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Article

Between saying and doing there is the health organization. How the health organization changes following the occurrence of sentinel events: a qualitative study within the South Tyrolean Health Organization

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Abstract

Background: The clinical risk in Italy is oriented to detect the technical aspects of risk management: how many reports of undesirable events are received in the company, what kind of events are most reported, the outcomes for patients and the organizational improvement measures identified for risk reduction. Aim of the authors is to analyze the process of management of sentinel events within the South Tyrolean Health Authority, to understand what happens in the health organization after the identification of the improvement measures, what kind of factors and strategies hinder organizational change or make its implementation effective.

Methods: 18 semi-structured interviews were conducted: 3 to head physicians, 5 to nursing coordinators, 4 to quality referents, 3 nursing managers, 3 to clinical directors. The following dimensions were investigated: the attitude towards risk, the communication of errors, the process of managing sentinel events, the perception of analysis meetings, the factors that hinder or favor the implementation of corrective actions, strengths and weaknesses of the risk management system.

Results: Timeliness and simplicity of the analysis tool are considered relevant for taking charge of the emotional aspects and for the greater involvement of collaborators in the process of managing sentinel events. The use of a simplified tool is considered functional, intuitive even for proactive risk analyzes. The authority of the leadership is considered relevant for the purposes of

organizational change. Organizational change occurs if the staff is motivated and perceives the improvement measures as useful.
Conclusions: Directing and leading people towards common goals does not only require that they are officially shared at different levels: social actors have primarily individual needs that they try to satisfy. To combat errors in clinical practice it is crucial to take the new perspective of the social nature of the decision-making process and of the organizational change.

Keywords: Sentinel events, organizational improvement, organizational change, organizational strategies, leadership, management, analysis meeting, exemplified tools, root cause analysis, health organization.

Introduction

Organizational change is something well established, inevitable, and although this is a certainty for most managers, there are still many questions about what factors contribute to the success of change processes (1),(2). The pressure to change is usually triggered by phenomena external to the organization, such as the globalization process, the development of new technologies, the economic crisis, etc. (3). However, internal elements within the organization also play a role. Elements within the organization can also generate change and, in order to be successful, organizations have to make considerable efforts to understand how the necessary changes are actually to be implemented (4)(5).
The various theories of organization that have followed one another over the years have all shown that change occurs following a sequence of phases (different sequences depending on the theories of reference) and according to customized mechanisms. However, its success is conditional on the existence of drivers that generate it. On the other hand, it fails when the interventions initiated by organizations are based on the choice of inappropriate drivers with respect to the goal to be achieved (6).

Although managers strive to identify changes that are capable of achieving improved performance and results, more than 75% of initiatives fail because the organization is not really ready and because few people actually support the change (7). When managers decide on strategies, they assume that their vision will be shared by the whole organization; actually, professionals often resist and do not support change processes, also because they are often not consulted and involved from the early planning stages (8).
According to Smith (9), the key factors for successful change are:

- creating a sense of meaning, need and urgency that justifies the need.
- Communicating the message of change widely, ensuring participation and involvement in the process at all levels.
- Provide anchor points and a basis for achieving the desired change.

Essentially numerous factors can contribute to the success of organizational change, and for changes that require large-scale implementation, specific steps need to be followed: recognition, planning and, of course, the actual implementation of the change (10), i.e. the implementation of all the necessary interventions to pursue the desired changes.

Depending on the nature of the change to be implemented, interactions between the intervention, its implementation and the setting in each context may occur at different levels (11):

- At a macro level: e.g. with reference to policies or regulations within the health system or national legislation.
- At meso level: e.g. following the introduction of new clinical care guidelines at hospital level.
- At micro level: e.g. through the promotion of preventive health behaviors for individuals or the community.

Interventions aimed at change generally require that their implementation takes place simultaneously within the different levels.

1. Regardless of the type of intervention that needs to be implemented, the context and the way in which a change is implemented can materialize or be compromised by other interventions that occur independently. For example, a health organization that promotes vaccinations on its territory (meso level), may find reinforcement and follow up in the population through a national campaign on the risks school children run if they do not get vaccinated (macro level). This shows how different interventions can influence the extent and effectiveness of change within a specific context.
2. In an organization there are certain factors that constitute obstacles or inhibit organizational change (12). This occurs when the goal is unclear, when the incentives designed for change are not linked to the effort needed to make it happen (2). Thus, change can lead to fear of failure, is often imposed by coercion, requires commitment, and commitment is deemed necessary for professionals who feel that they do not have sufficient resources to make it happen (7). As far as the choice of methods and techniques for its implementation is concerned, it would be advisable that imposed actions by the management should be reduced to a minimum, preferring instead communication, involvement, motivation, in order to encourage greater participation and motivation to change by those who can effectively contribute to achieving it (13).

The clinical risk in Italy is an area constituted and managed purely by technical health professionals (physicians, nurses, physiotherapists, etc.), who tend to be oriented to detect mainly the aspects defined as "more technical" of risk management, that is, how many reports of undesirable events are received in the company, what events are most reported, what outcomes they involve for patients, what organizational improvement measures are identified for risk reduction and how many of these are actually implemented with respect to those defined.

The aim of the authors, through the qualitative research carried out and described below, is to analyze the process of management of sentinel events within the South Tyrolean Health

Authority, in order to understand what happens in the health organization after the identification of the improvement measures defined in the analysis, that is, to understand which factors hinder organizational change and which strategies make its implementation effective, starting from the process of reporting these events.

In order to do this, the study aims to find answers to the following research questions:

- What are the perceptions of healthcare professionals regarding error reporting in clinical care practice?
- What are the organizational dynamics that are activated at the moment of reporting?
- How are perceived the analysis meetings, the tools used, the people involved during these events?
- Why don't people do what they say? In other words, what are the factors that hinder or slow down the implementation of the improvement measures considered necessary for organizational change? Which ones are able to foster improvement?

The empirical context

Sentinel events (SE) at the South Tyrolean Health Authority are managed according to a company procedure that has been in force since 2010 (14). The management process consists of five macro-phases:

1. Identification of an undesirable event.
2. Reporting of the sentinel event (SE).
3. Analysis of the SE and identification of corrective actions.
4. Validation of the information and sending it to the Ministry of Health.
5. Implementation and monitoring of corrective actions.

Meetings for the analysis of sentinel events are conducted using the RCA tool (Root Cause Analysis), according to a simplified mode compared to the original tool (15). It takes place in a limited time span of two hours, at the presence of the heads of the reporting departments (nursing coordinators and structure directors) and their respective managers, with the desired participation also of the staff members who were present during the occurrence of the event.

The decision to adopt a simplified, but nevertheless structured, instrument of analysis originated from the doubt that an excessive duration of the meetings could represent one of the causes of a possible reluctance towards the reports and make the process of managing the sentinel events be perceived as too onerous compared to what the professionals would actually be willing to invest in this activity. At the same time, it is believed that accurate organizational causes and appropriate, specific and effective improvement measures can be identified in a short space of time, without necessarily sacrificing the accuracy of the analysis.

The analysis process using the RCA tool consists of three steps:

1. The chronological description of the dynamics of the event (the timeline).
2. The identification of the organizational root causes that may have contributed to the occurrence of the event.

3. The identification of organizational improvement measures, the implementation of which will reduce the risk of similar events occurring in the future or contain the outcomes for patients and/or staff.

At the end of each analysis meeting, the Clinical Risk Centre (CRC) of the South Tyrolean Health Authority asks the participants to fill in a satisfaction questionnaire about the RCA carried out.

The questionnaire consists of 6 items, in the form of statements, for each of which the participants must express a degree of agreement (1: disagree at all - 5: absolutely agree). The items are as follows:

1. The planned time frame for the analysis of the event was respected.
2. The analysis method used is a useful tool for identifying the root causes of an event.
3. The identified corrective measures have been shared by the (analysis) team.
4. The working climate established was positive.
5. It is useful to have a multi-professional composition of the team for the analysis of the event.

In 2018, the baseline year of this research work, 18 sentinel events were reported, all of these were analyzed using the RCA tool. The satisfaction ratings of all analysis meetings conducted in the baseline year are summarized in **Figure 1.**

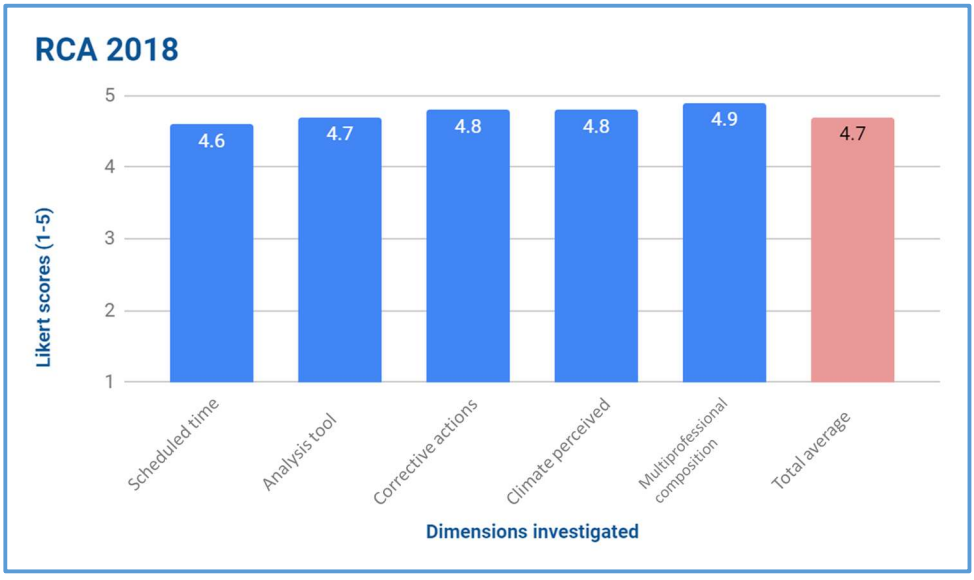

Fig. 1: Histogram representing the total satisfaction of the RCAs carried out in 2018 and of the individual dimensions investigated, at the level of the South Tyrolean Health Authority.

From the histogram it can be seen that the analysis meetings were on average very appreciated (4.7). The first item, which refers to the respect of the scheduled time for the analysis meeting, refers only to the extent to which the agreed time of two hours for the analysis was actually respected or not, but it is not possible to deduce from this whether the professionals believe that it is sufficient or not for an effective analysis.

With respect to the second item, asking participants whether the analysis tool used is considered effective in identifying the root causes of events does not really provide an opinion on how the three different moments that make up a RCA are perceived, to which they would devote more or less space and possibly why.

Asking participants whether corrective measures were actually shared by the whole analysis team before being officially defined is important to detect the degree of involvement perceived by employees, but this does not allow to understand whether the element of sharing is also a factor favoring the subsequent and effective implementation of the agreed improvement actions.

Similarly, the dimensions of the climate perceived during the meetings, as well as the multi-professional composition of the analysis team, are relevant aspects for the success of the meetings, but without further information it is not possible to correlate them to a greater or lesser effectiveness of the subsequent process of change desired.

All the aspects just described therefore required further investigation through a qualitative survey.

As a result of the analysis meetings, a total of 31 corrective actions were identified in 2018 by the departments of the healthcare company. As can be seen **from Figure 2**, out of the total number of measures identified, based on the analysis of the reports requested by the Health Authority to the management of the healthcare company, 7 actions were not implemented (22.6%), 9 were partially implemented (29%) and 15 were actually implemented (48.4%). According to the reports, the reasons for the lack of implementation or partial implementation are mainly due to structural changes, which require the involvement of technical departments or the adoption of tools that are not immediately available, or to organizational problems that need to be managed by the directorates/managers, because they involve several operational units.

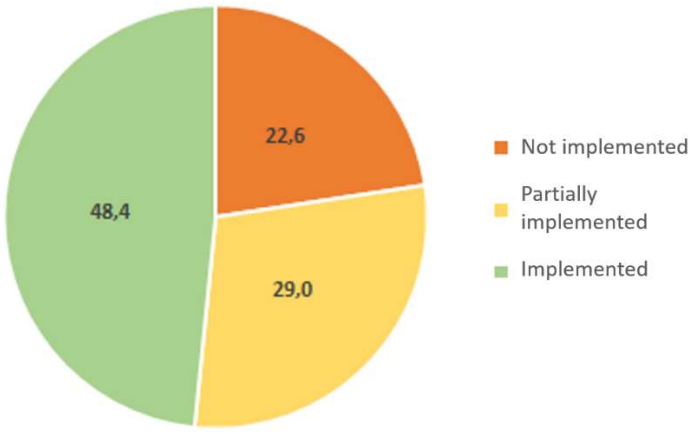

Fig. 2: Percentage (%) of corrective actions implemented, out of the total of those identified following the analysis of sentinel events reported in 201

Also the aspect of implementation required further investigation through a qualitative survey, in order to detect which are the difficulties perceived by the professionals at various levels, including the management, and which are the strengths, the strategies that have proved to be particularly effective for the implementation of the actions that were actually carried out.

Research hypothesis

On the basis of the empirical experience developed in the field of clinical risk management by the Clinical Risk Centre of the Autonomous Province of Bolzano, as well as of what emerged from the literature analysis, the research hypotheses described below were developed.

1. The timeliness and simplicity of the analysis tools used favor the implementation of the improvement measures identified in the analysis.
2. The use of a simplified tool makes it possible to arrive at effective solutions in a limited time. At the same time the measures are also shared by the employees.
3. Decisive for the change is not so much the type of instrument used, but rather the characteristics and functionality of the tool adopted.
4. The degree of implementation of improvement actions is proportional to the degree of complexity of the corrective actions identified during the analysis: it is more likely that they will be effectively implemented if their implementation involves a single organizational unit, rather than involving several operational units/multiple districts or the entire health company.
5. The degree of implementation of the improvement actions is also proportional to the degree of severity of the sentinel events that have occurred: the more an event has serious effects on patients and / or healthcare employees, the more it will constitute an input that instills in the organization the need or urgency for change.
6. The implementation of improvement actions is favored by the way and degree to which staff are involved in all phases of the sentinel event management process. The degree of understanding and participation of employees is decisive for change: the more they are involved from the very beginning of the change process, the more likely it is that the change will actually take place.

Table 1: Summary of the results that emerged from the qualitative study in relation to the research hypotheses and the literature.

Literature	N.	Research hypothesis	Outcomes of the study
The success of change is conditioned by the existence of engines that generate it; it fails when organizations choose engines that are inappropriate to the end they intend to achieve. 75% of change initiatives fail because the organization itself is not ready to change and because the number of collaborators willing to follow the change is small. Professionals are often resistant to change because management often determines the strategies to be adopted without consulting and involving its staff from the earliest planning stages. Among the key factors for successful change there are: the creation of a sense, a need, an urgency that justifies the need for change. Widespread communication of the change, to ensure participation and involvement of all levels of the organization.	1	Timeliness and simplicity of the analysis tools used favor the implementation of improvement measures.	Assumption refuted. Timeliness allows not to lose the emotionality of the people involved. Simplicity favors the understanding and involvement of the employees.
	2	The use of a simplified tool still allows effective solutions to be reached and shared by employees.	Assumption confirmed The RCA tool can be used for proactive analysis too
	3	The key to the change is not the type of tool used but its functionality.	Assumption confirmed The change is favored by the use of authoritative and institutionalized tools such as requests for sending reports and the institutional accreditation.
	4	The degree of implementation of the improvement actions is proportional to their degree of complexity.	Assumption partially confirmed The complexity of the measures is not the only variable responsible for the effectiveness of implementation. Corrective actions of a structural nature and which involve several operating units are more difficult to implement. Leadership has the ability to foster or hinder the change.
	5	The degree of implementation of improvement actions is proportional to the degree of severity of the sentinel events occurred.	Assumption partially confirmed An emotional shock can act as a stimulus for change. Change is accepted and pursued by employees if it contributes to the improvement of everyday life and working conditions.
	6	The key variables for change are the understanding and the involvement of employees from the earliest planning stages.	Assumption refuted. Change occurs if it is perceived as useful, necessary and not excessively complex to achieve. It is important that in every organizational reality there is a type of leadership that is similar to the related context.

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Methods

For the conduction of this research, the instrument of semi-structured interviews was used, due to the need to explore specific dimensions, as well as to allow the interviewees as much space as possible to be able to express themselves freely, in a fluid way, through the narration of their own experiences. The interviews were conducted ensuring the anonymity of all interviewees. Conducting the survey acted as a consensus for participation in the study. From the contents of the study it is not possible to trace sensitive data concerning patients and it is not even possible to associate the contents that emerged with the individual professionals who took part in the interviews.

The research was conducted for sentinel events that were reported and analyzed in 2018, in the 4 health districts of the South Tyrolean Health Company (Bolzano, Merano, Bressanone and Brunico).

The choice was motivated by the fact that the verification of the state of implementation of the improvement measures, identified during the analysis meetings of the events managed, was carried out by the Healthcare Authority of the Autonomous Province of Bolzano only starting from that year, which, through the Clinical Risk Centre (CRC) has requested a report from the management of the health company.

The production of these reports (one for each health district) was subject to the achievement of the BSC (Balance Score Card) objectives for the year 2019.

As all the reports had to be received by 30.09.2019, the interviews were conducted following the analysis of the information obtained from the monitoring on the state of implementation of the improvement actions. This made it possible to carry out the interviews in a more targeted way, as it was possible to have the following information in advance:

- the number of actions actually implemented, compared to the total number of actions identified, for the sentinel events processed in 2018.
- The reasons for their partial or non-implementation declared in the report.
- Any additional measures planned for the effectiveness of the corrective measures identified.

With regard to the definition of the unit of analysis, the authors were not able to include in the interviews the healthcare workers who participated in the analysis events, because the company procedure for the management of sentinel events provides that these meetings are necessarily attended by the managers (structure directors/head physicians and nursing coordinators) of the departments/operating units reporting. The presence of the collaborators is not binding and, in addition to this, their anonymity must always be guaranteed, also through the impossibility of tracing back ex post the names of the participating collaborators. Head physicians and nursing coordinators, on the other hand, are officially responsible for reporting and their names are indicated in the reporting form.

The unit of analysis initially identified for the administration of the semi-structured interviews consisted of 5 quality referents, 5 head physicians, 5 nursing coordinators, 4 medical directors, 4 nursing managers, for a total of 23 interviews.

Following the availability agreed and communicated, a total of 18 interviews were conducted: 4 quality referents (of the districts and of the health company), 3 head physicians, 5 nursing coordinators, 3 medical directors, 3 nursing managers.

The dimensions explored through the semi-structured interviews were the following:

- The attitude towards risk during daily work (there is a tendency to blame those who make the mistake or errors are reflected in the team).
- Error communication: if and how errors are communicated within the operational reality.
- Risk management: whether or not a well-defined and standardized procedure for error management is followed within the units of analysis studied.
- The analysis meeting: how the setting is perceived, the ways in which health professionals are involved and the tools used.
- The implementation of corrective actions: how effective the identified improvement measures were in reducing the risk and how much and how their implementation was organizationally favored or hindered.
- The strengths and weaknesses of the company risk management system and proposals for its improvement.

Results

The incident reporting process

With respect to the dimension of the process of reporting sentinel events, the research found that the structure directors believe that their direct collaborators, but also the nurses, would not be reluctant to report undesired events that occur in the clinical-assistance practice. The more complex and articulated an organization is, the more it tends to follow the process of managing SE according to the company procedure. In less complex organizations, however, structure directors are more likely to use the preferred channel of their medical directorate, which acts as a filter and decides whether or not to initiate the reporting process.

A possible obstacle to reporting is the time factor, i.e. the awareness that time is needed to analyze the reported events at a later stage would be the reason for not reporting, despite the fact that the CRC handles the analysis process in a simplified and resource-poor manner.

A possible obstacle to reporting is identified in the time factor: the awareness of having subsequently to dedicate a time space for the analysis of the reported events would be the reason to avoid the reporting, despite the fact that the Clinical Risk Center manages the analysis process in a simplified way, which involves a limited waste of resources.

Nursing coordinators, on the other hand, argue that nurses are more likely to report errors; where there are difficulties in reporting, these should be sought more in physicians. This would be attributable to different aspects:

- nurses experience the possible fallout of errors caused by organizational problems on a daily basis, "*on their own skin*", and therefore are encouraged to report and discuss them together within the team in order to find useful solutions for their daily work;
- physicians experience reporting not only as an increase in workload, but also as a factor that could "*put their professionalism in a bad light*", which is why they are inclined to solve problems within their own departments and, if necessary, to discuss them only among their colleagues.

A lack of dissemination of the error and the no-blame culture within the operational units is attributable not so much to the individual predisposition and/or seniority of the employees, but rather to the leadership of the departments, even if the weight of the head physicians is perceived as more incisive than that of the nursing coordinators.

According to what was expressed by the interviewed quality offices, there are realities more likely than others to report (for example the psychiatric field) and on some occasions the medical directorate has played a decisive role in stimulating the reporting of adverse events of which it had become aware. The involvement of management is not in itself perceived as an incentive to report, nor as a filter, but rather would have the merit of keeping it informed about what is happening within its own organizational reality.

The participation of health professionals in the analysis meetings is managed differently, not only by the single health district of the company, but also by the individual predisposition of each quality referent with respect to the willingness to act as an intermediary for this aspect: there are quality referents who decide to take care of the participation of employees in the analysis meetings and actively drive the departments throughout the process of managing sentinel events, others who instead consider this activity as parallel, as they are unable or unwilling to follow it directly, for reasons of time, or because it is not perceived as an activity of their competence. This therefore reveals a lack of organizational homogeneity among the various quality offices of the healthcare company (but also within them).

A different organizational configuration is also to be found among the various medical directorates. In some cases they are activated at the request of the departments, which inform them of the adverse events that have occurred, and only later are the relative quality offices involved in the continuation of the reporting process, but the possibility of reporting or not is left to the single operating units, without the directorates applying any kind of pressure in this sense. In other cases, however, the medical directorates play an active role: they have personalized the reporting procedure, foreseeing their own direct involvement for each serious adverse event that has occurred and arranging a meeting between the departments, the medical directorate, the nursing management and the quality office, in order to examine each case and to decide in a structured way whether or not to continue with the process of reporting to the Clinical Risk Center of the Healthcare Authority.

As regards the perception that the various professional roles reported during the interviews, with respect to the participation in the analysis meetings by the professionals, they all said that the collaborators have always participated willingly in the meetings, without any kind of fears or

apprehension, with the exception of the first analysis experiences, in which the professionals did not yet know what the outcomes and the possible consequences of such meetings would be. On the other hand, only some medical directors reported that the fear of reporting would still seem quite widespread for fear of being pointed out or being involved in judicial channels. This would be the reason that would be the background to the choice of some medical directorates not to push the departments to report, if they don't want to provide on their own initiative.

Analysis meetings

The dimension of the analysis meetings investigated allowed to focus the attention on several peculiar aspects of these meetings, summarized below.

The analysis setting

The analysis setting is positively perceived by all the professional roles interviewed. Some consider it an insignificant factor for the effectiveness of the analysis, while others consider it decisive, functional, able to effectively favor the interaction between all the participants and not to allow the different hierarchical levels to be perceived during the presentation of the events, as well as in the identification of organizational causes and improvement measures. Being all around a table, without there being a teaching attitude on the part of the moderators, allows the analysis team, but especially those who were directly involved in the event, to feel comfortable and not judged.

The analysis tools

The simplified RCA tool is considered by all interviewees to be effective, as it allows them to reach solutions shared by the analysis team in a limited time. It is also considered usable for proactive risk analyzes, as well as for the reactive management of unwanted events, it is intuitive even for professionals who are not familiar with its use. The simplified version chosen by the Clinical Risk Center allows to go into the details of the analysis, although it was necessarily commensurate with a reduced time frame. From an interview with a head physician it emerged that the use of a simple tool, within a short time span of two hours, can certainly be considered sufficient for the identification of the organizational causes that contributed to the occurrence of an event and the related improvement actions; on the other hand, if a complex event is being analyzed, it would be desirable not to oversimplify the analysis process.

The theoretical part on clinical risk management, which is presented at the beginning of the analysis meetings, is considered useful in the case of professionals who have never participated in such meetings, but it is mostly experienced as long-winded by most of the interviewees. If it is considered necessary, it could be anticipated by sending it by email to the participants, as a preparation for the analysis meeting, in order to devote more space to free discussion among professionals during the narration of the event.

The chronological description of the event (the timeline) is perceived differently by the interviewees, independently of their professional role. Everyone agrees that the timeline allows to bring out the weaknesses of the organization, but there are different perspectives on conducting it

during the meeting in the presence of all participants, rather than reconstructing it before the meeting by conducting interviews before the analysis meeting. The latter method would allow everyone to freely express their opinion on the dynamics of an event that occurred and would further reduce the analysis time (perhaps encouraging the participation of all the stakeholders necessary for the analysis, who would otherwise see their presence at the meetings as excessively burdensome). In this case, however, it would be necessary to identify who should conduct the interviews, how they should be conducted, and to foresee time and personnel resources for the fulfillment of this activity, especially if this competence were to be assumed directly by the Clinical Risk Center for the entire Province of Bolzano.

Some interviewees, on the contrary, believe that the tool of narrating the event, in the presence of all the stakeholders, is useful to make the dynamics of the event understood also by those who were not present during the event (e.g. the management). The storytelling process induces employees to listen to each other, to understand different points of view, to think about aspects that had not been considered or detected before they were openly exposed, thus promoting organizational learning.

Time devoted to analysis

From the interviews different positions emerged on the two-hour timeline of the analysis meetings: some professionals believe that the meetings could also be conducted in a shorter time, anticipating the timeline by conducting interviews aimed at collecting information from individual staff members on the dynamics of the events, or even sending the theoretical introductory part by email, as preparatory material for the analysis meetings (as already described in the previous paragraph). In spite of these inputs, the time dedicated to the analysis meetings is mostly considered adequate, even though it would perhaps be more appropriate to be able to adjust the timing of the individual meetings to the different types of events analyzed: simple meetings might require even a shorter duration, while more complex events might require a more in-depth analysis, not necessarily solvable in a single analysis meeting.

Participation in analysis meetings

Identifying the right interlocutors to be involved in the review meetings was for all respondents a crucial aspect of both the effectiveness of the review process and the subsequent implementation of improvement. The people involved in the meetings were generally considered to be those who are actually needed for an effective analysis of the cases, but the quality referents consider it important to support those employees who do not wish to participate, if they do not feel comfortable doing so.

The presence of the management at the meetings is experienced from two different perspectives: if in some ways its participation risks being perceived as a control action, acting as an obstacle to the free expression of collaborators, on the other hand the management is perceived, by some head physician, as disinterested in participating, "with little decision-making

competence". Furthermore, its role may fail and not be recognized, when the corrective actions pertaining to it are not carried out, hindering the resolution of the problems identified by the work of the departments. In this way, the analysis process risks losing its authority, attributing the effectiveness of the analysis to the culture present within the various organizational realities and not so much to the tool used or to the other factors inherent in the process.

Climate perceived during meetings

The climate within the analysis meetings is perceived positively by the various roles interviewed. It is generally believed that employees are aware that the purpose of the meetings is to be able to identify organizational improvement measures. Even if the operators' fear of being blamed for what happened exists, during the analysis meetings they would, according to the head physician respondents, have the opportunity to reduce their fears about blame, understanding the purpose and the meaning of the analysis meetings. According to the nursing coordinators, the perceived climate is not only correlated to the way in which the meetings are managed and moderated, but also depends on the subjectivity of the individual participants, on their character traits: some people are more confident, others more shy and feel differently free to express themselves.

The management of meetings by an external analysis team (the Clinical Risk Center in the role of Health Authority of the Province of South Tyrol) is seen as positive: the fact that the Health

Authority is not involved in the internal dynamics of the organization would be an added value: it would make it possible to detect facts and situations that might escape the attention of professionals, who are conditioned by the department's internal perspective. In addition, the Clinical Risk Center (CRC) is perceived as authoritative and its opinion, according to the nursing management, would be more easily accepted than that of colleagues working within the same department.

Generally speaking, the willingness of professionals to express themselves and to expose themselves depends, according to the medical management, mainly on the type of event analyzed: the situation is perceived as more complex, and the climate could be more tense, if the results of an event were serious for the patient involved or if an event involved more departments.

Implementation of corrective actions

In order for the improvement measures identified during the analysis meetings to be effectively implemented, they should be identified with a view to their feasibility: they should be considered realistic and not bordering on the theoretical. In this sense, the external analysis team of the Health Authority is perceived as competent and authoritative, but at the same time, precisely because of its specificity and its distance from everyday working life, it risks focusing too much on theoretical aspects, risking to lose sight of what the measures should actually represent for the daily practice.

Although, in general, the interviews revealed that professionals would be aware, even before the official analysis meeting, of the most important organizational causes that contributed to the occurrence of the reported events and what would need to be implemented at organizational level to improve the situation, the meetings would still be invested with added value: they allow professionals and management to organize institutional and structured moments to discuss

together, to confront each other through time slots that the commitments of daily work cannot guarantee, risking that salient organizational aspects are lost sight of and underestimated.

Within the investigated healthcare organization there are also realities that are accustomed to multi-professional and multidisciplinary meetings, as moments of confrontation among colleagues are considered essential to their professional activity: the psychiatric departments. Their daily work is based on the need for continuous exchanges, negotiations and renegotiations, which are as much an integral part of the clinical care process, as much as the prescription and administration of therapy is for the more 'traditional' departments. Organizational changes are therefore brought to the attention of the whole team, and are identified, negotiated and implemented by mutual agreement between managers and staff. However, the involvement of staff in the identification of improvement measures would not represent the only possible functional strategy, so that the change takes place as planned: for it to occur, it must be perceived as useful, necessary and not excessively complex to achieve, since *"satisfaction is what creates motivation towards change"*.

Structured meetings organized for the analysis of sentinel events would also be seen as useful for other more political/diplomatic reasons. The exploitation of the report represents an opportunity to try to force the use of certain tools, already thought out and discussed several times, but never formalized and actually activated. The improvement actions identified during the analysis meetings, according to this perspective, represent a simple confirmation of what the staff had already thought of achieving, but which had not been able to realize due to complex organizational problems or managerial unavailability at various levels

For corrective actions of a more structural nature, or involving several departments, it is generally considered that top management can and should influence the monitoring and implementation of change. On the other hand, for measures of an organizational nature and limited to single departments, according to what emerged from the various professional roles interviewed, it would be the leadership of the single departments that would play a fundamental role in their effective implementation (above all the figure of the head physician). Therefore, according to the interviewed nursing coordinators, the leadership is able to guarantee the organizational change, but in order to make it happen, it should be the first to believe in the importance of risk management, so that it does not act as an obstacle to change.

For some organizational realities, change is a step-by-step process that requires time, patience and perseverance. According to this vision, things cannot be imposed, people must be able to be involved in the change and they must be given the necessary time to internalize it. Feeling bound would not allow employees to understand the importance of change and to metabolize it so that it effectively becomes a new practice. For other organizational realities, however, control represents the *conditio sine qua* non for the effective implementation of improvement measures: the corrective actions identified during the analysis of sentinel events should be perceived as important goals to be achieved, because they are aimed at patient safety, but despite these ethical principles, as long as their implementation was not linked to the achievement of budget objectives, professionals would not worry about their realization.

The leadership approach can therefore make a difference: it should be situational and adaptable to the maturity level of employees. In a context where they work competently and with commitment, leadership can adopt a participative style, i.e. use the tool of delegation to allow professionals to work autonomously, mostly supporting them in developing their motivation and sense of personal security. Where, on the other hand, employees feel the need for direction from above, objectives and sanctions, in order to channel the commitment in the right direction, then leadership should necessarily take on a more directive style (16).

According to some quality referents and managers/directors interviewed, in order for organizational change to really occur, it should be monitored and supported within the operational unit itself. Being able to benefit from a contact person who monitors the implementation of actions may help, but it does not guarantee that the change will actually take place. Organizational change comes first at the individual level, through awareness, sharing of decisions, communication of changes and perception of professional responsibility. An event that has caused a serious injury to a patient and an emotional shock to the staff may serve as a stimulus for change, but in practice it is necessary that the event has an impact on daily life, on the work of the staff, on the organization, in order to decide to implement the right risk reduction measures.
At the same time, however, it is believed that it is difficult for people to be able or decide to take action themselves.

In one health district the quality referent has consciously took over the monitoring and supporting the departments, overseeing the implementation of corrective actions in a structured way. In the same district the medical directorate is very present and helps to spread the importance of the risk culture and the process of management of undesirable events among the staff. As it is not able to deal with it on the front line, it avails itself of the collaboration of the quality office, legitimizing its role. The presence of facilitators within the single departments, who have the task of driving the change process, is also seen essential to realize the planned improvements.

Since the authoritativeness of the system, according to what emerged from the interviews with the medical directorates, represents a winning weapon for organizational improvement. The directors complain about the need for a clear mandate from above (from the company top management) in order to be invested with the power to effectively influence the head physician when evaluating the achievement of their objectives. In this sense, the institutional accreditation, through compliance with the requirements for being able to carry out healthcare activities, represents a tool with a strong mandate, to which the management can refer in order to influence the leadership of the single departments.

Proposals for improvement

A first aspect that emerged from the research, and that is generally shared by the various professional roles interviewed, is related to the timing with respect to the conduct of the analysis meetings, according to two different perspectives:

1. From the reporting of an event to the analysis meeting, according to ministerial regulations, up to 45 days can pass. Respondents felt that meetings should be conducted closer to the events. Anticipating the analysis times would make it possible not to lose the emotionality of

the people involved. In fact, reporting should not only be understood as a rational, objective process aimed at change, but should also be able to take into account the emotional dimension of individuals.

2. Preparatory work by the collaborators - perhaps through the elaboration of the timeline before the analysis meeting, or by sending the theoretical part on clinical risk management to the participants, before the analysis meetings - could represent a valid possibility for the further reduction of the duration of the analysis meetings or to be able to devote more time to the discussion and the confrontation between professionals.

Some quality referents believe that it would be appropriate to provide a time for the validation of the improvement measures identified by the analysis teams, during which all the employees involved have the opportunity to propose further changes / additions, before the official document will definitively validated by the CRC and sent to the Ministry.

With specific regard to the identification of corrective measures, it is generally considered important that they will be more contextualized and placed in relation to the indications (procedures, protocols, guidelines) that already exist within the company system, so that no conflicts or opposing situations arise. In this sense, the quality offices could represent a functional interface between the districts and the Health Authority to monitor these aspects.

In order to monitor the implementation of the planned improvement measures, both the leadership of the departments and the management of the districts interviewed believe that it would be desirable to have a reference figure who would be responsible for supervising the organizational change and supporting the employees in its implementation. While the head physicians believe that such a figure should be placed within the district management, clinical directors and nursing managers believe that the management is already overburdened by numerous tasks and therefore think that this role could be taken on by the quality referents.

Post-analysis meetings, according to the nursing coordinators, should be organized on an *ad hoc* basis for the reporting departments, but not on occasion of company events, which are usually attended only by nursing coordinators and head physicians. This would be rewarding for the professionals and would make them perceive the real presence of the Clinical Governance of the Health Authority of South Tyrol, which would no longer be experienced as an abstract and purely theoretical entity. The quality referents interviewed believe that it would be useful to inform the collaborators - and not only the management - on the state of the company reports, to make them more aware and to give an informative return to those who have reported, maybe on the occasion of targeted training meetings, for example specific congresses on clinical risk, where virtuous examples are presented, models of resilience, which can stimulate the speaking up, also in the presence of authoritative speakers from outside the province, in order to allow a comparison with other realities that could act as a stimulus for organizational improvement.

Awareness and individual responsibility are considered crucial for the risk culture; they can also be developed through the narration of daily professional experiences. Stories can encourage

reflection on how practitioners have worked up to that point and on what needs to be changed to increase patient safety.

The importance attached to improvement should also be transmitted by the Health Authority through the adoption of control and sanctioning measures. Similarly, the Health Authority of South Tyrol should also provide for similar measures. According to the nursing coordinators, controls and constraints on the part of the company management and the Health Authority would ensure that the required organizational changes are actually implemented. According to the perspective of the medical directorates, control instruments could be functional, but they should be institutionalized and not embedded in budget targets that bind people one-off. Moreover, each health district has its own autonomy and its own way of assessing the achievement of objectives by its operational units. It is therefore not possible, at present, to carry out an objective and authoritative evaluation, which could effectively influence the predisposition of the leadership of departments to achieve the objectives agreed with the management. The budget tool is therefore ineffective, because it would lead people to work only with a view to achieving a goal - in the event of fear of being sanctioned - but if it is not maintained over time, the improvement process stops and is not pursued.

The physical presence of the Health Authority, in the guise of the Clinical Risk Center, is perceived positively, but it would be desirable for it to be more constant and not limited only to analysis meetings. The request to send reports on the status of implementation of corrective actions is considered important, but it should be institutionalized and timetabled throughout the year (for example, twice a year), in order to understand not only whether the desired change has actually taken place, but also how it has happened, what difficulties have been encountered, what problems have emerged and what solutions should be introduced to support professionals in the process of change.

Conclusions

In this paragraph we compare in detail the *research hypotheses* with what actually emerged from the qualitative study.

1. *The timeliness and simplicity of the analysis tools used favor the implementation of the improvement measures identified in the analysis*

The study showed that professionals would prefer sentinel event analysis meetings to be conducted at an earlier stage, as reporting should not only be understood as a rational, objective process aimed at organizational change. It is important to take into account the emotional dimension of individuals. Anticipating the time of analysis would make it possible not to lose the emotionality of the people involved. The characteristic of timeliness would therefore be correlated to the need to transmit to professionals the importance of taking charge also of the emotional aspects linked to risk management and not so much to the effective implementation of the identified improvement measures.

The same outcome is associated with the simplicity of the tool used for the analysis: this factor is attributed more than anything else to the ability of a greater involvement of the collaborators in the process of managing sentinel events and of making it more comprehensible.

2. *The use of a simplified tool makes it possible to arrive, in a limited time, at effective solutions that are also shared by employees*

   The results of the study confirm this hypothesis. It should also be noted that the tool, considered intuitive even for professionals not accustomed to its use, could be used for proactive risk analyzes too.

   It also emerged that the narration of the incident in the presence of all the interlocutors (an integral part of the analysis process), is useful for making the dynamics of the event understandable even to those who were not present at the time of the incident (e.g. the management). The storytelling process would in fact induce the collaborators to listen to each other, to accept the different points of view, to think about aspects that had not been considered or detected before they were openly exposed, thus favoring the organizational learning.

3. *The key to the change is not so much the type of tool used, but rather the characteristics and functionality of the tool adopted.*

   This research hypothesis was confirmed by the study conducted, in that it emerged that, regardless of the tool used, relevance in terms of organizational change is attributed to the messages that each tool is able to transmit to professionals, and to the level of authority that stems from (and is transmitted by) the organizational system that uses it.

   The request to send a report on the status of implementation of corrective actions is considered important, but it should be institutionalized and scheduled during the year, in order to understand not only if the desired change has actually been achieved, but also how it happened, what difficulties were encountered, what problems emerged and what solutions should be introduced to support professionals in the process of change.

   The binding formula of the budget tool is seen as ineffective because it would lead employees to work only with a view to achieving a goal, in the event that they fear being sanctioned, but in this way the improvement process would not be pursued, much less maintained over time.

   The authoritativeness of the system represents a winning weapon for organizational improvement. In order to be invested with the power to effectively affect the head physicians when assessing the achievement of their respective budget goals, the districts management believes that it must be invested with a clear mandate from above.

   The institutional accreditation, for its part, through the compliance with the requirements of the legislation, represents a tool with a strong mandate, to which the top management can refer to affect the leadership of the individual departments.

4. *The degree of implementation of improvement actions is proportional to the degree of complexity of the corrective actions identified during the analysis.*

This research hypothesis was partly confirmed. In other respects, however, it is believed that complexity is not the only variable responsible for the effectiveness of the process of implementing improvement measures.

For corrective actions of a structural nature, or which involve several operating units, it is generally believed that the management can and should affect the monitoring and the implementation of the change. Otherwise, for organizational measures limited to individual departments, the leadership of the operating units would play a fundamental role in their effective implementation.

Leadership is therefore credited with the ability to ensure organizational change, but for this to take place it should be the first to believe in the importance of risk management, so that it does not itself act as an obstacle to change.

5. *The degree of implementation of improvement actions is proportional to the degree of severity of the sentinel events that have occurred.*

   An event that has caused serious harm to a patient and an emotional shock to the staff could serve as a stimulus for change, but in practice it is necessary that the event has an impact on daily life, on the activity of professionals, on the organization, so that it is decided to implement the right risk reduction measures. At the same time, however, it is believed that it is difficult for people to be able or decide to take action independently (see the topic of organizational strategies and leadership).

   These are the considerations that emerged from the study, which partially accept the fifth research hypothesis expressed by the authors.

6. *A decisive factor for change is the degree of understanding and the participation of employees: the more they are involved from the very beginning of the change process, the more likely it is that change will actually take place.*

   The interviews conducted partially refute this research hypothesis. In fact, it emerged that the involvement of staff in the identification of improvement measures would not be the only possible functional strategy, so that the change is realized as planned: for it to occur it must be perceived as useful, necessary and not excessively complex to achieve, since "*satisfaction is what creates motivation towards change*".

   A relevant importance, in this sense, is attributed to the type of leadership, which should reflect the level of risk culture existing within the respective organizational reality, that is:

   - For organizational realities characterized by an *executive leadership style*, control represents the *conditio sine qua non* for the effective implementation of corrective actions: the measures identified during the analysis meetings of sentinel events should be perceived as important goals to be achieve, because they are aimed at the safety of patients. However, as long as their implementation is not linked to the achievement of budget objectives, there would be no concern about their implementation.
   - For organizational realities characterized by a *participatory leadership style*, change represents a gradual process, to which it is necessary to dedicate time, patience and perseverance. According to this vision, things cannot be imposed, people must be able to

be involved in change and must be given them time to internalize it. Feeling bound would not allow professionals to understand the importance of change and to metabolize it so that it effectively becomes a new practice.

Limitations of the research, strengths and possible developments

In the research conducted there are certainly some critical aspects to be noted. First of all, the fact that the semi-structured interviews were not conducted also with the employees: their involvement was not possible because the principle of anonymity meant that it was only possible to trace the clinical and nursing leadership - and the respective directors/managers - who participated in the analysis meetings in 2018 and not the individual employees. All perspective considerations ascribed to their views are therefore dictated by the perceptions of the head physicians and the nursing coordinators with respect to what they experience on a daily basis in their organizational reality. It would be interesting to further deepen the research through the adoption of analytical tools that can detect/describe the perspective of employees in order to make a comparison between what is narrated by the leadership (at various levels) and what is experienced by professionals in their daily practice.

A further critical element is the fact that the interviews were conducted by the CRC. This aspect could be critical for several reasons, explained below:

- The interviewees may have attributed an institutional role to the CRC, and therefore may have felt "controlled" or "under investigation" by the South Tyrolean Health Authority or by the health Company. An attempt was made to compensate for such a possible view by explaining very well to all the interviewees that the aim of the survey was to understand what difficulties, or strengths, staff members experience in implementing change and what strategies they believe could reduce or solve any criticalities in the organizational system.
- It was not possible to take into consideration the possibility of having the interviews conducted by another researcher, external to the Health Authority, because the dimensions investigated could not be separated from a thorough knowledge of the topic dealt with and, above all, the information on sentinel events reported must be kept protected, in compliance with the provisions of the legislation on privacy and the professional secrecy.

In addition to the considerations described above, the authors were able to detect an additional element: the interviews conducted were not experienced by the interlocutors as an end in themselves: perhaps due to the fact that the Health Authority was the commissioner of the qualitative research, the professionals interviewed, at all levels, more or less explicitly expressed the belief that the study was a prerequisite for a change in the sentinel event management process. On the other hand, they had expectations that important aspects could, or even should, change.
Interesting in this regard, and perhaps unexpected, is the fact that the management, which tends to be seen as the organizational structure that takes decisions from above without necessarily

having first shared them with the bottom up, has a very democratic attitude towards reports and does not bother to monitor the implementation of corrective actions, unless this is formally requested by the Health Authority, through objectives included in the Health Company's Balance Score Card (BSC).

It is the same underlying levels that request a greater institutionalization of the objectives, through the introduction of controls and appropriate sanctions; in fact, it would be these elements that would give authority and credibility to the organizational system and guarantee that the social actors actually do what is requested of them. Interpreting what has been observed on the basis of what has been described by Hersey and Blanchard (17) in their studies on situational leadership, it would seem that the management (clinical directorate and nursing management) is inclined to consider their employees sufficiently mature to be oriented towards a participative style of leadership, while, on the contrary, the leadership of the departments (head physicians and nursing coordinators) would like top management to assume a directive style of leadership. It would be interesting to deepen what apparently revealed with a further qualitative survey, aimed at highlighting the level of maturity of the professionals working within the healthcare company, depending on the organizational context they belong to (for example by comparing the psychiatric context with that surgery, internist, etc.), and to identify the appropriate strategies that can contribute to the evolution of the organizational maturity of collaborators.

Discussion

The peculiarity of risk management systems, through the dissemination of the risk and the no blame culture, lies in the affirmation that accidents and clinical errors should not be sought in the activities of the single health professionals, but in the organizational system. At the same time, however, focusing only on the organizational dynamics and on the strategies of managerial management, could help to ensure that operators use these factors as an alibi for not feeling responsible for adopting the reflexivity necessary for the complex and high-risk contexts that characterize hospital structures. If the causes of clinical errors are to be traced back to organizational structures, it is also true that organizations are made up of individuals, who among other things occupy decision-making roles (clinical directors and nursing managers, head physicians, nursing coordinators) and who direct the course of the healthcare organization they work for (18).

The reliability of an organization is characterized by the ability of each organizational actor to adopt the right cognitive and professional attitude, which is oriented towards the safety of patients. The organization, for its part, has the task of integrating and harmonizing the actions of individuals (19).

Risk management therefore does not only imply the implementation of specific risk management tools. Organizations are made up of people even before managers (20). Everyone can either adhere to organizational policies or oppose them, and this may occur explicitly but more often occurs implicitly. Directing and leading people towards common organizational goals does not only require that they are officially shared at different levels, because social actors have primarily individual needs that they try to satisfy (21), even at the expense of the organizational context in which they are embedded (3), (22), (23).

Managing risk therefore means, among other things, "carrying out an activity of persuasion of people, also at a subjective level, which requires social, political, material and symbolic actions" (18). Organizations are not objective realities, but the result of a social construction, of a shared construction of meanings, which must continuously negotiate. This complex negotiation process can lead to delays, deviations, slippage of objectives or may require a different definition from those previously defined. To combat errors in clinical practice, it is therefore crucial to take a new perspective, namely that of the social nature of decision-making processes and organizational change. The social sciences should therefore be able to fully contribute to the analysis of clinical risk within healthcare organizations and become an integral part of risk management systems.

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