1. INTRODUCTION

The current coronavirus emergency with its wide diffusion and virulence endangered in a short time the health of the worldwide citizens. It has not only shown the extraordinary precariousness of human existence and the extreme volatility of the socio-economic global balance, but it also exhibited the poor preparation of countries (even the most advanced ones) to intervene efficiently against epidemics (Beasley, 2020). The coronavirus pandemic has required prompt and massive intervention by the worldwide healthcare systems to offer care and assistance, further amplifying their instability and vulnerability and bringing out hidden disorganizations/inefficiencies.

Nowadays, the need to protect public health in such a critical historical context increased the interest in how national healthcare systems (NHS) manage emergencies and, at the same time, the risks they are exposed to (see A guide to the project management body of knowledge). On this point, the growing uncertainty of the macro-economic market conditions, the profound instability of the national and international economic balances and the urgency to protect firm profitability has stimulated curiosity about the current spread and implementation of the risk management and control systems.

The Italian healthcare sector is characterized by an intrinsic dynamism and by the exposure to a high and heterogeneous mass of risks with roots in various areas of healthcare governance. Such risks require new and cutting-edge tools to be managed efficiently. In such conditions, the adoption of ad hoc shaped ERM models could be the right solution for facing adequately the inefficiencies in pandemic management.
the healthcare structures and from the external context) to fulfil the economic efficiency consistently with the new business models.

Furthermore, bypassing the time, the NHS was asked to adopt a newer managerial approach, going far beyond the limits of the clinical governance concept which characterized the healthcare sector for years (Bridges, 2006; Cagliano, Grimaldi, & Rafele, 2011). The empirical evidence revealed that the Italian healthcare sector has a deep-rooted orientation toward the reduction of the clinical risk (Thomas et al., 2000; Ross Baker et al., 2004; Vincent, 2006), thus neglecting other risks. Such focus has led to disregarding potential threats of not aiming at the economic efficiency of processes and the control of business risk. The failure in managing economic and financial risks in healthcare threatens the fundamental principles of protecting patient’s health and hinders the survival of the healthcare services themselves (Dickson, 1995).

For several years, the difficulty encountered in the mitigation of business risks and the (vain) attempt to contain the deleterious effects on the national health system occupied considerable space in the news pages and encouraged the interest of Accounting scholars about the evolutionary path of risk management systems over time. The Italian healthcare sector felt strong pressure toward carrying out a process of change for increasing financial transparency and the efficiency of healthcare companies through strategic management intertwined with business values (Troyer, Brashear, & Green, 2005; Celona, Driver, & Hall, 2010).

The purpose of this paper is to propose an integrated reflection on how to manage business risks within the Italian Healthcare System in conjunction with the spread of the coronavirus pandemic, crossing the boundaries of long-standing management problems of the clinical risk and wearing the lenses of the Quality in Extreme Adversity (QEA) action framework to benefit from a greater depth of holistic analysis.

These are the research questions:

1. How the Italian healthcare sector can manage business risks during the coronavirus pandemic and grant the same time high levels of efficiency and quality of healthcare services?

2. Is it possible to adopt a new investigation approach to the process of risk management that allows for a complete and integrated vision of all risks each national healthcare sector is exposed to?

2. THE EVOLUTIONARY PROCESS OF ENTERPRISE RISK MANAGEMENT

Risk is a significant component of business management, even for the NHS. In the beginning, the approach to risk management was silo-based and risks were considered unrelated to each other. As a consequence, risk management was not adopted through an integrated approach but used ad hoc for dealing with every single risk under a short-term intervention perspective, thus damaging potentially the entity’s stability and survival in a long period.

The adoption of a holistic approach to risk assessment and management by mapping all risks which an entity is effectively exposed to (with a system of interrelationships and interdependencies) grants a deeper and more clear understanding of current threats and how to transform them into opportunities. Hence, the growing need to develop a more formalized and integrated risk management system capable of assuming an anticipatory attitude towards future critical issues, spread over time.

During the first half of the twenty-first century, all the efforts aimed at protecting the corporate value creation and the resolution of the long-standing issues associated with non-integrated risk management, together with the progressive diffusion of risk culture, materialized into more formalized risk management systems. In 2004 the Committee of Sponsoring Organization of the Treadway Commission (CoSo) issued the first model of risk management and control for enterprises called “Enterprise Risk Management – Integrated Framework”.

According to the ERM 2004, risk management is a process to be defined by the board of directors and top executives coherently with the idea of the corporate strategy and instrumental for guiding all company members to identify and manage risk within the limit of acceptable risk, thus ensuring the achievement of long-term objectives (CoSo, 2004). Moreover, the ERM 2004 defines the risk management process through eight phases strictly interrelated to four categories of objectives (i.e., strategic, operational, reporting, and compliance) each one under a specific corporate perspective. So, by overcoming the traditional fragmented approach to risk management, the company adopting the ERM 2004 model can intercept the correlations between different risks cutting transversely all the levels of the organizational structure (i.e., financial, operational, strategic, compliance) (Caldarelli & Marchi, 2018; Zagaria, 2018). Although this model offers tangible tools for a more holistic and systematized approach to risk management, it has not been adequately adopted, suffering from a jeopardized diffusion. In addition, empirical analyses showed that in the vast majority of cases the disclosure about the ERM formalization was a complaining function for pursuing reputational purposes (Lionzo & Rossignoli, 2013).

In 2016 the CoSo developed a new model for overcoming the limits discovered within the 2004 model and ensuring greater depth of integration

between risk, performance, and strategy, named “Enterprise risk management - Aligning risk with strategy and performance” (CoSo, 2016). The ERM 2016 model was then implemented the next year through the directives of integration, implementation, and commitment, thus turning into “Enterprise risk management - Integrating with strategy and performance” (CoSo, 2017).

One characteristic of the ERM 2017 model is the activation of a constantly evolving cyclical process of risk management, consistent with the corporate risk culture, aiming at supporting the strategic pursuit of the target performances. According to such a dynamic and circular approach, both risk appetite and risk tolerance influence the strategy to be defined. The gap between expected performance and results encourages the review of the entire corporate risk profile. So, the eight phases of ERM 2004 were then replaced by ERM 2017 five macro-areas of risk management cutting across the three lines of action of “Vision, mission, and core values”, “Strategy and business objective” and “Enhanced performance”3 and respecting the corporate risk culture4. Such a configuration of risk management is more integrated with the corporate value system, risk culture, and risk profile, thus allowing entities to fulfill the global value creation (CoSo, 2017).

Over time, the ERM 2017 model stood out for its ability to develop a complete and solid risk control system, creating a network of systemic interconnections between risks in order to supervise the variability of economic performance and pursue the aim of the “Total Quality Management” (Selleri, 2016). The adoption of enterprise risk management (ERM) systems in the healthcare sector was promoted by the dissemination of a culture oriented towards greater safety and focus on an integrated and holistic view of risks under a business perspective, (e.g., Committee on Quality of Health Care in America, 2000; da Silva Etges, de Souza, Kliemann Neto, & Felix, 2019).

In addition, the growing interest in the implementation of ERM models has been encouraged by the requirements to improve the service quality (Haney, Church, & Cockerill, 2013; Bruney & Salter, 2014) and achieve financial equilibrium within the healthcare sector (Gallagher et al., 2006). The tendency to adopt more holistic risk management systems within the healthcare sector reveals a deeper and more sincere awareness of the need to run hospitals with a corporate management logic with a strong orientation towards efficiency (Berkowitz, 2001; Carroll, Nakamura, & Troyer, 2010)5. Currently, the coronavirus pandemic contributed to creating many different interrelated risks which all kinds of organizations have to deal with (Beasley, 2020), especially in the healthcare domain. The complexity and urgency to overcome these health issues while controlling other kinds of treats require organizations to intervene immediately with integrated top-down enterprise-wide approaches to risk management (Beasley, 2020).

Since the core principles of ERM models can lead to a better understanding and awareness of risks related to critical value drivers for healthcare sectors, the adoption of ad hoc shaped ERM models could be the right solution for facing adequately the inefficiencies in pandemic management.

The coronavirus pandemic forced organizations to stop and reflect on the most relevant value drivers, both in terms of processes and technologies, on which were the most important strategic core business drivers to ensure the continuation of the activity (Beasley, 2020). This way of intervention helps to set a risk management process functional to the recovery of equilibrium conditions. Finally, since the risks generated by the COVID-19 are closely interrelated, the activation of concomitant monitoring of obtained results, in contrast with those expected, allows to immediately acquire awareness about the efficacy of risk management strategies, thus assuring a prompt intervention with corrective actions.

3. THE INTERPRETATIVE PERSPECTIVE OF QUALITY IN EXTREME ADVERSITY ACTION FRAMEWORK

The QEA action framework is an innovative approach to the management of healthcare systems capable to improve the service quality in contexts characterized by high adversity (Leatherman et al., 2020). This critical approach comes from an in-depth reflection on how to manage efficiently critical issues within inadequate health care systems. The contexts examined by the studies of QEA are characterized by extreme criticalities, such as deep political instability, civil wars, natural disasters, epidemics, and economic underdevelopment (National Academies of Sciences, Engineering, and Medicine, 2018).

As healthcare systems all over the world are still facing a virulent coronavirus pandemic that threatens humanity’s health and the ability of NHS to adequately cope with it, the investigation on how to manage risks in the healthcare sector by adopting the QEA viewpoint suggests some reflections. The adoption of a more formalized and integrated approach to risk management, as advised by the QEA action framework favors a broader vision on the areas of intervention and on synergies which encourage efficient management of critical issues in the Italian National Health System during the coronavirus emergency.

Although improving the quality of health care is a global need, in this period when the health of all humanity is threatened by coronavirus pandemic it is an absolute priority. Under the QAE viewpoint, steering an optimization of resources offers a health care service in line with the Total Quality Management imperative. When a healthcare system is exposed to significant adversities an integrated study of the critical issues and threats and a careful analysis of the potential health, social and economic consequences allows to understand better potential opportunities for improving efficiency (Caldarelli, Fiondella, Maffeì, Spanò, & Aria, 2013). The QEA action framework proposes some phases to define intervention strategies, such as setting objectives, identifying opportunities and threats to ensure high

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1 The five components of ERM 2017 are the following: “Risk governance and culture”, “Risk, strategy, and objective-setting”, “Risk in execution”, “Risk information, communication, and reporting”, “Monitoring enterprise risk management performance”.

2 “The risk manager learned how to work with and lead interdisciplinary clinically-based teams when the IDS core competence (and risk) was largely clinical. Going forward, the multi-disciplinary approach to risk continues, but the focus must shift to including IDS managers who drive the enterprises-wide business process of the IDS” (Berkowitz, 2001, p. 38).
levels of quality in the healthcare service, establishing a scale of priorities by identifying the medical needs and targets of population, predicting the actions to be taken and distributing tasks, powers, and responsibilities between internal and external actors (Leatherman et al., 2020). The distinctive feature of such an approach consists of guaranteeing a system of interrelationships between strategic activities and a holistic action plan (thus refusing the silo-based intervention logic).

In the Italian Healthcare System, the objectives are defined at the level of the Regional Health System but they respond to the silo-based logic and, sometimes, they are inconsistent with the objectives set at the national level (Caldarelli, Maffei, & Spano, 2012). In fact, the formalization of a hierarchical scale of healthcare services with qualitative targets for each of them allows directing the strategic intervention to address current challenges.

The second phase - identifying the challenges - will be the result of a context-specific investigation that highlights the opportunities to transform current threats into strategic opportunities.

The third phase is defining and ordering a set of priorities to guarantee a quality health system, such as, for example, providing the availability of intensive care rooms for severe coronavirus patients. The adoption of particular governance arrangements within the Italian NHS which accomplish different ideas proved to be fallacious since it generated a disconnection and a lack of interrelation between the initiatives oriented to better service quality (Spanò, Caldarelli, Ferri, & Maffei, 2020).

The intervention choices - the fourth phase of the QEA - constitute an effective action plan aimed at maximizing the quality of the healthcare service at a systemic level (Institute of Medicine, 1990; World Health Organization, 2006). Such proposals must be geared to individual essential needs (Leatherman et al., 2020). Furthermore, the correlation between interventions and specific objectives of strengthening the quality of healthcare services favors the declination of the former in an instrumental and functional key. In the specific case of the Italian Healthcare System, an absolutely urgent line of intervention during the coronavirus epidemic may be improving frontline clinical care and easing access to healthcare facilities in absolute safety. The coexistence of different levels of integrated and coordinated actions can be encouraged by the specific redistribution of tasks, powers, and responsibilities between subjects directly and indirectly involved in the activities of the health sector.

Therefore, the investigation about the state of the art of the Italian Healthcare System through the lenses of the QEA action framework suggests the need to deepen specific territorial criticalities for a rethinking in an integrated perspective for improving the quality of the health care service and creating value for the entire community. Moreover, as suggested by previous studies on ERM models, it is crucial to give to risk culture and leadership a central position inside the organizations’ risk management process, thus ensuring a supportive attitude toward a better understanding of current inefficiencies threatening the right functioning of the healthcare service.

4. SOME REFLECTIONS ON THE ITALIAN HEALTHCARE SYSTEM

The Italian Healthcare System was established in 1978 as a result of the pressures of a corporatization process of the public administration, coherently with the New Public Management movement (NPM). This orientation supports the introduction in the public dimension of the logic of effectiveness and efficiency typical of private companies (Jones & Mussaari, 2000; Jansen, 2008; Lapsley, 2008). Despite recognizing the differences between companies, the NPM claims that only correct economic management could guarantee the achievement of the institutional goals (Zappa, 1956; Giannessi, 1969; Coda, 2003).

The goal of the reforming process, which began in the early 1980s, was to achieve macroeconomic stabilization and microeconomic efficiency. It was a compound process progressively carried out through the issue of three legislative decrees (the first in 1992, the second in 1993, and the third in 1999). These regulatory interventions led to the current organizational structure of the Italian health system, articulated on three different levels: state, regional, and local. The state defines general objectives, uniform conditions of assistance, and necessary resources. The regions delineate the medium-term objectives, any specific purposes, and resources to be assigned to Local Healthcare Companies. At the local level, these organizations (considering national and regional directives) establish independently their own operating methods and offering conditions.

This structure means that the twenty-one Regional Health Services represent a fundamental control center of the Health System. The NHS (National Health Service) becomes a system of SSR (Regional Health Service) characterized by high heterogeneity. The regions cover the role of real holding companies with typical proprietary rights and control powers (Longo, Carbone, & Cosmi, 2003).

Consequently, in Italy the reform process spread heterogeneously, that is some regions lagged behind others. In this regard, some research has highlighted the strong influence exerted by cultural, contextual and governance factors on the different degree of corporatization among the Regional Health Services (Formez, 2007; Caldarelli et al., 2012; Caldarelli et al., 2013).

Over the time, the autonomy of each SSR, the managerial autonomy of the individual companies, and the political influence in the healthcare sector favored the free definition of processes, standards and targets, not guaranteeing uniformity and comparability on the national territory (Caldarelli et al., 2012). Today, the persistence of the aforementioned issues is further emphasized in times of emergency. This warrants a better understanding of crucial
aspects, and calls for the formulation of new questions and modern answers.

The main question lies in the real applicability of business criteria and logics to the Italian Health Service characterized by a high tendency to ally with the political parties (partly due to the high dependence on public funding), the continuous increase in costs, and the progressive accumulation of financial deficits. This supports the thesis that the reform process has sometimes failed to provide mechanisms that concretely incentivize and adequately support decision-making processes.

In the next section, we propose a brief critical examination of the elements of responsibility and complexity that characterize the sector in question, in order to acquire an awareness of the current critical issues and subsequently attempting to develop a response that can direct possible future interventions.

5. ACCOUNTABILITY AND COMPLEXITY IN ITALIAN HEALTHCARE SYSTEM

The compound pressures impinging on the Italian Healthcare System have highlighted the complexity of key health issues, such as greater patient safety and high-quality standards in hospital companies (Kuhllman, Allsop, & Saks, 2009). In this regard, the attempts of reforming had identified the desired way to achieve a reunification between logics of quality and economy in the recognition of the full corporate nature of the health organizations. This reunification constituted the “leitmotif” of the proposed actions, intended to improve performance, optimize spending, and reduce costs. This revolves around two essential guidelines: a) rethinking the consolidated, hierarchical-bureaucratic models - now obsolete and inefficient; and b) introducing more extensive accountability.

The concept of accountability constitutes the necessary starting point to reflect on the implications of the reforms that have affected the Italian Healthcare System. These have often been under the public scrutiny, and even more so at the present time due to the devastating effects of the COVID-19 pandemic.

Since the 1980s, accountability in the public dimension has become an imperative and timely concept to satisfy the pressing requests from stakeholders in search of more comprehensive answers on how to create value, despite the lack of a priori clarification about the meaning of value to be pursued (Porter, 2010).

It has been found that multiple actors with often conflicting objectives frequently determine an unjustified slowdown in performance improvement processes. In the Italian healthcare context, in fact, the achievement of a high value for patients (in terms of health results achieved compared to the financial resources invested) should be considered the primary objective, but it is often obscured by surface conflict dynamics.

Clearly, the value creation and accountability, which are closely interrelated, cannot be separated from the need for renewed resource distribution systems and the need for measures able to spread fair competitive and managerial logic.

The undeniable efforts made to achieve systematic conditions of service quality and the economy did not guarantee the expected result. The causes of persistent incompleteness, which are more evident today than ever, are numerous and very heterogeneous.

First of all, the accountability needs clash with the complicated relationship between the accountee - who delegates the health protection function (principal) - and the accountant - who has the responsibility to carry out this task (agent). A certain degree of confusion is evident about the following points: a) the identification of these figures; b) the understanding of which actions or results should be taken as a reference to empower the agent; c) the criteria to be adopted to judge their work; d) the most appropriate ways to reconsider decision-making processes in light of the results of the evaluations.

In addition, the pressure to contain expenditure and cut costs has sometimes led to sudden interventions implemented in an "emergency". This has directed managerial action towards an efficiency-oriented perspective that can only be guaranteed formally, rather than through a substantial rethinking of processes, procedures, and practices. Therefore, the adopted solutions demonstrated to be unable to grasp the aspects related to the difficult dialectic between economic-managerial problems and clinical processes, which is an intrinsic connotation of the healthcare sector (Jacobs, Marcon, & Witt, 2004). This has often accentuated the gap between economic and clinical management, reinforcing, and not mitigating the primary causes of those uncontrolled increases in spending. Repeatedly, the change was conducted as a crusade, without clarifying its boundaries, areas, objectives, methods, and priorities; hence, triggering conflicts between managerial teams and professional groups.

On the one hand, managers preferred a top-down leadership style, thus overlooking clinical and social implications requiring a phase of listening and consultation with the specific professionals involved. On the other hand, the professional groups resisted the introduction of planning and control tools, often reducing their usefulness, since they saw in them a threat to their autonomy rather than an opportunity to improve performance (Jacobs et al., 2004; Kurunmäki, 2004).

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8 The corporate governance system in Italian healthcare companies is characterized as follows. The Direttore Generale (CEO) is the most important person as he/she has great decision-making and administrative power inside the healthcare company. The CEO is appointed by the head of the regional council with a renewable contract, thus highlighting the strong influence of political bodies inside the Italian healthcare system. Since the regional councils assume the supervisory role upon CEO and organization’s performance, inside healthcare company there isn’t any board of directors. For Decree 229/1999 each region has the authority to choose a specific model of corporate governance for the local healthcare company, so Italian healthcare system can be affected by a varied heterogeneity in governance structures (Baroni, 2004; Caldarrelli et al., 2013).

9 Gamm claims that “Accountability of health services organizations is defined as taking into account and responding to political, commercial, community, and clinical/patient interests and expectations. Accountability is the process by which health leaders pursue the objectives of efficiency, quality, and access to meet the interests and expectations of these significant publics” (Gamm, 1996, pp. 74-86).

10 An interesting point of view on the situation of the Italian Health System affected by COVID-19 is provided by Armocida, Formenti, Ussai, Palestra, and Mosconi (2020) which identified three issues that should be considered. The first one is “the Italian decentralisation and fragmentation of health services seems to have restricted timely interventions and effectiveness, and strategic coordination should be in place”. The second one is “hospital care systems capacity and financing need to be more flexible to take into account exceptional emergencies”. The last one is “in response to emergencies, solid partnerships between the private and public sector should be institutionalised”.

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Another element of complexity is the difficult, and often overlooked, identification of roles and responsibilities within these organizations. In the absence of a clear definition of these elements, the planning and control systems envisaged for Italian healthcare companies are ineffective, turning into a mere expedient of external formal legitimation, with strategic and operational repercussions.

In addition, there are some concerns about performance measurement and evaluation issues. The doubts concern the clear identification of objects and subjects of the evaluation. Furthermore, it is often difficult to quantify certain aspects of both administrative and clinical performance. The uncertainty associated with the lack of commonly accepted indicators and criteria to support such processes is another critical aspect itself (Miller, 2002; Anthony & Young, 2005; Lapsley, 2008; Eeckhout, Delesie, & Vleugels, 2007). A matter of central importance pertains to the identification of the subjects assessed and the evaluators and their separation, especially in contexts characterized by high politicization.

Finally, it is important to underline the critical issue linked to the risk dimensions in the areas under examination, and to the need/difficulty of identifying, monitoring, and mitigating heterogeneous and very complex risk dimensions, capable of devastating impacts on the Italian Healthcare System.

6. CONCLUSION

The present paper offers some reflections on potential future implications for accountability and risk management in the Italian Health Service during the period of the COVID-19 pandemic. The emergency situation generated by the pandemic – accentuating exponentially the problems of the Italian Health Service – forced the organizations to deeply reflect on the most relevant value drivers, both in terms of processes and technologies. It is clear that in this context it is necessary to guarantee an increased level of quality and accountability and a more integrated risk management system in order to recovery previous equilibrium conditions.

This study initially provides a brief discussion on the theoretical models of risk management and their evolution in doctrine and practice. Then the analysis is dedicated to the logic of Quality Extreme Adversity, with reference to a rethinking of management and control guidelines in the healthcare sector. Subsequently, the paper addresses the main problems relating to the Italian health context, then focusing on the main elements of accountability and complexity that characterize this sector.

The idea of the paper, in summary, is that a QEA logic could and should stimulate a theoretical reflection and a practical push toward better implementation of risk management systems. Indeed, the adoption of a framework is a revealing instrument for the challenge of recognizing the characteristics of unity and integration in the Italian Healthcare System. Moreover, it could represent a crucial expedient to deeply rethink the consolidated and fallacious approaches adopted before.

In conclusion, the paper suggests approaching healthcare services with an inverse logic, i.e., starting from driving forces at local levels that contribute to the integrated definition of objectives, methods, and tools at the regional level – further consolidated at the national level. This reversal viewpoint could be helpful in favoring a logic of risk management integration and increasing levels of quality and accountability.

In this sense, this study is based on the question that in the healthcare sector the value creation must go through integrated risk management to achieve increasing levels of quality and accountability. To guarantee this, it is necessary to focus on the context and culture dimensions representing the main factors capable of simplifying or complicating any process of change. What emerges is that neglecting the implications of the context and culture dimensions in the Italian Healthcare System represented a significant and binding limit. A further in-depth study of the abovementioned dimensions could be helpful to build a common and integrated context and culture.

This study has some limitations. First of all, it examines only the Italian Healthcare System which, with its peculiarities and long-standing issues, cannot be compared to any other national healthcare system. In addition, the research perspective is influenced by critical phenomena resulting from a unique historical context, i.e., COVID-19 pandemic, in which the healthcare systems from all over the world are called to make their important contribution to saving humanity.

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