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GENERAL PRACTICE ACCREDITATION IN PRIMARY CARE

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ABSTRACT:

BACKGROUND: Accreditation is a qualitative assessment aimed at technical-professional quality, but above all, at organizational and measurable aspects through process and outcome checks.

METHOD: There are few references in the literature relating to the accreditation and improvement of the quality and safety of care and treatment in the field of primary care. Clinical Governance must also be applied and certified in the field of primary care

RESULTS: An accreditation system for general medicine is proposed based on a new dynamic model and implement that meets different requirements and assessed on the basis of indicators

DISCUSSION: In the current Italian health system, accreditation of health structures is addressed only to public hospitals and private structures and to providers of services and services, however primary care. GPs / PLS do not have quality and safety guarantee systems or models or systems. o public or private accreditation certifications with the SSR and SSN.

CONCLUSION: Given the fundamental importance in the NHS of primary care of MG / PLS as the main and fundamental provider of services to the patient in all his socio-welfare and clinical needs, it is considered essential to think and implement an accreditation system extended to the territorial general practice as already present and in place for all affiliated and provider structures on behalf of the NHS.

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Accreditation in General Medicine

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PREFACE

The term accreditation is used for the first time in healthcare in the "Minimum Standards for Hospitals" program, proposed by the North American Surgeons Association (in particular by Ernest A. Codman - 1917).

Accreditation means "a systematic and periodic evaluation carried out either by an external agency or another body whose aim is to verify whether the health services meet the standard requirements relating to the structural, organizational and operational conditions that affect the quality of care "(Celin & Wiendand 2002)

Therefore, Accreditation is a qualitative assessment of the technical-professional skills , but above all, at organizational aspects. This assessment is measurable through process and outcome indicators.
Accreditation in the healthcare sector is essential to provide users with safety and better quality assistance and care. This is the constitutional right of every citizen and has become a crucial legal requirement in Italy after the implementation of the recent law 24 (Gelli Law)

METHODOLOGY

ACCREDITATION AND QUALITY

In Italy, the Legislative Decree 502/92 and subsequent amendments and additions (from Legislative Decree no. 517/93 and from Law 724/94) regulates the relationships between SSN, and in particular between AA.SS.LL. and private structures. These conventional relationships are governed according to the so-called institutional accreditation mechanism, based on both the quality control of the practices and the services provided. (11)

Article. 8, 7th paragraph, legislative decree December 30, 1992 n. 502, dictates ".. that the regions and asl adopt the measures for the establishing relationships based on the criterion of accreditation by the ssn of the providers of welfare services, on the method of payment and the adoption of the system for checking and reviewing the quality of the activities carried out and the services provided "

Therefore the authorization - governed by art. 8-ter, of Legislative Decree no. 502/92, as amended by Legislative Decree no. 229/99 - is considered the basic condition for the exercise of the health activity and responds to the need to guarantee the minimum conditions regarding the quality of services required no longer only for health institutions, but also for subjects providing essential services and professional medical offices.

With institutional accreditation, or rather with the recognition of accreditation, we therefore intend to ensure and guarantee the seriousness and quality of the health services that act on behalf of the National Health Service and we intend to achieve the objective of guaranteeing citizens to take advantage of quality socio-health / welfare and social services.

In implementation of the Health Pact signed between the Minister of Health and the Regions from March 2006 onwards, the subsequent financial laws have provided for the transition to definitive accreditation in certain terms and methods for the various assistance entities operating on the territory on behalf of the NHS.

Last but not least, the recent European guidelines (Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011) have also indicated, within a common political and strategic framework, cooperation mechanisms between the Member States to ensure access to safe and quality healthcare within the Union.

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In 2015, therefore, in Italy, AGENAS (Agency of Health National Services) given the heterogeneity of the regional accreditation models, in Italy, the need to revise the accreditation legislation in order to define a common reference framework and redesign an instrument in harmony with the changed scenarios national and international and has therefore elaborated some operating manuals for different care realities with the aim of supporting the Regions and the Autonomous Provinces in the process of adaptation to the new national requirements.(15-16)

The accreditation system indicates the whole process that goes from the birth of a healthcare facility to its recognition, on request, as a provider in the name and on behalf of the NHS.

Authorization and accreditation are two processes that, to guarantee the citizen, evaluate the health, socio-sanitary and social-welfare structures (pursuant to Legislative Decree no. 502/1992, Presidential Decree 1997, DDL 229/99 and Law no. 328/2000 and subsequent amendments and additions), to verify the possession of requirements relating to structural, organizational and operating conditions.
In particular, accreditation evaluates the quality processes to guarantee citizens services that are increasingly in keeping with their needs, within the overall regional needs. Citizens must therefore have access to useful data in order to be able to choose consciously where to direct the path of treatment and diagnosis. It is therefore necessary to make public the data relating to the productivity, appropriateness, efficiency and effectiveness of the structures based on the results, a method of managing information that has existed abroad for some time also for general medicine studies and for primary care and which in Italy currently only applies to public and private hospitals and social and social assistance centers and ASLs

In addition to institutional accreditation, there are other types, such as:

- Voluntary professional accreditation: issued by the Italian Society of VRQ, by scientific societies and by professional groups of volunteers following the model of English-speaking countries, carried out through peer observations. This quality analysis must be compatible with the institutional accreditation. The contribution of professionals to the improvement of the quality of services is critical for specific activities of the care process.
- Certification: it is a voluntary quality certification issued by specific bodies on the basis of specific requirements (sometimes called standards), for example the ISO system; the EFQM model; the Joint Commission International system; the Canadian Council system; and other. (1)

Focarile (1998) identifies more in detail the contents of the Quality of assistance (2):

- Accessibility: ability to ensure appropriate care to those who need it;
- Appropriateness: degree of usefulness of assistance in relation to the clinical and knowledge problem;
- Competence: the application of the level of the scientific knowledge , professional skills and available technologies;
- Continuity: degree of integration over time between different health operators and structures that take care of the same patient or a group of subjects;
- Expected effectiveness: the ability of a potential treatment to favorably affect the health conditions of the patient in care; Qualitative parameters:
- Practical effectiveness: results obtained from the routine application of the intervention;
- Efficiency: ability to achieve health results with the least commitment of resources possible;
- Safety: degree to which the assistance provided puts the patient and operators in the lowest risk;

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- Timeliness: the degree to which the most effective intervention is offered to the patient when it is most useful;
- Humanization: level of respect for the culture and individual needs of the patient also with regard to information and quality of service.

In order to access and obtain accreditation it is essential that the social and health structures adopt valid organizational and managerial models by embracing the following principles:

1. Continuous quality improvement: the defined requirements encourage the structures to improve the quality and performance of the services provided;

2. Centrality of patients: the requirements refer to the centrality of the patient and the continuity of care;

3. Planning and performance evaluation: the requirements evaluate the efficiency and effectiveness of the organization;

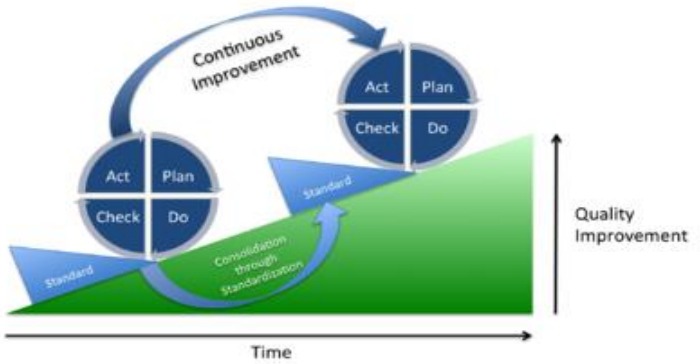
4. Safety: the requirements include interventions to improve and guarantee the safety of patients, visitors and staff;

5. Scientific evidence: the requirements are the result of national consensus, EBM, guidelines and analysis of international literature.

6. Training: the requirements that allow the certification of the acquisition of new knowledge and skills, capable of improving or modifying professional behavior according to citizens' health.

To objectively evaluate quality and safety, measurable and reproducible indicators are used to allows the verification of the effectiveness and efficiency of the measures taken, as well as their review for continuous improvement; all current accreditation systems require healthcare facilities to use clinical performance indicators. The aim is to create and to stimulate improvement which allows organizations to carry out a continuous evaluation of the application of these requirements, allowing, through measurement and analysis, to trigger continuous improvement processes.

The methodology must be based on the Deming cycle (PDCA - plan – do – check – act cycle) capable of promoting quality control aimed at continuous improvement of processes and optimal use of resources. This tool assumes that the constant interaction between planning, design, implementation, measurement, monitoring, analysis and improvement is necessary to pursue quality.



Constantly applying the four phases of the Deming cycle allows to continuously improve the quality and meet the needs of the citizen / patient.

These concepts find their maximum realization in Clinical Governance. (6)

Clinical Governance is a health policy strategy through which health organizations are responsible for the continuous improvement of the quality of services and the achievement-maintenance of

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high standards of care, stimulating the creation of an environment that favors professional and organizational excellence in function of the needs and safety of citizens-users.

In order to understand whether the interventions and services provided have been suitable and meet the needs expressed by patients, it is fundamental to monitor results. The term governance identifies the management of processes for achieving the objectives.

The Governance envisages a "system" approach which is achieved through the integration of numerous interconnected and complementary factors, among which there are continuous training, clinical risk management, audit, medicine based on Evidence, clinical guidelines and care pathways, management of complaints and disputes, communication and management of documentation, research and development, assessment of outcomes, multidisciplinary collaboration, patient involvement, correct and transparent information and personnel management.

Clinical governance cannot be imposed from above or from outside, but it is achieved through the interaction of numerous self-governing actors influencing each other and must therefore involve every element of the care chain from the territory to the hospital.

However, to make the structure or organization safe and certifiable in a univocal and uniform way, it is necessary to adopt a single common model that certifies the implementation of standards and that allows organizations to carry out a continuous evaluation of the application of the organizational, structural and managerial requirements. These requirements are organized in modules of incremental complexity, in order to be adopted gradually and adapt to the different territorial, local and national welfare situations.

In addition to the general requirements, the model must include three levels of certain specifications , from basic level to excellence, with an increased and further understanding this will provide a guarantee to the user who benefits from predefined services and procedures, as well as drastically reduce the risks of non-compliance.

The main objective is to build a system capable of:

- Provide a service and a level of high quality performance that is capable of directing the performance of activities to prompt and centered satisfaction of citizens' needs.
- improve the quality of patient journeys;
- improve the development of clinical, organizational and patient’s perceived quality;
- make visible the quality of the regional health system
- Optimize the available resources aiming at a better allocation of economic and professional resources

PRIMARY CARE

Primary care is the gateway, the first contact of people, family and community with the Health Service.
The areas of activity of primary care concern home care, general medicine assistance, pediatric and consultancy care, outpatient specialist services, services for the elderly and disabled adults.
A decisive role in primary care is played by General Practitioners, long-term care doctors and Pediatricians of free choice who work in close contact with professionals from other services to offer the most complete health care to the citizen, also combined with social services.
The primary care network is included within the national health organization at the level of the territory and provides 55% of the LEAs whose financing is guaranteed by the so-called "pro-capitae quota" providing benefits to citizens as established by the reform of the SSN and by the LEA on behalf of the SSN itself.

The "strength" of the primary care system is measured in relation to 10 different features.

Structural features (7):

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1) the financing system (general taxation, social insurance,health fees);
2) distribution of resources (primary care resources, starting from doctors, are distributed according to needs);
3) type of doctors (prevalence of family doctors vs specialists);
4) accessibility (the possibility of patients to use the services when needed);
5) longitudinality (the system's ability to provide a regular source of care over time).

The functional features:

1) Primary contact (primary care represents the gateway to the health system);
2) coordination (primary care ensures continuity of care between different levels of care);
3) globality (primary care includes preventive, curative and rehabilitative services);
4) longitudinality (the care for the patient is long term and not limited to a single episode of disease);
5) orientation towards the person, the family and the community (assistance is focused on the person and not on the disease and takes place in the context where the person lives, taking into account socialfactors).

The "strength" of primary care within international health systems (in particular in OECD countries) is related to a series of health and expenditure indicators: a) mortality from all causes; b) premature mortality from all causes; c) cause-specific premature mortality from bronchopneumopathies and cardiovascular diseases.

The countries with the strongest primary care systems - according to the ranking formulated by some authors - are: United Kingdom, Denmark, Spain, Holland, Italy, Finland, Norway, Australia, Canada and Sweden.(8-9-10)

Health systems with "strong" primary care systems are associated with better health among the population.

The evidence also shows that primary care (unlike systems based on specialist care) ensures a more equitable distribution of health in the population. The stronger the primary care, the lower the costs.

The changed demographic and socio-economic state, in particular in Italy, requires the strengthening and enhancement of the territorial network through the capillary presence in the territory of general practitioners (

DISCUSSION

In Italy, accreditation is issued by an institutional body and not by an external agency.

The person who intends to provide health services on behalf of the SSN has the obligation to register in the region in which he operates; for this reason, the accreditation system is defined as mandatory or institutional, i.e. specifically provided for and regulated by law.

However, in the current Italian health system, accreditation of health structures is addressed only to public hospitals, private structures and to service providers ;the accreditation is amandatory requirement for a health structure to become an effective provider of remunerated or rendered services on behalf of the SSN.

If a structure is not accredited, it cannot become part of the providers on behalf of the SSN.

An exception to this, are primary care providers, in particular MMG/ PLS, who despite being providers of services to citizens as established by the reform of the SSN and by the LEAs, do not

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have quality and safety guarantee systems or public or private models or systems or accreditation certifications with the SSR and SSN.

The quality of care understood as efficacy, efficiency and appropriateness and patient safety is an important problem in primary care and in particular in the field of general medicine / PLS.

In the literature some studies have shown that adverse events occur in MG as in any other healthcare setting. (3-4)

However, there are no studies showing how these events are preventable. In addition, both the reference studies and the interventions so far have mainly dealt with the quality and management of adverse events and errors relating only to the reality in the hospital environment; those relating to territorial medicine are limited.(17-18)

The general assessment indicators available in the PNE are not an exhaustive picture of the efficacy and safety of patients in the field of primary care and GP.
At a local and regional level there are numerous and different initiatives based on performance evaluations and collection of different indicators.
The reform of Title V has done nothing but make this framework even more uneven and unbalanced.
Furthermore (according to SIMG data) only 15% of General Practitioners in Italy provides indicators ,performance evaluations and quality of care data. It goes without saying that such a percentage significantly limits the collection in the database and therefore adequate monitoring of the quality of assistance. Furthermore, the lack and / or discrepancy of models of care and risk management and assessment of outcomes prevents a coherent and objective evaluation of the quality and safety of the primary care provided in the area.
International studies,, particularly in Israel and Denmark (19), provide us with different models based on the development of broad-spectrum indicators that can be used to improve the quality of primary care (Osce report on the quality of care in Italy 2014- 20-)

It is necessary to build and implement a system capable of monitoring and promoting the effectiveness and efficiency of the structures in the field of general medicine; this system aims at eliminating inappropriateness, rationalizing spending and reducing waste which in turn will improve-the effectiveness of the system and contribute to the continuous improvement of quality and safety of the performances and, above all, enable citizens to take informed decisions regarding their own health.

To achieve this goal, it is necessary to intervene by making the governance of primary care and in particular of GP truly transparent through the evaluation of pre-existing performances.

It is also necessary to implement step saimed at guaranteeing the assessment of the quality and appropriateness of the services, and at strengthening the capacity of the structures in order to prevent clinical risk and to guarantee the adherence to clinical-organizational guidelines; not only the quality of health-related services, but also the ways in which they are provided, the results of the outcomes and what satisfaction of the operators and citizens who must influence the logic of strengthening territorial skills, the only ones that can decongest hospitals and allow you to rationalize costs.

All this translates into an optimization of the available resources and above all in a possible saving in economic terms.

Although there are already clear regulations (Balduzzi law, national and regional agreements, ministry of health recommendations) regarding the need for a culture of risk prevention and the quality of an effective reorganization based on risk management in the area and in particular in medical studies, there are still many unresolved resistances and critical issues.

In particular, the current contractual regulatory framework and wide spread self-reference lead to dangerous "do it yourself" with discrepancies and disparities in the management and organization of individual surgeries or individual health associations which appear disconnected from the entire care chain.

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Therefore, given the fundamental importance of the primary care of the MG / PLS as a main provider within the SSN of services to the patient in order to meet all his socio-welfare and clinical needs, it is considered essential to think and implement an accreditation system extended to basic territorial medicine as already in place for all the affiliated and dispensing structures on behalf of the SSN and, as we have seen, in some OCSE countries guarantee universal access to fair and certified consistent care in all care settings for all citizens as required by article 32 of the Constitution.

It is necessary and correct to state that in order to achieve this objective, a unique standard valid not only at the regional level, but potentially applicable to the entire national territory is needed in order to standardize the organization, the quality and safety level of the assistance provided and the services provided as established by the LEA.

To this end, it is essential that a single dynamic model is adopted, which is, suitable to the individual territorial and local realities, sustainable and innovative and thus certifiable in order to reinforce the organizational paths and management in territorial health structures and in particular in the surgeries of GPs either individual or associated which will guarantee the quality in a uniform and equitable manner.

Lastly, the SWAT analysis of the project provides us with points of reflection and tools for possible realization.

STRENGTHS	WEAKNESSES
- Greater guarantee for the citizen of quality and safety of treatments -Variety of choice for the citizen on the basis of certification and accreditation levels made public in the selection lists of the MMG / PLS -Guarantee for the SSN of quality and safety in the delivery of care in all dimensions and care settings -Re-qualification and enhancement of the territory and in particular of the fundamental functions and the role of MMG/ PLS as a basis for access to the SSN -Active involvement and motivation by MMG/ PLS in the continuous improvement and implementation of the safety and quality of care for the citizen -Better allocation of resources based on accreditation levels	-Burocratization of the instrument, and complexity of the rules - Non-involvement of the professional component in the process -Resistance to change by MMG/ PLS and representative associations -Need to find incentives for the implementation of the system
OPPORTUNITY'	**THREATS**
-Redistribution of resources not only based on the needs of the citizen but also on the basis of the quality and safety of the care provided -Savings in terms of health expenditure based on expected outcomes -More clarity on the fundamental principles for focusing the system on the person	- Usage only to stay in the healthcare market instead of continuous quality improvement -Cultural resistance from the GPs and category representatives - Focus on structural elements rather than on assistance to citizens

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-Definition of guidelines for the application of the fundamental principles and standards envisaged by current national and regional legislation on the safety and quality of care, favoring strategies for involving them in the program objectives, in participation in quality and appropriateness policies, and in the spending control with a bottom-up logic	

CONCLUSIONS

The current demographic and epidemiological scenarios and the need to reduce the use of hospital access and emergency services as much as possible, both in economic terms and in terms of safety, requires that health care must address the patient's real problem in an integrated and synergic way, through the active involvement of health care providers at any level. This is an indispensable condition for it to be appropriately effective, efficient and safe and economically sustainable.

The recent pandemic events that have put a strain on our Italian SSN also force us to think that it is necessary to evolve our system from a hospital-centric logic, which has characterized Italian healthcare in the last 50 years, towards an integrated hospital-territory healthcare, able to respond adequately to the new scenarios and the arising care needs that derive from them.

All this makes us aware of a systemic crisis and the need for an adequate response to social, national and regional policies and of a cultural and operational challenge for decision-makers and sector organizations for a governance and sustainable development in the health sector.

Clearly, it is necessary to operate on the SSN in a univocal and systemic way in every health areas and not exclusively at the hospital level, in order to reduce the risk of incurring damage following treatment, increasing the improvement of the quality and safety of care and optimizing the resources available also and above all in the area of primary care at a territorial level through awareness, involvement, sharing, and the implementation of prevention and active improvement strategies for all operators involved in the process of assistance of every single patient.

We think that the main ground will be to think and propose new organizational and management models based on new assumptions capable of addressing the qualitative and quantitative change in health questions and support the sustainable development of a new Healthcare System in which Primary Care plays a strategic and fundamental role.

These models should be focused on the

- improvement of the quality of care in the local area, ensuring more appropriate access to care,
- coordination, planning and organization of assisted services and of General Practitioners individuals or within Associations, also for a better integration and synergy between the different levels of care (hospital / outpatient specialist / General Medicine)
- accreditation certified and made public, through the already existing published lists of available doctors, studies and associations of MG in order to provide citizens with a more informed choice focused on the quality and safety of the services provided both in professional and organizational.

Therefore, a critical review is necessary of the current Italian situation regarding the non-accreditation of territorial general medicine studies This can be achieved by analyzing and by providing the standards for reaching the minimum requirements, the certified levels of excellence and the objectives of the curriculum requested regarding patient safety and quality of care at national level.

It goes without saying that to overcome the difficulties and obstacles associated with the socio-political scenario and cultural resistance, it is necessary to listen and actively involve the various stakeholders and above all to find incentive methods that reward the achievement of objectives through pay-for-performance systems which, by connecting a portion of the remuneration of professionals upon reaching specific indicators constitutes an extraordinary motivational lever and introduces professional and organizational accreditation systems, with periodic revaluation certification procedures already tested and validated, in the most advanced health systems.

The model proposed for the accreditation of medical studies and associations related to primary care aims to promote a process of continuous improvement of the quality of services, the efficiency of the organization, the use of resources and training, in such a way that every citizen, in relation to their socio-health / care and social needs, receives a diagnosis and therapy, and the best assistance that guarantees the maximum results in terms of health, in relation to the current state of scientific knowledge, to the least cost and lower risks, in order to achieve the meeting of needs in respect to the interventions received and the outcomes achieved, with a constitutional view of providing citizens with true universal and accessible treatment.

The challenge is to combine a system of rules for the protection of citizens, by definition "rigid", with the "flexibility" of a system of continuous improvement of quality and safety.

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