The Italian institutional accreditation model for Haemophilia Centres

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Background. In Italy, basic health needs of patients with inherited bleeding disorders are met by a network of 50 haemophilia centres belonging to the Italian Association of Haemophilia Centres. Further emerging needs, due to the increased life expectancy of this patient group, require a multi-professional clinical management of the disease and provide a challenge to the organisation of centres.

In order to achieve harmonised quality standards of haemophilia care across Italian Regions, an institutional accreditation model for haemophilia centres has been developed.

Material and methods. To develop an accreditation scheme for haemophilia centres, a panel of experts representing medical and patient bodies, the Ministry of Health and Regional Health Authorities has been appointed by the National Blood Centre. Following a public consultation, a technical proposal in the form of recommendations for Regional Health Authorities has been formally submitted to the Ministry of Health and has formed the basis for a proposal of Agreement between the Government and the Regions.

Results. The institutional accreditation model for Haemophilia Centres was approved as an Agreement between the Government and the Regions in March 2013. It identified 23 organisational requirements for haemophilia centres covering different areas and activities.

Discussion. The Italian institutional accreditation model aims to achieve harmonised quality standards across Regions and to implement continuous improvement efforts, certified by regional inspection systems. The identified requirements are considered as necessary and appropriate in order to provide haemophilia services as "basic healthcare levels" under the umbrella of the National Health Service. This model provides Regions with a flexible institutional accreditation scheme that can be potentially extended to other rare diseases.

Keywords: standards and criteria, accreditation system, haemophilia care.

Introduction

Among the inherited bleeding disorders (IBDs), haemophilia A and B are the most known forms affecting worldwide around 1 in 6,000 and 1 in 30,000 males, respectively¹,². According to the Italian Association of Haemophilia Centres (AICE), there are 50 Haemophilia Treatment Centres (HCs) across Italy, meeting the basic needs for diagnosis, treatment, emergency management, home treatment and care of patients with haemophilia and other IBDs.

In 2008, AICE launched a voluntary professional accreditation project entitled Improve AICE³. According to the results of 21 HC audits, the AICE professional accreditation programme proved to be effective for promoting good clinical practice⁴. However, as HCs differ widely in term of size, expertise and services provided, the availability and quality of haemophilia care delivery across Italian Regions is not homogeneous; this finding is confirmed by the results of surveys carried out by patient organisations⁵,⁶.

The emerging needs of patients with IBDs require a multi-professional clinical management of haemophilia patients and provide a challenge to HC organisation⁷.

In order to achieve harmonised quality standards of haemophilia care across Italian Regions, an institutional accreditation model for HCs has been developed, driven by each Regional Authority (RA), through which public and private facilities are authorised to provide services in
the name, and on behalf of the National Health Service (NHS) General accreditation criteria specify the structural, technological and organisational requirements of health providers whose compliance is periodically verified by regional inspection systems.

Haemophilia and other IBDs meet the definition of rare disease provided by the European Commission as they are life-threatening or chronically debilitating diseases whose prevalence is less than 5 over 10,000 persons in the European Union. In Italy, the field of rare diseases (RDs) is regulated by a specific legislative framework and policies. A RDs network was established with the Ministerial Decree (MD) 279/2001, and reasserted by the Agreement between the Government and the Regions of May 2007, in order to support the prevention, surveillance, diagnosis and treatment of RDs patients. The RDs network comprises hospital-based centres as well as home-treatment programmes. A RDs network comprises hospital-based Centres of Reference (CoR), designed by each RA; this network has not been included in any institutional accreditation process to date.

In Italy, haemophilia knowledge and health care has a very long history and comprehensive treatment centres as well as home-treatment programmes have been in place since 1970. Therefore, a long-standing HC network was already in place when the MD 279/01 (National network of rare diseases) was adopted and many of the 50 HCs now belong to the RDs network.

This paper aims to provide a description of the Italian institutional accreditation model for HCs approved with the Agreement between the Government and the Regions no. 66 in March 2013. An outline of the complex process required and the role of multiple actors involved for its development is also provided.

Materials and methods

With the aim of promoting higher and harmonised standards of haemophilia care across Regions, the Italian Federation of Haemophilia Societies (FedEmo, www.fedemo.it) proposed the development of an institutional accreditation scheme for HCs to the Health Commission of the Permanent Conference for relations among the Government and the Regions (HCCGR). HCCGR appointed the Italian National Blood Centre (NBC, www.centronazionalesangue.it) to investigate the matter and to develop a technical proposal. In order to meet this commitment, the NBC convened a panel of experts belonging to medical (AICE) and patient (FedEmo) bodies, the Ministry of Health (MoH, www.salute.gov.it) and Regional Health Authorities (RHAs). The panel conducted a literature review from institutional sources in order to collect all the available scientific and regulatory references related to requirements, recommendations, as well as general and specific certification/accreditation systems. An analysis was conducted on critical issues specifically related to HC organisation and service management, that were not included in the general accreditation process carried out by Regions for health care centres. Particular concern was given to organisational requirements of HCs, since structural and technological standards were already considered and assessed in the institutional and voluntary/professional accreditation processes, respectively. After a public consultation, held in April 2011, a technical proposal in form of recommendations for RHAs was produced by the NBC and formally submitted to the MoH in February 2012. The MoH launched a further technical consultation process involving internal actors such as the Department of Health Care Planning (RDs Unit), and other institutions such as the National Medicines Agency (AIFA, www.agenziafarmaco.gov.it) and the National Institute of Health (ISS, www.iss.it). The proposal was reviewed after a careful evaluation of the legal nature of the document to be adopted (recommendations or more binding requirements) and of the current legislation and policies on RDs, and taking into account clinical disease-specific pathways to be adopted by RHAs as Basic Levels of Care. The document became the basis for a proposal of an Agreement between the Government and the Regions. The Agreement was approved in March 2013 and the Italian Regions had six months to transpose it into their legislation.

Results

The panel of experts convened by the NBC identified two levels of organisational requirements related to different functions assigned to HCs: one level for HCs providing basic haemophilia services and the other for HCs offering a more integrated and specialised multi-professional approach to patients. However, while 23 organisational requirements for basic HCs were substantially confirmed in the final document, 4 additional requirements for the Comprehensive HCs were amended since the Regions decided about the opportunity to recognise only one level of HCs and to adopt an unique accreditation system for it.

The organisational requirements for basic HCs cover different areas and activities, such as record-keeping, patient awareness and safety, treatment programme, periodical check-up, home treatment plan, access to laboratories, information, training and quality management.

In particular, they include the following activities:

1- preparation and updating of patient records;
2- formalisation of the diagnosis of coagulopathy, detailing a specific set of information;
3- drawing up of the certificate of diagnosis of rare disease, according to the procedures defined by the Regions, valid nationally, in order to release...
the certificate of exemption from co-payments of healthcare services provision by the Local Health Authority.

4. production of a detailed report in line with specific requirements while formalising the diagnosis of coagulopathy;

5. issuing of a treatment plan containing the personalised prescription of clotting factor concentrate to be used, with dosage and any other prescription the clinician deems appropriate;

6. issuing for each patient, of a sheet containing summary information about the therapeutic product to be used including the recommended dosages and procedures to be considered in the event of minor and major bleeding episodes, and practical references about services, patient rights and how to access them;

7. adoption of specific protocols that define the criteria to be used for research, titration and possible follow-up of inhibitor;

8. adoption of appropriate protocols in collaboration with the network of genetics laboratories aimed at ensuring the diagnosis of the patient's family members, including genetic counseling and pre-and postnatal genetic diagnosis;

9. for each patient, definition and regular updating of a specific treatment programme (including product, dosage, treatment regimen, the reasons for the choice of treatment and eventual home therapy modality in collaboration with the local health services) with informed consent from the patient;

10. provision of patients with written instructions and instruments for the recording of the infusions of therapeutic products in home therapy;

11. evaluation of the suitability of each patient regarding the self-infusion practice;

12. systematic registration of data regarding the home therapy of each patient infusion of therapeutic products carried out in home therapy, at the HCs or in other health facilities involved in the therapeutic pathway;

13. planning and organisation of periodical check-ups;

14. adoption of protocols for the multidisciplinary assessment of patients with complications associated with IBDs (inhibitor, arthropathy, chronic liver disease, HIV infection);

15. adoption of procedures for the procurement of therapeutic products, in order to ensure continuity of care and timely treatment of bleeding episodes and emergencies, in cooperation with the pharmacies;

16. delivering of multi-disciplinary treatment programmes based on written protocols, planned with specialised services;

17. access to laboratories performing a predetermined set of coagulation tests: Prothrombin time (PT); activated Partial Thromboplastin Time (aPTT); fibrinogen dosage; thrombin time (TT); mixing tests (PT, aPTT, TT; test for the research of lupus anticoagulant; factor VIII/IX dosage; research of FVIII/IX inhibitor; von Willebrand Factor Antigen (VWF:Ag); von Willebrand Factor Ristocetin Cofactor (VWF:RCo); Coagulation factors dosage: II, V, VII, X, XI, XII, XIII; study of platelet function through platelet aggregation induced by ADP, collagen, epinephrine, arachidonic acid, ristocetin;

18. access to laboratories for coagulation tests that guarantee the availability of results and reports in a timeframe compatible with the urgency of the request;

19. availability to patients and their families of appropriate updated information related to the characteristics of haemophilia and other IBDs, as well as issues related to the daily life of patients with haemophilia (PWH);

20. organisation of periodical events for informing and training the patients with IBDs and their families, including courses for home therapy, in collaboration with other HCs and local patient associations;

21. organisation of periodical training addressed to personnel of specialised services (emergency service, general practitioners and paediatricians, pharmaceutical services, etc.);

22. participation in registries related to IBDs, in compliance with current legislation regarding the protection of personal data;

23. conduct of systematic clinical and quality audits aimed at assessing compliance with established policies and procedures, and planning of specific quality improvement objectives related to clinical and organisational processes, also through the involvement of patients and their associations.

Therefore, in the first version of the document, 2 levels of haemophilia care delivery were originally developed by the panel of experts convened by NBC and inspired by the Hub and Spoke organisational model of haemophilia care. In this context, the "Hub" centre performs high resource and competence demanding activities and is linked to a network of "Spoke" centres providing basic services close to where the patient lives. This model would offer the opportunity to balance access to health care and sustainability. In addition, it would allow Hub centres to deal with a minimum number of patients necessary to maintain the multi-disciplinary and specialised expertise required for haemophilia patient management. Thus, four additional requirements/activities were identified for Comprehensive HCs (Hubs): coordination of a network of hospital facilities providing comprehensive care, 24-hours availability of a physician with experience in the treatment of
coagulation disorders, 24-hours access to a laboratory providing a set of specific tests within agreed turn around times; 24-hours availability of an advisory service to patients and their families, as well as other professionals and caregivers. However, after the consultation process, according to the Agreement between the Government and the Regions, RAs decided, in order to achieve greater autonomy in the organisation of health services, that these functions should be ensured through addressing indications provided in the context of current health planning procedures.

Discussion

In Italy, a designation process of CoR based on a disease-specific accreditation scheme had not been developed previously. The process that led to the final improvement of the Italian HC accreditation model proved to be complex and time consuming. Different opinions had to be compared and addressed, in particular on the feasibility of developing a specific process of accreditation for RDs. Other challenges are related to the large numbers of actors involved in the process and to the specific features of the relationship between Central State and Regions, influenced by political forces and characterised by a continuous negotiation effort.

The experience developed in Italy in the accreditation of HCs -both institutional and professional- provided the inspiration and drove the development of European standards in the context of the European Haemophilia Network project (EUHANET, www.euhanet.org). The two above-mentioned accreditation models comprised the main reference documents for the production of the European Guidelines for the certification of HCs, supplemented by other European national experiences and models (e.g. Belgium, the Netherlands, United Kingdom) and the European principles of haemophilia care.

The development of European reference networks in the MS is one of the core provisions of the cross-border health care directive. In particular, article 12 of this directive describes the general aims and objectives, as well as peculiarities, that reference networks should meet. The European Union Committee of Experts on Rare Diseases (EUCERD), which supports the European Commission with the preparation and implementation of Community activities in the field of RDs, has issued, among others, specific recommendations on centres of expertise (CoE) and European Reference Networks. In particular, such centres should be compliant with the EUCERD recommendations for quality criteria for CoE in RDs and Directive 2011/24/EU, mentioned above. Each MS should establish a procedure to define and approve designation criteria along with transparent designation and evaluation processes.

The institutional HC accreditation model could be regarded as a "pilot study" in the field of accreditation and designation of CoR for RDs. This experience has shown that an earlier involvement in the process of RD experts and policy makers would have facilitated the process and provided the accreditation model with better flexibility and acceptability. Indeed, it is the opinion of the authors that the specificities linked to haemophilia and other IBDs (number of patients, clinical history of the disease, pre-existing network of HCs, treatments costs, etc.) permit the development of a specific accreditation system for this group of diseases. However, it is necessary to introduce a continuous process of data collection on the model implementation to support decision making processes. It cannot be excluded that in the future, based on the evidence collected, the system of accreditation of HCs might be considered within a broader dedicated system of accreditation for all RDs with consideration of a set of common generic requirements for all CoR for RDs, and a set of specific requirements for each disease or group of RDs.

Conclusions

The Italian institutional accreditation system aims to achieve harmonised quality standards across Regions and to implement continuous improvement efforts, certified by rigorous and objective regional inspection systems. The identified requirements are considered as necessary and appropriate in order to provide haemophilia services as "basic/essential healthcare levels" under the aegis of the NHS. This system is the outcome of a long and complex consultation process involving experts from RAs and national institutions (NBC, MoH, ISS, AIFA, etc.), with the participation of representatives of patient associations (FedEmo) and learned scientific societies (AICE). All types of facilities providing haemophilia services are eligible to be involved in the accreditation model, regardless of the level, intensity and type of services provided.

It is the authors' opinion that this model could provide Regions with a flexible institutional accreditation scheme for HCs which can be potentially extended to other RDs. Regions, in fact, could adapt the requirements to their specific context and develop further more stringent requirements, for instance by taking into account EUHANET recommendations on the minimum number of severe patients followed by HCs. To date, 4 RAs out of 21 (Emilia-Romagna, Liguria, Autonomous Provinces of Trento and Bolzano) have already formally adopted it. A wider implementation will provide useful information in order to adapt and improve the model.

The Authors declare no conflicts of interest.
References


8) Decreto del Presidente della Repubblica 14 gennaio 1997: "Approvazione dell'atto di indirizzo e coordinamento alle regioni e alle province autonome di Trento e di Bolzano, in materia di requisiti strutturali, tecnologici ed organizzativi minimi per l'esercizio delle attività 8 sanitarie da parte delle strutture pubbliche e private".


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