Biopolitics, Risk and Organization in Health Care

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Abstract
The study and analysis of the organization in health care depends on some aspects that include the observation of social phenomena, law categories, and political strategies as well as the administrative behaviors. All these aspects have led to the overcoming of the traditional concept of bureaucracy, which finds a solid theoretical foundation in the studies undertaken by Weber. In the Weber's vision, bureaucracy is the organization of people and resources for a collective purpose, public, according to any criteria of rationality, impartiality and impersonality. The assumption is that it is hard to perceive organizations oriented towards an end in a rational way, unless as bureaucracies, even considering that there may be non-bureaucratic organizational forms, not rationally oriented to a purpose (Weber 1922). One of the most original contributions of the late twentieth century comes from Luhmann's theory of social systems that is applied to the concept of organization. It provides an understanding of the object that goes beyond tautological assumptions (e.g. the organization is composed of men) and that permits to talk about organization as autopoietic system, not "closed" but "operationally closed" and therefore independent on the structural and operational plan (Luhmann 2000, 29-30). In the theory of systems - although the organizations may arise freely – what is defined as "complex" organizations, are formed within functions systems distinguished in economic organizations, political organizations, trade union organizations, health care organizations, etc. Main features include the possibility that they have to communicate with other systems in their environment (Luhmann and De Giorgi 1994, 328) and the reduction of uncertainty and risk. The absorption of uncertainty occurs when an organization elaborates some decisions that are a prerequisite for other decisions. In the social systems theory, all the organization activities are classified as decisions, take place at a given time, and are always documented. However, the evolutionary path that is used to trace the organizational profiles of complex apparatus cannot ignore the importance of Kuhn's theory, according to which scientific revolutions are characterized by the transition from one paradigm to another (Kuhn, 1999). The application of this latter model to the public organizations, permits to understand that even these organizations are subjected to the dynamics of cultural paradigms, according to which the transition from one paradigm - that no longer recognizes the organizations themselves - to another one, that rather includes new models, methods and practices, definitely involves a revolution (Limone 2008, 17). In order to properly talk about organization and e-government, especially in the health and medical sector, we first need to verify the most suitable organizational context able to manage innovation solutions and, therefore, analyze the organizational conditions as a prerequisite for the technological conditions. In fact, if the organizational environment does not respond to concrete parameters such as transparency, efficiency and economy, even the same e-government process is likely to fail. That is the only viable way to rationalizing and improving the public organizational system, such as health care systems, that tend to have high level of complexity and risk due to their nature.

Keywords: organization; risk; health care; integrated governance

1. Introduction: historical and evolutionary trails

The organization of the current complex structures - in particular the organization of health care facilities - depends on some aspects that include the observation of social phenomena, law categories, and political strategies as well as the administrative behaviors. All these aspects have led to the overcoming of the traditional concept of bureaucracy, which finds a solid

theoretical foundation in the studies undertaken by Weber.

In the Weber's vision, bureaucracy is the organization of people and resources for a collective purpose, public, according to any criteria of rationality, impartiality and impersonality. The assumption is that it is hard to perceive organizations oriented towards an end in a rational way, unless as bureaucracies, even considering that there may be non-bureaucratic organizational forms, not rationally oriented to a purpose (Weber 1922).

The Weber's studies have been developed later on through the contributions of Merton, although with different epistemological assumptions. Merton envisions his model by performing an ambivalent step: a) on one hand, he criticizes the rationality concept of bureaucracy in the Weberian model by using a functional approach; b) on the other side, he retrieves some elements of Weberian analysis for making criticism on his ideal model. In addition, Merton makes a distinction between the overt functions and the latent functions. Only with the analysis of latent functions, he shows that the Weber's model contains some sources of irrationality even with respect to the purpose, which do not consist in deficiencies in organizational design, but in the unforeseen effects that the pressure exerted by structures can provoke on the personality and behavior of men (Merton 1968).

In the seventies, Gouldner makes a change in the rules of Merton's scheme in tayloristic terms: he adopted a critical functionalism on the distinction between manifest and latent functions, able to identify the latent functions of measures, norms and institutions (Gouldner 1973). He identifies three key regulatory models of the bureaucratic action: a) the apparent bureaucracy, which occurs when both the directors and the employees have indifference attitude towards the respect of a rule imposed by an outside authority; b) representative bureaucracy, which occurs when both the directors and employees agree on the usefulness of observing certain rules; c) the taxation bureaucracy, which occurs when the rules are imposed from one side against the will of the others (Bonazzi, 2008, 232-235).

The Selznick's theoretical model, developed through a structural-functional analysis (*critical functionalism between Parsons and Merton*), shows a theoretical method that is intended to have general validity for any formal organization which has an internal bureaucracy. In particular, he introduces *The institute of cooptation* (defined as the process of absorption of new elements in the structure that determine the organization policy, as a way for preventing threats to its stability or existence) and performing, then, a further distinction between formal cooptation and informal or substantial cooptation (Selznick, 1969).

Crozier is primarily interested in some aspects such as safety, regularity and the impersonality of the functioning that are only found in the public administration entities. The issue that arises regards the functioning of such organizations and the social relations that exist within it, moving away from the post-Weberian functionalisms when they consider the difficulties of the change in bureaucratic organizations and when they highlight the relationship between technological innovation opportunities and the growing autonomy and cultural sophistication of individuals. In particular, (Crozier 1994, 22-27) Crozier carries out a pejorative interpretation of bureaucracy term: he conducts a strategic analysis of bureaucratic behaviors and defines power as control of uncertainty, highlighting the importance of National cultural models (Bonazzi 2008, 266-273).

In the eighties, the overcoming of the traditional bureaucracy was mainly defined by the managerial literature attributed to the studies of Drucker and Mintzberg, in which the "management by aims" model proposed by Drucker (Ivi, 287), may be viewed as specular antithesis of the traditional Weber's conception of bureaucracy. In this model, they provide an open debate beyond the hierarchies; the identification and negotiation of aims; the personalization of social relations; the acquisition of skills on the field; mobility in the career path and the majority attention given to the purpose rather than to the norms, as well as a form of "competitive democracy" at the workplace (Ivi, 292). All these factors result in a complete reversal of the axioms of the traditional Weberian model.

One of the most original contributions of the late twentieth century comes from Luhmann's theory of social systems that is applied to the concept of organization. It provides an understanding of the object that goes beyond tauto-

logical assumptions (e.g. the organization is composed of men) and that permits to talk about organization as autopoietic system, not "closed" but "operationally closed" and therefore independent on the structural and operational plan (Luhmann 2000, 29-30). In the theory of systems - although the organizations may arise freely – what is defined as "complex" organizations, are formed within functions systems distinguished in economic organizations, political organizations, trade union organizations, health care organizations, etc. Main features include the possibility that they have to communicate with other systems in their environment (Luhmann and De Giorgi 1994, 328) and the reduction of uncertainty and risk. The absorption of uncertainty occurs when an organization elaborates some decisions that are a prerequisite for other decisions. In the social systems theory, all the organization activities are classified as decisions, take place at a given time, and are always documented.

However, the evolutionary path that is used to trace the organizational profiles of complex apparatus cannot ignore the importance of Kuhn's theory, according to which scientific revolutions are characterized by the transition from one paradigm to another (Kuhn, 1999). The application of this latter model to the public organizations, permits to understand that even these organizations are subjected to the dynamics of cultural paradigms, according to which the transition from one paradigm - that no longer recognizes the organizations themselves - to another one, that rather includes new models, methods and practices, definitely involves a revolution (Limone 2008, 17). In order to properly talk about organization and e-government, especially in the health and medical sector, we first need to verify the most suitable organizational context able to manage innovation solutions and, therefore, analyze the organizational conditions as a prerequisite for the technological conditions. In fact, if the organizational environment does not respond to concrete parameters such as transparency, efficiency and economy, even the same e-government process is likely to fail.

The building blocks of the new paradigm reveal the need to pay attention to the reorganization of structures and internal functions (back-office) even before external activities (front of-

fice). The systematic intervention on the back-office ensures, in fact, that technological innovation is the same for the front office. That is the only viable way to rationalizing and improving the public organizational system, such as health care systems, that tend to have high level of complexity and risk due to their nature.

2. *Organization in health: risk and quality*

The concept of clinical governance was born in England, in the late nineties of the last century, within the politics of organizational strategies and regulatory system of the British National Health Service (NHS). The adoption of this concept comes from the first interventions on the quality management of health services that is meant as institutional duty shared among clinical professionals, experts in organization, health professionals and, in particular, policy makers. In the philosophy of clinical governance - according to NHS's guidelines largely accepted by our National Health System (SSN), organizations are responsible for the continuous improvement of the quality of their services and the safeguarding of elevated standards of care, through the creation of an environment in which the excellence in clinical care need to flourish (NHS, Department of Health, 1998).

The clinical governance can be considered as a new expression that may change the cultural system totally. In these terms, it provides resources to develop organizational skills oriented on sustainable health care, focused on patient, along with guaranteed quality that is necessary for the different stakeholders. In this perspective:

· Patients needs are in the spotlight of clinicians and administrators, who take shared responsibility,

· Information related to the quality of services are available to professionals, patients and the public,

· Differences in performance access, care processes and clinical results are measured with the continued commitment to reduce them,

· All organizations work together to continuously improve service quality,

· Professionals work as a team to deliver better performance in terms of clinical outcomes and safety,

· The risks and dangers to patients are brought to the lowest level,

· Health care is based on evidence and on good clinical practice.

According to this approach, the concept of clinical governance implies that the management of power takes place inside and outside the formal decision tree; these decisions arise from the interaction between the various stakeholders. Any person involved in the process becomes the bearer of specific needs and expectations, different scale of priorities and different capacity of perception of the results obtained (Wright, Hill 2005, 22-23). However, it is interesting to observe that once it is stabilized the process of clinical governance, the problem becomes its integration with all the other elements that constitute the different aspects of the management of health care organizations. Integrated governance is a further concept introduced for the first time in England in 2003, with the document entitled: "Governing the NHS: a Guide for NHS Boards (NHS Appointment Commission, 2003). The aim of this document is the integration of the different sectoral systems of governance (health, clinic, financial, management, research and information) and delete the existing overlays, in order to standardize (harmonize) different basal processes. The need for an integrated approach is based on the recognition that working for sectors - in a not shared way - is scattered and unproductive, so it is necessary to develop a unifying methodology that helps the organizations to realize their mission and reach the objectives (Wall, Halligan, Deighan, Cullen, 2002).

The concept of integrated governance goes beyond the corporate governance that is defined as the set of rules and organizational structures by which companies are managed and controlled. Health facilities (especially public ones) are considered as a constellation of several complex systems: there is the system of hospital care and the one related to primary care, the system of professional clinicians, and the one of professionals in organization, the system of the most important centers and the one in peripheries (Wright, Hill, 2005, 25).

The management philosophy of integrated governance also includes risk management, a methodology employed in health care settings but derived from the financial sector and that,

in essence, involves the management of all those risks that threaten the value of an organization and that involve different aspects and different dimensions of organizational phenomenon: strategies, market processes, financial resources, human resources, technologies. However, the application of this methodology in the field of health care, cannot collapse in the transfer *sic et nunc* of principles and techniques designed in the industrial sector, financial or of the ICT (Novaco 2004, 24), although it is clear that even a health care company must deal with many risks that go beyond a particular risk and encompassing any general risks that any organization, regardless of the sector to which they belong, must know how to manage in terms of total quality.

Literature on organization, mainly from North American, was concerned to provide the definition of quality in health care systems and to draw up specific models (Donabedian 1966; Devlin 1990; Charlesworth 1993, 25). In 1984, Maxwell developed a model that includes six fundamental dimensions aimed to obtain efficient and effective level of quality in health care: 1) access to services; 2) the significance of collective needs (of the community); 3) the practical effectiveness for the "person" (individual patients); 4) the fairness and impartiality in the treatment; 5) social acceptability of the service supply; 6) the efficiency and economy of the service rendered (Maxwell, 1984, 1470-1472).

The study of Maxwell can be considered suitable for responding to the following questions:

a. Is the service physically and temporally accessible to the persons to whom it is addressed (in terms of physical accessibility and time)?

b. Do services, processes and procedures reflect the community and individual needs?

c. Does every single service allow obtaining the benefits or providing desired outcomes for individuals or groups of patients?

d. Is the service provided in an unbiased manner between the various categories or groups of patients?

e. Are the conditions for the provision of the service, the level of protection of privacy, the communication grade with patients, families and assistance team satisfactory?

f. Are the resources employed in the processes and in the phase of supplying services, used without waste?

g. Do detailed rules for the provision of the service (and those who provide it) meet the security measures that have to minimize the adverse effects of a treatment?

In any case it is observed that - regardless of the model used - the priorities linked to the respective principles depend on the needs and expectations of the parties involved that, in the health sphere, correspond to patients (beneficiaries of a service or a specific treatment), to professionals (medical staff and social health), managers (management and administrative staff) and finally to who really pays the service apart from services and performance received (taxpayers) (Wright, Hill 2005, 5-6).

A particular aspect related to health services quality, concerns the management of total quality (*Total Quality Management*), defined as a continuous improvement of quality (*Continuous Quality Improvement*) when it addresses to an organizational effort aimed at improving the overall performance. The key principles that are at the basis of the total quality management, are realized when: (a) the success of the organization resides in the accession of all its components to the needs of those who benefit from the service (patients); (b) quality is a consequential effect of the production processes in which the causal interactions are complex but understandable; c) the personnel involved in the process is intrinsically motivated to work with dedication and keep ethically corrected behaviors; d) the use of simple statistical methods associated with a correct collection and analysis of data, can constitute an effective procedure for the identification and understanding of problems related to operational processes and identification of risks.

In conclusion, total quality management implies the focus on operations and on expected results, analysis and the consequent identification of the needs of patients, analysis of the variations in processes or in results, the existence of multifunctional working groups for identifying and resolving quality issues, the use of data collected in a systematic manner at any point of the *problem solving* process for high-priority issues, causes, possible solutions and changes, learning and continuous improvement, process management tools to increase the effectiveness of working groups such as, for example, flowcharts, cause and effect diagrams, brainstorming, benchmarking (Wright, Hill 2005, 8).

3. *The clinical risk and the safety of the patient*

A correct definition of risk comes from the analysis of risk within the chain of genesis of the damage, with the purpose to clearly distinguish the different phases that often, in common parlance, are confused by the use of generic terms. The strategy is to start from some definitions laid down by the *Occupational Health and Safety Management system* (OHSAS 18001: 1999). In particular, it is distinguished between: a) hazard, situation or cause that enhances the damage; b) incident, occurrence that may give rise to damage; (c) accident, unexpected event and unfavorable cause of a damage.

These terms describe the stages of the chain by which it is generated a damage: the hazard represents an existing danger, which becomes a potential source of damage when it overlaps with an activity (e.g. the routine activities of a department or a health care facility). Sometimes, especially in health care, the link between activities and danger is so narrow that they may not be readily cleaved. This overlap determines the possibility that the danger is translated into an adverse event and this probability is the risk (risk) that may give rise to an incident, followed by a damage (accident). What binds event and damage are often unpredictable and fortuitous factors and very large number of events, which occur in the health and in other sectors without bringing any significant damage, demonstrates the lability of this bond. If the management of risk, in the health sector, is related to systematic processes of identification, assessment and treatment of actual and potential risks, the goal is focused on increment in safety of patients, to the improvement of the *outcome* and the indirectly reduction of costs, with a consequent reduction of preventable adverse events. For this purpose, the health care organizations - as it happens in industries and in other sectors - should analyze adverse events by using rigorous investigation techniques, in order to remove the system errors that are at the basis of such events.

In U.S., the publication of the report: *To err is human: building a safer health care system* (Washington, Institute of Medicine, 2000) allowed the starting of a series of researches on human errors in medicine. The report outlines a comprehensive strategy among government, market, patients and health services that try to reduce errors in medicine by inviting the Congress to realize a National-popular center for safety of the patients, who develop new tools and systems needed to solve this problem.

This turning point significantly contributes to analyze the relationship between ICT and risk management as part of the more general situation regarding the quality and safety of services (Esteves, Joseph, 2008). ICT are, in fact, powerful tools to support the organizational structure, decision-making processes (*Clinical Decision Support System, Health Technology Assessment*) and the monitoring of risk governance processes *(Clinical Data Repository, Electronic Medical Record)* (Friedman, Halpern, Fackler 2008, 69-76). However, this approach must take into account the transition from a purely reactive system (management of non-compliance, emergency management etc.) to a predominantly pro-active and preventive system.

A further aspect is the increasing attention on safety at all organizational levels. Adverse events are undoubtedly a problem of quality of care, and to that extent, they have a purely clinical relevance, but also have economic and social implications linked to the costs incurred by the health care facility that cause a general problem, but not less relevant, that is the loss of confidence of the population against the health service.

In this perspective, the safety of patients, assumes an importance that involves all phases and aspects of the organization. The lack of integration between the different organizational levels or the predominance of some over others, determine the loss of essential components of clinical risk management that lead to a partial vision and therefore not fully reliable.

If it is true that the primary purpose of a health care company is the protection of the health of patients and population, it is also evident that the strategies of *risk management* must be mainly oriented on prevention and risk management in accordance with the principle of Ippocrate *primum non nocere* (Reason 2004, 25).

In recent years, the safety of the patients was placed as a priority of the health services in many countries and this centrality could not be attributed to the occurrence of particular events, but rather to the dissemination of reports and epidemiological studies relating to iatrogenic damage. In the face of this importance, the management of risk becomes the strategic function of *a learning organization* model, i.e. an organization capable of sharing its knowledge, learn through participation in the various experiences and improve through the dissemination of new knowledge and culture technical-professional that characterizes it.

The cultural approach to the safety of the patients has a relief that cannot be overlooked, especially if you consider its bond with what is the vision of "Error" on which it is based. The determinant is found, in fact, in the passage from a vision of the error, as cause of system failure, to the vision of error generated by the complexity of the system itself.

The scientific and technological progress, the exponential process of specialization of medical sciences and the increasing organizational complexity, contribute to the increase in medical errors, although it has increased the awareness of the rights over time and thus the demand for greater transparency, clarity, accessibility, intelligibility and safety (Gainotti, Poppi 2004, 61). The debate on the issue is very intense and rich of paradoxes, "on one hand, no century has known such overwhelming progress in biomedical treatments and pharmacological properties as the twentieth century […], and everything suggests that the increasing pace of innovations diagnostic, therapeutic and rehabilitative services will continue. However, now as never, the uncertainties and suspicions are deep and widespread in fields such as science, basic health practices and in the chance of healing, as well as to ensure equal health care practice for not guaranteed patients "(Ardigo, 1997). According to this claim, the success of medicine is at the basis of its own weakness. Nowadays, failures that occur in diseases that were incurable in the past, are no longer perceived as tolerable but become errors. In addition, the hard and visible dispute between patient and clinician in the health care environment is becoming physiological. Today, patients expect to be guaranteed in terms of security and they demand to be in-

formed about all the risks associated with clinical practice, but, at the same time, clinicians feel heavily the risk of having transparent communication and free of complaints. That causes a gradual distancing and an unfair degradation of the fiduciary relationship between the parties involved, a fragile "wall of silence" (Gibson, Sing 2003) that is often subjected to attacks by the media and the specialized press. These situations lead medical staff to assume precautionary behaviors and the recourse of the so-called "defensive medicine".

In conclusion, in the relationship between clinical risk and patient safety, the recall of a socio-political role of active dialogue in drawing up strategies means, for the health system, the recognition and the assessment of risk, investing resources, introducing evaluation systems and organizational practices for proper management and prevention, making public the results (Cavicchi 2007).

The consuetude to provide data and information regarding clinical practice or other achieved performance data, lead to an internal comparison able to certainly increase the knowledge in a logic of community *empowerment*. This may gradually transform the cultural model in a model primarily oriented to the reconstruction of the fiduciary relationship between clinician and patient, despite the obvious difficulties concerning the measurement of the *outcome* in health.

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