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Abstract

Purpose – The European Union recommendations for patient safety calls for shared clinical risk management (CRM) safety standards able to guide organizations in CRM implementation. The purpose of this paper is to develop a self-evaluation tool to measure healthcare organization performance on CRM and guide improvements over time.

Design/methodology/approach – A multi-step approach was implemented including: a systematic literature review; consensus meetings with an expert panel from eight Italian leader organizations to get to an agreement on the first version; field testing to test instrument feasibility and flexibility; Delphi strategy with a second expert panel for content validation and balanced scoring system development.

Findings – The self-assessment tool – Clinical Assessment of Risk Management: an INtegrated Approach includes seven areas (governance, communication, knowledge and skills, safe environment, care processes, adverse event management, learning from experience) and 52 standards. Each standard is evaluated according to four performance levels: minimum; monitoring; outcomes; and improvement actions, which resulted in a feasible, flexible and valid instrument to be used throughout different organizations.

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Practical implications – This tool allows practitioners to assess their CRM activities compared to minimum levels, monitor performance, benchmarking with other institutions and spreading results to different stakeholders.
Originality/value – The multi-step approach allowed us to identify core minimum CRM levels in a field where no consensus has been reached. Most standards may be easily adopted in other countries.
Keywords Benchmarking, Clinical governance, Patient safety, Risk management, Self-assessment, Clinical risk management
Paper type Research paper

Introduction

Clinical risk management (CRM) is a key clinical governance component, defined by Scally and Donaldson (1998, p. 62) as:

> A system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish.

According to a shift from person to organization CRM responsibility, a failure in patient safety must be approached as a system gap resulting from interacting variables rather than a gap in a single individual performance. Healthcare staff are therefore expected to make patient safety a priority by introducing strategies and measures to identify eventual systems failures before an adverse event (AE) may occur and minimize/control healthcare risks (Øvretveit, 2005). Moreover, making patient safety a priority for healthcare managers is increasingly supported by studies demonstrating that specific safety interventions are cost-effective (Møller *et al.*, 2012) and that quality improvement makes care better for patients and saves money in many situations (Øvretveit, 2009). Systematically implementing a patient safety approach within the organizations is also emphasized by the council of Europe's 2009 recommendations where, in addition to focussing attention on clinical risk and healthcare associated infections issues, European Union (EU) health managers were asked to adopt precise actions for general patient safety. It is estimated that between 8 and 12 percent of EU inpatients are AE victims and member states were asked to make clear their CRM actions and their impact on patient safety by 2012 (The Council of the European Union, 2009).

In Italy, the patient safety theme has been addressed at various levels. At national (macro) level, Ministry of Health staff promoted many initiatives to promote patient safety, raise awareness and train operators and patients on clinical risk and its management. Specific CRM programs and organizational models have been implemented in many regions (meso level). Despite all these efforts, at the organization micro level (hospitals, local health authorities (LHAs)), implementing adequate patient safety programs still suffer from wide variability (Tartaglia *et al.*, 2007).

In this context, minimum required levels that are sustainable and consistent with the evidence and with European, national and regional recommendations (Italian Ministry of Health, 2007; Vincent, 2010; Marx, 2001), may represent the baseline for an effective patient safety approach inside healthcare organizations. At the same time, identifying indicators to measure each healthcare institution's performance on these standards may: allow managers to analyze and monitor their performance over time; promote benchmarking; foster exchanging best practices and also support transparent information flow on system evolution to stakeholders (Merle *et al.*, 2009). Furthermore, standards

measurement and performances evaluation identify the key healthcare quality improvement elements (Institute of Medicine, 2011; Swensen *et al.*, 2010). Our main aim, therefore, was to assemble standards and measurable elements that allow healthcare managers to evaluate CRM performance and guide sustainable safe practice.

Design

The self-evaluation tool was developed by a CRM expert panel coming from eight Italian organizations, followed by a field testing and a validation phase by a second external expert panel (using a Delphi technique). Specifically, the development process followed six steps:

(1) a systematic literature review on CRM evidence and best practices (updated regularly during the project's two-year life);

(2) expert panel evaluation to get an agreement on the instrument's preliminary version (consensus meetings);

(3) two pilot studies to test instrument feasibility and flexibility (field testing);

(4) updating the instrument after field testing (consensus meetings);

(5) a validation phase applying the Delphi process with a second independent expert panel not involved in the development process to finalize the instrument; and

(6) developing a balanced scoring system for minimum required levels.

Literature review and consensus meetings

To ensure the instrument was developed according to the best available evidence, two methods were used and integrated for the preliminary version: a literature review and an expert panel evaluation. A systematic literature review was performed using the following keywords and MeSH terms: risk assessment; quality improvement; risk management; patient safety; performance improvement; frameworks; safety indicators; self-assessment tools and safe practice. CRM, patient safety, quality management and improvement publications, along with international accreditation manuals and self-evaluation tools on specific safety themes (e.g. hand hygiene, infection control) have been included. While the literature review was primarily used for building tool content, two main approaches were considered pivotal for tool development: the French Government's Indicateur Composite des Activités de Lutte contre les Infections (ICALIN) (French Ministry of Health, 2004) and WHO's Hand Hygiene Self-Assessment Framework (World Health Organization, 2010).

The ICALIN framework was used as a model for building the standards progression, translating its original logical sequence, organization-moyens-actions (organization-means-actions), into organizational setup-activity monitoring-outcomes-improvement actions sequence that was developed for each standard. The WHO's framework was used as a model for a self-assessment tool to highlight existing achievements and focus on future plans and challenges, identifying issues requiring improvement. At the same time, experts needed to develop a tool to compare organizations of different sizes and complexity, and suitable for being used as an institutional monitoring tool, overcoming two limitations. Results from the systematic review were elicited and tabulated in a preliminary instrument. Specifically, main

priority areas for a CRM approach were identified together with main key elements (standards) for each area. Experts were then asked to express their opinion on the tool's appropriateness and completeness:

(1) Which are the main priority areas for an effective CRM approach able to create and maintain safe care, reduce AEs and improve human performance?

(2) What are the standards for evaluating such a CRM program?

(3) Which objective measures (indicators) can be implemented to evaluate standards implementation?

The panel met every four months for two years to get an agreement. After each meeting, the instrument was updated. The process was repeated until all standards/indicators were covered and no further improvements were deemed necessary.

Field testing and revision

Two pilot studies were carried out with different purposes. The first was testing indicator feasibility and calibrating minimum levels. The second was testing tool flexibility when applied in different healthcare institutions. Each leader organization recruited two satellite organizations from LHAs, residential care facilities (RCFs) and hospitals, creating two opportunistic samples (12 healthcare institutions each). The first pilot study was carried out in 12 hospitals, where local risk managers and other personnel involved in patient safety or quality management tested the first version. To collect eventual critical issues on item interpretation, clarity, response format and other feasibility issues, feedback was systematically collected during tool administration by two researchers. Field testing results, along with suggestions and advices from risk managers, were discussed by expert panel members and used for tool revision (e.g. item reformulation/explanation). The second pilot study was carried out in 12 other organizations (four LHAs, four RCFs and four hospitals), where the updated tool was tested by local risk managers. Specifically, each standard was translated on a four-point scale (0 – no implementation; 1 – organizational setup; 2 – activity monitoring; 3 – outcomes measurement; 4 – improvement actions) and average scores were calculated for each standard and area with institution type as the analysis unit. Second, testing results were discussed by expert panel members and used to develop the final version. Specifically, standards with the lower scores were reviewed to identify indicators not applicable for some institutions and the tool was modified accordingly. In this phase, having improvement actions implemented for each standard was deemed an unrealistic target and an excessive burden for users; therefore, improvement actions were taken out from single standards and considered relevant at area level.

Validation and scoring system: Delphi technique

To validate the final tool and develop an appropriate scoring system, a second external expert panel, not involved in the development process, was recruited to use the Delphi technique – a structured process designed to collect expert opinions on a specific field (Black *et al.*, 1999; Jones and Hunter, 1995; Philips *et al.*, 2004). For the new panel, 17 national and international experts were enrolled (three medical directors, nine clinical risk managers working in local health units or university hospitals, one healthcare worker specializing in CRM and three patient organization representatives). The project's aim and the methodological features were explained in detail to the reviewers and consensus was collected. Experts were then asked to evaluate the instrument's

relevancy, clarity, appropriateness and representativeness. Content-related construct validity was gathered for the validation process. According to the method, the peer-review process was organized in several rounds and characterized by the following elements:

- Selected reviewers' anonymous and critical contributions. Reviewers did not interact with project members or between each other.
- Preserving reviewer confidentiality and identity.

Panel feedback was managed electronically. Potential issues related to interactions among the reviewers, or between reviewers and project members were avoided. Gaps or shortcomings detected by the panel were systematically collected with proposed practical solutions and revisions to improve the assessment tool's diagnostic sensitivity. After each Delphi round, the tool was updated and independently shown to each panel member for a new peer-review round. When agreement was reached on the final tool, a balanced scoring system was developed for minimum levels. Experts were asked to rank each item's importance/relevance and a minimum level on a ten-point Likert scale. Mean scores were calculated for each standard to identify main priority areas. The weight was defined according to the mean value derived using expert scores. Every section was characterized by summary scores for which an interpretation was provided. Results were used to develop a weighted score attributed to each minimum level. Variables were analyzed descriptively to describe qualitative variable frequency. Means and standard deviations were computed to assess central tendency. Statistical analyses were carried out using Stata 9.0 (StataCorp, Stata Statistical Software Release 9, College Station, TX, USA, 2005).

Findings

Tool – final version

The final self-assessment tool, named Clinical Assessment of Risk Management: an INtegrated Approach (CARMINA), includes 52 standards, distributed in seven areas:

(1) governance, awareness and measurement (seven standards);

(2) communication (five);

(3) knowledge and skills (five);

(4) safe work context and environment (13);

(5) care processes (14 standards);

(6) AE management (four); and

(7) learning from experience (four).

Each standard is evaluated according to objective criteria (indicators) framed as questions with yes/no answers. For each standard, indicators have been selected to reflect CRM implementation levels according to the following aspects:

(1) organizational/functional setup;

(2) activity monitoring;

(3) outcomes; and

(4) improvement actions.

The first level (organizational/functional setup) measures whether the standard is active in the organization. The second level aims to measure whether and how activity is monitored, while the third level evaluates whether outcomes were achieved, systematically collected and spread within the whole organization. Lastly, the fourth level (implementing improvement actions) is considered transversal across the areas 2-5 and it is measured as a separate standard at the end (Figure 1); the remaining areas are not associated with improvement actions as they cover core risk management aspects (area 1) and tools (areas 6 and 7).

The minimum required level (Table I) is set on organizational/functional setup level for every standard and on at least one improvement action for areas. This final version was developed after several drafts elaborated throughout two years.

Results from the first field testing and second expert group evaluation allowed specific content and format improvements. Results from the second field testing are shown in Table II. Mean scores for hospitals (3.38 – SD: 1.17) and LHAs (3.12 – SD: 1.25) are significantly higher ($p < 0.05$) than RCFs (1.63 – SD: 1.64) for most areas and for the total score.

Scoring system

According to the balanced scoring system developed through the Delphi technique, each minimum level's implementation leads to a weighted score. Summing leads to the highest score obtained for each area. Range scores were identified within each area to obtain compliance with the standard from major gaps absent (higher scores), gaps demanding attention (intermediate scores) and major gaps present (lowest scores) (Table III). Moreover, as the tool was designed to be used in a hospital/healthcare institution, some differences on standards implementation between different facilities or single care units (CUs) are expected. To develop a scoring system able to take into account these possible different implementation levels, a diffusion table was included where pertinent.

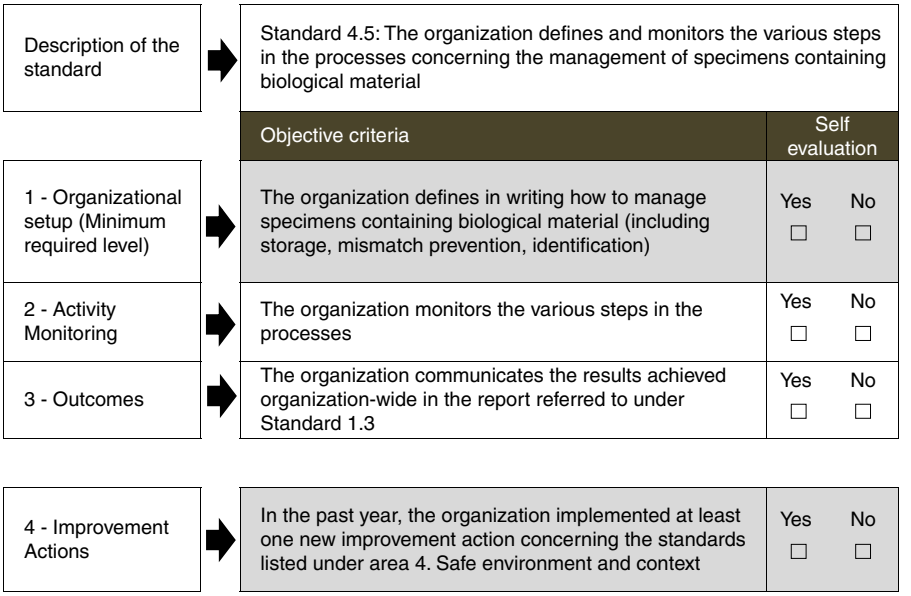

Figure 1.
Standards – structure (example)

Area 1: governance, awareness and measurement	
1.1: organizational strategy	In the organization[a], the clinical risk management strategy is organized as established in a defined, approved document, and all relevant responsibilities are identified
1.2: resources invested	The organization sets yearly clinical risk management goals
1.3: report	The organization draws up and distributes at least one yearly report on the clinical risk management results achieved
1.4: adverse events	The organization uses a defined process to collect adverse/near-miss events reports
1.5: monitoring system	The organization has in place monitoring systems for specific adverse events
1.6: information	The organization has a specific formal document describing how it informs citizens/patients about clinical risks
1.7: benchmarking	In the past two years, the organization adopted defined comparative programs
Area 2: communication	
2.1: communication with healthcare provider	The organization has formally adopted an internal communication system
2.2: communication between healthcare providers at admission/discharge/transfer	The organization has a policy for managing communication concerning admissions/discharges/transfers from the healthcare organization
2.3: communication between healthcare providers during hospitalization	The organization uses an integrated and uniform medical record which accompanies the patient
2.4: safety information to patient	The organization has defined and documented informative material for every care unit (in addition to informed consent) concerning at least one of the most significant patient safety risks
Improvement Area 2	In the past year, the organization implemented at least one new improvement action concerning the standards listed under Area 2: communication
Area 3: knowldege and skills	
3.1: physician's clinical care duties	The organization uses a defined process system to assign job descriptions to its clinical staff and leaders
3.2: other healthcare provider's clinical care duties	The organization has a defined process to assign job descriptions to its healthcare staff
3.3: ongoing training	In the past 12 months, the organization offered training on patient safety-related topics
3.4: training newly employed	The organization has a plan to provide newly employed staff with well-defined training on clinical risk management, within the first year of employment
Improvement Area 3	In the past year, the organization implemented at least one new improvement action concerning the standards listed under Area 3: knowledge and skills

Table I.
Minimum required levels

(*continued*)

Area 4: safe environment and context	
4.1: integration of functions	The organization has a defined model to integrate different hospital functions
4.2: non-compliance in maintenance plans	At least once a year, the organization checks all non-conformities resulting from the ordinary/extraordinary maintenance activities performed in the facilities, utilities and equipment
4.3: medications pathway	The organization defines in writing how to obtain, store, prepare and dispense medications
4.4: medical devices pathway	The organization defines in writing how to obtain (and perform risk analyses on) medical equipment
4.5: biological specimen pathway	The organization defines in writing how to manage specimens containing biological material (including storage, mismatch prevention, identification)
4.6: food pathway	The organization defines in writing the food management processes
4.7: sterilization pathway	The organization defines in writing the sterilization processes
4.8: waste pathway	The organization defines in writing the waste management process
4.9: transportation safety	The organization defines in writing how patients are to be transported inside the organization (and to/from other external organizations) and provides written instructions concerning the safety standards for such patients
4.10: structural internal emergencies	The organization has plans instructing on how to deal with internal structural emergency situations
4.11: external maxi-emergencies	The organization has plans instructing on how to deal with major external emergencies
4.12: recall procedures	The organization adopts procedures to recall products, medications, and medical devices, according to a defined schedule and involving both health practitioners and patients
Improvement Area 4	In the past year, the organization implemented at least one new improvement action concerning the standards listed under Area 4: safe environment and context
Area 5: care processes	
5.1: double identifier	The organization has a procedure requiring the use of two identifiers for all patients receiving care, treatment, or other procedures
5.2: read-back	The organization has a procedure to check if the order or report made by the sender was understood by the receiver
5.3: management of falls	The organization has a procedure on how to manage the risk of patient falls (including the use of a risk assessment scale)
5.4: decubitus ulcers	The organization has a procedure that is shared by all the care providers concerned, to manage the risk of decubitus ulcers (including the use of a risk assessment scale)
5.5: hand hygiene	The organization has a procedure on hand hygiene that is based on the WHO hand hygiene guidelines

(*continued*)

Table I.

5.6: standard/isolation precautions	The organization has a procedure on the isolation of patients with infective diseases
5.7: healthcare-associated infections	The organization has a procedure (shared by the HAICC[b] and the operative group) on the prevention, surveillance and control of healthcare-associated infections
5.8: pain management	The organization has a procedure on pain management (which includes adopting an assessment scale, performing an initial assessment and re-assessing pain periodically)
5.9: internal care-related emergencies	The organization has a procedure on internal healthcare emergencies
5.10: safety in the operating theater	The organization has a procedure on operating theater safety, and such procedure is based on the goals set forth in the *Ministerial Guidebook*
5.11: clinical-care pathways	The organization has in place 1-3 care pathways (with defined schedules, persons involved, and responsibilities)
5.12: maternal and newborn pathway	The organization defines in writing the pregnancy and childbirth clinical pathways, based on the estimated risk
5.13: ministerial recommendations	The organization applies the ministerial recommendations on patient safety
Improvement Area 5	In the past year, the organization implemented at least one new improvement action concerning the standards listed under Area 5: care processes
Area 6: adverse event management	
6.1: immediate and medium-term management of adverse events	The organization adopts defined methods to manage immediate and medium-term operational issues after the occurrence of an adverse or near miss event
6.2: communication with patients, family or relatives, media, and internal	The organization adopts a defined communication method to manage the adverse event *vis-à-vis* patients and family members
6.3: communication with institutions and/or associations	The organization adopts a defined method to support/assist staff involved in the adverse event, in the appropriate setting and in a non-punitive atmosphere
6.4: support/assistance to healthcare providers	The organization adopts a defined method to support/assist patient/family members involved in the adverse event
Area 7: learning from experience	
7.1: RCA	In the past year the organization conducted at least 1 response analysis using consolidated techniques to investigate adverse and near miss events
7.2: HFMEA/FMEA/FMECA	In the past two years, the organization conducted at least 1 proactive analysis using the HFMEA/FMEA/FMECA technique
7.3: safety culture	In the past three years, the organization conducted at least one survey (qualitative/quantitative/semi-quantitative) on the culture of safety among healthcare workers
7.4: peer assessment	In the past year, the organization carried out from 1 to 3 safety-oriented peer assessment activities

Notes: [a]The term organization refers to organization's legal representative; [b]healthcare associated infection control committee

Table I.

This table (Figure 2) works as a score modifier: full score when > 75 percent of CU staff implement the standard, three quarters when the percentage is between 50 and 75, half the score for a percentage between 50 and 25 percent and finally a quarter when the standard was implemented in less than 25 percent of the units.

A total score for the whole questionnaire was than developed. However, to calculate the total score, institutions need to reach the highest score range (major gaps absent) in each area. Whether in one or more areas, the score indicates gaps needing further improvements or major gaps, institution managers are encouraged to work on these gaps before getting to a comprehensive self-evaluation. Once major gaps are excluded for each area (minimum required levels implemented), the final total score can be calculated. Total score divided into three range scores from minimum required levels achieved (maximum total score achieved, total score = 877, space for further improvements (total score between 780 and 876) and major gaps absent, improvement needed (total score < 780).

Practical implications

Tool development method

The multi-step study design (literature review, consensus meeting, field testing and Delphi technique) was developed to gain higher content validity in a field suffering from no widely accepted and reliable assessment tools. The literature review offered the opportunity to start tool development from best evidence, whereas involving healthcare professionals at different levels (first round experts, feedback from healthcare professionals testing the instrument in their organizations and second round external experts panel) allowed us to integrate several viewpoints and experiences. This strategy allowed us to collect all relevant information from all existing sources and systematically organize them in a feasible and reliable instrument. Using a second expert panel (not involved in the developmental process) allowed us to ensure that all additional necessary improvements are taken into account, which helped to further refine the instrument after stakeholder contributions. Moreover, the Delphi technique avoided face-to-face interactions, overcoming limitations related to group discussions (personal conflicts, hierarchy issues limitation free opinion exchange, leadership influence) while preserving groups interactions advantages (experience and knowledge exchange, creative synthesis, integration, etc.). These characteristics makes Delphi a reliable strategy for content validation when there is no gold standard. The scoring system for minimum required levels was balanced according to main priorities areas (based on expert opinion) and to standards implementation within the organization. Total scores for area and whole assessment allow us to get a rapid and clear picture on CRM implementation. Synthetic scoring ranges represent verification and comparison within the organization or with other organizations; the final goal is promoting a gradual improvement, action list and programs.

	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Total
Hospitals	3.64 (1.21)	4.00 (0.00)	3.00 (1.41)	3.38 (1.01)	3.54 (0.90)	2.40 (1.72)	3.38 (1.41)	3.38 (1.17)
LHA	3.57 (1.16)	3.75 (0.58)	3.19 (1.11)	3.25 (0.98)	2.88 (1.40)	2.80 (1.20)	2.56 (1.82)	3.12 (1.25)
RCF	0.73 (1.42)	3.38 (1.19)	2.25 (1.75)	1.86 (1.55)	1.91 (1.51)	0.40 (1.01)	0.50 (1.41)	1.63 (1.64)
Total	2.89 (1.73)	3.72 (0.73)	2.91 (1.38)	2.95 (1.25)	2.82 (1.42)	2.03 (1.60)	2.25 (1.92)	2.82 (1.49)
p-value	< 0.05	0.329	0.420	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05

Notes: 0 = standard not implemented; 1 = setup; 2 = monitoring; 3 = outcomes; 4 = improvement

Table II. Compliance during second field testing ($n = 12$): mean scores (SD)

Standard	Average ± SD	Score
Area 1: governance, awareness and measurement		
1.1: organizational strategy	9.5 ± 0.9	19
1.2: resources invested	8.9 ± 1.4	18
1.3: report	8.5 ± 1.3	17
1.4: adverse events	8.8 ± 1.4	18
1.5: monitoring system	8.6 ± 1.2	17
1.6: information	7.3 ± 2.1	15
1.7: benchmarking	7.6 ± 2.0	15
Maximum score		119
Absence of major gaps		> 104
Presence of gaps demanding attention		89-104
Presence of major gaps		< 89
Area 2: communication		
2.1: communication with healthcare provider	8.5 ± 1.5	17
2.2: communication between healthcare providers at admission/ discharge /transfer	8.1 ± 1.8	16
2.3: communication between healthcare providers during hospitalization	9.1 ± 1.2	18
2.4: safety information to patient	8.3 ± 1.8	17
Improvement actions Area 2	8.0 ± 1.5	16
Maximum score		84
Absence of major gaps		> 69
Presence of gaps demanding attention		54-69
Presence of major gaps		< 54
Area 3: knowledge and skills		
3.1: physician's clinical care duties	7.2 ± 2.3	14
3.2: other healthcare provider's clinical care duties	7.8 ± 1.8	16
3.3: ongoing training	9.3 ± 1.3	19
3.4: training newly employed	8.7 ± 1.5	17
Improvement actions Area 3	7.5 ± 2.0	15
Maximum score		81
Absence of major gaps		> 66
Presence of gaps demanding attention		51-66
Presence of major gaps		< 51
Area 4: safe environment and context		
4.1: integration of functions	8.2 ± 2.1	16
4.2: non-compliance in maintenance plans	8.2 ± 1.5	16
4.3: medications pathway	8.5 ± 1.3	17
4.4: medical devices pathway	8.1 ± 1.6	16
4.5: biological specimen pathway	8.5 ± 1.7	17
4.6: food pathway	8.0 ± 1.8	16
4.7: sterilization pathway	9.2 ± 1.1	18
4.8: waste pathway	8.2 ± 2.0	16
4.9: transportation safety	7.8 ± 1.5	16
4.10: structural internal emergencies	8.3 ± 1.7	17
4.11: external maxi-emergencies	8.3 ± 2.0	17
4.12: recall procedures	8.4 ± 1.8	17
Improvement actions Area 4	7.8 ± 1.8	16
Maximum score		215
Absence of major gaps		> 200
Presence of gaps demanding attention		185-200
Presence of major gaps		< 185

Table III.
Weighted scores developed using the Delphi technique

(*continued*)

Standard	Average ± SD	Score
Area 5: care processes		
5.1: double identifier	9.0 ± 1.4	18
5.2: read-back	7.9 ± 2.1	16
5.3: management of falls	9.2 ± 1.3	18
5.4: decubitus ulcers	9.2 ± 1.1	18
5.5: hand hygiene	9.0 ± 1.1	18
5.6: standard/isolation precautions	8.7 ± 1.5	17
5.7: healthcare-associated infections	9.3 ± 1.3	19
5.8: pain management	8.9 ± 1.1	18
5.9: internal care-related emergencies	9.0 ± 1.2	18
5.10: safety in the operating theater	9.7 ± 0.6	19
5.11: clinical-care pathways	8.2 ± 1.0	16
5.12: maternal and newborn pathway	8.6 ± 1.3	17
5.13: ministerial recommendations	9.1 ± 1.4	18
Improvement actions Area 5	8.3 ± 2.1	17
Maximum score		247
Absence of major gaps		> 232
Presence of gaps demanding attention		217-232
Presence of major gaps		< 217
Area 6: adverse events management		
6.1: immediate and medium-term management of adverse events	8.8 ± 1.7	18
6.2: communication with patients, family or relatives, media, and internal	8.5 ± 1.5	17
6.3: communication with institutions and/or associations	8.4 ± 1.5	17
6.4: support/assistance to healthcare providers	8.5 ± 1.3	17
Maximum score		69
Absence of major gaps		> 54
Presence of gaps demanding attention		39-54
Presence of major gaps		< 39
Area 7: learning from experience		
7.1: RCA	8.2 ± 2.1	16
7.2: HFMEA/FMEA/FMECA	7.5 ± 2.1	15
7.3: safety culture	7.7 ± 1.8	15
7.4: peer assessment	8.2 ± 1.7	16
Maximum score		62
Absence of major gaps		> 47
Presence of gaps demanding attention		32-47
Presence of major gaps		< 32
Total score		
Minimum required level achieved		877
Space for further improvement		780-876
Absence of major gaps, improvement needed		< 780

Table III.

CARE UNITS (CUs)	
>75% of CUs meet the standard	☐
51 to 75% of CUs meet the standard	☐
25 to 50% of CUs meet the standard	☐
<25% of CUs meet the standard	☐

Figure 2.
Diffusion

Tool benefits

CARMINA can be useful at three levels:

(1) As it was conceived as a standards system, CARMINA can be used as a CRM monitoring instrument at national level, allowing the government to know where minimum levels were achieved – a starting point for reducing unevenness among healthcare organizations (directly at micro level) and also a possibility for a more persuasive strategy for CRM implementation through mandatory minimum level achievement.

(2) As a benchmark system, CARMINA makes staff compare orgiansiations, helping them to recognize strengths and weaknesses, and highlighting areas where interventions are more urgent. Comparing performance in similar institutions can also to identify and share good practices.

(3) As an improvement tool, using the questionnaire regularly helps managers track actions and progresses, helping to address efforts on weaker areas.

The tool has been developed for maximum flexibility and the second pilot study results are encouraging in that sense. Different realities (hospitals, LHAs, RCFs) are reflected in the results: hospitals and LHAs are almost at the improvement stage (4th level), while RCFs are between setup and monitoring (first and second level). Taking a careful look at area scores, the differences between three institutions are emphasized: RCFs are particularly underdeveloped in areas 1, 6 and 7 (governance, AEs management and learning from experience) where they struggle to reach the setup stage, while LHAs are behind the hospitals in areas 5 and 7 (care processes and learning from experience) where they fail to reach the outcome stage. These scoring differences among three organization types reflect the highest maturity level CRM reached in more complex institutions like hospitals, while RCFs underdevelopment in areas 1 (including resources invested, monitoring system and benchmarking strategies) and 7 (including event analysis and peer assessments) is not unexpected as these areas reflect a more awareness and CRM involvement.

Limitations

The self-evaluation tool's main limitation is subjectivity; even if the single standards are formulated clearly, there is room for interpretation or simply for different perceptions. Also, as the questionnaire covers several structural and organizational areas, more than one person can be involved (introducing even more subjectivity) or, if not, the single compiler may not correctly perceive how every single thing works inside the organization. Lastly, filling in a questionnaire (52 articulated standards) can be time consuming, especially if discussion with other staff members is needed for some standards.

Conclusions and recommendations

The European Commission report on implementing council patient safety recommendations, published in November 2012 (European Commission, 2012), highlighted priorities areas on which future work should focus raising the need to introduce, beyond the recommendations, clear and shared safety standards, considered also an indispensable condition for EU citizens as mobile patients (European Union, 2011). Adopting CARMINA in healthcare organizations can be useful for fulfilling these requirements as a starting point for achieving minimum CRM levels and as a benchmarking tool. At the same time, healthcare CRM is generally evaluated as a

broader approach based on quality assessment and verified through accreditation processes. An inadequate CRM program (e.g. either safety indicators are not implemented or do not reach acceptable levels) plays a fundamental role the entire organization assessment (Accreditation Canada, 2013; Joint Commission International, 2013), making CARMINA helpful as an instrument for monitoring improvement on recognized standards over time. As CARMINA was conceived as a monitoring instrument, it needs to be regularly updated and expanded over time. First, a scoring system upgrade to include all the objective criteria is needed: the Delphi weighted score assigned for minimum levels will represent each standard's half score, while the other half sums the remaining objective criteria. Second, as CRM is a fast evolving field, the tool needs to be kept fresh with emerging issues and policy initiatives. Third, as the risks inherent in using a self-reported evaluation tool for institutional monitoring are obvious, adding a proof mechanism (e.g. protocols, reports and improvement actions documentation) has been contemplated as the tool's first upgrade. Fourth, the tool was inspired by European recommendations that call for common safety standards across the union, but was developed for Italian healthcare services (with some standards strictly connected to Italian ministerial initiatives). Nevertheless, its core can easily be expanded and adapted for other countries. Finally, the tools need to be tested for reliability (e.g. Cronbach's α, test-retest study).

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