Presidenza del Consiglio dei Ministri

COMITATO NAZIONALE
PER LA BIOETICA

A CALL FOR SAFEGUARDING THE NATIONAL HEALTH SERVICE (NHS)

26 January 2017

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Presentation

In the document *A call for safeguarding the National Health Service* the NBC addresses some aspects that are of paramount importance for the defence, preservation, re-launching , equity and sustainability of the National Health Service (NHS). The NBC traces the main causes that have co-determined the serious crisis that mantles the system, among which - in the delicate moment of alignment of EU states' budgets at the threshold of the Eurocentric pact –the process of demographic transition, coupled with an increase in life expectancy, but in worse health conditions, with increased demand for health services by an older population affected by polypathologies, which require increasingly expensive therapies for the amount of medication administered, for conditions of disability and dementia.

After analyzing the status quo of the NHS and considering that Italy is in last place for spending on prevention as part of the 34 OECD countries, the Committee recommends investing the due- and so far neglected – portion of the National Health Fund (NHF), while creating at the same time new paths for prevention education to be widely guaranteed in the country from infancy. The NBC is extremely concerned about this issue, as it is clear that without a primary focus on prevention, the NHS will become less and less sustainable and will lose the undeniable benefits that have characterized nearly forty years of its existence.

The Committee also reiterates the need to make homogeneous the digitalization of healthcare in all regions, pointing to the continued experimentation of new organizational and management models, with particular regard to the treatment of chronically-ill and/or polypathological patients, with the related construction of Assisted Data Banks for these types of patients, thus creating the basis for the development of Individual Assistance Plans and the redefinition of a new and more appropriate tariff system. With particular regard to patients at risk of developing dementia or with full-blown cognitive decline, the Committee stresses the need to build a new healthcare system to protect vulnerable patients, aiming at the implementation of an integrated diagnostic-therapeutic-assistance pathway shared by General practitioners, specialist outpatient and home care services, and expert NHS memory clinics. In the case of fragile patients, it is also recommended that special attention be paid to children, from pre-natal prevention to the treatment of chronic disabling, congenital or acquired diseases, a growing trend, which requires urgent rebalancing of the differences which exist given the North and Centre-South gap, particularly regarding child mortality.

Furthermore, the Committee, aware of the recent approval of new essential assistance levels (LEA), recommends their periodic and programmed review, reiterating that this be based on the criteria of evidence and cost-effectiveness, otherwise the resulting non-sustainability of the system and dissipation of public resources, due to the provision of certain *non-evidence-based* care, would be to the detriment of other necessary patient care. In addition, the Committee highlights the huge and growing private expense borne by citizens and families, calling for its reduction in the short-term, also because of the existing unequal gap between citizens with the economic means to quickly resolve their problems, and those who are either subjected to long waiting times or are left without any assistance, as they can not afford it. In the current scenario, the

Committee also recommends that the NHS should provide for additional funds that must be "compulsorily" invested for vocational and interprofessional training throughout the country and, above all, in those regions subjected to a recovery plan, where in recent years the resources theoretically for this purpose have been drastically reduced or zeroed for reasons related to meeting the general objectives set out in the plans themselves.

It also seems indispensible to the NBC for research activity to be fully recognized as a fundamental part of the NHS, to which a predetermined annual budget should be allocated, initially guaranteeing a minimum of one percent of the NHF, with the aim of allocating additional resources, once the country's current financial crisis has been overcome. Lastly, with particular regard to protection against the fraud and corruption that pervades the NHS, the Committee, while appreciating the initiatives already launched in general in Public Administrations and in particular in the NHS, considers that the gravity of the current situation requires immediate effective action. Inspired by the effectiveness of the actions of the United Kingdom model - from which Italy has drawn the most important inspirational principles for decades - the Committee therefore recommends assessing the urgent establishment of a special Anti-Fraud and Corruption Directorate in Healthcare, within the Ministry of Health, with the presence of a corpus of multidisciplinary specialists, as already provided for in the past LD N. 32/2003, which so far has never been implemented.

The working group was coordinated by Profs: Massimo Sargiacomo, Maurizio Benato, Carlo Caltagirone and Silvio Garattini, who drew up the draft document.

Useful integrations for the final drafting of the document were received from Prof. Salvatore Amato, Francesco D'Agostino, Lorenzo d'Avack, Mario de Curtis, Antonio Da Re, Assunta Morresi, Laura Palazzani and Monica Toraldo di Francia.

Valuable contributions from external auditions came from Prof. Walter Ricciardi (Chairman of ISS), Dr. Angela Adduce (Chief of General Accounting for the State), Prof. Dario Sacchini (Universita' Sacro Cuore - Gemelli) and Dr. Carla Collicelli (Censis), as well as the internal audition of Prof. Massimo Sargiacomo.

The document was unanimously approved by the members present in the Plenary session on January 26, 2017, Profs: Salvatore Amato, Luisella Battaglia, Cinzia Caporale, Carlo Casonato, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Carlo Flamigni, Silvio Garattini, Marianna Gensabella, Laura Palazzani, Massimo Sargiacomo, Monica Toraldo di Francia; No abstentions.

The advisory members, Maurizio Benato, Paola Bernasconi, Carlo Petrini voted in favour.

Subsequently the approval of Profs: Carlo Caltagirone, Stefano Canestrari, Mario De Curtis, Riccardo Di Segni, Rodolfo Proietti were received; as well as the endorsement of the consultative member: Prof. Anna Teresa Palamara.

1. Premise: the general unsustainability of the NHS

The National Health Service (NHS) is facing the greatest crisis it has ever known since its foundation. Several international commentators strongly doubt that the current *welfare* system can be sustainable in the short to medium term, considering the convergence of some key factors that are undermining the stability and survival of key principles at the basis of the NHS since its beginning, in primis, gratuity, equity and the universality of care. In fact, as regards the process of demographic transition begun in 1992, Italy has experienced a marked deterioration in the ratio of people aged between 65 and under the age of 14 or equal to 14 years. This trend reversal was co-determined by the lowest rate of fertility ever observed in Italy and the contemporary increase in life expectancy (United Nations, 2017, http://data.un.org; World Bank, 2017, http://data.worldbank.org/).

The above phenomena also have the strictly economic consequences, as the elderly population bears on the one hand the risk that the new younger generation - outnumbered and largely unemployed – will not be able to support *welfare* spending in the future, while on the other there is no doubt that wealth is not growing, as evidenced by recent GDP data.

The worrying scenario outlined above is even more frightening when one considers that, although average life expectancy has increased in the last few years (recording a stop in 2015), the demand for health services will inevitably increase further due to the worsening of health with increasing age, and particularly in the last 12 years for men (whose average life expectancy is 80 years) and for the past 17 years in women (whose average life expectancy is 84 years) (Global Burden of Disease, *Lancet*, 2016).

At the same time the mix of health needs changes, as general practitioners are struggling daily with an aging population, affected by a set of chronic diseases; these diseases often involve increasingly expensive therapies for the amount of drugs administered, for conditions of disability and dementia.

In this succinctly sketched scenario of health needs, despite the general bounty of our NHS, Italy is in last place for spending on prevention as part of the 34 OECD countries (OECD-OECD, 2015), while the share of overall spending allocated to the NHS is similar to that of Spain, Portugal and Greece (where their NHS have already abdicated to a system of general *welfare* for Healthcare, or are supported by international donation programs) and are well below the levels of France and Germany. These differences are certainly not "just" attributable to the unequal weight of salaries, but to resources that are not allocated to our NHS, despite the investment in "health" that other countries instead continue to make.

The status of our country's spending is the result of several NHS cuts that have been underway for several years with the clear objective of aligning ourselves to the parameters required by the balance of states' budgets imposed by the European budget pact. Today, in regional budgets, health absorbs on average 80% of resources, and the 2016 Stability Law initially allocated 111 billion to the NHF (http://www.rgs.mef.gov.it/VERSION-I/Activities-i/Expense-members/activity-monitoringRGS/2015), providing for Essential Assistance Levels (LEAs) which in the last decade unfortunately have not been guaranteed - or indeed achieved - in many Italian regions (e.g. Tediosi, Gabriele, Longo, *Health Policy*, 2009; Lega, Sargiacomo and Ianni, *Health Services Management Research*, 2010). In fact, the 34 million people belonging to the regions

subjected to recovery plans in our country have in recent years been well known for a lower quality of services, with higher cuts - and extra regional taxation - to balance budgets and align themselves with the objectives of the recovery plans. Moreover, apparent criticalities are found in the private healthcare sector, where Italy is the only country in the world where citizens spend about 40 billion euros entirely at their own expense, i.e. 31% of total health expenditure, while a minimum percentage is covered by insurance or funds; it should also be added that some citizens declare that they renounce to care due to a lack of personal funds (Longo, *Health* Policy, 2016), pointing out that the iniquity and absence of universality of healthcare are affecting certain sections of the population with marked evidence in some regions (Del Vecchio, Fenech and Prenestini, *Health* Policy, 2015).

In this context, it is also necessary that LEAs - whose updating has been adopted by the Government with an additional financial compatibility of €800 million - rely entirely on the criteria of evidence and *cost-effectiveness*. Unfortunately, at present, while our system sometimes does not have sufficient public resources to assist patients with various types of illnesses, especially serious or rare diseases, on the other hand, in some cases, it funds hospitals that provide alternative therapies. This, along with other factors, can help stimulate the demand of citizens and taxpayers for assistance from private entities, giving additional stimulus to the aforementioned spending at the citizen's own expense or to insurance, or *intra-moenia* services, accessible only to citizens belonging to the more prosperous social groups.

The Government, especially the Ministry of Economy, as well as that of Health, are fully aware of the social and health inequalities that have arisen, as evidenced by various reports on the health status of the country: for example, 2012/13 (Section 5.1 was significantly titled "Italian health: a question of social inequalities?"). It is obvious that the financial crisis that has hit Italy and Europe has only worsened the already considerable inequalities. To this regard, it is sufficient to think how, in the regions of the Centre and South (some of which are still subjected to a Recovery Plan), the decline in regional GDP, the increase in bankruptcy proceedings, receivership or judicial agreement have raised the level of non-performing loans, obligation on non-accrued status, and insolvencies, have, *ceteris paribus*, reduced VAT and regional IRPEF revenues, including those from gasoline consumption, significantly reducing the co-financing of regional healthcare systems. This has created a vicious circle that spins on itself and leads to foresee the possible "chronicle of a death foretold".

In this opinion, the NBC intends to focus attention on certain aspects considered to be of paramount importance for the defence, preservation, revitalization, equity and sustainability of the NHS[1].

2. Promoting prevention to safeguard the NHS

A serious shortcoming of the NHS has always been, from the beginning, the lack of attention to its sustainability for the future, sustainability requires assignation of a central role to promoting prevention. Most illnesses depend on lifestyle habits. Everyone knows what should be done and what bad habits to avoid: from smoking to excess alcohol, from inconsistent eating to physical

[1] Among the various opinions that the NBC has developed in the past, touching on similar arguments, it is worth mentioning at least *Ethics, Healthcare system and Resources* (1998), *Bioethical guidelines for equal access to healthcare* (2001).

inactivity, from drug use to obesity, to mention just the most known. The problem lies in the difficulty of implementing lifestyles that are consistent with maintaining health[2]. Medicine and its practitioners have so far missed the target of prevention, partly because of the central role that therapy has taken in the training of the doctor. However, prevention should not be a medical practice, but a commitment of the whole of society. It is difficult to ask citizens to consider it a duty, and not just a right, to maintain health when all of society does the direct opposite: there are private economic interests that operate through advertising, promoting consumption contrary to health, but also the public interests of the State itself which derives profit through taxes on bad habits. All this prevents a common effort being made to prevent the onset of illness. It is precisely the set of preventable diseases that affect health spending, draining resources that are no longer available for areas where prevention is much less feasible.

It is therefore necessary for the NHS to change perspective by creating the conditions for prevention education to begin from infancy and continue over time, involving all social forces that can somehow facilitate this change and in addition hoping that a good example may be provided by the lifestyle of doctors.

3. The need for a general revision of organizational models

The organization of our NHS has drawn inspiration for decades from a cultural model that was limited to addressing the "objective" dimension of healthcare provision. This has led to underestimating the quality of the service provision, which is not based solely on scientific and technological features, by their nature more easily measurable, but it necessarily includes "subjective" elements, starting with the positive perceptions experienced by the patient accessing health services. It is a fact that the final product of health activities, namely the improvement of the health of the population and of the individual (*outcome*), obtained through a modification in the positive sense of the natural course of the epidemiological framework, is intimately linked to the healthcare organization and its performance.

The expression *patient-centeredness* - or "patient-centred care"- is commonly used internationally. It is proposed above all in partial opposition to the vision of care that is *technology centred*, *doctor centred*, *hospital centred*, *disease centred*, *economics centred*. According to the approach of *patient-centeredness*, the patient is placed in a qualified care project as a unitary process, which is articulated through integrated pathways, a clinical process which is multidisciplinary (from first diagnosis to *follow-up*) ultimately a process of care that is homogeneous by level of care (*modular nursing*). In summary, patient care is favored by the integration of all "accessory" processes that focus on the main process. This is a new concept that calls for innovative organizational solutions, with structures and hospitals that take into account the intensity of diversified healthcare and are therefore able to follow up particularly complex patients both clinically and in terms of care[3]. The focus is directed to

[2] In this context, for a more detailed analysis, see the NBC Opinion, *Lifestyle and Health protection* (2014).

[3] On the concept of intensity of care, complexity, organization and *governance* of healthcare and hospital structures, see, among others: F. Lega, M. Mauri, A. Prenestini (edited by), *L'ospedale tra presente e futuro. Analisi, diagnosi e linee di cambiamento per il sistema ospedaliero italiano*, Egea, Milan 2010; B. Cavaliere, *Misurare la complessità assistenziale*

the patient and not to the disease and responds to the concrete concerns of patients (be they explicit or implicit, latent needs or expectations, etc.)

Healthcare is still today a matrix of "positivist" thought, conceptionally it is mainly based on the "Taylorist" model while being "Fordist" in its implementation[4]. It is still heavily dependent on the way medical professionalism was structured at the end of the nineteenth century, through diversification and progressive fragmentation of medical specialties. It is an articulation of knowledge and medical practice that now appears dated compared to today's issues. The adoption of the systemic paradigm seems, however, to capture more effectively the complexity of medicine and its tasks and how these can be translated into the healthcare organization.

The adoption of a new approach requires different professional and service conceptions to be made consistent with patient-centred purposes, in order to avoid conflicts, problems and misunderstandings; Nowadays there is a significant gap between the expectations of patients and the service models they favour on the one hand and the concrete ways of offering health provision on the other.

The hospital can no longer be a generic container, it should be a structure balanced on the needs of the patient, a place where the congruency between the vertical dimension, consisting of the intensity of care-and hence the level of care and assistance is appropriate to need - and horizontal intervention, ensured by integration between various health professionals. By working towards highly integrated multi-disciplinary processes there is a reorganization and differentiation in clinical, managerial and logistical responsibility. The evolution of the hospital sector towards a high intensity of therapies and levels of specialization due to the extension of non-invasive surgery, recourse to outpatient procedures, the rationalization of beds, calls for a reorganization of territorial healthcare. The latter is already called on to cope with long and complex care processes related to the aging of the population and increase in disabilities; and now it is also called upon to take charge of citizens given increasingly early hospital discharge. The goal is the structural transformation of the system of General Medicine, which involves integration between the different levels of the sector. The entrustment to General Medicine of entire service blocks according to the British model of *commissioning* and the global takeover of whole parts of the system and supply chain by General Medicine Units (see, among the various possible new models, the experimentation of the *Chronic Related Group* - CreG - in Lombardy and Emilia Romagna) is producing today its first positive results. This is a new way of managing chronic patients that draws inspiration from the *Population Health Management* model, coined by Prof. Donald Berwick of the *Institute for Healthcare Improvement* (Berwick et al, 2008). It represents the unblocking of a wider system of medical management models. A functional vision is the basis of a rethinking of the entire sector based on the principles and rules of allocative efficiency (*primary care allows the release of specialist resources*), organizational efficiency and

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Strumenti operativi per le professioni sanitarie, Maggioli Editore (Social and Health Series 2009).

[4] F. Taylor's Model applies to the production process in a way that disassociates movement and the time, making the various phases of the process predefined, with the aim of increasing worker productivity (Taylor F.W., 1911). H. Ford's model applies these principles to the car assembly line, so beginning industrial mass production, which has changed production methods and opened the doors to the economy of mass consumption (H. Ford, 1922).

erogation (*primary care provides services and care where needed and avoids dispersion of supply, causing indirect and social costs*) and clinical efficacy (*an excellent organization of care processes produces good results in terms of promoting health, which can substantially modify morbidity profiles and mortality related to the most frequent acute and chronic diseases*). Primary care must acquire the set of clinical, social, and welfare functions related to the health of people and communities.

In this context, it should be emphasized that the main strategic instruments for integration (intra- and extra-hospital) are: a) a virtual environment based on the real-time electronic medical record; b) teleconsulting modules that allow clinicians to share specific information about each individual patient; c) home-help care tools for patient care at their own homes or at their GMP and for interaction with the health network.

With particular regard to the adoption of the new CReG model, it is necessary that in each Region: I) there should be a constantly updated Assisted Data Bank which identifies chronic patients; II) therapeutic diagnostic paths should be the starting point for delineating Individual Care Plans, tailored to the needs and care of individual chronic patients; III) new charging systems should be introduced to apply remunerative criteria.

In this respect, it comes naturally to point out that in many regions of our country, sometimes also as a consequence of the measures taken in recovery plans, the outlined instruments (sub a, b and c, and I, II and III) have not been implemented at all; Regardless of the CReGs mentioned among the various possible examples, it is clear that in Italy it is no longer possible to procrastinate the initiated experimentation of new organizational-management models for the treatment of chronic patients and/or polypathologies, which can also overcome and refine the current public health financing system.

4. Healthcare in defence of fragile patients

Despite the considerable development and consequent applications of scientific research on pharmacology, neuroscience, neuro-technologies, access to prevention protocols and the most advanced therapies for fragile patients, because of their age or their suffering from neurodegenerative diseases, remains limited. On the other hand, increases in life expectancy and consequent ageing of the population have resulted in a dramatic increase in the prevalence rates for dementia: the progressive deterioration of cognitive functions due to an organic disease causes the loss of the patient's functional autonomy. This is a real emergency, to the point that its management has become a central issue for international and national health policies.

To date, individual factors, such as level of education, economic position or social role, still prevail over access to early diagnosis and rehabilitation services, while assistance currently provided by the NHS remains largely confined to the management of cases of utmost criticality when the disease manifests itself in an overt and acute way. Conversely, encouraging studies have shown that the complex interaction between biological and environmental factors (for example, improving the quality of life and lifestyle) has had an effect on brain resilience to dementia, causing a reduction in the number of observed cases compared to those expected on the basis of the forecasts of the 1990s. This hypothesis suggests the need for a review of health care models, especially in terms of the right to health of patients where advanced age, or

accumulation of pathological events that develop years before the onset of symptoms, will result in a significant cognitive decline, such as to impair occupational and social functioning.

In this context, the re-launching of the NHS, particularly in the light of unsustainable welfare costs, should focus on the prevention and cure of dementia, in order to ensure the protection of the fragile patient's[5] right to maintain physical and mental integrity, for as long as possible.

The prerequisite for any kind of therapeutic approach of dementias is a correct diagnosis of syndromic and etiologic framework and this requires a systematic approach, in-depth evaluation protocols and the use of standardized diagnostic regulations. Since the new international criteria for the identification of patients even in the early stages, when mild damage in various cognitive areas is still potentially not perceived by the individual and his family, new services should be drawn up by the NHS in order to maximize the system's ability to promptly intervene at an early stage. In this context, the Italian Ministry of Health recently funded a network project aimed at the development and validation of operational criteria for the diagnosis of Alzheimer's dementia in the preclinical phase and the implementation of standardized and harmonized diagnostic interventions for the management of dementias. The development of a multifactorial protocol that integrates clinical, neuroradiological, genetic risk profiles and biomarker data and the subsequent establishment of standard operating procedures for their detection should lead to the spread of an integrated pathway for diagnosis and dementia care within the NHS. In fact, four biomarkers have long been shown to be sufficiently sensitive to justify their clinical use in early diagnosis: hippocampus atrophy measured by structural magnetic resonance imaging, temporal and parietal region hypometabolism, and high levels of the protein amyloid evaluated in a PET scan, and altered levels of certain proteins in cerebrospinal fluid. Facilitated access for fragile patients to these new diagnostic strategies would help speed up the process of referral to specialists - currently not optimal in our country, with considerable delays in recognizing dementia - and early implementation of therapeutic strategies aimed at limiting the impact of cognitive-behavioural deficits on the autonomy of the individual. However, this also involves risk and leaves open central questions: Is it really useful to make a diagnosis before symptoms appear? Are we running the risk of "delivering" to the patient a reality that can be experienced as an inevitable sentence? The delicate theme was recently addressed by the National Committee for Bioethics, whose opinion aimed at the right but not the duty to know within the context of the therapeutic relationship: this knowledge looks to the ability to interpret those cognitive and behavioural changes which are felt by the sick person from the onset of the disease, and which create anxiety and confusion.

Although most dementias are progressive, there is a widespread awareness that a systematic, intensive, continuous and interdisciplinary therapeutic approach can lead to a substantial improvement in the quality of life of the patient and his family and, in many cases, slow down the evolution of cognitive deficit and its functional impact. In addition, performing a standardized cognitive training and modifying lifestyle in order to reduce additional risk factors

[5] Among the various documents that the NBC has developed with regard to the need for protection of various types of "fragile patients", to note, among others: *Bioethics and the rights of the elderly (2006), The living conditions of women in the third and fourth age: bioethical aspects of social health care* (2010), *Dementia and Alzheimer disease: ethical issues* (2014).

(hypertension, hypercholesterolemia, smoking), would seem to enhance the brain's ability to tolerate the processes of ageing and the pathological changes that determine the onset of dementia symptoms. In particular, training that uses the computer, so that performance is accurately recorded and exercises adapted to the individual's abilities, have been shown to have positive memory effects in patients with mild cognitive impairment, producing a general improvement in the global cognitive abilities of people with early-stage Alzheimer's dementia. In the latter, a cognitive training period attenuates the decline in brain metabolism observed in a control group engaged in non-specific therapy and increases the activity of the mesial areas of the brain, particularly involved in tasks involving attention and memory, especially vulnerable in patients with Alzheimer's disease and mild cognitive disorder; moreover, the cognitive training period increases functional connectivity or interaction between different brain areas while performing a task, demonstrating how exercise determines plastic changes in the brain in response to the experience. In the light of the above, it emerges very clearly that there is an urgent need for a new systemic approach which uses an integrated diagnostic-therapeutic-care path extensively throughout the country.

Special attention must surely be paid to children, included in those most fragile, also because the early stages of life are the most critical period of a person’s existence and can affect the future positively or negatively. Many diseases in adulthood, as well as many disabilities, should, where possible, be prevented by careful and equitable health policy. Of course, prevention must begin in the prenatal phase and in the treatment of women's health during gestation and very often even before pregnancy itself. Equally, early provision must be made for children with chronic disabilities, congenital or acquired chronic diseases, this ever-increasing number of people, require an approach and management that is integrated and multidisciplinary. The fight against child poverty, which has steadily increased in recent years, represents social intervention that can significantly improve the state of health, since children living in poor families more frequently develop acute and chronic diseases.

5. Revitalization of professional and interprofessional training

Over the last few years, there has been an increasingly evident need for rethinking and "revitalization" of the professional and interprofessional training of the many diverse figures present throughout the entire chain of care. In this regard, it is enough to think that metamorphosis alone - as hoped for in paragraphs 2 and 3 of this document - will never be possible without preventative and targeted training of the healthcare professionals involved, in various ways, in the process of organizational and clinical change as well as in improving management efficiency. The training of the professional figures involved does not require passive teaching according to the current rules of the system, but rather active didactics, analysis and problem solving, with the aim of making everyone aware of their role. Training in this new context takes on various meanings and must be understood not only as a process, but also as an instrument: the process through which the individual and the organization learn as well as being the instrument which accompanies and supports action, growth and development. Today, training sometimes tends to be separated from the organizational and work environment, but it can no longer be so in the near future, because it is part of the process and is itself a process. Through the

analysis of concepts such as "networking", "integration", "multidisciplinarity" and "*shared care*", innovative and practicable solutions can be identified by the NHS service.

If the organization is "horizontalized", there can be within it knowledge, control, management and even widespread modalities of power; Specific professional skills can be enhanced, while the historical hierarchies of the system lose importance due to the emergence of integrated and multi-professional social-care teams, in which different and complementary specialized knowledge meet. An integration process is carried out not only in the reconstruction of their respective roles in responsible health management, but it also provides different levels of intervention, each of which have specific instruments, content and professional skills, in response to the centrality of the person's needs. The best organization and work management studies indicate that the organization is operative because those working in the organization together build meaning in practices, procedures, and communication. While in recent years professional and interprofessional training has been largely overlooked, it is certain that, in the light of the changes required in the NHS, it needs to be strongly revitalized and re-oriented. It also seems certain that the matrix of the organizational changes of those working in the NHS can not only be for top-ranking figures, but must also be endorsed by culture and the ethical practice of people, because it is in its practical application that relational empathy is generated.

"Ethical" training is crucial for everyone, doctors and healthcare workers; it should provide the instrument and the criteria to evaluate different situations also from an ethical point of view and seek ways, on a case-by-case basis as is most appropriate each time, for a practical translation of the principles within the context of the service.

6. Orientation towards health research

The NHS is an extremely complex institution which must absorb, in a very short space of time, the changes in society, knowledge and technology. For these reasons, the NHS can not prescind from an intense research activity that must cover the best way not only to properly perform prevention, diagnostics, therapy and rehabilitation, but also to modify its organizational and administrative systems so as to be as efficient as possible.

It is a matter of promoting independent (no-profit) research that establishes the true innovative extent of the diagnostic and therapeutic "novelty", through comparative studies to determine whether these "novelties" truly represent progress compared to what already exists. There is also a great need for research to evaluate in itinere the various activities of the NHS in order to bring them to the highest possible level of efficiency, reducing the current heterogeneity of services at local and regional level. Today, health research is a residual and discontinuous activity, whereas it should be re-launched, adequately funded and recognized as an integral and substantial part of NHS's service by allocating to it a specified share of the National Health Fund.

7. Protection against fraud and corruption in healthcare

It is certainly not new that fraud and corruption constitute a social phenomenon within Italian society, their severity has reached such a level as to

induce the President of the Court of Auditors to define it in the opening remarks of the 2013 judicial year, as a "bureaucratic/poisonous phenomenon, a political-administrative-systemic phenomenon" and to point out that "the response can not only be specific, limited measures –restricted, moreover, to individual norms, of the criminal code – rather, the response must be articulated and in itself systemic." "In fact" – these are always the President's words - "systemic corruption, undermines prestige, impartiality, and the smooth running of public administration, as well as the very legitimacy of public administrations and, (.....) the economy of the nation"[6].

The Corruption Perception Index (CPI)[7], compiled annually by *Transparency International*, puts Italy in 2016 at 60th place, jointly with Cuba- preceded by Romania and followed by Sao Tome and Prince and Saudi Arabia - in the sad world ranking for perceived corruption. The first three countries ranked where corruption does not find easily fertile ground are, respectively, Denmark, New Zealand and Finland.

The Censis survey conducted in 2012[8] indicates that 87% of Italians, compared to 74% of the EU average, believe corruption is a serious problem, and 43% consider it, along with the moral crises of politics, as the main cause of the ongoing economic recession. This result has also been confirmed by the European Commission in the last edition of the Eurobarometer 2012[9] on corruption, in which 89% of the Italian respondents considered our economic system to be seriously affected by the phenomenon of corruption, which, together with fraud, inflict not only economic damage on society, but also constitutes an example of "*bad practices*", that are unethical, in use in our country, as well as squandering public resources. These resources could otherwise be allocated to sectors in desperate need of them, such as, e.g. assistance - especially for families with Alzheimer's patients and for different categories of people with "disabilities", -health research, prevention, etc.

The White Paper on Corruption (2012)[10], also known as the "Garofalo report", has highlighted the high levels of the risk of corruption in the health sector related to various situations that may give rise to attempts at unlawful conditioning, namely unnecessary expenditure, contracts negotiated without a tendering procedure, tenders carried out in an illegal way, illegal recruitment and contractual framework, falsehoods and irregularities in the prescription of medicines and the like, non-compliance and irregularities in the execution of works and supply of goods. Furthermore, mismanagement and the waste of resources designed to meet the health needs of citizens mean that health activities are carried out inefficiently.

According to reports by the Guardia di Finanza and the Court of Auditors, the health sector is contaminated by fraud and corruption and appears to involve over a thousand subjects, totalling over €1 billion in damage to spending alone in 2013[11]. This figure, also corroborated by ISPE (Institute for the Promotion of Ethics), is truly a national emergency, as the total cost of this

[6] See Report of the President of the Court of Auditors, Luigi Giampaolino, 2013, pp. 1-12.
[7] *Corruption Perception Index,* www.transparency.org/news/feature/corruption_perceptions_index_2016.
[8] Rapporto Censis 2012.
[9] Special Eurobarometer n. 397 of 2013.
[10] See " Rapporto della Commissione governativa per l'elaborazione di misure di contrasto alla corruzione", chaired by Cons. Roberto Garofoli, Ministry of Public Administration, 2012.
[11] Annual Report of the Guardia di Finanza 2014, http://anticorruzione.eu/2015/04/le-cifre-della-corruzione-nel-rapporto-annuale-2014-della-guardia-di-finanza/.

"contamination" - obtained by summing up the inefficiencies and waste from fraud and corruption - amounts to 23.6 billion euros a year[12]. The absolute gravity of the situation is emphasized in the words of the President of ANAC in 2016: "Healthcare, because of the huge turnover surrounding it and the fact that, even in times of crisis it is a sector that can not be undervalued, is the hunting ground of felons of all kinds"[13].

The phenomenon, however, is so complex and systemic - as the President of the Court of Auditors rightly pointed out in the aforementioned discourse - which must necessarily be broken down in order to attain a classification in micro-containers whose tendency, compared longitudinally over time and space between the various Italian regions in parallel, could allow for "*best and/or good practices*" to be drawn up; these should serve as a point of reference for the prevention of various cases of fraud and corruption - per single subtype - and be implemented in the regional and local NHS structures as well as in the GdF/NAS Corps. Such knowledge would be of great use and would also allow the development of specific policy measures for good public health management. Acting otherwise, health policies would be the cause of public administration failures, and would not be "tailor-made and packaged" for the urgent and serious needs of the NHS.

In this regard, however, the efforts made should be underlined, starting from the second quarter of 2016 with the Memorandum of Understanding of April 21, 2016 between the National Anti-Corruption Authority and the Ministry of Health, aimed at verifying - through AGENAS (National Agency For Regional Health Services) - the enforcement and implementation of Corruption Prevention Plans (PTPCs) by Health Professionals and similar entities. In order to carry out the activities included in the Protocol, a Nucleus for Operational Coordination (Nuoc), composed of representatives of the Ministry of Health, ANAC (National Anti-Corruption Activities) and AGENAS, for carrying out inspection activities under the responsibility of ANAC and, in particular, for the drafting of a special audit program for the health sector and the identification of subjects to be inspected. The subsequent National Anticorruption Plan[14] has devoted a number of in-depth analyses into these aspects, providing also appreciable suggestions on various issues, including the role of the Public Health Officer (RPCT) in charge of preventing corruption.

In Italy, the chameleon-like phenomenon of fraud and corruption in health care appears so varied and composite in different regions, it might be appropriate to establish a special unit exclusively dedicated to the analysis, prevention and fight against fraud and corruption in health care, following the English model successfully adopted by the NHS (National Health Service) for about twenty years, with the NHS Counter Fraud and Security Management Service/Division.

In the face of absolute emergency of this phenomenon in our country, given the serious damage caused by corruption in healthcare both ethically and economically, it would be desirable to hypothesize different solutions from those provided for in the memorandum of understanding, which assigned this burden to AGENAS (Article 4), which has already been abundantly overwhelmed by a

[12] White Paper on *Corruption* in Health, ISPE, 2014, www.ispe-sanita.it/1/libro_bianco_3743257.html.

[13] www.repubblica.it/politica/2016/04/06/news/cantone_sanita_scorribanda_delinquenti_di_ogni_risma_-137015392/

[14] Resolution no. 831 of ANAC, August 3, 2016.

number of general auditing and control activities, carrying out all the specific activities by committing it to providing the necessary human, logistical and instrumental resources, in accordance with timelines and agreed arrangements following the drafting of the protocol through appropriate implementing documents. Even, the provision in Article 3 of a Nucleus for Operational Coordination (Nuoc) – with only supportive and propositional functions – urges to evaluate new possibilities for organization, implementation and control.

8. Recommendations

The Committee, recalling the importance of maintaining and strengthening the NHS in all regions of the country, makes the following recommendations - not necessarily in order of importance - for the defence, preservation, re-launching, equity, universality and sustainability of the right to health.

1. Considering that Italy is in last place for spending on prevention as part of the 34 OECD countries (OECD-OECD, 2015), the Committee recommends investing the due- and so far neglected – portion of the NHF for prevention, while creating at the same time new paths for prevention education to be widely guaranteed in the country from infancy. The NBC is extremely concerned about this issue, as it is clear that without a primary focus on prevention, the NHS will become less and less sustainable and will lose the undeniable benefits that have characterized it for nearly forty years.

2. In relation to the urgent need to improve the NHS, the Committee recommends making homogeneous the process of digitalization of healthcare, in the short term in all regions, with particular regard to the treatment of chronically-ill and/or polypathological patients, the Committee recommends continuing the experimentation of new organizational and management models, with the development of Assisted Data Banks for these types of patients, thus creating the basis for the development of Individual Assistance Plans and the redefinition of a new and more appropriate tariff system.

3. With regard to patients at risk of developing dementia or with full-blown cognitive decline, the Committee stresses the need to build a new healthcare system to protect vulnerable patients, aiming at the implementation of an integrated diagnostic-therapeutic-assistance pathway shared by General practitioners, specialist outpatient and home care services, and expert NHS memory clinics. The implementation of an integrated care model based on best evidence and national and international guidelines will help to implement preventive measures, improving early diagnosis and the process of referral to specialists, thereby reducing ineffective or even damaging interventions, and would allow to address the needs of fragile patients, especially those with dementia.

4. With regard to those most fragile, the Committee recommends that special attention be paid to children, from pre-natal prevention to the treatment of chronic disabling, congenital or acquired diseases, a growing trend, which requires urgent rebalancing of the differences which exist given the North and Centre-South gap, particularly regarding child mortality.

5. In the light of what is called for in this document the Committee, while acknowledging the recent updating of the LEAs - whose financial coverage by the Court of Auditors and subsequent publication in the Official Gazette is still pending – recommends their periodic and programmed review, reiterating that this be based on the criteria of evidence and cost-effectiveness, otherwise the resulting non-sustainability of the system and dissipation of public resources, due to the provision of certain *non-evidence-based* care, would be to the detriment of other necessary patient care.

6. The committee recommends to achieving in the short term a reduction in the substantial expense borne solely by citizens and families. The recent studies cited have shown that there are many cases where patients are obliged to turn to private entities, resulting in increased spending at their own expense, or for insurance, or intra-moenia services, while at the same time accentuating the iniquitous gap between citizens with the economic means to quickly resolve their problems, and those who are either subjected to long waiting times or are left without any assistance, as they can not afford it.

7. In recent years, the need for a revitalization of professional and interprofessional training has become increasingly evident. The process of organizational-clinical change will never be possible without the planning of continuous and systematic training activities involving all the health professionals acting throughout the entire chain of care, thus incorporating a process of continuous improvement through which professionals and NHS organizations learn and improve their performance at the service of patients. In this regard, the NBC recommends that the NHS should provide additional funds to be "compulsorily" invested in training throughout the entire country and, above all, in those regions subjected to a recovery plan, where in recent years the resources theoretically for this purpose have been drastically reduced or zeroed for reasons related to meeting the general objectives set out in the Plans themselves.

8. It also seems necessary for research to be a fully recognized activity as a fundamental part of the NHS, to which a certain pre-established budget should annually be allocated. It should be emphasized that without research it will never be possible to determine whether LEAs are based on scientific evidence. In this context, the Committee recommends guaranteeing a minimum of one percent of the National Health Fund, aiming, once the country's financial crisis has been overcome, to gradually reach three per cent of the NHF, consistent with the objectives and requirements laid down in the Lisbon Pact.

9. With particular regard to defense against fraud and corruption that pervade the NHS, eroding a portion of public resources which could be used differently, the Committee underlines the urgent need to achieve useful policy-specific guidelines, widespread in regional and local NHS facilities. These guidelines, in agreement with the action of the GdF/NAS Corps, could allow us to make useful adjustments to prevention and detection procedures and to propose appropriate anti-fraud and anti-corruption policies at the Ministry. Given the seriousness of the current situation, useful action can not be delayed, to this purpose, inspired by the effectiveness of the actions of the United Kingdom model - from which we have drawn the most important inspirational principles

for decades - the Committee suggests assessing the urgent constitution of a special Anti-Fraud and Health Corruption Directorate within the Ministry of Health, with the presence of a corpus of multidisciplinary specialists, as already provided for in the past by L.D. n. 32/2003, which has not so far been implemented.