

Definition of criteria and indicators for the prevention of Healthcare-Associated Infections (HAIs) in hospitals for the purposes of Italian institutional accreditation and performance monitoring

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Key words: Healthcare-Associated Infections (HAIs), Patient safety, Institutional accreditation, Performance monitoring, Outcome indicators

Parole chiave: Infezioni Correlate all'Assistenza (ICA), Sicurezza del Paziente, Accreditamento, Monitoraggio delle performance, Indicatori di esito

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Abstract

Background. Healthcare-associated infections (HAIs) are an important issue in terms of quality of care. HAIs impact patient safety by contributing to higher rates of preventable mortality and prolonged hospitalizations. In Italy, analysis of the currently available accreditation systems shows a substantial heterogeneity of approaches for the prevention and surveillance of HAIs in hospitals. The aim of the present study is to develop and propose the use of a synthetic assessment tool that could be implemented homogeneously throughout the nation.

Methods. An analysis of nine international and of the 21 Italian regional accreditation systems was conducted in order to identify requirements and indicators implemented for HAI prevention and control. Two relevant reviews on this topic were further analyzed to identify additional evidence-based criteria. The project team evaluated all the requirements and indicators with consensus meeting methodology, then those applicable to the Italian context were grouped into a set of “focus areas”.

Results. The analysis of international systems and Italian regional accreditation manuals led to the identification respectively of 19 and 14 main requirements, with relevant heterogeneity in their application. Additional evidence-based criteria were included from the reviews analysis. From the consensus among the project team members all the standards were compared and 20 different thematic areas were identified, with a total of 96 requirements and indicators for preventing and monitoring HAIs.

Conclusions. The study reveals a great heterogeneity in the definition of accreditation criteria between the Italian regions. The introduction of a uniform, synthetic assessment instrument, based on the review of national and international standards, may serve as a self-assessment tool to evaluate the achievement of a minimum standards set for HAIs prevention and control in healthcare facilities. This may be used as an assessment tool by the Italian institutional accreditation system, also useful to reduce regional disparities.

Introduction

Systematic measurement of healthcare processes and outcomes is essential in order to promote a continuous improvement of quality of care. Reliable measurements require the implementation of international quality indicators and the adoption of shared databases that allow adequate comparisons. These measurements, together with an increased focus on evidence-based medicine and international recommendations, can provide valuable information for improving the safety profile of healthcare assistance and for a more effective and efficient use of available resources. The healthcare system is a complex environment, where organizational, procedural, and economic evaluational elements affect the level of quality of care. In order to account for all of these elements and to accurately describe such a complex

reality, it is useful to adopt synthetic indicators. An effective set of indicators provides sufficient information to efficiently describe and evaluate the care offered to the patient; further, it provides simple, clear, and easily comparable results. These characteristics are essential for guiding healthcare decisions and promoting continuous improvement of quality and safety (1-3).

Another crucial aspect necessary to guarantee quality of care is the introduction of specific standards. Introduction of regulatory elements is a powerful tool for promoting patient safety, because they facilitate the adoption of specific best practices (4, 5). Indeed, accreditation processes of hospitals, professionals and training programs represent an extremely important aspect of patient safety improvement (6-9).

The need to routinely implement structure, process and outcome indicators, as

well as to efficiently adopt accreditation or certification processes as instruments to promote the adherence to best practices, is also highlighted by a specific European Council Recommendation of June 2009 (and its subsequent updates) (10). The document includes a set of recommendations to promote patient safety and, specifically, to guide organizations along the prevention and control of healthcare-associated infections (4, 10, 11). Indeed, the activities of monitoring and preventing HAIs are essential aspects of patient safety and quality improvement programs. HAIs are often associated with several poor outcomes such as prolonged length of stay, long-term disability, increased microbial resistance to antibiotics, an excess of preventable deaths and, generally speaking, massive increases in both healthcare and financial burdens (6, 12). The worldwide burden due to HAIs is well documented. Global estimates indicate that HAIs affect hundreds of million patients around the world, both in low and high-income countries (13). In Europe, prevalence rates range from 2.0% to 9.5%, with more than 4 million affected patients (data for 2013) (14). The impact of such high rates is huge. Annually, HAIs account for approximately 37,000 deaths and 16 million additional days of hospitalization; they cost an estimated 7 billion euros per year (13). An Italian study that explored prevalence rates of HAIs in patients admitted to Intensive Care Units (ICUs) reported an even higher prevalence rate of 21.8% (15). Moreover, HAIs are calculated to add approximately 4,155 euros on the average for each surgical site infection (16, 17).

During the last decades, several countries have set up surveillance systems. For example, the United States (US) surveillance system of HAIs (i.e., National Healthcare Safety Network [NHSN]) allows network participants to compare their performance with the national level. Participation is voluntary and results are confidential. In the French accreditation system (Haute

Autorité de Santé [HAS]), HAI management and prevention performances are based on six different assessment tools (ICALIN.2, ICSHA.2, ICATB, ICA-BMR, SARM, and ICA-LISO). These tools allow for the identification of defense measures and control systems that each organization can put in place based on its risk profile. Data collected from each organization are published and disseminated through an annual report. These data help organizations to learn from best practices and to identify further corrective measures that need to be implemented (18). A German surveillance program, based on a monitoring system called KISS (Krankenhausinfektionen Surveillance System), is specifically focused on evaluating a limited number of settings or conditions that deem to be the most at risk, such as ICUs, surgical wards, Neonatal Intensive Care Units (NICUs), and treatments of patients with Central Venous Catheters (CVCs), mechanical ventilations or bone marrow transplantations (19). In Italy, issues of patient safety and HAI control have been addressed at several levels. At the national level, existing legislation urged for the development of well-organized risk management systems. Moreover, the Ministry of Health has promoted several initiatives to increase the awareness of Healthcare Professionals (HCPs) about safety priority issues, including HAI prevention and control. Regional governments are responsible for ensuring compliance to requirements established at the central level. Finally, at the micro-level, health organizations have tried, albeit unevenly, to translate these requirements into daily professional practice (20). In addition, those who intend to provide services in the name of or on behalf of the Italian National Health Service need to complete the statutory institutional accreditation requirements. This process aims to verify the compliance of an organization with the minimum required structural, technological, and organizational standards. Italian institutional accreditation

is regulated at the central level by a specific law (the so-called “Third Reform of the NHS” of 1999). However, the actual organization and implementation of this process is established at the regional level. Indeed, each regional authority defines the most appropriate model and develops adequate quality criteria, procedures, modes of inspections, and the appropriate budget and financing. Italian regions (including the autonomous provinces of Trento and Bolzano) have therefore regulated authorization and institutional accreditation using different means and organizational models (21).

This research aims to identify a “core set” of requirements and outcome indicators to guide HAI management, control, and prevention. The goal is to develop an assessment tool able to monitor hospitals’ performances on these important issues. This tool should be useful to the Italian national and regional regulatory systems for the purpose of institutional accreditation and should help to eliminate the current heterogeneity.

Methods

This research assumes that each area of healthcare quality can be evaluated with a specific set of indicators. A review of several international and national accreditation systems was conducted in order to identify all the requirements and indicators implemented for HAI prevention and control. Additional data were obtained from two important literature reviews recently published on this topic (13, 22). A specific set of requirements and indicators was then identified by the project team. The team included experts in clinical risk management and HAI prevention and control from different Italian universities and hospitals.

Specifically, the process that led to the “core set” of requirements for the prevention of HAIs in hospitals was developed according to the following steps:

1. An analysis was conducted of the accreditation systems of nine countries. Specifically: United States of America (Joint Commission International [JCI]) (23); Denmark (Danish Institute for Quality and Accreditation in Healthcare [IKAS]) (24); Holland (Netherlands Institute for Accreditation in Healthcare [NIAZ]) (25); Cataluña (Department de Salut - Generalitat de Cataluña- January Cat) (26-28); France (Haute Autorité de Santé [HAS]) (29-37); United Kingdom (Care Quality Commission [CQC]) (38-39); Australia (Australian Council on Healthcare Standards [ACHS]) (40, 41); Canada (Canadian Council on Health Services Accreditation [CCHSA]) (42, 43); Germany (Krankenhausinfektionen Surveillance System [KISS]) (44).

2. Each nation’s available regulatory documents for HAI management and control were reviewed and analyzed. Specifically:

- a) The accreditation manuals for all Italian regions (19 regions and two autonomous provinces) (45-65);

- b) The AGENAS (National Agency for Regional Health Services) proposal that describes quality factors/criteria for the authorization/accreditation of HCOs in Italy (66);

- c) Ministerial Decree number 70 of April 2, 2015, which refers to regulations that define quality, structural, technological, and quantitative standards concerning hospital care (67-70).

3. All selected documents (both international and national) were analyzed by means of comparative methodology in order to identify both shared and distinctive requirements and indicators.

4. Two main literature reviews recently published on the topic of HAI prevention and control were further analyzed to identify additional evidence-based criteria (13, 22). Specifically:

- a) The European Consensus on standards and performance indicators for the prevention and control of healthcare-associated

infections published by Cookson in 2011 (22);

b) The systematic review and expert consensus on hospital organization, management, and structure for the prevention of healthcare-associated infections published by the European Centers for Disease Control (ECDC) in 2015 (13).

5. Identified requirements and indicators were then grouped into a set of “focus areas”. These areas were validated by the project team using the consensus meeting methodology.

6. For each area, requirements and indicators adaptable to the Italian context were identified and selected.

Results

The analysis of nine international accreditation systems led to the identification of 19 standard criteria (Table 1). Results show great heterogeneity in the definition of most of requirements. The United Kingdom (UK), Australia, France, and the United States of America (USA) have higher numbers of requirements (16 for the UK and Australia and 14 for the USA and France, respectively). The German system covers six of the 19 identified standards. Two criteria are reported by all the included systems, the “presence of a policy and an organization for the prevention and control of HAIs in the hospital” and the requirement to perform HAI surveillance in the hospital. Moreover, protocols for reporting HAI surveillance results and incidents related to the risk of infection are required by 7 of 9 systems; Denmark and Canada are the exceptions. Similarly, the presence of procedures for the sterilization of medical devices and electro-medical equipment as well as for the proper management of surgical site infection are explicitly reported by all systems except two. Finally, four standards are included in 6 of the 9 systems (e.g., the presence of a

staff training program for HAI prevention and control and the presence of protocols for proper hand hygiene, for the prevention and control of multidrug resistance bacteria and for the proper use of antibiotics).

Table 2 shows the results from the analysis within the Italian context. Differences and similarities between accreditation criteria defined by each region were examined. In Italy, institutional accreditation systems are defined at the regional level. Results show a wide variability in the standards implemented by each region, which was expected because of the heterogeneity of accreditation models implemented throughout Italy (21).

All regions define requirements, specific precautions, or best practices for HAI management. Implementation of specific indicators is clearly stated by seven regional accreditation systems. Specifically, 3 regions implement process indicators, while outcome indicators are used in 5 regions. Piedmont implements both process and outcome indicators. Regarding the types of indicators implemented, 5 and 3 regions employ surgical wound and ICU infection rates, respectively. One region requires “Alert” pathogens surveillance as a process indicator. Eight of 21 regions evaluate the presence of protocols that facilitate proper hand washing. Moreover, in 8 regions, a training program for HAI prevention is required.

Three specific evaluation areas are feasible for the Italian context, such as surgical site infections surveillance, ICU infections surveillance, and Pathogens Alert surveillance. Out of the 21 Italian regions, these were included in the accreditation manuals of 13, 8, and 4 regions, respectively. In different regions, surgical site infection monitoring was implemented for arthroplasty, elective rectal resection, inguinal and femoral hernia repair, femoral endarterectomy, saphenectomy, and cesarean section. Regarding infections associated with devices in the ICU setting, requirements focused on incidence infection rates associated with the presence of urinary

Table 1 - Comparative analysis of criteria adopted by the major international accreditation systems.

Criteria	United States of America JCI: Joint Commission International	Denmark IKAS: Danish Institute for Quality and Accreditation in Healthcare	Netherlands NIAZ: Netherlands Institute for Accreditation in Healthcare	Catalonia Gen Cat: Departament de Salut - Generalitat de Catalunya	France Has: Haute Autorité De Santé	United Kingdom Cqc: Care Quality Commission	Australia Achs: Australian Council On Healthcare Standards	Canada Cchsa: Canadian Council On Health Services Accreditation	Germany Kiss: Krankenhaus Infektions Surveillance System
Presence of a policy and an organization for the prevention and control of HAIs in the hospital	X	X	X	X	X	X	X	X	X
Appointment of a supervisor/committee for control and surveillance of HAIs in the hospital			X	X	X	X	X	X	
Performing HAI surveillance in the hospital	X	X	X	X	X	X	X	X	X
Presence of a program to train staff on the prevention and control of HAIs				X	X	X	X		X
Presence of protocols for reporting results of HAI surveillance and incidents involving the risk of transmitting infection			X	X	X	X	X		
Defined protocols for proper cleaning of the environment		X	X		X	X	X		
Detection and measurement of air and water quality			X		X	X			
Presence of protocols for proper hand hygiene	X	X			X	X	X	X	
Presence of procedures for sterilization of medical devices and electro-medical equipment	X	X	X	X		X	X	X	
Presence of guidelines on the reusing medical devices	X	X				X	X		
Presence of specific procedures for cleaning and disinfecting flexible endoscopes	X	X	X			X	X		
Protocol for proper management of laundry and linen	X	X				X	X		
Presence of provisions for proper waste disposal	X		X		X	X	X		
Defined surgical site infection prevention and control		X		X	X	X	X	X	X
Presence of specific protocols for preventing infections associated with urinary catheters/peripheral and central venous catheters					X		X	X	X
Presence of protocols for the prevention and control of multi-drug resistant bacteria (especially methicillin-resistant <i>Staphylococcus Aureus</i> [MRSA])	X	X			X	X	X	X	
Presence of protocols for the proper use of antibiotics and the correct identification of processes that require antibiotic prophylaxis		X	X	X	X	X	X	X	X
Presence of systems that ensure the isolation of patients with infectious diseases	X			X		X	X	X	
Defined indicators	X				X		X	X	X

Table 2 - Comparative analysis of the prevention and monitoring of HAIs at the regional level in Italy.

	Region Abruzzo	Region Basilicata	Region Calabria	Region Campania	Region Emilia Romagna	Region Friuli Venezia Giulia	Region Latium	Region Liguria	Region Lombardy	Region Marche	Region Molise	Autonomous Province of Bolzano	Autonomous Province of Trento	Region Piedmont	Region Apulia	Region Sardinia	Region Sicily	Region Tuscany	Region Umbria	Region Aosta Valley	Region Veneto
Presence of requirements	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Presence of protocols/procedures	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Presence of best practices																					
Presence of precautions		X			X		X				X			X		X					X
Presence of criteria		X					X						X	X							X
Presence of outcome indicators		X											X	X				X			X
Presence of process indicators									X					X				X			X
Presence of basic standards														X				X			X
Requirements for hand hygiene					X		X							X				X			X
Requirements for the prevention and control of respiratory tract infections			X		X					X				X			X				X
Requirements for the prevention and control of Central Venous Catheter CVC-related infections										X				X			X				X
Requirements for the prevention and control of urinary tract infections			X		X					X				X			X				X
Requirements for the prevention and control of surgical site infections	X	X	X		X		X		X	X				X			X				X
Staff training			X		X				X					X							X

Table 3 - Set of requirements and indicators proposed for preventing and monitoring HAIs

AREA A	Presence of a policy / program and of an organization for the HAIs prevention and control in the hospital
	A1. There is strategy to control the risk of infection
	A2. The organization and the resources are defined
	A3. There is a program and a multi-modal approach to reduce patients' risk of healthcare-associated infections
	A4. There is a program and a multi-modal plan to reduce the staff's risk of healthcare-associated infections
	A5. The program includes systematic and proactive surveillance activities to determine the usual infection (endemic) rates
	A6. The program includes the application of epidemiological investigation systems to examine hospital outbreaks
	A7. Regular feedback on the results of active surveillance programs/epidemiological investigations implemented by the organization are provided to the staff
	A8. Final objectives for risk reduction and related short-term measurable targets are established and monitored regularly
	A9. The program is appropriate for the organization's size and its geographical location as well as for the services it provides to patients
AREA B	Appointment of a manager/multi-disciplinary committee for the control and surveillance of HAIs in the hospital
	B1. The hospital has started a multi-disciplinary group (i.e., Infection Control Committee [ICC]) tasked with coordinating control of HAIs in the hospital
	B2. The hospital has a coordinator to monitor infection surveillance and control activities
	B3. There is an infection control team responsible for monitoring and controlling daily activities
	B4. The hospital has supporting nursing staff to control HAIs
B5. Such nursing staff is consistent with standards described in the Ministry of Health Circular n. 8/1988 (full-time equivalents for active beds)	
AREA C	Performing HAI surveillance within the hospital
	C1. Procedures and protocols for surveillance and infection risk prevention are established
	C2. Procedures and protocols related to infection risk control are established and consistent with the hospital's risk areas and patients' characteristics
	C3. These documents are available and updated
	C4. There is an active surveillance program for surgical site infections and Central Venous Catheter-related infections
	C5. Results of this program are analyzed and provided to the relevant staff
	C6. A prevalence or incidence survey is conducted annually (outside of surgical site infections, multi-drug resistant bacteria)
	C7. There is a procedure for cause analysis in the case of a severe infectious event
C8. Results of this analysis are analyzed and provided to the relevant staff	
AREA D	Presence of a staff training program on HAI prevention and control
	D1. There is an evidence-based program for training professionals in hygiene and preventing risk of infection
	D2. The training for HAI prevention and control takes into account the identified needs and objectives
AREA E	Presence of protocols to communicate HAI surveillance results and incidents involving the risk of infection transmission
	E1. There is an annual report by the ICC on HAI control and antibiotic resistance (at least on the "alert" pathogen)
AREA F	Defined protocols for proper cleaning of the environment
AREA G	F1. Validated and updated procedures and protocols are in place for hospital cleaning and for management of operating rooms, delivery rooms, and "protected zones"
	Detection and measurement of air and water quality
	G1. Validated and updated procedures and protocols are in place for the environment (i.e., water and air)
	G2. Hot water service is subject to microbiological surveillance during the year
G3. There is a protocol of behaviors to adopt in case air or water quality fails to meet minimum established standards	
G4. There is preventive maintenance of hot water service in the structure during the year	

AREA H	H. Presence of protocols for proper hand hygiene
	H1. There is a protocol for hand hygiene updated within the last 5 years
	H2. Devices for hand hygiene are easily accessible at the point of contact with the patient
	H3. Consumption of hydro alcoholic solution or gel is monitored
	H4. This monitoring is subject to feedback by area of activity at least once a year
	H5. An assessment (at least) was made of hand hygiene practices within the last 5 years
	H6. There is evidence of an annual training program on hand hygiene
AREA I	Presence of procedures for the sterilization of medical devices and electro-medical equipment
	I1. Sterilization methods for devices/equipment in the central sterilization site are appropriate to the type
	I2. Sterilization methods for the devices/equipment conducted outside of the central sterilization site are appropriate to the type
AREA J	Presence of guidelines for the reusing medical devices
	J1. There is a policy and procedure that conforms with national laws and regulations, and with professional standards, which identify how to reuse devices and equipment
	J2. The maximum number that each device or piece of equipment can be reused are defined in the procedure
	J3. The type of wear (e.g., cracking, etc.) and any other basis on which the device cannot be reused are set out in the procedure
	J4. The process for cleaning each device, which begins immediately after use and following a precise protocol, is set out in the procedure
	J5. The process for collection, analysis, and use of data on the prevention and control of infections related to the reused equipment and devices is described in the procedure
AREA K	Defined proper management of laundry and linen
	K1. Management of laundry and linen is appropriate and minimizes the risk to staff and patients
AREA L	Presence of provisions for proper waste disposal
	L1. Disposal of infectious waste is managed in order to minimize the risk of transmission
	L2. Handling and disposal of blood and blood components are managed in order to minimize the risk of transmission
AREA M	Defined strategies for the prevention and control of surgical site infections
	M1. There is a tool to help observe preventative measures of peri-operative risk
	M2. There is a hygiene protocol specific for operating rooms and delivery rooms updated within the last 5 years
	M3. There is preventive maintenance of systems that supply air to operating rooms (e.g., microbiological surveillance, preventive maintenance during the year, etc.)
	M4. There is a protocol to prepare a patient's skin prior to surgery that has been updated within the last five years
	M5. There is a surveillance program for surgical site infections and results are analyzed and provided to the relevant staff
	M6. All surgical disciplines in the hospital perform surveillance for surgical site infections
	M7. At least one discipline performs surveillance within a network
	M8. Surgeons are systematically involved in the clinical evaluation of surgical site infections
M9. Surveillance results are sent to the ICC at least once a year	
AREA N	Presence of specific protocols to prevent CVC-related infections
	N1. There is a surveillance program for CVC-related infections and results are analyzed and provided to the relevant staff

AREA O	Presence of protocols to prevent and control multi-drug resistant bacteria (especially methicillin resistant <i>Staphylococcus aureus</i> [MRSA])
	O1. There is a protocol that lists major multi-drug resistant bacteria updated within the last 5 years
	O2. There is a control strategy for multi-drug resistant bacteria, according to the activity, updated within the last 5 years
	O3. There is a plan to be implemented in case of a high-risk organism is detected
	O4. Multi-drug resistant bacterial surveillance results are sent to the ICC
	O5. There is a procedure for the rapid exchange of information among the Microbiology Unit, the Recovery Unit, and the hospital's operational team to facilitate the control of hospital-acquired infections
	O6. Communication to patients that carry multi-drug resistant bacteria is systematically made
	O7. There is a communication protocol in case of an inter-structural or intra-structural transfer of patient colonized with multi-drug resistant bacteria, and in case additional infected patients are admitted to the same structure, updated within the last 5 years
	O8. There is a procedure that enables the hospital's operational team, which is responsible for hospital-acquired infection control, to verify the adoption of recommended precautions
	O9. There is surveillance which enables the rate of infection with multi-drug resistant bacteria to be calculated
	O10. There is a network of surveillance to monitor infections with multi-drug resistant bacteria
	O11. Surveillance results are provided to the relevant staff
	O12. Specific procedures are implemented and monitored for the identification and treatment of patients hospitalized with MRSA
	O13. There are hospital policies based on best practices for screening high-risk patients in order to detect high-risk organisms (e.g., MRSA)
O14. There is potential access to a support microbiology laboratory, typing included	
AREA P	Presence of protocols for the proper use of antibiotics and for the correct identification of processes that require antibiotic prophylaxis
	P1. The hospital has a group responsible for antibiotics and their use
	P2. A controlled delivery system is used
	P3. Guidance and protocols for the proper use of prescriptions are distributed to professionals
	P4. The patient's medical records show reevaluation of antibiotic therapy between the 24th and 72nd hour
	P5. A surveillance system of antibiotic resistance is actually implemented
	P6. The correct use of antibiotics is evaluated, in particular by monitoring indicators
	P7. Improvement actions are implemented according to the results of monitoring reports
	P8. There is evidence of an annual training program on antibiotic resistance
	P9. There is surveillance of antibiotic consumption in Defined Daily Doses (DDD)
	P10. There is a documented hospital policy for antibiotic prophylaxis which is annually assessed
	P11. The hospital has antibiotic prophylaxis protocols updated within the last 5 years
P12. An evaluation of antibiotic prophylaxis practices was conducted during the last 5 years	
AREA Q	Presence of systems to ensure the isolation of patients with infectious diseases
	Q1. The hospital has a policy for the treatment of patients in isolation (e.g., guidelines for protective isolation and for the transport of infected patients)
	Q2. There is a documented annual evaluation of standard precautions adopted
AREA R	Communication with patients and caregivers
	R1. Information is given to patients and caregivers about the risks of healthcare-associated infections and about initiatives implemented to minimize these risks
AREA S	Existence of a vaccination program for staff
	S1. A vaccination program for staff is implemented according to national guidelines
AREA T	Defined indicators
	T1. Indicators are used to control the risk of infection
	T2. There is evidence of performing periodic audits for control of hospital-acquired infections
	T3. The rate of surgical site infections for arthroplasty operations is included among the outcome indicators used
	T4. The rate of bloodstream infections associated with central venous catheters is included among outcome indicators used
	T5. The point prevalence rate of healthcare-associated infections in acute care hospitals is included among the outcome indicators used

catheters, vascular devices, or assisted ventilation devices. The choice of which of these indicators had to be implemented was again decided at the regional level.

Finally, analysis of the literature identified reference standards related to some of the main areas. Specifically, the European consensus published by Cookson and colleagues identified 13 national and international indicators in five different areas: i) Organization for HAI control, ii) Prevention and control policies, iii) surveillance policies and resources, iv) resources, and vi) education. The authors highlighted the importance of implementing organized models for HAI control. For example, specific requirements were: i) the presence of prevention and control programs that reduce the burden of infections and monitor and reduce antibiotic resistance, ii) the adoption of validated guidelines to monitor and control HAI and antibiotic resistance rates, and iii) the implementation of surveillance and adequate feedback systems to guide resource distribution, to share good practices for the prevention of HAIs, and to promote the diffusion of a safety culture (22). In the “surveillance policies” area, main indicators identified by the literature review were surgical site infection surveillance, ICU infection surveillance, and Pathogens Alert surveillance. The same area was already discussed within the analysis of Italian documents.

Furthermore, the systematic review and the evidence-based guidance on organisation of hospital infection control programmes (SIGHT) study group systematically analyzed 833 scientific papers and, through the methodology of “consensus among experts”, identified ten key components and related indicators for prevention of HAIs. Some examples are: definition of a minimum dedicated staff for a satisfactory infection control program, implementation of adequate staff training and education programs, use of audits with timely feedback, participation in prospective surveillance

programs, implementation of infection control programs based on bundles and *ad hoc* checklists and promotion of a positive organizational culture (13).

Set of proposed requirements and indicators for preventing and monitoring HAIs

Table 3 summarizes all identified criteria according to the three sources of information considered. It was possible to identify 20 different thematic areas (identified from “A” to “T”) with a total of 96 requirements for preventing and monitoring HAIs.

The presence of an organizational policy or program to prevent and control HAIs within each hospital is a recognized standard in the analyzed literature as well as the examined national and international accreditation systems. It is also specifically required by Italian law, as indicated in the Ministerial Document 52/1985 concerning the fight against hospital-acquired infections (69). Moreover, it is one of the recommendations regarding patient safety (including the prevention and control of healthcare-associated infections) established in 2009 by the European Council (10). Furthermore, according to the law, each Italian hospital has a multidisciplinary committee with dedicated nursing staff, whose role is to prevent and control HAIs (68).

The World Health Organization (WHO) recommends to dedicate a full-time nurse for infection control every 250-400 beds or for every 9,000-10,000 annual admissions, depending on the type of clinical ward and required skills. With regards to medical staff, a physician specializing in hospital hygiene must be considered in hospitals with more than 1,000 beds or with 25,000-35,000 annual hospitalizations (71).

The need to perform adequate HAI surveillance programs and report the results to all stakeholders (Area C and E) is a recognized standard in all analyzed international accreditation systems, and it is specifically required by law in Italy as indicated in the

recent Ministerial Decree number 70 of April 2, 2015 (67). Moreover, it is one of the five areas and ten key components, respectively, identified by the recent literature reviews (13, 22).

A staff training program about HAI prevention and control is expected by most of the national accreditation systems analyzed (i.e., American, Catalan, French, English, Australian, and Canadian systems) and by several of the Italian regional accreditation systems (8 out of 21). Moreover, both the analyzed literature reviews highlight the importance of adequate education (13, 22). Nevertheless, knowledge and improvement of the so-called “human factor” are key elements of risk assessment and management and they are traditionally recognized as a core safety aspect in other “high-risk” organizations (e.g. different branches of the Army) (71).

The presence of specific protocols for proper cleansing of the environment is required by IKAS, NIAZ, HAS, CQC, and ACHS accreditation systems; further, it is described in the guidelines of the Centers for Disease Control (CDC) (72). Air and water quality monitoring, as a measures of HAI prevention, are required by Dutch, French, and English accreditation systems; and are expected by international guidelines. Adequate hand hygiene by patients, health professionals, caregivers, and all other people within the healthcare structure is an internationally recognized crucial factor in HAI prevention, because there is strong evidence of a direct correlation between proper hand hygiene and decreased infection rates (4, 13, 22). Internationally recognized guidelines for proper hand hygiene (Area H) are available from the WHO, CDC, ECDC, and other national and international organizations (72, 73). In France, such a requirement is measured by a specific indicator, the ICSHA.2 (Indicateur de consommation des produits hydro-alcooliques). In Italy, the presence of a procedure for proper hand hygiene is explicitly required by the Ministerial

Decree number 70 of April 2, 2015 (67). Furthermore, in the same decree, hospitals are expected to adopt procedures that ensure adequate and efficient facilities for disinfection and sterilization (67). Regarding the proper reuse of medical device (e.g., endoscopes), requirements highlight the need to develop clear guidelines in order to ensure an adequate level of safety. Proper management of laundry and linen as well as proper disposal of hospital waste are essential hygienic standards for HAI prevention. These are required by the JCI, NIAZ, CQC, and ACHS accreditation systems. In Italy, hospital waste management is regulated by the Presidential Decree 254/2003.

The last ECDC report showed the cumulative incidence rate for surgical site infections; after colon surgery and cesarean section, the rates were 9.7% and 1.4%, respectively (14). Several studies have shown the efficacy of adequate surgical site infection surveillance programs that promote and guide actions designed to reduce the risk of infectious postoperative complications (14, 17). Almost all of the analyzed accreditation systems (JCI, Gen Cat, HAS, CQC, ACHS, CCHSA, and KISS) report, as a requirement, the adoption of adequate measures to prevent and control surgical site infections.

In Italy, available data on HAI rates among patients admitted to the ICU show percentages up to 21.8% (74). In this setting, infections associated with CVC take on special significance because the adoption of a few but effective healthcare practices may radically reduce the incidence rate (5).

Prevalence of HAIs related to the presence of multidrug resistant microorganisms is increasing with severe consequences for patients, healthcare workers, and the healthcare system as a whole. Although the last ECDC report showed a decreased rate of MRSA spread, MRSA rates in southern and eastern European countries need particular attention and antibiotic resistant bacteria are still a priority issue (14). Therefore, in order

to play a strategic role in limiting this alarming phenomenon, all hospitals must adopt the recommended best practices summarized in Area O (75, 76).

Similarly, an appropriate antibiotic management policy is useful to reduce the occurrence of multidrug resistant microorganisms and to improve the global efficiency of the system (4, 13, 22, 77). The involvement of patients and their caregivers in preventing infections is also recognized as relevant (4, 13, 22).

Further, appropriate immunization of the health workforce is critical for preventing and controlling infections. Indeed, well-designed vaccination programs may substantially reduce the number of susceptible operators; and consequently, this strategy could reduce the associated risks of getting and transmitting dangerous vaccine preventable pathogens to patients or healthcare workers (4, 13, 22).

Finally, outcome indicators proposed for HAI surveillance in hospitals are reported. Selection of appropriate indicators for monitoring HAIs is recommended by the Healthcare Infection Control Practices Advisory Committee (HICPAC) of the CDC (8). This committee has identified the rate of bloodstream infections (confirmed by laboratory tests) associated with CVC in ICUs and the rate of surgical site infections as efficient indicators.

In their annual report on healthcare-related infections, the ECDC recommends a set of minimum standards, which include regularly collecting and updating prevalence data among all healthcare organizations in order to perform adequate HAI surveillance, evaluating the effectiveness of undertaken interventions, and identifying priority actions. These requirements are consistent with recommendations expressed by the Council of Europe in 2009 (10, 11, 78, 79). The experiences of some projects, such as, at the national level, the SPIN-UTI project (Italian Nosocomial Infections Surveillance

in Intensive Care Units) conducted by GISIO (Italian Study Group Hospital Hygiene) since 2005, have highlighted the actual feasibility of introducing instruments for HAI monitoring in the context of Italian hospitals (74, 80-82).

Discussion

The accurate description of complex phenomena, such as HAIs, requires significant information in order to make it possible to give a clear picture of all the aspects that concur to define it. Several studies conducted at the international level suggest that an approach that uses a set of indicators could represent a feasible solution (22). For example, the Directorate General for Health and Food Safety (DG Santé) of the European Commission has developed standards, recommendations, and indicators to assess the control of healthcare-related infections and has also carried out a public consultation in order to identify strategies to improve HAI prevention and control (22, 79). The research project entitled 'Improving Patient Safety in Europe' helped to identify a limited set of standards and performance indicators that were able to improve the prevention and control of HAIs and to enhance skills related to the management of antibiotic therapy (77). Defining a set of process and outcome indicators and their use and diffusion throughout public HAI reports is also recommended by the HICPAC of the CDC (79). Review of existing institutional accreditation systems in 19 Italian regions and in the autonomous provinces of Trento and Bolzano has highlighted the heterogeneity of standards and indicators currently implemented in Italy. This evidence, together with results from some nationwide HAI monitoring projects, suggests the need for, and the opportunity of, adopting a uniform system for HAI prevention and control (71, 83, 84). Furthermore, the recent "Health

First Europe” report suggests that “in order to facilitate mutual learning and make data more comparable, a common terminology for patient safety and common surveillance set of indicators need to be developed” (4, 85). Currently, the international debate on the plurality of methods implemented for HAI surveillance and benchmarking remains unresolved. Evidence of a direct effect of benchmarking on the incidence of HAIs is currently weak (9, 77, 82). Implementation of the accreditation systems’ mandatory recommendations (including standards and indicators) to evaluate an organization’s ability to prevent HAIs has shown positive results in terms of reducing the number of HAIs (7, 9, 82). However, there is little evidence that this trend is completely related to the accreditation process. Instead, it could be related to changes at the organizational level (7, 9, 82). In contrast, voluntary participation in surveillance programs seems to promote more participant interest; and consequently, better outcomes and improved quality are achieved. On the other hand, voluntary participation entails a wide variability in the number of hospitals participating in the surveillance project (7).

Despite the discussed limitations, as already stated by the ECDC, developing a set of minimum standards to be implemented in the area of HAI prevention and control is strongly recommended to guarantee continuous patient safety improvement (4, 79).

Conclusions

Introduction of a uniform assessment synthetic instrument, based on the review of national and international standards and literature published on this topic, may provide more information about healthcare quality and improve patient safety. Specifically, it may serve as a self-assessment tool to evaluate the achievement of a set of minimum standards for HAI prevention and control in

healthcare facilities. This may be particularly useful for healthcare organizations providing services on behalf of the National Health Service.

In this context, it may be a useful tool within the same organization and between similar organizations as well. Considering the wide heterogeneity observed within the accreditation systems implemented in Italy, this tool may also help to define a minimum, standardized criteria for HAI control and prevention that eliminates such disparities and promotes best practices. Accordingly, it may be used as an assessment tool by the Italian institutional accreditation system.

Riassunto

Individuazione di un set di criteri e indicatori per la prevenzione delle infezioni correlate all’assistenza in ospedale ai fini dell’accreditamento e del monitoraggio della performance

Introduzione. Le infezioni correlate all’assistenza (ICA) rappresentano un problema prioritario in termini di qualità dell’assistenza. Le ICA condizionano negativamente la sicurezza del paziente determinando un aumento della mortalità prevenibile e un prolungamento della degenza. In Italia, i sistemi di accreditamento attualmente disponibili mostrano una sostanziale eterogeneità nell’approccio alla prevenzione e alla sorveglianza delle ICA in ospedale. L’obiettivo dello studio è di sviluppare e proporre l’utilizzo di uno strumento di valutazione omogeneamente applicabile in tutto il territorio nazionale.

Metodi. È stata condotta una revisione di nove sistemi di accreditamento internazionali e dei 21 manuali di accreditamento delle Regioni italiane al fine di identificare i requisiti e gli indicatori impiegati nella prevenzione e il controllo delle ICA. Due rilevanti revisioni di letteratura sull’argomento sono state analizzate al fine di identificare ulteriori criteri evidence-based. Il gruppo di lavoro ha valutato con metodologia comparativa e selezionato attraverso un consensus i singoli requisiti. Gli indicatori e i requisiti applicabili al contesto italiano sono dunque stati strutturati in aree tematiche omogenee.

Risultati. La revisione dei manuali delle Regioni italiane e dei sistemi di accreditamento internazionali ha portato all’identificazione rispettivamente di 14 e 19 requisiti principali eterogeneamente impiegati nei diversi sistemi. Ulteriori criteri di provata efficacia sono selezionati attraverso l’analisi della letteratura. La

“consensus conference”, attraverso metodologia comparativa, ha valutato gli standard identificati individuando 20 aree tematiche. È stato quindi prodotto un set di 96 criteri ed indicatori per la prevenzione ed il monitoraggio delle ICA.

Conclusioni. Lo studio evidenzia una notevole eterogeneità nei criteri di accreditamento in uso a livello regionale. L'introduzione di un set di indicatori sintetico ed esaustivo derivante dalla revisione dei criteri nazionali e internazionali può rappresentare uno strumento di autovalutazione nel raggiungimento di requisiti minimi nella prevenzione e controllo delle ICA. Tale strumento può essere utilizzato anche ai fini dell'accREDITAMENTO istituzionale contribuendo a ridurre le disparità regionali.

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