Cultural approach to healthcare risk management – an Italian experience with look-alike, sound-alike drugs

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Abstract: Risk management is fundamental in healthcare organisations at both the institutional (organisations) and sectorial (health) levels, not only as an operational technique but also as part of a managerial model. Thus, it is essential to highlight the strategic importance of the cultural impact, both clinically and financially, of correct risk integration between professional and organisational functioning. This research presents a case study of the Casa di Cura Tortorella S.p.a. (Salerno, Italy), which adopted a unique solution to handle logistical risks concerning medicines that have the potential to lead to dangerous confusions due to their similar names, dosages, packaging, and other elements (i.e., look-alike, sound-alike [LASA] drugs). Using the case study technique, the investigation highlights that the adoption of an operational mechanism for risk management, although useful, is limited if it is not supported by thorough training (for every operator) and a new organisational and cultural role, i.e., 'nursing team leaders', with responsibility for coordination and reporting, and has direct and indirect impacts on the financial performance of healthcare organisations.

Keywords: risk management; healthcare; drugs logistics; drugs management; look-alike, sound-alike drugs; sound-alike, look-alike drugs; look-alike, sound-alike; LASA; sound-alike, look-alike; SALA; managerial reporting; financial performance.

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1 Introduction

Risk management is one of the most important competences that are currently required in the organisation of healthcare services; for example, in several countries, the implementation of training courses on risk management is mandatory for all health and social care personnel to obtain accreditation from national health services. However, it is crucial to highlight that healthcare risk management, which naturally involves the adoption of operational mechanisms (clinical audits, incident reporting, failure modes and effects analysis, root cause analysis, safety walk arounds, and so on), primarily belongs to a managerial culture model in which confronting the 'unexpected' is a normal part of organisational functioning, both in institutional terms (as organisations) and sectorial terms (as health organisations) (Card et al., 2012).

In fact, attention to risk, in addition to being an inherent component of clinical/healthcare environments, has over time become a managerial competence, mainly due to the increasingly corporatised vision of healthcare services (at least in Italy, where public health has been based on these criteria since 1992). Risk management is part of the global commitment connected to health delivery, considering performance in professional and organisational quality overall and impacting every aspect of healthcare governance and management, from corporate social responsibility (Fuzi et al., 2014) to financial management (da Silva Etges et al., 2019).

The present study does not aim to investigate the differences between risk (more quantitative and objectively measurable) and uncertainty (more qualitative and subjectively considerable), which have been investigated by key previous studies (Knight, 1921; Golinelli, 2000; Metallo, 2007). However, uncertainty and consequent risk are constant features of professional services that are associated with healthcare services (Tramarin, 2002); thus, they are always taken into consideration altogether.

For example, in the most popular model of customer satisfaction measurement, i.e., SERVQUAL (Parasuraman et al., 1988), there is an institutional difference between the risk of the perceived quality (which is influenced by communication) and the uncertainty of the expected quality (which can also be influenced by communication: for example, healthcare services bills, public relations offices, informed consent, and so on). Therefore, in healthcare, communication, whether organisational and/or interpersonal communication, also plays a strategic role within the overall risk management system.

At least two fundamental objectives seem to emerge in managing healthcare risks: internal quality (mainly with reference to standards) and external quality (mainly with reference to perceptions). Thus, in clinical, organisational, and financial terms, it is beneficial to constantly adopt an approach based on stakeholder theory, as the single healthcare organisation inevitably is in communication with a total relationship system, from the single patient to the entire community, because the organisation deals with health (Wang et al., 2019).

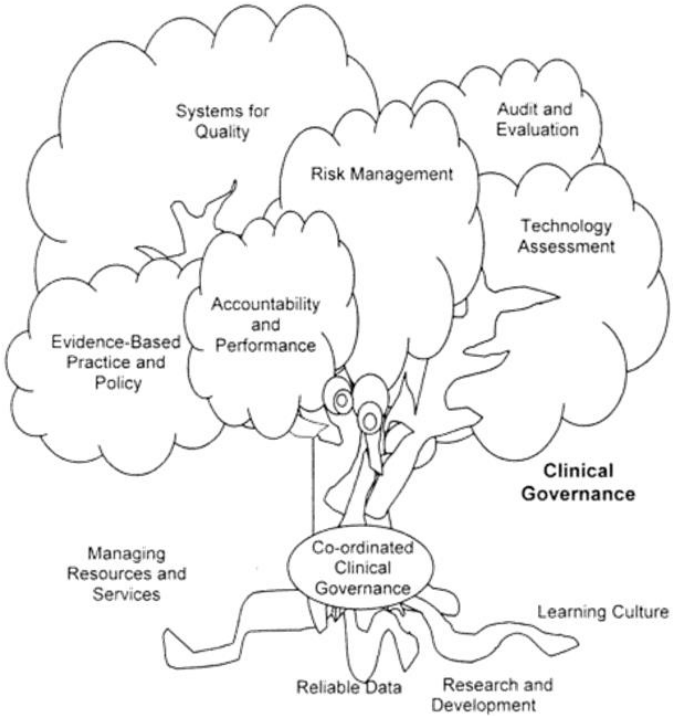
In this vein, a correct approach to risk should be as systemic as possible, considering various stakeholders from an organised and integrated perspective (Kamaruzaman et al., 2019). A similar requirement cannot be satisfied solely in practical terms (i.e., adopting operational solutions for risk management, even if they are sophisticated) but must also be satisfied in terms of business culture (indoctrinating and training the entire staff involved in risk, including strategic management), business management (adopting appropriate procedures, both operational and organisational), and business economics (handling all financial aspects of risk).

The paper is organised as follows. After presenting a literature review of the field, the paper provides a theoretical framework for risk management that has been adopted and then applied to a case study in the healthcare sector, yielding evidence with scientific and managerial implications, followed by considerations regarding the current limits and the potential development of the research.

2 Risk management and governance in healthcare: a literature overview

An integrated system of managerial expertise for governing and handling risk, which is a generic but probably acceptable definition of risk management, must be considered, at least in a modern healthcare organisation, as a fundamental element of wider clinical governance, i.e., the directional perspective is oriented to appropriate provision of health services, efficient use of health resources, and continuous improvement of health services (Hackett et al., 1999; Onion, 2000; Som, 2004; Braithwaite and Travaglia, 2008; Brennan and Flynn, 2013). A conceptual model that could be of great utility in the understanding of the concept of clinical governance is the related 'tree' (cf. Figure 1), as proposed in Chambers integrated vision.

Figure 1 Chambers tree of clinical governance



Source: Authors' elaboration from Fontana (2005)

In this conceptual map, risk management plays an essential role, representing managerial competence grafted onto the roots of the effective and efficient management of activities and utilities ('managing resources and services'), data and information ('reliable data'),

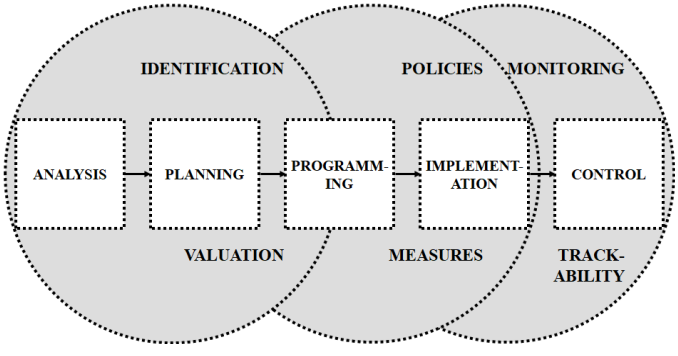
innovation processes ('research and development'), and continuous improvement ('learning culture'). In the coordinated development of clinical governance, risk management interacts with other managerial functions, identified by Chambers with the skills that are necessary to provide evidence of results ('accountability and performance'), behaviours ('evidence-based practice and policy'), and excellence ('systems for quality'), exploiting available and new knowledge ('technology assessment') and measuring clinical and economic outputs and outcomes ('audit and evaluation').

2.1 Managing risk in healthcare: a systemic approach

As mentioned above, any operational process in healthcare organisations is inherently exposed to risk, and in the integrated vision proposed by Chambers, the management of operational processes is combined with other managerial skills involved in clinical governance. In the case study that will be analysed further, which focuses on a risk management solution for look-alike, sound-alike (LASA) or sound-alike, look-alike (SALA) drugs, there are specific references to multidimensional actions that simultaneously work at operational, organisational, and cultural levels, with the aim of embracing a risk management solution through a broad, comprehensive scenario as proposed by Chambers.

Such a multidimensional intervention, if wisely developed, should also have positive economic and financial impacts: in fact, as in every situation involving expenditures, risk management justifies costs through the related benefits (Ferdosi et al., 2020; Poursoltan et al., 2020; Fattoruso et al., 2021). In this respect, the risk management solution to the problem of LASA drugs, as proposed in the case study, corresponds to a corporate circumstance (in a healthcare organisation) that is firmly embedded in the balanced scorecards perspective (articulated through four dimensions: economic, organisational, relational, and cultural), which is gaining increasing importance in the management control of healthcare organisations (Vignati and Bruno, 2002; Shukri and Ramli, 2015; Khiew et al., 2020).

Figure 2 An integrated view of the risk management cycle



Source: Authors' elaboration

In terms of application, after the determination of the strategic setting, it is necessary to adopt a conceptual model to represent the risk management cycle, possibly articulated on at least two axes, a horizontal axis and a vertical axis (cf. Figure 2). The horizontal axis

develops a traditional management cycle (for 'any' management), i.e., analysis, planning, programming, implementation, and control (Thiry, 2002, 2007; Matsui, 2009; Tam, 2010; Morita et al., 2011); the vertical axis instead develops a traditional risk management approach, i.e., identification/evaluation, policies/measures, and monitoring/tracing (Merna and Merna, 2004; Sinibaldi, 2007; Eppler and Aeschimann, 2009; Stern and Arias, 2011; Yaraghi and Langhe, 2011).

First, it is essential to draw up a list of possible risky situations, with subsequent analysis of probabilities and potential damages; second, it is necessary to implement adequate procedures (at the strategic and operational levels) to avoid, prevent, decrease, respond to, or address risky situations (primarily in clinical terms in the healthcare context, but also in economic and financial terms from the perspective of healthcare sustainability). Finally, to apply a managerial approach to risk, an indispensable knowledge management activity for correctly handling obtained information must be implemented, regardless of whether the risk management operation has yielded the desired results (Chen, 2013; Ghasemi et al., 2017; Shahmoradi et al., 2017).

Understandably, in the engagement in this cycle, a risk governance system emerges that is broader than 'just' risk management, which in some solutions, relies solely on the adoption of operational mechanisms. However, in a healthcare system that is continuously and wholly exposed to perceived quality, it is essential to conceive an integrated view of the global process that is inevitably and perpetually composed of two components: a clinical/health component and a technical/administrative component, which synergistically affect the appropriateness of the overall health service.

Perceived quality is a fundamental aspect of the evaluation of customer satisfaction in any scenario: the SERVQUAL model, which was already mentioned, is the most popular instrument for the assessment of customer satisfaction, especially (but not only) for products that are services, as is the case in healthcare (Butt and de Run, 2010; Talib et al., 2015; Pekkaya et al., 2019). However, specifically regarding health, there is considerable information asymmetry between operators and patients (Festa, 2004), so greater caution is necessary in the detection 'sic et simpliciter' of the quality perceived by patients and/or their families; in fact, there could be a deficit in the communication aspect of the service but not the technical aspect (Focarile, 1998), thus requiring major effort by the healthcare professionals in professional communication (that is, the operator) and institutional communication (that is, the organisation).

2.2 Managing risk in healthcare: a cultural perspective

Risk management systems for healthcare organisations have the inherent difficulty of measuring the outcome of health services, having to constantly address 'risky' situations (the likelihood of adverse events, economic evaluation of damages, the choice of the most appropriate treatment procedure, and so forth). Even from this perspective, it becomes increasingly more important in the organisational context to manage the cultural impact of risky situations and their related management from the points of view of the operator and the patient to properly 'integrate' risks in professional and corporate functioning (Lega et al., 2018).

Moreover, the cultural approach to risk management influences, if not properly produces, even operational mechanisms, which are the natural consequence of a mindset oriented toward a culture of risk: an example is double-checking within the overall clinical/health process (Gershon et al., 2004; Armitage, 2009; Cagliano et al., 2011;

Alsulami et al., 2012; Kellett and Gottwald, 2015). In fact, an integrated view of risk should prompt operators to finally make their contributions to the overall health service from a process perspective, reminding them of the control of correctness, both for inputs received from upstream stakeholders and for outputs produced for downstream stakeholders (substantially and formally).

Double-checking should also be managed through documentation, at least for critical processes, with the reminder that, as always happens in reasoning about 'control', excessive formalisation could hinder efficient functioning (Soin and Collier, 2013). In the case of healthcare, this reflection is considerably more involved and uncertain than in other sectorial areas given the complexity of the dimensions involved (Carroll and McSherry, 2020); however, in the healthcare context, it is essential to make non-compliant operators (who might feel restricted by the procedure) understand that appropriate regulations, if well conceived, are allies and not necessarily enemies in daily clinical/medical practices and to make the regulations strongly engaging in terms of organisational communication (Liu et al., 2017; Yilmaz and Flouris, 2017).

From another point of view, in overall health service provision, it is indispensable, as previously mentioned, to maintain the consistency of the appropriateness of performance with its economic and financial sustainability since a benefit may not seem perfectly appropriate in hindsight if it is not sustainable. This aspect refers above all to the dimension of the 'economicity' of public health, while in the case of for-profit and non-profit healthcare organisations, it is evident that sustainability is an essential factor for the survival and development of health services (Marinò, 2008).

In fact, perhaps most of all for public health, attention to the provision of the best possible health service is fundamental, counterbalancing the mission (effectively and efficiently delivering good health services to the community) with equality (respecting the public nature of the financing to ensure that health services are also provided to those in need) (Falivena and Palozzi, 2020). In all cases, this perspective requires a consistently managerial approach to the organisation and provision of healthcare services, including risk management (Baldassarre et al., 2016).

Consequently, equality inevitably has a cost, at least in terms of outputs, which becomes an investment, but in terms of outcomes, savings could also emerge in the medium/long-term from this cost (Green, 2001). An example is health fragmentation: with the aim of reaching the greatest possible number of patients (actual and potential), inefficiency may inevitably occur (e.g., a hospital in an area that is sparsely populated but also logistically disadvantaged), but in the long run, the inefficient operations may cause fewer serious and/or chronic cases in the patients, with savings on other health fronts (Dirindin and Vineis, 2004).

3 Research design

The objective of the investigation is to verify which potential solution can be effectively adopted for a specific risk management problem that can occur in the internal (administered drugs) and external (distributed drugs) functioning of the drug logistics process in healthcare organisations, i.e., the potential confusion regarding LASA drugs. This matter has gained institutional relevance in Italy, particularly since August 2010, when the Ministry of Health made a recommendation regarding the issue (http://salute.gov.it). Thus, the main research question is as follows:

RQ1 'How can LASA/SALA drugs be managed from a risk management perspective?'

Starting from a previously developed conceptualisation, the current research first conceives a theoretical/methodological framework for systemic risk management in general and then applies this framework, with all its contextual features, to the challenge of the presented case study (Casa di Cura Tororella S.p.a., Salerno, Italy); this case study was selected because, as further discussed, it is simultaneously 'more than common' at the national level and 'almost extreme' at the regional level. The case study methodology allows specific evidence and practices – the at operational, organisational, managerial, and cultural level – to be highlighted regarding the problem of LASA drugs, which are believed to be successfully applied or at least to be examples of successful application for other similar healthcare organisations.

4 Risk management for LASA drugs: the Casa di Cura Tortorella S.p.a. case study

In light of previous reflections, in the current research, a specific risky circumstance is taken as the object of analysis. The study investigates a private hospital that adopted a unique operational mechanism for risk management aimed at strengthening the drug logistics process due to the potential for confusion and accidental exchange of drugs in the process from the entry of the drugs into the warehouse to their withdrawal from the pharmacy based on their similar names, dosages for use, packaging, or other elements, which in some cases could be harmful, if not fatal. This research adopts the case study methodology to highlight that the adoption of only a risk management operational mechanism (in this case, affixing a red sticker to LASA drug packaging), although useful, would have a very limited clinical and economic impacts if not supported by an overall training program (for every involved operator) and by a new organisational and cultural role, i.e., 'team leader nurses', with responsibility for coordinating and reporting.

The company under analysis is the Casa di Cura Tortorella S.p.a. (approximately 170 employees in 2019, 143 hospital beds accredited by the National Health Service, and a turnover of approximately 19 million euros), one of the largest private healthcare organisations in the province of Salerno and in the Campania region (Italy). By virtue of these characteristics and the operating levels (treated pathologies, accredited specialties, complexity of the case mix, intellectual capital, and so forth), the scenario examined in this case study can be considered as both 'more than common' and 'almost extreme' (Eisenhardt, 1989) in the panorama of the Italian National Health Service at the institutional level (in Italy, approximately 40% of accredited private hospitals have more than 100 hospital beds, with an overall national average of 120) and territorial level (with even lower values in the Campania region) (data from Cergas Bocconi, 2019).

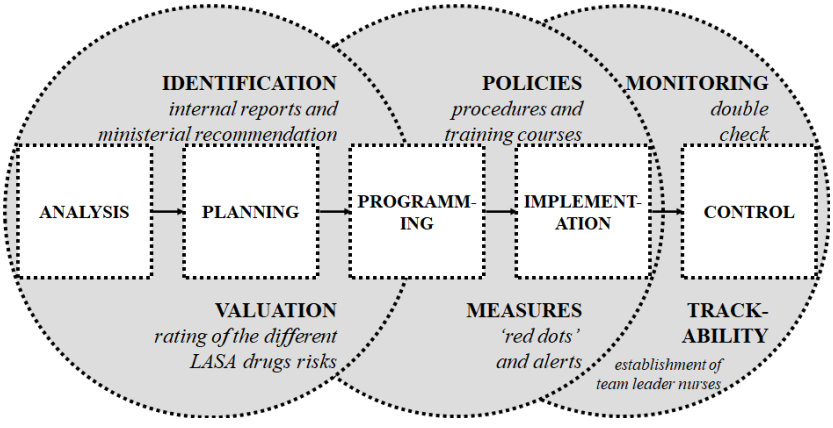
The problem of LASA drugs has emerged in private hospitals and been under investigation since 2009 in reports addressed to the Health Direction by internal medical, nursing, and social care personnel. These personnel were the first to highlight the riskiness of drug therapy operations for drugs with similarities (names, dosages, packaging, and so forth).

Thus, there has been good organisational communication, in which the ownership and management of the Casa di Cura Tortorella S.p.a. has always invested considerably, both planning training courses on interpersonal communication and orienting the

organisational structure towards process computerisation (in not only technical/ administrative areas but also clinical/health areas). Furthermore, the issue of risk management related to LASA drugs was later defined and codified in mandatory terms (and not just as good practice of the single organisations) by the recommendation from the Italian Ministry of Health No. 12 of August 2010.

Based on this background, a systemic approach was established, constituting one of the potential responses to RQ1 ('how can the LASA/SALA drugs be managed from a risk management perspective?'). Figure 3 shows a synopsis of the application of the above-analysed scheme for risk management to the issue in question that has been adopted in the Casa di Cura Tortorella S.p.a.

Figure 3 The application of the integrated risk management cycle to LASA drug issues



Source: Authors' elaboration

From an operational perspective, after the receipt of reports from the organisational periphery, a mechanism to be used in risk management in the case of LASA drugs was identified; the mechanism was found to be methodologically coherent and to follow the ministerial recommendation. There are ample references regarded the traditional risk management cycle, as presented above.

First, the Health Direction identified all possible LASA drugs (*identification*), also with reference to the list reported in the ministerial recommendation, which allowed the subsequent allocation of a risk level (*rating*). The operational solutions that were chosen to contribute to the solution of the problem (*measure*) were the application of a red sticker to every package any drug on the list to alert the operator involved in the overall drug therapy logistics process (withdrawal from the warehouse, collection from the departmental pharmacy, administration to the patient, and so forth), as well a large range of alerts along this logistics process.

Logistically, medicines are stored in the warehouse and in the departmental pharmacy in alphabetical order (from the first shelf in the upper left proceeding to the right and starting again from the left on the next shelf), while outgoing medicines are organised according to *first in first out* (FIFO) to allow the precise and rapid control of stocks and deadlines (which are executed monthly); the departmental pharmacies have their own minimum allocations, which are calculated on the normal frequency of departmental

pathology trends and on the historical consumption of medicines. The red stickers are applied in the departmental pharmacies by the operator on duty who stores the drugs.

Currently, in pharmaceutical warehouse management, computerised cabinets are common; these cabinets ensure correspondence between the input (on the prescription) and the output (as taken from the cabinet). Regardless, in the presented case study, the red sticker paradoxically allows different operators to draw attention to the drug (which, in a computerised pharmaceutical cabinet, might even be removed unethically).

Furthermore, it is important to consider that an information system is not necessarily better simply because it has more sophisticated information technology (IT) components because a health information system, even in a single healthcare organisation, is still an organised, integrated, and coordinated set of equipment, procedures, and, mostly, people. The most effective and efficient healthcare information system, therefore, is the system that best suits the individual healthcare context while complying with institutional regulations and managerial organisations (Teti and Festa, 2009a, 2009b); this principle also applies to advanced solutions for global pharmaceutical governance and management (Festa et al., 2018).

When drugs are collected from the departmental pharmacy, if the prescription is for a drug with a 'red sticker', the operator is alerted to do a *double check*; the double check involves the prescription (preventing a possible error, for example, because of a wrong interpretation, by applying a further control) and on the administration (practicing even greater treatment diligence than what is normally practiced for non-LASA drugs, is possible). This practice alone is not the unique operational solution that has been identified as the overall risk management solution: in addition to the operational dimension (the red sticker warning and the other alerts along the medicine logistics process), at least two other dimensions have been implemented, namely, the structural dimension (updating the technical procedures and the related upstream organisational procedure and creating the new role of 'team leader nurses') and the cultural dimension (offering specific training on operations related to LASA drugs and general training on risk management).

As a result of this solution, the Casa di Cura Tortorella S.p.a. has faced and solved a specific risk management problem connected to LASA drugs to be compliant in both the organisational context (because this good business practice, although not yet imposed by the law in 2010, had emerged and been addressed since 2009) and the institutional level, meeting the specific requirements of the Italian Ministry of Health (according to the Ministerial Recommendation No. 12 of August 2010). The solution has also resulted in documented improvements in organisational satisfaction, both for operators (who are more confident in addressing problem associated with LASA drugs) and above all for patients (regarding the avoidance of LASA drug problems in particular and regarding overall customer satisfaction level in general, with consistently higher customer satisfaction than the targets established through system quality management over the years). In addition, taking advantage of the knowledge gained through sensitivity to the issue and through the adoption of a viable solution, since 2010, the Casa di Cura Tortorella S.p.a. has implemented further procedures for labelling anaesthetic syringes (even though these are instruments and not drugs), which has also led to relevant economic and financial benefits (due to risk prevention, increased control, improved efficiency, and so forth).

5 Scientific and managerial implications

From a theoretical point of view, the research is in line with the scientific literature on the subject, providing further confirmation of risk management as essential skill for any organisation (especially for organisations with inherent potential for risk, such as healthcare organisations), thus a managerial approach is always required, even if for a primarily logistical situation such as the presented problem with LASA drugs (which had clear potential for health damages). In fact, in the case study under examination, the use of only the operational technique (the red sticker) would not have been an efficacious, efficient solution to the risk management problem if it had not been accompanied by adequate organisational (procedural) and cultural (training) interventions, thus highlighting the ever more relevant contribution of intellectual capital to global pharmaceutical process governance and management (Festa et al., 2020).

From a practical point of view, moreover, the research reveals at least two fundamental warnings for the proper functioning of healthcare organisations regarding risk management. First, the importance of internal/organisational communication must be recognised (the General Direction and the Health Direction of the Casa di Cura Tortorella S.p.a. had already been alerted about the issue in question by internal reports, even before that the case the issue of LASA drugs gained institutional relevance due to the recommendation by the Italian Ministry of Health of August 2010). Second, executive management (in this case, the general management and the health management) must be committed to considering risk management as a practice with which to engage concretely and not only a procedure to comply with because of mandatory provisions.

6 Research limitations and future directions

The investigation had limitations regarding its scientific nature due to the case study methodology, which does not generate results that can be extended statistically to other organisational contexts. The ‘more than common’ conditions at the national level and the ‘almost extreme’ conditions at the regional level of the case study in question suggest that the results of the investigation can be reasonably extended, but repetitions of the analysis with other case studies, and especially empirical investigations that would be more statistically representative, are necessary in future research to overcome the above limitations.

Furthermore, it would be desirable for such future work to focus on not only healthcare organisation characteristics (geography, economy, typology, and so forth) but also the nature of the problem under examination (in the presented case, LASA drugs). In this respect, the objects of investigation could/should also be health-related cases in the strict sense, such as examinations, interventions, and rehabilitations, to further investigate the human element of the complexity of risk management in healthcare.

7 Conclusions

Empowerment of the entire stakeholder community, first and foremost patients and their families, can greatly contribute to changes in the relationships between healthcare professionals (individuals and/or organisations) and patients, with clear advantages of fairness and transparency (regarding the valuable role of tribunals for patients' rights, various associations in defence of the patient, and so forth). In some cases, however, there are also vicious cycles that are inevitably connected to risk, for example, the increasing litigation due to health issues, the 'automatic' practice of defensive medicine, and so forth, which currently have impacts not only clinical but also economic impacts, influencing the global sustainability of healthcare services.

These harmful practices, which are not the result of the proper exercise of the respective rights, also contribute to the burden of healthcare expenditures for public budgets; obstructions to the fluency of healthcare operations; and mutual loss of confidence in the continuous improvement of the relationship between healthcare doctors, nurses, and technicians on one side and patients on the other. Insurance solutions, which favour operators and/or patients, represent concrete developments for correct healthcare praxes, but since they are based on socio-economic-financial interactions, they are perpetually exposed to correct and/or incorrect changes (moral hazard, adverse selection, and so on).

The adoption of a good risk management system, therefore, can never avoid the need for a multidisciplinary approach; because the problem of risk is certainly multidimensional, its approach can only reflect a similar nature. The case study under analysis is thus a testimony to the need for an integrated solution to any problem of risk management in healthcare, even when the problem is 'limited' to possible confusion about medicines in the global process of drug management. An operational, organisational, and cultural point of view must be assumed; otherwise, there is very likely a high potential of failure.

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