Validation of Patient Safety Indicators (PSIs) for the Spanish National Health System. Summary 2008

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD Y CONSUMO
Plan de Calidad para el Sistema Nacional de Salud

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Recognition

This report is part of the series of studies included in the Variations in Medical Practice and Quality of Health Care Project developed by the Atlas VPM Group*. Data is transferred from the Regional Health Authorities involved in Atlas VPM Group*. (For more details you can consult the web http://www.atlasvpm.org).

Conflicts of interest and disclaimers

Most of the members of the Atlas VPM Group* are working for the Regional Health Services or Health Institutions of the country. The aforementioned Institutions do not necessarily share the contents of this report, which is entirely the responsibility of their authors.

This publication should be cited as: Validation of Patient Safety Indicators (PSIs) for the Spanish National Health System. Summary 2008. Madrid: Ministerio de Sanidad y Consumo; 2008.

Validation of Patient Safety Indicators (PSIs) for the Spanish National Health System. Summary 2008

This study has been conducted by Aragones Institute of Health Sciences through a contract with the Spanish Ministry of Health and Consumer Affairs.

Contents

1. Context

All recent initiatives connected with assessment of health systems are based on the availability of information systems. The only system that provides a systematic and exhaustive record of the activities of all healthcare providers in Spain is the hospital discharge minimum basic dataset (CMBD).

A number of international initiatives use this hospital discharge dataset to develop quality indicators, particularly the Patient Safety Indicators developed by the Agency for Healthcare Research and Quality (AHRQ) for assessment of Medicare and Medicaid centres in the United States.

Despite the ease of incorporation and analysis of the indicators proposed in our information systems, the inherent limitations of the CMBD, the different way in which clinical-administrative databases are used in healthcare systems other than the Spanish National Health System (SNHS) and the weaknesses in terms of rational design of these indicators are all arguments for their validation for the SNHS.

2. Objective

To determine the validity of the Patient Safety Indicators (PSI) for assessment of healthcare provider quality in Spain and, in particular, to conduct their empirical validation for application in Spain.

3. Scope

This report provides information on the performance of each PSI by hospital, the face validity of the codes and their empirical validity, proposing recommendations for use and, where appropriate, alternative indicators.

4. Methodology

The method used aims to provide answers to a number of key questions regarding the indicators, namely:

Do they measure what they aim to measure?
Do they measure differences between patients or between providers?
Do they measure similar providers similarly? And different providers differently?
Are the differences between healthcare centres due to chance?
Are the measurements precise?
Are the indicators able to detect providers with a higher than expected number of cases?

Population and setting

All hospital discharges due to the following were analysed Individually: death in low-mortality DRGs (PSI02); decubitus ulcers (PSI03); postoperative hip fractures (PSI08); postoperative pulmonary embolism or deep vein thrombosis (PSI12); infections due to medical care, including catheter-related infections [PSI07]; postoperative sepsis [PSI13]; birth trauma, injury to neonate (PSI17); and obstetric trauma in vaginal delivery (PSI18 and PSI19) and in Caesarean delivery (PSI20). These included all discharges from public-sector acute care hospitals and publicly-funded healthcare institutions in 12 Spanish regions in the period 2003-04. Table 1 shows the number of hospitals included in each indicator and the percentage of all discharges analysed.

Table 1. Description of sample

		Hospitals included by indicator	Percentage of total discharges included
Death in low-mortality DRGs	PSI 02	177	11%
Decubitus ulcer	PSI 03	173	35%
Catheter-related infection	PSI 07	172	53%
Postoperative hip fracture	PSI 08	173	17%
Postoperative PTE or DVT	PSI 12	175	25%
Postoperative sepsis	PSI 13	149	5%
Birth trauma, injury to neonate	PSI 17	149	3%
Trauma, vaginal delivery with instrument	PSI 18	134	1%
Trauma, vaginal delivery without instrument	PSI 19	152	6%
Trauma, Caesarean delivery	PSI 20	146	2%

For each of the conditions studied the numerator and denominator were defined on the basis of the definition proposed by the AHRQ. http://www.qualityindicators.ahrq.gov/downloads/psi/psi_guide_v31.pdf

Variables

The relationship between the hospitals where patients received care and the adverse event risk was estimated. The hospital variable acted as a proxy for the entire organisation effect. The case-mix of each hospital was analysed to determine the effect of the differences between patients; the different characteristics of each hospital were also analysed.

Study of case-mix differences

Different patient variables were used (age, sex, Elixhauser Index) to rule out possible deviation effects.

Elixhauser comorbidity: this indicator, an alternative to the classical Charlson-Deyo Index, includes 30 diagnostic items identifiable via ICD codes that accompany the principal diagnosis of each patient included in the study. An index was designed for each PSI able to be studied as a rate. (see table 2)

To use Elixhauser's comorbidity conditions in this study, each patient was allocated a rating (risk) based on the beta coefficients obtained after logistic regression modelling.

In the case of the obstetric PSIs, a different risk indicator was designed, namely the "delivery risk indicator", defined as the risk in women of 35 or over who also present one or more of the conditions indicated in table 3.

Table 2. Estimated logistics model for each PSI

PSI02	elixPSI02=1.943142*chf+.9257763*perivasc+.5388771*htn_c+1.394814*para+1.667849*neuro+.6406306*chrnlung+.9550525*dm+1.100152*dmcx+1.966576*renlfail+.7500545*liver+1.074865*arth+1.744347*coag+1.289112*wghtloss+2.157059*lytes-1.019706*bldloss+.5565431*anemdef
PSI03	elixPSI03=.5704182*chf-.2186243*valve-.5616491*pulmcirc+.3762693*perivasc-.1531894*htn_c+1.731656*neuro-.2398155*chrnlung+.3385837*dm+.9038941*dmcx-.5959449*liver-.63291*lymph-.1782521*obese+1.765819*wghtloss+1.510793*lytes+.3037865*bldloss+.7401774*anemdef-.8622918*alcohol-.9509681*drug+.3946171*psych
PSI07	elixPSI07=.5573381*chf+.7083054*perivasc+.1291583*htn_c+1.006557*para+.5279264*neuro+.2720184*dmcx+.318817*liver+1.34986*coag+1.302607*wghtloss+.9045539*lytes-.902452*bldloss+.5333053*anemdef+.3806688*alcohol+ .5076428*drug+.7414649*psych
PSI12	elixPSI12=.8434178*chf+.7055897*pulmcirc+.743575*perivasc+.3358397*htn_c+1.0808*para+.670366*neuro+.2665863*chrnlung+.5094155*renlfail+.9242732*lymph+1.471739*mets+1.024681*tumor+1.138959*coag+.6131134*obese+1.05524*wghtloss+1.124107*lytes+.7528184*anemdef
PSI13	elixPSI13=1.439344*chf+1.0222*perivasc+.541951*neuro+.7665745*dmcx+1.116567*renlfail+.4875288*liver+2.798655*coag+2.118293*wghtloss+2.495405*lytes+.6371177*alcohol

Table 3. Clinical conditions that suggest delivery risk

Conditions	ICD codes
Multiple pregnancy	651*
Malposition, malpresentation except high head at term	6520*, 6521*, 6522*, 6523*, 6524*, 6526*, 6526*, 6527*, 6528*, 6529*
Disproportion	653*
Previous Caesarean delivery	6542*
Obstructed labour	660
Multiple birth	V272, V273, V274, V275, V276, V277, V31, V32 V33, V34, V35, V36, V37

Hospital characteristics

Following assessment of the overall hospital effect, individual hospital characteristics that could influence the results were analysed. As hospital data is plentiful, a set of key variables was chosen: number of beds (using 150 beds threshold); existence of medical residency program (MIR); tertiary centre category (including those centres with cardiac catheterization units and linear accelerator); medical-surgical discharges (using tertiles as a threshold); surgical discharges (tertiles); total medical staff (tertiles); internists and surgeons (tertiles); surgeons (tertiles); total nursing staff (tertiles); registered nurses (ATS-DUE) (tertiles); maternity and children's unit (more than two delivery rooms); obstetric-gynaecology beds (tertiles); obstetric discharges (tertiles); vaginal deliveries (tertiles); Caesarean deliveries (tertiles); obstetricians (tertiles); midwives (tertiles); existence of midwife training program.

Data sources

The hospital discharge minimum basic dataset (CMBD) for the period 2003-04 of 13 Spanish regions was used to obtain the numerators and denominators of each risk indicator, to determine the age and sex of the patients included in the sample and to calculate each patient's Joint Elixhauser Index. This dataset was also used to determine the number of procedures conducted in each centre. The 2004 Inpatient Healthcare Institution Survey (EESRI) was used to determine the key variables of each centre.

5. Analysis

Descriptive and bivariate analysis

The crude risk was estimated for each Patient Safety Indicator (PSI) and for each hospital.

To determine how much of the risk variability between centres was systematic and how much was random, the Systematic Component of Variation (SCV) was estimated. This measures the variation in deviation between the rate observed and the rate expected, expressed as a percentage of the rate expected; the higher the SCV, the higher the systematic (not expected at random) variation.

To determine the effect of the case-mix (patient) and hospital characteristics described above, the adverse event risk for these conditions was estimated. The statistical differences were analysed using ANOVA for the quantitative variables and Pearson's X^2 test for the qualitative variables. In addition, bivariate logistic regressions were made and the OR and its confidence interval (CI) were estimated, accepting type I error of 5%.

Logit type multilevel analysis

Studies that assess healthcare results on the basis of both individual variables and variables under cluster effect are subject to bias. The cluster effect may be corrected by using multilevel methods. Accordingly, to determine the effect of the hospital (overall organisation) on the adverse event risk, logit type multilevel multiple regression models were designed in which level 1 includes the patient variables and level 2 the hospital variable. Following adjustment of the most complete model, the rho value (and its confidence intervals) was estimated to assess the proportion of the variance explained by the second study level.

Multivariate analysis: negative binomial regression

To determine the sensitivity of PSIs for identification of hospitals recording a worse than expected performance, the regression model was used to calculate the ratio between observed and expected values. This analysis was made for those indicators for which the hospital level was sufficiently explanatory and for those which could be used as rates (not sentinel events).

Different equations were constructed for each condition studied using the negative binomial regression model and the best model was used to estimate the expected values.

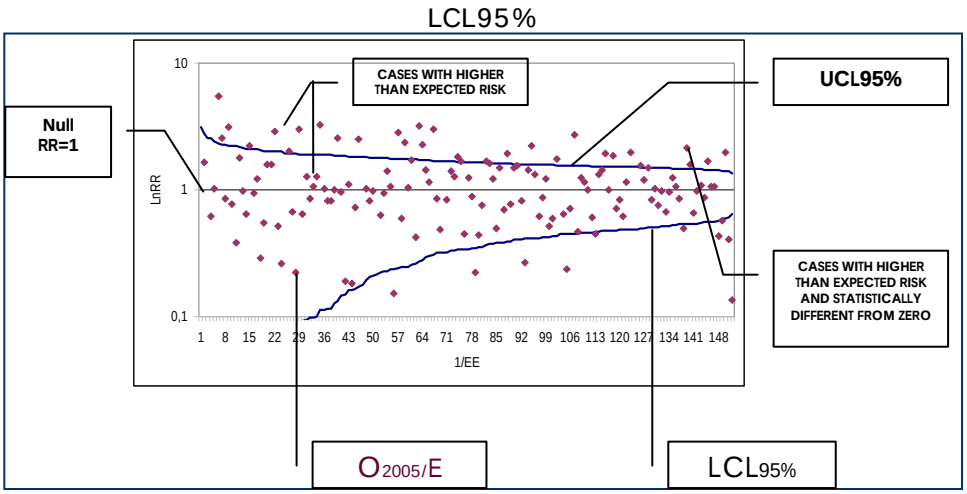
What role do hospitals play? Funnel plot representation

A funnel plot (see figure 1) was used to depict the estimated ratio between observed and expected values. The wide end of the funnel represents the lack of precision connected with the low number of cases expected (and in consequence higher standard error), whilst the narrow end of the funnel represents the effect of a higher number of cases expected (and in consequence lower standard error). In other words, the graph is more demanding when it is a case of identifying hospitals performing ahead of expectations, when the number of expected cases is more subject to the effect of chance. For the purposes of this study, the degree of confidence required of the estimate was 95%.

Interpretation of graph: the dots lying above 1 represent hospitals with a higher than expected number of cases. Only those above the upper confidence interval limit should be included in further studies.

Due to the important impact of hospital type, and with a view to achieving greater uniformity and enhanced interpretation of the results, separate funnel plots were also compiled by hospital types (see figure 2).

Figure 1. Funnel plot and interpretation



All analysis conducted using the STATA® 9 SE program.

6. Results

Do the indicators measure what they aim to measure?

No judgment is made of the construct validity of any of the indicators, although as may be seen in table 1, minor modifications are proposed in the codes that define the following indicators: death in low-mortality DRGs, pressure ulcers, postoperative thromboembolism, hip fractures and injury to neonate.

Table 1. Modifications to indicator definition

		Numerator	Denominator at risk
Death in low-mortality DRGs	PSI 2	-	All cases Spanish case-mix
Pressure ulcer	PSI 3	-	Not excluding MDC-9
Catheter-related infection	PSI 7	-	-
Postoperative hip fracture	PSI 8	-	All patients
PTE or DVT	PSI 12	-	-
Postoperative sepsis	PSI 13	-	-
Injury to neonate	PSI 17	Use 767.1	-
Obstetric trauma in delivery with instrument	PSI 18	Add 6651-3-5	-
Obstetric trauma in delivery without instrument	PSI 19	Add 6651-3-5	Eliminate risk deliveries
Obstetric trauma in Caesarean delivery	PSI 20	Add 6651-3-5	Eliminate risk deliveries

Do they measure differences between patients or between providers?

Table 2 depicts the type of strategy followed in the original definition of the PSIs to reduce the effect of patient characteristics on adverse event risk. Save in the last three cases (deliveries), the exclusions made in the original AHRQ definitions make sense insofar as they reduce the differences between patients.

Table 2. Strategies followed in original definitions to reduce the case-mix effect

	Strategy to reduce patient effect
Death in low-mortality DRGs	AP-DRG set, risk<0.5%
Pressure ulcer	Eliminates 3 risk groups
Catheter-related infection	Excludes certain procedures
Postoperative hip fracture	Only surgical patients
PTE or DVT	Excludes certain patients at risk
Obstetric trauma in delivery with instrument	No strategy
Obstetric trauma in delivery without instrument	No strategy
Obstetric trauma after Caesarean delivery	No strategy

Nevertheless, as shown in table 3, all the indicators must be adjusted for various characteristics, especially comorbidity.

Once adjusted for case-mix (see table 3), a variable proportion of the variance is explained by the hospital: between 13% (rho=0.13) in the case of PSI 2 and 30% (rho=0.30) in the case of PSI 18. This implies that all the PSIs measure differences between centres, independently of the case-mix of patients receiving care in the centres.

Table 3. Multilevel model for each PSI

	Death in low-mort. DRGs	Pressure ulcers	Catheter-related infection	Post-op. hip fracture	PTE or DVT	Post-op. sepsis	Injury to neonate	Obst. trauma, with instr.	Obst. trauma without instr.	Trauma Caes. delivery
	PSI 2	PSI 3	PSI 7	PSI 8	PSI 12	PSI 13	PSI 17	PSI 18	PSI 19	PSI 20
Necessary adjustments										
Age	⇧	⇧	⇧	-	⇩	⇩	-	-	-	-
Sex	⇩	⇧	⇩	-	-	-	NA	NA	NA	NA
Comorbidity	⇧	⇧	⇧	-	⇧	⇧	-	-	-	-
Number of codes	⇧	⇧	-	-	⇧	⇧	-	-	-	-
Interaction comor*ndx	-	-	⇧	-	⇩	-	NA	NA	NA	NA
Risk	NA	NA	NA	NA	NA	NA	NA	⇧	⇧	⇧
Hospital variance										
rho value	0.13	0.18	0.22	-	0.24	0.27	-	0.30	0.25	0.14
(CI 95%)	0.1-0.2	0.1-0.2	0.2-0.3	-	0.2-0.3	0.2-0.3	-	0.2-0.4	0.2-0.3	0.1-0.2

Comorbidity: Elixhauser Index. Number of codes: number of diagnostic codes used in each discharge. Interaction comor*ndx: interaction between number of codes and estimated comorbidity. Risk: high-risk delivery. rho value: proportion of variance explained by hospital, once adjusted for case-mix. ⇧: direct, statistically significant, correlation between variable and adverse event risk. ⇩: inverse, statistically significant, correlation. In the case of the sex variable: ⇩ more risk in men; ⇧ more risk in women; - no statistical correlation. NA: Not applicable.

Do they measure similar providers similarly? And different providers differently?

Table 4 shows that the effect of the hospital variables analysed always lies in the same direction, which suggests that the PSIs have convergent and divergent validity and that they should be analysed by hospital subgroups.

Table 4. Impact of hospital characteristics on emergence of adverse events

	Death in low-mort. DRGs	Pressure ulcers	Catheter-related infection	Hip fracture	PTE or DVT	Post-op. sepsis	Injury to neonate	Obst. trauma, with instr.	Obst. trauma without instr.	Trauma Caes. delivery
	PSI 2	PSI 3	PSI 7	PSI 8	PSI 12	PSI 13	PSI 17	PSI 18	PSI 19	PSI 20
Hospital variance										
rho value	0.13	0.18	0.22	?	0.24	0.27	?	0.30	0.25	0.14
(CI 95%)	0.10-0.17	0.15-0.22	0.18-0.28		0.16-0.35	0.21-0.36		0.22-0.41	0.19-0.32	0.07-0.25
Hospital variables										
Beds (>150)	⇩	⇩	-	⇩	⇧	⇧	⇩	-	⇧	-
Graduate (MIR) training	⇩	⇩	-	⇩	⇧	-	⇩	⇧	⇧	-
Tertiary (cardiac catheterization)	-	⇩	⇧	⇩	⇧	⇧	⇩	⇧	⇧	⇩
Medical-surgical discharges	⇩	⇩	~⇧	⇩	⇧	⇧				
Surgical discharges				⇩	⇧	⇧				
Total medical staff	⇩	⇩	~⇧	⇩	⇧	⇧				
Internists & surgeons	⇩	⇩	⇧	⇩	⇧	⇧				
Surgeons				⇩	⇧	⇧				
Nursing staff	⇩	⇩	~⇧	⇩	⇧	⇧				
Registered nurses (ATS/DUE)			~⇧							
Maternity & children's unit	-	⇩	⇧	⇩	⇧	-	⇩	⇧	⇧	-
Obstetric-gynaecology beds							J	⇧	~⇧	~⇧
Obstetric discharges							J	⇧	~⇧	-
Vaginal deliveries							J	⇧	J	⇧
Caesarean deliveries							J	⇧	J	⇧
Obstetricians							~⇧	⇧	~⇧	-
Midwives							J	⇧	J	-
Midwife training							⇩	⇧	⇧	~⇩

rho value: proportion of variance explained by hospital, once adjusted for case-mix. ⇧: direct, statistically significant, correlation between variable and adverse event risk; ⇩: inverse, statistically significant, correlation; -: no statistical correlation. ~: variable divided into tertiles: second tertile has no significant effect; J: variable divided into tertiles; second tertile presents less risk than first, third tertile presents more risk than first.

Are the differences between centres due to chance? Are the measurements precise?

Table 5, which analyses the reliability of the measurements, shows that the SCV, that is, the systematic component of variation (not attributable to chance) ranges between 0.22 (in general considered moderate) and 3.23 (extreme). Most of the PSIs give a high or very high systematic variation, ruling out the possibility that this variation may be due to chance.

Table 5. Reliability of measurements

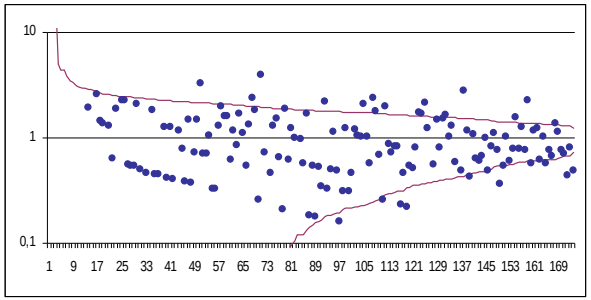
	Death in low-mort. DRGs	Pressure ulcers	Catheter-related infection	Post-op. hip fracture	PTE or DVT	Post-op. sepsis	Injury to neonate	Obst. trauma, with instr.	Obst. trauma without instr.	Trauma Caes. delivery
	PSI 2	PSI 3	PSI 7	PSI 8	PSI 12	PSI 13	PSI 17	PSI 18	PSI 19	PSI 20
Variance statistics[1]										
CV	0.96	1.04	1.62	1.74	1.14	1.74	4.62	4.32	2.55	2.62
SCV	0.50	0.57	0.92	0.40	0.22	0.23	3.23	0.46	0.55	0.57
Stability / sensitivity										
Expected ranges	0-83	0.51-268	0-83	0-2	0-69	6-33	0-161	0.02-82	0.01-78	0-7
Number (% of total)	8 (7)	16 (14)	21 (13)	-	8 (5)	5 (3)	-	8 (6)	10 (6)	-

CV: coefficient of variation; SCV: Systematic component of variation.

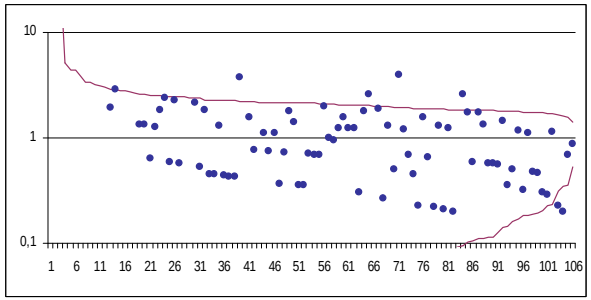
Are they able to detect providers with a higher than expected number of cases?

The sensitivity for identification of centres with higher than expected numbers is moderate to low, ranging between 3% in the case of PSI 13 and 14% in the case of PSI 3 (see table 5).
However, once the effect of the small numbers is corrected using the funnel plot, the indicators are sensitive for detection of hospitals with higher than expected numbers, save in the case of PSI 20 (obstetric trauma - Caesarean delivery).
Figure 2 shows the example for PSI 12 (pulmonary embolism or deep vein thrombosis) and different hospital types.

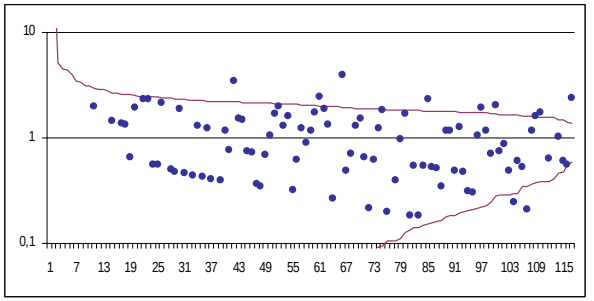
All hospitals



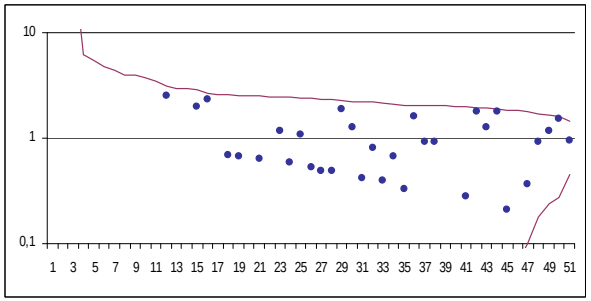
Hospitals with fewer beds



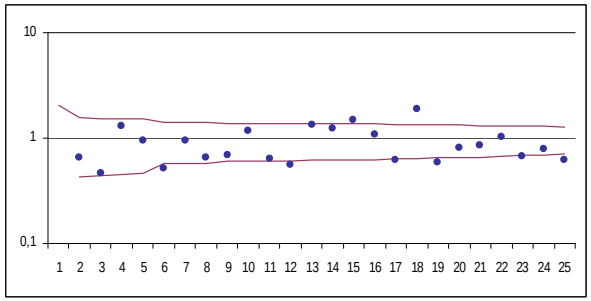
Non-tertiary hospital



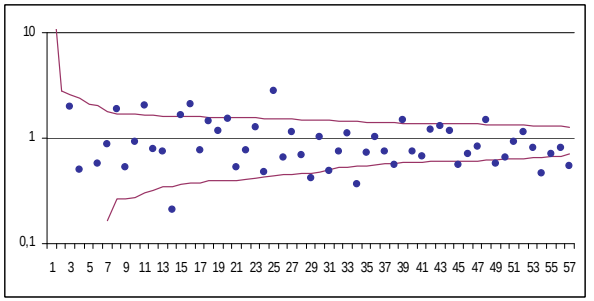
Non-teaching hospital



Hospitals with more beds



Tertiary hospital



Teaching hospital

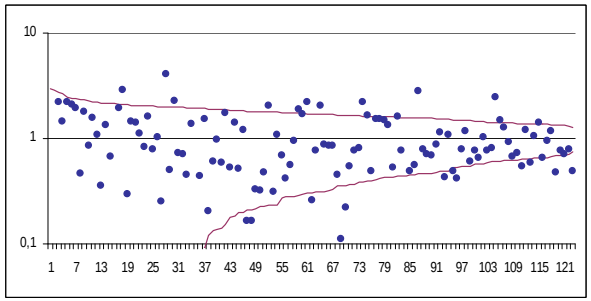


Figure 2. Example for PSI 12 - Pulmonary embolism or deep vein thrombosis

7. Conclusion

All the PSIs may be used as “rates”, save for PSI 8 (hip fractures) and PSI 17 (birth trauma – injury to neonate).

All the indicators present moderate or high variability, once corrected for chance.

All the indicators require case-mix adjustment, despite their definitions aimed to reduce the risk of measuring differences between patients.

The hospital factor explains part of the variance, even after correction of individual variables. But the significant convergent and divergent validity means that analysis by subgroups is required.

The indicators are, in general, sensitive for detection of higher than expected numbers of cases. In the smaller centres they are more limited when it comes to detecting those with fewer than expected cases.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