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Evaluation of the Health Care Performance after the Process of Humanization:

to measure social dimensions of health services.

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Introduction

Quality improvement is one of WHO's and national health policies' primary goal; if quality is meant as equity in access, life quality, patient satisfaction, and a cost-efficacy use of resources, quality improvement leverages organizational culture and the relationship among healthcare system's stakeholders.

Each country has to develop its own quality definition in agreement with its own culture, values, population expectations; nonetheless, OECD countries are facing common problems in terms of dissatisfaction towards the insufficient quality and high costs of health services. «In all countries, both health and long-term care will be driving up public spending. …For OECD countries average public health care expenditure is projected to increase from 5.5% of GDP in 2010 to 8% in 2060; whereas public long-term care expenditure is projected to increase from 0.8% to 1.6% of GDP in 2060» (OECD, 2013, 7). In simple words, industrialized countries' expenditures in healthcare increase more than the economy as a whole (Rebba, 2012). The causal factors of the increasing health expenditures are demographic and epidemiological events, such as the lengthening of life spans, the improvement of quality of life, and the development of chronic diseases, which increase a long-term care demand. Hence, health systems are challenged by the need of guaranteeing public healthcare's economic and finance sustainability, ensuring equality of access and quality of care. However, long-term interventions should be preferred, in order to favor citizens co-participation in health financing, to monitor performance volumes and prices, define a maximum cap of expenditures.

Because of current economic crisis, health care role is increasing in term of helping citizens reaching their individual well-being. Sure enough, to cure pathological conditions means also to promote a general person's well-being (in line with WHO); this, however, requires more resources than the available. Health care system has to employ the available resources to support citizens dignity, guaranteeing them the opportunity to take their own decisions and to satisfy their aspirations. In other words, health care has to offer citizens the best opportunities to rea-

lize the life they want to live, working on a global individual well-being, protecting the environment where people live, beyond taking care of their individual physical health conditions. Health promotion consists of the increase of population ability to control and improve their health; therefore, governments, social and health workers, voluntary associations, and citizens themselves are coordinated actors working on a strategy dealing with territorial needs determined by social, economic and cultural specific conditions. This is the reason why WHO talks about the strengthening of community action as previous requirement to reach a community empowerment by developing the existing human and material resources to enhance self-help and social support and to obtainflexible systems to strengthen public participation at and direction of health matters. «Health services need to embrace an expanded mandate which is sensitive and respects cultural needs. Reorienting health services also requires stronger attention to health research as well as changes in professional education and training. This must lead to a change of attitude and organization of health services, which refocuses on the total needs of the individual as a whole person» (WHO Europe, 1986, 3).

Furthermore, urgent requests of self-determination are advanced by citizens in our complex societies, entailing a change into care interventions toward patients as stakeholders and as a whole human beings. Health systems have to redefine their supply, in order to offer person-oriented services; the relationship between providers and consumers has to value and mobilize patient's participation into his/her wellbeing promotion. In addition, the necessity of guaranteeing and encouraging citizens' rights protection arises, in term of receiving accessible high quality services - from both a professional and relational point of view - that are designed around the person as-a-whole.

Consequently, "humanization" is the process of transformation of health care aimed at keeping together all the individual dimensions - physical, psychological and relational - contributing to the person's wellbeing or health, promoting patient's activity in the patient-doctor relationship (Toia, 1991; Fappani, 1991). Patients become interlocutors in the medical relationship, then a subject rather than

an object; indeed, the patient is not anymore a group of symptoms, damaged organs and altered emotions, but a human being who feels emotions and needs both clinical and personal help and support (Hellĩn, 2002). The Ljubljana Charter issued by WHO states that «health care reforms must address citizens' needs taking into account, through the democratic process, their expectations about health and health care. They should ensure that the citizen's voice and choice decisively influence the way in which health services are designed and operate. Citizens must also share responsibility for their own health» (1991,1). As interlocutor, patient plays an active role in the entire decision-making process, expressing his/her opinions, evaluating the several options, taking effective choices.

To summarize, the process of humanization of health services concerns many changes useful to achieve health services' quality and effectiveness; in particular, patient empowerment as self-determinacy and involvement at the treatment decision-making, autonomy in the disease-management and participation in the health performance assessment. Health performance itself changes because it adopts a new idea of patient, who is at the heart of the whole healthcare process. Health assistance is no more diagnosis/treatment-centered — so doctor-centered — but patient-centered and some authors even talk of people-centeredness, in order to bright up the importance of healthcare inside a community framework, especially in dealing with chronic diseases.

Regarding my research project, the starting point of my work has been my the interest toward quality in health care, conceiving health as a social right guaranteed by the Italian Constitution. In Italy, health has a long tradition as recognized and guaranteed citizens' right, even though only in 1978 it has been institutionalized within an integrated system of healthcare. But quality, which is a goal of the health services supply, has become also an issue for health organizations insomuch the contraction of the available economic resources has limited the possibility to offer a high-quality health service to the whole population. Even though the financial stringency is a global condition and inevitably affects Governments' policies, it becomes a urgent problem to solve insomuch involves health, that in

Italy is a value whose quality is protected by the Constitution. Consequently I have considered quality of health care as presenting two main dimensions: one dealing with health as a social value to guarantee and another dealing with the management of health services. Even though the managerial dimension should be developed in order to support the achievement of population's health, it prevails as an independent goal in the health organizations' administration and planning of services. Hence, my goal has been to analyze how the two dimensions of quality are related and may be combined in order to achieve the highest level of quality in a context of reducing resources..

The first chapter presents the historic evolution of health protection in Italy through the perspective of the Italian healthcare as a public service utility subjected to the "responsiveness-réactivité", that is the ability to respond to citizens' social and health needs providing integrated services (Alfano, 2003). I will describe the succession of the theoretical approaches adopted to structure the health system, passing from the organization of health service as a sector of public administration to the one corresponding to a private corporation model (what is called "aziendalizzazione"); changes in the payment/reimbursement system; changes in assistance provision towards the personalization of services. In my opinion these changes have received a strong theoretic and ideological support but have not received the same amount of evidence-based analysis; the Italian frame has always been intricate and affected by cultural issues, such as clientelism and bureaucratism, that are getting more and more influential because of the unreasoned and unjustified implementation of purely economic models in healthcare. Finally, I will list the advantages and disadvantages of the Italian health system.

The following chapter focuses on the process of humanization of health care services as a source of value for citizens. The evolution of the relationship between doctor and patient will be described through social theories, from the doctor-centered till the patient-centered perspective, which evolved from mutuality to a collaborative decision-making. The main aim is trying to understand how to reach the health of both single person and the community within the relational dimen-

sion of care and its performance. In simple words, it is necessary to overcome the naturalistic model of health where quality is only a technical-professional performance's dimension, to move toward a model of collaborative decision-making, in which quality consists of two dimensions: the healthcare performance and the relationship between physician and patient, on a singular level, and among all the healthcare stakeholders, on a more general level.

Then, Chapter III analyses the general concept of quality in health care systems. First of all I will report and discuss the definitions of quality of care presented in the international literature which is mainly a US one, trying to keep in mind the basic differences between the US Health care model and the European welfare state system, particularly in its Italian version. . In fact my main goal in doing this is to underscore that the definitions and implementations of quality in a system where health care is mainly a service supplied within a market relation might not be fully applicable to a system where health care is mainly the provision of a constitutional social right; and thus to highlight the peculiarities of the Italian health system, avoiding a blind application of american management healthcare model to the Italian context without any kind of adaptation to its history, conditions and goals. In addition, I will study the definitions of quality of care within health systems meant as complex organizations, hence within a general management theoretical frame.

Chapter IV is focused on the process of assessment and evaluation of health systems. Quality assessment seems to me the main connection point between quality implementation and patient-centeredness. The theorization of healthcare quality has a solid tradition in literature and legislation, while the development of evidence-based models of quality assessment, whose validity is recognized and accepted, is still ongoing and somewhat disputed. After a review of the definition and history of Health Systems Performance Assessment models, the methodological and socio-political issues dealing with the “measurement” of the quality of health performance will be delineated. Indeed, in my opinion the procedures adopted to assess quality should take into full consideration also the relational as-

pects of care, which are instead usually put aside in favor of the technical or economic ones.

Finally, the last chapter focuses on the patient-centeredness in the organization and quality assessment of Italian Departments of diabetes, which have been chosen as a case study because diabetic patients are involved in a long-term (even life-long) relationship characterized (at least a priori) by empathy, knowledge of the system, and a first-hand understanding of department assistance's strong and weak points, possibilities and limitations. Hence, diabetic patients seem to have the right expertise to be an active actor in the entire process of health assistance design and evaluation.

After a brief analysis of the indicators adopted in the performance quality assessment of Italian Diabetes clinical departments, I will move to the two case studies, a Tuscan and a Sicilian Department of Diabetes, in order to understand how quality is defined within the department, which one of quality's dimensions prevails, and in which phases patient-centeredness is actually taken into consideration.

Chapter I

How the promising propensity to change of the Italian National Health System has been braked by legislative red-tape and stake-holders' resistances.

1.1 An overview of the Italian Health Care System.

The Italian National Health Care System is a public health system designed in line with the Beveridge model, whose value lies in a centralized structure providing a «universal coverage for comprehensive and essential health services through general taxation», with the aim of «supply a uniform capacity of response for citizens» (Nuti, Seghieri, 2014, 71). The model consists of, first, a social protection system able to assist citizens in any critical moment of their life — such as unemployment, accidents at work, sickness, old age —; second, a universal and accessible health assistance provided for free to any citizen independently from his/her economic or social conditions, from the cradle to the grave as Churchill used to say. The 1942's Beveridge report gives birth to the welfare state in order to solve the social problems caused by first industrialization. So government takes control of its citizens' security and socio-economic wellbeing through a centralized system financed by general taxation; in particular, any individual contributes to the system according to his/her economic possibilities, but receives assistance in line with his/her needs.

Local Health Units in the National System are considered as public organizations because they belong to an institutional system providing a public service; this means that they respect the rules of a hierarchically structured public service which works out of a market or price regulation. In addition, the Italian health system works on personalizing its service by the integration and coordination of its structures in order to to respond to the singular patient needs. So, strategic-organizational choices are designed linking interdependently the productive pro-

cesses, as much as clinical, administrative and certification practices, aiming at the stakeholders mobilization. By doing so, health planning would get visibility and political legitimation (Tanese, 2002). Many sources showed that this can happen only if health system would considerably invest in technological updates, modernizing its structures and technologic tools, hence empowering cure and information systems (Borgonovi, Zangrandi, 1988).

The Italian health system provides essential public services apt to implement the enjoyment of important constitutional rights; this is made explicit in the Presidency of the Council of Ministers' directive (issued on January 27th 1997) listing the principles health services have to respect. In particular, patient equality in term of uniformity of supplied services and absence of discriminations (neutrality); efficacy; efficiency and continuity of services; patient's right to choose a service among the ones available in the community and to participate at the service itself; patient's right to receive a correct performance and to facilitate the cooperation among suppliers. To strengthen these principles, the National Health Plan for 1998–2000 prescribed further principles the National Health System should be based on. First of all, human dignity (no discrimination for personal or social characteristics); equity, as elimination of all economic, social and geographical or informative barriers limiting citizens' access to appropriate services; solidarity with the most vulnerable people; thus, resources should be directed primarily to the most relevant episodes with a social, clinical and epidemiological relevance. This leads to another principle, the satisfaction of health needs, that is to consider the satisfaction of the basic needs of the population as a priority goal of the health system, together with the protection and promotion of citizens' health status. Then, health organization has to pursue cost-effectiveness of services, in other words to seek financial balance and guarantee effectiveness and appropriateness of health interventions (Donatini et al., 2010).

The last of the listed principles is one of the most important issues of present health care policy, even if it was mentioned in the Italian legislation since the 1980's. Indeed, it is really hard to combine economic sustainability with a universal cove-

rage and an equal provision considering that the Italian health system provides an essential public service, and does not pursue profit. Thus, in order to evaluate administration's policies it is necessary to use more criteria in addition and beyond the strictly economic one. Control depends as well on the approach adopted by the organization's administration; a managerial approach entails performance measurements based on volumes and allocated resources, while a political one looks at the impact of political decisions on social environment, in the interest of precisely define the desired outcomes. Politics aims at the representation of citizens given its responsibility to reach the interest of the community; management aims instead at the realization of this mandate responsibly allocating citizens resources (Anthony, 1984). Providing essential public services means to increase the attention toward fair and responsible expenditures, guaranteeing a high quality service and patient satisfaction. Recently, governments have started asking citizens bigger economic tributes for technological resources and programs on lifestyle changes; indeed, the resources allocated to health care are not sufficient.

During the current economic crisis (started in 2008), the role of the health care in helping citizens to reach their individual well-being has increased. Sure enough, to cure pathological conditions means to promote person well-being as well (according to WHO guidelines), but this concept is too broad, and must face economic constrains which get more strict. According to a political perspective, citizens are not just electors useful to reach political and economic goals, hence the health care system has to use the available resources to support citizens dignity, guaranteeing them the opportunity to take their own decisions and to satisfy their aspirations. In other words, health care has to take care of citizens' health, also by assuring them occasions to realize the life they want to live, working on a global individual well-being and protecting the environment where people live and take care of their health. We know this function is affected by other elements such as social, political, environmental factors or personal skills and health status, but health care aims at the valorization of citizens also through the choice of certain indicators of health. As Cartabellotta (2013) claims, outcomes indicators —

chosen in accordance with the Italian National Outcome Program — are not exhaustive in the performance assessment insomuch exclude the individual freedom of health service choice.

Health care is anyway a service where provider and client meet up; then, even though the Italian health system is structured out of market, healthcare has been influenced by a marketing vision characterized by an exchange relationship (patients demand a service and pay for it) where actors trust each other seeing the service immateriality and the human factor is relevant. In addition, the service cannot be stored up before being supplied and there is a relationship between the production and the quality of service. That is, patients are compared to any other client whose participation at the service is helpful to identify his/her needs and to overcome the antagonism between the two categories of actors (Fraccaroli, 1991). Consequently, the patient-provider relationship should be equal, inasmuch the patient could adhere to the program the organization presented him/her, and the organization should guarantee the implementation of the service as it was presented to the patient (Parsons, 1970).

Nevertheless, the attention has been focused on power and procedures, rather than on outcomes congruence; and also, globally the Italian health system has showed limited performances in quality, equity and economic sustainability of services (Wholey, Newcomer, 1997). The recognition of these limitation has fed the orientation toward market competitive techniques (Nuti, 2008). Yet, health organizations cannot satisfy a vision oriented only to productivity and quantity of performances (Alfano, 2003). Although these critical points, the Italian healthcare represents one of the world's best practices for equality, access, cost-containment and humanization of its services.

1.2 Social and economic factors affecting Health Care Systems.

«In all countries, both health and long-term care will be driving up public spending. Focusing on the cost-containment scenario, for OECD countries average public health care expenditure is projected to increase from 5.5% of GDP in 2010 to 8% in 2060; whereas public long-term care expenditure is projected to increase from 0.8% to 1.6% of GDP in 2060» (OECD, 2013, 7). Industrialized countries' expenditures in healthcare increase more than the economy as a whole, and future perspectives advanced by OECD, European Commission, IMF show that spending in health will reach the 60% of GDP in the next 40 years; this is a big issue for public finance (Rebba, 2012).

The causal factors of increasing health expenditures are demographic and epidemiological events, such as the lengthening of life spans, the improvement of quality of life, and the spreading of chronic diseases, which increase a long-term care demand; in addition, there are the growth of information owned by citizens and the biomedical technology innovation (Pammolli et. al, 2012). So, the challenge health systems face is that of economic and finance sustainability of public health care, ensuring equality of access and quality of care; long-term interventions should be preferred, in the direction of favoring citizens co-participation in health financing, monitor performance volumes and prices, define a maximum cap of expenditures. A balance between public and private financing has to be aimed, supporting new mechanisms of supply and demand, such as new tools of territorial governance, promoting new lifestyles and structures working at community level, and concretely applying evaluation reports (Rebba, op. cit.).

Currently, citizens are satisfied by the achieved technical-scientific progress, but show disappointment for the organizational and political backwardness in healthcare (Mengozzi, 2002); effectively, citizens expect "responsiveness-réactivité" from the health organization, that is the ability to respond to citizens' social and health needs according to the goal of integrated services (Alfano, op. cit.). As WHO (2000) affirms, when a health system satisfies citizens desires and expectations, it contributes to a better general health status, to the extent that patients who are well treated are more satisfied. However, the European Council (1997) stres-

ses that for an organization is difficult to manage and be receptive to changes in a dynamic environment, given the huge number of interdepend relationships and the skills needed to build an appropriate environment. Hence, a continuous productive process of assistance should be activated, integrating prevention, diagnosis, therapy, rehabilitation, and home-care (Ruta, 1993). «There are often continuing problems of under-resourcing, skill shortages, insufficient capacity, poor morale and low pay. Public health functions are fragmented and sections of the workforce may work in an isolated way. While research capacity is well established in some countries, effective facilitation of research capacities to support policy development and programs still lags behind. Essential Public Health Operations (EPHO) assessment in several countries have revealed important deficits in the governance of public health, including a lack of inter-organizational collaboration on data collection, unclear decision-making processes, and variations in assessment and evaluation approaches» (WHO Europe, 2012a, 4).

In the next paragraph, we will see what factors affect the Italian Health System, in order to understand the specific causes of the economic crisis in health care and the consequent conceptualization of quality.

1.3 Historical evolution of health protection in Italy.

The historical evolution of health protection in Italy includes three phases, in accordance with Rafti's account (2002). The first one begins in the 1860's with the birth of the Italian unitary State; health protection is provided fragmentarily by privileged classes and charity institutes, above all in terms of epidemic fights (in line with the law no. 5849 of the 24/12/1888). In 1890, hospitals and charity institutes are transformed in public institutes of assistance and charity (Istituti pubblici di assistenza e beneficenza or IPAB). Later, during the fascist regime, many mutualistic institutes for the social and health security such as INAIL (Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro) or INPS (istituto nazionale della previdenza sociale) are established in order to offer workers protection. On

the national level, in 1945 the Alto Commissariato per l'igiene e la sanità (ACIS) is founded to guarantee health protection, beyond coordinate and control all the institutes in charge of the prevention and treatment of social illnesses. Only in 1958 the Ministry for Health is established to govern healthcare through a central structure of power.

In the 1980's, health assistance in industrialized countries changes, by reason of the complexity of the functioning and provision of services, biomedical progresses, and the development of a new health culture. The organizational separation in the health system, meant as the differentiation of assistance, involves the rising of both economic and human resources, as well as patient expectations. Health demand increases, as much as quality and quantity of health performances; on the contrary operation rules are quite stable and poorly flexible.

A mile stone in the Italian health care's history is Law no. 833/1978, which creates the National Health System, introducing universal coverage to Italian citizens and adopting human dignity, health needs and solidarity as guiding principles. This Law aims at the abolition of any kind of obstacle to equality in health care, from a social and geographical viewpoint, and at the control of health expenditure growth. A «public democratic control (exerted by political parties) over the management of the whole system» and a mixed financing scheme, associating general taxation and statutory health contributions, are the instruments chosen to support an equal and uniform level of supplied health care.

The Italian health system is a national institution with decentralized administrations at national, regional and local level. The central Administration issues the National Health Plan every three years (where the objectives to achieve are defined); then, it is responsible for the resources management, and provides funding to the regions, trying to adequately provide financing and «progressively reduce regional imbalance. Since 1978, regional authorities are responsible for local planning according to health objectives specified at the national level, for organizing and managing health care services and for allocating resources to the third tier of the system: local health units. Instead, local health units represent operatio-

nal agencies responsible for providing services through their own facilities or through contracts with private providers. They are directed by management committees elected by assemblies of representatives from local governments» (Donatini, op. cit., 14-15).

The health system is characterized by a capitation-based reimbursement, so compensation is linked to the number of citizens to assist, reached outputs, and level of expenditures, according to the improvement of the population health. But the combination of an ex post and "a piè di lista" (retrospective) capitation-based reimbursement with a political management of local health services (local health units were headed by an elected president who represented political parties) involved massive interventions; this unlimited provision of health services which in turn implies a gradual service decay and expenditure increase and, consecutively, the growth of public deficit and fiscal pressure. To contain costs, the central government sets budget caps (which were regularly surpassed), and introduces user co-payments. In addition, as usually happens in Italy, the legislative proliferation and the consequent expansion of public tasks do not receive the necessary support from a systematic organization, where responsibilities and power are coherently separated among the national, regional and local level. These dysfunctions are a breeding ground for the politicization of the health system, so a "clientelare" (crony) and particularist management of health structures. Inefficiencies and citizens dissatisfaction are the drive to a new conceptualization of the health system (Rafti, op. cit.; Nuti, op. cit.).

The third step of the Italian health system's history starts in 1992 with the issuing of the legislative decrees no. 502 and no. 517/1993 (lately reinforced by the decree no. 229 of 19/6/1999), which affirms the "aziendalizzazione" (corporatization) of health system. This involves a stronger selection of health offer, the recovery of quality, efficiency, in addition to usability of services, in order to control expenditures and raise both quality of services and patient satisfaction, still guaranteeing universal coverage and patient self-determination. The process of corporatization aimes at the adoption of a market orientation within the health sy-

stem, conferring the responsibility for health services provision on providers, then evaluation of population needs, epidemiological data analysis, interpretation of health demand, and implementation of service charter, while the definition of health objectives remains a political representatives' commitment.

On financing and decision-making, local health units and hospitals become autonomous bodies, whose top management team are responsible for used resources and the quality of delivered services and, in particular, the general manager is «chosen for technical reasons by the regional health care authorities». Competition among public and private providers would be an instrument to «secure the macro-level objectives of containing costs and promoting equity and incorporate micro-level incentives for promoting efficiency and enhancing responsiveness to consumers through competition among providers».

The reimbursement system changes as well, by the introduction of fees for single standardized performance according to the "Diagnosis Related Groups" method; in other terms, reimbursements are calculated and distributed in line with the supplied services. To distribute resources among regions, central government starts using parameters aimed at the uniformity of assistance across the country, contemplating elements such as number of citizens per region, types of health performance, conditions of structures, technologic equipment, and so on. At the same time, Italian government adopts the Maastricht treaty, accepting to reduce till 3% the odd between deficit and GDP; hence, financial resources available for health care decreases. Furthermore, an evaluation system using indicators of efficiency (Ministerial Decree 24/7/1995) and efficacy (Ministerial Decree 15/10/1996), and health services chart are introduced.

Law no. 59/1997, Legislative Decree no. 446/1997 and later Legislative Decree no. 229/1999, reaffire the regionalization process, «making clearer the division of responsibilities among levels of government». Regions get new management powers in the time fiscal federalism is approved, to provide autonomous financing to the regions. Lately, Legislative Decree no. 56/2000 prescribes the «abolition of the National Health Fund to be replaced by various regional taxes. Regions unable

to raise sufficient resources will receive additional funding from the National Solidarity Fund to be allocated annually based on criteria recommended by the government and the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces» (Donatini et al., op. cit., 32, 15-16). 21 distinct regional health systems are created to organize and deliver health care, in spite of a stasis in the development of information infrastructure and the distribution of technical capacity. Effectively, many regional health budgets run into substantial deficit, involving the approval of supplemental financial measures by central authorities, called "Piani di Rientro" (Recovery Plans). This represents a step back to the centralization of control, because the Ministry of Finance becomes an actor of national health care policy while the attention to quality of care as a fundamental governance principle fell again.

We can identify a fourth phase in the process of Italian health reform, characterized by the promotion of cooperation among health care providers and partnerships with local authorities, called community care. Community care networks and community hospitals belong to the strategy adopted to face the challenge of a rising of chronic diseases in an aging population, through the coordination of health professionals and services. But, as we know, the Italian health system always lacked co-ordination and integration of care; more, relevant differences persist among Italian regions in responding to health demand. Transparency, performance measurement, accountability strengthening become the achievable objectives of contemporary health system while since, in accordance with OECD (2014, 14-15), «the development of a set of standards around the processes and outcomes of primary care, the setting-up of smarter payment system, and increase the involvement of primary care physicians in preventive activities are options that Italy should consider pursuing if it is to meet the challenge of an increasing burden of long-term conditions. Key priorities are to develop a more consistent approach to using information to manage performance and strengthen local accountability. Ensuring that regional resource allocation has a focus on quality, and is linked to incentives for quality improvement, will also be important». Governance has to be

reframed into a stronger regional approach, in such a way to enhance health care delivery in term of quality improvement and financial control (Naylor et al., 2013; Hofmarcher et al., 2007; Lattanzio et al., 2010).

To experiment new models of community care services for complex chronic conditions, meeting patients need through a comprehensive pathway of care, primary care sector has been chosen as main field of reorganization. Both Balduzzi Law No. 189/2012 and the Patto per la Salute 2014-2016 established Aggregazioni Funzionali Territoriali (AFT) and Unità Complesse di Cure Primarie (UCCP), as primary care physicians (cooperating with nurses, specialists, administrators and other social workers) functionally integrated in a homogeneous territory working in the community health care facility. If primary and community care structures become the interface between the population and the health care system, hospitals are transformed in specialized and technologically equipped for acute care structures; anyways, community care networks and hospitals are directly connected. The objective of this system reorganization is the reduction of unnecessary hospital admission and the prevention of inappropriate visit to emergency services, aiming more generally for the improvement of healthy behavior and patient's quality of life (especially patients affected by chronic conditions). Community care services are distinguished in Casa della Salute (CdS), where social and health services are integrated, more Unità Territoriali di Assistenza Primaria (UTAP), characterized by a high multidisciplinary and inter-professional integration, and Unità Complesse di Cure Primarie (UCCP), dedicated to the management of chronic diseases by multidisciplinary care teams through personalized care plans. A more effective prevention, a better co-ordination and a lower use of technical resources are the purpose of the new service differentiation (Calvaruso and Frisance, 2012; Carbone et al., 2012; Compagni et al., 2010).

1.4 The obstruction of economic, managerial, territorial and organizational issues in the complicated Italian health system's development.

1.4.1 Economic and social issues.

The ex post and "a piè di lista" (retrospective) capitation-based reimbursement is one of the main issues of 1978's health reform, insomuch it discouraged the employment of demand control as tool to regulate offer productivity; by doing so, structures supplying health services spent more than they could afford according to the available budgets, producing deficit. Moreover, the disregard for any kind of knowledge about care processes, technology development, environmental change, in line with the belief that health demand could not be limited or rationalized, intensified the necessity of different management and financing systems to guarantee a public health system. The 1992's health reform triggered a process of expenditures decrease, notwithstanding the pessimistic expectations leading to the aging of population and scientific progresses in diagnosis and treatments. Even if health expenditures weighed moderately on the GDP, the adoption of the European stability agreement involved a lower Italian government's economic contribution to health care financing, going to the detriment of Italian citizens. Health services supply does not change, but the cost/benefit odd and appropriateness still need to be monitored and pursued.

Another inconvenience for citizens derives from the 1992's reform which separated social and health assistance services, the former planned by Regions in coordination with the Department of Social Affairs (afferent to the Presidency of the Council of Ministers) but supplied by Municipalities, the latter addressed by the Ministry of Health and managed by Regions, in cooperation with Municipalities for planning and monitoring. Actually, this division is perceivable when regional and local governments have majorities with a different political orientation and, in general, represents a typical Italian example of excessive legislative and organizational proliferation, with consequences on service efficacy (Giunti, 2002). Conceptually, this administrative measure established the separation between health protection and the operational management of health services, including diagnosis, treatments and rehabilitation for many diseases. On one hand, the structures on charge of health protection had political-representative restrictions, on the

other health organizations combine public administration's and private firms' economic rules. If health is conceptualized as a community interest, it has to be guaranteed through a continuous activity of planning, monitoring, prevention and scientific progress; sporadic evaluations, strict efficiency and money saving are not sufficient.

As Capitani (2002) underlines, health organization's decisions or interventions are open to use for political ends, since their social and economic dimensions; seeing that they are applied through juridical-administrative interventions, it should be recommendable to avoid keeping the distance between politics and management, rather focusing on how to influence health demand. In simpler words, organization's actions produce consequences on services validity, in term of justified existence, and on the ability to strengthen the relationship with citizens. National Health System has three pillars, effectively. The former is a juridical-organizational structure typical of public administration, apt to assure transparency, impartiality, as much as equality between users and providers in favor of the general interest. A second one is the political management of consensus, which sometimes causes the implementation of interventions according to parties' interests. Last one is corporatization, adopting a new operation philosophy, giving Regions more power and redistributing patients among health structures. Health services should satisfy population health needs, aiming at publicly announced goals that are managers' responsibility and, in the mean time, object of operation unit's autonomy. Health organizations have to adopt a goal oriented rather an activity oriented management style, employing new operational tools. To combine the three pillars is not easy especially because, even if health is a constitutional right according to the Italian Constitution, health demands is linked to potential profits (Giunti, op.cit.). Ruta (op. cit.) describes the healthcare-environment relationship in an opposite vision than Capitani's, inasmuch he affirms that health care is influenced by many different factors, such as social and cultural values, economic policies, level of autonomy prescribed by governance, and other elements often forgotten or neglected, for example technological progress, epidemiological or

demographic changes, the surfacing of new professionals. All these contribute to the uncertain balance between financial resources availability and performances to supply. If rules to manage planning and control instruments are needed, however flexibility is required for operational autonomy, to distribute resources with discretion and to evaluate the reached goals.

Undoubtedly, healthcare is an immaterial service and this increases the difficulty of its management, since in the Italian tradition a management culture has always be missing in term of technical responsibilities and conditioned by a conception of the system as the simple sum of different productive processes. Theoretic models and empirical methods and tools are still kept apart, because of the belief that management techniques and interventions fit better in the private field, nourishing the gap between the public and private health services supply. Nevertheless, there are some areas of public health care where a managerial vision can be applied, seeing that the health production process has to be meant as global and continuing. Diagnosis rather than treatment has to be the focus of the production processes, so that these can turn more comfortable and manageable; in addition, monitoring health demand through epidemiological and demographic data helps patient differentiation, therefore the definition of diagnostic-therapeutic strategies, the reduction of waiting lists, the rationalization of admissions from both a qualitative and a quantitative viewpoint. But to realize these product lines, it is necessary to plan an integrated and coherent operational network out of any specialistic vision, clearly specifying who is going to fulfill a precise function and what tools he/she is going to use. Finally, the development of invisible assets should be fostered in health organizations, since their importance in the production process and their competitive advantages. Ruta adds that to rethink health care as a global and continuing production process means to keep patients as the process core.

It looks like a continuing reorganization is the key to manage health services, insomuch it allows to focus on the demand-offer relationship without underrating the performance complexity. To reach this goal, management needs to be particularly sensitive to the professional expertise each performance or service requires,

in order to identify an evaluation methodology appropriate to each specific demand, both internal and external; more, management has to choose decision instruments suitable for organization's abilities and opportunities, in agreement with the technological and scientific progress. In addition, to enable the broadest participation to decision-making, it is necessary to remind that responsibility weighs on providers as well, since directly in charge of patients; thus, managers and providers functions are put under periodic assessment, to value those spirits of initiative apt to improve performance or organization quality in accordance to business economics. This implies everyone's commitment to teamwork co-operation, improve his/her own job, appraising both good and bad performances (Capitani, op. cit.).

1.4.2 Managerial and organizational dimensions.

Health organization should be redesigned as an organizational system put into a hospital-territorial network of services; this would allow the supply of coordinated services, more the reconversion of already inappropriate structures according to the surfacing functionalities leading to the clinical-assistance process. This significant change requires an internal revolution into the organization, considering the prevailing control-oriented management of the personnel and a predilection for technology, that have to give way to a training-orientation and based on human resources. In other terms, to guarantee the flexibility needed to reconvert structures and functions and not to exceed economic budgets, it is necessary to invest on human resources, especially on their training; this would permit the decrease of the gap between the technological progress and the organizational involution in conjunction with the mobilization of every single employee, whose responsibility, expertise and motivation contribute to the total quality pursued by an goal-oriented health organization.

The health organization as complex qualified institutional system has to face the distribution of authority proper to governance (Borgonovi, 1993), but to the

extent it is a public institution its organization is affected by the absence of an mechanism apt to evaluate the economic value of supplied products, as much as by the presence of juridical and behavioral rules aimed at the safeguard of public interest. This is the Italian health dilemma: the health organization is public, thus the sacrifice-benefit relation is different than a private company's, nonetheless it is undergoing a corporatization process. Therefore, the organization reflects a closed bureaucratic model influenced by a public-sector structure and political mechanisms, that limits administrators as neutral executors of the Public Administration. Moreover, we need to consider the repercussions produced by political and cultural factors' settling on health employees' behavioral attitudes.

In addition, even if Law 833 conferred homogeneity of the organizational model upon national health system, it was actually incentivizing local health units to manage service offer and expenditure as they see fit. Differences between regional health systems have been established through the legislative decrees no. 502/92 and 517/93 in the form of regionalization and corporatization. Hence, Regions get decisional autonomy as much as responsibility in settling their own organizational model, performance provision, financing criteria, while Local Health Units get autonomy in choosing their organizational structure. The general goal is to reduce the gap between formal and real models, while the particular is to recognize any single area's diversity with regard to health needs, social and economic conditions. The adherence to a national model has been guaranteed by the legislative decrees no. 229/99, that obligated any single health organization to provide basic performances issued by law and to enter in the market, introducing the payment for the services as additional financing. In addition, Local Health Authorities and the hospitals of the same area acquired legal personality (Unità Sanitarie Locali became Aziende Sanitarie Locali and hospitals became Aziende Ospedaliere), and get unified under only one management direction. Corporatization has both positive potentialities and negative uncertainties. On one hand, the organization can develop strategic abilities to improve the service offer and the choice of the organizational model better fitting for their own goals; thanks to a broader autonomy,

the organization can adapt its structure to the surfacing (community, scientific, and economic) needs falling in line with the national and regional directions. On the other, corporatization encourages a management attitude operating on different aspects. First of all, a money management administrated through DRG and a financial accounting, under constant pressure of reductions in financings and resources, even independently from the social or clinical relevance of the service or the disease cured through the service (Rafti, op.cit; Bergamaschi, 2000).

1.4.3 Health organizations: the precarious balance between public services and corporations needs.

The adoption of a business orientation in health care involved the evolution from a self-referential to a product oriented, and later market-finance oriented vision of health organizations. In other terms, initially health organizations were based on its own and its own employees' needs, excluding any kind of external people's needs. Lately, the orientation moved to the product, driving to the adoption of productivity, efficiency and demand as main principles to pursue. The increasing demand of health services involved an unnecessary growth and surplus of the offer, pushing to a market orientation, soon transformed in finance orientation, since the attention to the financial management and the concept of "selling well" rather just "selling". But the organization structure and procedures get complicated, since the need to be constantly updated to the environment changes, involving the adoption of cost, system and process control policies which flow into a quality-ethic orientation. Indeed, attention to not properly health elements (such as patient and family perception) is conferred, insomuch public opinion about organization's responsibility and ethic acquires relevance; hence, transparency and social accountability become instruments to manage consensus and legitimation.

We distinguish two rates that health system can adopt to measure their ability in adaptation to contemporary needs: criticality and newness rates; the former measures the challenges faced in re-orienting the structure, the latter measures the

innovation in orienting the structure. Nevertheless, this process is overwhelming and brings about some issues. First of all, a disproportion between the top and the bottom of health structure in term of power management; often, professional autonomy is misinterpreted as organizational autonomy, obstructing an organizational integration and facilitating the impermeability to any kind of change and innovation. When an organizational culture and operational mechanisms lack, single structures do not perceive their membership to a broader system, thus the achievement of the established common goals becomes more difficult. However, business management and rate of change are proportional, as long as to drive change is necessary a strong and active business management able to pursue both internal and external demand (Hinna, 2002).

In addition to the claimed interventions, as simplification and integration of structures, clarification of responsibilities and range of autonomy, patient orientation, Tanese (op. cit.) suggests to work on organization's openness, communicating more with external people but also making some changes in the organogram. Talking of communication, that is the base for a humanistic conception of the organization, according to training assumes a fundamental role and has to focus on psychological, motivational, and cultural elements to tear down as many resistances as possible. The valorization of human resources and organizational learning is worthy because keeps high the level of expertise shared by providers and the adherence of interventions to established goals, conferring dynamism upon the health organization apt to harmonize routine procedures with innovation. In particular, this is true for clinical governance goals since the diversification of functions and sub-systems requires information transparency and diffusion, to allow providers to deeply know how all the sub-systems work (Patrini, Confortini, 2010). This kind of knowledge would help the ability to distinguish the health demand, so to modify organizational models and professional behaviors. Effectively, the flexibility required to health organizations consists of the removal of operational barriers to favorite a horizontal integration among sub-systems; this would permit the cohesion necessary for an efficacious diagnostic-therapeutic path for patients. Sure

enough, the integration cannot be reached just through the managerial style and the organizational culture; these are conceptual instruments to combine with operational ones, such as advanced technological (both clinical and informative) tools, machines, or programs (Nuti, 2008).

Even if health care takes part at public sector, this does not involve that the process of change has to be slow and confused, since health is considered as a primary good par excellence (Hinna, op. cit.). Patients dissatisfaction, providers inconveniences, administrators difficulties are all symptoms of a problematic situation, where market rules based on efficiency are applied to a field of constitutional and social relevance. This contradictorily situation is often camouflaged by surrounding economic crises, reforms of professional orders, recommending business orientation and rationalization as the instrument to merge efficacy and efficiency. Nonetheless, efficiency is dangerous because limited economic resources facilitate the underdevelopment of knowledge and backwardness of tools to afford competent objective evaluations. Reducing assistance quality and rick coverage, the right to health is reduced as well. Expert, professional, ethically and socially responsible providers are the key tool to an organization's success (Galanti, Giachetti, 1990). For around 50 years, the national health system justified its lacks through a quantitative inappropriateness rather a performative inefficiency (Kelman, 2006). In Nuti's opinion (op. cit.), controls over the system and performance assessment need to be intensified as much as citizens' power of choice; by doing so, concurrency between private and public providers would increase which its way would arise service quality and productivity. Although public and private sector operate in two systems different for opportunities and limitations, they are somehow comparable insomuch regulated by the quality accreditation and aiming at service innovation, efficacy and efficiency. Some authors believe that patients' choice would reveal the most suitable service for a specific disease, instead it is my opinion that there are many elements influencing patient choice (waiting list, price, distance, and so on) which denies a direct connection between the phenomena.

1.5 Why the Italian National Health System's propensity to change is not maintaining the expected promises.

When the subject matter for discussion is organization in health care, news produced by infrastructural interventions and management systems involves phenomena such as resistance to change or difficulties in governance, that are intensified by a sharp separation between technical and immaterial expertise. Once again, the main idea is that a deficiency of knowledge and organizational abilities — rather of resources — causes obstacles or delays to changes in the Italian national health system, especially if we consider that organizational factors are expected as the core of successful reforms (Tanese, op. cit.). One of the organizational abilities particularly decisive in the evolution of the health system is autonomy, since it leads to the commitment of local health authorities as main actors in a local and contingent planning suitable with community needs. However, organizational autonomy is not a legislative property but a real ability to design and implement interventions, hence it is not the solution rather a condition to activate an innovation process (Bergamaschi, op.cit.). Organizational autonomy is based upon a conception of organization as contingent and continuously evolving model, where the interconnection among structures, procedures, relationships, behaviors, and cultures permits the change. This one can be efficacious only if it concretely brings out modifications toward the new organization's goals, when all its members are able to give a new configuration to the relationships they are involved with, hence the establishment of papers or decrees (typical of the Italian scenario) would guarantee just announced but never realized changes, or showy but low effective interventions.

Resistances to change are intrinsic and related to the system where they show up, thus to manage them it is necessary to work on their causes rather. Organizations often underestimate their internal resources as well as learning, so do not give value to the surfacing signs of innovation and an opportunity to people

who show availably to assume an active role in change (Tanese, op. cit.; Fappani, 1991; Crozier, Friedberg, 1977). Transformation comes real through a collective learning, seeping through a cultural, symbolic, and cognitive rearrangement of organizational expertise. Moreover, it is necessary to design and implement an entire process of innovation, that starts when change is conceived as a need; lately, change objectives are defined, so it comes the time for problem analysis and solving, followed by the planning of change implementation; last step is to experiment this plan and evaluate change.

Management has the task to promote change as an additional element in the organization's knowledge and culture, a critical factor instead of a temporary and isolated episode (Bergamaschi, 2009). In addition, it has to identify some change agents designated for the integration of old and new values; indeed, old values cannot be totally left even if employees have to adopt the new. In other terms, we talk of cultural incrementalism, surely sustained by the utilization of technological supports helping the performance and the employees as well. Organizations move from bureaucratic fulfillment to continuous improvement and a flexible attitude toward the environment (Patrini, Confortini, op. cit.).

In Italy, a few instruments have been adopted to change the National Health System's structure, revealing a government and policies' incapability to design a new model of health care based on citizens health needs first, rather than other needs (i.e. economy). Sure enough, our health system's structure involves the establishment of short-term goals, however this is a limitation for its adaptation to contemporary demands, such as chronic diseases, and a menace to guarantee the right to health. A necessary condition to realize a substantial change like the one just described, is a "historic compromise" among the actors involved in health care (Aceti, 2013). If it is true that a transformation of the organization's structure or mission requires undoubtedly the involvement of all the organization members, maybe we should think about giving a chance to patients-citizens as well. I start by saying that I cannot understand the reasons why health care providers, administrators, employees sometimes do not cooperate for an improvement (or for the

regular operation) of the organization they work for, especially because they are either patients of that same structure. I think it should be implied that people contribute as much as they can to a system where they would be patients if they need, but it frequently happen that employees show ostracism to donor putting more diligence in their job. However, if it is true that the change needs to start from inside, I believe that it can be run also through external people, such as patients. Citizens show more and more their commitment to understand and take part at the health process and treatments, both in person and by patient associations, collecting information, taking decisions, and giving suggestions. If patients are educated about new procedures, processes, behaviors, they will apply them and will accelerate the process of change. Patients are not properly external actors or cooperator of the health system, they are part of it, so it is important to contemplate them as piece of the puzzle and include them in the transformation plan, considering them as an additional force.

In the next chapter, we are going to see how the relationship among the main actors of health care evolved in the centuries, according to the evolution of health care from a clinical but also social point of view.

Chapter II

The creation of value for citizens: the process of humanization of health care services.

2.1 What is the humanization of health care and what fields it interests.

In the Ottawa Charter for Health Promotion, health is claimed as a everyday life resource rather than aim (1986). Good health is that kind of resource that, besides political, economic, social, cultural and behavioral dynamics, influences the social, economic and personal development of life quality. The conceptualization of global health has been strengthened in terms of a complex of physical abilities, social relationships and individual resources while health promotion is meant as increasing population ability to control and improve its health. Therefore, the government, social and health workers, voluntary associations, and citizens become coordinated actors within a healthcare strategy based on the health needs, within the context of the specific social, economic and cultural conditions of the territory. This is the reason why WHO talks about the reinforcement of community action as a necessary requirement to reach a community empowerment. «Community development draws on existing human and material resources in the community to enhance self-help and social support, and to develop flexible systems for strengthening public participation and direction of health matters. The role of the health sector must move increasingly in a health promotion direction, beyond its responsibility for providing clinical and curative services. Health services need to embrace an expanded mandate which is sensitive and respects cultural needs. This mandate should support the needs of individuals and communities for a healthier life, and open channels between the health sector and broader social, political, economic and physical environmental components. Reorienting health services also requires stronger attention to health research as well as changes in professional education and training. This must lead to a change of attitude and or-

ganization of health services, which refocuses on the total needs of the individual as a whole person» (WHO Europe, 1986, 3).

In our complex societies urgent requests of self-determination are advanced by citizens, entailing a change into care interventions toward patients as stakeholders and as individual human being. Health policies have to redefine health images and needs in order to offer person-oriented services; the relationship between providers and consumers has to give value to patients' participation and resources in the perspective of person's wellbeing promotion. In addition, the need to guarantee and encourage the protection of new citizen rights arises in term of high quality services, that are designed around the person as-a-whole and accessibility, from both a professional and relational viewpoints.

Consequently, it has been called humanization the process of transformation of health care aimed at keeping together all the individual's dimensions - the physical, psychological and relational - in the person's wellbeing/health through the promotion of patient's activity in the patient-doctor relationship, which is influenced by actors' personality and relational networks, beyond environmental factors (Toia, 1991; Fappani, 1991).

In Ljubljana Charter (1996), it is affirmed that «health care reforms must address citizens' needs taking into account, through the democratic process, their expectations about health and health care. They should ensure that the citizen's voice and choice decisively influence the way in which health services are designed and operate. Citizens must also share responsibility for their own health» (1991, 1). Furthermore, WHO adds that improvements into population health are an indicator of social development, that is achievable through health reforms inspired by dignity, solidarity, equity, professional ethics.

This means that patient becomes an interlocutor into the medical relationship; hence, he/she is a subject and not anymore an object in the medical context. Patient is active in the entire decision-making process: so he/she can express his/her opinions, assess the several options, take a choice. Humanization means also to give value to the interpersonal dimension of the doctor-patient relationship, gi-

ving particular attention to the psychological side (Fappani, 1991). As Hellĩn (2002) claims, the patient is not anymore a group of symptoms, damaged organs and altered emotions, but a human being who feels emotions and needs both clinical and personal help and support. Illness affects the whole person and his/her equilibrium, not an isolated sectional side of his/her body. Therefore, the nature of health care services as single - although high quality - performance has to change (Ranci Ortigosa, 1991), as mush as the physician's role. «Physician must possess not only the scientific knowledge and technical abilities, but also an understanding of human nature», because «an accurate diagnosis, as well as an effective treatment, relies directly on the quality of this relationship» (Hellĩn in Kaba and Sooriakumaran, 2007, 57). Szasz & Hollender (1956) defined the relationship as an abstraction embodying the activities of two interacting systems (persons), rather than a structure or a function. A peculiarity that distinguishes this unique relationship is its intimacy, the intrinsic quality allowing two unknown people to talk about highly personal and private matters in a safe and constructive environment.

If in the last 20-30 years, people have developed the awareness that health cannot be treated exclusively from the technical-medical point of view, even if clearly the relationship between men and health/sickness, or doctor and patient have always been the result of a mixture of historical contexts, social phenomena and relationships, medical approaches, scientific theories. In next paragraphs, I will describe the evolution of the relationship between men and health/sickness and between doctor and patient, beginning from the doctor-patient to the patient-doctor perspective.

2.2 Evolution of the relationship between doctor and patient.

2.2.1 Historical frame for social theories.

In order to outline the historical frame of the men-sickness relationship, I refer to the three basic models of the doctor-patient relationship identified by Szasz and Hollender (op. cit.). They develop a historical overview through the analysis of the social conditions and medical practices in force, distinguishing the activity-passivity, guidance-co-operation and mutual participation models (Check table 1).

Table 1. Szasz and Hollender's (1956, 587) three basic models of the doctor-patient relationship.

Model	Physician's role	Patient's role	Clinical application of model	Prototype model
Activity-passivity	Does something to the patient	Recipient (unable to respond to inert)	Anaesthesia, acute trauma, coma, delirium, etc.	Parent-infant
Guidance-co-operation	Tells patient what to do	Co-operator (obeys)	Acute infectious processes, etc.	Parent-child (adolescent)
Mutual participation	Helps patient to help himself	Participant in *"partnership"* (uses expert help)	Most chronic illness, psychoanalysis	Adult-adult

The activity-passivity is a paternalistic doctor-centered model, in which the doctor-patient relationship recalls the parent-infant one. The patient is helpless in front of physician's expertise and superiority (Marmor, 1953). The beginnings of this first phase are in Ancient Egypt (approximately 4000 to 1000 B.C), where there was a strong connection between medicine and magic. Healers were as much magicians and priests and the doctor-patient relationship looked like a priest-supplicant one. Later in Greece (approximately 600 to 100 B.C), there is a parenthesis in which medicine adopts an empirical-rational approach to justify bodily disfunction, based on naturalistic observation, practical trial and error experience. After the Greek democratic social organization, the relationship between doctor and patient evolves from a social viewpoint; the Hippocratic Oath is an example of medical ethics and attention towards the patient as person. This is a primordial version of the guidance-co-operation model, which has a paternalistic conception of the doctor-patient relationship; nonetheless, it implements a higher level of humanism in dealing with people's needs, well-being, and interests. During the

Middle-age (approximately 1200 to 1600 A.D), the doctor-patient relationship takes a step backward due to the restoration of religious and supernatural world beliefs. Once again doctor is considered as a glorious powerful magician with a high social regard while patients regress to helpless infants.

At the end of the "Middle-age" of the doctor-patient relationship, there is a restoration of the guidance — co-operation model, in which doctor control decreases because, in spite of his/her illness, patient is conscious and have feelings and aspirations. Therefore, he/she can cooperate and "voluntaristic" put doctor in a position of power. This period covers the late Renaissance to the 18th century, ending with the French revolution. Protestantism, man's search for liberalism, equality, dignity and empirical science are the motor for a new image of illness and patient, the starting point of a co-operation between patient and doctor. «During the 18th Century the symptom was the illness. The model of illness that developed was one based on the interpretation of the patients' individual symptoms. The doctor found that it was less necessary to examine the patient but rather more important to be attentive to their needs and experiences manifest in the form of their symptoms» (Kaba, Sooriakumaran, 2007, 58). The rising microbiological knowledge and surgical skills supported a new Medicine, focused «on the accurate diagnosis of a pathological lesion inside the body and the biomedical model of illness;…the symptom was no longer the illness, but instead acted as a unique indicator for the presence of absence of a particular pathology». Notwithstanding the surfacing of a new model, the doctor's dominant and patient's passive roles didn't change, in virtue of physician's expert clinical and anatomical knowledge.

Only in the late 19th century, with the emergency of psychology, patient starts being considered as person and communication becomes the key point of the doctor-patient relationship (Kaba, Sooriakumaran, ibidem). The last model, mutual participation, «is based on the belief that equality amongst human beings is mutually advantageous». Thus, patient becomes an active participant in the medical consultation and the doctor-patient interaction should be based on having equal power, mutual independence, and equal satisfaction. Nevertheless, as we

will see later, both actors can manage their own power - especially the power of information - as they prefer, moving the needle of balance (Kaba, Sooriakumaran, ibidem, 60).

In the next paragraphs the three steps of the doctor-patient relationship will be described from both a sociological and medical care viewpoint. We will go through a doctor-centered relationship to a patient-centered perspective, which later evolved in the patient-oriented shared decision-making.

2.2.2 The doctor - centered perspective in sociological theories.

The relationship between patients and doctors is a basic element in health care, but it is not directly touched by public policy. Despite the need to assess the health care performance - as the doctor performance - with specific indicators, there are many difficulties in evaluating objectively the doctor-patient relationship. Nowadays, patients' dissatisfaction usually comes from long waits in hospital clinics and doctors' offices, a skimpy attention and an unsatisfying information coming from doctors, and their feeling of being regarded as a "case" rather than as a person. On the contrary, doctors complain of overwork and of "demanding" patients (Gallagher, 1976).

According to Bloom and Summey (1976), health relates to the functional prerequisites of the social system inasmuch a too low general level of health and a too high frequency of illness are dysfunctional. More, because of their importance, sickness and health care are part of the culture; effectively, health care is a relationship with a social role seeing that there are a helping agent and a person needing help who act according to the learned sequences of behavior.

These observations constitute the premise for the Parsonian ideal-types of sick and professional roles. In his model, Parsons outlines the sick role as involuntary form of deviance, which has to be controlled to prevent a sick person abuses a legitimized dependency of illness. On the other side, the professional role is a combination of technique and social control responsibility, apt to ensure benefits

for the patient and the society in the mean time. The technical expert is responsible to recognize the legitimate condition of illness or good health in such a way to judge when a sick person, occupying a temporary, undesirable, and socially disruptive position, has to come back to his/her normal role in society. The centrality of doctor's role stands in his/her expert knowledge, necessary to define illness upon biological evidence, even if sickness is as well a source of social implications and consequences such as deviance.

Undoubtedly, Parsons' is a paternalistic approach assuming that patient and provider share the same goals, but that only the provider can judge patient's preferences and use his/her expertise to determine what should be done. In this way, it spares patients the worry of decision making. Deber (1994) claims that it is the role of the physician to act in the best interest of the patient, to direct care and to make decisions about treatment, according to the paramount moral principle of beneficence. According to this "priestly model", a good patient has to comply with the physician's orders without questioning physician's decisions.

When I talk about the paternalistic approach, I refer to the four alternative ideal types of the doctor-patient relationship, that is paternalism, consumerism, mutuality, default. These models show the expression of power and the dynamics of negotiation given that they are based on the three key elements developed by Emanuel and Emanuel (1992): «who sets the agenda and goals of the visit (the physician, the physician and patient in negotiation, the patient); the role of patients' values (assumed by the physician to be consistent with their own, jointly explored by the patient and physician, or unexamined); and, the functional role assumed by the physician (guardian, advisor, or consultant)» (Roter, 2000, 6) (Check table 2).

Table 2. Prototypes of the doctor-patient relationship (Roter, 2000, 6).

Prototypes of the doctor–patient relationship

Patient power	Physician power	
	High physician power	Low physician power
High patient power	Mutuality	Consumerism
Goals and agenda	Negotiated	Patient set
Patient values	Jointly examined	Unexamined
Physician's role	Advisor	Technical consultant
Low patient power	Paternalism	Default
Goals and agenda	Physician set	Unclear
Patient values	Assumed	Unclear
Physician's role	Guardian	Unclear

Paternalism is characterized by an idealized therapeutic relationship, in which the patient is passive and dependent while the physician is dominant, autonomous, and emotionally detached «to act in patient's interest in accordance with professional ethics» (Roter, Hall, 2006, 28-29). The source for this power imbalance lies in the imperfect knowledge that the patient has about biomedical components of illness and disease. When sick, the patient evaluate the possibility to consult a doctor, without having the necessary expertise or tools to assess the encounter's outcome (Gill, 1976). Medical paternalism has been identified as a danger for patients when medical authority started to be used for manipulation and exploitation of the vulnerable and ill. Nevertheless, Schneider affirms that it is quite illusionary to believe in a defeat of medical paternalism because the procedures established to assure patient autonomy, such as informed consent and treatment decision making, have become pro forma and useless autonomy rituals (1998).

It seems that little room is granted patient for participation. But, although Szasz and Hollender (1956) agree with Parsons on dependence-independence as the most significant behavioral quality in the doctor-patient relationship, they clarify that the seriousness of illness influences doctor's role. If a patient is in coma, certainly doctor musts take charge; but if the patient suffers of a chronic disease, diabetes for example, patient becomes an active partner involved in the treatment. Consequently, an authoritarian attitude by doctor side might be failing.

In Bloom's opinion (1963), in the interaction between doctor and patient something else than the personalities of participants and the skill of the physician as "medical scientist" should be included. He particularly refers to the physician's major reference group, its professional standards and values; therefore, the main elements of the doctor-patient relationship would be: «the individual predispositions of the physician; the standards of professional behavior which have been internalized in the physician; the specific stimulus complex provided by the patient, perceived as a "medical problem"». In the same manner, «patient's behavior

in the sick role is modified by his membership in selected social institutions. The patient's family itself, however - and the same must be said of the medical profession - sensitively reflects the prevailing currents in the culture at large» (Gallagher, op. cit., 26-29).

2.2.3 The physician - centered perspective: the information gap between providers and patients.

Bloom defines the doctor as a "medical scientist" and McWhinney reminds that the structure of the health care system reflects the Enlightenment's concepts, that is positivist power to science, devotion to abstraction, and generalization. «According to the ontological model, a disease is an entity located in the body and conceptually separable from the sick person. According to the physiological or ecological model, disease results from an imbalance within the organism and between organism and environment. …It becomes difficult to separate the disease from the person and the person from the environment» (1995, 5). Consequently, the clinical method is analytical and impersonal, operates on the level of the physical pathology to define illness. Human relationships and moral insight are implicitly learned by young students by observing their teachers and, predictably, patient's life experience is out from any clinical procedure.

Since now, health care (then the doctor-patient relationship) adopts a "provider perspective" (Bensing, 2000), where physicians dominate agenda setting, goals, and decision making thanks to a bio-medical knowledge ignoring patient's voice. If it is true that physicians' obligation is to act in the patient's "best interest", the determination of best interest is largely based on the presumption that patient's values and preferences are the same as physician's (Roter, op. cit). In this traditional model, so-called doctor-centered or disease-centered, «the disease becomes the only issue and the patient's experience is ignored or is seen as a hindrance to be removed» (Daghio et al., 2003).

It clearly appears a potential conflict between patient's autonomy and physician's authority, especially in the area of medical knowledge (Roter, Hall, op. cit.). On defense of physicians' superiority, Parsons (1951, 1975) claims that there is a knowledge gap between physicians and patients that can't be filled up by virtue of the dedication physicians show towards increasing their medical expertise and gaining experience in the application of a vast and complex knowledge. In case of conflict between doctor and patient, physician's authority meant as the assumption that " the doctor knows best" and patient confidence in doctor's adherence to the moral code will be the resolution key (Roter, Hall, op. cit.). Friedson (1970) has a different opinion on the information gap between doctor and patient in terms of physicians sharing information with patients. This gap would be justified by the safeguard of the high status and professionals standing; in addition, a less knowledgeable patient is less likely to predict the doctor or detect medical errors.

However, there always will be an information and knowledge gap between doctor and patient: while the first is looking at the disease from a biomedical viewpoint (that is the physician's essential expertise), the patient will talk about his/her symptoms through his/her personal experience and expectations. Nonetheless, patients recently changed their attitude towards information; indeed, they have become more active in seeking information and usually resort to an autonomous interpretation of the package leaflets or to internet search about their illness. As we will see in Chapter V, this may constitute a conflictual issue between clinicians and patients; the first could face difficulties in changing patients' mind on wrong or imprecise medical information; also, the second might feel more powerful because of the possession of information and develop the tendency to denounce physicians' mistakes. Nonetheless, a bigger patient's activity in information research may be seen positively because patients can make a few observations or advance suggestions useful for the diagnosis and treatment choice.

2.2.4 Moving to the patient-oriented decision-making: the patient-centered perspective.

As seen previously, political and social movements since the late 18th century till today promote individualism and freedom in the form of greater independence and self-determination; egalitarianism in term of equality between interacting people; freedom from labeling and stigma. The main issue of discussion are patients' rights - to live and even to die with dignity - and the value of patient self-examination and self-treatment, in opposition to the excessive insistence on professional autonomy and dominance, the monopolization of medical knowledge, and the mythologizing of the physician role. Patients and their families ask to interact with doctors into an egalitarian relationship free from labels and stigma usually associated with illness, and to increase controls on medical profession in order to guarantee more equity.

When analyzing patient's role in the relationship, early theories of the doctor-patient relationship refer to the voluntaristic nature of the relationship itself. Patient's individual choice of seeking for care and choosing who consult were entirely up to the patient; indeed, «the individual patient was assumed to be the decision maker» in the therapeutic relation (Gallagher, 1976, 36-37). Bioethics literature even claims patient's autonomy as obligation to respect the wishes of competent people and as the new centre of care; it distances itself from the "engineering" model, which supports the extreme position of patient's full autonomy in decision-making and physician's limited role in the assertion of technical advices (Deber, 1994b). Then there is the realistic position of who believe that patients have full power of choice only when he/she chooses the doctor.

For sure, there is unanimity on the different contributions that patient and doctor give to their relationship: the patient sets up the interaction according to his/her personal experience of sickness, moral values and life-style preferences; while the physician brings technical expertise on diagnosis and disease management, with the aim of obtaining a full understanding of patients' questions and solving their problems.

The new image of the patient as a thoughtful person has not only philosophical basis, but also practical medical and social (plus more extended economic) implications. Patients who are more active in their own care increase their sense of control and, by doing so, generate “health-maintaining” behaviors and attitudes, improving their medical outcomes (Daghio et al., op. cit). Consequently, costs are contained and quality, safety and access to care improved (Richards, 2011). As Eijk et al. affirm, «the current challenge is to “reestablish” a peer playing field in which patients and health professionals are equal members of the health care team» (2013, 293). In order to confer patients a central role, it is necessary to shift the classical model of professionalism towards a more consumerist one (Berwick, 2009; Delbanco et al., 2001), which is the object of next paragraph.

Moving to the social theories, Parsons, Bloom and Summey define the doctor-patient relationship as a social system’s relationship with its own roles and rules that are learned through the culture. Waitzkin and Waterman (1974) and Navarro (1975) adopt a Marxist perspective, according which «the doctor-patient relationship is a “typical collectivity” within the institution of medicine» (Gallagher, ibidem, 34) and, as social institution, it has to be considered as part of the society’s sociopolitical structure to be understood. Emanuel and Emanuel (op. cit.) identify as consumerism the power relationship in which patient and doctor have reversed roles compared to paternalism. In this model, patients set the goal and agenda of the examination, demand for information, and have full responsibility in choice and decision-making. Health care becomes a technical service in which physicians are “cooperating" with patients even if in reality they are obliged to provide information and services contingent on patient preferences (and within professional norms).

The doctor - patient relationship looks more like a marketplace transaction, where patient holds the buying power (Haug, Lavin, 1983) and there is the tendency for the “customer to be right”. «As reflection of societal change, the person is defined as a consumer rather than a patient, while the terms “doctor” and “physician” are replaced by the term “health care providers”» (Roter, op. cit., 30).

Consumerism is definitely interpreted as a challenge to physician authority inasmuch it restricts physician's role to a seller's obligations in supplying services. For example, in this model the doctor has to convince patients about the importance of prevention through non curative services, as periodic checkups.

According to a Hibbard and Weeks' study of the consumer as a cost-conscious health shopper (1985), there are four indicators of the doctor-patient consumerist relationship. First of all, patient cost-consciousness in term of attentive and analytical choice of the doctor, which is based on physician's fees; then, information search through several media; also, patient's independent judgment or choice to precisely follow or not doctor's instruction; in the end, consumer knowledge in terms of understanding when it is time to seek care, what are the elements for a successful negotiation in the medical encounter, whether to accept medical advice, and where to look for alternative sources of information (Hibbard, Weeks, 1987). Haug and Lavin (1983), on the other hand, investigat physician's viewpoint on the transition from a passive to a consumerist patient. Notwithstanding a high percentage of endorsement of consumerist attitudes, half of the doctors interviewed were still using persuasion to resist the requests of what they considered reluctant or challenging patients, while only a 8% accepted to cope with patients' demands for decision-making power in term of expressing believes, asking more information, denigrating doctor authority.

Emanuel and Emanuel (1992) identify even the situation in which actors may reach a dysfunctional standstill, called default. Goals, values and roles of the doctor-patient relationship become blurred and undefined, hardening the feelings and the interaction among all the actors involved (Levinson, 1993).

2.2.5 The challenging adoption of the patient - centered perspective in the clinical method.

The adoption of the patient-centered model in the clinical relationship consists of redressing the balance between the conventional biomedical approach, that

ignores the person and centers on the disease, and the emergent request of patient's autonomy. This looks particularly challenging inasmuch it presupposes a change in the mind-set of the physician and in the health care hierarchy. The clinician is no longer the professional in charge of a passive patient and has to renounce to part of his/her control in favor of a patient's empowerment into an egalitarian relationship (Stewart, Weston, 1995). Indeed, patient and doctor have to find an agreement on the nature of problems and priorities, goals of treatment, and their roles. The starting point is the exploration of the disease and of its experience by the individual patient through taking in full consideration patients' ideas about what is wrong with them and what is the impact of problems on their everyday life. The next step is the sharing of patient's feelings and expectations about what should be done and the last one is an allied problem management. Doctor and patient share a common ground to build an effective long-term relationship based on the understanding of the whole person, in order to allow clinician to deepen his/her knowledge of the patient's condition and the different responses to sickness people are showing and to work on both health promotion and sickness prevention.

However, Stimson (1976) believes that there are specific conditions in which the general practitioner could still exert control. One of the physician's means of control is the decision to consult; if patients have freedom to consult the doctor, they have not the freedom not to consult him/her in case of serious illness. In most cases, patients are free to choose self-treatment or to consult a doctor, but in some specific situations the voice is only up to the clinician. Legal and administrative measures reduce patient choice in whether to consult a doctor especially in situation needing controlled drugs or certificates for absence from work, or getting access to hospital specialist services. Doctors have the monopoly over certain knowledge or skills, which is reinforced by the State and embodied in statuses; but «physician does not have the power to force the layman to use his services» (Goode 1957, 198), even though sometimes it is difficult for people to decide not to consult a doctor if this last has been fairly successful in defining

what a patient needs in the way of medical services, or in the way of what constitutes illness (Zola, 1975).

Another means of control is the choice of doctor; this situation occurs when there is only one contact on the list of primary medical care and the patient has to take it or leave it. Conditions should be more favorable for patients during the consultation. They can influence the interaction in face-to-face consultation selecting the kind of information they want to share and the way they are going to do it. Nonetheless, patient's chances to conduct the interaction decrease considering that clinicians have their "diagnostic routines" (Bloom, 1963). They use to hold consultations applying specific strategies they developed themselves; for example, controlling the timing of consultation or examination; interrupting or changing the subject; providing cues to the patient; dismissing a problem which they consider unimportant or even merely refusing to take any action. Once again, it seems that doctor-initiated information-seeking exchanges are more frequent and plausible than patient-initiated information-seeking exchanges (Stimson, 1974; Coulthard and Ashby, 1975; Fletcher, 1975). Doctor-initiated exchanges would be supported by patients themselves who, respecting good manners, maintain a passive attitude towards doctors and hold back their curiosities. During the consultation, there is usually a complicity which rarely results in an overt expression of conflict in virtue of what Stimson calls the idealization of ignorance. «Ignorance and knowledge are idealized in relations between professionals and clients»; thus, patient takes on the position of the respectful and compliant interlocutor of a professional representative of medical knowledge rather than a peer interlocutor. Consequently, even though the patient does not feel ignorant and the doctor does not have a huge expertise, they will act "like a patient" and "like a doctor", allowing doctor to maintain control «by acting in such a way that the patient is continually reminded "who is the doctor"» (Stimson, ibidem, 79).

Interests of patients are hold by patients' Associations that, notwithstanding their involvement to influence medical care in order to improve the conditions and the services is offering, do not exert a strong power. The reason is that medicine is

practiced in an individualistic way, so that patients are encouraged to consider themselves as isolated, unique, and weak clients or consumers within the health care system.

Another way in which, according to the literature, patients exert power within the relationship is the decision whether or not to comply to the prescribed treatments/ medications. It is a practice that I consider more typical of a private healthcare systems, as the North American, than of a public health system, as the Italian. In order to exercise control after being controlled during the consultation, patients may decide not to take the prescribed treatment and take it partially hiding this behavior to the doctor. A deterrent to a patients' weak or lacking compliance to treatments may be doctor's attitude toward communication, that is sharing as much information as possible in a positive talk (J.A Hall et al., 1988; DiMatteo, 1994; DiMatteo, DiNicola, 1982; DiMatteo, Reiter, Carbone, 1994). If a deeper, informative and egalitarian communication improves patient's health outcomes and quality of life, why could not improve the doctor-patient relation itself? Stewart (1995) suggests that a shift in the balance of power between patient and physician is required; on the other hand, Roter and Hall (2006) believe that the main difficulty is to change well-learned roles such as those of doctor and patient: participants are acting "like a doctor" and "like a patient". Patients feel they are not supposed to do things, like offering opinions or asking questions, and fear to be wrong; moreover, doctor's attitude is not much more helpful, because their training is conducted by other clinicians and is often dehumanizing.

In conclusion, the patient-perspective has the good intention to emancipate patients in the decision-making, recognizing them as peer actors. However, the involved actors maintain some attitudes of the physician-centered model. Providers usually claim that patient-perspective is unreasonable, spoiled, and ungrateful, while patients look dissatisfied, showing hostility toward the health-care establishment and its providers. Apparently, the solution is in the contribution of both actors and in the leveraging a fair cooperation rather than in the assumption of power by a single part. But it is still a little bit blurred how this fair and balanced

relationship can be achieved, overcoming the prejudices linked to roles they play within the social and medical systems.

2.2.6 The patient as client in the process of corporatization of the Italian health care.

The Italian health care system has gone through a process of "aziendalizzazione" (corporatization), apt to introduce some managerial models in health care to respond to the increasing demand of management elicited by Public Administration (since now PA) changes. The process of transformation interests in particular the organizational dimension in terms of organizational complexity, diversification, multi-functionality, and competitiveness. Health care has moved toward a market-orientation characterized by productivity, cheapness, demand-orientation and patients' need priority, leaving its self-referentiality oriented toward organization's and employees' needs (Hinna, 2002).

Health care is now conceived as "service to persons" with the aim of a continuous improvement of the internal organizational processes and service performance, through the verification and review of service quantity and quality. The goal is to produce outcomes apt to satisfy the health demand. The "service to persons" is characterized by its own inputs — such as mandate, needs, resources, demand, context, information —; outcomes; operational procedures; internal variables — such as structure, technical, managerial, social processes, procedures, objectives —. In spite of its difficult measurability, the "service to persons" has to be congruent with some general guide lines; moreover, their design has to be consistent with the principles of clinic autonomy and performance personalization and at the same time reflect the standardization on a clinical, economic and resource requirement level (Koch, 1995).

The corporatization of the Italian health system has been run formally through the legislative decree no. 502/1992, later integrated with the legislative decree no. 517/1993 that focuses on citizens and their needs, the quality of health

care performance and the promotion of citizens participation. Citizens participation changes from a joint-management model (stated in law no. 833/78), where all the social parties take part at the managerial and decisional processes within local health units, to an advisory model in which political representatives (as external subjects of health care) are commissioned to establish and ascertain service objectives in terms of output and quality. Instead providers are assigned to evaluate community needs, analyze epidemiological data, interpret potential demand (service supply), and citizens have to be consulted during the planning and the check of outcomes (Del Gesso, 2014; Rafti, 2002). From a management-theoretical point of view, the one adopted by New Public Management, the citizens-PA relationship looks like a consumer-oriented market trade. In order to offer a better quality service, public health care competes with private subjects, focusing on transparency, accountability, and efficiency; emphasizing managerial professional abilities; introducing the customer evaluation. The patient becomes a proper client who chooses and rates the service he/she wants to receive.

The patient-citizen centeredness is affirmed also in the most popular organizational models adopted in the health systems, but it is applied as patient-citizen participation at the health services design and planning in the Public Administration. Once again, patients are considered like clients who choose the service they want to receive, evaluate it and advance suggestions about how it should be supplied. However, in this field the client role is played according to the objectives of the process of humanization, aimed at the supply of personalized services and at citizens empowerment in public affairs (Giarelli, 2002).

From a clinical point of view, clinical governance is the mediation between a patient-centered perspective and business efficiency, and adopts indicators to evaluate health performance (Patrini, Confortini, 2010).

The adoption of managerial models in health care caused the prioritization of quality on quantity and the adoption of a client-centered perspective. Customer satisfaction has been adopted to collect patients' rates and suggestions given that the client is the essential element in the relationship between who offers and who

receives a service. The customer satisfaction consists of the client's opinion on (the positive or negative) difference between his/her expectations and perceptions of the service received. Customer satisfaction derives from the concurrence between expectations and perceptions but its outcomes have not been as much positive as expected, although its potential as instrument of acceleration and orientation to a change in the management of organization and people. The reason stays essentially in its uncritical and unshared application (Laterza, 2011).

The consumerist-managerial model has another weak point. Patient does not exert exactly the same power clients have in a purchasing relationship. Patient's conditions and the family involvement are not sufficient conditions to allow patient to freely choose health services and thus to proclaim the success or collapse of a local health authority or hospital department. Health care clients do not have a real freedom of choice and exert a direct influence on health care, rather exercised from the regional government and other intermediary actors (Giunti, 2002; Hinna, ibidem). As observed by Pratt, consumers would not shape the client-professional relationship as much as professionals (doctors) do because they lack a systematic frame of reference reflecting their own interests and the ability to focus sharply on obtaining good health service. «Consumers need to approach health care as a problem-solving endeavor that requires active coping effort… rather than passive compliance with professionals directions; second, the doctor-patient relationship is an organized system of social behavior, which consumers must learn about in order to negotiate effectively for services. Persons who obtain the best medical care, both preventive and restorative, are those who strive for mastery over their health needs, are experienced in dealing with professionals and formal agencies, and are ready to negotiate assertively to obtain good care». According to the consumer orientation, the doctor-patient relationship works as an organized system and social behavior fostered by the structure of medical care rather than on an interpersonal level. In addition, especially in the public health systems, it is the Government rather than citizens that holds the totality or the majority of performance costs; thus, patients cannot be considered as consumers subjected to

the conditions and constraints of the competitive free-market. There is no total competition among health services suppliers because they all depend on one huge client, the Government; in addition, many services are provided in monopolistic conditions.

Therefore, there are many elements delaying the patient transformation into client. First of all, doctors employ the full range of managerial devices to maintain their own dominance, controlling medical information about diagnosis and therapy, records and test materials. They can count on the formal channel of authority within the hospitals, where institutional processes use to protect physicians. In addition, patients do not have the necessary knowledge to make appropriate choices distinguishing high risk and low risk forms of care (1976, 197).

To summarize, the consumer orientation has the positive basic principle to give patients more power in medical care inasmuch their choice is an indicator of the quality of a health service. Actually, the conditions mentioned before limit the evolution of patient role. In addition, physicians do not look interested in renouncing to their power and the health organization is still supporting their attitude. Another step is necessary to grant patients more power and opportunities to act consistently with the principles declared into the process of humanization of health care in the doctor-patient relationship.

In this regard, I do not believe that the concept of client fits with the person-centered orientation promoted by the humanization of health care. The Italian health care system aims to respond to people's health need as a primary need, on one hand, and to guarantee a constitutional social right, on the other. In literature, legislation, culture, people talk about citizens and then about patients. To adopt a capitalistic concept of consumer or client will lessen the importance of the role played by patients into health care and, above all, eradicate the social humanitarian nature of health care and its political, ethical theorization. Personally, I defend the definition of patients as citizens because it includes people as members of a society, of the community where the local health authority is working and responding to the territorial needs. In addition, the health care system has a multi-

dimensional nature, medical-scientific, political, economical and social as well; talking about citizens would involve their rights and duty to participate to the health care system. However, I would not separate the terms citizen and patient, in order to avoid an extreme politicization of the issue. Discussing with some administrative employees of a local health authority, it emerged that maybe the word that could better describe who is receiving health services is just the word person to bring out the humanitarian function of health care and do not allow the focus only on economic criteria or needs.

2.2.7 The last step of the doctor-patient relationship: the strengthening of the patient-centered perspective.

Beginning from the end of the XVIII century, when a new school of thought promoted an independent and self-determinate image of human being. This facilitated the adoption of a patient-centered perspective in health care that, however, recognized patients only a theoretical autonomy in decision-making, restricting patients in a persistent passive role. Actors didn't quit the roles they played in the paternalistic relationships, while the clinical method, for sure, was nourishing the hierarchical interaction.

As Ranci Ortigosa observes (1991), till the first half of XIX century the clinical method was based on hard sciences' epidemiological foundations, due to their rationality based on experiment and observation. The kind of absolute naturalism involves a material-organic conception of illness, reducing the personal dimension of patient condition. Only when medical foundations have firmly re-established their psychological and social dimensions, patient has been seen also in his/her biographical and personal elements and his/her values, hope, self-realization have been taken into account. Balint (1964), arguing that illness is at the same time a psychological and biological event, proposes concept of the doctor-patient relationship that includes emotional elements. In other words, he thinks

that patient and doctor do a “mutual-investment” in the therapeutic and diagnostic processes, because they have to develop insight into the other’s own needs.

The new conception of patient-centered medicine contemplates five key dimensions, listed by Mead and Bower (2000). First of all, the biopsycosocial perspective meant by Stewart et al. (1995) as the «willingness to become involved in the full range of difficulties patients bring to their doctors, not just their biomedical problems» (Szasz, Hollender, ibidem, 60). Then there is the “patient-as-person” dimension, which prescribes the understanding of patient’s personal experience and conception of illness as a necessary step into the medical treatment. Then, there are shared power and responsibility meant as democratic and peer relationship between doctor and patient within a so-called “mutual participation” model (which substitutes the previous model of the guidance-co-operation). The fourth dimension is the therapeutic alliance, in which greater priority is recognized to the personal relationship because clinician attitudes of empathy, congruence and unconditional positive regard are both necessary and sufficient for effecting therapeutic outcomes (Rogers, 1967). In the end, “doctor-as-person” claims the idea of “two-persons medicine”, where patient and doctor influence continuously each other, thus they can’t be considered as isolated factors.

The last step of history of the theoretical development of the patient-doctor relationship, instead of highlighting the technical or experience contribution that each of the actors is offering in the therapeutic relationship, emphasizes the personal-emotional dimension of the interaction. This sounds as a radical change compared to the previous steps, starting with the physician role that, in Hellĩn’s opinion (2002), pivots on doctor’s interest in humanity, since the secret of the care of patients is in caring of the patient. This is nothing but the core of the process of humanization of health care: evaluating the scientific progresses reached by medical research, the increasing but less efficient amount of money spent every year in health care, the dissatisfaction shown by the involved categories of actors toward the health care system (measured through the indicators and models of assessment adopted), it is necessary to review the principles on which the health care services

are organized and managed. More attention to people as human beings has to be given and more attention to the humanitarian side of health care (and especially quality, as we'll see later) has to be developed into clinical method and health care services supply.

An important aspect of humanization implied in this conception of the patient-doctor relationship is patient empowerment. That is the process of personal development through which the patient is recognized as knowledge-, capability-, and awareness-endowed and thus able to self-determine him/her health (Bellio et al. 2009). Patient can identify his/her health needs, take an active part in the medical decision-making and be in condition to adopt the prescribed behaviors (Buccoliero, 2010; Bellio et al., 2010; Lemire et al., 2008; Salmon and Hall, 2003). Patients can build and control the socio-economical relationship they are involved in (Pires et al., 2010; Zimmerman and Warschausky, 1998). In other words, patient can autonomously find information, get knowledge and awareness and thus develop capabilities to take decisions about his/her health (Skelton, 1994; Funnell et al., 1991). Providers then play the role of facilitator in a partnership (Bellio et al., op. cit.). Broom (1995) even talks about patient empowerment as the power exerted by the patient in such a way to invert the doctor-patient into patient-doctor hierarchy. The patient becomes an expert who participates in the processes of diagnosis and treatment, taking his/her own responsibilities. Patient empowerment means also that the patient can choose to not exert the power of get information, take on his/her responsibilities, make a decision and, by doing so, delegating the physician.

2.2.8 The definition of patient-centered care in social sciences theories: from mutuality to collaborative decision-making.

The model fitting the new concept of patient-centered care is called mutuality, because of the contribution advanced from both actors during all the steps of the decision-making process. Actors both express their views, preferences

and values, and cooperate sharing their resources and strengths, trying to overcome eventual disagreements into an atmosphere of equal power, mutual dependence, and equal satisfaction (Emanuel and Emanuel, op. cit.; Daghio et al., op. cit.).

Despite the fact that the concept of patient-centered care aims at incorporating patients' preferences into clinical decision, the main attention is focused on doctors, who apparently have to accomplish the bigger change. As previously said, it is up to clinicians do the first step, that is changing their mentality in order to encourage mutuality through four steps (Brody, 1980). Doctors should establish an atmosphere conductive to participation, encouraging patients to perceive their contribution as appropriate and appreciated; then, physicians should ascertain patient's goals and expectations, and educate patients about the nature of their problems and the alternative treatment approaches, showing pros and cons, and explaining his/her recommendations. Doctors should also elicit patient's informed suggestions and preferences, with the aim of negotiate any possible disagreements. Physicians often feel as they are in the trenches, because of pessimism, frustration and professional crisis due to the dichotomy between patients' expectations and the awareness of the limitations of medical interventions.

Quill (1983) underlines the importance of a personal contact, in order to make the nature of patient and physician rights and responsibilities explicit. In this way the process of negotiation will be as much transparent and relaxed as possible, giving patients the opportunity to expose their expectations and questions and clinicians the opportunity to explain why they do or do not comply with patients' requests. The main objective of the new approach is to achieve a real communication, a meaningful exchange between actors, to give patient the necessary guidance and support to take a therapeutic decision. Patients may loose control because they feel vulnerable and their self-image is altered; in this context, physician's intervention assume the important function of reshaping the perception of symptoms explaining the disease and the available treatment options, recommending reliable sources of information, trying to engage the patient and his/her family. Further, if caregivers show sympathy and comprehension, it will be easier for pa-

tients to develop trust and confidence into a cooperative relationship (Rozenbaum, 2009).

An example of mutuality is the management of chronic disease. Some authors focus their attention on the level of complicity-intimacy that actors reach in their relationship, resulting in friendship or, at least, partnership. Here, patient's feeling of being understood and empowered combined with doctor's satisfaction of the service he/she is supplying are positively correlated in terms of clinical outcome, patient functioning and quality of life (Szasz and Hollender, op. cit.). Other authors define the organization of care for chronic patients as collaborative patient-centered care, since the central elements in the delivered treatments are collaborative goal-setting, practical care planning, self-management and monitoring of outcomes within a team of professionals that also involves the patient (Ouwens et al., 2005; Von Korff et al., 2011).

This is the crucial point of the new conception of patient-centered care: patient-centeredness in this case means more than a respectful attitude towards patients or a personalized style of clinical interviewing; it aims at mobilizing patients as active participants in their own care (Bauman et al., 2003; DerGurahian, 2008). By doing so, the compliance of chronic patient to treatment can increase and improve, as much as job satisfaction among professionals. When the main international health organizations talk about patient-centeredness as crucial element in quality of care, they mean patients can take more conscious choices and get autonomy into the management of their disease, if the health care offer is respectful of their individual preferences, needs, and values, and supports their clinical decision (Corrigan et al., 2001). In this way, patients can face the health care services with better information knowledge, feel more comfortable into hospitals and take care of themselves outside of the health care system, with benefits in their quality of life and physical health conditions as well (Bauman et al., 2003; Michie at al., 2003). The implementation of the collaborative patient-centered care is far away from being settled in everyday clinical practice. The Joint Commission International (2007) recommends a culture change focused on communi-

cation, in such a way to make patients feel comfortable, rather than blamed or shamed, and offer a quality care. More concretely, to accelerate the adoption of a collaborative patient-centered performance, health care system - in particular the single local health authorities - should work on the reduction of fragmentation, improving the coordination between health services on a territorial base, implement tools for a better access to health care, and provide a better emotional support and tailored information, training physicians and all the other providers directly in touch with patients to develop competencies (Eijk et al., 2011). In order to achieve an evidence-based patient-centeredness, performance assessment usually represents one of the first steps a health care unit should adopt.

The collaborative patient-centered care should facilitate a shared decision-making, which is founded upon information sharing. It plays an important role because it is necessary to give patients unbiased medical information enabling them to an autonomous decision; however, sometime there could be exceptional conditions in which it is up to the clinician to take a decision on the treatment instead of the patient. Sharing information, in this case, can help finding an agreement about the treatment to implement (Charles et al., 1997). Talking about information, it is necessary to remember the exponential increase in the use of the Internet by patients, with a consequent improvement of their general information. Surely, sometimes information online is not reliable and correct but, in general, it facilitates the patient-centeredness, certainly posing problems for the clinician (Kaba and Sooriakumaran, op. cit).

To define the latest development of the patient-doctor relationship, in the early 1990s the Pew-Fetter Task Force on Advancing Psychosocial Health Education coined the term relationship-centered care. Here the stress is on the dimension of personhood, that of both the patient and the physician, instead of the shared decision-making as technical transaction (Tresolini, 1994), and the concept of being in a relationship is itself a value to pursue (Beach, Inui, 2006). Not only the individual relationship between doctor and patient, but the whole medical care

community is influenced by the expression, recognition, and reciprocation of emotion.

Some authors talk about reciprocity to describe the patient-doctor relationship, inasmuch people do or give each other in the spirit of exchange, that includes both warm feelings and cool calculations. Even though actors constantly evaluate the adequacy of each other's performance in order to respond adequately to the other's behavior, they do it according to their own values and expectations, finding a trade-off between reciprocal feelings and specific duties. In simple terms, «the doctor can do things for the patient, but the patient can do things both for the doctor and for himself or herself» (Roter, Hall, ibidem, 17).

2.2.9 Peculiar elements of the collaborative decision-making.

In the first paragraph, the process of humanization has been defined as the process giving a new perspective to health care, the patient-centered. This is characterized by the patient self-determination, which allows the patient to actively take part at the decision-making, and a new relationship between clinician and patient. Authors often talk about a partnership or even a friendship between two cooperating level actors, built on the conception of patient as human being. Thus emotions play «an important role in the human contact between patient and health care personnel, quite apart from any direct involvement in the patient's condition. The degree of distancing is probably the main element in the feeling of humanness of human interaction, and as such, has intrinsic value beyond any immediate implications for health and illness» (Scheff, 1976, 113).

Emotional intelligence has been first defined by Mayer and Salovey (1990) as the ability to monitor one's own and others' feelings and emotions in order to guide one's thinking and actions, to be reviewed later as the ability to perceive and understand emotions, integrate them to facilitate thought, and regulate them to promote personal grow. Instead, Weng (2009) speaks about emotional intelligence as a mental ability, rather than as a group of personality traits.

The bond between patient and doctor is established on emotions, thus it is shaped on the expression, recognition, and response to feelings. In the process of medical care, both clinician and patient feel and express emotions that shape their relation through time. In this way, even though patients are usually considered the only ones whose emotions have to be taken into account, both physicians' and patients' behavioral choices, and possibly health consequences, deal with their respective emotions (Roter, Hall, ibidem). «The psychological aspect of general practice is no longer rejected. Indeed its acceptance is now a fashionable cliché». Clinician's role is to understand the whole of patient's communication, in pursuance of considering «the effect of any intervention in an illness upon the whole life of his patient» (Browe, Freeling, 1976, 1-2).

Patient's emotions, fears, expectations enter into symptoms and surface as emotional response to doctor's statements, thus clinician have to deal with them. De facto, awareness of feelings guide the flow of information and the actions that will be taken; in particular, emotions influence the amount and quality of the information obtained from patient and the level of satisfaction that patient is feeling with the received care, independently of the success of that care. I.e., a cold or distanced doctor, even if owning a high level of technical expertise, will be less successful of his/her more perceptive colleagues (Lazare, 1976; Weng 2008). Consequently, it's important to teach health professionals how to deal with the degree of distancing in patient care. By doing so, they would be able to control their own feelings, distinguish between over and under distanced patients, helping them moving toward optimal distances. Sympathy, for example, has to be managed from an automatic reaction to an instrument to be used under conscious intellectual control, to avoid its transformation in a barrier to effective communication between actors or an instrument to manipulate one of them. Beside an appropriate education, another necessary condition for a reasonable and profitable management of emotions is time. Doctors usually visit too many patients in a day, having a few available minutes to make up their mind about diagnosis and treatment. It is hard to communicate in an effective way and establish an emotional contact with

the patient when in a hurry. Even if physician and patient know each other, it can be hard to reduce patient's dissatisfaction or unhappiness (Browe, Freeling, ibidem; Shahidi et al., 2007).

There is a strong evidence linking physician-patient communication to a variety of patient health outcomes, such as symptom resolution, pain control, and emotional status (Stewart, 1995). Talk contributes the routine medical visit to reach its therapeutic potential because participatory visits, marked out by an informative powerful communication and an active partnership, enhance physical and emotional outcomes (Roter et al., 1995; Haezen-Klemens, Lapinska, 1984). Patients will be facilitated in effectively communicating their stories, expressing the full spectrum of their concerns, and asking questions, and at the same time practitioners will be favored in identifying the right treatments for the disease and the best way to propose them. «Patients who perceive themselves as capable of affecting their own health in a positive manner may act healthier, and in fact become healthier, than those with poor health self-concepts and a lack of confidence in their own abilities» (Roter e Hall, ibidem 159). To adopt an appropriate technique allowing patients to feel a sense of control and increase their hopefulness is not easy (Beste, 2005). Doctors need a knowledge of the techniques to communicate delicate issues with patients, in order to produce positive effects on patient's prognosis and quality of life, lowering emotional pressure and supporting sense of hope (Tang et al., 2013). They should be trained to show a certain level of disclosure in sharing medical information, because patients respond in an empathetic and attentive manner, so too much information can be overwhelming and afflict the patient (Sarafis et al., 2014). The doctor's tendency to use an objective and detached communication style, typical of the supernatural scientific model, paradoxically has negative outcomes on patient's emotional sphere; indeed, the patient may interpret the detachment as positively aggressive or ruthless. This may produce a loss of meaningful information, leading one or both of the actors to feel confused, dissatisfied, frustrated, or angry. On one hand, patients may feel over-

whelmed by demoralization, complexity, helplessness, on the other hand, clinicians may experience grief, helplessness and fear of do a mistake (Hilfiker, 1985).

The inclusion of emotions in the medical care have the decisive consequence - at least on a theoretical level - to recognize patients and clinicians as experts operating on the same level. As asserted many times, in the encounter doctor is bringing his/her own technical professional expertise in diagnoses and treatments, whereas patients' knowledge is their story, values, intentions, and experience. «Both the physician and the patient are experts, though the domains of their expertise are typically different. In this context of heightened emotions and defensive responses, the stereotypical encounter is characterized as a retreat from rational (logical) communication on the part of the patient, and a retreat to pure rationalism (to the "science" of medicine) on the part of the physician» (Roter et al., 1995, 28).

This re-evaluation of the role of emotions has been determined also by the overspread of chronic rather than acute diseases in the last century; in effect, the condition of the chronic patient pushes to the reconsideration of patient's self-evaluations of health as stronger predictors of disease course than objective indicators. Likewise, doctor's role has changed into an egalitarian and collaborative educator model, in agreement with the definition given into Webster's dictionary; the "doctor" is a "teacher" who, beyond his/her duty to share own medical expertise giving clear information, provide a correct diagnosis and treatment, and express empathy and reassurance, has to equip his/her learners (patients) with what they need to take care of themselves. Physicians have the responsibility to educate their patients, in order to share knowledge in the most meaningful way for the patient, and to contrast their tendency to consider patients as only "incompetent" (not able to understand) or "ambitious" (who wants too much power into decision-making) (Roter et al., 2006, 5).

There has been a shift also in the concept of compliance, based on the assumption that the doctor-patient relationship is inherently asymmetrical, therefore characterized by a one-way downward communication, a one-way upward

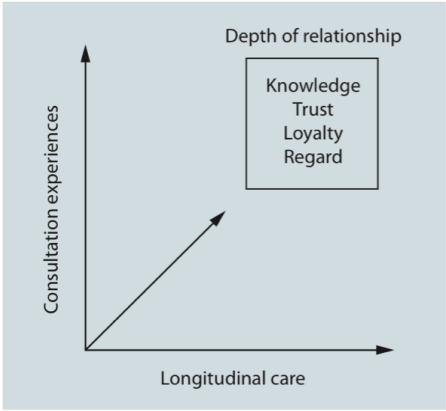
conformity and, above all, obedience and faith shown by patients to the doctor. On the opposite, noncompliance is a form of deviance. Now the doctor-patient relationship is an egalitarian relationship in which both participants are problem-solvers invested with responsibility for managing health care, and the communication is two-way. Compliance becomes «the willingness to conform to the expectations for performance prevailing in the relationship» (Pratt, 1976, 208). The contemporary society confers a high level of tolerance and acceptance of illness, that is recognize sanity to patients even though affected by permanent or temporary disability (Lorber, 1975). The question is whether physicians have the strength to face independence demands of patients and share with patients and family responsibility for health care. The orientation toward medical care focuses on consumers' involvement in managing their own care, while good health is obtained by selecting professionals services, and communicating effectively with physicians.

2.3 Suggestions for a more incisive negotiated approach to patient-hood.

In collaborative decision-making, information exchange and integration-coordination of health services are the main elements aimed at a deeper relationship between patient and doctor. Some authors give great emphasis to continuity as the most important feature in the organization's services supply. Continuity would be the cornerstone for a long-term relationship (usually the one established with patients suffering of chronic illness), given that doctor can expand his/her knowledge on the patient in term of medical history, lifestyle, family, while patients can develop familiarity with the doctor and even know what to expect with him/her, besides confidence (one of the main source of satisfaction) (Gabel et al., 1993). To establish a continuing relationship with a doctor will instill a sense of security into patients with a long-term chronic illness, well-founded on coherence, trust in care and in the relationship, and accessibility (Von Bültzingslöwen et al., 2006).

Wiles and Higgins (1996), synthesized the importance of continuity in Table 3.

Table 3. Conceptual framework of the patient-doctor relationship (Wiles, Higgins, 1996, 343).



The factors analyzed in the Wile and Higgins' survey are longitudinal care and consultation experiences. To see the same doctor, preferably one who is showing a caring attitude and interest, explaining clearly, listening well and being open to discussion, and involving the patient in decision-making as active participant, would be positively correlated to developing and maintaining a patient-doctor relationship. In the survey emerges also that knowledge is a dominant aspect in strengthening the depth of the doctor-patient relationship. Actors reach a basic familiarity as there is a sense of shared story. Doctor is able to see changes in patient's appearance and accumulates personal knowledge about the patient and his/her expectations, while patient feels to be understood because is treated as an individual with a personal story, rather than an anonymous patient. «Viewing the patient-doctor relationship in terms of longitudinal care, consultation experiences, and depth of relationship represents one unifying framework by which to investigate questions about its value for patient care. It is a framework grounded in empirically-derived data from several qualitative studies, which provides an explicit conceptual underpinning for future research in this complex field» (Ridd et al., 2009, 124).

Lazare (1976) describes the five major sequential stages of the negotiated process helpful to optimize its advantages, and precisely: «1) developing and sustaining an atmosphere for negotiation; 2) establishing the nature of the conflict; 3) general educative strategies; 4) specific strategies; 5) end-state negotiations (Lazare, ibidem, 128). The main advantages of this approach are the easy integration into primary care units and its usefulness in training, beyond patient satisfaction. The author proposes also suggestions on what kind of data should be collected in this negotiated approach to patient-centeredness, in such a way that the medical process would be meaningful and exciting, rather than routine and tedious (with negative outcome on physician's behavior and work), beyond patient-oriented. The physician should listen to what afflicts the patient and how the patient would like to feel or act (the goal); indeed, the patient should share his/her theory about the causes of disease and the expectations about what is going to happen, even in terms of results; finally, the doctor should listen to the desired goals the patient would achieve according to his/her opinion. The collection of this kind of data could appear expected, but clinicians advance several reasons to ignore patient requests, such as patients' unawareness or distortion about what they want, considering that illness and a negative emotional state can compromise people's capacity for autonomous decision-making (Beste, 2005). Moreover, even if patients will never get a knowledge comparable to that of a doctor (Gold, 2004), it is possible that they would try to turn over the authority in the relationship. Another reason to ignore patient request is the fear of opening a Pandora's box, that is an insatiable demand overwhelming the doctor. Some other times, doctors give synthetic information and pay little attention to check how much patients understand or wish to know, with consequences on the level of patient adherence to the treatment or satisfaction toward the doctor. As already asserted many times, information as well plays an important role on patient satisfaction, because more information is shared, nicer and more interested looks the clinician (J.A. Hall et al., 1998; Jackson et al., 2001; Krupat, Fancey, Clearly, 2000). It could also happen that patients will not spontaneously verbalize requests, accusing clinicians of conspiracy

(in accordance with what has been said about the physician guild) or to not believe enough in their role of cooperators in the relation of care. Clinicians should spend more time on the beginning of the encounter eliciting requests and giving the necessary explanations about diagnosis and treatment, to let patients understand that doctors are interested in negotiation rather judgements and save time in the next visits (Rosenbaum, ibidem; Maguire, Pitceathly, 2002). Moreover, clinicians should be prepared for the common responses like "I don't know; you are the doctor", or "you tell me; I would not be here if I knew" (Lazare, ibidem, 128).

Even if patient' judgements have been denigrated due to some prejudices on patients' knowledge and abilities, in several assessment models patient satisfaction, and dissatisfaction, is employed as indicator of the quality of medical consultation. What is more, a study showed that patient satisfaction increases according to doctor satisfaction with their work (Poot, 2009). The more important prejudice against patients is their supposed ignorance of the technical aspects of medicine and its jargon, that often encourages them to to be taken in by charlatans with good bedside manners, distorting their comprehension about what is important in medical care. Professionals would claim for autonomy and freedom from the laymen's evaluation, asking for colleagues' assessment, because patients would be unable to distinguish poor from good medical care (Stimson, 1976). However «some studies do suggest that patients can be appropriately sensitive to variations in quality and are more satisfied when quality is high. Research has definitely shown that patients have reasonably accurate perceptions of the interpersonal manner of the physician and can report the extent of the nature of communication received from the physician. Moreover, patient satisfaction studies have reflected patients' abilities to recognize variations in medical care» (Roter, Hall, ibidem, 144).

Generally, patient satisfaction concerns with doctor and specifically with the doctor's humanity, technical competence, and the health outcome of care. There is plenty of literature asserting the existence of patient characteristics predictive of satisfaction, such as a healthy status, and the way patients are treated by the doctor

in relation to their emotional distress (J.A. Hall, Feldstein, Rowe, Epstein, 1990; J.A. Hall, Horgan, Stein, Roter, 2002; Jackson, Chamberlin, Kroenke, 2001; Krupat, Fancey, Cleary, 2000; J.A. Hall, Milburn, Roter, Daltroy, 1998). As asserted previously, if doctor spends more time with the patient, employing more nonverbal interest and communication, showing a closer interpersonal distance, adopting a more partner-like manner of interaction, reducing a critical rather more social conversation, patient satisfaction will increase (Bertakis et al., 1998). Furthermore, a patient-centered interviewing style (like the one suggested by Lazare) is positively associated with patient satisfaction (Stewart, 1984; Roter et al., 1997). Obviously, patient affected by chronic diseases interacts more frequently with the medical care system, consequently has more opportunities to experience bad medicine or an upsetting interaction with the practitioner.

2.4 Resistances to the negotiated approach to patient-centeredness.

The actors' roles in the doctor-patient relationship have been reviewed and in literature there are several detailed suggestions about how to run effective and involving communication and relationship between the actors; and yet, the transformation has not achieved a satisfying level of implementation. To explain the phenomenon it could be useful to take a look to the actors' perspective about the patient-doctor relationship, in order to better define what kind of obstacles come between theoretical developments and practical implications.

There are some surveys realized in the past that are still useful to understand the physician state of mind, that appears hard to modify. In 1969 Herding Kaupen-Haas interviewed 321 physicians in a small university town, most of all favoring an authoritarian doctor-patient relationship, even if they were not displaying the attitude of absolute authority. Three years later, in Koch's survey (1972) emerged that physicians (a sample of 800 people) perceive themselves as charismatic, according to their authoritarian role, so they prefer leading an asymmetric commu-

nication; furthermore, doctors do not perceive any kind of patient disappointment, but faith and confidence.

Herzlich (1976) analyzed the articles and letters appeared on the Concours Medical, a medical journal most frequently read by French doctors, in the time intervals 1956-60 and 1970-72. It emerged that physicians usually speak as individuals rather than member of a professional class; moreover, they concern for the "good of the patient" and the quality of the relationship, but here there is a divergence between doctors. A subgroup believed that the relationship overcame the mistrust of a bureaucratized relationship, in favor of an easy, confident, and competent atmosphere; on the contrary, another subgroup was highlighting the dissatisfaction shown by both actors in their relationship, even though the doctor was considered as the only one responsible for the asymmetric interaction. Practitioners generally complaint about a consistent time investment in trivial consultations, reply to patient's requests and expectations, administrative compiling, and too little time with the patient to investigate the disease (Cartwright, 1967; Consumer's Association, 1974; Mechanic, 1970; Ferris, 1965). There is even a description of the troublesome patients, the ones who cannot understand when to ask for consultation, and once in the encounter are taking time demanding, describing vaguely their symptoms, showing ungratefulness, unawareness of their limited skills, uncooperativeness, lack of trust toward the doctor and effort toward the healing. It frequently happen that the doctor should investigate about hidden real problems bothering their patients, who consciously or unconsciously mask the real problem (Mechanic, 1970).

To summarize, there are three main obstacles to an effective patient-centered and collaborative decision-making: doctors' monopoly of resources and information with a consequent limited patient's accessibility to health services; the persistent patients' attitude of submission, supported by patients' association that have a weak power in defending patients' interest. «In order to investigate patterns of control by patients and practitioners it has been necessary to look at the organization of health care as well as the everyday level of social

interaction» (Stimson, ibidem, 82; Gill 1976). Ranci Ortigosa (1991) talks about the persistence of a bureaucratic ratio into the Italian health care system, promoting the efficiency of single standardized operations, which contrasts with the personalization of health services promoted by humanization. Autonomy, availability to choose, and patient satisfaction are the key elements to work on a global but deeper and more effective level. The human and social side of health services is not substitute of the technical medical one, as much as technical preciseness and comprehension are not alternative; on the opposite, to pursue the process of humanization is necessary to improve technical expertise. The relationship between clinician and patient needs to change in the perspective of patient empowerment. WHO continues affirming the importance of transparency, accountability, shared political and civic commitment in a whole-of-society perspective, because health improvements facilitates governance for health and the involvement of civil society in policy-making «builds on a long-standing appreciation of relationships between community development and health promotion» (2012, 11; 2013).

The process of humanization affirms the necessity of some changes in healthcare dealing with a conception of community as combination of social, medical, individual and also economic phenomena (let us see at the changes approved by chronic disease in the life organization of the single person as much as in the community and services organization). However, humanization is one of the dimensions of the quality of health care performance. In particular the humanization of health services as dimension of the performance quality consists of the personalization of health services, patient participation in treatment decision-making and assessment of health services. Productivity and efficiency in the healthcare management should be considered as criteria contributing to quality achievement rather than alternative standards in health services re-organization. However, unfortunately productivity and efficiency relevance and role is often misunderstood, with a consequent prevail on the criterion/goal of quality.

Chapter III

The quality and the humanization as necessary component of the health services.

3.1 Introduction.

One of WHO's, and consequently national health policies', primary aims is quality promotion. Quality is meant as equity in access, life quality, patient satisfaction, and the optimization of the use of resources in terms of cost-efficacy. By doing so, a high quality health assistance is an every patient's right (Patrini, Confortini, 2010) even though the organizational management models are centered on costs and their containment; in these conditions, health care organizations compete on the basis of quality and «those hospitals, group practices, and health maintenance organizations that offer high-quality services will be the ones to survive the intense competition» (Ziegenfuss, 1993, 1).

There is an unanimous agreement on the transparency, accountability, and value for money of the health services delivery, but there is concern over the best policies ensuring the delivery of a safe, effective and pleasant health care, in the perspective of the best care at the least cost.

Focusing on Italy, in recent decades the country significantly improved the quality of health care, showing markers of the quality of primary care, such as admission rates for asthma, chronic pulmonary disease and diabetes, as much as markers of the quality of hospital care, such as case- fatality after stroke or heart attack, lower than OECD averages. However, because of the coincidence of the economic crisis and the evolvement of the health needs, «Italy must urgently prioritize quality of its health care services alongside economic sustainability» (OECD, 2014, 3), ensuring that knowledge and skills developed by health care workforce match with population's health needs within a frame of governance (Bevan, 2008).

According to Carbognin (1991), the organizational culture and the management style would be the crucial variables affecting the concept of quality in force in health services and hospital departments. In the production, management and health policy areas, there is often a prejudice towards quality based on the idea that offering a better quality health service means to raise costs, decreasing production volume. As Ruta (1993) underlines, many other areas show instead that quality causes a more correct utilization of resources, limiting costs and increasing production. If Local Health Authorities have to manage the increase of service costs, it is due to a weak attention to quality rather than quality improvement strategies. Quality is not synonym of waste and luxury: it is a continuous improvement in terms of production organization to supply the service, acquisition of the necessary resources, design of the organizational structures, personnel training, and design of an informational-communicational system apt to be the patients' reference point. A weak attention toward quality causes mistakes in the productive, administrative processes, increasing costs weighing on the Local Health Authorities, i.e. Regions, and consequently on patients as much as on the whole society.

The main reasons identified by EU members to explain the general dissatisfaction with health services, observable in the public, political, and professional environments, are the inequality in acceding to healthcare services, the unaffordable costs to society and wastes from poor quality, the inefficiency leading to healthcare technology and/or delivery, a lack of safety in health systems, and waiting lists. Within this general framework, each country has to define the values and priorities according to its own cultural and political values, in order to «recognize the various legitimate expectations and to reconcile them in a responsive and balanced health system», according to the WHO's definition of quality as «the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population».

The population health depends on the quality of the health system, which in its turn depends on the country's social, economic, educational and cultural envi-

ronment; in other terms, models of financing, legislation and other regulatory mechanisms influence the provision of health care (Shaw, Kalo, 2002, 1). Donabedian (1990) states that there is a fundamental point in the definition of quality − in particular the social-ethical one − , that is the balance between damages and benefits for health, evaluated by a totally aware patient or his/her legitimate representative. Since costs of health assistance are paid by society, doctors are responsible for the wellbeing of all the people they are taking care of. But there is an Achille's heel in the service model applied in the developed countries' healthcare systems, a contradiction afflicting their reform based on a cultural frame, that is the realization of a constitutional and socially relevant right through market rules. Business management and rationalization processes are not sufficient to reach health system efficacy and efficiency; it is dangerous to decrease funds in a field where the knowledge about performance efficacy is limited and an objective evaluation is hard to realize, because the most likely consequences are reductions in assistance quality and risk coverage. Providers who are up to the situation, accountable, respectful of social, ethic, and professional values seem to be one of the elements to guarantee success to health care systems. Many authors, in fact, affirm that the relational activities run in the social-health services are preponderant, because the output is produced by both who offer and who uses the service; moreover, health care services have to be adapted according to each patients' expectations (particularization), notwithstanding similarities between different patients and the tendency to speak abstractly about a general public (Ghetti, 1991; Raimondi, 1987; Normann, 1985). The process of particularization would be the meeting point between public services and universalism of performances, thanks to its flexibility, bigger variety, lower bureaucratization of services (Fraccaroli, 1991).

To summarize, quality is the last frontier in health care services; although each country has to adopt its own definition of quality, in agreement with its own culture, values, population expectations, OECD countries are facing common problems in terms of dissatisfaction towards the insufficient quality and high costs of health services. Two elements seem like particularly involved in the definition

and application of quality improvement strategies: the organizational culture and the relationship among stakeholders in the health care system. In order to understand which political and social mechanisms are involved in the definition and application of quality, in the next section I will discuss the main models for delivering health care.

3.2 Definitions of quality.

Quality is a property of the health care assistance activity that concerns different organizational levels and its evaluation allows to establish if a healthcare performance owns — and eventually how much — this property, through the investigation on the providers, the environments, the systems of the delivery.
Quality's object is thus the management of a pathology presented by a patient that is treated by a physician or provider. Another definition of quality of health assistance is the utilization of medical science and technology seeking for the better balance between maximum benefits and minimum risks for health, contemplating factors as social values and rules, patient expectations and the medical professional ethics.

Technical assistance and humanistic caring compose quality and, as Donabedian (op. cit.) claims, they cannot be distinguished as science and art or care and cure; they mutually influence each other, even if sometimes it would better to keep them apart. Maybe, it is possible to sum up a third element, that is comfort; a quiet waiting room, warmed spaces, a comfortable bed, the availability of a phone in the room are all examples of the private side of the structure where the performance is delivered (and not a feature of the assistance itself). Brook and Williams (1975), instead, add another element, as represented in the following equation:

Quality of Health Assistance = [(technical assistance) + (art of assistance)] + e

where e is the randomized error of any theory, while both technical assistance and humanistic qualities have a scientific and an "artistic" component.

Ziegenfuss (op. cit.) describes quality identifying nine aspects, any of them producing an impact upon health care organizations: technology; economics; politics; laws and regulations; demographics; cultural changes; sociological changes; resources; educational demands. First of all, technology which is considered as an indicator of quality in terms of acquisition and use of advanced technology, even though it has been recently developed the awareness of the impossibility for health care organizations to keep up with last developments. Surely, the organization has to be equipped with a data system apt to dispense information about new technologies, treatment options, and outcomes, to check service availability and quality, guaranteeing high-quality health care and appropriate utilization. A second aspect is economics, in the form of cost containment and increase, inflation, recession, that puts managers under pressure to plan strategies to deal with competition. An example is represented by the demand of more cost-benefit analyses aimed to examine the financial and clinical returns of technology and its contribution to quality of care. More complex, instead, is the element of politics, which deals with the provision of health services in line with the community's needs and implies the institution of an inter-organizational task to ensure quality. Then there are laws and regulations, like those leading to the reimbursement system centered on the principle "to reduce costs but not quality", and demographics, that is the consequences of the aging of population, such as an increasing demand for health services and a more difficult access to health services. Again, other aspects defined by Ziegenfuss are cultural and sociological changes, that is the adaptation of culture, attitudes and objectives to the implementation of new strategies and new ways of thinking, such as quality, business thinking, profitization. Last aspects are resources and educational demands. Resources affect quality because administrators and physicians have to scrutinize how to allocate them, responding to cost-conservation measures without influencing patients service capacities, taking in consideration that the more information is circulating, the more patients will know more clearly what kind of services they are looking for. This means that it is ne-

cessary to spread more information about institutions, specific techniques, expected outcomes among patients and providers as well.

The author quotes Kast and Rosenzweig (1985 b), who theorized the five-subsystems model of quality. According to the model, quality is made up by five subsystems, that is technical, cultural (goals and values), structural, psycosocial, managerial. The model has been reviewed by The Conference Board which, in its report "Making Total Quality Happen" (1990), listed six benchmarks of total quality:

- «Quality is neither a technical function nor a department. It is a systematic group of processes extending throughout the company (technical, psychological);
- Quality must be everyone's job. It will become no one's job unless this process is correctly structured to support both the quality work of individuals as well as the quality teamwork among departments (structural);
- Quality is what the buyer says it is, not what the company says it is (external environment: patients, professional societies, governmental societies, accreditation organizations, advocacy groups, state health councils, litigants);
- Quality is an ethic. Widespread quality improvement is achieved only through help, participation and enthusiasm from everyone in the company and its suppliers (cultural);
- Continuous quality improvement requires the application of both new and existing quality technologies ranging from quality design techniques to computer-aided quality management. It is not simply a matter of dusting off a few traditional control techniques (technical);
- It takes a relentless disciplined methodology to establish and maintain the total quality process just as it does for finance, marketing, and production (technical and managerial)» (Ziegenfuss, op. cit., 33).

Undoubtedly, the most famous quality paradigm is the one proposed by Donabedian (1990), that is based on the adaptation to health care of the industrial manufacturing's concept of input-process-output. The model aims at the examina-

tion of health services to assess the quality of health care by three categories. Structure is the category that includes the factors affecting the context of care delivery, in other words that exerts a control over physicians' and patients' behavior. Since it is relatively easy to observe, the structural aspect of quality is a measure of the average quality of care within a facility or system in term of investment — availability of human, financial, technical resources —, access — how the resources are allocate din time, place, and responsiveness to the needs of population —, and equity — fairness in cost and benefit sharing —. The next category, process, consists of the combination of the actions of healthcare delivery, such as preventive care, patient education, diagnosis, and treatments run both in technical and interpersonal processes. Process gives information about healthcare quality in terms of the employment of resources; efficiency and economy in delivering health care (how resources and time are used avoiding wastes); moreover, process helps measuring quality through the safety, appropriateness and continuity of services, delivering a limited risk, evidence-based and patient-focused care, within an accountable and transparent activity. Finally, outcome contains, as foreseeable, the effects achieved by the health performance on patients or on the general population, through the changes observed in health status, behavior, knowledge, patient satisfaction, and health-related quality of life. Recently, the importance reached by the evidence-based approach has moved the attention to outcomes, considered as the most important indicator of quality. But even though outcomes are useful to collect data about the health performance, its clinical effectiveness, value for money, and the satisfaction produced in both patients and providers, they are not to be used in isolation. The connection with, more immediately, the process means that each health care system needs to accurately define quality, in order to choose specific indicators belonging to the three categories, drawing exact connections among them, and balancing between their advantages and disadvantages (Donabedian, op. cit.; Shaw, Kalo, op. cit.).

3.2.1 Is quality ascribed to services, assistance or performance?

Quality is an attribute ascribable to different the levels of health care processes. Donabedian (op. cit.) talks about the quality of the health assistance, affirming that is a (Parson's) normative behavior, whose rules come from medical science as much as from society's values and ethical principles. Because of their social origin, rules are effective irrespective of whether they affect assistance outcomes or not; for this reason, sometimes it is necessary to let the patient take his/her own decision even if dangerous for him/herself. Ruta (1993) as well refers quality to the health assistance, declaring that it relates to technical-operational and productive transfuncionality issues, that is the integration, fluidity and flexibility running through the different structures of the health services, both hospital and territorial, administrative and clinical. The "chain of value" balancing high quality and cost containment would direct actions. Moreover, services have both "hard" and "soft" components, the first leading to the technical and professional service, the second related to the production and use of service from a relational viewpoint. It frequently happens that the hard and soft dimensions are misunderstood, so that the technical quality of performance, the quality of the supply system and the perceived relational quality of service get confused. But if the objective is to measure (so to ascertain and record quantitatively) the quality of the performance, it is hard to measure in an interconnected way the quantity of health with the quality of health, considering the impossible standardization of the human body reactions to cures as much as the quality of the performance.

For this reason, the author suggests to move from the assistance output to the process of service production, supply, as object of quality evaluation. The production process and its output cannot be distinguished so easily, because the relational component of quality invests all the company processes, via mechanisms concerning the whole organization as much as the administrative or communicational processes, etc.

The quality of the process involves the optimization in the use of technical and human resources (efficiency), the capability of a quick adaptation to the the envi-

ronmental changes (flexibility), the definition of priorities (fluidity), the utilization (promptness) and rationalization of the available time. Working on the processes and their transfuncionality will help the standardization and rationalization of the issues, therefore quality and its assessment.

Instead, if we talk about the quality of health performance we refer to the combination of professional skills, resource availability, access to services, patient and providers satisfaction dealing with efficiency, efficacy, property, technical and scientific quality (Koch, 1995).

In Italy, the Article 11 of the D. Lgs. No. 286/1999 defines the quality of public services and the related "carta dei servizi", introducing new tools such as standards for the quality of services, the assessment of quality of services supplied by public institutes, principles to check the congruence of practices with standards and patient satisfaction, reimbursements in case of a service than would prove worse than the one described by standards. The quality of health services is not just a normative affair, it leads to central and local policies, giving public health administrations the responsibility to establish standards, and to involve patients and their associations in the evaluation of services (Hinna, op. cit.).

3.2.2 Quantity and quality of the health assistance.

The quality of assistance is not independent from the quantity of assistance. The access to health services and their fruition, for example, are both necessary elements to be considered in order to evaluate quality; if the assistance is dispensed in small quantities, and the benefits for patient health and wellbeing are inadequate, a quantitative inadequacy causes a mediocre quality.

For example, monetary costs are included in the criteria to judge quality, in the form of adequate structures, sufficient personnel working on the tasks it was hired for. In this way, health assistance is supplied efficiently. If the assistance received by a patient is judged excessive or unnecessary, so unhelpful for the patient health and wellbeing, it is a waste of money and resources for the system, but

even dangerous for the patient him/herself. Even if quality and inefficiency may be considered as separate in the evaluation of health performance/assistance, surely the "costs for method" have to be included in the expenses (I'm talking about the expenses to define criteria and standards to elaborate and interpret information). «A central goal of health care quality improvement is to maintain what is good about the existing health care system while focusing on the areas that need improvement». Typically, in health care the main problems related to quality are practices which does not keep pace with the evolution of health sciences, the underuse of services, the increase of costs while productivity decreases (AHQR, 2002, 1-2).

Donabedian (op. cit.) believes that there aren't particular difficulties in evaluating health performance/assistance through a general parameter, considering as a whole the benefits and disadvantages connected to the various objectives of health assistance. The standards of quality can include benefits, risks, and costs of assistance, because patients can assess benefits, risks and costs of a structure and even non measurable attributes. For example, talking of chronic diseases the main objective is to help patients in facing their disability notwithstanding little (or even no) improvement in their physiological functions: thus the management of relational aspects becomes really important.

Three different ways to define quality have been distinguished by Donabedian et al. (1982). The first model, the absolutist, is characterized by a technical and scientific vision. According to it, it is professionals' responsibility to define the state of health, how physician intervention can contribute to it, and how this intervention has to be evaluated. If quality is the management apt to produce the better balance between benefits and risks for health, it is the provider's task to recommend and realize this kind of assistance. Other factors such as monetary costs, patient expectations and evaluations can be obstacles as much as incentives to the implementation of quality standard, even if they do not affect structure.

The patient wellbeing, instead, is the primary health assistance function in the "personalized quality" model. Provider and patient share the responsibility to de-

fine assistance objectives, and to assess expected benefits and risks produced by alternative managerial strategies. The physician, as expert, supplies the information useful to the patient to take a decision, as the final judge of his/her wellbeing; it might happen that the patient gives the power of choice to the doctor because he/she feels unable to correctly evaluate risks and advantages for him/herself. By doing so, the judgment about quality contemplates patient's desires, expectations, evaluations, and economic possibilities, in order to respect and take into full consideration the intrinsic diversity of each patient, as determined by his/her personality as much as his/her social and demographic conditions and, especially, the degree of development of his/her disease. On one hand, patients will is totally respected but, on the other, physicians faces a moral dilemma, because the adopted standards and criteria are not specific and universally applicable as much as in the absolutist model; in this way, the provider sometimes has to accept a choice ensuring less benefits than the ones guaranteed by medical science/art.

The attention moves to a more economic and collective social dimension in the third model, the social. Here, social values and economic factors influence politics: then, social evaluations are oriented by "what is socially useful" rather "what is right" according to the physician or the patient. Therefore, potentially, costs fall on society rather on a single individual, through to a control system; once more, physicians are confronted with a moral dilemma, insofar as they are responsible both towards the patient and society. The main difference between the social and the personalized models resides in the social distribution of the reached total net benefit, run by the conviction that social evaluations represent a superior ethical principle (which is a debatable idea, in my opinion) (Ruta, 1993).

Donabedian justifies each of the above-mentioned models of quality, since anyone would be legitimate in the appropriate context, fairly in accordance with a definition of health referred to a physic-physiological or psychological or social function; or to the aggregation and organizational level of the providers of assistance (single worker, formally or informally recognized equip of workers, pro-

gram or institution); or to the aggregation level of potential/actual beneficiaries of assistance. Hence, the author advances some specifications and examples.

We may call a patient the individual who received assistance in the period under study in a survey, while a person is an individual who may or may not have received a health assistance; a group of patients makes a case load, instead a group of people might be composed by a target population, a community, or even a nation. When a population is the subject of a survey, the difference between person and patient is relevant to study and assess the access to health assistance as an element of quality, but also the distribution of resources. Easily, we may understand that a high quality health assistance supplied to the entire population is unimaginable; in public systems, the choice is between a poor assistance accessible to everybody or a good assistance accessible to a few people. Consequently, the net population health benefit is usually the parameter used to judge the accessibility and distribution of resources, as a component of quality.

In a survey, the object of interest usually is the performance supplied to a single patient, in order to evaluate, improve or preserve its quality; anyway, it is not possible to fit the survey's field of interest exactly on an exhaustive definition of quality, since the aspects of the definition of health not taken into consideration under this perspective lack in evaluating the health performance. Moreover, the assistance to a single patient may be offered, in a single or many episodes, by many providers working on different tasks in different departments.

In these conditions both the definition and assessment of quality have to take into consideration the different roles, objectives, values, and technologies of the people working in the health performance. In addition, the definition of quality should always include the continuity and coordination in health assistance, which are features of both the assistance process and the performance of single doctors treating single patients, especially during several morbid episodes. Continuity is the harmonization of the health assistance's elements and relations in a global project, while coordination is the following step, that is the work that interruptions in supply and communication. Indeed, it is relevant to collect the in-

formation about past outputs, evaluations and decisions, to set managerial objectives and methods and to orient their evolution. By doing so, coordination will be coherently realized in a managerial plan. In general, to achieve a better coordination and continuity, it would be recommendable that the patient would be treated by the same team of doctors within the same structure. This would help a better comprehension of the patient problem, expectations, values and personality, facilitating the definition of proper clinical judgements, and consequently the patient participation and satisfaction. Nonetheless, continuity, meant as being visited by the same doctor, might have some disadvantages such as the reduction of physician's attention to the small developments of patient conditions, the persistency of mistakes and omissions, a dissatisfied doctor-patient relationship (Shortell, 1976; Bass, Windle, 1972).

In conclusion, the definition of quality has to be carefully designed, avoiding the risk of a poor analytical usefulness and incisiveness, of that of becoming an empty slogan of the administration. Benefits and risks can be defined only according to the adopted definition of health and the consequent distribution of responsibilities. Furthermore, the choice between the personalized and social definition of quality depends on the way responsibilities and interests are allocated and assessed in the community and its health system.

Undoubtedly, quality should be assessed from the viewpoints of all the major stakeholders — patients, administrators, care providers — taking into account the explicit criteria reflecting the values of a given society — with reference to Donabedian's adaptation of input, process, output taken form the industrial manufacturing (Shaw, Kalo, op. cit.). Nonetheless, «the information generated by quality-monitoring activities is neither available to, nor usable by, the general public. Large-scale purchasers of health care services are in a much in a better position to ask for more detailed information generated by quality monitoring, and to use that information… It follows that the degree to which care is purchased collectively, the values that guide the purchasers, and the methods they use would be major

determinants of how effective information generated by quality monitoring is going to be in enhancing the quality of care» (Palmer et al., op. cit., 117).

3.3 Actors involved in the definition and assessment of quality.

As noted *supra*, the actors involved in the definition and assessment of quality are managers, patients, providers. The Agency for Healthcare Research and Quality's (AHRQ's) (2001) distinguished four categories of customers. First, the clinical decision makers who work on informed choices about treatments and their costs; second, there are the health care system decision makers, who are dedicated to increase the access to care and to deliver high-quality and high-value care; third, policy makers who work on monitoring and evaluate the impact produced by system changes on outcomes, quality, access, cost, over designing policies to improve system performance; patients constitute the fourth and last category.

Donabedian (op. cit.) talks about administrators and supervisors as indirect driving forces in health care. As expectable, the hospital administrators are concerned about the financial issues, in particular the provision of an efficient and effective service within the established budget. Moreover, they will invite doctors to collaborate on projects and to work congruently with the organization's articulated mission and vision, even if the main drive to the incorporation of the guiding principles in the everyday work is in the managers' hands. Administrators fulfill also the function of propulsion toward the service improvement in accordance with the goals established in the organization's strategic plan; «a manager can't control people and can't control disease, but can and should control the processes involved in the delivery of care» (Dlugacz et al., op. cit., 35).

Klein et al. (1961) realized a survey on administrative officers and the way they were looking at the ambulatory organization. They were often talking about satisfactory performances without mentioning some intrinsic elements of the health assistance; for example, if patient satisfaction was usually considered, on the contrary assistance effects on patient health, medical abilities and service availability

were ignored. The researchers affirmed that there are many features of a satisfactory assistance are hard to assess, while the easier cannot be clustered in a single, inclusive indicator.

Doctors as well usually tend to define quality in a more general way, referring to the technical aspects of the clinical performance. «The professional and personal values and behaviors of staff play a fundamental role in their conception and co-production of quality in everyday practice. Managing quality is clearly not all about monitoring systems and regulation, but also concerns health care workers' values, training and personal behaviors and, importantly, how service quality becomes co-produced in service encounters» (Farr, Cressy, 2015, 1-2).

Physicians play a great role in the quality of health performance inasmuch they are the face of the health care system, the ones who are directly in a relationship with patients. To center on the adversarial relationship between doctors and patients wouldn't be correct, because if it is true that patients are getting more and more informed by themselves, asking for a more active participation, it is true as well that doctors are not just on a defensive position; part of them are open to patients, treat them as cooperators in the policy-making, naturally as much as in the choice of treatment. Patient satisfaction could be a strong factor favoring the improvement of physician performance, for example a good judgement about the structures, the conditions of work, the assistance offered by the same doctor or the intervention of other colleagues (Donabedian, op. cit.).

Sanazaro e Williamson (1968 a,b) modified the Critical Incident Technique (a set of procedures used for collecting direct observations of human behavior that have critical significance and meet methodically defined criteria) with the aim of verifying if doctors define quality as direct intervention to obtain the desired outcomes. The 94% of the interviewed doctors described an efficient intervention talking about him/herself, rather referring to colleagues in case of an inefficient intervention. Physical functions primarily, but also social and psychological functions, costs, and patient attitudes were the categories used by physicians to classi-

fy benefits and damages of health assistance, with an almost total exclusion of risks.

Moving to patients, the relationship between patient and caregiver, as seen in Chapter II, is getting nowadays more and more rational and equal/symmetrical. . Patients are more informed about medical interventions and changes in clinical status, therefore they expect to receive the highest quality of care as interventions improving the way they feel and they tend to autonomously scrutinize the received tests and evaluate the effectiveness of doctor interventions. Beyond the conception of health, the conception of health assistance is involved in the patient's definition of quality, based above all on the expectations advanced by the patient toward the provider. These expectations usually are higher than the providers' real availability or capability to satisfy patients' requests; and they are influenced by the expectations for and evaluations on the interpersonal relationship, further evaluations on risks and benefits for health.

Another element of quality dealing with patients is their satisfaction, that is considered as both an objective outcome of health assistance and a tribute to adjunctive objectives and outcomes. In effect, patient satisfaction increases the chances that patient will efficiently cooperate with the provider and will choose again the structure in the future. Moreover, patient satisfaction is a measure of quality because it is connected with the comfort of the structure, the quality of technical management, of interpersonal relationships, and the social, physiological and physical consequences of health assistance. As an indicator of the success reached by the provider trying to satisfy patient values and expectations, patient satisfaction is an instrument for research, management and planning. But patient satisfaction has some limits, inasmuch patient usually have limited knowledge about the scientific and technical sides of assistance; in addition, since it is a judgment about assistance quality, it is not contemplated in the definition of quality (Donabedian, op. cit.; Ruta, op. cit.).

Anyway, patient judgments are part of the global assessment influencing the organization budget (and indirectly the manager's own position), although they

are difficult to manage seeing as each patient has his/her own social and emotional state and psychological response to treatment. The only way to manage the diversity in patient satisfaction, trying to homogenize the collected data, is to educate patients about the rules, procedures, processes running in the health service as soon as they get in contact with. «Patients need to understand informed consent forms, discharge plans, and medication regimens; they may also need orientation to hospital services, pain management, patient and consumer rights, and medical procedures» (Dlugacz et al., ibidem., 4). Palmer, Donabedian, and Povar assert that patients are agents of political and social change, because they regulate the quality of care choosing what care to seek and to accept, from whom, etc. This means that patients need to be fully informed about «what constitutes quality and where it is to be found, especially insofar as technical care is concerned, since this is the aspect of care about which consumers know least. To choose prudently, consumers would also need to know not only what the prices are, but what the total cost of care is going to be». Furthermore, «information about quality to be effective, it needs to be available at the time when decisions on health care are being made, in a manner relevant to these decisions» (op. cit., 116). Moving to the other side of the fence, Fraccaroli (op. cit.) reminds the importance of training every so often providers, in line with professional improvement and support of motivation. Indeed, to pursue objectives correlated with humanization, it is important to know the patients' opinion about health assistance as much as providers' opinion; by doing so, management should be properly prepared to strategically manage the internal marketing.

Obviously, this is not a resolutive action, considering that patient expectations as much as quality are based on both technical competence, easier to assess thanks to standard criteria, and humanistic qualities, more difficult to judge in an objective and uniform way. But technical excellence and humanistic qualities are reciprocally intersected. Technical excellence is something more than scientific knowledge and adequacy of the diagnostic and therapeutic processes, because is also about manual, perceptual, and judgmental skills; it is "more art than science".

Humanistic caring is a combination of philanthropic attitude — milieu, manner, and behavior of the provider in delivering care to and communicating with the patient — and attention to the "amenities" of care, for example comfort, convenience, and privacy (Donabedian, op. cit.; Brook at al., 1976). In order to find equilibrium between technical and humanistic components of quality definition and assessment, Donabedian suggests to define quality as the production of health improvements able to satisfy the patient (both goals of medical care). In fact, the goodness of technical performance is judged according to the available knowledge and technology, in comparison with the best practice, the one believed to produce the greatest improvement in health. This means that expectations are part of the judgement, as long as it can take time to see if care produced the expected improvement outcomes. «The interpersonal process is the vehicle by which technical care is implemented and on which its success depends. But the conduct of the interpersonal process must also meet individual and social expectations and standards, whether these aid or hamper technical performance» (Donabedian, 1995, 34). These clarifications allow explaining that all the actors-stakeholders involved in the health care system share their responsibility in the definition, implementation and evaluation of quality. Health care is a community affair. It is hard to precisely identify the quality improvement strategy to adopt inside a Local Health Authority or Hospital Trust, but a first move to progress is to leave behind all the supremacy of competences and skills owned by a single category of stakeholders, combining equally all the pieces of the puzzle.

Patient and physician viewpoints were contemporaneously studied by Price at al. (1971) in a survey focused on the core of the medical performance and the quality of the service supplied to patients. The starting point was the question "Concerning your specialistic field, what are the successful factors, in your opinion?", that was asked to 372 doctors. The list of successful factors was later reviewed by a hundred between professors and students of medicine and healing or discharged patients, to distinguish the desirable (82) and undesirable (29) features. Even if the question did not mention quality or assistance to patients, the study

was interesting because an agreement between patient and physicians surfaced on the importance of features such as knowledge, ability in judgement, accuracy in tests, and doctors' self-consciousness about their own limits. If physicians who have bigger awareness of their own limits believe that intellectual honesty and learning ability, working hard and collaborating with colleagues are the most important features in their work, patients privilege the acquisition of knowledge, the correct keeping of medical records and the ability to transmit trust to patients.

There is a particular element we need to consider in taking into accoutn actors who define and evaluate the quality of health care: the way they are allowed to express their opinion. Usually, and reasonably, both patient and physician express their opinion through some questionnaires listed by a competent team; but, often, the level of satisfaction that patient can express is about providers and their attitudes, rather health assistance outcomes. By doing so, patient develops a less focused and clear conception of quality, in comparison with the physicians' (Donabedian, op. cit.).

3.4 Historical development of the models for delivering health care.

The history of quality in health care begins in the fifth century B.C. in ancient Greek, where Hippocrates declared "First, do no harm!", to specify the it is the physician job to manage quality of the care supplied to the patient (Dlugacz et al., 2004). In accordance with a physician-oriented definition of care (see Chapter II), the definition of quality has been based on two prerequisites that are also two ethical obligations: to ensure the best possible care (as defined by physicians) to patients, and to ensure the competence of professionals to society. On one hand, the attention has been focused on the provider or physician competence and, on the other, the focus has been on individual patients rather than to a general population (Palmer et al., 1991).

A big change was promoted by Florence Nightingale during her experience as a nurse during the Crimean War. Through a data-driven analysis based on statistics and evidence, she observed that quality management was not just the indivi-

dual physician achievement, but rather a functio involving the entire health care organization. Her intuition consisted in the causal connection between the weak doctors' hands hygiene and a high infection and mortality rates among patients, that suggested the use of data to drive policies and procedures, over to assess their effectiveness. Since Nightingale's work, quality management has required the collection of information to assess the quality of care in health care institutions.

Recently, Codman bring into the debate on quality the discussion point to the outcomes of the health care delivery, suggesting that hospital responsibility deals with a successful treatment as much as with an effective prevention; thus, the quality of care has to be observed in the entire process, while the outcomes analysis becomes the base to quality analysis (Dlugacz et al., 2004).

In the same century − the twentieth − three models for delivering health care were established, each with a specific consideration of issues like control, responsibility, production, and financing.

The first model adopted to organize health care was the professional (since 1930s), according to which «quality control is the personal responsibility and integrity of each physician». Physicians organize and control their work, and the evaluation of professional standards is run by peers; there are also some external mechanisms promoting quality such as the Joint Commission on Accreditation of Healthcare Organizations, and the State licensing departments (Graham, 1995, 3-4). Good medical care consisted of the definition of physician's role in accordance with the care needed by patients and doctors' attention toward the individual patient rather than on a target population. In this way, physician interventions are the main determinants of the patient health status after care, even if the standards chosen to measure quality were the effectiveness of existing technology and the severity of patient illness (Sanazaro, 1980), or the match between the decisions taken by physicians and expert professional opinion. In this situation, quality is the "the ability of the provider to coordinate available technology, skill, and judgement to improve the health of patients (Palmer et al., op.cit., 6).

The second model was named bureaucratic and developed around the 1960s. The changes in medical sciences and health care caused in turn some changes in the organizational design. Services became more varied and complex because of the emersion of new technological and organizational practices demanding the cooperation of many different professions working together. The new approach was called quality assurance, in which patients became beneficiaries and physicians vendors. Around the 1970s, the bureaucratic model was enforced through the virtual obligation for hospitals to be accredited by the Joint Commission International, the enforcement found a resistance by doctors, who felt their professional autonomy threaten by this model.

In the next decade, the 1980s, an industrial model was introduced in healthcare; by doing so, the need to survive in a competitive environment was the stimulus for quality and externally valued criteria, such as profitability and market share, while conformance to rules became the standard to evaluate job performances. Therefore, patients were not beneficiaries anymore, but customers or consumers. Since mid-to-late 1980s, the Total Quality Management made inroads, as much as its assumption that the system (not its people) is the origin of organization's quality problems; consequently, organizational culture is the key to facilitate or obstruct quality improvements. Top leaders held the reins of quality, that was defined from the customer perspective but declined to profitability. Quality is a way to satisfy patients, aiming at exceeding their expectations, then emphasis is conferred to the costs-outcomes relationship (with the purpose of limiting wastes of resources and risks due to inappropriate diagnostic and therapeutic procedures) and to health services research (Graham, op. cit.; Ghetti, op. cit.).

Actually, research helps to evaluate health care assistance in order to monitor clinical efficiency, cost containment, performance efficacy, therefore it helps assessing the maximum benefit for health conforming to the available means and scientific progress (Galanti, Giachetti in Donabedian, op. cit.). However, to evaluate health care it is necessary to remember that patient participation and contextual elements (such as the kind of service) can combine, making it harder the ap-

ply standards and criteria for quality. Furthermore, services are often offered in an inter organizational network, in which more strategies are applied at the same time (Ghetti in Carbognin, op. cit). To define as much as to understand how to measure quality, it is necessary to take into account the perspective of various subjects: doctors, patients, managers, government. Before focusing on the contribution that each actor can give to quality definition and assessment (see § 3.5), let us see deeply how the theoretic approaches to the quality of the health delivery developed.

3.5 Theoretic approaches to the quality of health delivery.

3.5.1 The Quality Assurance approaches.

The interest and inclination to the quality of health delivery was initially theorized in the quality assurance approach, whose origins come from two traditions, the industrial and the healthcare (Ellis and Whittington, 1993). According to the industrial tradition, quality is defined as «the formal and systematic evaluation of health care» pursued according to the Total Quality Management (since now TQM)/Continuos Quality Improvement (since now CQI) (Racine, 1995, 16). Some historians of health care contest such a recent dating of the origins of quality (in the last half of twentieth century), and least of all the Fine and Meyer's belief that quality assurance activities in health care started around the Seventies by the Joint Commission on Accreditation of Hospitals (1983). Hence, the quality of care is dated back to to the beginning of recorded medical history in Egypt, Greece, China, Assyria, Rome. Even if the quality of care was embryonic, because clinical techniques were implicit and not specifically referring to quality, there were already some codes of professional conduct, for example the 5th century BC Hippocrates'. Bull (1992) affirms that the small developments of assessment systems during the Middle Ages, the Renaissance, and every succeeding historical era

cannot justify the idea that the systematic evaluation of health care is something new, originating in the late 1900s.

«A few historians, usually nurses, start their accounts of quality with Florence Nightingale, the founder of modern professional nursing», because of her commitment in the improvement of hospital care based on the data analysis of death rates. Ernest Amory Codman is Nightingale's competitor, inasmuch many historians start their chronicles with the doctor of the "end result" of medical care in the early twentieth century. Codman was the first one advocating the regular review of medical practice, recalling patients a year after discharge in order to assess treatment benefits and side effects. He was «a premature proponent of the idea that professional competence is not the only determinant of quality» as well (Racine, op. cit., 17).

The development of all the major approaches to quality assurance got a foothold from 1960s to 1970s, when quality assurance — in terms of costs reduction and quality improvement— became an issue for all the actors involved in health care, government and other third-party stakeholders beyond physicians. Lately, from the 1970s to the 1980s, quality assurance was once again the object of new studies, apt to reinforce the connection between quality assurance and clinical process development, linking management and biomedical sciences. Both Williamson (1978, 1982) and Juran (1988), though through different perspectives, worked on the convergence between quality controls and financial processes. As seen in § 3.2, till the 1970s the bureaucratic model was in full swing, moving the focus from the inspection of individual cases to the the statistical analysis of patterns of care, without particular impacts on quality. Indeed, quality assurance was well theorized but weakly implemented, leaving the scene to the traditional approach.

Quality assurance, as stated by Ziegenfuss (op. cit), is the dynamic process apt to check, inspect, and guarantee quality through the outcomes evaluation and the improvement strategies. The same author believes that «the ultimate purpose of quality assurance studies … is to determine whether in a given case an inter-

vention known to be efficacious or otherwise appropriate for that type of case was indeed the one selected and whether it was carried out with the requisite skill and competence» (op. cit., 15).

Donabedian (op. cit.) describes quality assurance as the combination of system design, the way financing and delivery of care influence the access to services and assistance, performance and system functionality monitoring in the same cycle, which should include:

- identification of the issues causing problems in care and assistance;
- selection of priority actions;
- choice of the methodology to adopt;
- definition of criteria and standards to measure processes, outcomes, and structures;
- description of the gap between standards and reality;
- explanation of the phenomena for a better problem solving;
- review of cures and assistance.

In his theorization, quality assurance considers a wide variety of medical professionals in positions of responsibility (each one individually, out of a common system), and includes the public among the main actors necessarily involved in the process of change of the health system (Brook et al., op. cit.). Nonetheless, an external monitoring philosophy is on force, supporting an oversight from outside the organization, although quality improvement is a clinical and administrative leaders' duty. In addition, the approach focuses on technical quality and excludes the interpersonal and organizational aspects of quality; moreover, it adopts a reparative strategy, aimed to correct the internal processes individuating the bad apples, removing them from the lot, using implicit judgements. Quality is pursued by inspection through conceptual tools that should own simultaneously high sensitivity and specificity, also to limit the error produced by the people under survey who try to distort data or change measurement. In spite of its good intentions, the logic focuses on voluntary and episodic actions run by a few trained personnel

working with a poor availability of technology and resources. Consequently, weak outcomes are produced (Berwick, 1995).

This is a quite static picture. The goal of conformance to standards is in force, so there is an emphasis on physician performance rather on the contributions of other participants in the health organization and the definition of quality does not meet modern providers needs (Palmer and Adams, 1993; Laffle and Blumenthal, 1989). In these conditions it is difficult to detect effective means of changing professional and organizational behavior; if changing providers' actions is the key to quality assurance, it is necessary to describe which attributes of providers, especially individual professionals, facilitate or impede the change of behavior. People usually refer to professional autonomy, accountability in the practice of medicine, to «the processes of recruitment, training, and socialization of members of the profession, and the preference for informal rather than formal quality assurance interventions». There is poor attention to educational interventions, directives, incentives and disincentives, and to forms of organizational adaptations facilitating professional growth and change, routinizing behaviors, and promoting personnel, institutional, and individual capabilities as organizational support (Ziegenfuss, op. cit.). Moreover, patients are empirically excluded from any responsibility, even if they play a further role in quality of care inasmuch "coproducers of care"; effectively, «a broad definition of quality assurance would include all that a society does to maintain and enhance the quality of care». Another issue is the relationship between system design and performance monitoring, apt to evaluate structural dimensions as indicators of the quality of care, even though the monitoring of performance is based on the collection of information about the process of care and its outcomes, achievable formally (producing credible information in a bureaucratized, continuous and predictable way) and informally (the exchange of information between colleagues) as well. Furthermore, the formal monitoring permits the assessment of quality through a set of activities such as the localization of specified performances in time, person, and place.

Generally, the activities of monitoring aims at the measurement of quality effectiveness means as the degree of efficacy of current health in practice. Surely, there are some difficulties in defining exactly and calibrating efficacy, since the improvement in health depends also on a «specified baseline of ill health or by the degree to which a pre-specified level of health is attained». In addition, we have to consider the effectiveness of monitoring in terms of the alteration of a case, improving its ability to improve health more effectively and more conforming to social norms and individual preferences; indeed, beyond the definition of quality and the assignment of responsibilities for attaining it, we need to consider the «commitment of society to providing quality care», that is the search of a balance between the emphasis on quality and the attention to costs. Moreover, a systematic check needs an organized structure to sustain it; also, the ability to implement actions based on its findings (Palmer et al., op. cit., XVI; 62; 66). By doing so, quality assurance promotes a definition of quality that is outcome-centered, confusing studies of efficacy (treatment outcomes) with studies of quality, that involve structure and process as much as outcomes, and consider separately the technical clinical work and the interpersonal aspects.

3.5.2 The Quality Improvement approach.

In the previous paragraph, two traditions of quality assessment have been introduced. One of them is the industrial that, as stated in the industrial approaches of Total Quality Management/Continuous Quality Improvement, can be applied to health care under the name of Quality Improvement. Officially, the transit from quality assurance to quality improvement was established by the Joint Commission in 1992, by retitling the quality assurance section in the Accreditation Manual to quality assessment and improvement. Hence, the responsibility for quality in health care was conferred to managers, even if it is the «effort by all members of an organization to meet the needs and expectations of a customer» (Laffle and Blumenthal, op. cit., 2871).

As seen before, quality assurance is oriented towards bad apples, that is the outliers who do not satisfy standards, and does not investigate general processes or system variations. Quality improvement, instead, «provides a set of tools to understand, measure, and manage the health care delivery process and their associated costs»; it adopts a methodology for process management based on a single coordinated effort of employees and managers, the utilization of scientific tools and promotes a deeper cultural change in the organization.

The development of quality improvement began in the late 1980s and continued through the 1990s, when quality assurance professionals and researchers investigated on the contributions of industrial quality improvement, in order to find suggestions capable to solve the deficiencies of traditional quality assurance. The transition to total quality management has been considered a paradigm shift, that is a new philosophy and practice of quality, where quality is not just clinical but organizational, it has to be improved rather just guaranteed, and the research on it is guided by more strictly empirical criteria (McLaughlin and Kalunzy, 1990). The organizational vision implies the evolution of the individual responsibility of professionals into administrative and professional authority and autonomy, inside an organizational common plan, since a collective, management-led, team-oriented approach, implemented within a proactive/developmental logic. A new organizational structure has to be designed, in such a way to permit the total involvement of employees and to abandon the "one-clinician-is-the-problem" perspective.

A key role is played by goals, that are oriented by the responses to complaints, and whose attainment or failure is a step to the retrospective review of the performance. In order to achieve continuous improvement, planning activities are flexible and periodic and concurrent benchmarks are the tools adopted to assess progresses. Poor quality is costly, so the application of a scientific and statistical thinking (borrowing strategies and methods from the industrial sector and leaning on strong case experience and extensive research in industry) is useful to monitor the most vital processes and to understand their variability, because quality defects

generally originate in the process. Quality planning, quality control and quality improvement are, indeed, the basic activities of the quality management, that is characterized by a strong relationship with customers. Even if the planning and monitoring activities are internally driven, they are supported by an external regulatory system, partly based on the standards set by the Joint Commission on Accreditation of Healthcare Organizations (Ziegenfuss, op. cit.).

Before extensively describing the quality improvement approaches applied to health care, let us see the main elements of the original total quality management model.

3.5.2.1 The organizational model of Total Quality Management and the alternative New Public Management model.

Since the 1970s and mainly in the 1980s, the delivery of high-quality products at competitive price distinguished Japan as global leader in the market. A high-quality production allows its producers to capture a greater share of the market and to decrease organization unit costs, with a greater pricing flexibility. The combination of the classical industrial engineering, statistical-process control and human behavior theory is the base of the total quality management, the organizational model aimed «to create a process for improving the quality of products and services produced by an organization».

The participation of the whole organization at the planning and implementation of quality improvements is driven by the definition of quality as «meeting or exceeding the customer's expectations at the price that is reasonable to the customer». Employees carry out some management principles in their daily work activities, in order to continuously search for new ways of exceeding customer expectations. The customers are external and internal as well, inasmuch any department or employee who is sending or receiving input from another part of the organization is a customer. The output improvement relies on the process improvement, directly run by experts — the employees — who are considered the best source of infor-

mation on weaknesses and possible improvements, and are the actors of a systematic documentation, analysis and improvement of the process. Such a deep employee involvement entails employee cross-functional knowledge and receptivity to change. To realize the P-D-C-A (plan, do, check, act) cycle typical of total quality management, managers as well are involved in a process of continuous adaptation of their directional style and relationship with workers. The total quality management model affirms the process standardization that, thanks to a scientific approach, offers the measurement and monitoring of small and incremental improvements, to provide a benchmark and ensure that processes are not changing unexpectedly (Whetsell, 1995, 80).

The quality improvement can be achieved also through the application of the new public management approach, that is «based upon combining "new institutional economics" (public choice, transactions cost theory and principal agent theory) with managerialism, which considers organizations in a detached, rational, scientific way». This approach shares with the total quality management the fundamental role attributed to staff professional and to personal values and behaviors in the «conception of and co-production of quality in everyday practice». Beyond monitoring systems and regulations, health workers values, training and personal behavior concur to manage quality.

Contrary to the total quality management, which is constitutively holistic, new public management affirms the disaggregation of public services into specific units, whose inputs, outputs and costs can be measured and controlled, according to the management techniques imported from the private sector manufacturing. Quality can be managed adopting the logic of formal rationality, hence considering it as a part of the wider performance, and privileging the rational rather than interpersonal and affective dimensions of care. Undoubtedly, this approach is more coherent with the Taylorist tradition, according to which to increase efficiency and standardization it is necessary to separate the conception and the execution of the task or service (Farr and Cressy, 2015, 2,1).

3.5.2.2 The application of the industrial and market-oriented models to health care.

In health care there are two recurrent assumptions: «that individual medical and health care practitioners are the cause of low quality, and that isolated actions are sufficient to improve quality»; consequently, problem solving focuses on isolated faulty components and related single-dimension solutions. This restricted resolutive frame and the lack of an organization wide vision of quality are inappropriate for multidimensional, complex problems (Ziegenfuss, op. cit., 21). Health organizations are systems, this means that the behavior of each person has an effect on the behavior of the whole organization (since the behavior and its effect are interdependent). If the person belongs to a subgroup. If the system is a whole, and all its elements are interdependent, quality cannot be raised by a single element or subsystem (Ackoff, 1981).

The application of total quality management to health care proposes the adoption of some methods to guarantee quality improvement through the knowledge on the influence of biomedical technologies, cure processes, information, health policies and patients on health outputs and outcomes. Moreover, patients are essential because they participate and share information on their expectations and needs, and on their level of satisfaction (this last is the essence of every total quality management project). Patient participation contributes to the perspectival vision of quality improvement, aimed to redesign health services and to improve their quality and value through a programmatic planning and a systematic evaluation of processes and outcomes. It is really important to define deadlines, to recognize a central role to management and to offer training to employees. Personnel has to be supported by the development and application of specific strategies apt to sustain an efficacious management of the structure, increasing the responsibilities but delegating them broadly through the organization, from the top to the bottom. Indeed, to ensure an efficient, effective, economic, accessible and acceptable service to patients, it is necessary to respond to patient needs with more sensitivity

and promptness. Patients are the primary objective of health services, information and communication, so all the operating units and their employees have to reciprocally respect their commitments, recognize each other, be righteous.

To implement the quality improvement approach, first of all, it is necessary to assess the quality of unit performance collecting patient opinion about the level of assistance quality and the services actually offered. In the mean time, the personnel awareness has to be sensitized on the necessity of quality improvement and the main areas where to work on, showing cooperation benefits to increase everybody's commitment. Once standards to check the performance quality have been defined, the program can be realized and a capillary system of communication can be activated inside the organization.

If patients are the primary objective of health services, the organizational culture is the primary condition of the total quality management model. Although there is not a specific plan to promote the organizational culture, it can be oriented through some projects aimed at training the personnel on the improvement content and deadlines. More, the organizational culture is decisive to combat possible employee resistances (aimed to defend traditional skills, roles, authority), adopting both vertical and horizontal approaches to mobilize the personnel, realizing a continuous action for the improvement. Actually, costs increase also because of poor quality, not only when there is high quality. Distributing costs on the phases of prevention and evaluation is useful to monitor quality and to prevent both external and internal failures (Koch, op. cit.). Mol (2008) underlines the importance of a "customer-oriented bureaucracy" in health care, admitting that the «logics of formal rationality and Taylorist mass production encourages efficiency», but it is the personalization and the orientation to the individual within the patient-centeredness that make a mark of quality (Farr and Cressy, op. cit., 3). Furthermore, workers involvement is required, because team development and peer negotiated standards, the motivation and values of workers, over sharing the knowledge, are fundamental elements of a high-quality performance as much as the patient intervention.

When market orientation is adopted in health care, customer orientation, competitor orientation, and inter functional coordination characterize the health system (Narver & Slater, 1990). Hospital profitability, product development, sales growth, customer retention, and cost control are all effects of market orientation (Lonial & Raju, 2001; Raju, Lonial, Gupta, & Ziegler, 2000; Wrenn, 2002), but necessary and timely health care is the main objective, in order to reach patient satisfaction and trust in a hospital or its medical staff (Weng, Huang, & Huang, 2006). But before achieving an external consensus, it is important to reach an internal one by the provision of «friendly hospital staff management activities, including employees' understanding of the hospital's vision, human resource development and the reward system, and hospital culture that enhances service quality for patients» (Tsai & Wu, 2011 in Huang et al., 2012, 207). Finally, market orientation should offer the ability to connect with patients to the health system's staff, by realizing in advance patient expectations and satisfying patients needs offering an adequate medical service.

In this regard, some authors remind that the comparison of health services to industry is not totally justified, inasmuch standards and pre-codified rules are integrated in a broad patient participation (Raimondi, 1997; Carbognin, op. cit.). The comparison to industry brings out the "hard" organizational components such as technology, financial resources, formal rules and structure, and logistical conditions. Nonetheless, the relational dimension in the organization is also very important, seeing as it is built upon the concept of health through the intervention of both patient and physician, whose meeting is crucial for the perception of quality (Norman, 1985). Focusing just on the "hard" component would mean eclipse the "human" or "social" nature of the organization, such as cultures, ambitions, personalities and professionalism, to enhance a technocratic logic (Raimondi, op. cit.). Quality of health care is made up by the personalization of the service, according to the specific conditions of the patient within the organization complexity. Even if all the cases share something, there is the risk of abstraction of the service beneficiaries into a generic public without expectations, acceding to a medio-

cre service offered by bureaucrats. But bureaucrats usually homologate procedures without paying to much attention to the individual. Hence, a bureaucratic attitude is at opposite of the quality of health performance (Lipsky, 1991).

3.5.3 The Outcomes movement.

Health assurance is subject to a third revolution, run in the late 1980s by the public and private sectors, and characterized by quality, documentation, and accountability as trends for medicine: «we have entered an era of unprecedented growth in activity directed at the assessment of outcomes, the analysis of effectiveness, and quality assurance. For example, the Joint Commission on Accreditation of Hospitals, moving away from its traditional reliance on structural measures, has formally embraced quality assessment based on severity-adjusted outcomes as the cornerstone of its future strategy for monitoring hospitals» (Epstein, 1995, 188).

During this period the main propose of a theoretical frame is the Outcomes Movement (Graham, 1995), that affirms the research on outcomes as the main informational channel to assess effectiveness, and as a useful tool «to increase the efficiency of existing systems for monitoring the quality of care». Hence, the information collected through this approach has clinical relevance, since, beyond the development of more effective means to communicate new findings to physicians and information to patients, it contributes to a better decision making and to the expansion of medical knowledge. Also, the emphasis on the assessment of outcomes and effectiveness responds to the need of cost containment and resource optimization, helping eliminating the unnecessary expenditures and monitoring not only improvements but also quality deterioration.

Anyway, a broader and more comprehensive information does not ensure an increased understanding of the investigated phenomenon and of the collected data (Epstein, op. cit., 188, 189).

3.6 Suggestions for a real quality improvement.

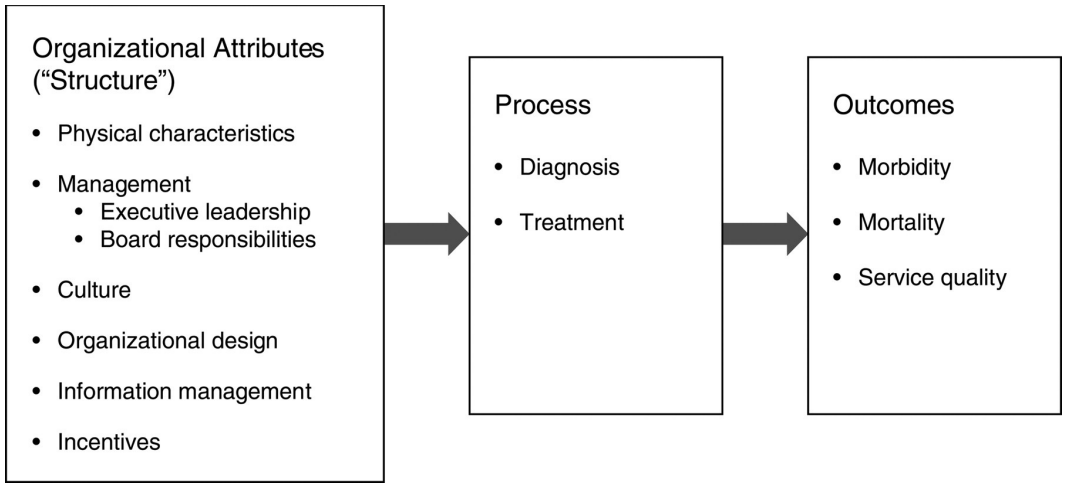
To apply an industrial vision and/or a market orientation to health care aims at the development of a patient-oriented professional culture, so the increase of patient satisfaction and providers' feeling of belonging to the organization, as much as the improvement of the managerial skills in the politic and technical field. In order to improve service quality, Fraccaroli (1991) suggests to facilitate the patient-doctor communication to show the organization's interest in problem solving and allow patients to share their opinions, reclaims, suggestions; in addition, the patient would receive clearer and more sincere information, while the provider would be directly responsible for the health process and its outcomes. Moreover, organizations should adopt more dynamic delivery models, managing with particular attention the more visible aspects of services (the first aspects people see in services).

Different authors dedicate their attention to the development of key strategies and models able to meaningfully change health services in a positive way. Ziegenfuss (1993) distinguishes five key strategies for quality improvement, beginning from the creation of a quality-oriented organizational culture. It is important to value quality and continuous improvement, although people would think that quality already exists and does not need any positive change. In order to develop a culture of quality and provide education and training about health care quality, Quality Grand Rounds could be developed by health organizations. Another strategy aims at the evaluation and redesign of the technical subsystem to improve quality, constantly reviewing and adapting the way services are delivered. Since services' relevance, organizations' external investment help, research and development are recommended. A third strategy, named "change the structure to support quality", calls for the definition of the internal organizational elements affecting quality, to identify the structural options that best support high-quality services. The next strategy, instead, pursues people's (rather structure's) orientation to quality; so, it is up to administrative and clinical leaders to influence the

employees' attitude and commitment toward health quality, and to avoid delegating the individual responsibility.

The last of the five strategies proposed by Ziegenfuss assigns quality improvement to managers, through an effective (and updated) application of tools from quality management, considering that «management commitment is pertinent to every successful quality revolution; no exceptions are known!» (Juran, 1989 in Glieckman at al., 2007, 341, 342). Within this last strategy, Glieckman et al. focus on the key organizational attributes with regard to quality of medical care, defined as «the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Although there is now a robust evidence-base in the quality-improvement literature on process and outcomes, structure has received considerably less attention» (ibidem; Meyer and Masagli, 2001). Human capital, leadership, information management systems and group dynamics (such as culture and incentive systems) are both effective organizational capabilities and essential structural elements of quality improvement in health organizations. The authors advance a broader description of Donabedian's original classification, listing many organizational attributes as structure's categories from a management perspective.

Figure 1. Key managerial elements evolved as crucial tools and management capabilities in successful business. (Glieckman et al., 2007, 341).



First of all, senior leadership, since «quality management has become a priority for senior executives and chief medical officers» have to «set the direction of the organization and guide quality-improvement efforts» (Glieckman, ibidem). Leaders have to support and propagate new ideologies, showing personal motivation, action-oriented judgment and capacity to motivate others (Osland, Kolb, Rubin, 2000), inasmuch as even their physical presence and visibility impact on organization culture and commitment to quality improvement become relevant (Waldman et al., 1998). The whole board has some responsibilities — the second organizational attribute — to promote clinical involvement in quality improvement; indeed, it has to support a direct and rich communication across the departments, in order to facilitate the information exchange and increase the trust among employees. Board responsibilities are great because quality-improvement programs can be costly and there is not yet evidence demonstrating a positive return on investment of capital for quality-improvement efforts (Weiner et al., 1997). Consequently, culture — the third attribute — is the "glue" apt to hold the organization together while it is changing, and the organizational design — the fourth attribute — is the guided process aimed at the integration of people, information, and technology of an organization. The objective is to maximize value adapting the organization's design to the overall strategy, overcoming the conflict between central control and local autonomy and accountability. There is agreement on the relevance of incentive structure, another organizational attribute, especially on the balanced scorecard, helpful to implement corporate-level strategy and goals while continuing the unit's specific plans (Pointer, Totten, Orlikoff, 2005). A last attribute is the information management and technology, to disseminate information across the health-care delivery system and among the external institutions.

The main challenges health organizations have to face are the underuse of the evidence-based approach and a poor identification of priorities for quality improvement to realize in sustainable processes. In the following scheme there are some questions helpful in planning quality improvement strategies.

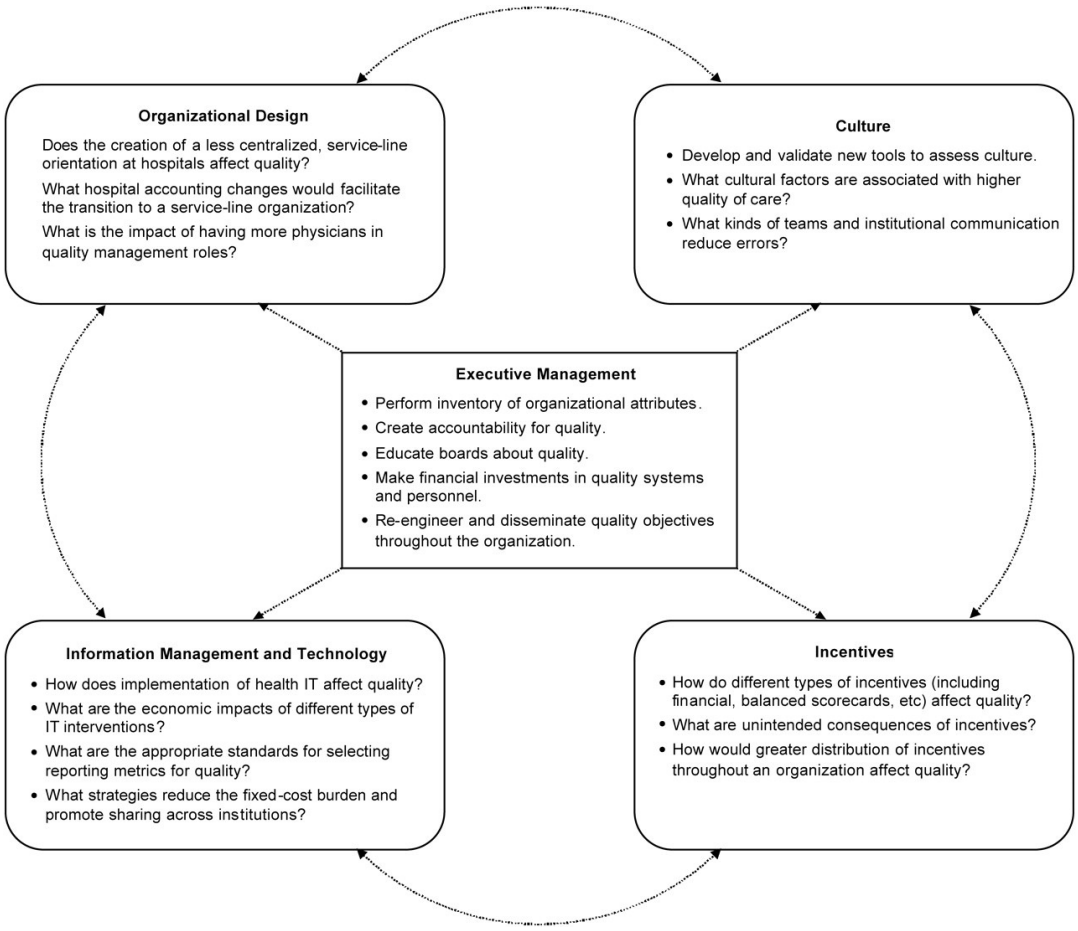


Figure 2. Future directions for improving quality. (Glieckman et al., 2007, 348)

Because of «the outcomes from an episode of care are the result of a complex and highly integrated series of processes performed by the medical staff and the health care organization» (Bolster et al., 1995, 115), the processes that directly impact on patient outcomes have to be identified and improved. The design of a new process should proceed step by step, to avoid the "fix and repair" work as much as possible, and after implementation each step should be evaluated to justify by evidence the difficulties faced by employees during the process of change, and to establish the organization's baseline performance. It is relevant to avoid an overmonitoring, because the attention should be focused just on those key process

indicators assuring the realization of the implementation and showing outcomes improvement.

Since the limited availability of resources, these ones should be invested in those systems or processes vital for each facility's interests. On the contrary, improvement strategies have to be planned for and adopted in the whole system, and to be successful they have to involve stakeholders. Quality improvement and organizational change do not produce the desired benefits, if they are realized only through an external action by management and consultants. First of all, it is necessary to work on team building inside the organization; in this way there will be cohesion, trust and respect among the team members, useful to respond rationally and productively to the charge of the change. «Adversarial behavior and hidden agendas must be openly identified and recognized as resistance to change» (Bolster et al., 1995, 119); moreover, the adoption of a "blame and punishment" strategy would not stimulate employees in cooperating on a conscious dynamic improvement. «In clinical improvement teams, this common ground is improving the health status of populations» (Bolster et al., 1995, 119), but this objective is usually insufficient to support employees in doing their best and cooperate for the delivery of an efficient and efficacious service (as they would not be patient of the health system as well).

3.6.1 Quality improvement and chronic diseases.

Batalden and Davidoff (2007, 2) define quality improvement as the combined and unceasing effort of healthcare professionals, patients and their families, researchers, payers, planners and educators to realize the necessary changes for «better patient outcomes (health), better system performance (care) and better professional development». When changes will become an intrinsic part of everyday's and everyone's job, in the whole system, healthcare will reach its full potential; to achieve this successful condition, people need scientific and experimental learning, both at general and particular level, about design and execution of stra-

tegies. Indeed, knowledge does not guarantee improved performance, because everyone has to be concretely involved in doing his/her work and also in improving it. Better health outcomes, a better care delivery and a better professional development are all linked, need sustainability and creativity beyond a basic understanding of work standards, as well as the skills to test changes for implementation.

«The inclusion of evidence-based approaches can bring increased coherence and efficiency to healthcare systems and provide a means for improving quality across a range of chronic health problems». The CHRONIC CARE MODEL (since now CCM) is an evidence-based model with the purpose to describe those improving practices in the health system on chronic disease patients' outcomes. The aim is to promote a more active and informed interaction between physician and patient, through self-management support, that is enabling patients and their families in managing the illness by themselves in an ongoing collaborative process between patients and professionals. This does not exclude interventions on the delivery system design, such as the valorization of non-physician members, who play a clear complementary role.

Then, talking of chronic diseases, decision making has to be run according to clinical expertise and experience, that is evidence-based practice guidelines or protocols beyond the basic clinical knowledge. By doing so, decision making will have a meaningful impact on patient care. A tool of decision support is a clinical information system, convenient to provide physicians timely and useful data about population or a single patient. «A disease registry or database that includes information about the process and results of care for all patients is the essential ingredient. Healthcare teams with access to a registry can contact patients with specific needs, deliver planned care, receive feedback on their team's performance, and benefit from reminder systems. The focal point of the CCM is productive interaction between informed activated patients and prepared proactive practice teams».

Another element typical of the application of the CCM model at the micro level is «the partnership between patients and families, healthcare teams, and

community partners». When members are all informed, motivated, and prepared with the required skills to manage chronic conditions, there is a large involvement inside the healthcare organization, community is broad, there are all the conditions for a successful patient-team-community triad; this one is the key element of the Innovative Care for Chronic Conditions (since now ICCC), evolution of the CCM model. In this way, patients evolve from ‘‘informed and activated’’ into ‘‘informed, motivated, and prepared’’, because they need to have access to medications, self-monitoring tools, and self-management skills. Naturally, progresses at the micro level can be reached if there are as much progresses in a macro level: «legislation, leadership, policy integration, partnerships, financing, and allocation of human resources are examples of policy activities that occur at the macro level and are depicted in the ICCC framework». Exactly, the integration of policies for chronic diseases minimize wastes and discontinuity in the health system, especially if policies enclose prevention, promotion, and control strategies, with explicit links to other governmental programs and community based organizations (Epping-Jordan et al., 2004, 300, 301).

Since the continuous spread of chronic disease conditions and the relevance and efficiency of a centralized system to cure and help patients in self-managing the disease, it is necessary to promote consistent long term investments in the infrastructure for care and to develop human resources. To meet the growing demands of care for chronic diseases, it is imperative to build a system offering widespread and interconnected services characterized by a pondered allocation of human resources. Well-trained health professionals are not sufficient anymore; new categories of healthcare workers such as self-management counsellors have to be included in the personnel map, beyond policy and service planners, researchers, information technology designers, and support personnel. On the other hand, the health system have to strengthen and coordinate inter-sectoral partnerships on the outside, with other governmental sectors, the private health sector, and community groups and organizations.

«The goal of quality improvement research is weighted toward identifying how to implement effective changes, not assessing the efficacy of those changes» (Baker, 2006, 150). Undoubtedly, the implementation of improvement interventions might be impeded by unforeseen or difficult to control variables; especially the strategies apt to improve chronic diseases are particularly complex, as they include «multiple components such as guidelines, patient education, communication between care providers, and the development of registries and information systems. Such interventions target multiple caregivers as well as patients». This means that the quality of care depends on the level of precision with which the intervention is defined and on the logistical interconnection between the health system's substructures (Baker, ibidem). Campbell and colleagues (2000) suggest to plan the design and evaluation of the quality improvement intervention as a complex action, by specifying the intervention's components, how they relate to each other, and how they influence proximal and final outcomes. As recommended by studies in the field, qualitative research has to be undertaken «to test well designed bundles of changes, identify barriers to change, and determine how to scale up the intervention efforts from a few organizations to many» (Baker, ibidem). Monitoring and documentation are included in research design, as they allow to define the changes happening in the process and in outcomes too. In this way, a health care system fitting the local context's needs would be justified by evidence-based certified quality improvements.

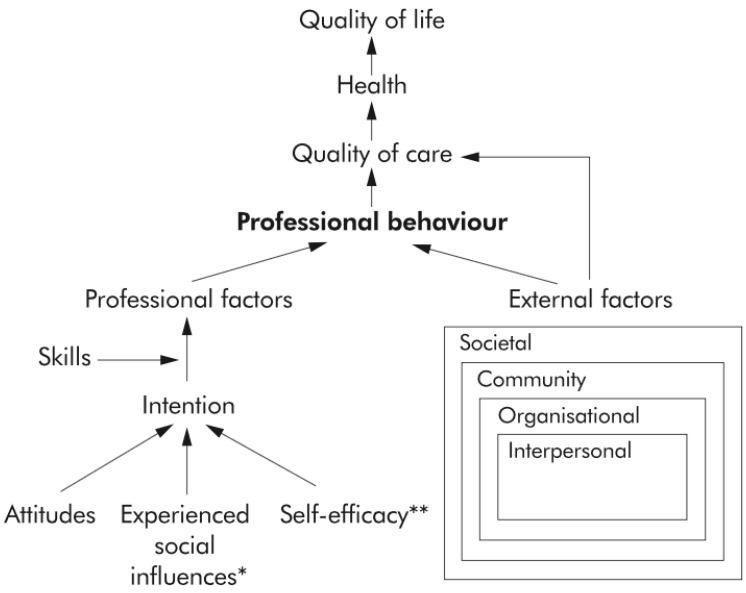
3.6.2 Facilitators and barriers to quality improvement.

Shaw and Kalo (2002) clearly state that «one common experience is that improving quality depends less on having more staff, equipment or money than on reorganizing the use of resources we already have, and changing the way we work. It is about behavior more than technology. Openness, confidence, motivation and commitment are the foundations of a quality culture. But often, traditional practices and attitudes towards authority, mutual support and individual re-

sponsibility actively resist improvement. These create a culture of low expectations, vertical command structures, restricted information and a negative view of accountability and responsibility. Quality improvement is seen to refer primarily to structure, equipment, buildings and staff rather than to operational processes and results». By doing so, in absence of performance data and adequate monitoring, people will continue assuming that the service with the most resources is the best. In addition, errors are considered as individual blames rather an opportunity to improve the system, and quality management is compared to inspection and control rather a way to improve the system. Furthermore, there are a bunch of tools to facilitate and achieve more efficiently the quality improvement, such as collecting information inside and outside the organization (beginning from the collection of teams' feedback for a peer-group benchmark) and training employees. Indeed, one of the main obstacles to quality is the lack of knowledge. Then, there are incentives, that need to be publicized and have to satisfy the formula "more tangible, more efficient".

Finally, the authors suggest a model of barriers and facilitators to change the professional behavior, first, and quality of life, later.

Figure 3. Model of barriers and facilitators.



The basic concept of the model is PRECEDE–PROCEED, that locates barriers and facilitators within the person of the professional or in his/her external context. «Factors inherent in the professional — such as attitudes, perceived social influence, and self-efficacy — stimulate the intention to change, while skills are needed for actual change. Context factors can have different levels. External influence can come from other individuals (interpersonal level) — for example, a patient requesting treatment — but also from a larger group such as a nursing team (organizational level), a local professional society (community level), or a whole nation (societal level) — for example, through legislation or insurances. Major factors at the organizational level include the organization's mission, goals, policies, procedures, structures, technologies, physical setting, collaboration, and resources. At the community level, barriers and facilitators include collective self-efficacy, political efficacy, and motivation to act. At the societal level changes take place through political influence. Factors influencing the political decision process include the place where policies are made — whether outside or within the government, or within the government but requiring support from outside for passage — and groups influencing the policy makers such as professional societies or patient groups» (2002, 7).

It is deducible that the organizational culture is one of the two main reasons of the "consistent inconsistency" of quality improvement, since the context is a fundamental variable influencing the effectiveness of quality improvement interventions. The other main reason is the complex nature of quality improvement as heterogeneous organizational intervention, continuously evolving during its development and implementation. Consequently, as the adoption of a quality improvement strategy is indisputable, the organization management has to work on which approach to quality improvement to select and on its long term planning. At the same time, quality improvement evaluation has to declare what are the determinants of effectiveness, or more simply how and why the intervention worked. Thus, it would be easier and more efficacious to adopt quality improvement ac-

tions which have been developed and have worked elsewhere, identifying the differences impeding or facilitating their realization in a different organization. To achieve this objective, it is recommendable to use participant observation and in-depth longitudinal organizational case studies and to develop a theoretical framework in order to explain the results of these studies, in order to achieve more generalizable and transferable findings. In addition, the quality improvement program should be "auto-evaluative", «so that the program itself produces information about its own effectiveness» (Walsche, and Freeman, 2002, 87).

Moving back to a general description of facilitators of quality improvement, Shaw and Kalo give another interesting contribution, that is the phase of population targeting. It is one of the steps of problem analysis, broader described by Prochaska (1984), and includes five stages, such as the pre-contemplation, when the target population is not conscious of the duty and possibility to change its behavior, followed by the contemplation, when the target population considers benefits and disadvantages of changing its behavior. Later, concrete plans for change are designed and applied — preparation and action — before the target population's choice to maintain the new behavior or return to the previous.

The Cochrane Effective Practice and Organization of Care (EPOC) group studied the interventions developed to intensify the implementation of research findings or innovations in daily practice to change team or professional performance, blaming the difficulty of changing existing practice on inadequate or non-optimal methods to design intervention strategies and to evaluate interventions. It usually happens that the development of the improvement strategy is intuitive rather scientific, so based on the developers' familiarity with a specific strategy rather on a research method; in addition, the intervention is designed on its format rather than its content, even if «it is generally accepted that, to be effective, interventions should be targeted at specific barriers and facilitators of change. Systematic development of interventions and tailoring their content and format to the specific features of a target group and setting seems necessary to improve the ef-

fectiveness of patient care». The choice of a familiar approach is often due to the complexity of the scientific method, that requires study, creativity, time and resources to collect information during each step; high cooperation between project group members, target population, materials designers, and implementers. Moreover, it is necessary to balance pragmatic skills with theory-based methods (Bokhoven et al., 2013, 215).

Discipline and methodology acquire importance inasmuch quality improvement in health care leads to patient safety. It is necessary to have an evidence-based support to «challenge the assumptions and preconceptions about how health systems work» and to update to present patients the assumptions on which plans are designed, in order to achieve relevant outputs both in a larger scale than in a single clinical intervention. In health delivery design, it is important to include variability, feedback loops, and human behavior, hence to understand how processes work and to offer a better service and experience to patient, avoiding waitings. The use of technique is relevant at every single level of health delivery, also in the doctor-patient interaction. In order to apply new and more efficacious models of service delivery, non-health care settings for routine care, information technology to deliver care in patients' houses, and the inclusion of patients as designers and co-producers of care are fundamental (Edwards, 2005, 75).

3.7 Legislative history of the quality of health in Italy.

Each government chooses how to pursue quality in health care; some choose to «express quality values, such as access, equity, and effectiveness in general statements of policy», others «publish explicit standards such as patients' charters, health improvement targets and service frameworks». Others promote the performance measurement through clinical indicators or «set up national centers for quality methodology and licensing of institutions». What often lacks is not the theoretical or legislative frame defining and supporting quality inside a strategic

reform, rather an evidence-based operational initiative that implements quality as clear priority of a management agenda (Shaw, Kalo, op. cit., 9).

Italian Government has always been steady committed in the development of policies and reforms intended to offer first, and lately guarantee, quality of health services. In 1984 the Italian Society for Quality in Healthcare (SIQuAS-VRQ) was established, aiming at the research, codification and diffusion of tools, techniques and methods to design, organize, assess and improve quality and safety in healthcare. Even if SIQuAS-VRQ is the representative of the International Society for Quality in Healthcare and the European Society for Quality in Healthcare, it involved the Local Health Authorities' and Hospital's Offices for Quality in a network designed to support the diffusion of quality in health care.

A few years later, the Art. 1 of Legislative Decree No. 502/1992 established the Piano Sanitario Nazionale (National Health Plan, since now NHP) to supply a strong legislative basis for monitoring and improving the quality of health care. The NHP is the main programming tool used by government, according to the proposals advanced by the Ministry of Health and by the Regions and Autonomous Provinces, to define public health objectives. Its adoption is made official by decree of the President of the Republic after deliberation by the Council of Ministers and agreement of the Standing Conference on the Relations among the State, the Regions and the Autonomous Provinces. The NHP occurs every three years since 1994, to address national health policies toward quality improvements, providing uniformly and appropriately health care services across the country.

The Legislative Decree No. 502/1992 left a mark in the history of the quality of health performance also because its Art. 1 defined the Livelli Essenziali di Assistenza (Essential Assistance Level, LEAs since now) as well, that is a whole set of performances the National Health System is going to guarantee for free, inasmuch as they represent a benefit for the individual or collective health considering the spent resources. After some legislative updates, that is the legislative decree No. 29/1999 and the law No. 405/2001, LEAs entered into force in 2002 after having been organized in three fields: public health services, community health and pri-

mary care services , and hospital care services. LEAs are defined on criteria such as human dignity, effectiveness, appropriateness and efficiency, and they are continuously revised through appropriate indicators.

The article 14 of the above-mentioned legislative decree, instead, affirmed citizens rights in term of adjustments of health structures and performances according to the citizens-patients' needs. This is the reason why the Ministry of Health, together with the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces, defines content and modalities of indicators of health services and performance leading to the assistance personalization and humanization, right to be informed, and preventive care. The monitoring of these indicators by the Regions has also a political function, as it permits focused investments of human, technical, and financial resources. This article is relevant also because it aims at the activation of an information system apt to collect and share information about the supplied performances, allowing voluntary and patients associations to take part at it, giving information about patients experience and satisfaction. Then, it should be a Local Health Authority's duty to adopt the necessary measures to eliminate disruptions affecting the quality of health assistance.

To monitor quality of health performances, the article 10 of the above-mentioned legislative decree set up the adoption of a unique method going beyond quantity and costs, that assigned an inspection power on Local Health Authorities to Regions, while Ministry of Health had to exert a role of high surveillance. Later in 1995, the Agenzia per i Servizi Sanitari Regionali was instituted under authority of the Ministry of Health with the aim of supporting Regions in activities of evaluation and monitoring quality, efficiency and equity of health care services (through survey, indicators, accreditation, guidelines, and so on); analysis of health expenditure; support to regions in health planning, evaluation, and management; and management of continuing medical education. This Italian governance structure was later named Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS).

The attention toward appropriate level of quality of health assistance, both at organizational and service level, is the theme of the National Program For Quality, quoted in the National Health Plan 1998-2000. To promote and assess the quality of health assistance, it is necessary to act in all the dimensions making up health assistance, that is the professional, the organizational, and the relational, whose objectives, activities and outcomes have to be clearly described in the Local Health Authority's public service charter.

Another tool adopted in the Italian NHS to enhance the quality of care and support the appropriateness of care is the Patto per la Salute, a three year financial and programming agreement between the government and the regions. The most meaningful should be the one that is underway, the Patto per la Salute 2014-2016, whose scope is to guarantee the access to care services of high quality to each citizen, especially through «the expansion of community care networks such as Unità Territoriali di Assistenza Primaria (UTAP) and Unità Complesse di Cure Primarie (UCCP)». Talking of local care co-ordination and integration between health and social care need to support leadership at national level, Balduzzi Law (No. 189/2012) introduced new organizational forms in primary care such as community care networks (for example Casa della Salute) and Community hospitals (Ospedale di Comunità), «characterized by a high level of integration between levels of care and rely on multidisciplinary care teams and personalized care plans» (OECD, op. cit., 52, 26).

But the toolbox of quality is not yet full since in 2013 the Commission for Health started the activities within the Programma nazionale per la promozione permanente della qualità nel Servizio sanitario nazionale (PROQUAL), a national program aimed at the design of tools for the design and evaluation of services, and the design of regional policies.

Last intervention in time realized by Italy is the proclamation of the decree No. 70 of 02/04/2015 about qualitative, technical, structural and quantitative standards for hospital care.

I believe that this is the last of unnecessary interventions worthy on the theoretical level but not incisive on the practical, that can hardly be efficaciously implemented. There is a lack of experimentation as previous step of the policy implementation, sign of a weak scientific and evidence-based support over a weak system of control, typical of the Italian context. LEAs, for example, represent the minimum performances that have to be guaranteed to each citizen by the NHS, but how do they fit with the above-mentioned dilemma of offering a good service to a few patients versus offering a poor service guaranteed to anybody? Of course, LEAs cover certain kinds of health services, but this does not give an exhaustive answer. In Italy, the affirmation of the quality of healthcare has been too intense and punctilious at a theoretic level, without a concrete support and praise of real actions of quality improvement or humanization of health services. Patient are still too often considered as obstacles or enemies of providers and clinical procedures, seeing as they do not own the necessary clinical knowledge. Patients are not even seen as the reason why the health system exists, rather a source of complaints and delays (as if providers would not be themselves patients or customers of healthcare). In this way, it is not possible to imagine how patients could use data about the quality of health performance, especially to improve it. Maybe the roots of this problem lie in the priority accorded to budgetary control instead of quality.

3.8 OECD's suggestions for quality improvement.

OECD agrees on the idea of a quality improvement based on the reorganization of the available resources rather the adoption of a new organizational system, because attitude is more incisive than technology. Quality improvement should be supported by leadership as promoter of, on one hand, the cooperation between departments and services, and on the other, the performance as a corporate organization. «The European Organization for Quality is focusing on management as one of the key social dimensions of quality improvement in health care. Many

professionals, particularly older doctors, are uncomfortable with patient empowerment, peer review and team working, and with sharing information and power. A key stage in developing a national strategy is an assessment of the prevailing culture and the long-term implications for reassurance, training and information for the major stakeholders: users, health professionals, politicians and payers».

Quality improvements should be pursued at every single structure level, so in every care performance, hospital, procedure, institution, avoiding a too broad fragmentation, usually poorly factual or operative. Anyways, the European directives suggest to distribute among different institutions the political, executive, and informative functions. By doing so, someone will work on the formal procedures apt to promote and support a long-term and integrated policy of quality, while someone else will be responsible for technical issues such as standards, measures, audits, and so on. Also, there will be someone working on information, by collecting national and international information about experiences and techniques.

Quality improvement process will take some years, achievable and sustainable goals in agreement with available resources and within a defined time will be set, and incentives for performance improvement will be defined and publicized. Training will be fundamental for the development of knowledge about effective methods for quality improvement, attitudes and skills for an evidence-based performance measurement. The relationship with public is important for both information and consultation, realizable also through the publication of an annual account.

The following scheme represents the classification of the conceptual approaches about quality of health care, each one suggesting defined standards, measurement tools and methods, and change management (Shaw, Kalo, op. cit., 7).

Table 4. Conceptual approaches of healthcare quality, Shaw and Kalo, 2002, 34.

OECD advances specific suggestions for each one of its participant countries, recommending to Italy the adoption, both centrally and locally, of incentives

Clinical practice				
5. Clinical effectiveness	Variations in practice Biomedical research Clinical effectiveness Technology assessment Clinical freedom Public demand	Guidelines Protocols Critical care pathways Recovery pathways	Clinical audit Clinical indicators, benchmarking Adverse patient events Delay analysis Confidential enquiries	Peer pressure Feedback, information, training Audit action plans Specialization
Management				
6. Service delivery	Team working Service integration Patient-centred care Public accountability	Training programmes Planning guidelines Internal policies Accreditation standards Service frameworks Health care contracts Industrial QA standards Licensing regulations	Self-assessment (indicators, EFQM) Occasional surveys External certification, accreditation External quality assurance (labs, X-ray) External performance indicators Peer review visiting Statutory inspection	Pathology, radiology accreditation Quality strategy, leadership Organizational development Team working Award schemes
7. Risk, health and safety	Risk management Cost containment Public relations	Internal risk procedures Accreditation, ISO standards Guidance from insurers, inquiries, government Statutory regulations	Self-assessment, risk assessment Adverse event analysis see 5B External review: ISO, insurance, accreditation Statutory inspection, licensing, registration Public inquiry	Training e.g. lifting, fire Financial incentives Preventive maintenance Whistle-blowing Litigation
8. Resource management	Efficiency Equity Rationing Opportunity costs Cost-benefit	Resource allocation formula Planning guidelines Staffing, equipment targets Clinical guidelines, HTA	Clinical costing Utilization review Efficiency indicators Capital asset, supplies audit National surveys	Waste reduction Resource re-allocation Insurance, payment incentives Clinical budgeting
9. Communications	Patient involvement Management control Clinical evaluation Cost recovery	Record content standards Data quality standards Patient information standards	Communications audit Audit of records, data accreditation Accreditation survey Communications audit	IT strategy Records committee Casemix-based funding Training in clinical coding

and sanctions to encourage guideline implementation and manage more efficiently chronic diseases at primary care level. The Italian initiative to standardize accreditation for continuing medical education (CME) providers has the scope of ensuring nationally consistent workforce training programs and trying to reduce regional disparities in quality and outcomes. It has been a good move, but the country still needs to innovate its self-regulatory models of workforce quality insurance, ensuring an adequate medical knowledge for the continuing evolving delivery system through recertification or relicensing protocols for physicians. The first recommendation for improving health care quality in Italy is to strengthen quality governance in health care conferring more value on data. In this way, the spread of best practices would be easier and theoretically justified, as much as patient involvement would increase by more extensive and systematic surveys. Italy has to focus on physicians, working since their education at school on communication, team working, self-reflection on practice and competency, that is the same qualities proper of a health professional, and preferring active exploration and participatory learning approaches. Inside the system, instead, physician should work on conferring more productivity to their own results, so improving their own care.

To enhance data management and use, OECD recommends Italy to create a «single national institute for health system information to collect, analyze and disseminate health system metrics», in order to reduce fragmentation in the information infrastructure and strengthen local accountability. Moving to chronic conditions and primary care, the coordination between primary care physicians and patients inside community networks is fundamental. «More widespread collection of physician-level or practice-level quality and outcome indicators would be highly desirable, if challenging to introduce. In other countries doctors have in fact been pleased with the availability of data that allows them to reflect upon their own practice, and compare it to that of their peers».

To facilitate quality improvement and realize these recommendations, health organizations should define performance management as a multidimensional collective exercise rather as a technical problem, designing indicators to collect data on physician-level and practice-level quality or outcome. In addition, although the rapid emerging burden of chronic disease, preventive care is not yet promoted and practiced as much as it should (OECD, op. cit., 32-33).

3.9 Last observations about quality.

The quality of health care consists in the personalization of health services, that is the adaptation of health service delivery to patient's specific conditions (within a homogeneity typical of a certain disease, especially if chronic), conferring attention to patient's physical and mental health. But quality responds also to the contemporary economic needs of efficiency and fight against wastes, through a directional style applied into an institute or corporation, where there should be a strong and widespread organizational culture based on transparency, accountability, and value for money of health services delivery. This theoretic description is often only partially realized, because both the program and the physicians should take care of a defined number of patients, that would allow and guarantee a higher level of quality for everybody. However, the choice is often between an almost

perfect assistance for a few patients or an imperfect assistance for many patients (Ruta, op. cit.).

Hence, Coffey et al. suggest the elements contributing to a critical path, a tool useful to define an optimal sequencing and timing of interventions. It aims at the maximization of quality of care by minimizing delays and improving the utilization of resources, involving the entire organization personnel — doctors, nurses, administrative staff —. «Typically, critical paths are developed for high-volume, high-risk, and high-cost diagnoses and procedures. The following aspects of the care process are typically tracked: consults and assessments, tests, treatments, nutrition, medications (both intravenous and other), activity or safety, teaching (patient, significant other), discharge planning and coordination, and other additional categories based on the specific diagnosis or procedure». The progression of intervention is based upon the comprehensiveness of many elements such as decision making, service delivery, patient-doctor interaction, and the collaboration between multiple health care professionals. Since critical paths are planned on the patient care process, they have to be developed including patient inputs, in order to achieve at least one of the main objectives coordinated with critical paths. To clarify the big picture is one of these objectives, since each professional has a clear idea about his/her job or intervention but not on the overall care plan — that is the outcome of many disciplines are rarely coordinated in a single collaboration plan. Consequently, next objective is to provide planning and coordination of care by mixing data, expert opinion, and consensus, to create common expectations among physicians, nurses, and other care providers. Obviously, regular communication among caregivers is a necessary condition to promote an early problem detection and intervention, beyond the reduction of variations in the process and outcomes of care. Critical paths could be adopted also to to educate staff and students, as much as patients and their families about treatment plans and expected outcomes. By doing so, the firsts would learn about key interventions and variances, while the seconds would learn about expectations about treatment progresses. The cooperation among professionals and a mutual understanding of everyone's

role in providing quality are the conditions simplifying improvements in the working environment; indeed, they foster communication and mutual respect among health professionals as much as between professionals and patients. Last but not least, guide-lines could be defined and applied for benchmarking. For a successful implementation of critical paths, it would be recommended a multidisciplinary team working during the entire process, from design to evaluation of critical paths, avoiding that only a case manager would be in charge to check the adherence to the critical path, to facilitate the desired outcomes, and to evidence variances. The team should establish a few clear key measures of conformance and outcomes to define the timeliness or the types of variances on which focus on. These measures can be adapted as the process goes on and eventual weak or force points come out. In order to realize and improve critical paths, it is necessary to educate the involved staff and orient it toward the main affecting elements (1995, 140, 141).

Europe has been a pioneer of quality in health care while Italy, notwithstanding its cultural commitment to quality control, has invested later and less in improvement programs than other countries. The delay in the adoption of quality improvement programs, nonetheless, can be read as an opportunity to reflect about other countries' experiences and mistakes. The legislative decrees No. 502/1992 and No. 517/1993 introduced general values such as Regions' autonomy and accountability, corporatization of structures, competition in services offer, and the separation between political and directional functions. Health organizations are financed in accordance with the supplied performances and the outcomes of costs, outputs, organizational efficiency analysis. In this way, a more systematic and informative process should be triggered, as data on costs and performance should be collected more extensively, timely and reliably, in order to allow a comparison among the operating units and justify decisions by showing both clinical-scientific and organizational-economic support. Consequently, the most important strategy to improve quality is to conduct survey systems so that each team's or individual's contribution could be observed in a more detailed and pre-

cise way. If system services would be structured on patient's free choice, there will be a push to functionality, efficiency, and quality (Koch, op. cit.).

The enhancement of survey systems leads to the definition of quality, codified in the questions and expressed in line with the respondent's professional role. Hence, quality is defined in term of providers' attitude and tributes, rather assistance outcomes, and the expectation of satisfying outcomes is the main factor affecting the definition of desirable providers' tributes. If providers focus on physical, social and psychological functions and the activities positively or negatively affecting them, patients usually focus on the relationship established with providers, on the technical knowledge of these, and on the structure's comfort.

As we know, quality's tributes cannot be defined in a unique concept, as much as a physician's performance will not be perfectly fitting the ideal quality. This is the reason why it is important to clearly specify the adopted definition of quality as much as the indicators that are going to be used in its evaluation. Now it is the time to focus and develop studies and experiences on the quality assessment, in order to guarantee the efficiency and validity of quality improvements.

Chapter IV

Evaluation of health systems and quality of the health care performance.

4.1 The Health Systems Performance Assessment.

The «health systems performance assessment (since now HSPA) can help optimize health systems for health authorities committed to improving the health of their people. HSPA is an indispensable tool for governing the health system and WHO Europe encourages all of its Member States to carry out periodic HSPAs to inform policy-making and align stakeholders» (WHO Regional Office for Europe, 2012c, 2). As asserted in the Tallin Charter (2008), health performance monitoring and assessment aims at the promotion of accountability and transparency, fundamental for stakeholder cooperation. Effectively, spreading information about performance and progress favors the creation of a shared understanding and vision among stakeholders of the actions needed for improving health services, in line with an evidence-based policy-making and priority-setting. Moreover, a global review and assessment of running interventions is indispensable within as much as without the organization since its providers and employees can acquire awareness about the influence of joint actions on health outcomes. This can be reached by providing a platform for dialogue between different programs and sectors. Furthermore, on a national level HSPA allows the monitoring of health system reforms and health strategies, as far as the potential areas of efficiency and equity improvements, necessary to design eventual adaptations of the processes and instruments to the actual needs, are concerned. Usually, while weaknesses are easily detected, their causes and remedies are harder to identify; in addition, it is still challenging to select balanced process and input indicators «to assess outcomes directly or to predict outcomes in areas where results are difficult to measure, slow to develop or influenced by factors outside the health sector» (WHO Regional Office for Europe, op. cit., 9). HSPA can produce a variety of results as the

mobilization of internal and external health system actors through dialogue, participation and engagement; in addition, it can reveal conflicts between health system values or objectives, and foster consensus on priorities or promotion of a culture for performance enhancement. These goals are achievable when assessment is applied to long-term results that require continuing investment in capacity and resources (included the human' , whose enthusiasm and trust is fundamental for the success of such process).

Health System Performance Assessment is a proper scientific strategy employing research cycle steps. The process begins when there is a stimulus to identify new priority health issues and best practices in order to increase knowledge about the determinants of healthcare outcomes, quality, accessibility, and costs. As a first step in an evaluation process, this is the time for needs assessment, namely «the assessment of gaps in the knowledge base and the needs of patients, clinicians, health care managers, institutions, plans, purchasers and State…». The next step is the development of applications and instruments for measuring, collecting and anyalysing data, thus generating knowledge that can then be applied to enhancing care. This is possible through the translation and dissemination of observations/ insights since «simply producing knowledge is not enough. Findings must be presented in ways that are useful and made widely available to clinicians, patients, health care managers, and other decision makers». Finally, the expertise on quality has to be summarized and translated by health organizations into information that can be understood and used by consumers and patients in decision making, but also by health managers to evaluate the impact of both their clinical and informational activities (AHRQ, op.cit., 8).

As concerns quality assessment, Donabedian (1990) affirms that quality is a property of health assistance, which is meant as a process that can be judged through a direct observation or the examination of registered data in such a way to accurately retrace circumstances.

4.2 Is healthcare quality assessment an intrinsic methodological challenge?

4.2.1 How to measure quality of health performance.

In chapter III the quality of health care has been described, explaining the importance of scientific and empirical evidence-based support to national and local systematic quality improvement. Health system performance assessment has a quantitative and a qualitative component, respectively an utilization review to determine how many resources physicians use, along quality assurance to verify if resources have been used by the professionals in charge in a rational way. In particular, the assessment of health performance quality consists of monitoring four elements — efficacy, efficiency, appropriateness, technical-scientific quality — in three areas — service, management, and outputs — (Koch, op. cit.).

During the operational definition of quality, evaluators will define what they want to assess, choosing among the dimensions of service, management, outputs. Professional service quality is assessed by experts who evaluate if a performance is appropriate for a context in term of procedure — as an ideal sequence of actions — contribution offered by each professional, and potential criticisms. Here, technical and relational aspects are both considered to assess output efficacy. Instead, if we want to evaluate management quality we will rather focus on how human resources, communication, evaluation itself are run. Furthermore, to assess output quality we will concentrate on the definition of who is going to evaluate, why, and what kind of indicators have been chosen in agreement with the established goals (Koch, op. cit). This mirrors TQM theory, however knowledge developed by industry is not exhaustive to understand quality of health services because the social values mobilized in order to define it explicitly refuse performance standardization, which is a standard TQM goal (Cherubini, 1987). Effectively, in accordance with an economic-manufactural culture, quality standards can be chosen before selling the product/providing the service and entering into contact with consumers, but this is not possible in health care. Here, customization of assistance and

the relationship between provider and patient are substantial components of services; hence, it is not possible to assess positively a process of care that is standardized, because it would not represent an effective model of health organization. Consequently, it would be better to evaluate a single health performance insomuch it represents an explicit reduction of complexity through a measurable, repeatable, quantifiable, standardizable action (Carbognin, op. cit.). Health organization management could choose to assess a whole program, which represents a temporary and limited contribution to the offer of health services, by checking its outcomes, flexibility, costs in term of resources and community consensus. Operational units as well can be assessed given that they directly provide assistance (Donabedian, op. cit.).

Moving to measurement, «quality of care is measured by comparing data describing patients and the care they receive to standards. Quality measurement is commonly used for quality assurance, which is a cyclic activity; it requires measurement of quality and, if measurement reveals deficiencies in care, intervention to improve care, followed by re-measurement of quality to determine the success of the intervention» (Palmer et al., op. cit., 28). About that, Garvin (1984) suggests different perspectives to measure product quality through different types of data. A first one is a product-based perspective of quality, which deals with productivity; high quality is a desirable and measurable propriety of the product and push to price increase. When this perspective is applied to health care, quality is measured through structure; thus, higher quality would lie in more equipment, more spacious facilities, more and better-trained staff, more organizational policies and procedures. Quality measurements using structural data are relatively inexpensive to take, but limited in information exhaustiveness; sure enough, to meet structural standards does not ensure the provision of good care seeing that best quality standards may be necessary but not sufficient conditions to ensure quality of care.

An alternative approach is the manufacturing-based, which assumes the supplier perspective, according to which quality and conformance to specifications are

equivalent. More, “making it right the first time” will prevent rework, repair, or replacement, and allow to save money in the long run. Quality of care is measured through process standards, which define what should be done to ensure the best possible outcome for the patient. «Process measurements usually focus on individual cases and use data from patients’ medical records» whose quality and reliability influence the validity of measurement; therefore, it would be recommended to collect additional data from an institution’s management information systems or directly from the physician in charge. Process-based measures are more accurate than structure-based because they reveal what must be differently done to improve care, showing failures in process standards; anyways, the goodness of this kind of measurement depends upon the knowledge/awareness of what should be done for patients, taking into account the difficulty of broadening the same few process standards to heterogeneous groups of patients.

Last of Garvin’s proposals is a user-based definition of quality. In this case, quality corresponds to the satisfaction/preference of the majority of patients and is assessed in an aggregated way through outcome measures. Although outcome data deal with the ultimate goal of health care (the improvement of patient health), they are difficult and expensive to collect given that measurement should be done after each episode of care and many factors might influence patient health after care provision as «the severity of disease, the presence of complications, patient age and resilience, patient willingness to comply with recommended therapy, and the effectiveness of the therapies available» (Palmer et al., op. cit., 38). There is another interpretation of quality leading to patients, the value-based, which identifies performance quality in acceptable prices or service conformance at an acceptable cost. However, this definition restricts quality to a cost issue.

As we know, the most applied model of health care quality is Donabedian’s according to which «there are three categories of information we can infer to quality of care: structure, process, outcome» within quality assurance, whose steps are system design and performance monitoring (1995, 38). Donabedian states that measuring quality means to represent it more concretely, giving it some degree of

quantification through the «criteria and standards of structure, process, and outcome. Criteria and standard should derive from a scientifically validated fund of knowledge, or the best informed, most authoritative opinion available on a particular subject, or the practice of eminent practitioners in a community. Standards and criteria can be implicit or explicit, so more or less flexible and adaptive according to the specific characteristics of the case, and more or less pricy and imprecise» (Donabedian, op. cit., 42). This clarification is relevant inasmuch it reminds us that quality can be measured and assessed objectively and scientifically only through an explicit conceptualization and theoretical analysis of, first, the system of structures, processes, outcomes whose quality we want to assess and, second, the theoretical definition of the properties of each analyzed element (structure, process, outcome) of the system which the researcher judges relevant for the quality dimension of the system referred to. Quality is a multidimensional attribute that can be operationally defined and objectively assessed only if occasional evaluators (for example patients) receive the necessary knowledge and tools. Too often people who are external to health care, such as patients or other professionals, are accused of incapability to judge health services or performance seeing that they do not have a clinical expertise or cannot understand hospital procedures, responsibilities, charge of work, and so on.

Moving back to the categories of information necessary for inferring to quality of care by Donabedian, the author affirms that process is helpful in assessing quality of health performance since it tells us, through direct observation, what kind of relationship is there between health assistance and its outcomes on patient health in terms of individual and social wellbeing in comparison with established social values. Process is characterized by some sub-categories; first, technical management meant as the relationship between assistance features and its consequences in agreement with technological and medical knowledge development. Second, management of interpersonal relationships as communication between providers and patients ruled by norms valid in themselves, coming from medical science and social ethical and values. Thus, quality is defined as a normative behavior

model congenial for health professions, strengthened by tradition, and legitimized by routine.

Instead, structure and outcomes are tools for an indirect analysis of health services. On one hand, structure gives information about buildings, administrators, providers, instruments, and tool features, that is formal and informal organizational methods and (both material and human) resources employed in health service financing and provision. Structure, which includes quality audits and organizational charts, leads to a quality assessment of what increases or decreases the chances of a satisfying performance; nonetheless, it looks to be more efficient as tool of quality promotion rather than quality monitoring because it produces a general and weakly efficacious information on general trends. Finally, outcomes show present or future changes on patient health that lead to health assistance, with regard to physical and physiological aspects, social and psychological functions, patient behaviors and knowledge. In Donabedian's opinion, to define quality as effective changes in people health and declare changes in people health as indirect measures of assistance quality at the same time is a paradox insomuch assistance process elements do not intrinsically express quality but need to be compared with desirable changes on health.

To summarize, «structure, process, and outcome data all have a place in measurement of quality. Which data are used depends upon the circumstances. Structural measures are used to ensure that staff, facilities, equipment, and organizational features meet minimal necessary conditions for good care. Process measures are used for detailed and definitive judgements of care that lead to actions intended to improve care. Outcome data, adjusted for case severity, are used to screen large patient data bases for evidence of disproportionately bad outcomes that may indicate poor quality of care» (Donabedian, op. cit.; Palmer et al., op. cit., 36, 38, 30).

Donabedian's model has been reviewed by other authors; De Geyndt declares that the extent of health definition and its corresponding services influence the definition of quality so it would be necessary to introduce two more elements, content and impact of health assistance, distinguishing the organization of health

services from services themselves. Williamson (1971) defines instead the process as causal succession of linked events and distinguishes five categories in health assistance: structure; diagnostic process; diagnostic outcomes; diagnostic process; therapeutic outcomes. Other authors talk about program evaluation, focusing on the patient-doctor relationship inside clinics. In particular, Freeborn and Greenback (1973) differentiate between efficiency and efficacy evaluation of a program; the first is made by input-output and costs-outputs relationships, while the second is composed of technical and psychosocial efficacy. On one hand, technical efficacy is made by the renown categories of structure, (technical) outcomes (of the assistance), and process, which is sub categorized in accessibility, provider performance, and continuity. On the other, psychosocial efficacy consists of patient and provider satisfaction, both divided in attitudinal measures and behavioral observations. Also, authors detail outcomes leading to patients; first, cognitive outcomes linked to patient knowledge about his/her disease, its management, and the mechanisms to access health assistance in specific or general situations. Second, attitudinal outcomes as perceptions and attitudes on the above-mentioned cognitive outcomes, plus judgements on structure, process, and outcomes in specific or general situations. Third and last, behavioral outcomes that are distinguished in utilization of health services (i.e. performance volume and resources, promptness of assistance recourse), promotion of health through different lifestyles, health status (f.e. morbidity, mobility).

4.2.2 Obstructions in quality measurement.

The difficulty to measure healthcare quality clearly surfaces. Quality itself is hard to define operationally because of its high dependence on personal emotional experiences; consequently, to choose measurement tools and collect evidence-based, understandable and usable information is even harder. One feature that measurement tools and the information they produce should both have is validity insomuch involves measurement precision, data accuracy, and deductions legitima-

cy. We distinguish the causal validity, which affirms what presumptions in a process drive to certain outcomes or viceversa what outcomes are leaded to certain processes, and the attributive validity, which states the capability to produce specific outcomes conferred on a process or procedure. Nonetheless, outcomes have a limited, temporary attributive validity given the interfering factors that might affect the process-outcomes relationship. Applying causal validity to health care processes, an appropriate assistance involves expected outcomes but it is necessary to prove that those outcomes have been produced by that specific assistance. In simpler words, attributive validity is harder to prove in health care; thus, a normative validity is preferred since indicates doctor responsibility for a specific choice or procedure efficacy on the basis of professional agreements stating what procedures have to be used in specific situations (rather than scientific appropriateness of treatments). Sensitivity and specificity are two subcategories of outcomes validity. Outcome sensitivity used as healthcare quality measurement tells us what changes are happening in healthcare compared to changes required by the community, taking into consideration both frequency and extent of outcomes. Specificity is useful to identify the causal relationship between an outcome and a process, so depends on the preliminary definition of causal and attributive validity. More, it is more reliable when the process-outcome relationship has positive results, that is when expected outcomes are produced; on the contrary, when expected outcomes do not show up it is harder to identify whose the responsibility for failures is. This is the reason why some authors prefer a comprehensive vision of quality, taking into account the influence of both quality and quantity of health assistance on life conditions. To outline, sensitivity and specificity do not entail independently of quality assessment; they depend on the process-outcome relationship. When causal validity is uncertain, process and outcomes should be both put aside as quality measurement tools, and other instruments should be chosen. Nevertheless, this does not often happen. Administrators and managers prefer to use imprecise measurement tools with two possible results: if outcomes are positive, it is possible that a useless or dangerous procedure is classified as efficacious; on the opposite,

if outcomes are negative, a process is monitored and the possibilities to identify a risky or useless procedure increase (Donabedian, op. cit.).

Another preferable measurement tools' characteristic is the promptness of the produced information. High promptness is required when organization's goal is to influence or settle the assistance provided to patients, so process measurements are more useful than outcomes'. Effectively, process is usually employed in a contemporary and prospective evaluation; instead, the retrospective perspective has preventive or rehabilitation goals. Outcome measurements take longer and do not exclude the interference of external factors in the causal process-outcome relationship. This kind of measurement is generally used in a retrospective perspective whose timing is often negative; indeed, people tend to move up the evaluation when outcome do not show up yet or to delay it when outcomes lose they efficacy. In addition, outcomes are often included in quality assessment as indicators of the administrative and organizational function only because health status might change during assistance. In this regard, Cochrane (1972) is interested in informational and innovative functions of healthcare quality monitoring and assessment in administration. He believes that quality monitoring itself cannot produce instruments and evidence to establish the legitimacy or appropriateness of the best management methods. To validate the causal relationship between process and outcomes is necessary a rigorous research project, precision in evaluation, more analysis and interpretation skills which usually are hard to develop in monitoring an operational system.

Moving back to the choice of the evaluation approach, it concerns managers preference for a maximalist or optimalist approach; a technical or interpersonal viewpoint; patient or society optimum as preset goal; practitioner or patient or health system performance as assessment object. In addition, manager decision involves method technical feasibility but also provider readiness in accepting an assessment method whose acceptability and persuasiveness influence the importance conferred by physicians, administrators, and providers to their commitment and output attempting to provoke change (Brook et al., 1976). Any decision about

the evaluation approach entail an ethic issue. This happens when experimental procedures are adopted in which useful treatments are not provided; while as concerns outcomes, ethic issues come out when negative outcomes are employed to justify a model or the probability that something may happen. Anyway, even if process seems to be more reliable than outcomes as indicator of assistance quality, it cannot be considered the only reliable and indisputable criterion (Donabedian, op. cit.). «Many countries have sought to define aggregated indicators of routine activity and outcome data as objective measures of quality and performance. The aims of indicator development vary between internal self-assessment and governance, and external evaluation, accreditation and control. Common problems with data systems and their users include at local level:

- Lack of reliable, networked computer access;
- Lack of realistic strategy for information management;
- Lack of internal validation of records e.g. of diagnosis, by doctors;
- Clinical data capture and incomplete or inaccurate coding;
- Data not made available to relevant local staff before reported upwards;
- Lack of training in quantitative methods (clinicians and managers);
- Failure to share data with colleagues, patients and other departments» (Shaw, Kalo, op. cit., 24-25).

To solve these issues, health care organizations can adopt external or internal mechanisms to assess the quality of their services. External mechanisms are systematic and check the implementation of international criteria, i.e. ISO, but provide an incomplete information; for this reason, it is necessary to adopt internal assessment mechanisms as well, based on any department's or operational unit's self-evaluation. However, the central administration has the commitment to promote local actions aimed at the definition of new criteria leading to organizational and clinical procedures, the adoption of reliable instruments to measure health performance, and the attribution of significance to changes. In several countries, governments opted for the aggregation of activity and outcome indicators in health care quality measurement, bringing about some issues. At the natio-

nal level, an excessive attention toward structures and resources caused a disregard of patients and performances, involving confusion between general population and population of patients concepts. Moreover, data collection is slow, chaotic and inaccurate, also because of the conflict between privacy and freedom of information. At the local level, data collection has been incomplete and the access to information obstructed given a lacking strategy for the information management; in addition, knowledge about qualitative methods is limited, increasing mistakes in data sharing among patients, physicians, and managers. When information is not exhaustive and broadly spread, the actors of health system do not increase their knowledge, so are encouraged to autonomously look for information (on internet for example) with the risk of strengthening their prejudices or partial knowledge. By doing so, they will not develop an expertise useful in the health assistance provision and assessment, denying any possibility to improve health services; no less important, people will continue act for his/her interest rather community's (Shaw, Kalo, 2002).

4.3 The socio-political challenges in the health care quality assessment.

In its early days, healthcare evaluation adopted morbidity and mortality rates as main indicators in the collection of aggregated quantitative data on service efficacy, but during the 1980's the issue of quality of health care emerged allowing for further consideration of health care consumer opinions (as seen in Chapter II, in that moment patients were framed in an economic perspective). Thus, patients were firstly an object of clinical attention and the efficacy/inefficacy of health interventions were affirmed according to patient "cured - not cured" status; then, patients became active partners of physicians in cure treatments. Recently, the process of humanization and its support to quality has legitimized the definition of health performance as a combination of medical and assistance elements, such as accessibility, structure comfort, patient-doctor relationship. Patient opinion on health services and assistance is now a tool to design performance moni-

toring and to verify measurement instruments. Certainly, people know that health-care measurement is hard because of the social component of services however this is the reason why patient satisfaction can be used as indicator of quality and contribute to the individuation of problems affecting health assistance provision. Satisfaction surveys effectively contribute to the humanization of health services since the information they convey help managers addressing issues that can be hardly be dealt with ordinary assistance information sources and are useful to empirically verify quality (De Ambrogio, Battistella, 1991).

Attention over the physician's relational ability is another innovation introduced by the process of humanization as instrument to value health services and interpret community's social, environmental and legislative orientation. In particular, the contribution given by medical class (whose profession has a cultural, scientific and economical dimension) consists of its participation at the department procedure design since health institutions, both at the national and local level, have to continuously develop new organizational dimensions to respond to society demands and evolution. Unfortunately, the development of chronic diseases, the ageing of population, and the increasing reduction of economic resources pushed health administrators to adopt an orientation to social and economic profit. By doing so, organization goals radically changed, a new organizational strategy has been designed, and an assessment system have been introduced also to predict patient behaviors (Capitani, op. cit.).

Notwithstanding the legitimization of "subjective" measures in health performance assessment (Meier, Brudney, 2002; Zeithmal, 1988; Mc Laughlin Curtis, 2000), organizations providing public utility services do not offer the necessary conditions to let external people assess correctly. The monopoly and self-reference shown by organizations, along information asymmetry, limit the possibility that patients have to wittingly choose and judge a service in accordance with their criteria of assistance quality. Service structure often seems like to be oriented toward heath system employees rather than patients as evidenced by the lack of unsystematic, reliable and sure information flows. Information flows require huge

but worthy investments in time, technology, human resources insomuch they spread information on long term processes that, if continuously monitored, give us information on health system and population health improvement. If, on the opposite, the health organization is more interested in short term process effects, it would rather design an "ad hoc" not systematic data collection with a specific and limited analysis object (Nuti, 2008). Capitani (2002) claims that service quality lies in the commitment shown by the organization toward ethics, in the form of achievement of community goals and rapidity of problem solving, meant as ability and flexibility to quickly find solutions and combine internal and external demand with supply. In addition, to monitoring and assessing the efficacy and usefulness of organizational rules and behaviors allow to reflect on strategic plans and their implementation, in order to analyze the real possibilities available to health organizations to improve public service management. On the other side, patient satisfaction leads to individual expectations, which are usually considered as an imprecise tool of scientific measurement; however, it has already been accepted that patients during their healthcare experience develop a knowledge and expertise useful to objectively assess the health services (Nuti, op. cit.).

In Ruta's opinion (1993), problems concerning service quality are intrinsic to the contemporary health system; a macro process includes several micro processes characterized by interdependence and fluidity and involves many units or departments at the same time. This brings about the realization of different transactions that often are hard to control because the output of a first micro process could be the input of a second micro process. Therefore, in order to monitor and distinguish different processes/phenomena (each of them designed to achieve a specific goal), health organizations should periodically choose indicators in order to pursue a health service ongoing improvement in line with patients needs. In addition, indicators should be used to evaluate long term effects of health performance since they are efficacious in the evaluation of intervention validity; despite the succession of many managers and action plans, data about long term outcomes give a more effective information when framed in the strategic evaluation map (Ospit,

1993). System complexity undoubtedly slows down patient understanding of health process and affects his/her experience of quality of care, that is codified through transparency, efficiency, efficacy, and appropriateness. Procedures have to be simplified reducing redundant decisional tangles and increasing single decision's information content, within the health organization's policy of clinical governance (that is the meeting point between the patient-centeredness and the clinical management).

To recapitulate, a system with an integrated organizational structure needs to design an evaluation process able to look both at the individual performance and its position in the whole coordinated system, conferring importance to the motivational component of individual action. Organization strategy has to be meticulously described through clear goals, priorities, and cause-effect relationships to align actions with plan, create synergy among several departments, and avoid that particular (single department) goals could get precedence over the general's (organization's). Thus, health organization has to involve each of its members in the strategic process, its implementation and evaluation (Otley, 1999).

Focusing on the Italian assessment system, it evaluates manager and employee performance using two elements such as organization's goal achievement and developed skills. Evaluation system associates the organizational with the individual performance in order to distribute incentives within the bonus system as affirmed by the rationalization of health services, which involved a redefinition of effective returns as sum of a rigorous respect of procedures and an effective usefulness of organizational power. Hence, evaluation criteria represent an instrument to assess professionalism in agreement with demand, profit, and the ability to produce scientifically relevant documents; simultaneously, the value coming from expertise, knowledge, experiences emphasizes technical and professional aspects as much as individual and team skills that improve resource management. In a model of global quality, any provider acts with the objective of exercising both a profession and the power to improve outputs, rationalizes organization mechanisms, and proposes new developments. This is the reason why con-

text, guidelines, national, regional and local health plans are unavoidably adapted to the demand-supply and citizen-provider centered relationships, taking into consideration citizen hierarchy of values, health service evolution in line with internal and external demand, and potentialities offered by different strategies (Capitani, op. cit.). However, this is a delicate issue in the Italian frame because the prejudice against evaluation as negative and punitive judgment is embedded in the corporate culture even though decision-making is based on measurement and evaluation. Outcome assessment activates information circulation which supports transparency; more, it is the procedure adopted to estimate and reward employees' merit and commitment to work. When health organizations endorse a performance assessment leading to an incentive system, first measurements requires particular attention seeing that their outcomes would be used as benchmark in the following measurements. Another rick for the reliability of collected data could be the premature conclusion of the assessment process, for example right after the questionnaire draft, or the falsification of the performance judgments, which happens when the employees or managers give higher scores despite the real performance goodness in order to increase the incentives to receive. The reason is a lack of awareness in the Italian culture that the management of public resources is an ethic duty and an obligation of public system toward community (Nuti, 2008; Marino, 2008).

4.4 History of the assessment of the health system performance.

The development of measurement systems of health performance started paralleling to the attention toward assistance quality with the aim of improving health services and cures provided to patients. In the 1970's health administrators developed, later than doctors, an interest in HSPA given the increasing need to contain costs of health assistance and to reduce risks of inappropriateness of diag-

nostic and therapeutic procedures. Nonetheless, to assess quality of health performance means to consider it globally, measuring clinical efficiency through the utilization review and paying attention to its efficacy in order to avoid expensive and dangerous cures. Evaluation is apt to verify whether provided health performances produce the maximum expectable benefit in terms of health, considering available instruments and scientific progress. The application of rules and procedures, as much as the implementation of interventions, stands in need of flexibility and adaptation because of the unavoidable gap between expected and real world. However, evaluative research methodology in health care is rigorous as much as in scientific research; indeed, the starting point of evaluation project is a clear definition of objectives, criteria and standards, which have to be coherent with available resources, technological and scientific progress.

There is a shared agreement on the solidity of assessing methods for quality of health assistance while weaker is the theoretic support to indicators' and monitoring systems' validity and reliability so that the formulation of indicators identifying more precisely differences among patients independently from health service is still ongoing (Galanti, Giachetti, op. cit.). As Hurst claims, outside the health arena assessment of health performance is rarely supported by the mobilization of political will and authority, slowing down the individuation of more successful parameters and structural changes in health systems. Therefore, beyond political "windows of opportunity" there are other «factors which may improve success in realizing reforms», i.e. «the existence of appropriate institutions to support reforms from decision to implementation; reform agendas, timing and interactions across different policy areas». But probably factors such as «the use of incentives — both sticks and carrots — to align the motivation of the main actors in the system with the objectives of policy» or « the availability and use of information, evidence and analysis about the performance of the health system and about - the ways of performance could be improved» could be more incisive. In simpler words, an evidence-based support — so a severe outcome measurement — is the key to make health reforms more efficient (2010, 10).

Moving back to HSPA's history, in the 1970's the traditional data collection based on loose, unwritten, implicit criteria was replaced by the review of health care records drawing upon explicit criteria and aiming for objectivity and reliability (Rosenberg, 1990). The Joint Commission International firstly developed the Performance Evaluation Procedure (PEP), a retrospective outcome-based approach using patient record analysis to identify possible problems in care delivery (Joint Commission, 1974), and in 1994 launched the Indicator Measurement System (IM System), a national database of process and outcome measures. One year later, the institution reorganized its activity into three sectors: patient care functions (patient assessment, patient, and family education); organizational functions (leadership, prevention, and control of infection); essential structural components (the governing body, management and administration, medical staff and nursing, and medication use) (Graham, op. cit.).

In Italy, «the evaluation of quality and outcomes has been increasingly considered by the national institutions and the Regions and Autonomous Provinces as a fundamental tool to improve the effectiveness of policy making» (OECD, op. cit., 69; Quaderni AGENAS, 2008; Carinci et al., 2012; Agenzia Sanitaria Regionale Emilia Romagna, 2010; Piano regionale per la Salute e il Benessere Sociale 2011-13, 2011). Italian legislation about HSPA dates back to 2009 with the issuing of the legislative decree. n. 150, which regulates performance assessment in Public Administration. Here, performance is depicted as the contribution every subject — meant as a system, an organization, a team, or a single person — can give to reach organization's expected goals, objectives, and need satisfaction. This reform, better known as Brunetta (named after the Minister who approved it), introduced new responsibilities, duties, but also instruments, managerial procedures, values leading to transparency weighing on any of the organization members in any operational unit or department, from top management till employees on the bottom of the organization. This reform focuses itself because focuses on the individual performance which "should" be assessed through meritocratic criteria; therefore, a singular act needs to be coherent to both individual and team's objectives

to achieve a certain level of quality through professional behaviors and expertise (scarcely considered in the past) and be assessed according to a model made by four components. These are the objective system, the expertise system, the supportive information system, and training for managers and division agents. The integration of several management systems, and consequently of different methodologies, drives to the elaboration of integrated evaluations which take consideration of organization specificities and history, more analytical areas to develop, i.e. prevention, territorial services, etc.

The Legislative Decree in question linked to the collective labour agreement (CCNL) given that Legislative Decrees No. 592/1992 and 29/1993 (on corporatization of health systems) established an integrative agreement on the distribution to departments of extra resources in line with assessed productivity. By doing so, quality has to be pursued both on an administrative and a clinical level, and controls are run on managers and employees as well (so-called internal controls). The purpose of evaluation systems is to verify that people working in a public structure and representing citizens' interests would pursue community's rather than individual opportunistic goals. Assessment of managers and employees performance is a monitoring instrument that operates if there are control systems, which in turn are helpful to fight information asymmetry, distribute incentives to drive people behavior, and increase efficiency of the whole organization action. The Legislative Decree No. 592/1992 «established the principle of continuous adaptation of the facilities and services to meet the growing needs of citizens» assigning Regions to provide methods for patient involvement «in activities related to health planning, monitoring and evaluation of services at regional, organization or district level». Three years later, the Italian Government established the importance of involving patients in the evaluation of quality of health services by issuing the Service Charter by a Presidential Decree (May 1995), establishing «the 2003 and 2006 National Health Plans, and by the national regulations on accreditation (Decree of the Council of Ministers of January 1994 - principles on health services delivery)» (OECD, op. cit., 81-82). Service Charter aimed at the introduction of

quality standards and their communication as means for health organizations to evaluate their services and reimburse patients if their performance would not be adequate to standards. In this way, customer satisfaction and patient participation in health quality assessment has been introduced into public sector.

Monitoring is affirmed separately in the Legislative Decree No. 286/1999, which distinguishes four types of control: on accounting-administrative regularity — in terms of legitimacy and correctness of administrative actions —; on management, to optimize policies according to efficacy, efficiency, cheapness; manager assessment; strategic control to assess output consistency with established goals. Strategic control is the predecessor of 2009's performance assessment since it institutes the analysis of congruency among rules, objectives, human and economic resources, interventions before and after the performance is fulfilled, contemplating obstructive factors, singular responsibilities of incomplete actualizations, and possible solutions. In effect, internal control links to the achievement of established goals as much as the definition of interventions apt to adapt services, procedures, or assistance to reality, helping a more precise correspondence of organization strategic plan with community needs. To realize internal controls, organizations need to set a statistical information system, useful to compare costs and outputs of the different operational units; moreover, health organizations have to define their efficacy, efficiency and cheapness indicators after having established service quality standards, and finally involve citizens in the assessment of health and administrative services.

One year later, CIVIT (Commissione per la Valutazione, la Trasparenza e l'Integrità delle amministrazioni pubbliche) issued the deliberation no. 88/2010 to provide guidelines for the definition and measurement of quality standards, in which the improvement of economic standards and the optimization of service costs were included as measures of efficacy. First of all, health organizations have to give their own definition of quality explaining its several dimensions — especially accessibility, transparency, efficacy, and promptness which are considered essential — and indicators, which are supported by "valore programmato", the

value defining high quality performance respectful of the established standards. In addition, organizations have to identify the actual quality public services may offer, and make explicit who are health assistance stakeholders. In second instance, Local Health Authorities have to chose the methodological structure to apply to the definition of quality standards, the cycle of performance management and the implementation of the Legislative Decree no. 150/2009 to achieve an ongoing performance improvement. After designing service charter, it is time to define quality standards which indicate the level of quality that should be guaranteed by health services and will be the terms of comparison in next quality measurements; organizations may establish a minimum level of quality referring to a set of performances, a single one or a part of it. But two important elements are often underrated or forgotten; firstly, the need of standards or indicators enabling to monitor service performances from both a diachronically and synchronical point of view plus the activation of benchmarking practices apt to compare both different managers and administrators of a same organization and different organizations at the same time; secondly, the prescription of stakeholder involvement in the definition of quality standards. Indeed, methodological structure and phase sequence of the design process of quality standards are the same for any health organization since they are disciplined by the Legislative Decree no. 150/2009. Instead, decisions about processes, procedures, monitoring and control systems depend on the single organization; moreover, sometimes standard planning and monitoring are performed by regional health departments, agencies for health or public health observatories apt to to provide technical and scientific advice to the regional health departments and Local Health Authorities. Beside these institutions there is an "Organismo indipendente di valutazione della performance" (OIVP since now), which has been established by law no. 15/2009 to monitor operation of evaluation systems and integrity of internal controls. Thus, OIVP is charge of guaranteeing the correctness of measurement and evaluation process and incentives; promoting and verify accomplishments linked to transparency and integrity obligations. Every health organization has its "Nucleo Aziendale di Valutazione" to annually veri-

fy outputs of managers responsible for simple and complex structures taking into account available resources, established objectives; over the strategic control, the "Nucleo Aziendale di Valutazione" has functions of strategic control.

To conclude, it is clear that evaluation has not been the object of the typical Italian excessive legislative productivity. Also, monitoring systems are committed to incentive people to be responsible for and contributor to quality of services in order to spread a broader evaluation culture. However, this new evidence-based policies era began just a few years ago so an evaluation culture (besides in favor of quality) has not been assimilated yet.

4.5 Instruments for the assessment of health care performance in Italy.

After describing legislation and organizations in the evaluation of health quality, let us see the data sources. Starting from databases on quality of care, Italy has established health databases both at national and regional level in the effort to strengthen the information infrastructure. Clinical registers are further tools in data collection even if their adoption has not yet achieved the optimal level to address comprehensive monitoring and improvement in quality of care at national level. In 2001, the Nuovo Sistema Informativo Sanitario (New Italian Health Information Infrastructure) was established by national legislation to furnish information for governance and to assess the qualitative and quantitative standards of the LEAs for local, regional and national administrators. Thus, it represents the official common information infrastructure of "Flussi Sanitari" (health information flows), that is the channel used by all regions foe the mandatory share information about their services. Nonetheless, Italy needs to continue working on «collecting more quality indicators around processes and outcomes at the primary and community care level» seeing that related databases are still underrated than those in the hospital sector, especially for what concerns management of chronic diseases or care co-ordination between hospitals and primary care providers. Additionally, the persistence of technical issues is noticed insomuch there are some

barriers to the practical usa of available information in terms of inefficiency of data linkage but also in accessing data for research purposes (OECD, op. cit., 74).

Moving to indicators, the Ministry of Health issued the form LEA, which is one of the official national systems of indicators for monitoring regional health system performances and is published (in a paper and an online version) once a year in the National Health Status Report (Ministry of Health, 2012). «This report includes 131 indicators around prevention in life and work environments (immunization, screening, costs, veterinary and food control), community care (avoidable hospital, residential care for disability and elderly patients, hospice, ambulatory care, home care, mental health, pharmaceutical prescriptions) and hospital care (hospitalization rates, caesarean rates, hip fracture intervention within 72 hours, appropriateness indicators, emergency interventions)» (OECD, 2014, 70). It is employed to monitor and compare the provision of standards in each Italian region and autonomous province, in order to produce stratified regional data to employ in performance assessment with regards to the accomplishment of national standards. «At present, most indicators refer to hospital care but the coverage of the program is going to be extended by including primary care indicators. The definitions and number of indicators included in the PNE is constantly evolving. At national level, the availability of primary care and community indicators is still limited and only covered by the OECD Health Care Quality Indicators, for instance around avoidable hospitalizations for asthma, diabetes or COPD. The calculation of population-based indicators is usually supported by a regularly updated national population data warehouse at the National Institute of Statistics (ISTAT), freely accessible to the public via the official website» (OECD, op. cit., 71). Instead, at the regional level the Tuscan Performance Evaluation System is particularly successful, so much that it is going to be adopted by a network of regions while other regions are producing their reports and scorecards for general practitioners as well aiming at the control and optimization of health expenditures.

To develop evidence-based documents, the Ministry of Health, AGENAS and the ISS established the “Sistema Nazionale per le Linee Guida” (SNLG, Na-

tional Guidelines System) to bring about diagnostic and therapeutic paths useful in the monitoring of governance variability and implementation of local and regional recommendations; beyond the understanding of nature and causes of variability, SNLG's goals are the improvement of quality and appropriateness of care, the promotion of education and training of health care professionals, and the monitoring of undesirable outcomes. The SNLG is the result of the "Piano nazionale per le linee guida" (PNLG, National Guidelines Plan), whose scope is to provide health organizations and their professionals with operational tools, included LEA, to implement appropriate interventions and define the criteria for service accreditation. Another tool more explicitly associated with the evaluation of health performance is the Piano Nazionale Esiti (PNE, National Outcome Plan), which supports clinical and organizational audit to improve health system's efficiency and equity. However, PNE is not aimed at the production of judgements and classifications but rather of observations about health interventions' efficacy and effectiveness when experimental assessments are unavailable, for example to publish data about outcomes produced by structures designed for patients empowerment or to make comparative assessments among populations. Another goal of PNE is try to forestall management and assistance lacks and avoid that some criticisms become chronic.

4.5.1 Suggestions for patient assessment of health performance.

«The value people assign to a health state may depend on their knowledge of the state and their experience with it; however, decisions must be made prospectively» (Deber, 1994, 174), that is a realistic evaluation of patient satisfaction should be conducted periodically in order to analyze how patient opinions change in time; Indeed, synchronic data collection usually brings out high satisfaction linked to the gratification implied in the condition of being visited (De Ambrogio,

Battistella, 1991). Consequently, initiatives such as the ISTAT's "Health Conditions and Utilization of Health Services" periodic survey are not sufficient if they are measures of an evaluation system where patient surveys are not conducted systematically on primary, community and long term care ((Ministry of Health, 2011a; OECD, op. cit.).

Patient surveys are efficacious instruments in the process of humanization of health services insomuch they help defining the demand of performance and possible interventions for service improvement; however, great attention is necessary in the questionnaire construction and use; sure enough, questionnaires can be used by organizations as self-gratification tool through questions apt to highlight the consensus shown by patients towards positive aspects of the provided assistance, which sometimes can become a real manipulative survey piloting. Simplicity is one of the main features necessary in the questionnaire construction in such a way to collect data that can be analyzed and used by health organizations themselves and their employees. So, questions should be short and focused on delimited aspects; furthermore the participation of the patient's family during the questionnaire compilation should be allowed in order to help patients to better understand questions and give plausible answers reflecting his/her opinion. But questionnaire is useful also to collect data on the general opinion about a service seeing that it can be distributed some time later than assistance supply.

In the following paragraphs, two of the Italian health performance systems will be described, giving an overview of patient participation at the process of evaluation. The Tuscany's and Sicily's systems have been chosen because they represent the top and the bottom of the Italian best practices in healthcare.

4.6 Tuscany's system for health performance assessment.

Tuscan performance evaluation system (PES) was developed by the Laboratorio Management e Sanità of Pisa Istituto Superiore Sant'Anna in 2004 to be implemented one year later; its aim is to measure the quality of health services in

order to improve population health and achieve higher quality of life. PES is adopted in eight other Italian regions because of its completeness and innovation essentially represented by its graphical reporting system, that is a ‘‘target’’ diagram looking like a pie-chart divided into sectors, clustered in six circular sections (one for each evaluation dimension). Each sector has five different colors (ranging from green to red) representing the value of the score achieved for each of the 130 indicators chosen by the research team and the chief executive officers from the 12 Local Health Authorities in the Tuscany Region. If the pointer positions itself in the green section, a good score has been achieved otherwise the pointer would fall in the red section; the more pointers falling in the center of the pie-chart the better the hospital's overall performance. The pie-chart should be interpreted together with the performance map, in order to see whether the individual hospital performed better than in the previous year. Moreover, if the overall performance is better, costs appear lower, because «improvements in performance indicators such as quality and appropriateness may be useful in reducing overall healthcare costs» (Nuti et al., 2011, 6). The Tuscany performance evaluation program is apt to measure service quality and capacity of the health system to meet citizens' need in order to achieve population's better health and quality of life, on one hand, and to preserve financial equilibrium, on the other. This is the reason why the following performance dimensions have been selected: capacity to respect regional guidelines; population health status; clinical performance (i.e. quality, appropriateness, effectiveness, clinical risk management and primary care); patient satisfaction; staff satisfaction and finally efficiency and financial performance. Performance indicators were selected by a team of Tuscan Health Authorities (HAs) and Regional Administration professionals and are reviewed and updated every year, while performance results are monitored every three months. PES feedbacks, that are linked to the CEOs' reward system, are applied to the health care professionals and managers.

Regarding patients, they are involved in the performance evaluation insomuch their opinions are considered useful to the strategic and organizational

choices, even though they are collected after a while the health assistance has been provided considering this delay as favorable to an accurate and less emotional judgment. Patients, except for oncologic ones who are involved in qualitative surveys, are interviewed by CATI and CAWI systems and postal questionnaires on fifteen indicators, referring to patient evaluation and experience on primary care, emergency department service, home care, hospital service, maternal care, and services for the elderly. Surveys are carried out every two years on a population of (over 18-year-old) adult Tuscan citizens living in Tuscany on the following indicators:

- patient evaluation of general medicine:
    - home medical examination;
    - clarity of information;
    - time devoted to patients;
    - involvement in choice of treatment or test;
- abandonment of emergency room:
    - discharge from hospital;
    - voluntary hospital discharge;
- patient evaluation of local services:
    - opening times;
    - courtesy of staff;
    - facilities and comfort;
    - clarity of information;
- evaluation of assistance received in healthcare initiative projects:
    - information requested from the patient about management of the disease, monitoring, diet, weight, physical activity, alcohol consumption, smoking;
    - monitoring by physicians of the patient's state of health: pressure, glycaemia, circumference and weight, feet;
    - team-work;
    - proactivity in terms of reminders of appointments;

- outcome regarding patient's health: home management of the disease, supplementary information, benefits for health.

Complying with transparency, citizens can check data on health performances by surfing on the website of the Region — health care area — and consulting the reports published by Scuola Superiore Istituto Sant'Anna till the last but one, while the last is available on the Sant'Anna website only for registered users. Beyond general reports, people can check the target diagram and scores referring to any single Tuscan Local Health Authority by three drop-down menus concerning best practice, dimension, goodness of performance. Instead, the questionnaire distributed to patients is not available.

4.7 Sicily's system for health performance assessment.

Sicily is one of the first Italian regions participating at experimentations of methods for a systematic outcome evaluation and taking part at Agenas' PNE with the aim of promoting assistance quality and equity through the development of methodologies for health assistance evaluation. Sicily designed its own program for a comparative assessment of health intervention outcomes as timely support to health regional programs through a data collection linked to indicators, methodologies and procedures inspired by PNE as well as the Joint Commission International (JCI). Indeed, this organization establishes the guidelines and indicators Sicilian health organizations have to adopt to obtain quality accreditation, whose chart goes from not applicable to totally achieved; however, manuals published by JCI deal with a few specific issues such as patient safety and emergency department, standards tool assessment. Based on JCI standards, activities as biannual self-assessment, training for regional evaluators and local directors, on-site visits to evaluate performance compliance to standards are implemented.

Sicily evaluation system includes also Balanced Scorecard (BSC) and Performance Prism models specifically aiming at the incorporation of stakeholder viewpoint on health performance. BSC is a multidimensional strategic planning

and management system apt to translate organization's mission and strategies in univocal evident measures. The model consists of four different perspectives — client orientation, value creation, process management and organization development — through which underscore hard and soft elements simultaneously. The main goal of BSC adoption is to improve of performance efficacy and efficiency resorting to resource optimization and quality management systems, i.e. ISO 9001:2000. Concerning Performance Prism, it represents the new generation of performance measurement and management framework adopting as perspectives stakeholder satisfaction, stakeholder contribution, strategies, processes, capabilities. Effectively, this model is stakeholder-centered and spurs organizations to define strategies able to ensure that value is delivered to its stakeholders.

The Dipartimento per le Attività Sanitarie e Osservatorio Epidemiologico (D.A.S.O.E.) is the authority responsible for performance assessment surveys, even if surveys are concretely conducted by any single Local Health Authority through questionnaires (attachment A in the Appendix). Questions investigate patient opinions about service quality — in accordance to own expectations and the real experience —, the reason why the patient chose that specific health organization/hospital, booking service, physical accessibility to the structure, punctuality of medical examination and report delivering, waiting lists to be visited and to pay the service, information about disease and home-treatment, privacy, doctor attention and provider kindness. Data collection by questionnaire has not been efficient as expected because questionnaires were often left on the department's entrance desk with the hope that patients will fill them, and that the evaluation authority will cyclicly collect and analyze them. But starting from 2016, a new methodology, designed by Palermo University, the Regional Office for Health Care, and Catania Hospital "Policlinico Vittorio Emanuele", is going to be adopted. A new questionnaire, modality of questionnaire distribution and sample survey are going to be implemented in order to collect more specific and reliable data on smaller samples. The main goal is to collect patient opinions in such a way to improve services through interventions that could be concretely useful, over to train health

organization providers to conduct self-evaluations involving them in the assessment phases of service monitoring and improvement. Initially, patient surveys will be conducted by phone on the patients who signed for informed consent at the hospital or clinic where they received treatments, to be later realized also online through a dedicated web service.

Sure enough, concerning the Sicily assessment system, to find information and data coming from assessment activities is harder than in Tuscany; information about surveys and referring reports are not achievable as easily as in the assessment leader's website. Word of mouth with health organization employees seems to be a more efficient informational channel.

4.8 Conclusions.

In both cases (Tuscany and Sicily), it looks quite hard to get detailed information about a specific service (i.e. Diabetes, Pediatrics, Orthopedics), but it looks clear why Tuscany is the head of the line of an innovative and successful evaluation system that involves patients. For sure, Tuscany system can be improved for a better information circulation and transparency, to provide complete and detailed data on applied methods and survey results, over patient involvement and assessment. Nevertheless, these changes have to be reasonably designed and implemented given that the evaluation system and, in general, culture are young and still in evolution. To speak about the Sicilian system in the same positive way is harder because even if there are good intentions to realize a shared patient-centered evaluation system, their implementation is quite insufficient. The Sicilian system appears still conditioned by old bureaucratic viewpoints and formal duties rather than to current and citizen-centered methods.

There is another question to answer; how patient participation at the evaluation process can be spread outside healthcare into the community, that is how the information produced through patient evaluation is shared and eventually explained outside. It would be a pure self-referred formalism to involve patients into health

performance assessment without sharing in clear and understandable words what are the patient evaluation outputs; as we know, outputs lead to outcomes and the evaluation goal is not just to distribute resources or help hospitals to get higher scores to increase their patient numbers, but rather to help health organizations understanding of how good, comfortable, efficacious is their assistance in order to improve it towards patient needs. If patients cannot have the chance to understand how they can impact health system or what changes are happening in health care, any kind of assessment as objective as it may be, tensions among stakeholders will last and the evaluation culture will never spread.

To analyze the evaluation of health performance quality, I chose two Departments of Diabetes as case studies because is one of the few hospital departments where doctors and patients have a long term relationships; this should allow not only closeness and empathy necessary in the interpersonal relationship, but also a deeper knowledge of patient needs and reactions from the physician viewpoint and a broader knowledge of the healthcare system and illness from a patient point of view. In addition, in long-term care departments treating chronic diseases, it should be easier and conceivable to implement a peer relationship among managers, doctors, and patients in the policy-making dealing with the informational and social activities for patients and their families. Thus, next chapter focuses on the diabetes, how hospital departments curing this disease should be organized to globally take care of the patient well-being and how evaluation of health performance is run in this department.

Chapter V

Patient-centeredness in the policy-making and assessment in two Italian Departments of Diabetes. An exploratory survey.

5.1 People-centeredness and spread of chronic diseases: the case of diabetes.

The Center for the Advancement of Collaborative Strategies in Health, belonging to the New York Academy of Medicine, introduced the idea of community health governance as involvement of the community in health decisional and managerial processes. In particular, community is asked to define the major issues of health services in such a way to produce benefits on the collective learning as much as on the local and national authorities-community relationships (Lasker at. al, 2001; Giarelli, 2002). The Coordinated/integrated health services delivery (CIHSD) broadens health organizations' horizons sharing the «WHO Regional Office for Europe's priority of people-centered health systems», which are «focused and organized around the health needs and expectations of people and communities, rather than on diseases themselves». Patient-centeredness is limiting because focuses on the individual searching for care while people-centeredness pays attention to «the health of people in their communities and the crucial role of citizens in shaping health policy and services», beyond the need to be informed and empowered in promoting and protecting own heath as people rather than patients (Health Services Delivery Programme, Division of Health Systems and Public Health, 2013, 4; WHO Regional Office for Europe 2012a; WHO 2010).

This is particularly true referring to chronic diseases such as diabetes, which involves the whole person (body, lifestyle, mind-set, quality of life) and produces implications on the entire community. Effectively, diabetes has a considerable and increasing incidence; in 2015, In Italy diabetes has been diagnosed and cured to 3 millions people (4,9% of population) and it has been esteemed that this number will increase to 5 millions in 2030. Moreover, the therapy for diabetes has high costs and demands a substantial assistance charge in terms of services, structures,

medical supports, medications, etc. First, it requires timely treatments, included self-medications that patients need to learn; health organizations have to educate patients to an informed disease and therapy management, letting them being autonomous — as far as possible — within standard adherence. Second, the disease at issue demands assistance continuity, hence a specific service organization which is different from the one for acute illness, that crucially depends based on an efficacious communication among different assistance levels and services. The assistance network needs good communication with voluntary associations, on one hand, and multidisciplinary integration among professionals, on the other. Indeed, diabetes should be cured in specific clinics or departments of general medicine by a team of physicians such a specialist in diabetes, a podiatrist, an eye doctor, a cardiologist, over a nutritionist and a psychologist. Third, diabetic patients should be involved in systematic follow-up examinations useful to monitor the treatments defined in national guidelines and to collect data in administrative and clinical databases. Data collection is fundamental for this kind of disease insomuch it gives information about a patient who needs treatments for a long time period in different structures. In effect, diabetes is usually combined with other diseases; so, patient receives different diagnosis and therapies from different physicians. Thus, health organizations need to implement professional and organizational interventions apt to train providers about diabetes and its peculiarities in such a way to offer assistance appropriateness and efficacious treatment. This is achievable providing health providers a continued education and diagnostic machines of new generation; indeed, in diabetes care human and technological resources are key factors for a successful assistance that goes beyond the mere medical sphere (AMD, SIMG, SID, 2010; AMD, SID, 2010).

Indications about the department of diabetes' organization and goals in Italy are deducible from Law no. 115/ 1987, which affirmed that health organizations belonging to the National Health Service have to promote both diabetes prevention and diagnosis, improve treatments but also providers, patients, patient family's and community's information and knowledge about the disease, in order to

favor a real awareness and education about diabetes and its consequences or complications. Information is considered as the key to promote the inclusion of diabetic patients in the social, work, sport and school environments. In addition, the Law established departments and clinics specifically devoted to diabetes (even though for economic or management reasons they are often included in the department of general medicine), which are all ruled by national criteria and parameters. Also, regions have to plan activities of health education for the whole community counting on local social and health structures, beyond educational and sports centers.

Thanks to this diabetics' health protection, Italy was an avant-garde country in 1987; however, in 2001 the reform of "titolo V della Costituzione", in particular the article no. 3, made some changes at the constitutional article no. 117 in terms of central government's functions. General principles, indications about programs, LEA were issued as a central government's duty while the executive organization of social-health assistance network and uniform LEA implementation became a regional function. This involved the proliferation of disorganized and sketchy regional interventions, more resource dissipation and disparities in healthcare access and treatments. In 2012, the Permanent State-Regions-Autonomous Provinces Conference issued the "Piano sulla malattia diabetica", that is a plan to create a national system where diabetes and primary care services are integrated to guarantee a uniform diagnostic-therapeutic process. But, as professional associations claim, there are still administrative obstructions or disparities to patient access to diabetes services, which are enforced by the efficiency-centeredness and a limited availability of economic resources that are typical of a management style. The humanization of health services consists of the provision of the assistance apt to satisfy both human needs, such as the quality and personalization of health services, and managerial needs, such as the monitoring of wastes; however, the attention to efficiency usually prevails on the general objective of quality.

Another big issue in diabetes care is patient commitment in respecting treatment standard and changing the lifestyle. To better understand the reason why I chose the department of diabetes to study patient-centeredness as indicator of quality of care and what is the current level of patient participation in it, let us see first what are the main features of diabetes care, especially from a social viewpoint (AMD, SIMG, SID, op. cit.).

5.2 Social dimensions of diabetes care.

In the previous paragraph, diabetes has been introduced as a chronic lifelong disease with considerable effects on the community. Diabetes is linked to the contemporary lifestyle distinguished by inactivity and unhealthy nutrition (and can be caused by other diseases or medications); more, it is a disabling illness with chain reactions on patient body and society as well. Indeed, a diabetic patient needs different expensive services, continuos medical examinations, and supportive tools for self-treatments, whose cost increases in case of an advanced stage of infirmity. Even though diabetes has a rising level of incidence, the information about it is not yet broadly diffused and there are some prejudices against diabetic patients as disable people, who consequently feel discomfort and live integration problems in social and work life. In other words, there should be a bigger knowledge of this chronic disease and a broader awareness of its extent from a social point of view rather than medical (where there have been already achieved good results).

With the aim of improving physical and mental health, Italian diabetes care is shaped around favoring the patient-doctor relationship. Research showed that therapeutic education really involves changes in lifestyle, such as long-term and healthy attitudes improving patient health and clinical results and minimizing the consequences of this chronic disease. This goal is achievable if information is patient-based, that is focused on patient's hopes, fears, familiar, social and work relationships over therapeutic and physical aspects. The benefits of the integration between the biomedical and human side of medicine would be proved by group

therapeutic education. The University of Turin realized the “Progetto Romeo”, a study on 815 patients showing that the ones attending group therapy improved their knowledge and ability in managing their disease and life quality. Thus, the combination of medications with communicative support would be more beneficial than the only use of medications (Montebelli, 2008). Information and communication in a monitored environment would help the patient-doctor and patient-health organization relationships, beyond patient empowerment, that is patient’s ability to self-manage his/her disease by improving his/her knowledge about illness and getting a higher level of autonomy, in order to have a better quality of life. According to Dawn2 (2014) — a global study conducted in collaboration with the International Diabetes Federation (IDF), the International Alliance of Patient Organizations (IAPO), the Steno Diabetes Center and a range of other national, regional and global partners —, to get optimal treatment outcomes, diabetics need on-going support to effectively and actively self-manage their condition. The majority of health professionals involved in DAWN2 affirmed that self-management education is necessary for a patient active engagement, hence improvement; to have some questions for the consultation, being involved in community activities, practicing some sport, eating healthy are helpful for patients; however, only 33% of providers admitted to have received adequate training to provide such an education and support to diabetics.

An Italian study, AWARE, realized by the Associazione Medici Diabetologi (AMD) in 2003 confirmed that patients have a conflicting relation with diabetes since they receive the first diagnosis of diabetes. Patient’s emotional well-being is strongly affected by diabetes because of its consequences on physical health such as cardiovascular and ophthalmic complications, on daily routine because of the implementation of prescribed treatments and drug delivery, and even on their moral mood. In effect, patients might experience diabetes-specific emotional distress, depression or the perception of being discriminated against, which have a negative impact on their relationship with family, friends and peers, as much as on leisure, work, studies activities and even over their financial situation. Clearly,

health organizations should provide services apt to satisfy both the clinical and psychosocial needs of diabetic patients and their families. Thus, diabetics should have the opportunity to access and benefit from services of psychological support offered inside the department of diabetes, whose providers should have been properly trained for this function.

Nonetheless, even though patients usually consider education programs helpful to learn more about diabetes and to provide better support for their relatives, they often avoid the programs, as they feel overburdened by continuous monitoring, daily treatments, changes in lifestyle.

Summarizing, improvements are necessary in the interaction between general medicine physicians and other specialists, on one hand, and in the doctor-patient communication, in the other. Effectively, when the patient-doctor relationship is not optimal, patients develop doubts and fears about their conditions which decrease their willpower, dedication to treatments, and application of doctor's recommendations. Hence, in diabetes care patient-centeredness seems to be the key for successful treatment outcomes in terms of physical and community improvement. However, patient-centeredness in diabetes cannot be meant only as patient participation at the decision-making about cures, but also as taking part at the policy-making about the education programs, informational and social activities and therapies. As just said, evidence showed that medications have to be flanked by training, learning and social activities apt to improve the knowledge and autonomy of patients and their families about the disease as much as their self-confidence and comfortability in the community. Thus, patients should have the opportunity to express their opinions and suggestions about their needs for psychological support, treatment tools (i.e. for insulin infusion), and so on; maybe, by involving them since program design, they would comply more with treatments. Finally, if health services for diabetes upgrade patients' quality of life, they could be evaluated as high-quality services.

This hypothesis is the starting point for the research on the selected case studies; the department of diabetes has been chosen because its dimension of quality can

be observed and assessed not only in terms of compliance to clinical procedures, but also of global attention toward the individual (different from the patient) and of realization of the principles stated in the process of humanization, above all the patient-centeredness. In addition, given the long-time doctor-patient/citizen-health organization relationship and the knowledge acquired by patients, it is totally meaningful (over worthy) to include patients in the health performance assessment.

Diabetes is an organic disease which has a strong impact of patients' life because, beyond its life-long duration, it requires a strict discipline: moreover, it influences patient's life in terms of social relationships, spare time, social and work activities. This means that the disease itself and the leading clinical practice stay in between the health structure and the community; also, diabetes deals with communication insomuch requires a specific socialization for both patients and citizens. Hence, a better social relationship between patients and physicians, as much as between patients and health structure, is a constituent element of therapy. Consequently, patient satisfaction as dimension of quality is particularly relevant insomuch the achievement of specific therapeutic goals, the so-called compensation rather than just a consumerism fulfillment. Given that diabetes care is a socialized practice, the components of service quality are all integrated; I particularly refer to quality's components values, the medical-technical one and the organizational ones. This means that the involvement of patients as stakeholders should consist of patient participation at the treatment as much as in the organizational planning and assessment.

5.3 Italian legislation on diabetes care.

Italy has been a pioneer in the legislation about diabetes care although has issued a limited number of laws and decrees; 115/1987 is the first Italian law on diabetes care and represents an original case in Europe. This law defines diabetes

as a disease with a high social importance that consequently needs prevention and early diagnosis beyond a continuous improvement in treatment techniques through a specialized assistance network to prevent complications. Furthermore, the law states the enhancement of population's health education and health providers' training, the inclusion of the diabetics in school, work, sport and the identification of populations with a high rate of risk. Finally, the Law 115/1987 establishes free distribution of diagnostic and therapeutic devices and the creation of the individual card for diabetics; in addition, it entrusts its implementation to Regions and Autonomous Provinces through regional health plans in addition to giving minimal standards which must be homogeneously met throughout the country. According to article number 5, community health centers must guarantee a multi-specialized assistance which might be constantly accessible during weekdays and offering continuing, integrated, and coordinated consultations. Also, these health structures must offer the assistance of a general practitioner to accomplish therapeutic and epidemiological procedures, health education programs, patient participation at the organization and coordination of activities for diabetes care, home help. Physicians' activity has to be supported by a proper availability of (non-medical) health providers such as qualified nurses, nutritionists, specialized technicians in a three-level assistance organization; the first level is dedicated to specialized assistance coordinated by a general practitioner and a pediatrician (who is chosen by patients) in line with community health services, while the second and the third levels supply assistance for more complicated health problems.

In 1999, the law was included in the National Health Plan, nonetheless its application at the regional level has been fragmented; in the meanwhile, the government issued Law n. 104/1992 about work benefits reserved to diabetics and their families and Law n. 68/1999 about the access of diabetics to the work market. One year later, a specific decree about driving licenses and a plan on diabetes disease were issued; this last reported goals and strategies for priority improvement areas in diabetes care. Moreover, in 2015 Italy published its Manifesto of rights and du-

ties of the diabetic person that has been promoted by different Associations that work on the regional level.

Looking at the selected case studies, Sicily started to legislate about diabetes in 1989 till 2005, always focusing more on the clinical side of diabetes care. Indeed, the thirteen issued decrees list the therapeutic devices for patient self-treatments and the criteria for their distribution and exemption; more, guidelines for the prevention of diabetes complications, codification of clinical information in discharge reports, and treatments in case of rheumatoid arthritis. The Regional Decree of the 28th September 1998 states a disease management based on the integration and collaboration of the hospital and community services, which have to share the knowledge of international and national diagnostic-therapeutic procedures as much as of the available resources. Disease management's strong points are the combination of primary and secondary care services to offer high quality performances and performance pertinence, with higher cost control and service usability on one hand, and shorter waiting time. Also, this diabetes care strategy provides a concrete possibility of secondary prevention and outcomes evaluation, highly involving patients. However, there are some weak points as well, such as costs for professional training and the computerized communication system, cost-centeredness, the overlapping of acute symptoms that are not interrelated with diabetes so cannot be cured by integrated services.

Instead, Tuscany has been more prolific in promulgating decrees on diabetes given that from 1984 till 2012 has established 41 decrees. As the Sicilian, Tuscan regulation focuses on the clinical side of diabetes care: indeed, it issues guidelines for diabetes care during pregnancy, devices for self-management, assistance for non-residents, with a superficial intersection in the social sphere through the patient's rights and duties decalogue, rules about driving licenses and sport suitability, and educational therapy. In 2009 the Chronic Care model (see Chapter III) has been adopted within the activities of "sanità d'iniziativa", that is the activity of information to prevent the diffusion of chronic diseases that is designed and provided in accordance to the prevalent risks detected in the community.

In both cases, regional legislation about diabetes specify the policies within the limits established by the national framework laws, which outline the key points for chronic disease care but leaves to the regions the task to state time limits, specific recommendations, directives for educational programs, psychological support services, patient involvement. In addition, guidelines for diabetes care are established internationally by the scientific community and defused through the doctors and patients associations devoted to this disease, which perform an important role in the patient and patient's family support. The most important information, suggestions, support necessary for patient self-management comes from professional and patient associations through websites and forums, self-help meetings, but also from conferences organized by the pharmaceutical industries selling medications and devices for diabetes treatments. Thus, public health system has limits in the provision of the basic level of assistance required by the disease itself and stated by the process of humanization, and this would be confirmed by what came out by the two analyzed case studies.

5.4 Measurement of patient-centeredness.

An overview of the evaluation of health performance and its typical methodological problems has been introduced in chapter IV, while the assessment of patient-centeredness is brought up in this one to better understand its strong points and issues in relation to diabetes care and the leading conceptualization of patient. My goal indeed is to monitor the feasibility of patient-centeredness through the analysis of the implementation level of quality assessment.

Mead and Bower claim «a "patient-centred" approach is increasingly regarded as crucial for the delivery of high quality care by doctors. However, there is considerable ambiguity concerning the exact meaning of the term and the optimum method of measuring the process and outcomes of patient-centred care» (2000, 1087). Hence, five conceptual dimensions can be identified in patient-centeredness evaluation: biopsychosocial perspective; "patient-as-person";

sharing power and responsibility; therapeutic alliance; and “doctor-as-person”. Sharing power and responsibility represents the shift from a “co-operation-guidance” to “mutual participation” model in the doctor-patient relationship (as already introduced in Chapter II) with the aim of recognize patients’ needs and preferences through ideas sharing, listening, reflection, and collaboration (Byrne & Long, 1976). In accordance with the biopsychosocial perspective, the scope of medicine goes from organic disease to a far wider range of “dysfunctional” states (Silverman, 1987) so the doctor adopting a patient-centered method shows the willingness to get involved in the full range of difficulties patients exhibit, not just their biomedical problems (Stewart et al., op. cit.). If this dimension focuses on the «understanding of patients’ illnesses», “patient-as-person” concerns with «understanding the individual's experience of illness» (Mead and Bower, op. cit., 1089), starting from a patient representation as idiosyncratic personality rather a diagnostic — physical, psychological or social — label (Bower, 1998; Balint, 1964). On the contrary, “doctor-as-person” is the dimension leading to the influence of the personal qualities of the doctor since physician’s subjectivity, in particular sensitivity and empathy, might be helpful in improving his/her disease management. Nonetheless, the doctor-patient relationship might be exposed to the risk of countertransference (when therapist develops positive or negative feelings toward the patient according to the psychodynamic literature) provoking limitations or negative responses in patient behavior (Balint et al., 1993). If negative emotional responses by patients or physicians may complicate medical judgement, cause diagnostic errors, weaken patient adherence to treatment, positive emotional responses may enhance patient's conditions. Thus, authors define as therapeutic alliance the importance conferred to the personal bond between doctor, «patient's perception of the relevance and potency of interventions offered», patient’s agreement upon treatment goals, and the «perception of the doctor as caring, sensitive and sympathetic» (Bordin, 1979; Squier, 1990; Mead and Bower, op. cit., 1090). Therapeutic alliance is a fundamental requirement rather than a useful addition in patient-centered care, and patient-centeredness is considered as

a proxy for the quality of interpersonal aspects of care such as the physician's ability to give patients sufficient information and time, to treat patients as individuals using empathy (Hall, Dornan, 1988; Baker, 1990; Williams, Calnan, 1991; Wensing, Jung, Mainz, Olesen, Grol, 1998).

Concerning the measurement of patient-centeredness, it presents the same difficulties as medical care standardization, but in an emphasized way. First, generally speaking, the managerialism throughout the public sector has fostered the quantification of quality of care (Roland, 1999); second, patient-centeredness is characterized by the difficulty of measuring complex relationship processes, more through valid and reliable measures supported by an explicit theory (Meehl, 1978). Given that patient-centeredness is usually conceptualized as a clinical method in most of the empirical literature, measures involving the observation of consultation behaviors predominate; i.e. rating scales to measure how much or how well a specific behavior was performed and coding systems for verbal behaviors as doctor and patient speech. Nonetheless, as Mead and Bower state (op.cit., 1105), «the utility of any measure depends on its validity, reliability, sensitivity and feasibility, and a trade-off between these criteria is often necessary»; consequently, to take into account only the measures of patient-centeredness leading only to medical procedures rather than also to patient's experience would be reducing and incomplete. In effect, patients' perception of care is another measure to include, even if it carries a methodological issue such as the implicit assumption that patient-centered behaviors and outcomes — as satisfaction and compliance to therapy — may be associated in a simple linear relationship (Locker, Dunt, 1978; Fitzpatrick, Hopkins, 1983; Williams, 1994). Thus, Pascoe (1983) highlights the difference between satisfaction and evaluation reminding that the first is the cognitive process of assessment of some aspects of care and the second refers to patient's emotional response to the whole experience of health care.

Wensing and Elwyn (2002, 153) take into consideration patients' preferences and expectations, distinguished in normative and predicted expectations, respectively the «beliefs about what should occur or what people want of care and beliefs

about what will actually happen, irrespective of whether this is wanted». To elicit preferences, individual interviews and focus groups are the preferable techniques to enable interaction and opinion sharing and to overcome patient indecision on what is important in general terms, while quantitative methods are better to bring out preferences for the most desirable alternatives. Instead, patient reports are commonly considered more "objective" insomuch do not necessarily bring out patient's perspective on care quality but only his/her perception of the professional performance. However, patient report represents a tool for quality improvement because of their information accuracy about patient's pathway through different healthcare institutions (Brown, Adams, 1992). Regarding quality improvement, Pouwer and Snoer (2002) studied patients' views on the quality of diabetes care, with particular interest in knowledge, communication, convenience, and accessibility. They chose to employ self-administered standardized questionnaires aimed at the detection of the dissatisfying aspects of care according to patients' opinion. Self-administered standardized questionnaires were considered as tool of health organization's internal improvement because evidenced when physicians could become more responsive to patient preferences, contributing to a better implementation of clinical guidelines and improving adherence to treatment, health status and satisfaction with care. Effectively, patients are co-producers of health care insomuch they influence the patient-doctor relationship through their attitudes and take decisions about treatments; so, outcome measures should take into account patients' contribution. The following table presents all the uses of patients' view that Brown and Adams (op. cit.) confer to quality improvement.

Table 5. Brown and Adam's uses of patients' view (1993, 405).

Table 2 Use of patients' views for quality improvement

Provision of data to those who seek health care:
- Health education
- Internet communication
- Public reports

Eliciting patient preferences in episodes of care:
- Needs assessment
- Tailored patient education
- Shared decision making
- Patient-held records

Patients' feedback on medical care:
- Written surveys
- Complaint procedures
- Patient participation groups

Patient involvement in healthcare systems:
- Assessment of priorities
- Involvement in guidelines
- Patient organisations

According to the table, which looks recapitulatory enough, patients' feedback on medical care may be collected through written surveys, patient participation groups, and complaint procedures; if the first two techniques might be "piloted" by health organization in line with its scopes and goals, the third one is totally linked to patient satisfaction. In literature, the concept of satisfaction is sometimes described as not adequate given that deals with meeting patient expectations, which do not necessarily lead to a high level of quality since «patients can be satisfied with low quality care or can be dissatisfied with high quality care» (Pouwer, Snoer, op. cit., 131; Cleary, Edgman-Levitan, 1997). Consequently, some authors prefer the conception of patient-centeredness as patient participation at the decision making process. OPTION (acronym for "observing patient involvement") is a scale designed to «evaluate shared decision making specifically in the context of general practice» by examining «whether problems are well defined, whether options are formulated, information provided, patient understanding and role preference evaluated, and decisions examined from both the professional and patient perspectives». The results of the study realized by Elwyn et al. look interesting insomuch reveal that patient-centeredness and patient participation in decision-making processes are broadly accepted by clinicians; hence, the true limiting factors of patient-centeredness would be skill deve-

lopment and structural constraints as lack of time and hard accessibility to information (2003, 94). If patient participation in treatment decision-making is defined as patient's right to be informed and will to be involved in decision processes (Guadagnoli, Ward, 1998), the process of involvement becomes more important than its outcomes. Information delivered on treatment options, checking of understanding and preferences, and making a shared decision in addition would be the indicators to measure the effectiveness of shared decision-making (Edwards, Elwyn, 1999).

In relation to diabetes care, the five dimensions defined by Mead and Bower to measure patient-centeredness can be applied to diabetes care seeing that it aims at the treatment of the whole person and his/her dysfunctional states, through a mutual participation of patient and clinician who are both personally involved in the relationship. If the patient has to share his/her individual experience of illness, from a clinical, emotional and social point of view, the doctor has to use his/her personal qualities as empathy to better understand the disease and its consequences on the person, to find the most appropriate and efficient treatment. In addition, the therapeutic alliance is one of the load-bearing axis of diabetes care because it is based on quality of care in terms of patient-centeredness, time given to the patient, attention to patient's psychic conditions, and so on. On the issue of the validity of patient satisfaction or perception as a measure of quality or patient-centeredness, let us remind that diabetics do not receive just a consultation on medications and treatments, but also suggestions about lifestyle, self-help groups, over self-management of the disease. Patient empowerment is particularly relevant for people suffering of diabetes given that they are typically educated and trained during medical examinations; moreover, in the time patients spend in the department, they develop a knowledge about the health organization or hospital and its services, structure, availability of economic, human, and technological resources. Thus, diabetic patients have that expertise that can limit an arbitrary subjective evaluation (of health services). Nonetheless, evaluation is a controversial issue; in Italy, as previously said, a positive diffusion of the evaluational culture struggles

with prejudices against punitive judgements and individual incapability of assessment by patients. If the adoption of evaluative programs is recent, even more recent is the openness of evaluation programs to all the involved stakeholders, both internal and external, specifically patients. Diabetes care could be a positive example of the openness to external stakeholders/evaluators, above all in the quality performance assessment; indeed, diabetes care is centered on the basic principles of quality, patient-centeredness and humanization of health services, and the external evaluation of health services can be interpreted as concretization of these principles.

Thus, patients affected by diabetes seem to be good candidates to cooperate in research and evaluation. Actually, I preferred to involve people with type 1 diabetes because younger, more forceful and motivated towards research than type 2 diabetes' (who are elderly). Dealing with research techniques and instruments, choices lead to organization's and research goals since diabetics look competent and open to dialogue.

5.5 Research goals, sampling and techniques.

5.5.1 Research goals and sampling.

The starting point of my research is the process of humanization of health services, mainly centered on the introduction of quality as principle both to organize and assess health assistance. Quality means to give more attention to the person as human being (rather than patient or consumer), whose physical and psychological dimensions are connected in conditions of both health or sickness (WHO Regional Office for Europe, 2013a). So, first, in the doctor-patient relationship clinician's personal qualities would improve the understanding of patient's conditions as much as the diagnosis and treatment. Second, medicine aims at patient empowerment rather than care; so, health organizations start providing the necessary knowledge and devices to allow patients to self-manage their own

disease (as much as permitted by illness) and get autonomous. Consequently, patients acquire an active role in the relationship with doctors and in literature authors talk about the patient-doctor relationship not anymore of the doctor-patient (Buccoliero, op. cit.; Bellio et al., op. cit.; Lemire et al., op. cit.; Salmon and Hall, op. cit.; Hellĩn, op. cit.). But, patient's active role is required in the decision-making of treatment as much as in the assessment of health performance. Indeed, quality of health services implies that quality has to be applied as a criterion of assistance provision to be evaluated through proper indicators by all the involved healthcare stakeholders, including patients. The theorization of health quality and general evaluation has a long tradition, on the contrary of the application of quality assessment models; this implies that the theme of quality has reached a well-established scientific maturity in terms of strategies and techniques while the consensus on the reliability of assessment models is weak because of patients' subjectivity, for example. Surely, the contrast stays between theory and empirical research rather than quality and quality assessment. In addition, problems dealing with judgement impartiality, such as patients' weak medical knowledge or subjective perspective on satisfaction, which are still discussed in the methodological literature, appear to be less relevant in the case of diabetes given the socialization and expertise normally acquired by patients dealing with such a chronic disease. As previously said, time and modalities of care allow diabetic patients to develop a knowledge on their disease and its management, as much as on healthcare's organization, resources, potentialities and limits. Finally, the choice of diabetes as research object within a humanization of health services perspective is justified by the importance of a personalized health assistance, including a psychological support, in order to manage patients' lifestyle habits and to deal with diabetes' physical and social complications.

Starting with these assumptions, first of all, I wanted to analyze the Italian current situation of quality assessment in healthcare in order to understand if it is genuinely patient-inclusive and aimed at the health service's efficacy measurement (rather than efficiency). The department of diabetes seems to have some of

the best conditions to investigate the recent theme of quality assessment as well as patient-centeredness, which derives from the humanization of health services and seems to me the key to improve patients' compliance to treatment and treatment efficacy. In my opinion, to involve patients and their families in the policy-making of social and informational department's activities could be an alternative way to identify patients' needs (both clinical and psychological), to offer a useful and accurate assistance, and to help diabetics in changing their everyday-lifestyle habits, with a consequent increase of treatment's efficacy or decrease of complications. Moreover, the social network made by patients and their families would be an additional support for patients, reducing the pressure on health services.

Another reason justifying the choice of an Italian case to study the performance quality in diabetes care is that this country is a favorable field for the evolvement of healthcare's social dimensions leading to the humanization. Indeed, the Italian is a public health system that is recently inspired at the eudaemonic conceptualization of health as strategic goal of the health system. This involves a humanistic conception of patient as person (rather than consumer as in the North American profit-centered health system), so the commitment toward quality and evaluation (even if recent and obstructed by a diffused cronyism and bureaucratism) as conditions for an advanced assistance provision. Naturally, this is influenced by clinical progress and social developments as much as by practical economic issues.

I chose to realize an exploratory research involving patients affected by type 1 diabetes. As previously stated, this kind of patients are more likely to cooperate because of their age and conditions, beyond being more appropriate to the research's goals because of their needs. This suggestion came from some experts — including a sociologist and a diabetes specialist — of the "Osservatorio per la qualità e l'equità - ARS Toscana". Considering the exploratory research's goals and the small number of type 1 diabetics, it has been possible to involve the whole population of type 1 diabetics cured in the two selected case studies, a Tuscan and a Sicilian hospital. In addition, the department of diabetes' manager and medical

staff has been involved; they are, respectively, the doctor supervising and the specialist doctors assigned at the above-mentioned department. My objective was, indeed, to involve all the main categories of stakeholders and check if they can be even actors in the social and informational hospital policy-making, definitely overcoming the tensions and inequalities characterizing the doctor-patient relationship (as seen in Chapter II). Given the primordial level of the study, I preferred excluding other two categories of stakeholders involved in diabetes care: non-medical health providers, i.e. nurses, and patient associations. The study field would have been too broad and dispersive; furthermore, in literature the attention on healthcare relationships has been focused almost exclusively on physicians and patients, while the other actors have been studied separately (Broom, op. cit.; Emanuel and Emanuel, op.cit.; Szasz and Hollender, op. cit.). Recently, managers (Hinna, op.cit.; Del Gesso, Rafti, op.cit.) start being included in the study of healthcare relationships seeing the application of managerial models in the healthcare organization. Moving to patient associations, they are usually founded by chronic or rare diseased patients in Italy. In my research, to involve patient association would have meant to consider an actor playing mainly outside the health organizations; by doing so, I would have contemplated further interests in an already complex frame.

5.5.2 Techniques and tools.

Each category of stakeholders is characterized by specific inclinations because of its history and role; so, different techniques and tools have been used in the research to get a general knowledge of the department of diabetes, its dynamics, strong and weak points. The choices have been driven by literature and the discussion with a UW Madison Hospital's diabetes specialist, working on PCORI (a program for patient-centeredness), and a UW Madison Population Health De-

partment's professor, who is expert in the coordination of multiple chronic conditions and methodological issues in pay for performance measures. Although the US health system is completely different from the Italian one, to give a look at some of its programs for diabetes care and patient-centeredness might be useful given the seriousness and dissemination of diabetes across the country; moreover, US is the birthplace of the evaluation of public policies.

A manager of the Tuscany department of diabetes and another of the Sicilian department of general medicine, have been interviewed through a semi-structured form. In effect, to interview managers adds up to major difficulties because department's managers are both administrators and doctors; the first generally show the typical diffidence of someone who is running an office and has to justify his/her management, especially if it is built on economic cuts and savings (as nowadays often happens); while the second belong to a category with a defensive attitude. As seen in Chapter II, the medical class has always shown an attitude of superiority typical of guilds or professional castes, which is supported by the paternalistic model of doctor-patient relationship and motivated by the possession of a medical knowledge. Therefore, at the beginning of the interviews I showed a reassuring attitude of incompetence and comprehension of his/her job, responsibilities and commitment to job, to let him/her feel comfortable and answer to all the questions, even the thorny or delicate. A semi-structured interview seemed to me the best technique to balance research's goals, interviewees' attitude with the acquisition of information about diabetes care and administrative or economic processes influencing health care management and services.

To increase my knowledge about the mechanisms, strong points, problems, prospects of diabetes care, I organized a focus group with three physicians and three patients of the Sicilian health system; I chose the Sicilian case insomuch the Sicilian healthcare is more complicated than the Tuscan one, so the focus group would have been more useful to understand the situation. Although the reverential attitude generally manifested by patients towards doctors (above all in the Sicilian context) could inhibit the sincerity of patients' answers, putting together

the two actor categories allowed me to get at once two perspectives on professionals' and patients' needs, over the patient-doctor relationship. Also, I could understand the diabetes care key points which are: the therapeutic alliance, the importance of a psychological support, and the availability and employment of devices as infusers as both economic and educational question. Focus group helped me in order to become familiar with diabetes disease, management, and effects on society, enabling me to structure to write the questionnaires for patients and clinicians.

Regarding questionnaires, I wrote two slightly different versions, one for clinicians and one for patients. This choice of a self-administers form permitted me to simultaneously collect data in two different regions and overcome the problem of time. On one hand, doctors are really busy; so, to distribute them questionnaires and ask to fill them within a few weeks would increase the rate of filled questionnaires. On the other, diabetics generally go to the hospital for inpatient treatments rather than admissions, in accordance to both their free time and hospital's waiting lists; then, to interview would have taken too many weeks and maybe would have been uncomfortable for patients. Even though diabetes is a current disease with a high rate of prevalence, diabetic patients often feel uncomfortable when they speak about their illness and conditions, so questionnaires would have increased patients' collaboration and answer sincerity.

During the months spent in data collection, from the first contacts with mangers to receive the access authorization to the hospital till the collection of filled questionnaires, I had the opportunity to realize some covert observation in the hospital. It was interesting insomuch I could observe how the hospital space is organized (if privacy is respected, if there are waiting rooms for families or teaching rooms for educational programs, what is the organization for medical examinations, and so on) and what are the main behaviors and feelings manifested by clinicians and patients in a usual day in the department in conjunction with routine better or worse practices.

In my opinion, resorting to mix techniques for collecting information seemed to be the way to do an exploratory research in healthcare considering time and space limitations in my research. In healthcare, the habitual research obstacles as the in/acceptance to participate and collaborate to the project or the interviewee's unavailability are amplified given that the environment is exposed to different ethical and normative rules, physicians are really busy — also because can do medical examinations in different hospital departments —, and patients can sometimes miss their medical appointments because of their health. More, despite diabetes care's social dimension, for example the educational, to find hospital's availability to cooperate has been laborious. Maybe this might have been interpreted as a first clue on the Italian situation of healthcare quality and patient-centeredness in diabetes care. I mean that there is a gap between the acknowledgement and the adoption of the principles of humanization of health services. Health organizations usually admit the importance of their openness to patients and other external actors/stakeholders to collect their opinions, suggestions, evaluations and improve the quality of care. Nevertheless, it is not so easy to find a health organization that is truly open to external actors and available to cooperate even for research goals.

5.6 Performance indicators in diabetes care.

In the Italian diabetes care, medical and evaluational procedures are established on the national level. As concerns indicators, structure's are issued by the singular health organization while process', outcomes' and quality's are the same in the whole country (and the majority adopted in the whole OECD area). Process indicators are:

- Number of patients admitted during a ketoacidosis episode;
- Number of pediatric medical examinations (type 1, type 2, and MODY) on follow-up patients with a new diagnosis and registered on the regional level;

- Odd between the number of appointments that diabetics or glucose intolerants have with a nutritionist and the number of diabetic children/teenagers;
- Odd between number of psychological counseling received by diabetics and number of diabetic children/teenagers;
- Percentage of patients in good compesantion;
- Percentage of patients receiving a ophthalmological exam during the current year or during the prior year;
- Percentage of patients with at least one test for microalbuminuria during the measurement year;
- ADP's (Attività Diabetologia Pediatrica) and SSDP's (Struttura Specialistica Diabetologia Pediatrica) report on the utilization of advanced technologies to send to the CRRDP (Centro Regionale Riferimento Diabetologia Pediatrica);
- CRRDP's report on the utilization of advanced technologies sent to the Region;
- Number of meetings of the diabetic RRPS (Rete Regionale Pediatria Specialistica).

Regarding outcomes, there are a few indicators:

- odd between the number of diabetic patients or overweight and diabetic children/teenagers;
- odd between the number of diabetic patients with one or more ketoacidosis episodes in the measurement year and diabetic children/teenagers;
- odd between the number of diabetic patients with one or more severe hypoglycemia episodes and diabetic children/teenagers.

Finally the quality indicators for the diabetes performance:

- Percentage of patients with the most recent HbA1c level within the recommended values according to the age range compared to the diabetic children/teenagers;
- Percentage of patient with most recent LDL<100 mg/dl;
- Percentage of patients with most recent blood pressure within the recommended values;

- patient satisfaction on diabetes assistance received by the general practitioner or pediatrician (to measure through regional surveys to be still designed);
- patient satisfaction on diabetes assistance received by SSPD /ADP /CRRDP (to measure through regional surveys to be still designed).

Looking at process and outcome indicators, it is easy to state that these measures are weakly leaded to the quality assistance declared by institutions, national health plans, literature. There are specific indicators for quality that, according to my opinion, are not sufficient to measure and assess quality of care. The Italian health system offers social and medical assistance, but the social dimension of diabetes care is not adequately represented by the adopted measures. To use patient satisfaction as an indicator of the performance quality, it has to refer to a specific element of health assistance that is provided by a general practitioner or a regional institution. Educational programs, psychological support, doctor-patient relationship, medical devices provision are all fundamental components of diabetes care which are not included in quality indicators. In addition, some improvement areas in diabetes care have been already identified (Ministero della Salute, 2011; 2012):

- Diagnostic delay of diabetes;
- Shared diagnostic and therapeutic procedures in order to guarantee a proper therapy even when patients are admitted because of other diseases;
- An homogeneous pediatric assistance on the regional level;
- Epidemiological monitoring;
- The implementation of regional deliberations, also by strengthening the relationship with volunteering associations;
- Identification of performances to exempt (economically) such as examinations with nutritionists, examinations for diabetes-associated diseases, educational programs;
- Telemedicine.

Even though becoming conscious of lacks is the first step to improve, it is not a guarantee for improvement implementation in the Italian context. In conclu-

sion, the current indicators for diabetes care are not adequate to evaluate its quality; they are neither exhaustive nor valid to assess the social dimension of assistance. Nonetheless, these lacks could be filled through the adoption of a broader conceptualization of patient-centeredness that puts together the socialization of the therapy and the participation in the treatment decision-making, but also in the social and informational department's policy-making, and in the process of evaluation. In effect, as previously affirmed, diabetes is a global disease permanently affecting person's physical and emotional health as much as his/her social life. Diabetics are patients difficult to manage because, from a clinical point of view, are subjected to many complications and, from a personal/human viewpoint, they resist changes in their lifestyle, diet, and so on. Furthermore, they need a global assistance concerning treatments, education, medical devices which has to face the policies of money savings. Thus, patient involvement in the evaluation process could be the way to strengthen the citizens-health system cooperation and find a way to increase health system/performance quality by conscious managing available resources.

Let us finally see the results of the surveys realized on the case studies.

5.7 Results on the patient-centeredness in the Sicilian diabetes care.

5.7.1 Manager's viewpoint on the humanization of department's services.

In the Sicilian hospital chosen as case study, there is not a department of diabetes, which is a division of the department of general medicine; however, its manager is a diabetes specialist that I could meet for 20 minutes in between two different appointments with medical sales representatives, patients, health organization's employees, doctors. The manager runs the department as concerns both administrative and clinical procedures guaranteeing that national, regional and local health systems' guidelines are implemented; patient security and satisfaction

are achieved by a good performance of the doctor, who has to be protected by eventual unjustified accuses of medical malpractice.

My first interest in interviewing the manager was to understand if quality, and specifically patient-centeredness, is the department's objective. My first question focused on the department's manager assuming a double role of administrator and physician in order to understand if this function convergence is worthy but also the workload weighing on the professional.

In the interviewee's opinion, being a doctor is helpful in the department administration because of the comprehension of both physicians' and patients' viewpoints, such as the professional difficulties or patient needs. The doctor offers assistance provision so knows what really happens in the hospital, what resources are needed, what mechanisms direct the doctor-patient relationship and what is the influence of hospital activities on community's health.

Nevertheless, expertise and the ability to include the perspectives of all stakeholders are not sufficient conditions for a good management, which requires resources as well. In diabetes care, resources shortlist is made by human resources, as health providers with different qualifications and specializations, nurses, and technicians able to use the machines for the examinations. In effect, even if in the ideal department of diabetes there should be a team of specialists — diabetes specialist, cardiologist, infection specialist, neurologist, orthopedic, hepatologist, internal medicine expert — for a global evaluation of the patient.

In the department, there are only four doctors (two of them working in the community care system) while the others work in different departments and intervene in case of consult. The small number of department's doctors is due to the lack of economical resources, which affects also the availability of advanced machines for monitoring, examinations, medication administration. Naturally, it follows that economical resources lack also for any kind of learning program for physicians on the humanization and personalization of health services. Then, the inclusion of the department of diabetes in more general department of general medicine is surely another aggravating factor to the blackness of resources (given

that resources have to shared among the wards belonging to the department). Hence, clinical priorities are the only criterion used to manage the available limited resources, which are not directed to any program for patients.

Even though the awareness of the important effects of psychological counseling and education programs on treatment efficacy and patients' health, health organization does not offer a service of psychological assistance inside the department, where patients cannot count neither on the support of volunteering associations. Generally, diabetics and their families receive psychological and educational support outside the hospital, by patient associations and pharmaceutical companies; these last usually provide for the information about medical devices or lifestyle habits that is not supplied by the hospital.

This frame excludes the pursuit of patient-centeredness as a quality frontier and even quality itself is obstructed by the isolation of all the actor categories in health care. As stated by the interviewed manager, service personalization has contributed to service quality insomuch the communication in the patient-doctor relationship has increased. On one hand, patients are more informed so more demanding, but also more pro-active in suggesting treatments and therapeutic approaches that could be forgotten by the doctor during the examination. Nonetheless, this does not exclude the increase of complaint risks (already grown recently) and tensions between the clinician and patient categories. On the other, doctors show more empathy, which sometimes is misunderstood with the freedom to do whatever believed by the professional. Consequently, the individual commitment, responsibility and involvement are necessary conditions to pursue the performance quality. Time is the main resource lacking to doctors seeing that the criterion of efficiency has reduced the time available for singular examination to increase the productivity rate; for example, the double function administrator-doctor has some benefits on the department management, but at the same time produces disadvantages on the health performance because of a medical staff member is busy in other activities rather than that of receiving and treating patients. Productivity is often adopted as a performance indicator however it cannot

be employed as an indicator of quality seeing that less a limited time devoted by the physician to the patient often implies worse diagnosis and treatments. We need to pay attention and distinguish the indicators of efficiency from the indicators of efficacy even though the first are often presented equivalent than the second.

In conclusion, despite the improvement of the patient-doctor relationship, performance quality is affected by a limited resources availability, which affects the opportunities to implement the principles stated by the process of humanization from the phase of organization, through service offer, till the phase of evaluation. The difficulty of organizing high quality and patient-centered health services is mirrored in the assessment process. As described in Chapter IV, Sicily has an evaluation system that is not completely efficient on the external evaluation (the one apt at the collection of patients' opinion), as confirmed by the department's manager. Evaluation is considered as a bureaucratic additional obligation more than an essential element to foster the quality of services through patient participation within the broader perspective of patient-centeredness (proper of the process of humanization).

I finally asked the manager what are the prospects for diabetes care. The manager replied that diabetes is a "malattia del benessere" (so-called lifestyle disease) hence it requires devoted clinics or departments offering the assistance of a proper number of clinicians with different specializations. In addition, hospital department's manager need a smaller charge of responsibilities because, otherwise, the risk of nominating a director lacking the necessary expertise and of taking inappropriate treatment decisions will increase with consequences on the quality service and patient's health.

5.7.2 Doctors' point of view on the department's quality performance.

The questionnaires for physicians distributed were four but only three of them have been sent back to me. One doctor chose to not participate at the resear-

ch, the same one I had the opportunity to observe at the hospital during one of my waitings. As I could observe, the doctor did not pay particular attention to some arrangements (actually some of them are procedure rules) for a quality service such as respect patient privacy closing the door during an examination, or respect patients without interrupting the examination for something not compelling, give explanations in case of hitch, and so on. Without judging the doctor's behavior or jumping to any hasty conclusions, I interpreted this episode as confirmation of the importance and incidence of the individual commitment and responsibility in the pursuit of service quality.

Moving on the other questionnaires, there is a uniformity of answers, so opinions about the conditions of the studied ward of diabetes and its service quality. Physicians agree on the excessive charge of responsibility and red-tape they have to carry out, which means a time insufficiency to perform a good diagnosis, treatment or monitoring. The number of patients to receive every day is too big compared to the estimated time for a high quality assistance, which would include the analysis of patient's state of mind, expectations, perspectives. There aren't the conditions to carry out the examination of a "person" rather than a "patient" although the awareness that human qualities as empathy and availability facilitate the relationship with the patient, particularly improving treatment pertinence and efficacy.

Time is not the only resource missing in the department where an insufficiency of human resources, in particular nurses, is reported. According to clinicians, indeed, it is not necessary a high number of doctor but a proper number of nurses with an expertise in diabetes care. Devoted nurses would compensate for patient education, at least training about medical devices or giving other small recommendation about good habits. Information seems to be a sensitive subject for physicians since bad information is the main point of conflict in the patient-doctor relationship; patients who look for information surfing on internet or reading by themselves the package leaflet usually are stubborn and it is hard that they would change their opinion. Consequently, it is difficult for physicians to communicate

with them keeping the authority typical of the medical class, which is meant as practice of the clinical knowledge aiming at the identification of the most precise diagnosis and the best treatment in line with approved procedures. Well, the functions leading to this authority are limited also by supplemental administrative assignments; to fill activity registers and sign patient's entrance and exit time seem to be more important than fill medical records and take note of treatments and conditions. To certify the level of productivity seems to be more important than offering a high quality service to enhance or protect patient health and all forms of red-tape are more persistent than the process of humanization. This opinion about the feeling of pressure toward productivity and efficiency surfaces also through the answers to questions about evaluation. Physicians state that assessment is still considered as a strategy to distribute money inside a complex bureaucratic system and the interest toward quality improvement is not perceivable in a context where data are not verified but just collected and assembled to obtain strategically, in order to attain an intended economic result.

Finally, the interviewed physicians affirm an evolution in the doctor-patient relationship, which is improved over time. Clinicians caught the process of humanization of health services in terms of patient participation at the decision-making about treatments and patient empowerment; nonetheless, quality is not totally achievable inside a system where efficiency and expenditure cuts drive directly or indirectly physicians' activity, limiting the possibility to establish an empathic contact between patient and doctor because of time, lack of professional training and resources to invest in patient learning. Thus, doctors suggest patients workshops offered by pharmaceutical companies or self-help associations to fill public health system's lacks.

5.7.3 Patients' opinion on the quality and patient-centeredness of the department's performance.

The questionnaire has been distributed to twenty patients aged between 39 and 55, 7 women and 13 men. Two of them have elementary school degree, other two a bachelor degree, while the other 16 are equally divided between middle school and high school degree. Their jobs are housewife (4), management consultant (1), retired (3), and employed workers (12).

The first question is centered on the doctor-patient relationship; although the availably of six answer options — professional, informal, collaborative, non-cooperative, empathic, detached —, patients chose only two options. The majority (10 people) thinks that the patient-doctor relationship they take part to is professional, while the minority (3) thinks that it is collaborative; more, six patients believe that the relationship with their clinicians is both professional and collaborative. It is interesting that nobody, in his/her opinion, talks about an empathic relationship. Being professional is absolutely a doctor's positive and unavoidable feature; however, the skill itself does not represent a desirable condition claimed by humanization but a basic feature of the profession.

Nonetheless, the interviewees appreciate the quality of the health service, which has been almost equally defined as excellent or good. The main obstructive factor to service quality has been unanimously identified in waiting lists (17), followed by a limited hospital's economic availability (6), while the insufficiency of medical devices, advanced machines, doctors and difficulties in the patient-doctor communication do not look as limitations to quality rather than factors to enhance the department's service quality. Only waiting lists are respectively considered factors of limitation or improvement of service quality.

This could be interpreted as patients' disposition to comply with current conditions of health performance provision, even though the awareness of the possibility to make some improvements. Maybe this is due to the approach of patient empowerment shown by doctors which, rarely, is supported by psychological counseling. 13 patients believe that the department's doctors show a disease management approach based on patient empowerment, that is focused on helping patients to be autonomous in diabetes self-management through an appropriate

information and a empathic support. On the opposite, 5 people answered that clinicians act like they are holding patients to the hospital since they do not share the necessary information to help patients self-manage their disease, and 2 patients did not express an opinion. As regard the psychological support, only three respondents have the opportunity to be psychologically supported within the health organization and admit the usefulness of this service, and one of them affirms that the doctor can substitute the counselor. moving to the patients who do not receive this support, 7 admit the importance of the psychological support offered by a therapist while 8 believe that the doctor can afford this task. Well, we have contradictory data; patients feel to be involved in a professional or collaborative but not empathic relationship with the doctor, but believe that the approach to the diseases management is characterized by a proper empathic support. I would suggest that probably empathy is not the most marked skill or quality shown by physicians or is considered as worthy but is not yet identified through specific attitudes.

Moving to extra clinical activities, the interviewed unanimously state that they have not been involved in any kind of activity with social or informational goals. Neither the health organization nor patient associations offer educational programs or any kind of support. Nonetheless, patients would accept to participate at evaluation activities, at least 18 of the interviewed, given that only one person took part at assessment activities.

5.8 Results on the patient-centeredness in the Tuscany diabetes care.

5.8.1 Manager's viewpoint on the humanization of department's services.

The Tuscany case study is represented by a hospital's department of diabetes, directed by a specialist in diabetes who agrees with the Sicilian colleague about the benefits and disadvantages of fulfilling the double function doctor-administrator.

Tuscany is on top of the classification of regional health systems because of its quality, based on diffused community services, innovation and ongoing learning, attention and proximity to patients. However, last years' policies aimed to reduce economic wastes (especially in terms of useless exams or medications) turned out to be themselves as indiscriminate cuts to one of the most important public sector, health care. National budgets for healthcare decrease year after year and influence all regional health systems, included the most efficient and efficacious. Thus, even though the Tuscany regional government's attention toward one of its diamond points, the decrease of available economic resources affects Tuscan health services as well. The pressure of productivity is not considered as heavy as much as it is by our Sicilian manager but influences anyways the charge of work hanging on physicians and managers. The interviewee affirms that the central — regional — government offers conditions of service quality in which patient-centeredness cannot totally be executed because of the lack of resources. Technological resources do not lack, but human do; in the Tuscan department of diabetes, physicians have a limited time to examine patients respecting the time limits established to keep waiting lists short and accomplish the administrative tasks.

Regarding training, the Health Regional Office offers a rich program for physicians; notwithstanding the declared the attention toward the personalization of health services, there are not seminars about the management of the doctor-patient relationship from a human or psychological point of view — with the aim of offering a high quality service to diabetics and protect doctors from the degeneration of empathy in emotional involvement —. Instead, patients are involved in educational programs organized within specific campaigns, even though the information shared with health providers during examinations is the most frequent way of spreading information.

In manager's opinion, patient-centeredness in health services is a concrete horizon. The dissemination of territorial services and clinics, an efficient system to book medical examinations, patient involvement in a systematic assessment system, data transparency are already signs of a high quality health system. Ob-

viously, the current commitment is not sufficient given that many other improvements can be realized in diabetes care. For example, the hospital does not offer a devoted service for the psychological support for diabetics but only for oncological patients.

Quality as well is an achievable goal provided that managers are truly committed to pursue it, designing appropriate strategies and realizing step after step any single attempt. Also, all health providers have to be involved in the improvement process through personal, ethical and professional commitment. Surely, the assessment system patented in Tuscany represents a turning point in the patient-involved evaluation of quality of care insomuch it is a transparent, systematic, patient-involving instrument useful for quality improvement. Finally, the diabetes specialist affirmed that the humanization of diabetes care can be pursued through a bigger intervention of volunteering associations in patients support (somehow in line with the last frontier of health care assistance which gives more room to private sector's services).

5.8.2 Doctors' point of view on the department's quality performance.

I distributed six questionnaires in the Tuscan department of diabetes and once again I might observe a certain uniformity among physicians' answers, which I interpreted as guild's attitude of unity and firmness even though my belief in the importance of the personal commitment for quality achievement.

Physicians define their relationship with patients as professional and collaborative within the limits of the charge of work and deontological rules. Though they are aware of the importance of the human dimension beyond the clinical in healthcare, it is difficult for clinicians to show in a limited time particular empathy that would not be misunderstood with informality or excessive closeness. Even though the importance of patient participation in the treatment decision-making, patients do not have the same medical expertise as doctors' so can be tricked by information easy to get but not explained (as the one found on internet, i.e.). Pa-

tients sometimes are aggressive in defending their rights or taking decision; hence, to keep distances is considered by doctors as a way to reduce regrettable inconveniences. In addition, it should be counselor's function to take care of the psychological patient well-being.

Concerning health services quality, doctors feel satisfied by their performance even if a bigger time availability would help increase assistance quality. A higher number of physicians and non medical providers would help offer a better assistance characterized by communication, attention and information. Indeed, social and informational activities are considered as key factor in the management of diabetics, first, and diabetes, second. Information and communication are fundamental factors in the Tuscany health system but are even more important in the management of a chronic diseases suffered by patients who hardly change their lifestyle or need a huge quantity of information about different aspects (medical, physical, psychological, etc.). Pharmaceutical companies or patient/doctor associations could substitute health organization in supporting patients within monitored services, even though it would be preferable to take global care of the patient inside the same structure within the same care path and avoid mechanisms of consumerist addiction to private companies' services.

Despite time limits and the difficulty to organize systematic activities involving patients and their families, physicians try to work as much as possible in favor of patient empowerment trying to take advantage of any single conversation with the patient to give him/her the tools to self-manage the disease. Even the conversation between a nurse and a patient during the distribution of medical devices can have positive consequences. Undoubtedly, patients of the Tuscany system are more involved in health care activities than Sicilian, so they are used to debate in a system where patient participation is an important piece of the evaluation system. Even if assessment take into account only a sample of patients, data dissemination and transparency represent two of the strategies adopted to run an inclusive patient-centered health system. The Tuscany's looks as a system really

designed to improve health services, combining both efficiency and efficacy indicators.

5.8.3 Patients' opinion on the quality and patient-centeredness of the department's performance.

The questionnaire has been distributed to thirty six patients aged between 35 and 63 years old, 17 women and 19 men. 4 of them have an elementary school degree, other 6 a bachelor degree, 12 have a middle school and 14 a high school degree. Their jobs are housewife (7), self-employed (5), retired (6), and employed workers (18).

The doctor-patient relationship is defined as professional by 20 patients, as informal by 3, as collaborative by 5 and both collaborative and professional by last 8 patients. The health service quality has been judged as excellent by the majority of the interviewed (29) and good by 7 of them. Moreover, quality would be limited by (in order of preferences): limited hospital's economic availability and waiting lists, as the first two main reasons; then, availability of doctors and possibility to communicate with him; and, finally, with a few votes medical devices and technological resources, structure comfortability, and extra clinical activities. On the contrary, quality facilitators would be shorter waiting lists, number of providers in the department, and a bigger economic availability, followed by the opportunity to talk to the doctor, the availability of other resources as medical devices and advanced machines, beyond informational and social activities for patients.

Regarding to the approach to the diabetes management, also the Tuscan patients (28) define physicians' attitude as promotive patient empowerment given that services of psychological counseling are not provided. Almost the totality of the respondents (32) do not have the opportunity to receive psychological support by a hospital therapist; as in the Sicilian case study, patients agree on the presence

of a psychologist in the department, but 19 people think that this presence can be substituted by doctors.

Moving to patient involvement, 12 patients have taken part at social or informational activities for patients and their families organized by the health organization while 2 participated at activities organized by volunteering associations. 7 patients only took part at the evaluation activities, but the whole sample would participate at the assessment if they would have the chance.

In the Tuscany case study, a richer resources availability is inferred by the answers about quality limitations and facilitators. Except for human resources, which anyways are not considered as an urgency, technological resources are considered sufficient to satisfy patients needs. Improvements can be achieved in the communication with the doctor, but patients do not look interested in extra medical activities aimed at the information diffusion or self-management; maybe the reason is the physicians' approach towards patient empowerment that, in a patient-centered context, would fill patients doubts, curiosities, needs.

Talking about evaluation, the small number of patients who took part at assessment activities is due to the evaluation strategies and sampling given that sampling is done on the whole population of health organization's patients rather than the departments'. The unanimous declared availability to participate at evaluation processes can be surprising in the Sicilian case, but certainly not in the Tuscany.

Conclusions.

The theorization about quality of health care is wide and covers the economic, social, and demographic phenomena related with it. Moreover, the concept of quality is accepted by the medical and administrative classes as much as by citizens/patients; nevertheless, the design of quality measures have not yet reached the same development as quality theorization. Quality is an intrinsic methodological challenge and the difficulties to measure it are fed by a problematic acceptance of evaluation by people. Indeed, the culture of evaluation has not yet been absorbed by the Italian Public Administration, and the persistence of prejudices against evaluation (considered as judgement aimed at the mere distribution of economic resources and incentives) would prove this. As seen in Chapter I, there is still a strong contrast in quality issues between the official statements and the praxis implemented by the health organizations, mainly because their organizational culture is weak and not adequately shared by the employees.

In addition, a lack of cohesion is observable among the actors within the health organization as much as among the external ones. In Chapter II, a peer and collaborative symmetric relationship among the healthcare stakeholders has been highlighted as necessary within the frame of quality and humanization of health services; however, there is still a kind of tension among the stakeholders caused by the persistence of an asymmetric relationship between professionals and patients supported by the traditional culture.

Regarding quality and its measurement, the definition of standards resides on two methodological levels: the descriptive and the normative. But if the desirable status or goal to be achieved is not explicitly set, expressed and shared, the necessary basic elements to design and realize the performance evaluation lack. Moreover, the achievable goals have to include the management dimension of quality dealing with the health performance as much as the relational dimension of care, even though this last is not completely quantifiable. A nice word, an em-

pathic attitude, a suggestion or just the respect of privacy in clinical procedures can change everybody's experience of health assistance.

In the Italian context (according to what has surfaced in my case studies), the majority of patients and physicians are aware of the importance of cooperation in the health assistance for a better health service supply and a higher performance quality. Indeed, the individual willingness to contribute to the health system's quality could compensate for the lack of economic, technological, human, and time resources. Budget cuts affect the availability of the technological and human resources required in a chronic disease department to supply a personalized service in accordance to patients' needs. It follows that health organizations should give priority to the realization of programs for the education and training of physicians — rather than for patients — with the aim of helping them to manage an informed and more active patient. If the Tuscany health system is well-tried concerning stakeholder involvement, the Sicilian needs to be improved; in the first one the performance and assessment goals set by the organization are clearly shared among the personnel, contrary to what happens in the Sicilian case.

The observations on quality of care and the importance of the relational dimension in the protection of health as social value and as a constitutional right; the essential connection between quality and humanization of health services; the need of a broader and concrete patients' involvement into the entire process of design, evaluation, and re-organization of the health services: each of this elements justifies the shaping of quality control processes within the frame of the humanization of health services, with reference to the design of specific indicators on performance and outcome quality and on the actual conditions of the doctor-patient relationship. This is influenced by both quantity (i.e. examination time, number of visits per year) and quality (i.e. of communication, of information) dimensions.

Patients need to have a voice in the organization of a health system that would not be self-referential, in order to realize the performance quality also through its relational dimension; in particular, patients should be involved both in the process of

evaluation and re-organization of the health services. This idea of patients' mobilization seems particularly relevant in structures for chronic diseases, where a system in which patients and physicians are peer actors in the treatment decision-making and also in the organization of the service, particularly in activities of psychological support, technical training and information for patients would afford both economies and better results in treatments.

As emerged in my case studies, information and transparency can be improved; the Tuscany health system makes public the adopted indicators and collected data, while less detailed is the information communicated by the Sicilian hospital, actually almost totally missing. Undoubtedly, in both cases it would be necessary to implement a strategy to keep data more transparent and understandable by patients. In my opinion, it is hard to imagine that the information referring to a health organization's performance (as published on the Tuscany health system website or annual report) can be really for patients, unless these ones work in healthcare or have been educated to read data. Moreover, in both cases the adopted indicators of quality seem inappropriate to measure the two dimensions of quality; surely, the relational dimension is not sufficiently taken into account.

Community health services, whose efficacy essentially depends on citizens being involved in decisional and managerial processes, should constitute in my opinion, a strategic site in pursuing the humanization of health services and the culture of evaluation. The diffusion of chronic diseases increase the necessity to design health services in line with the health needs of the local comunity, hence the personalization of health services and patient empowerment. Patients involvement would be useful to define the major issues of health services and produce benefits on the collective learning and the authorities-community relationships.

The Italian diabetes care has many potentialities but the political, economic and administrative environments hinder the reaching of better outcomes. There are opportunities rather than conditions for a high quality of care and patient participation. Personal commitment and evaluation culture seem to be the most pow-

erful tools to contrast cultural and economic obstructions, but they are still too weak to affirm a full patient-centeredness in the health care provision as much as in its organization. It would be necessary to supply the human dimension of diabetes care through a deeper involvement of external actors, such as patient association or even pharmaceutical companies (which usually finances seminars about the use of medical devices).

Nonetheless, I would like to outline the positive aspects of our health system which is one of the best in the world. Beyond being public and based on "health as right", it is the vanguard of the humanization of health services. For sure, there are still different interventions to implement, but patient-centeredness and quality have been broadly established by law; they also seem widely accepted by stakeholders at least at the local level, though less at the regional level — where money are managed and budgets are planned. Patients are becoming a more active subject, along with doctors and managers in health care especially in diabetes care, where there is a strong share of patient-centeredness.

Also, the Tuscany health performance assessment system represents a good try to consider patients as relevant actors, who are directly involved in the evaluation process of health organization . Undoubtedly, more can be done on the resource management, that is still affected by dissipation and cuts in already thrifty budgets and on the definition of quality indicators that take the humanization of health care issue into full consideration.

Attachments.

1. Track for managers

• Il manager usualmente è una figura isolata dal resto dell'organico; il manager-medico si distingue dal manager classico? Essere sia un amministratore sia un medico è un aspetto positivo o negativo?

• Sono previste delle attività formative volte alla sensibilizzazione del personale medico verso una cura totale del paziente, nella sfera fisica e sociale?

• All'interno del reparto vengono svolte delle attività extra cliniche per coinvolgere i pazienti e le loro famiglie ?

• Quello che sembra mancare nella programmazione o implementazione di progetti che coinvolgano i pazienti sono le risorse economiche e temporali; manca anche qualcos'altro?

• Esistono le condizioni per una reale patient-centeredness?

• La qualità è un obiettivo concretamente perseguibile? Quali sono gli eventuali fattori ostativi?

• Per quanto riguarda la valutazione della performance, com'è organizzato il reparto? Qual è la strategia adottata per la valutazione esterna della soddisfazione dei pazienti?

• Quali sono i punti di forza e di debolezza dell'attuale sistema sanitario?

2. Questionnaire for doctors

Indagine esplorativa entro il progetto di ricerca "La valutazione della performance sanitaria dopo il processo di umanizzazione: misurare le dimensioni sociali dei Servizi Sanitari".

Questionario rivolto ai medici

- Come definirebbe la relazione fra lei, medico, e i suoi pazienti (può segnare più risposte):

□ professionale
□ informale
□ collaborativa
□ ostativa
□ empatica
□ distaccata

- Come definirebbe la qualità del servizio erogato presso questo reparto?

□ eccellente
□ buona
□ mediocre
□ scarsa

- A suo parere, quali sono i fattori che limitano la qualità dei servizi erogati? (può segnare più risposte)

□ un esiguo numero di medici
□ un esiguo numero di operatori con qualifica tecnica (p.e. infermieri, tecnici per i macchinari) in reparto
□ attrezzature non all'avanguardia o insufficienti in reparto
□ un eccessivo numero di pazienti per medico
□ oneri burocratici
□ la mancata/limitata organizzazione di campagne informative o attività di natura sociale rivolte ai pazienti
□ la limitata disponibilità economica delle Aziende Sanitarie

- A suo parere, quali sono i fattori che fanno incrementare la qualità dei servizi erogati? (può segnare più risposte)

□ una maggiore disponibilità di risorse umane con qualifica medica
□ una maggiore disponibilità di risorse umane con qualifica tecnica
□ attrezzature all'avanguardia o in numero sufficiente in reparto
□ un adeguato numero di pazienti per medico al giorno
□ limitare gli oneri burocratici
□ l' organizzazione di campagne informative o attività di natura sociale
□ una più ampia disponibilità economica delle Aziende Sanitarie

- Per quanto riguarda l'empowerment del paziente, ritiene che la strategia adottata dal reparto/ambulatorio presso cui lavora sia:

□ un appropriato supporto all'autonomizzazione del/della paziente nella gestione della malattia, attraverso l'erogazione delle necessarie informazioni e di un adeguato sostegno globale alla persona

□ un insufficiente supporto all'autonomizzazione del paziente nella gestione della malattia, a causa di una carente informazione delle necessarie informazioni e un inadeguato sostegno globale alla persona

- Da quando lavora in questo reparto è stato invitato dall'Azienda Ospedaliera a partecipare a delle attività d'aggiornamento sull'umanizzazione o personalizzazione dei servizi sanitari?

□ Si, sono stato invitato e vi ho preso parte
□ Si, sono stato invitato ma non vi ho preso parte
□ No

- Da quando lavora in questo reparto è stato invitato dall'Azienda Ospedaliera a proporre a delle attività di natura sociale o informativa rivolte ai pazienti?

□ Si, sono stato invitato e ho avanzato delle proposte
□ Si, sono stato invitato ma non ho avanzato delle proposte
□ No

- Secondo la sua opinione, l'attuale sistema di valutazione della performance adottato dalla sua Azienda è incentrato

□ sulla rilevazione di indicatori d'efficienza
□ sulla rilevazione di indicatori d'efficacia
□ sulla rilevazione di indicatori sia d'efficienza sia d'efficacia

- Secondo la sua opinione, l'attuale sistema di valutazione della performance adottato dalla sua Azienda è

□ un sistema per migliorare l'assistenza sanitaria offerta
□ un sistema per distribuire risorse e incentivi
□ un sistema per rispondere a obblighi normativi

- Qualora lo ritenga opportuno, può avanzare degli ulteriori suggerimenti o riflessioni, sui temi trattati nel questionario, che non sono stati oggetto di domanda.

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La ringrazio per la gentile ed apprezzata collaborazione.

3. Questionnaire for patients.

Indagine esplorativa entro il progetto di ricerca "La valutazione della performance sanitaria dopo il processo di umanizzazione: misurare le dimensioni sociali dei Servizi Sanitari".

Questionario rivolto ai pazienti

Gentile paziente, il presente questionario rappresenta uno degli strumenti impiegati per raccogliere i dati sulla qualità della performance sanitaria e la partecipazione dei pazienti al policy-making nei reparti di diabetologia, entro la tesi di dottorato dal titolo "La valutazione della performance sanitaria dopo il processo di umanizzazione: misurare le dimensioni sociali dei Servizi Sanitari". La Responsabile del trattamento dei dati è la Dr.ssa Laura Faraci, mentre il titolare del trattamento è il Dipartimento di Scienze Politiche e Sociali dell'Università degli Studi di Firenze, il cui referente per la dottoranda di cui sopra è il Prof. Sandro Landucci.
Nel rispetto dell'art. 2 comma 2 del D.Lgs. 196/2003 - per il quale "Il trattamento dei dati personali è disciplinato assicurando un elevato livello di tutela dei diritti" - si ritiene dunque opportuno fornire la presente informativa. Essa deve essere letta ed interpretata senza prescindere da tale scopo meramente "precauzionale", e da una lettura meramente formale, non funzionale, del trattamento delle informazioni acquisite tramite la compilazione del questionario.

Informativa
La finalità del trattamento è quella individuata dall'art. 105 del D.Lgs. 196/2003 (inserito nel Titolo VII - Trattamento per scopi storici, statistici o scientifici, Capo III - Trattamento per scopi statistici o scientifici).
In tutte le fasi dello studio le informazioni saranno trattate solo da parte dei soggetti autorizzati, ovvero la Dr.ssa Faraci, unica ricercatrice del progetto in questione. Raccogliendo dati già fortemente anonimizzati nella fase di somministrazione del questionario, nella fase immediatamente successiva questi saranno trattati, anche utilizzando idonei supporti informatici, in modalità aggregata e comunque in modo da perdere ogni possibile indiretto elemento di identificazione. La pubblicazione del risultato della ricerca conterrà solo dati aggregati.

Si ricordano i diritti previsti dall'art. 7 del D.Lgs. 196/2003. *L'interessato ha diritto di ottenere la conferma dell'esistenza o meno di dati personali che lo riguardano, anche se non ancora registrati, e la loro comunicazione in forma intelligibile. L'interessato ha diritto di ottenere l'indicazione: dell'origine dei dati personali; delle finalità e modalità del trattamento; della logica applicata in caso di trattamento effettuato con l'ausilio di strumenti elettronici; degli estremi identificativi del titolare e, dei responsabili del trattamento; dei soggetti o delle categorie di soggetti ai quali i dati personali possono essere comunicati o che possono venirne a conoscenza in qualità di responsabili o incaricati. L'interessato ha diritto di ottenere: l'aggiornamento, la rettificazione ovvero, quando vi ha interesse, l'integrazione dei dati; la cancellazione, la trasformazione in forma anonima o il blocco dei dati trattati in violazione di legge, compresi quelli di cui*

non è necessaria la conservazione in relazione agli scopi per i quali i dati sono stati raccolti o successivamente trattati; l'attestazione che le operazioni di cui sopra sono state portate a conoscenza, anche per quanto riguarda il loro contenuto, di coloro ai quali i dati sono stati comunicati o diffusi, eccettuato il caso in cui tale adempimento si rivela impossibile o comporta un impiego di mezzi manifestamente sproporzionato rispetto al diritto tutelato. L'interessato ha diritto di opporsi, in tutto o in parte: per motivi legittimi al trattamento dei dati personali che lo riguardano, ancorché pertinenti allo scopo della raccolta.

Età: ____ Sesso: M F

Titolo di studio: _____

Professione: _____

- Come definirebbe la relazione fra lei, paziente, e il suo medico (può segnare più risposte):

  □ professionale
  □ informale
  □ collaborativa
  □ ostativa
  □ empatica
  □ distaccata

- Come definirebbe la qualità del servizio erogato presso questo reparto?

  □ eccellente
  □ buona
  □ mediocre
  □ scarsa

- A suo parere, quali sono i fattori che limitano la qualità dei servizi erogati? (può segnare più risposte)

  □ la mancanza o difficoltà di comunicazione col medico
  □ un esiguo numero di medici ed altri operatori in reparto
  □ attrezzature arretrate o in numero limitato in reparto
  □ un'insufficiente o inadeguata fornitura di dispositivi per la terapia (p.e. microinfusori)
  □ strutture poco accoglienti o funzionali
  □ liste d'attesa troppo lunghe
  □ la mancata/limitata organizzazione di campagne informative o attività di natura sociale
  □ la limitata disponibilità economica delle Aziende Sanitarie

- A suo parere, quali sono i fattori che fanno incrementare la qualità dei servizi erogati? (può segnare più risposte)

  □ la possibilità di comunicare col medico
  □ un adeguato numero di medici ed altri operatori in reparto
  □ attrezzature all'avanguardia o in numero sufficiente in reparto
  □ una sufficiente o adeguata fornitura di dispositivi per la terapia (p.e. microinfusori)

□ strutture accoglienti e funzionali
□ liste d'attesa contenute
□ l' organizzazione di campagne informative o attività di natura sociale
□ una lauta disponibilità economica delle Aziende Sanitarie

- Per quanto riguarda la gestione della malattia diabetica, ritiene che l'approccio promosso dai medici del reparto/ambulatorio presso cui è in cura sia:

  □ di empowerment del paziente, ovvero di supporto all'autonomizzazione del/della paziente nella gestione della malattia, attraverso l'erogazione delle necessarie informazioni e di un adeguato supporto empatico
  □ di ancoraggio alla struttura sanitaria, cioè di spinta del/la paziente al ricorso alla struttura sanitaria per gestire la malattia ed episodi della vita quotidiana ad essi connessi

- Nell'équipe del reparto o ambulatorio presso cui è in cura è presente un/a psicologo/a?

  □ No, ma ritengo che dovrebbe essere inserita in pianta organica
  □ No, ma ritengo che il medico possa assolvere le funzioni di supporto psicologico e allo stile di vita
  □ Si e la ritengo una figura necessaria per il supporto psicologico e allo stile di vita
  □ Si, ma non la ritengo una figura necessaria, il medico potrebbe assolvere le funzioni di supporto psicologico

- Da quando è in cura in questo reparto lei o la sua famiglia siete stati invitati dall'Azienda Ospedaliera a partecipare ad attività di natura sociale o informativa (per esempio campagne informative, attività ricreative o di mutuo aiuto)?

  □ Si, siamo stati invitati e vi abbiamo preso parte
  □ Si, siamo stati invitati ma non vi abbiamo preso parte
  □ No

- Da quando è in cura in questo reparto lei o la sua famiglia siete stati invitati da Associazioni dei pazienti a partecipare ad attività di natura sociale o informativa (per esempio campagne informative, attività ricreative o di mutuo aiuto)?

  □ Si, siamo stati invitati e vi abbiamo preso parte
  □ Si, siamo stati invitati ma non vi abbiamo preso parte
  □ No

- Da quando è in cura in questo reparto è mai stato invitato a partecipare ad attività di valutazione della qualità del servizio (tramite questionario, interviste, ecc.)?

□ Si e ho partecipato
□ Si, ma non ho partecipato
□ No, ma parteciperei volentieri
□ No e non sarei interessato a partecipare

- Qualora lo ritenga opportuno, può avanzare degli ulteriori suggerimenti o riflessioni, sui temi trattati nel questionario, che non sono stati oggetto di domanda.

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