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Essential strategies in HAI prevention and control: performance assessment through the implementation of the HAI-CoSIP tool of the GISIO-SItI group. A pilot study in a sample of Italian Organizations

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Abstract

Background. *Healthcare-Associated Infections are a great concern for worldwide healthcare systems and represent a considerable threat to patient safety, leading to adverse clinical outcomes. A defined panel of indicators represents a key element to guide Healthcare Organizations towards identification of main gaps, implementation of effective actions and continuous improvements on Healthcare-Associated Infections prevention and control activities. A review on accreditation systems conducted by the Italian Study Group*

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of Hospital Hygiene of the Italian Society of Hygiene Preventive Medicine and Public Health revealed a substantial heterogeneity of implemented standards and led to the development of a core set of indicators and requirements for Healthcare-Associated Infections' prevention and control within the hospital setting. The main aim of the study was to test the feasibility of the Healthcare-Associated Infections' prevention and control within the hospital setting tool to calculate performance scores on a sample of Italian Healthcare Organizations and to identify major critical issues. The potential benefits of the possibility of future implementation of the tool within Institutional Accreditation Programs is discussed.

Study Design. *Cross sectional pilot survey.*

Method. *The Healthcare-Associated Infections' prevention and control within the hospital setting included 96 criteria and 20 key areas including an area for outcomes indicators. For applicable criteria, standards fulfilment was evaluated according to a 4 point Likert scale. A composite score was calculated for each Healthcare Organization and five performance levels were identified. Data were further analysed by computing performance scores at the level of each area and requirement.*

Results. *20 Healthcare Organizations agreed to take part in this pilot study including two rehabilitative Healthcare Organizations. Among the whole sample a mean of 12.20% of requirements resulted not fulfilled, leaving space for further improvements. Critical areas were easily identified and the instrument was able to capture substantial differences between Healthcare Organizations. Only a few number of standards resulted "Not Applicable" (Mean = 4.71%) and most of them regarded Rehabilitative Healthcare Organizations. Mean composite performance index resulted 74.06% (SD = 16.96, range 36.30 - 94.27%); area of outcome indicators obtained a mean score of 56.17%.*

Conclusions. *The Healthcare-Associated Infections' prevention and control within the hospital setting resulted an useful tool to assess Healthcare Organizations' performance in the field of Healthcare-Associated Infections prevention and control and to identify necessary actions for further improvements. The distribution of total scores by Healthcare Organizations showed a high heterogeneity. Implementation of the Healthcare-Associated Infections' prevention and control within the hospital setting tool as an institutional accreditation tool may help to drive the required harmonization at a national level of Healthcare-Associated Infections management and control strategies and overcome current substantial regional differences.*

Introduction

Healthcare-associated infections (HAI) are a great concern for worldwide healthcare systems and represent a considerable threat to patient safety, leading to increased morbidity, mortality and other adverse clinical outcomes such as an increased length of hospital stay and a wider spreading of antibiotic resistance (1). HAI prevalence in European Hospitals was estimated to vary between 4.5 and 7.4 % with an estimated incidence between 1.9 million and 5.2 million new cases/year and a point estimate of 3.2 million patients with at least one HAI per year in European acute care hospitals (2). Actions focused on HAI control, prevention and monitoring are strongly required and represent a major priority for all developed countries (3, 4).

Several strategies have been developed and tested to improve HAI management such as behaviour-based interventions, surveillance programs, staff education and training, approaches based on organizational and structural changes and standardized processes (5). The effectiveness of these interventions showed a considerable variability (e.g. between 10-70% of cases) (6). Although implementation of a multimodal approach is currently recognized as a cornerstone in fighting HAIs spreading, Health Care Organizations (HCOs) still face the difficulty to recognize a clear and well established set of strategies.

The availability of a set of performance indicators represents a key element to guide HCOs towards the identification of main gaps, the implementation of necessary and effective actions and the achievement of continuous improvements.

Indeed, the use of a defined panel of indicators within an efficient surveillance program allows a comprehensive systematic collection, analysis, and interpretation

of all the data considered essential for planning, implementing, and evaluating HAI prevention and control activities.

The development of an informative and exhaustive core set of indicators and standards by regulatory authorities and its implementation within institutional accreditation may allow to keep monitored the level of achievement of essential performance standards and constitute a crucial driver to promote quality improvements within national HCOs (7).

Examples are represented by the French ICALIN.2 system (that proposed a measurement process based on the implementation of specific surveillance programs and data disseminations) or the German national nosocomial infection surveillance system (KISS): both have shown to give a substantial contribution to quality improvement and HAI control (8, 9).

These systems are based on standardized data collection methods that allow participating HCOs to benchmark themselves on reference data; moreover, such an amount of data allows the timely identification of risk factors and critical issues regarding HAI control and may guide management and dedicated Infection Control Committee towards the development of all the necessary corrective actions (10, 11).

Finally, all collected data may be disseminated throughout the entire population in order to raise awareness, promote informed choices and allow stakeholders to be drivers of changes, in particular in pay-for-performance contexts (12).

As emphasized by the European Council, the development of a standardized surveillance system based on a set of specific indicators and standards represents a priority to share good practices and promote mutual improvement and learning between healthcare systems (13).

As reported in a recent revision of international and national accreditation systems conducted by the GISIO-SItI (Gruppo Italiano Studio Igiene Ospedaliera della Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica – Italian Study Group of Hospital Hygiene of the Italian Society of Hygiene, Preventive Medicine and Public Health) there is still wide variability among developed HAI prevention and control programs (14).

In Italy a strong heterogeneity in accreditation standards was also observed at the regional level with a consequent high variability of implemented models and proposed requirements.

The review conducted by the GISIO-SItI identified a core set of 96 indicators and requirements for HAI prevention and control (HAI-CoSIP - HAI Core Set criteria & Indicators Prevention) within the hospital setting.

The main aim of the study was to test the HAI-CoSIP on a convenience sample of Italian HCOs and to evaluate the feasibility of the tool to assess the level of performance (on HAI prevention and control activities) of different HCOs.

The capability of the tool to identify major critical issues and guide the development of required improvement actions was highlighted.

Finally, opportunities to improve the feasibility of the tool were identified in order to refine it for a possible use within Institutional Accreditation programs.

Methods

The HAI-CoSIP system

The HAI-CoSIP included 20 key areas for HAI prevention and control evaluated through a total core set of 96 criteria and requirements as reported in Table 1 (14).

Among these, a specific area (T Area) is focused on outcome indicators such as the Surgical Site Infection (SSI) rates after joint replacement surgery, the Catheter-related bloodstream infections (CRBSIs) rates and

Table 1 - HAI-CoSIP Key Areas

Area	Description	Items (N)
A	Presence of a policy/program and of an organization for the HAIs prevention and control in the hospital	9
B	Appointment of a manager/multi-disciplinary committee for the control and surveillance of HAIs in the hospital	5
C	Performing HAIs[1] surveillance within the hospital	8
D	Presence of a staff training program on HAIs prevention and control	3
E	Presence of protocols to communicate HAIs surveillance results and incidents involving the risk of infection transmission	1
F	Defined protocols for proper cleaning of the environment	1
G	Detection and measurement of air and water quality	4
H	Presence of protocols for proper hand hygiene	7
I	Presence of procedures for the sterilization of medical devices and electro-medical equipment	3
J	Presence of guidelines for reusing medical devices	6
K	Defined proper management of laundry and linen	1
L	Presence of provisions for proper waste disposal	3
M	Defined strategies for the prevention and control of surgical site infections	9
N	Presence of specific protocols to prevent CVC-related infections	1
O	Presence of protocols to prevent and control multi-drug resistant bacteria (especially methicillin resistant *Staphylococcus aureus* [MRSA])	14
P	Presence of protocols for the proper use of antibiotics and for the correct identification of processes that require antibiotic prophylaxis	12
Q	Presence of systems to ensure the isolation of patients with infectious diseases	2
R	Communication with patients and caregivers	1
S	Existence of a vaccination program for staff	1
T	Defined indicators	5

[1] HAI: Healthcare-Associated Infections; [2] CVC: Central Venous Catheter

HAIs point prevalence estimation.

Standards fulfilment was evaluated according to a 4 point Likert Scale:

• Score 0: "no, the Organization fails to meet the requirement under evaluation";

• Score 1: "Organization partially satisfies the requirement under evaluation, e.g. either the process to fulfil the requirement has just started or the level of fulfilment is limited to just some of the organizations work units";

• Score 2: "Organization mostly satisfy the requirement under evaluation, e.g. either the process to fulfil the requirement is almost concluded or the level of fulfilment is already extended to the majority of the organizational work units";

• Score 3: "yes, the Organization totally satisfy the requirement under evaluation".

A fifth possible answer is referred to the feasibility of the requirements within the HCO under evaluation (Requirement "Not Applicable": the services provided by the organization don't include the requirement under evaluation").

The tool included a section focused on some general characteristics of the HCO: type of HCO (e.g. rehabilitative, University Integrated Hospital, etc), number of Hospital Beds (HBs), number of Intensive Care Unit Beds (ICU-HBs), number of ordinary hospital admissions, number of day hospitals and one-day surgery in the last year.

Scoring system and identified performance classes

The performance of an HCO can be calculated by each standard, by area or as a total score. Score assignment followed the same methodology as the NHS and ICALIN.2 systems.

The method consisted of transforming performance, as expressed across a number of indicators, from continuous into categorical variables using the percentiles distribution of results. Specifically, the percentiles 20, 40, 60 and 80 of the distribution of results were selected to define the boundaries of five classes of increasing performance from A to E. A composite (total) index score of performance was assigned to each organization by calculating the following proportion: total score obtained among the entire set of requirements (on the) maximum score available for each organization given the number of requirements found to be applicable.

The five classes are described below:

• Class A: it included organizations that showed the highest index of performance (e.g. corresponding to a score above the 80 percentile of the score distribution of the whole sample). They showed to implement sustainable continuous improvements to monitor and control HAIs;

• Class B: it refers to 60-80 percentile distributions and included organizations that require improvements in a few number of areas in order to obtain excellent performances;

• Class C: it refers to 40-60 percentile distribution and included organizations that require improvements in limited areas;

• Class D: it refers to 20-40 percentile distribution and included organizations that require improvements in several areas.

• Class E: it included organizations with the lowest index of performance (below the 20 percentile) and showed to require substantial corrective actions in multiple areas.

Overall performance score per area can be also calculated. The score was calculated in order to weight results according to the different number of indicators resulted applicable on each area so that performances at this level were comparable.

Pilot sample

All the members of the GISIO-SItI working group were asked to take part in the pilot study. The HAI-CoSIP system was sent via web to participating HCOs through the Survey Monkey platform. The survey was conducted in April 2015.

Data analysis

Data were analysed according to three different levels:

1) by HCO, calculating the Composite Performance Indicator;

2) by area, in order to highlight the most critical areas;

3) by stratifying the sample, according to 4 categories of HCOs: rehabilitative HCOs (Category 1), acute HCOs ≤ 300 HBs (Category 2), acute HCOs with 301 - 799 HBs (Category 3) and acute HCOs with ≥ 800 HBs (Category 4).

The percentage distribution of "Not Applicable" (NA) requirements was calculated according to the four above mentioned categories in order to compare results. Descriptive statistical analysis was performed with the Software STATA-14.

Results

Sample description and class of performances identification

Twenty HCOs agreed to take part in this pilot study. The HCOs were distributed as follows: 1 Provincial Healthcare Trust, 4 Local Healthcare Trusts, 1 University Polyclinic, 2 Scientific Institutes for Treatment and Research, 6 Integrated University Hospitals, 4 Hospitals Trust

Table 2 - HCO characteristics and score distribution

HCOs[1]	HCO type	N Ho[2]	N HBs[3]	N NA[4]	N[5] Score 0[6]	N[5] Score 1[7]	N[5] Score 2[8]	N[5] Score 3[9]	Total Performance[10]	Outcomes indicators Performance (T Area)[11]
1	Provincial Healthcare Trust	7	2,132	1	7	12	10	66	80.70%	44.4%
2	Local Trust	1	248	4	19	20	25	28	55.80%	11.1%
3	Local Trust	1	223	4	18	20	26	28	56.52%	11.1%
4	Local Trust	3	472	6	6	7	1	76	87.78%	66.7%
5	Local Trust	4	450	1	13	14	15	53	71.23%	11.1%
6	University Polyclinic	1	527	1	8	6	13	68	82.81%	77.8%
7	Scientific Institute for Treatment and Research	1	1,049	10	13	20	14	39	63.95%	0.0%
8	Scientific Institute for Treatment and Research	1	1,033	3	0	14	12	65	83.51%	33.3%
9	Integrated University Hospitals	2	1,440	2	0	16	19	59	81.91%	66.7%
10	Integrated University Hospitals	5	800	0	6	5	4	81	88.89%	33.3%
11	Integrated University Hospitals	3	987	3	1	1	11	80	94.27%	100.0%
12	Integrated University Hospitals	1	537	6	54	5	0	31	36.30%	33.3%
13	Integrated University Hospitals	2	1,040	0	6	10	8	72	84.03%	66.7%
14	Integrated University Hospitals	1	1,090	0	7	7	4	78	86.46%	33.3%
15	Hospital Trust	1	222	6	3	7	10	70	87.78%	100.0%
16	Hospital Trust	1	362	3	0	11	6	76	89.96%	66.7%
17	Hospital Trust	2	1,008	1	27	23	6	39	53.33%	22.2%
18	Hospital Trust	1	1,353	5	7	16	20	48	73.26%	22.2%
19	Scientific Institute for Treatment and Research Rehab	1	115	20	37	14	1	24	38.60%	0.0%
20	Scientific Institute for Treatment and Research Rehab	1	296	16	7	6	5	62	84.17%	100.0%

[1]HCOs: Healthcare Organizations; [2]Ho: Hospitals; [3]HBs: Hospital Beds; [4]N NA: Number of "Not Applicable" criteria among the total set of criteria; [5]N Score: Number of criteria fulfilling each score among the total set of criteria; [6]Score 0: not fulfilling; [7]Score 1: Partially fulfilling; [8]Score 2: Mostly fulfilling; [9]Score 3: Totally fulfilling [10]Total Performance: calculated as the score for the entire set of criteria on the maximum score for each HCO excluding "Not Applicable" criteria; [11]Outcome Indicators Performance (T Area): calculated as the score for the set of criteria including in T Area on the maximum score in T Area for each HCO excluding "Not Applicable" criteria.

and 2 Scientific Institutes for Treatment and Research with rehabilitative purposes. These 20 HCOs were spread along the whole Country (10 different Regions) and included 40 different hospitals. Table 2 shows the main characteristics and the performance of all these HCOs.

In 2014 overall mean number of HBs was 769.2 (SD = 503.7, Range 115-2,143) with a mean number of ordinary hospital admissions of 24,337 (SD = 16,249.28, range 680-50,226).

According to the classification by HCO type and number of HBs, the sample included 2 rehabilitative HCOs (with 115 and 296 HBs, respectively), 3 acute HCOs with HB < 300 (mean = 230.33, SD = 13.57), 5 with a number of HBs between 301 and 799 (mean = 469.6, SD = 70.36) and 10 with HBs > 800 (mean = 1,193.4, SD = 377.65).

Performance classes thresholds resulted: i) class A performance ≥ = 86.72%; ii) class B, performance between 86.71% and 83.09%; iii) class C performance between 83.08% and 72.45%; iv) class D performance between 72.44% and 55.37%; v) class E, performance < 55.37%. Considering performance classes, we found 5 Healthcare Trusts in class A, 4 in class B, 4 in class C, 4 in class D and 3 in class E.

Performance scores:

The 20 HCOs resulted not fulfilling at all (score 0) a mean of 12 requirements out of 96 (12.20%) (median 7, range 0-54), partially fulfilling (score 1) 12 out of 96 (12.20%) (median 12, range 1-23), mostly fulfilling (score 2) 10 out of 96 (10.91%) (median 10, range 0-26) and totally fulfilling (score 3) a mean of 57 out of 96 requirements (59.87%) (median 64, range 24-81). A mean of 5 requirements resulted "NA" (4.71%) (median 3, range 0-20).

The overall mean composite index score resulted of 74.06% (SD = 17.39%) with a range between 36.30 % and 94.27% (the HCOs 12 and 11, respectively). Figure 1 shows total score and T Area score distribution among the 20 HCOs.

The mean scores by area showed a wide variability, from 44.4% SD (J Area "Presence of guidelines for reusing medical devices") to 100% (K Area "Defined proper management of laundry and linen").

It is worth to be noted that scores by area showed a high variability between each HCO (figure 2).

K, L and S Areas ("Defined proper management of laundry and linen", "Presence of provisions for proper waste disposal" and "Existence of a vaccination program

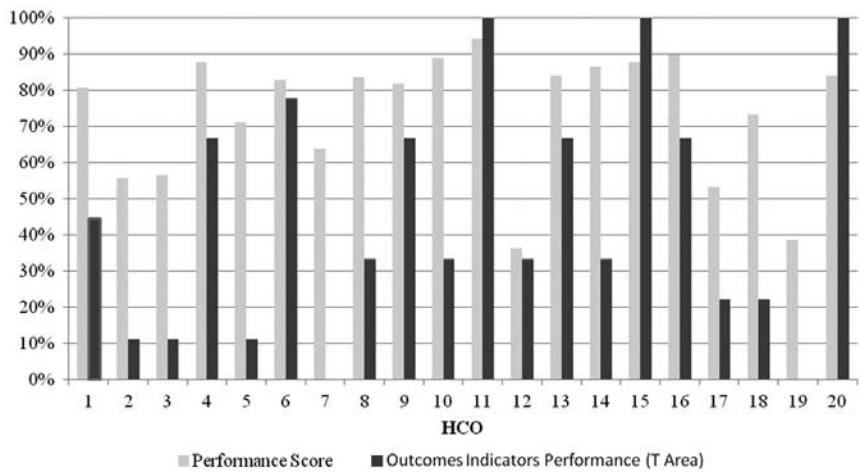

Figure 1 - Total performance score and T area performance score by HCO (Healthcare Organization)

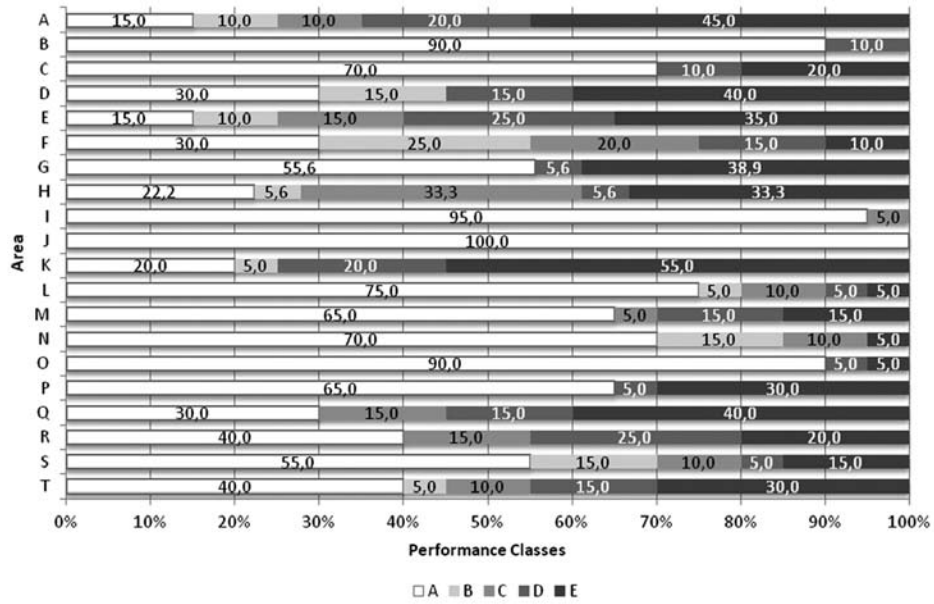

Figure 2 - Percentage distribution of HCO[1] by performance class (A, B, C, D, E)[2] within each Area[3] (from A to T).

[1]HCO: Healthcare Organization; [2]Performance class: performance level by the percentiles distribution (Class A: higher 80 percentile, Class B: 60-80 percentile, Class C: 40-60 percentile, Class D: 20-40 percentile, Class E: below the 20 percentile)

for staff") show a high percentage of HCOs performing in class A (respectively 100%, 95% and 90%); while all other areas show a high variability of performance classes obtained.

Table 3 shows performance score distribution by HCO category. Among the whole sample, the distribution of total scores by HCO category showed a rising trend with increasing number of HBs. Specifically, rehabilitative organizations showed a mean performance score of 61.4%, "acute" organizations - with less than 300 HBs - a mean performance score of 66.70%, "acute" organizations - with a number of HBs between 301 and 799 - a score of 73.61% and, finally, "acute" organizations - with more than 800 HBs - a score of 79.03%.

However, this trend needs to be interpreted cautiously. Indeed, total score distribution among each HCO showed a high heterogeneity (table 2) and this heterogeneity persists even within the same HCO category. As shown in Figure 1, when the total performance score is imputed to the corresponding class of performance, the different categories of HCOs resulted homogeneously distributed among the 5 classes (Figure 3).

Performance among the T area (outcome indicators) showed a mean score of 56.2% (SD = 32.5%) with a range from 0% (2 HCOs) to 100% (3 HCOs). This area includes 5 requirements with 3 requirements evaluating the regular use among the HCOs of 3 specific outcome indicators. The mean composite score for these 3 requirements resulted as follows: "The SSI rate for arthroplasty operations is included among the used outcome indicators" reported a mean score of 31.4% (SD = 25.2%); "The BR-BSI rate is included among used outcome indicators" showed a mean score of 49.0% (SD = 42.7%); finally the requirement "The point prevalence rate of healthcare-associated infections in

Table 3 - HCO Performance by Area and HCO category

Area	Rehabilitative HCOs[1]	HCOs ≤ 300 HBs[2]	HCOs 301 < HBs < 799	HCOs HBs ≥ 800	Mean	Standard Deviation
A	53.70%	65.43%	74.07%	78.15%	72.78%	27.06%
B	63.33%	68.89%	89.33%	91.33%	84.67%	19.48%
C	72.22%	52.78%	71.55%	79.88%	72.97%	23.55%
D	55.56%	48.15%	66.67%	67.78%	63.33%	29.75%
E	50.00%	33.33%	100.00%	76.67%	73.33%	39.88%
F	100.00%	100.00%	73.33%	100.00%	93.33%	23.20%
G	87.50%	88.89%	90.00%	95.83%	92.50%	13.49%
H	76.19%	71.43%	93.33%	86.59%	84.96%	18.99%
I	100.00%	100.00%	76.67%	93.33%	90.83%	16.84%
J	33.33%	22.22%	46.67%	52.67%	44.67%	38.56%
K	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%
L	100.00%	100.00%	100.00%	97.78%	98.89%	4.97%
M	NA	65.43%	64.44%	73.26%	69.51%	23.23%
N	100.00%	55.56%	50.00%	66.67%	62.96%	46.00%
O	54.76%	80.16%	77.62%	83.81%	78.81%	16.94%
P	31.48%	51.85%	61.52%	71.11%	61.86%	26.19%
Q	58.33%	61.11%	60.00%	76.67%	68.33%	29.07%
R	100.00%	55.56%	73.33%	90.00%	81.67%	31.48%
S	100.00%	100.00%	100.00%	93.33%	96.67%	10.26%
T	50.00%	51.11%	63.33%	55.33%	56.17%	31.44%
Overall Performance	**61.38%**	**66.70%**	**73.61%**	**79.03%**	**74.06%**	**16.96%**

HCOs: Healthcare Organizations; HBs: Hospital Beds; NA: Not Applicable

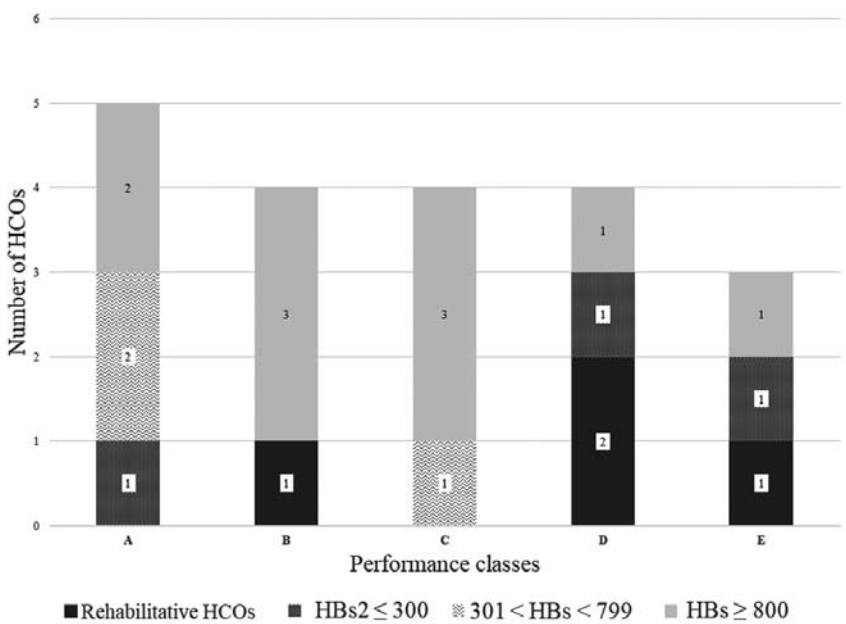

Figure 3 - Distribution of HCO (Healthcare Organization) by performance class and category of HCO

acute care hospitals is included among the used outcome indicators" evidenced a mean score of 63.0% (SD = 45.2%).

Considering "NA" criteria, among the whole sample we found a mean of 5 "NA" criteria per HCO (median 3, range 0-20). The 2 rehabilitative HCOs showed a higher number of "NA" indicators (respectively 16 and 20) compared to "acute" HCOs (mean = 3, range 0-10).

The percentage distribution of "NA" requirements both by area and HCO category was calculated. Most of the "NA" requirements regarded rehabilitative HCOs, the J Area ("Presence of guidelines for reusing medical devices") and requirement 2 of I Area ("Sterilization methods for the devices/equipment conducted outside of the central sterilization site are appropriate to the type"). Specifically, the two rehabilitative HCOs showed a proportion of "NA" requirements respectively of 16/96 (16.7%) and 20/96 (20.8%); J Area resulted "NA" for an average proportion of 32.5% of the whole sample of HCOs, while the criteria I2 for 25% of the whole sample (additional data are available upon request).

Discussion and Conclusions

The main aim of the paper was to test the feasibility of a tool developed to evaluate the HCOs performance according to a set of requirements for the management and control of HAIs within a hospital setting. The selected convenience sample included different HCOs categories with different HBs number. Thus, although small, the sample shows a high heterogeneity that allowed to test the tool in different settings.

Almost two-thirds of the requirements resulted "fully satisfied" in the sample. However, the distribution of satisfied requirements was highly variable and this variability persists even within the same HCO category. Moreover, approximately more than ten percent of the requirements scored "zero" and resulted "not fulfilled". This amount is quite relevant considering that all the evaluated requirements refer to minimum standards that should be met in order to ensure sufficient safety of HAIs prevention and control activity. Furthermore, the distribution of not achieved criteria showed a highly heterogeneous distribution as observed for fully satisfied requirement. This situation highlights the urgent need of setting up an unified evaluation system able to overcome the observed substantial differences, while taking into account all the regulations already arranged at a regional level.

As expected, total performance score distribution reflects the high variability observed when analysing each requirement. Indeed, the included HCOs resulted distributed among the entire set of the 5 obtained classes of performance. Specifically, only one-fourth of HCOs achieved high quality performance level in HAI prevention and control (class A); while almost fifteen percent of HCOs attained a low performance (class E), requiring relevant interventions in several areas of HAIs prevention and control.

These results confirm the important role that may be played by an unified evaluation system able to identify each HCO performance, to benchmark each performance according to other HCOs and to easily highlight which is the level of improvements that need to be implemented in order to satisfy the minimum standards.

The distribution of total performance score by HCO category showed a raising trend of performance with increasing number of HBs. First of all, this trend may be related to the activity volumes performed by different HCO categories. For example, considering orthopaedic surgery, literature shows an inverse correlation between the number of hip and knee joint replacements performed each year and clinical outcomes, including the risk of HAIs (15). Moreover, HCOs with the highest numbers of HBs

generally include organizations at high level of specialization. These HCOs are also more likely to participate in specific Accreditation Programs for Excellence that require the adherence to strictly defined high qualitative standards (16).

Despite this observation, the different categories of HCOs resulted distributed in all the 5 classes of performance, underlying again the heterogeneity of results. The identification of different classes of performance according to the 4 identified HCO categories may be useful in order to improve the value of benchmarking data. Indeed, such an evaluation may allow a performance assessment according to the complexity and structural peculiarities attaining to different HCO categories.

Considering the analysis by area, few areas obtained high level of performances among almost all the HCOs. These areas relate to environmental safety issues highly regulated, such as the definition of proper management of dirty laundry and linen (K Area), the effective management of health-care waste (L Area), the presence of specific protocols for proper cleaning of the environment (F Area), the detection and measurement of air and water quality (G Area), the presence of procedures for the sterilization of medical devices and electro-medical equipment (I Area).

S Area ("Existence of vaccination programs for staff") shows very high level of performance, with 90% of HCOs in class A. Despite these positive results, the presence of a well-defined vaccination program does not always ensure an adequate vaccination coverage. Italian available data show low vaccination coverage among healthcare staff with percentages between 24.8% and 30% for influenza and approximately 70% for Hepatitis B. (17, 18) These data suggest the opportunity to establish a specific outcome indicator of staff vaccination coverage.

T Area (implementation of specific outcome indicators) resulted the most critical. The indicators "rate of SSI for arthroplasty operations" and "rate of CRBSIs" were implemented respectively by half and two thirds of the HCOs. These low performances are noteworthy: SSI and CRBSI show high rates among European countries, respectively up to 19.6% and 10.7% cases/year (2). Collecting surveillance data is essential in order to increase the accountability of HCOs toward the development of best practices able to reduce these HAIs rates. It also allows to assess the effectiveness of implemented strategies. Finally, it may help to identify the most effective interventions (benchmarking data) and contribute to their dissemination among other HCOs. According to the European Center for Disease Prevention and Control (ECDC) recommendations, the estimate of the "point prevalence rate of HAIs in acute care hospitals" contributed to the achievement of a better performance, pointing out the need for a systematic implementation of such a measurement.

P Area ("Presence of protocols for the proper use of antibiotics and for the correct identification of processes that require antibiotic prophylaxis") resulted quite critical, with only one third of the HCOs performing in class A and B and more than half in classes D and E. ECDC data confirm this negative result showing that Italy is one of the Countries with the highest rate of antibiotic use in hospital settings (2.23 DDD/1000 patient day) (19). Italian data show low adherence to antibiotic prophylaxis guidelines for knee and hip joint replacement with appropriate prescription limited to only 43.6% of procedures (20). Inappropriate antibiotic prescription (included inappropriate antibiotic prophylaxis) is a priority intervention area, considering its strict relationship with the development of antibiotic-resistance phenomena (21, 22). Indeed, also O Area ("Presence of protocols to prevent and control multi-drug resistant bacteria - especially methicillin resistant Staphylococcus aureus [MRSA]") show low

performance with almost half of the HCOs performing in class C, D or E.

It is noteworthy that a low performance for O and P areas has been observed specifically in the two rehabilitative HCOs (respectively one HCO in class E and one in class C for O Area and both in class E for P Area). Although these data cannot be generalized, it is worth reminding that the two selected rehabilitative HCOs are both classified as "Institutes for Treatment and Research" with rehabilitative purposes. Therefore, they are centres of excellence within their field and are expected to perform better than other rehabilitative HCOs. This observation highlights the urgent need of improving antibiotic prescription among these setting, especially considering their central role as reservoir of antibiotic resistance bacteria (23-25).

Another unsatisfactory area resulted the one related to staff training (D Area: "Presence of a staff training program on HAIs prevention and control"). In 2009 the ECDC commissioned an assessment of the training needs for infection control in Europe (TRICE) and (through a contract with the University of Udine, Italy) produced a list of core competencies with the goal of developing a training strategy at the EU level in the area of infection control (26-28). The promotion at a national level of new training initiatives for HAI control professionals according to EU standards should be considered a vital investment to strengthen the fight against HAIs.

Finally, J Area ("Presence of guidelines for reusing medical devices") resulted surprisingly critical. The most critical issues referred to criteria exploring whether the procedure reported specific technical warnings (such as the maximum number of reuses for each medical device or the level of wearing out that should impede the further reuse of the device) or whether it described how to collect, analyse, and implement data related to the reused equipment in order to monitor its impact on HAI prevention and control. Although medical device management and reuse are heavily regulated within the Italian context with guidelines available at regional and national level, the continuous development of new technologies may have produced new issues related to maintenance, sterilization and retention of medical devices with the development of procedures not always updated and suitable to conform to EU regulations. On the other hand, several HCOs of different categories reported the majority of the criteria within J Area as not applicable. This observation raises doubts whether the negative results for J Area may be either ascribed to a lack of clarity of the present regulations or to a poor clarity of the questionnaire (e.g. an inadequate formulation of the criteria within J Area).

J Area resulted the only area with a substantial number of "NA" criteria distributed among all four HCOs categories. The analysis of "NA" criteria evidenced a few further issues related to rehabilitative HCOs. The definition of SSI prevention and control strategies (M Area), the definition of outcome indicators (T Area) and criteria related to ICUs (Criteria C4 and C5) resulted not applicable for both the rehabilitative HCOs, while other criteria resulted not applicable for just one of the two HCOs. The other HCOs were quite concordant in defining which criteria could be considered applicable within their context. According to these results it would be useful to implement, within the questionnaire, a more strictly definition of the situations or type of HCOs for which the criteria may be considered as not applicable.

This study suffers from some limitations. First of all, the category and number of HCOs included in this study raise concerns regarding the generalization of results. In the sample, indeed, both the integrated university HCOs and the Scientific Institutes for Treatment and Research are overrepresented, and they are generally more innovation-oriented and easily achieve excellent performances.

On the other hand, rehabilitative HCOs are under-represented because only two rehabilitative HCOs participated in the study; in addition, both represent a selected reality compared to other rehabilitative HCOs, because they are classified as Scientific Institutes for Treatment and Research, of high complexity and with a high number of HBs. This potential selection bias may lead to an overestimation of results. However, according to the main purpose of the project, the sample was considerably heterogeneous and has allowed to test the feasibility of the tool among different HCO categories.

Secondly, the self-assessment nature of the questionnaire may have contributed to the retrieved variability of the results. In order to propose the questionnaire as a tool of institutional accreditation, it would be useful to develop a user manual with criteria description and limits of applicability for each HCO type.

Finally, the evaluation of specific psychometric measures may contribute to strengthen its use as a benchmarking tool and to test the improvements over time gained by each HCO.

Despite these limitation, the questionnaire was able to provide an overall view of the level of performance achieved by each HCO in developing an adequate program for HAIs prevention and control. It permitted to identify main critical areas and to provide useful data to support management to establish needs for improvements and priorities and to prepare future changes.

The fight against the occurrence and dissemination of HAIs requires a straightforward and clear set of minimum standards well recognized by every Hospital Hygiene and Infection Control staff. If these elements are present and practiced consistently, the risk of HAIs for patients and healthcare personnel could be efficiently and drastically reduced.

The developed tool satisfies this essential need and resulted useful to assess different HCOs performance regarding HAIs prevention and control. Moreover, it allowed each HCO to gain self-awareness regarding the straightness and weakness of implemented infection control program. Furthermore, its use as a benchmarking tool may help organizations to evaluate their results as compared to other similar HCOs and encourage a process of self-accountability able to promote and manage major changes.

Finally, its potential implementation as an institutional accreditation tool may help to drive the harmonization process of HAIs management and control strategies and overcomes regional differences that actually impede benchmarking activities and reciprocal learnings as recently underlined by The National Agency for Regional Healthcare Services (29).

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Riassunto

Strategie essenziali nella prevenzione e nel controllo delle infezioni correlate all'assistenza: valutazione delle prestazioni attraverso l'implementazione dello strumento HAI-CoSIP del gruppo GISIO-SItI. Uno studio pilota su un campione di Organizzazioni italiane

Introduzione. Le Infezioni Correlate all'Assistenza costituiscono una difficile sfida per i sistemi sanitari di tutto il mondo e rappresentano una considerevole minaccia per la sicurezza dei pazienti, con potenziale importante impatto negativo sugli esiti clinici. Disporre di un set definito di indicatori rappresenta un elemento

chiave per guidare le Organizzazioni Sanitarie verso l'identificazione delle principali criticità, la messa in atto di efficaci azioni correttive e il continuo miglioramento delle attività di prevenzione e controllo delle Infezioni Correlate all'Assistenza. Una revisione sui sistemi di accreditamento condotta dal Gruppo Italiano Studio Igiene Ospedaliera della Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica ha messo in luce una sostanziale eterogeneità degli standard implementati e ha portato allo sviluppo di un "Set di indicatori e requisiti chiave per la prevenzione e per il controllo delle Infezioni Correlate all'Assistenza".

Obiettivo principale dello studio è di testare l'applicabilità dello strumento "Set di indicatori e requisiti chiave per la prevenzione e per il controllo delle Infezioni Correlate all'Assistenza" su un campione di Organizzazioni Sanitarie italiane, misurarne la performance e identificare le principali criticità. Vengono inoltre discussi i potenziali benefici di un'eventuale futura implementazione dello strumento all'interno dei programmi di accreditamento istituzionale.

Disegno dello studio. Indagine trasversale pilota.

Metodi. Il "Set di indicatori e requisiti chiave per la prevenzione e per il controllo delle Infezioni Correlate all'Assistenza" include 96 criteri e 20 aree, inclusa un'area per gli indicatori di esito. Per i criteri risultati applicabili, l'adempimento agli standard viene valutato su una scala Likert a 4 punti. È stato calcolato un punteggio complessivo di performance per ciascuna Organizzazione identificando cinque diversi livelli di performance. I dati sono stati ulteriormente analizzati calcolando le performance a livello di ciascuna area e requisito.

Risultati. 20 Organizzazioni Sanitarie hanno accettato di prendere parte a questo studio pilota, incluse due Aziende di tipo riabilitativo. Sul totale del campione una media del 12,20% dei requisiti è risultata "non soddisfatta", lasciando spazio per ulteriori miglioramenti. Le aree critiche sono state facilmente identificate e lo strumento è stato in grado di catturare differenze sostanziali tra le diverse Organizzazioni Sanitarie. Solo un numero limitato di standard è risultato "Non applicabile" (media = 4,71%) e la maggior parte di essi ha riguardato le Aziende di tipo riabilitativo.

La performance complessiva è risultata mediamente del 74,06% (DS = 17,39, range 36,30 - 94,27%); l'area inerente gli indicatori di esito ha ottenuto un punteggio medio del 56,2%.

Conclusioni. Il "Set di indicatori e requisiti chiave per la prevenzione e per il controllo delle Infezioni Correlate all'Assistenza" è risultato un utile strumento per valutare le performance delle Organizzazioni Sanitarie nel campo della prevenzione e del controllo delle Infezioni Correlate all'Assistenza e per identificare le azioni necessarie per ulteriori miglioramenti. La distribuzione dei punteggi di performance complessiva ha mostrato un'elevata eterogeneità tra le Organizzazioni Sanitarie incluse nello studio. L'implementazione del "Set di indicatori e requisiti chiave per la prevenzione e per il controllo delle Infezioni Correlate all'Assistenza" come strumento di accreditamento istituzionale può aiutare a guidare l'armonizzazione necessaria a livello nazionale delle strategie di gestione e controllo delle Infezioni Correlate all'Assistenza e superare le attuali sostanziali differenze esistenti a livello regionale.

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