AGENAS between 2014 and 2015 as a retrospective analysis of linked aggregate data by groups of providers, using automated data extraction from different national databases.

Study population

The study population included all subjects admitted for acute care in public hospitals of the regions Emilia Romagna, Lombardy, Lazio and Sicily, discharged between 2011 and 2013. The participating regions were all actively involved in the actions for patient safety promoted by the MoH. The application of other methods on a regular basis was very limited.

The sample was selected according to the following criteria: (i) including at least one region from the North, Centre and South, so that different policies implemented across the country could be examined[25]; (ii) using a limited sample to involve local clinical risk managers and to allow direct checks on relevant data; (iii) excluding private providers, due to their heterogeneity and variable participation to the voluntary data collection; and (iv) choosing a time interval of minimum 3 years to ensure that an adequate number of adverse events could be observed.

Data matrix and interpretative model

The study was conducted using four key national data sources held by AGENAS as part of its mandate on patient safety: (i) malpractice claims[20]; (ii) implementation of MoH recommendations to prevent adverse events[21]; (iii) application of safe practices[18]; and (iv) SDO database (pseudo-anonymized to track hospital readmissions).

The details of the above data sources, including their coverage and limitations, are presented in table 1.

A quality of care interpretative model was adopted to evaluate the consistency of a range of patient safety indicators that could be automatically calculated from the above data sources.[26]

The characteristics used to populate the data matrix adopted for the study are presented in table 2.

All characteristics were either directly derived or calculated at the level of groups of acute care providers pre-specified by the study coordinators, identified by the type of provider in the data matrix.

Table 1 Characteristics of databases used for the analysis

Description	Coverage, accessibility and limitations
Database of the 'Observatory of Good Practices for Patient Safety'	
Since 2008, AGENAS, in collaboration with the Government, Regions and Autonomous Provinces, launches an open call for all public and private institutions, accredited or authorised, to identify and collect practices to improve quality and safety in health care (http://buonepratiche.agenas.it/practices.aspx). The data collection tool, periodically revised by a national network for safe practices, is based on SQUIRE principles ('Standards for Quality Improvement Reporting Excellence', www.squire-statement.org). Practices are classified as: safe practices (evidence-based and completed), potential safe practices (partially fulfilling the above criteria) and initiatives (interventions that are not specified in detail).	Between 2008 and today, AGENAS collected a total of approximately 3500 practices, whose comparability over time may be hampered by changes in the data collection tool. In 2013, a total of 36/397 providers submitted safety practices, of which 25 reported a total of 65 safe practices (3 involving surgery) and 11 potential safe practices or initiatives. Information is in the public domain and easily accessible. A limitation of the database consists in the voluntary basis of the data collection.
Monitoring system for the implementation of recommendations to prevent adverse events	
In 2005, the Italian Ministry of Health specified a list of 'Recommendations' to prevent the occurrence of adverse events, considered as a high priority for patient safety due to their burden for patients and relevant consequences on health care providers. The list has been regularly updated and their implementation in Regions and Autonomous Provinces directly monitored by AGENAS since 2009. In 2018, a total of 17 recommendations were regularly followed up using a targeted questionnaire available online (http://www.salute.gov.it/portale/temi/p2_6.jsp?id=250&area=qualita&menu=sicurezz).	In 2013, a total of 158 institutions participated to the monitoring system, of which 132 implemented surgical recommendations and 129 an operating room checklist. The database can be queried directly by the Regions and Autonomous Provinces using credentials provided by AGENAS.
Information System to Monitor Errors in Health Care (SIMES)	
In 2009, a Decree of the Ministry of Health (11 December 2009) established the central Information System to Monitor Errors in Health Care (SIMES). The data collection was finalized to report and classify all claims of malpractice. Two types of cases enter the database: adverse events and damages for malpractice. The Ministry of Health and AGENAS have direct full access to all records, including requests for compensation due to malpractice and all legal cases raised against accredited health care providers. The submission of cases to the Ministry of Health has been made mandatory since 2014.	The SIMES database includes claims submitted since 2009. In 2013, a total of 97 institutes reported $N = 5397$ claims to the central database, 91 contributing with 3810 cases of personal injuries or deaths and 54 reporting 835 surgical cases. A limitation of the database consists in the voluntary basis of the data collection for the timeframe considered in this study.
National Discharge Database (SDO)	
The SDO database has been established with the Decree 28 December 1991 as a common tool to collect information for each subject discharged by any hospital across the country (public or private). The Decree 26 July 1993 established the electronic database and the format of files to be submitted by Regions directly to the Ministry of Health. The database includes specific characteristics extracted from the medical record, including personal data (sex, date and place of birth), clinical information (diagnosis, procedures and other data on admission and discharge) and several organizational arrangements of the stay. Various changes have been made over time to improve the content and timely submission of data to national institutions. In 2018, data were sent from the hospital to the Region every 3 months, then transmitted to the Ministry after further control.	The SDO database has a complete coverage of discharges from all public and private accredited hospitals. The database is accessible only by accredited users (either centrally or in each Region for their relative data) and can only be used with a motivated and approved request. Information is mainly of administrative nature and is based on the ICD9CM/DRG system, which is of limited use for epidemiological investigation and health services evaluation.
Open data by the Ministry of Health	
The dataset includes data related to organizational resources e.g. the total number of beds accredited to each hospital by type of care (acute, day hospital, day surgery), as well as the composition of local health authorities by constituent hospitals and the type of hospital. The composition of workforce on a permanent contract is also available for all accredited health care providers, by type of professional (physician, nurse).	Available data are generic and not sufficiently updated. Access to the database directly maintained by the Ministry of Health is open and unrestricted.

Table 2 Characteristics included in the quality of care interpretative model for each provider cluster

Area	Indicator		Description
Structures	Type of healthcare organization		Classification in one of the following categories: Research Institute (IRCSS), Hospital trust (AO) and University clinic or Local Health Authority (ASL)
	Volume of cases		Total no. annual discharges per year, categorized by tertiles of average annual discharges (low: less than 25 715; medium: 25 715 to less than 38 000 and high: 38 000 or above)
Processes	Number of safety practices implemented		Safe practices, intended as surgery procedures properly performed by hospitals (e.g. surgical safety checklist, tools for the correct identification of the patient), categorized ex-post as present/absent by analysts using agreed evaluation criteria.
	Number of recommendations implemented for preventing adverse events		Total no. records during the reference period, categorized as none, between 1 and 9, 10 or more.
	Average number of secondary diagnoses		Average number of fields in each record of the SDO database included in the calculation for each PSI (see below).
Outcomes	Malpractice claims for personal injuries and deaths		Rates per 100 000 discharges of claims for malpractice leading to personal injuries or deaths, including claims for damages, civil and criminal court notifications against health care providers after a potential case of malpractice.
	PSI[a]	Foreign body left during surgery (FB)	Rates per 100 000 discharges of patients aged 15+ with any ICD code of foreign body left in during procedure in a secondary diagnosis field during the surgical episode and in any diagnosis field during readmissions within 30 days of the surgery
		Deep vein thrombosis (DVT)	Rates per 100 000 discharges among patients aged 15+ operated for hip and knee replacement, with any ICD code for deep vein thrombosis in a secondary diagnosis field during the surgical episode and/or any diagnosis field during readmissions within 30 days of the surgery
		Pulmonary embolism (PE)	Rates per 100 000 discharges among patients aged 15+ operated for hip and knee replacement, with any ICD code for pulmonary embolism in a secondary diagnosis field during the surgical episode and/or any diagnosis field during readmissions within 30 days of the surgery
		Post-operative sepsis (SE)	Rates per 100 000 discharges among patients aged 15+ with surgical abdominal procedure, with any ICD code for sepsis in a secondary diagnosis field during the surgical episode and/or in any diagnosis field during readmissions within 30 days of the surgery
		Dehiscence of surgical wound (DE)	Rates per 100 000 discharges among patients aged 15+ with procedure code for re-closure of post-operative disruption of abdominal wall during the surgical episode and/or readmissions within 30 days of the surgery

a: The calculation of Patient Safety Indicators (PSIs) was based on the OECD specifications used for the data collection 2014–15 of the Health Care Quality Indicators Project (HCQI).[27] The algorithm chosen was based on the 24th Revision of ICD Classification, Clinical Modification (ICD-9-CM) used by the national SDO database in the reference years.

The list of 'clusters' of care providers in the four participating regions was based on the principle of attribution of the 'clinical risk manager' in charge by the law of all patient safety procedures.

Statistical analysis

Descriptive statistics were used to compute the cross-tabulated frequencies of outcomes for each level of structural and process characteristic included in the quality data matrix.

Multivariate logistic regression modelling was used to evaluate the consistency of information in the data matrix through the analysis of associations between its different elements, as measured by adjusted odds ratios (ORs) and 95% confidence intervals (CIs).

A separate logistic model was run for each outcome of interest, with all structural and process characteristics included as potential predictors. Further covariates added to the model included: dummy variables used to adjust for the different level of event rates in 2012–13 vs. 2011; average number of secondary diagnoses per discharge, used to adjust for the potential imbalance in the probability of recording an adverse event (in PSIs only).[28]

Two different types of multivariate models were applied: (i) clustered logistic regression via generalized estimating equations (GEE), using all observations in the data matrix ('All In'), which considers correlated outcomes within provider clusters and (ii) multivariate logistic regression, using observations for 2013 only, with categories of safe practices and recommendations attributed from the previous year (Longitudinal 'Lag' Model). In this case, we allowed for a 'delayed' effect of improved safety management and could not apply the GEE model, due to the number of observations that was insufficient for the convergence of the iterative estimation method.

SAS software[29] was used for the calculation of all characteristics included in the data matrix. All regression models were carried out using STATA.[30]

Results

The study population included a total of $N = 88$ clusters of care providers in the four participating regions, adding up to a total of $N = 8\,719\,910$ hospital discharges.

The descriptive statistics of the study sample are presented in table 3.

Over 3 years, the incidence of claims for injuries or deaths was equal to 123 per 100 000. The rates of adverse events varied among PSIs: while retention of FB showed to be rare (with just over 2 cases per 100 000), DVT and PE were more frequent (49, 47 cases per 100 000, respectively) and much higher for DE (139 per 100 000) and SE ($168 \times 100\,000$).

Hospitals with a medium to high volume of cases experienced lower rates of claims for malpractice (121, 122 vs. $134 \times 100\,000$) and FB (2 vs. $3 \times 100\,000$). However, the situation appeared the reverse when comparing high vs. mid, low volumes for DVT (59 vs. 38, 42), PE (51 vs. 45, 43) and SE (193 vs. 149, 143), with a u-shaped trend for DE (117 vs. 165, 145).

The rates of outcomes appeared also quite different by type of institution. Higher rates were observed for malpractice claims among Local Health Authorities (LHAs, $155 \times 100\,000$) and for FB at University hospitals ($3 \times 100\,000$). PSIs were systematically higher

Table 3 Descriptive statistics of study sample

		N Observations		Claims (injuries, deaths)				Foreign body					Deep vein thrombosis					Pulmonary embolism					Sepsis					Dehiscence				
		Struc-tures	Dis-charges	Ev.	*N*	Rate × 100 000	%	Ev.	*N*	Rate × 100 000	%	Av. no. sec. diag.	Ev.	*N*	Rate × 100 000	%	Av. no. sec. diag.	Ev.	*N*	Rate × 100 000	%	Av. no. sec. diag.	Ev.	*N*	Rate × 100 000	%	Av. no. sec. diag.	Ev.	*N*	Rate × 100 000	%	Av. no. sec. diag.
N		264	8 719 910	10 768	8 719 910	123	100.0	122	5 599 142	2	100.0	1.6	2395	4 914 301	49	100.0	1.7	2336	4 943 277	47	100.0	1.7	6086	3 613 353	168	100.0	1.6	490	353 210	139	100.0	1.3
Years	2011	88	3 013 024	3197	3 013 024	106	29.7	53	1 917 967	3	43.4	1.6	898	1 681 253	53	37.5	1.7	802	1 690 815	47	34.3	1.7	2008	1 239 725	162	33.0	1.6	181	119 665	151	36.9	1.3
	2012	88	2 965 675	3803	2 965 675	128	35.3	32	1 882 911	2	26.2	1.6	798	1 651 899	48	33.3	1.7	841	1 661 833	51	36.0	1.7	2055	1 214 264	169	33.8	1.6	158	118 065	134	32.2	1.3
	2013	88	2 741 211	3768	2 741 211	137	35.0	37	1 798 264	2	30.3	1.6	699	1 581 149	44	29.2	1.7	693	1 590 629	44	29.7	1.7	2023	1 159 364	174	33.2	1.5	151	115 480	131	30.8	1.2
Volume of cases	Low	88	1 534 920	2055	1 534 920	134	19.1	32	1 126 879	3	26.2	1.6	428	1 016 920	42	17.9	1.7	436	1 022 559	43	18.7	1.7	1054	734 674	143	17.3	1.5	101	69 581	145	20.6	1.2
	Medium	88	2 759 002	3332	2 759 002	121	30.9	39	1 790 899	2	32.0	1.5	589	1 567 702	38	24.6	1.6	713	1 577 112	45	30.5	1.6	1775	1 188 628	149	29.2	1.5	194	117 342	165	39.6	1.2
	High	88	4 425 988	5381	4 425 988	122	50.0	51	2 681 364	2	41.8	1.7	1378	2 329 679	59	57.5	1.8	1187	2 343 606	51	50.8	1.8	3257	1 690 051	193	53.5	1.6	195	166 287	117	39.8	1.3
Type of healthcare organization	IRCSS	24	476 414	489	476 414	103	4.5	5	286 375	2	4.1	1.6	176	256 089	69	7.3	1.5	131	257 083	51	5.6	1.6	270	145 196	186	4.4	1.2	33	19 642	168	6.7	1.3
	Hosp. Trust	114	3 775 522	4215	3 775 522	112	39.1	56	2 529 521	2	45.9	1.4	987	2 210 761	45	41.2	1.4	1026	2 224 948	46	43.9	1.4	2868	1 641 595	175	47.1	1.3	239	168 582	142	48.8	1.1
	Uni	30	1 273 536	1125	1 273 536	88	10.5	24	727 932	3	19.7	2.0	596	653 786	91	24.9	2.0	430	657 835	65	18.4	2.0	1142	456 265	250	18.8	1.9	64	51 151	125	13.1	1.8
	LHA	96	3 194 438	4939	3 194 438	155	45.9	37	2 055 314	2	30.3	1.8	636	1 793 665	35	26.6	1.9	749	1 803 411	42	32.1	1.9	1806	1 370 297	132	29.7	1.8	154	113 835	135	31.4	1.3
No. of safe practices	0	207	6 641 890	8283	6 641 890	125	76.9	100	4 268 153	2	82.0	1.7	1700	3 747 489	45	71.0	1.7	1692	3 768 414	45	72.4	1.8	4479	2 757 755	162	73.6	1.6	395	268 698	147	80.6	1.3
	≥1	57	2 078 020	2485	2 078 020	120	23.1	22	1 330 989	2	18.0	1.4	695	1 166 812	60	29.0	1.5	644	1 174 863	55	27.6	1.5	1607	855 598	188	26.4	1.3	95	84 512	112	19.4	1.1
No. of recommen-dations	0	115	3 786 588	4194	3 786 588	111	39.0	54	2 400 742	2	44.3	1.7	1006	2 106 601	48	42.0	1.7	939	2 117 517	44	40.2	1.7	2424	1 570 305	154	39.8	1.6	215	147 019	146	43.9	1.3
	1–9	39	1 127 506	1529	1 127 506	136	14.2	24	710 873	3	19.7	1.6	264	629 527	42	11.0	1.7	283	633 215	45	12.1	1.7	813	447 667	182	13.4	1.5	58	43 094	135	11.8	1.3
	10+	110	3 805 816	5045	3 805 816	133	46.9	44	2 487 527	2	36.1	1.6	1125	2 178 173	52	47.0	1.6	1114	2 192 545	51	47.7	1.6	2849	1 595 381	179	46.8	1.5	217	163 097	133	44.3	1.2

IRCSS, research institute; Hosp.Trust, hospital trust (AO); Uni, university clinic; LHA, Local Health Authority (ASL).

Table 4 Results of multivariate logistic regression for selected adverse safety events: GEE Model 'All-in' (white background) and Longitudinal 'Lag' (grey background)

		Claims (injuries, deaths)		Foreign body		Deep vein thrombosis		Pulmonary embolism		Sepsis		Dehiscence	
		OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*
Year (R.C. 1/4 2011)	2012	**1.18 (1.14–1.22)**	<0.01	**0.53 (0.32–0.88)**	0.03	**0.84 (0.79–0.90)**	<0.01	0.99 (0.91–1.07)	0.78	**1.05 (1.02–1.08)**	<0.01	0.85 (0.67-1.07)	0.16
	2013	**1.25 (1.19–1.31)**	<0.01	0.60 (0.33–1.06)	0.08	**0.75 (0.69–0.82)**	<0.01	**0.81 (0.73–0.90)**	<0.01	**1.10 (1.06–1.15)**	<0.01	0.79 (0.59-1.06)	0.12
Volume of cases (R.C. 1/4 low)	Medium	**0.91 (0.86–0.96)**	<0.01	0.73 (0.46–1.16)	0.19	0.78 (0.69–0.88)	0.44	1.01 (0.89–1.16)	0.82	**1.08 (1.02–1.15)**	0.01	1.22 (0.93-1.60)	0.15
		0.87 (0.80–0.95)	<0.01	0.96 (0.42–2.19)	0.92	1.20 (0.95–1.51)	0.13	1.13 (0.91–1.41)	0.27	**1.21 (1.06–1.38)**	<0.01	1.03 (0.68-1.56)	0.89
	High	**0.84 (0.79–0.89)**	<0.01	0.66 (0.43–1.02)	0.06	1.01 (0.90–1.13)	0.90	0.97 (0.85–1.10)	0.63	**1.12 (1.05–1.20)**	<0.01	0.84 (0.64-1.10)	0.21
		0.97 (0.89–1.06)	0.55	0.59 (0.23–1.52)	0.28	**1.57 (1.26–1.95)**	<0.01	1.21 (0.98–1.49)	0.08	**1.52 (1.33–1.73)**	<0.01	0.67 (0.42-1.05)	0.08
Type of institution (R.C. 1/4 Research Institutes—IRCSS)	Hospital Trust (AO)	1.03 (0.89–1.18)	0.70	1.38 (0.58–3.30)	0.47	**0.73 (0.57–0.94)**	0.01	0.92 (0.71–1.20)	0.55	0.92 (0.75–1.13)	0.44	0.80 (0.52-1.24)	0.31
		0.70 (0.58–0.84)	<0.01	3.70 (0.44–31.08)	0.23	0.73 (0.53–1.00)	0.05	0.92 (0.64–1.32)	0.65	0.96 (0.74–1.24)	0.73	0.95 (0.40-2.24)	0.91
	University clinic	**0.83 (0.71–0.97)**	0.02	2.04 (0.80–5.23)	0.14	**1.32 (1.01–1.73)**	0.04	1.11 (0.83–1.48)	0.50	1.07 (0.85–1.35)	0.55	**0.59 (0.35-0.99)**	0.05
		1.05 (0.89–1.22)	0.58	1.61 (0.20–12.82)	0.65	**0.64 (0.48–0.87)**	<0.01	**0.67 (0.48–0.92)**	0.01	1.03 (0.81–1.30)	0.81	1.05 (0.48-2.31)	0.90
	Local Health Authority (ASL)	**1.37 (1.19–1.57)**	<0.01	1.04 (0.43–2.55)	0.92	**0.51 (0.39–0.66)**	<0.01	**0.74 (0.56–0.97)**	0.03	**0.60 (0.48–0.74)**	<0.01	0.72 (0.47-1.11)	0.14
		1.40 (1.20–1.64)	<0.01	0.79 (0.09–6.77)	0.83	**0.34 (0.25–0.46)**	<0.01	0.73 (0.52–1.01)	0.06	**0.62 (0.48–0.79)**	<0.01	1.07 (0.49-2.32)	0.87
No. of safe practices (R.C. 1/4 0)[a]	≥1	**1.08 (1.04–1.13)**	<0.01	0.72 (0.44–1.18)	0.20	1.08 (1.00–1.17)	0.07	0.99 (0.89–1.09)	0.83	0.98 (0.94–1.02)	0.39	0.79 (0.62-1.02)	0.07
		0.99 (0.90–1.08)	0.78	0.69 (0.27–1.81)	0.45	**1.42 (1.18–1.71)**	<0.01	**1.43 (0.18–1.73)**	<0.01	**1.14 (1.02–1.28)**	0.02	0.73 (0.45-1.20)	0.22
No. of recommendations (R.C. 1/4 0)[a]	1-9	**1.15 (1.09–1.21)**	<0.01	**2.00 (1.14–3.52)**	0.02	1.03 (0.93–1.14)	0.58	1.09 (0.96–1.23)	0.18	1.00 (0.95–1.05)	0.92	1.00 (0.72-1.39)	0.99
		0.97 (0.88–1.07)	0.57	0.65 (0.23–1.81)	0.41	1.09 (0.86–1.38)	0.47	0.97 (0.76–1.24)	0.80	**1.35 (1.17–1.54)**	<0.01	1.01 (0.63-1.61)	0.98
	≥10	1.02 (0.98–1.07)	0.39	1.17 (0.68–2.03)	0.57	**1.18 (1.08–1.29)**	<0.01	**1.18 (1.07–1.31)**	<0.01	0.97 (0.93–1.01)	0.18	1.08 (0.83-1.42)	0.55
		1.05 (0.97–1.13)	0.20	0.92 (0.42–2.00)	0.83	1.15 (0.96–1.38)	0.14	1.13 (0.94–1.35)	0.20	**1.25 (1.12–1.39)**	<0.01	0.85 (0.58-1.25)	0.41
Average no. sec. diagnoses[b]				0.90 (0.55–1.49)	0.96	**1.36 (1.16–1.59)**	<0.01	**1.38 (1.18–1.62)**	<0.01	**1.37 (1.24–1.51)**	<0.01	1.30 (0.97–1.76)	0.08
				1.45 (0.54–3.87)	0.46	**2.16 (1.73–2.69)**	<0.01	1.03 (0.83–1.28)	0.80	**1.67 (1.47–1.89)**	<0.01	**1.65 (1.02–2.68)**	0.04

R.C., reference category. OR, adjusted odds ratios. Significant values at alpha=.05 are displayed in bold.
a: Unit increase.
b: Recorded in the year 2012.

at University hospitals and research institutes, except for DE, where University hospitals reported the lowest rates.

As far as processes are concerned, rates appeared difficult to interpret.

The category of care providers contributing to the national database of safe practices showed only minimal advantages compared with the others: while results seemed better for claims (125 vs. $120 \times 100\,000$) and DE (147 vs. $112 \times 100\,000$), they were worse for DVT (60 vs. $45 \times 100\,000$), PE (55 vs. $45 \times 100\,000$) and SE (188 vs. $162 \times 100\,000$).

Similarly, an increasing number of recommendations implemented showed to be in no case associated with lower rates of outcomes for any outcome.

The average number of secondary diagnoses appeared to be constantly higher among hospitals with a higher volume of cases (between 1.3 and 1.8), and in LHAs (1.3 and 1.8) and University hospitals (1.8 and 2.0).

The results of all multivariate models are included in table 4, presenting estimates obtained from the GEE 'All in' model and the 'Lag' regression model in two consecutive rows, to highlight differences in the direction and level of the association found.

Between 2011 and 2013, there was a 25% increased risk of claims for malpractice supposedly leading to injury or deaths (OR = 1.25; 95% CI: 1.19–1.31) and a 10% increase for SE (OR = 1.10; 1.06–1.15). On the other hand, there was a significant decrease of 25% for DVT (OR = 0.75; 0.69–0.82) and 19% for PE (OR = 0.81; 0.73–0.90). Changes were not significant for FB and DE.

A higher volume of discharges was associated with a significantly reduced risk only for claims: high vs. low was 16% lower (OR = 0.84, 0.79–0.89), while mid vs. low 9% lower (OR = 0.91, 0.86–0.96). There was an opposite direction for SE (mid vs. low: OR = 1.08, 1.02–1.15; high vs. low: OR = 1.12; 1.05–1.20). Results at 1-year lag were not qualitatively different, except for the 57% higher rates of DVT at high volumes (OR = 1.57; 1.26–1.95). The association observed between higher volumes and rates of SE was considerably stronger (between +13% and 40%).

In terms of type of institution, Hospital Trusts had 27% lower rates of DVT compared with research institutes (OR = 0.73, 0.57–0.94). The same direction was observed for University hospitals with claims (OR = 0.83, 0.71–0.97) and DE (OR = 0.59; 0.35–0.99), but not with DVT (OR = 1.32; 1.01–1.73). LHAs showed +37% claims (OR = 1.37, 1.19–1.57), but significantly lower rates of DVT (OR = 0.51, 0.39–0.66), PE (OR = 0.74, 0.56–0.97) and SE (OR = 0.60, 0.48–0.74). The application of the 'lag' model did not change results in terms of direction of the association, except for Hospital Trusts with claims (OR = 0.70, 0.58–0.84) and University clinics for DVT (OR = 0.64, 0.48–0.87) and PE (OR = 0.67, 0.48–0.92).

Over 3 years, the adoption of safe practices appeared to be associated only with malpractice claims (OR = 1.08, 1.04–1.13). Limiting observation to year 2013, the lag model did not find this relation to be significant any more, while safe practices signalled the year before were associated with an increased risk of DVT (OR = 1.42, 1.18–1.71), PE (OR = 1.43, 0.18–1.73) and SE (OR = 1.14, 1.02–1.28).

The implementation of recommendations did not appear to be associated with any reduction in the risk of adverse events. In the 'All in' model, an intermediate level was associated with a 15% increased risk for claims for injuries/deaths (OR = 1.15, 1.09–1.21) and twice the risk of FB (OR = 2.00, 1.14–3.52). On the other hand, implementing over 10 recommendations (out of 14 initially introduced by the MoH) was associated with increased risk of DVT (OR = 1.18, 1.08–1.29) and PE (OR = 1.18, 1.07–1.31). The 'lag' model highlighted an asynchronous association between a higher number of recommendations and SE (10 or more vs. none: OR = 1.35, 1.17–1.54; 10 or more vs. 1–9: OR = 1.25, 1.12–1.39).

As expected, increasing one unit in the average number of secondary diagnosis recorded at discharge was associated with a +36–38% increased risk of DVT, PE and SE. The association was found to be even stronger in the lag model, ranging between +65 and 67% for SE and DE to more than doubled for DVT.

Discussion

The Linkage project aimed at identifying a national model that could be adopted to exploit the available data sources for monitoring, evaluating and benchmarking patient safety across Italian regions. As the Italian SSN gets increasingly decentralized, the need to harmonize practices for risk management has become paramount to gain efficiency and reduce waste at all levels: from care providers to the system as a whole.[31]

The application of a quality of care interpretative model allowed us linking national databases and populating the data matrix specifically designed to address our fundamental research questions.

We found that the available data sources could be used to investigate the association between structural, process and outcome characteristics at the level of cluster of care providers.

The most appropriate definition of cluster was considered to be the level of the SSN where the risk manager was designated to operate by the law, i.e. either a local health authority, hospital trust, research institute or university clinic. This solution has shown that the data collection (and quality) management process can work in parallel with the evaluation of quality of care strategies. Through the use of multivariate regression of grouped data, we could formally test the direction and significant level of associations, while adjusting for annual trends and depth of coding. The methodology provided a solid basis for further future refinement.

At the same time, the study highlighted trends of associations that are worth specific reflection.

Over 3 years, in four regions of Italy, the number of claims constantly increased, but the rates of all adverse events investigated, with the exclusion of sepsis, have decreased. The volume of acute care was found to be directly associated with lower rates of claims for malpractice and higher rates of deep vein thrombosis and sepsis.

Compared with high level research institutes (IRCSS), LHAs generated more claims, presenting substantially lower rates of PSIs in terms of deep vein thrombosis, pulmonary embolism and sepsis. University hospitals were associated with lower rates of claims for malpractice and wound dehiscence, but higher rates of deep vein thrombosis. A potential clinical explanation for the latter might be a higher availability/use of diagnostic means, e.g. extended ultrasound detection. Both deep vein thrombosis and pulmonary embolism appeared to be lower when considering year 2013 alone. Hospital trusts were associated with a reduced risk of claims for malpractice and deep vein thrombosis in 2013.

On the other hand, the analysis of the consistency of interpretation for policy showed that the associations between structural and process characteristics with safety-related outcomes were counter-intuitive and difficult to justify.

In particular, the key process measures were associated with outcomes differently from expected. A higher number of safe practices and recommendations implemented showed to be associated with a higher risk of all adverse events, even when taking into account a delay of 1 year.

There may be several explanations for this.

First, the observed levels of implementation of safe practices and recommendations may be highly subjective, while trends over time of claims for malpractice may more likely reflect the degree to which patients chose to pursue law suits, rather than changes in the underlying epidemiology of the safety problem of interest.

Second, the calculation of PSIs may be prone to an overall undercount, with uncertain effects on the final estimates, due to the potential bias in the levels of explanatory variables mentioned above.

Different aspects are known to potentially limit the ability of the SDO database for patient safety. In Italy, the assignment of principal codes is based on the condition that has consumed most resources, rather than the actual condition specified in OECD algorithms.[32] Furthermore, hospital discharge abstracts are affected by known limitations: they only allow one principal diagnosis/procedure and up to a maximum of five secondary diagnoses/procedures for each discharge, with a date indicated only for primary intervention and no diagnosis coded as present on admission.

Third, part of these hospital-level associations may be the results of the so-called ecological fallacy, rather than reflecting associations found at patient level.[33]

There are positive messages, though, that can be derived from the consistency analysis.

First, the increased level of average number of secondary diagnoses and sepsis seems to indicate that the data quality of the SDO database for patient safety monitoring is generally improving, although not at the level advocated by recent investigations.[34] Progress in this area continues with the inclusion of the field 'present on admission' and the plan to update coding systems beyond ICD9CM.

Second, the inverse relation found between safe practices and recommendations and PSIs may imply that risk managers are raising the level of attention of coders on safety issues.

Finally, the feasibility of the data matrix encourages further integration of data sources, in collaboration with stakeholders and domain experts. The 'Linkage' project provided input to different actions, including ways to improve data quality with the direct involvement of coders, indications on how to improve algorithms in a collaborative manner[35] and how to expand the national data collection with more targeted instruments, e.g. global trigger tools.[10,11]

To enable proper methods, e.g. multilevel regression methods, the national databases will need data sharing between regions[36] and a more advanced analytical information infrastructure,[37] in compliance with strict privacy and data protection rules.[38,39]

The results of the present study are paving the way for the implementation of recommendations included in the above mentioned OECD quality review.[22] These developments will be the subject of a companion paper dedicated to actions recently undertaken to establish a cohesive framework for patient safety in Italy.

Finally, key limitations of our study are worth to be outlined.

First, for feasibility reasons, the study included only four regions of Italy. However, they were densely populated, accounting for 41.5% of the national population and 50% of the total GDP in 2011, ensuring an adequate geographical coverage and cultural/organizational variety.

Second, several databases used in our analysis are based on voluntary participation, including malpractice claims, safe practices and the implementation of recommendations. As non-respondents were substantially more frequent among private hospitals, they were not included in the study. Recent regulations made data collection mandatory for all, allowing including private institutions in future analyses.

Third, among the outcome measures selected for the study, only malpractice claims covered the whole spectrum of services provided by acute care hospitals. To what extent counts of malpractice claims are an accepted and appropriate proxy for clinical outcomes remains open and should be further consolidated by scientific literature. On the other hand, all chosen PSIs focused on post-operative events, which certainly allow only a partial view of the activity performed on surgery. However, these indicators offer the best international comparability due to the standardized definitions adopted by the OECD for the analysis of hospital discharges.

Finally, public hospitals were classified as belonging to hospital trusts or local health care authorities based on regional coding, which may not necessarily correspond to objective criteria.

Key points

- A set of characteristics related to structures, processes and safety-related outcomes was conveniently extracted from routine databases to evaluate the feasibility of a national monitoring system.
- The analysis of consistency of patient safety outcomes shows different areas for improvement, whereas there is a clear gap between the monitoring systems in place and the number of adverse events estimated through routine national data sources.
- A quality of care interpretative model can conveniently assess the strengths and weaknesses of national databases for patient safety monitoring.

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