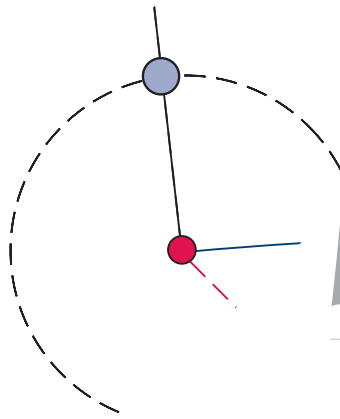


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# Baby Heart Project



# Manual

for the accreditation  
of excellence for quality  
in paediatric cardiology  
and cardiac surgery



MANUAL  
FOR THE ACCREDITATION OF EXCELLENCE  
for quality in paediatric cardiology and cardiac surgery

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## Preface

I have fully evaluated and shared in the “Baby Heart Project” which follows the accreditation criteria of the Ministry in its development in order to identify Centres of Excellence in the public healthcare service.

Eight paediatric cardiology and cardiac surgery centres have enrolled in the project promoted by the Italian Society of Paediatric Cardiac Surgery and by the Paediatric and Adolescent Cardiac Surgery section of the Italian Society of Cardiac Surgery in 2005.

The project defines the minimum number of surgeries required to be classified as a Centre of Excellence both in regards to the problems during the paediatric years and for those in adult congenital heart disease patients. In addition, the manner of training medical and paramedical staff that are qualified to work in accredited centres is defined.

The evaluation of the outcomes performed over the three-year period from 2005-2007 by the Paediatric Cardiac Surgery and Paediatric Cardiology centres which participated in the Baby Heart Project represents an important element in order to define the results achieved by the Centres of Excellence.

Therefore, in addition to sharing in the Baby Heart Project, I advance the expectation that similar projects for accreditation and the relative “Gold Stamp” consider the evaluation of all discipline sectors in public healthcare services.

*Prof. Ferruccio Fazio*  
Undersecretary of State for Labour,  
Health and Social Policies  
with commission for Health



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## Introduction

Congenital heart disease surgery in Italy began more than 40 years ago and, for many years, it developed with a large quota of “creative spontaneity”. The first centre which developed the school concept by favouring the affluence of numerous illustrious professionals coming from the most prestigious institutions in the world, was the one in Bergamo. Subsequently, other Italian groups entered the category of centres qualified in the surgical treatment of paediatric congenital heart disease and, only later, the experimental model of the medical-surgical department of paediatric cardiology was developed. Nevertheless, the development of paediatric cardiology and cardiac surgery, as with adult cardiac surgery, did not happen due to national planning based on the true need for care services, but rather it happened in a non-homogeneous manner without any planning.

The Paediatric and Adolescent Cardiac Surgery section of the Italian Society of Paediatric Cardiology has been thinking about the opportunity to rationalise the relationship between the supply and demand in this specialist area. The incidence of congenital heart disease is estimated at around 8‰ of live births. Based on National Statistical Institute data of births in 2005 (560.000 live births), it is therefore possible to estimate that the live births with congenital heart disease vary between 4.500 and 5.000. Forty percent of these newborns require cardiological and/or cardiac surgery within the first year of life. Added to this demand for specialist services is that, in constant and significant increase, related to “return pathologies” which manifest in adulthood. Over the last decade, in fact, the realisation of the necessity to guarantee continuous improvement in the quality of services in level III centres which handle the treatment of congenital heart disease in young adults has progressively developed. This activity, even though it represents a small niche in the national epidemiology, lends itself, due to its characteristics of very high specialisation and due to close and inter-disciplinary collaboration between paediatric cardiology and cardiac surgery, to being placed in an ideal department-type organizational and care model.

The first step of the ideal path towards continuous improvement taken by the Paediatric and Adolescent Cardiac Surgery Section of the Italian Society of Cardiac Surgery, is represented by the start up of a project which annually collects data about paediatric cardiac surgery activities in Italy. In this regard, the participation in the project of all of the Italian centres which are members of the Paediatric Cardiac Surgery Section since 2003 is significant. Subsequently, between the years 2004-2005, an external and impartial commission was formed with the mandate of performing a check of the reliability of the data from the various paediatric cardiac surgery centres which voluntarily submitted to the audit conducted by the commission.

Based on this positive experience, the Paediatric and Adolescent Cardiac Surgery Section of the Italian Society of Paediatric Cardiology has conceived an even more ambitious project, the **Baby Heart Project**, with the aim of defining the minimum organizational-structural requirements and the treatment and result standards as a guarantee of the quality of the services performed in the centres whi-

ch carry out their activities in the field of paediatric cardiology and cardiac surgery and of adult congenital heart disease.

The project, which began at the end of 2005 under the auspices of the **Italian Society of Paediatric Cardiology** and of the **Paediatric and Adolescence Cardiac Surgery Section** of the **Italian Society of Cardiac Surgery**, was realized by a team made up of cardiologists and cardiac surgeons enrolled in the two Societies and belonging to those centres which specifically perform activities of paediatric cardiology and cardiac surgery with sectors dedicated to the treatment of adult congenital heart disease patients.

Thanks to the technical-methodological and logistic-organizational support of CERMET\* and to the scientific contribution of Professor Bruno Turinetti\*\*, the requirements for guaranteeing the excellence of the specialist services in paediatric cardiology and cardiac surgery with specific reference to the treatment of paediatric and adolescent and, subsequently, also adult congenital heart disease were defined.

These requirements are listed in this manual in terms of:

- organizational and structural characteristics
- volume of activity
- services with indication of the quality characteristics which connote them
- main courses of treatment and result indexes to achieve in the diagnostic and therapeutic cardiological and cardiac surgery treatment
- necessary professional profiles and relevant training courses
- indicators for the verification of such characteristics and the related reference standards

The result of the work done by the team of professionals involved in the **Baby Heart Project** represents an important step towards the opportunity to start an experimental phase of the professional accreditation of our centres with the view of improving defined requirements over time and of the evaluation process of the same.

The necessary thanks goes to all of the professionals who have participated in the project and to all of those who want to have a constructive debate about the proposed requirements, helping us to continue along the path taken.

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\* Certification body with consolidated experience in the healthcare field.

\*\* Organisational secretary of the Italian Society of Cardiac Surgery.

# 1. The administration of quality in healthcare

Over the last decade, the regulations for the reorganisation of the National Healthcare System have introduced completely new concepts in the administration of healthcare with respect to the previous management model such as: business, citizen's choice, programmatic decentralization, cost control, diagnosis-related group payment for services (DRG), etc.

At the same time, awareness of the necessity to adopt tools in support of the clinical administration of the healthcare organisations and words like *clinical audit*, *evidence-based medicine*, *guidelines*, and *indicators* have already entered the daily language of the professionals.

In this context, and in a climate of continuous innovation, various reference models to qualify the performed services have been adopted due to urging by the state or by the will of individual organizations.

In the following pages, some basic concepts are summarized. These allow for the distinction between the most widespread approaches in our country. All are united by the logic of the "evaluation" seen as the road for comparison and measurement, and, therefore, as the basic element in the push towards improvement.

It is held to be especially useful to pay attention briefly to the following methods:

- State Accreditation
- ISO 9000 Certification
- Total Quality - EFQM
- Professional Accreditation

## State Accreditation

In Italy, the topic of accreditation was set out in a formal manner with the decrees D.lgs 502/92 and D.lgs 517/93 which, by modifying the 502, introduced the concept of accreditation in the regulatory field (art. 8, c. 7) for the first time: "Regions and Local Healthcare Units, who however much adopt the necessary measures in order to establish the new relationships foreseen by the current decree based on the criteria for state accreditation, on the manner of payment for services and on the adoption of a system for verification and review of the quality of the performed activities and services".

From this point of view, accreditation is clearly understood as being a tool for regulating the market of accessing the National Healthcare Service for public and private suppliers, in order to:

- guarantee the citizen has the minimum elements of quality;
- avoid unregulated competition which could lead to a deterioration of the levels of quality in the service or to a unchecked increase in costs.

State accreditation for the organisations that intend to operate in the name of the National Healthcare Service becomes formally and fundamentally obligatory in a ministerial system in which the national level supplies the general directives and the regional level defines the specific standards and manner in which the accreditation processes are managed.

This configuration of the accreditation institution has been maintained in all of the other subsequently issued legislative dispositions, which further clarified and specified the contents.

The main steps with which the path to define the logic of state accreditation are seen in the following acts:

- D. Lgs 502/92 and subsequent changes and supplements;
- Sentence 416/95 of the Constitutional Court;
- D.P.R. 14/01/97 with regards to the authorization to practice and the functioning of public and private healthcare structures;
- D. Lgs 229/99 about the rationalisation of the National Healthcare Service;
- the 2002-2004 National Healthcare Plan.

From the beginning, the concept of accreditation has appeared to be an element in a larger picture which also includes the concepts of authorization and agreements. This picture is clarified and explained in D.Lgs 229/99. Especially:

- in article 8b, the logic of the scale is confirmed: authorization, accreditation, agreements;
- in article 8c, the reasons for the authorization of “new” structures (built, adapted, transformed, transferred) are distinguished. Therefore, a compatibility check by the region is foreseen. For already functioning structures, which must respect the minimum requirements laid out by DPR 14/01/97, they must be integrated and updated;
- in article 8d, the issuing of the accreditation is dependent on having further qualification requirements, on the practicality of regional planning and on the positive audit of the performed activities and achieved results;
- in article 8e, contractual agreements are regulated by foreseeing the stipulation of contracts which indicate:
  - healthcare objectives and integration of service programmes;
  - maximum volumes of services and remuneration;
  - informative debits for the monitoring of pacts and for quality and appropriateness checks.

The role of the regions appears to be fundamental in this framework. The regions are called upon to give substance to everything by autonomously regulating, while respecting the common minimum criteria, the procedures for checking the working of regional planning, the requirements to satisfy in order to be authorized and accredited, the procedure of checks and controls to be put in place.

Actually, the regions began to regulate their competences with regards to authorization, accreditation and agreements in different ways and with different timeframes and the overall picture is quite varied. However, it is possible to trace the various situations back to:

- regions which have formally set up, approved and set in motion their own models (by model meaning the whole process composed of requirements, authorization/accreditation, evaluation mechanisms, etc.);
- regions which have drawn up drafts of models but which have not gotten to the point where the models have been formally approved;
- regions which have drawn up laws which give some basic indications referring the formulation of requirements and procedures which have not yet been drawn up to other acts;

- regions which have essentially limited themselves to acknowledging the DPR 14/01/97 without establishing further requirements.

However, the lack of homogeneity is not only related to the state of progress of the work but also to the type of approved requirements and procedures. This is clearly the result of regional autonomy but it causes certain musings about the need for “mutual recognition” of the various models.

### **ISO 9000 Certification**

ISO 9000 certification, recognised and adopted in more than 80 countries worldwide (the European Union is one of them), is issued on a voluntary basis by third party independent certification bodies which are coordinated by national and international associations that guarantee the equivalence of the certificates issued in the various countries.

All companies, regardless of the business sector or size, can ask for and obtain ISO 9000 certification of their quality systems, thus guaranteeing their clients a measured and controlled quality standard. Certifying that a quality management system is in conformity with the UNI EN ISO 9001 regulations means recognising through periodic inspections and checks that the company has put an organisational structure in place and it applies procedures that, by respecting the rules of the reference regulations and of the applicable laws for the sector in which it operates, allows them to ensure the supply/distribution of a product/service in line with the client’s expectations. So, the client/purchaser who turns to a certified organisation is certain of finding an interlocutor who has realised a work method which has the aim of “the satisfaction of the client and of the interested parties”.

In the world of healthcare organisations, a course of comparison with the administration logic of the quality systems based on ISO 9000 regulations began some years ago. This course, which involved more particularly the world of laboratories in the first phase (which, due to specific characteristics, were more “at ease” with the proposed approach) is now spreading to all activities (hospital, territorial, etc.) also due to based on the push given by state accreditation considerations.

The experience of ISO 9000 quality systems in the world of healthcare had some critical aspects in the initial applications:

- difficulty in translating a regulation worded in a language that was very far from the culture of the professionals;
- suspicion towards the request for attention to planning and standardisation by a field that was often used to operating “in science and conscience” and the consequent perception of the desire to “bureaucratise” the activities;
- tendency to limit the Quality System to the organisational part only, thus creating a conflict, in the interpretation of the professionals, with the “true” quality linked to topics such as efficiency, pertinence, etc.;
- presence of other approaches to quality management and improvement, some founded in the sphere of the scientific societies or, in any case, professional fields, with the effect of a methodological conflict (a fight, at times sterile) between schools of thought.

These critical aspects were widely overcome by the 2000 edition of the regulation which satisfied the following needs:

- compatibility with other management systems;
- common structures for both ISO 9001 and 9004;
- ease of use, clarity of language, translatability and ease of comprehension;
- help with self-evaluation;
- adaptability to all of organisations of any size and in all financial sectors;
- importance of evaluating services based on objective measurements and not based on impressions;
- introduction of the concept of continuous improvement;
- establishment of a point of reference for integration with the culture of improvement;
- conformity with the primary needs and with the expectations of specific sectors, including healthcare;
- documentation targeted at obtaining the desired results.

Thanks to this vast qualitative leap in the regulations which tries to develop efficient and dynamic ways of managing quality, there are numerous public and private healthcare structures which have chosen the criteria of ISO 9000 in order to develop an administration system for its organisation which guarantees internal efficiency, in terms of optimizing and rationalising costs, and the effectiveness of the performed services with an eye to satisfying clients and interested parties.

Notably, in order to obtain ISO 9000 certification, a healthcare organisation must:

- develop a quality management system which foresees:
  - clear identification of clients and all interested parties;
  - identification of the needs and expectations of clients and interested parties in order to realise services able to meet those expectations;
  - definition of the quality characteristics of the services offered in order to have transparency in communicating externally and control of the level of expectation, and for the commitment to the achievement of the declared service level;
  - identification and making adequate and necessary human, technological and structural resources available in order to perform the services;
  - application of a set of procedures for the design, planning and supply of the controlled diagnostic, therapeutic and care services;
  - optimisation of the costs connected to the quality of the service and the level of requested services;
  - systematic application of methods for managing “problems”;
  - ongoing review of the characteristics of the supplied service and the related results achieved in order to identify improvement opportunities;
  - adoption and systematic application of tools for the management of ongoing improvement.
- request for the start-up of the certification process for the issuing and subsequent maintenance of the certification from an accredited certification body (SINCERT in Italy).

The certificate is issued after positive debate by the certification committee representing all of the interested parties. This evaluates the result of the documentary analysis and of the performed checks of the structures in order to ascertain their conformity to the Quality Management System which has been developed in consideration of the ISO 9000 requirements. Maintaining the granted certifica-

tion depends on the positive result of the periodic supervisory checks which are aimed at ascertaining the existence of the original conditions which brought about the granting of the certification and the ability of the organisation to activate actions for improvement. In the event that serious deficiencies with respect to the regulations are found during inspections, the certification may be annulled or suspended. This sees to it that the enormous effort on the part of the organisation during the initial phase, in the desire to achieve certification, takes shape in a dynamic “quality management system” which is applied daily and in continuous improvement, thus constituting a profitable investment for the organisation and not just a “financial burden”.

### **Total Quality – EFQM**

Total Quality began and developed widely in Japanese corporate organisations and entrepreneurial culture. It later gradually and slowly spread to the western industrialized world, perhaps also in order to understand, slow down and compete with the “phenomenon” of Japan which had quickly imposed its products on the international markets.

The focal centre of *Total Quality Management* revolves around the acquisition of the ability to produce ongoing innovation and improvement in global quality, maintaining (or introducing) the following into the organisational system:

- agility in processes;
- quickness of decisions and actions;
- precision (accuracy) in the implementation tasks;
- visibility of organisational commitment to manage processes with flexibility (exposed management);
- variety of services, products, tasks, knowledge and professional approaches;
- consistency of the values (vision and missions) which make up the true strength of the organisation and make it distinguishable (visibility = image).

These six characteristics have a basic role. In fact, if the organisational change (subjective or collective) is aimed at the achievement of a quality system, numerous advantages may emerge, among which:

- increase in customer satisfaction since if these are satisfied, they help the organisation to further improve;
- reduction of financial, procedural and regulatory waste which bind the organisation because the substance and dynamicity of the real organisation replace the rigidity of the formal organisation;
- increase of the investment with responsibility, autonomy and the morale of the operators because the relationship between services and its result is visible. Involvement and participation increase and the ability for problem solving develops. Therefore, the quality of services and each operator’s work increases;
- global increase of the motivation of the organisation because the aims of the organisational system are known, discussed, identified and realised;
- increase in the social role of the organisation because if the relationship between client and organisation becomes mutually proactive, the quality of the image increases both within the organisation (with notable motivational effects on the operators) and outside in relation to the environment in which the organisation finds itself (with notable social effects);

- increase of social interaction inside and outside the organisation because if the organisational image improves, if the quality of the internal and external communication of the organisation grows, if the quality of the internal and external attention increases, the quality of the relationship between the people (whether they are clients, collaborators, other operators in the sector, suppliers) improves.

Therefore, it is possible to state that quality concerns the whole of the organisation and it is fed by the ongoing retrospective effects and interactions which exist in the organisational fabric, since the thick network includes:

- the client (as inter-organisational human capital);
- the personnel, collaborators, partners, the entrepreneur (as intra-organisational human capital);
- the competitors, suppliers (as inter-organisational human capital);
- the incorporated capital, material and immaterial (structures, technology, information, financial assets and balance sheet, etc.), or rather “the capital” created from “human capital”;
- the natural capital; that is the resources, such as raw materials, used in the production process, incorporated into the product and used by the client.

An important contribution to the promotion of total quality is favoured by the European Union which sponsors the “*European Foundation for Quality Management*”. This body, founded at the end of the nineties as a *non-profit* association, proposes to stimulate the promotion of quality projects, above all through the push towards self-evaluation and presentation of annual European awards.

The origin of the model, as in the case of ISO 9000 regulations, can be found in the industrial world. The model is based on the assumption that “excellence results regarding performance, clients, human resources and society are reached through actions of guidance, by the leadership, on policies and strategies, personnel, partnership and resources and processes”.

The EFQM model for excellence is based on nine criteria (dimensions) of which five are defined as factors (leadership, personnel management; policies and strategies; partnership and resources; processes) and four are results (results related to personnel; results related to clients; results related to society; results in performance). Each criteria is given a related weight expressed in percentages. The nine criteria are then divided into sub-criteria.

The model is currently used in various European states, also in reference to healthcare organizations.

Actually, the principles of *Total Quality Management* which seem to be extremely coherent with the characteristics and peculiarities of the healthcare sector, are at the foundation of the principles which imply the development of a system of quality management in accordance with ISO 9000:2000 and which must guide the direction towards the ongoing improvement of the services through:

- organisation directed towards the client;
- leadership;
- involvement of personnel;
- approach for processes;
- systematic approach to management;

- ongoing improvement;
- decisions based on facts;
- mutually beneficial relationship with suppliers.

### **Professional Accreditation**

Accreditation seen as a spark for opportunities for performance review and improvement of services aimed at ongoing improvement of offered products/services is found alongside/in opposition to obligatory state accreditation.

This form of voluntary accreditation is generally defined using different expressions: of excellence, between equals, professional. To a purely simplifying end, we will use the definition of professional accreditation.

The philosophy on which this form of accreditation is based is that contained in a passage from the final statement of the III congress of the *American College of Surgeons* in 1912: “[...]standardisation of hospital equipment and hospital work should be developed, to the end that those having the highest ideals may have proper recognition before the profession and those of inferior standards should be stimulated to raise the quality of their work. In this way patients will receive the best type of treatment and the public will have some means of recognising those institutions devoted to the highest ideals of medicine.”

The logic of accreditation for healthcare structures was initiated in the United States of America at the beginning of the twentieth century by the *American College of Surgeons* with the intent of promoting a higher quality of care and giving visibility to the best structures in such a way as to make them the terms of reference for all of the organisations. The *Hospital Standardization Program* dates back to 1919. In it, the first minimum criteria for accreditation of healthcare structures were identified. In 1951, the *Joint Commission for Accreditation of Hospitals* was created. This groups the main professional associations together with the objective of producing and updating the quality standards over time and to see to checks of accreditation. Subsequent to the extension of accreditation activities to non-hospital structures, in 1988, the commission took on the name of *Joint Commission on Accreditation of Health Organizations*.

The ongoing search for quality standards led this body, currently fundamental in the American healthcare system, to publish the first *Standard for Hospital Accreditation* based on minimum organisational, structural and technical-professional requirements and, later, to publish the standards aimed at “promoting and maintaining better quality of treatments, through analysis, checks and evaluation of existing clinical practices”.

To date, this form of accreditation involves more than 80% of the healthcare structures in the United States, even though it is a voluntary activity carried out by professional and independent agencies at the request of the interested healthcare structures. This level of diffusion is explained in light of the specificity of the American healthcare system, where the accreditation programmes intersect with the interests of state and private insurance companies in order to essentially respond to two necessities: on the one hand to guarantee the quality of performed healthcare services to the public, on the other hand, to rely on a serious and strict control system on which to base the programmes of fees, hospital stays and medical compensation.

Making reference to the American experience, a growing number of countries have started initiatives with this form of accreditation. Especially meaningful are those developed in Australia (*Austra-*

*lian Council on Healthcare Standard*) and in Canada (*Canadian Council on Health Services Accreditation*).

Even some Italian regions have developed experimental projects based on the application of these models (e.g. Lombardy, Veneto).

Considering, instead, the aspects which are more appealingly professional, there are various experiences aimed at experimenting with the logic of professional accreditation of the scientific societies or, in any case, conducted in collaboration with the same. In fact, it is possible to find references to the experiences, to the established standard requirements and to the planned procedures on many websites of the various scientific societies.

These experiences, of a voluntary nature, are missing a rigorous approach that is codified on a national or international level on which to base the organisation of a professional accreditation programme. The experiences are among some of the most varied and differ in various aspects. But beyond the inevitable differences, we believe it useful and possible to identify the common elements in these experiences:

- professional accreditation does not have the objective of regulating the market but rather, as already mentioned, the improvement of offered services;
- participation in the programmes is always voluntary in such a way as to guarantee the candidate's true interest and willingness to identify critical areas and opportunities/needs to set in motion improvement activities;
- main focus on the scientific/professional aspects and on the organisation of healthcare processes;
- quality requirements/criteria/standards used as evaluation references are periodically updated in light of the experience and of the evolution of knowledge (e.g. evolution of the scientific guidelines);
- evaluation activity is performed by professionals in the branch/discipline who are specially trained (thus introducing the concept of peer review, unlike state accreditation);
- evaluation is performed periodically (not a one-off accreditation) so as to be able to observe the improvement or not of the structure.

## Professional accreditation for paediatric cardiology and cardiac surgery: document objectives and structure

This document is intended to spread the concepts of quality management in paediatric cardiology and cardiac surgery throughout the professional scientific community of reference based on four keywords which have guided the **Baby Heart Project** team, that is:

<i>evaluation</i>	quality must be defined in terms of objective criteria with which to verify the suitability of the administration, management and technical-professional system developed within various organisations;
<i>sharing</i>	standards to be used for the checks must be clear, known and recognised. It is necessary to publicise the document and to favour debate with the rest of the professional scientific community of reference;
<i>debate</i>	debate between peers with other professionals in the face of defined criteria is a useful and important activity. There is always room for improvement and a process of debate and control helps to identify it;
<i>improvement</i>	the objective pursued in the sphere of the <i>project</i> is that of steering the paediatric cardiology and cardiac surgery centres towards an approach of ongoing improvement. As a result, the model itself, its requirements and its implemented procedures must be improved over time with a view to a tendency to excellence.

The next chapter, *The definition of the professional accreditation model*, is a brief history of the **Baby Heart Project**, of its organisational structure and the achieved results. It is the nucleus of the manual and it is subdivided into two parts: the first is dedicated to the requirements for accreditation of excellence of a paediatric cardiology and cardiac surgery centre and the second focuses on the added requirements for the accreditation of excellence of those centres which also deal with adult congenital heart disease patients through dedicated sectors.

In the third chapter, *The training of assessors*, there is a description of the training course and the achieved results.

The descriptive part of the *Manual* concludes on page 33 with an evaluation of the *Prospects for future development* of the **Baby Heart Project**.

In Appendix 1, the requirements defined within the sphere of the project, which are subject to periodic fine-tuning and updating, are found.

In Appendix 2, the volume of activity related to the period from 2005 to 2007 of the cardiac surgery and cardiology centres which participated in the **Baby Heart Project** is reported.



## 2. The definition of the model for professional accreditation

### Requirements for the accreditation of excellence of the paediatric cardiac surgery and cardiology centre (up to 18 years of age)

#### *The organising bodies and participating centres*

The Baby Heart Project, begun at the end of 2005 and promoted by the Italian Society of Paediatric Cardiology and by the Section of Paediatric and Adolescent Cardiac Surgery of the Italian Society of Cardiac Surgery, was proposed to all members. Eight hundred paediatric cardiac surgeons and cardiologists subscribed to the project and they have supported it economically through the signing of a contract with CERMET. Each centre has participated in the project with its own cardiologists and cardiac surgeons who have offered their scientific contribution.

#### Centres which have participated in the Baby Heart Project

Centre	Institution	Location	Professionals
Cardiovascular Department	I.R.C.C.S. Istituto Giannina Gaslini	Genoa	Dr. Lucio Zannini Dr. Giacomo Pongiglione Dr. Ubaldo Rosati
Paediatric Cardiology Surgery Department	I.R.C.C.S. Ospedale Pediatrico Bambino Gesù	Rome	Dr. Roberto Di Donato Dr. Stephen P. Sanders Dr. Sonia Albanese
Department of Paediatric Cardiology and Paediatric Cardiac Surgery	Ospedale G. Pasquinucci	Massa	Dr. Sandra Giusti Dr. V. Stefano Luisi
Department of Paediatric Cardiology and Cardiac Surgery and of adult congenital heart disease	Policlinico San Donato	San Donato Milanese	Dr. Massimo Chessa Dr. Alessandro Frigiola Dr. Mario Carminati Dr. Giuseppe Pomè
Centre for Paediatric and Adolescent Cardiology and Paediatric and Adolescent Cardiac Surgery	Policlinico Sant'Orsola Malpighi	Bologna	Prof. Fernando Picchio Prof. Gaetano Gargiulo Dr. Roberto Formigari Dr. Carlo Pace Napoleone
Paediatric Cardiology and Cardiac Surgery Centre	Università di Padova	Padua	Dr. Giovanni Stellin Dr. Ornella Milanese Dr. Massimo Paladino Dr. Roberta Biffanti
Paediatric Surgery Centre	Ospedale Arnas Civico	Palermo	Dr. Carlo Marcelletti Dr. Davide Calvaruso Dr. Antonio Rubino
Department of Paediatric Cardiology and Cardiac Surgery	Ospedale Infantile Regina Margherita	Turin	Dr. Piero Abruzzese Dr. Stefano Longo Dr. Donato Montemurro

***The aim of the project***

The most meaningful aim of the project pursued by the team was that of developing excellence in specialist services in the paediatric cardiology and cardiac surgery sectors by stimulating emulation mechanisms.

The premise is that excellence in the provision of specialist services includes structural, organizational and technical-professional elements.

In particular, the project proposes to develop the following **general objectives**:

- to guarantee adequate care;
- to verify the effectiveness of the service;
- to promote ongoing training and the exchange of knowledge and experience;
- to stimulate improvement in the quality of healthcare professionals, not only from the point of view of technical skills, but also in the ability to work within a structured and organised system;
- to identify the structural characteristics, the volume of work, the main treatment therapies and the necessary result indexes in order to achieve certain quality standards during the diagnostic-therapeutic treatment of a congenital pathology occurring in paediatric patients and, during adulthood, as far as the treatment pertains to heart patients affected by congenital heart disease;

and the following **specific objectives**:

- to define the professional requirements that represent the common value shared by those interested in the provision of specialist services;
- to define management and organisational requirements in order to guarantee the quality of the environment in which the clinical practice is carried out;
- to define and improve the provision of specialist services;
- to enhance the contribution of the professionals in the management of the supply process for the specialist services;
- to enhance the opportunity for paediatric cardiology and cardiac surgery centres to obtain professional accreditation. The goal is that of making the commitment undertaken in professional management and technical administration visible and recognisable to the market for excellence in the provision of healthcare services.

***Regulations and the Project Outline***

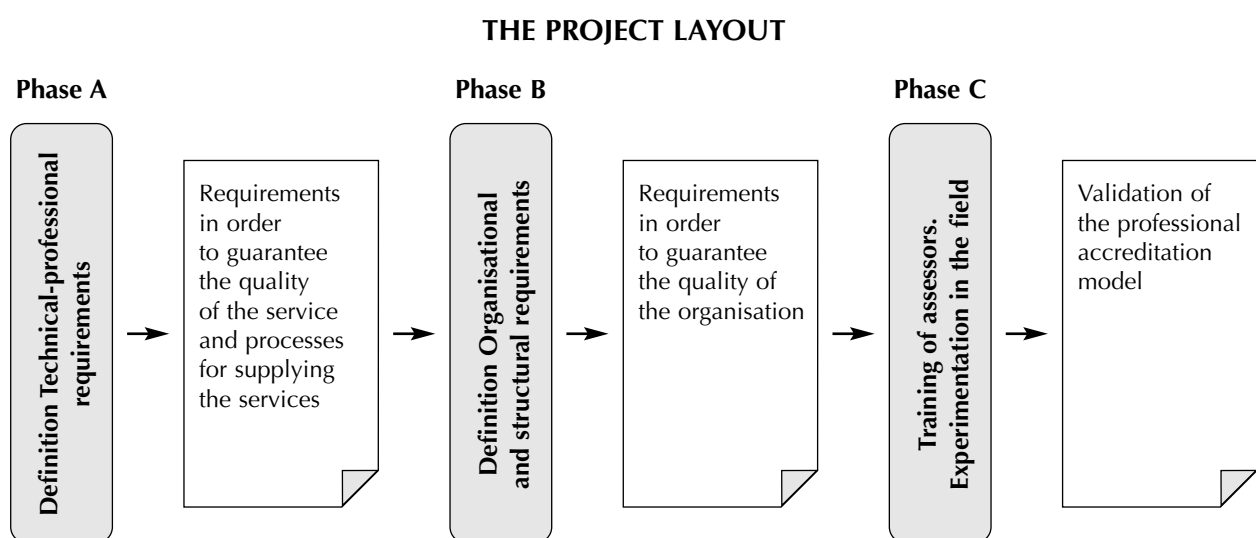
In order to pursue the aim of the project and the general and specific objectives, the team adopted regulations approved by the participating centres and listed hereafter.

**Regulations for the management of the Baby Heart Project**

1. The Paediatric and Adolescent Cardiac Surgery section of the Italian Society for Cardiac Surgery and the Italian Society of Paediatric Cardiology supervised the team's work through its representative Dr Giancarlo Crupi with respect to the contractual commitments.

2. CERMET is responsible for the technical coordination of the team and it makes use of the collaboration of an expert in the field.
3. The contracting centres contribute to the realisation of the project by supplying their technical-scientific knowledge.
4. The team is supported by a technical secretary whose tasks are:
  - to convene the participants for meetings;
  - to prepare the material for the meetings;
  - to take the minutes of the outcomes of the meetings;
  - to supply logistic-organisational support to the team members.
5. The team intends to work in the following manner:
  - initial sharing and approval of the programme of activities and related general calendar;
  - agreement on the date of the next meeting by majority vote in accordance with the general programme at the end of each meeting;
  - in case of dispute, CERMET takes the final decisions;
  - the meetings are valid when the majority of the team members are present;
  - justification for absence which lowers the participant quorum is allowed.
6. Decisions taken during the meetings are ratified by the majority of those present.
7. All of the team meetings are held in Bologna, preferably at CERMET in Via Cadriano, 23 in Cadriano di Granarolo.

In accordance with the defined rules, the team has developed its activities as shown in the following table:



Phases A and B of the project outline have led to the identification of the technical-professional requirements and of those that are structural and managerial in order to guarantee organisational,

methodological and service quality. Phase C involves the training of assessors in charge of verifying respect to the identified requirements by the paediatric cardiology and cardiac surgery centres. Phase C also includes a further experimental phase in the field of the developed model in order to test its true application for subsequent validation. This phase, not yet implemented, will be extended to all interested paediatric cardiology and cardiac surgery centres as well as involving centres participating in the project.

### ***Data collection form***

Preparatory to phases A and B, a data collection form was written and filled in by the centres in order to collect information of the state-of-the-art which would serve as a reference for the definition of the standards that a paediatric cardiology and cardiac surgery centre of excellence must possess. The data collection form contains, in brief, the following items (see Appendix 1, page 37 for the complete version):

- registry;
- name of the centre;
- client base;
- amount of surgical and cardiological activity;
- index of complexity (*Aristotle Score*) referring to all case histories up 18 years old: average value/year;
- index of complexity (*Aristotle Score*) exclusively referring to open-heart surgeries up to 18 years of age: average value/year;
- structural and organisational set-up;
- equipment of the personnel.

### ***Standard form***

The completion of the data collection form by the centres and the subsequent plenary discussion have allowed for the identification of the requirements, which were extrapolated and summarised in the standard form (see Appendix 1, page 53).

This form identifies the quantitative and qualitative requirements which a level III centre of excellence must have. These types of centres are defined as “departmental type structures where paediatric cardiology/cardiac surgery activities are performed”. The standard form contains, in brief, the following items:

- definition of Level III Centre;
- classification criteria of Level III Centre;
- centre policy;
- volume of surgical activity;
- volume of cardiological activity;
- structural and organisational set-up;
- number and equipment in the operating theatre;
- instruments for cardio-pulmonary bypass;
- general equipment of the surgical service;
- number and equipment for the hemodynamic room;

- characteristics and equipment in the paediatric cardiology-cardiac surgery ICU;
- characteristics of the IT system;
- medical personnel (*clinical competence, job description*) of the Level III centre: identification criteria.

Where it is held to be pertinent, the requirements are defined in relation to two types of level III centre, identifying the minimum standards of activity:

### **Criteria for the identification of a level III centre**

**Centre A:** performs up to 250 surgical procedures and up to 150 intervention procedures with about 400 intakes into intensive care

**Centre B:** performs up to 400 surgical procedures and up to 250 intervention procedures with about 600 intakes into intensive care

Minimum standard for cardiac surgery activities: 200 operations

Minimum standard for cardiological activities: 120 intervention procedures

In order to safeguard a suitable professional cause in the definition of the requirements, the team decided to share the drawing up of the standard form with their anaesthetist colleagues for the parts believed to be their competence.

The anaesthetists worked in the *back office* acting on the behalf of CERMET and they attended a team meeting to validate the requirements proposed with regards to the following topics:

- organisational set-up of the Anaesthesia and Reanimation Service;
- management and organisation of Intensive Care Units;
- *job description* of the paediatric cardio-anaesthetist;
- *clinical competence* of the paediatric cardio-anaesthetist;
- number and equipment in the operating theatres;
- number and equipment in the hemodynamic rooms;
- number of beds and equipment in the Intensive Care Unit.

Some of the anaesthetists involved followed the entire validation process of the standards in their sphere and contributed to the adjustment of the model.

### Anaesthetists who contributed to the Baby Heart Project

Centre	Institution	Location	Professional
Cardiovascular Department	I.R.C.C.S. Istituto Giannina Gaslini	Genoa	Dr. Elisabetta Lampugnani
Paediatric Cardiology Surgery Department	I.R.C.C.S. Ospedale Pediatrico Bambino Gesù	Rome	Dr. Sergio Picardo
Department of Paediatric Cardiology and Paediatric Cardiac Surgery	Ospedale G. Pasquinucci	Massa	Dr. Riccardo Moschetti
Department of Paediatric Cardiology and Cardiac Surgery and of adult congenital heart disease	Policlinico San Donato	San Donato Milanese	Dr. Marco Ranucci Dr. Concetta Carlucci
Centre for Paediatric and Adolescent Cardiology and Paediatric and Adolescent Cardiac Surgery	Policlinico Sant'Orsola Malpighi	Bologna	Dr. Guido Frascaroli
Paediatric Cardiology and Cardiac Surgery Centre	Università di Padova	Padua	Dr. Paola Cogo Dr. Raffaele Bonato
Paediatric Surgery Centre	Ospedale Arnas Civico	Palermo	Dr. Daniele Monteverde
Department of Paediatric Cardiology and Cardiac Surgery	Ospedale Infantile Regina Margherita	Turin	Dr. Sergio Grassitelli Dr. Alberta Rizzo

### **Organisational and procedural requirements**

The data collection form and the standard form prepared and favoured reflection with regards to organisational and procedural requirements in order to guarantee the management quality of a level III centre.

The organisational and procedural requirements related to the ideal path for the patient, from admission to discharge, have been proposed by CERMET in the form of a self-evaluation form completed in the *back office* by the team. The processing of the data collected and the observations which emerged allowed the plenary discussion and subsequent validation.

**Organisational requirements** (Appendix 1, pg. 63) and the **process requirements** (Appendix 1, pg. 77) express the approach of the “quality system” that a level III centre should adopt in order to guarantee the improvement of its performance over time. These requirements are derived from the UNI EN ISO 9001:2000 regulations with the intent of facilitating the possible need to integrate the system of excellence for paediatric cardiology and cardiac surgery with systems already existing within the centres (authorisation, state accreditation, certification, etc.). In selecting the proposed organisational requirements, those with direct impact on the control of the process of healthcare service performance and on user satisfaction, safeguarding their central position within the system, were preferred. The requirements were reduced compared to those foreseen by ISO 9001:2000, simplified and translated into a specific language.

### **Document system**

Quality Manual

Documents

Registrations

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### **Policy, objectives and review**

Policy

Objectives

Review

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### **Organisation**

Responsibility and Authority

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### **Resources**

Human resources

– internal communication

– training and research

Technological resources

Infrastructure and work environment

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### **Planning and supply of services**

Planning

Supply (see process requirements)

Supply and preservation of consumables

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### **External communication system**

Communication with the user

Information in the phase of:

– reception and acceptance into care

– performance of the service

– transfer and/or discharge

– *follow-up*

---

### **Measurements, analysis, improvement**

Client satisfaction

Clinical audit

Management of non-conformities, corrective and preventative measures

According to the same logic that guided the team in the definition of the organisational requirements, the **process requirements** were defined, that is, those related to the management of the patient's course of treatment, with reference to the main phases of the diagnostic, therapeutic and care course (see following table).

**Reception**

- emergency patients
- elective patients

**Diagnosis and Treatment**

- diagnostic classification
- prescription and administration of treatment
- medical and nursing care

**Pre-operative period**

- management of the surgical list
- anaesthesiologic preparation
- management of the anaesthesiologic record and surgical registry

**Intra-operative period**

- entrance into operating theatre
- operation
- awakening

**Post-operative period****Transfer and/or discharge*****Follow-up******Product requirements***

Surely the most important commitment of the team consisted in the definition of product requirements, that is, the technical-professional requirements for the following pathologies (Appendix 1, pg. 85).

**Pathologies of surgical interest****Age group****Pathology**

&lt; 30 days

Hypoplastic left heart syndrome  
Isolated ductus arteriosus coarctation of the aorta  
Transposition of the great vessels with intact septum

1-12 months

Tetralogy of Fallot  
Complete atrioventricular septal defect

1-18 years

Partial atrioventricular septal defect  
Sub-aortic fibromuscular stenosis  
Total cavo-pulmonary connection  
Right ventricular– pulmonary artery conduit substitution

### Pathologies of medical interest

Chronic Insufficiency

Paroxysmal Tachycardia

Intervention:     – critical aortic valve stenosis  
                           – pulmonary branches stenosis (angioplasty and/or stent)  
                           – re-coarctation (angioplasty and/or stent)

The product requirements were defined using the following methods:

- each centre was given the task of developing a form for an assigned pathology in accordance with a defined format which foresaw the definition of one or two indicators for monitoring the aspects which were significant and/or believed to be critical during the journey of a patient affected by the indicated pathology, corresponding with each significant phase (prenatal, postnatal, *follow-up*);
- each centre was asked to associate the identified indicators with the Baby Heart standards, correlating them to suitable bibliographical sources;
- the forms, drawn up in the *back office*, were first sent to CERMET which took care of collation and sending them to the team members for accurate analysis for subsequent plenary discussions;
- the “pathology forms”, after a phase of content sharing among the sub-teams, were subjected to review by the whole team. For further details of the product requirements, see attachment (Appendix 1, pg. 85).

### Added requirements for the accreditation of excellence for the centre which deals with adult congenital heart disease

Over the last 40 years, improvements in surgical treatment have radically changed the natural history of patient affected by congenital heart disease.

In fact, about 85% of the children with congenital heart disease currently have the possibility of reaching adulthood and this percentage is destined to increase in the next 20 years.

In Italy, patients with congenital heart diseases who have reached adulthood number about 75.000, even if this statistic is only indicative since there are no accurate statistics.

A recent study, conducted in England, has performed a retrospective analysis of all of the births in the Newcastle region between 1985 and 1994 and it has hypothesised that the incidence of adults with a congenital heart disease who need *follow-up* should be more than 200 cases for every 100.000 live births, and, that is, more than 1.600 cases every year if one considers a national population of 50 million inhabitants. This data can be extrapolated for the Italian population.

Adult congenital heart disease patients have a greater risk of secondary problems (pulmonary and systemic hypotension, kidney problems, haematological pathologies, coronary pathologies and arrhythmia, etc.) with serious consequences for treatment, both medical and general.

About 55% of these patients could be a mid-high risk for sudden death, repeat surgery or greater complications and therefore require regular treatment at a specialist centre.

**Conditions which require ongoing care in a specialist centre**

Cardiopathies corrected with valved and non-valved conduits  
 Cyanogenic cardiopathies  
 Double outlet right ventricle  
 Eisenmenger's syndrome  
 Fontan procedure (all types)  
 Mitral atresia  
 Serious Ebstein's anomaly  
 Pulmonary atresia with variously corrected intact septum  
 Pathologies with pulmonary hypertension  
 Congenitally corrected trans position of the great vessels  
 Transposition of the great arteries with physiological (Senning/Mustard procedure)  
 or anatomical correction  
 Surgically corrected Truncus arteriosus  
 Serious aortic stenosis/insufficiency after replacement with valve prosthetic or after Ross  
 surgery (pulmonary autograft)  
 Pathologies operated on with palliative operations (systemic-pulmonary shunts)

About 45% of the patients with heart diseases involving light or moderate hemodynamics do not require ongoing checks at specialist centres but they can equally benefit from a specialist evaluation in order to have specific information about possible risks and limitations.

**Conditions which require periodic evaluation at a centre for adult congenital heart disease**

Aortic-ventricular fistula  
 Partial or total anomalous pulmonary venous return  
 Partial or total atrioventricular canal after surgical correction  
 Ebstein anomaly  
 Atrial septal defects  
 Small ventricular septal defects  
 Patent ductus arteriosus  
 Moderate-severe pulmonary valve stenosis  
 Coronary fistula  
 Aortic sub- and supra-ventricular stenosis  
 Moderate aortic valve stenosis  
 Moderate aortic insufficiency  
 Tetralogy of Fallot after surgical correction  
 Aortic coarctation

The passage from childhood to adulthood is especially difficult and intermittent and inadequate care could favour the appearance of further problems and complications.

The attending doctor may, in fact, change for various reasons, impairing the possibility of a complete communication of information to the new attending doctor. Therefore, it is easy to understand what damage may occur with the interruption of the care chain, or, better yet, its dispersion without careful organisation similar to that created to care for the same patient in childhood. The commitment of necessary human and financial resources in order to follow congenital heart disease patients to adulthood is quite considerable.

Anglo Saxon countries were the first to create a monitoring system for this problem by discussing which system would be the most efficient and least costly in order to care for congenital heart disease patients even in adulthood.

Therefore, the first step is to identify the specific needs of these patients, or rather:

- managing the transition into adulthood;
- supplying specific information.

Each patient/family should be well informed about:

- evolutionary potential of the pathology (*follow-up*);
- contraception;
- pregnancy;
- risk of recurrence;
- work and physical capabilities.

Based on these assumptions, the centres participating in the ***Baby Heart Project*** decided to complete the accreditation model by adding those requirements which are indispensable for a centre which has set up sectors dedicated to the care and study of adult congenital heart disease patients. The decision was taken from a viewpoint of stimulating debate and of favouring collaboration and willingness on the part of all of the clinically independent centres to diffuse, as widely as possible, cultural knowledge in this field with the goal of creating a network of centres of excellence.

### ***Data Collection Form, Standard Form and Product Requirements for adult congenital heart disease patients***

The team accepted the challenge of including the added requirements that apply to centres which deal with adult congenital heart disease patients in their accreditation model. The objective is that of increasing awareness of the need, both from a healthcare planning point of view and from that of the medical culture, of taking care of adult congenital heart disease patients by referring to requirements and standards of excellence.

After a first data collection, obtained from the six centres that take care of adult congenital heart disease patients (see following table), the drafting of a data collection form (Appendix 1 pg. 101), a standard form (Appendix 1, pg. 107) and two pathology forms referring to typical pathologies (Appendix 1, pg. 114 and 115) followed.

Centre	Institution	Location
Paediatric Cardiology Surgery Department	I.R.C.C.S. Ospedale Pediatrico Bambino Gesù	Rome
Department of Paediatric Cardiology and Paediatric Cardiac Surgery	Ospedale G. Pasquinucci	Massa
Department of Paediatric Cardiology and Cardiac Surgery and of adult congenital heart disease	Policlinico San Donato	San Donato Milanese
Centre for Paediatric and Adolescent Cardiology and Paediatric and Adolescent Cardiac Surgery	Policlinico Sant'Orsola Malpighi	Bologna
Paediatric Cardiology and Cardiac Surgery Centre	Università di Padova	Padua
Paediatric Surgery Centre	Ospedale Arnas Civico	Palermo

The standard form identifies the added, quantitative and qualitative requirements a Level III centre that takes care of adult patients with congenital heart disease must have.

The organisational and procedural requirements, instead, were not changed since those already in place were held to be valid and exhaustive (except those obvious adaptations highlighted directly on the forms already drafted).

The methodology followed was essentially the same as that adopted for the paediatric part, even if the majority of the work was developed in the back office. Still, all of the centres collaborated and supervised the drafting and the definitive validation of the added requirements, also helped by the anaesthetists who attended the meetings from time to time.

The final part of the work regarded the drafting of the product requirements which, for the adult congenital heart disease patients, are shown in the following pathology forms:

- inter-arterial defect;
- Tetralogy of Fallot.

### 3. The training of assessors

#### The aims of training and the group of participants

As foreseen by the project outline (see page 19), PHASE C of the project involved the training of a group of participants, chosen by the centres which participated in the project, in the methods and techniques of conducting inspections aimed at subsequent experimentation and later at a field trial of the developed professional accreditation model.

#### The group of participants

Centre	Institution	Location	Professional
Cardiovascular Department	I.R.C.C.S. Istituto Giannina Gaslini	Genoa	Dr. Lucio Zannini Dr. Ubaldo Rosati
Paediatric Cardiology Surgery Department	I.R.C.C.S. Ospedale Pediatico Bambino Gesù	Rome	Dr. Sonia Albanese
Department of Paediatric Cardiology and Paediatric Cardiac Surgery	Ospedale G. Pasquinucci	Massa	Dr. Michela Rial
Department of Paediatric Cardiology and Cardiac Surgery and of adult congenital heart disease	Policlinico San Donato	San Donato Milanese	Dr. Mario Carminati
Centre for Paediatric and Adolescent Cardiology and Paediatric and Adolescent Cardiac Surgery	Policlinico Sant'Orsola Malpighi	Bologna	Dr. Roberto Formigari Dr. Carlo Pace Napoleone
Paediatric Cardiology and Cardiac Surgery Centre	Università di Padova	Padua	Dr. Massimo Padalino Dr. Roberta Biffanti
Paediatric Surgery Centre	Ospedale Arnas Civico	Palermo	Dr. Nicoletta Salviato Dr. Antonio Capodicasa
Department of Paediatric Cardiology and Cardiac Surgery	Ospedale Infantile Regina Margherita	Turin	Dr. Stefano Longo Dr. Laura Odetto

The training of the assessors was done through attendance of a CERMET course called CEPAS (Body of Certification of Professionalism and Training) for assessors of quality management systems in the health-care sector valid for subsequent third party certification.

The following training objectives were intended to be achieved with the course:

- knowledge and understanding of the international regulations by which the audits must be performed;
- knowledge of the regulations which regulate the authorisation to practice and the accreditation of healthcare structures;

- knowledge of the audit methods and processes listed in the UNI EN ISO 19011:2003;
- know-how of planning and conducting the audits;
- know-how of obtaining and correctly evaluating the objective evidence;
- know-how of presenting the results and writing audit reports;
- development and consolidation of suitable attitudes and behaviour for effectively conducting the audits.

## The training programme

The course, which lasted a total of 40 hours and was divided into two phases in April 2007, is divided into the following training modules:

### The training modules

#### MODULE 1 (duration: 3 hours)

- Voluntary and mandatory certification
- The main regulations of reference for quality management systems: UNI CEI EN series 45000, UNI EN ISO series 9000:2000, UNI EN ISO 19011:2003; UNI CEI EN ISO/IEC 17025

#### Individual practice (duration 1 hour)

Multiple choice test on knowledge of regulations

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#### MODULE 2 (duration: 3 hours)

- The concepts of authorisation and accreditation in the healthcare field: national reference framework
- Regulatory evolution in Italy; the main legislative references: D.Lgs 502/517 of 92/93, DPR 14/1/97, D. Lgs. 229/99, The National Healthcare Plan and Regional Plans
- State accreditation and decisional autonomy of the regions (model examples of regional accreditation)
- The Authorisation, Accreditation, Contractual Agreements path
- The organisational requirements for authorisation interpreted as the first nucleus of a quality management system: general and specific requirements.
- The size of the organisation for authorisation; general requirements:
  - policy, objectives and activity;
  - the organisational structure;
  - human resource management;
  - management of technological resources;
  - management, evaluation and improvement of quality, guidelines and internal regulations;
  - the IT system.

#### Individual practice (duration: 1 hour)

Multiple choice test on the national regulatory framework dealing with authorisation and accreditation

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#### MODULE 3 (duration: 4 hours)

- Types of audits and mention of the aims of preliminary audits
- Planning the audit:
  - communication with the organisation being audited: the notification
  - selecting the audit team: the difference between the roles within the team and in the management of the audit;
  - preparation of the audit and team meeting.
- The preparation of the audit:
  - documentation analysis: the pre-examination of the case;
  - preparation and use of checklists: the checklist;
  - opening meeting: planning and timing.
- Performing the audit:

- the behaviour of the auditor with regards to the parties: roles, behaviour and the most common causes for error;
  - the emphasis of the findings: classification, techniques and investigation method, reporting;
  - the discussion between the parties: the final meeting.
  - The *follow-up*
  - The evaluation of quality in the healthcare field (VRQ; analytic QC, etc.)
  - Ethical code of the certified auditor
  - Outline of the CEPAS certification for the auditor in the healthcare sector
- Group practice** (duration: 4 hours)
- Audit planning simulation:
- reading and analysis of company documents;
  - preparation of the audit plan.
- Discussion
- 

#### MODULE 4 (duration: 8 hours)

- Group practice
  - Preparation of the checklist
  - Simulation of the performance of an audit
  - Evaluation of non-conformities
  - Drafting of the audit report
  - Closing meeting
  - Discussion of results
- 

#### MODULE 5 (duration: 4 hours)

- The evaluation of a ISO 9000 quality management system in healthcare structures:
    - structures for acute and post-acute admission on continuous cycle and day hospital;
    - residential and semi-residential structures;
    - diagnostic and/or therapeutic outpatient structures;
    - home care.
  - Relationship of elements/objectives in the QMS in a healthcare structure
  - Integrated systems in Healthcare (Quality/Safety/Environment)
  - Legislation applicable to quality and safety in healthcare services
  - Differences and priorities of reference documentation in healthcare
  - Elements of industrial metrology, statistical techniques, reliability techniques (*failure analysis*) applicable to the sector
- Group practice** (duration: 4 hours)
- Identification of the critical processes and factors to police in healthcare structures
- 

## Training results

The course ended with a final exam lasting eight hours, thus divided:

### *Final exam*

- written general test on the course material
- written specific test on the regulations and on the ability to interpret the situations on the topic of the audits
- written test on topics related to the healthcare sector
- oral test to further examine the topics treated and evaluation of the personal character of the candidate and aptitude for the role of Auditor or Lead Auditor of QMS – Healthcare

All of the participants sat the final exam since they conformed to the admission requirements, that is:

- they attended the lessons (allowed absence rate not higher than 5% of the 40 hours);
- they actively participated in the practice sessions in the training modules.

All of the participants positively passed the exam.

All of the participants received a certificate of attendance and passing grade of the final exam for the course for “Quality Management Systems in Healthcare Assessor” valid for subsequent certification by independent third party bodies. In addition, they were given 30 educational credits that were assigned to the course by the National ECM Commission

At the end of the training activity, the participants gave their opinions on the course.

### ***Processing of the opinion questionnaire***

- 67% gave a GOOD mark to the coherence of the contents in relation to the objectives presented at the beginning
- 78% held that the topics were treated in an exhaustive manner
- an EXCELLENT mark was given to the trainers (Prof. Alfano, Engineer. Brolli, Dr. Cavallo) for their interaction with the participants and clear explanations
- 67% held that the logistic aspect was GOOD
- 78% considered the help supplied by the CERMET personnel as EXCELLENT.

## Conclusions and development prospects

In full awareness of the need for ongoing fine-tuning for the improvement of the professional accreditation model developed within the sphere of the **Baby Heart Project**, it is held that the work done represents a valid reference for the centres that voluntarily intend to take on a path of organisational and technical-professional excellence.

A first and unavoidable step, necessary for testing the applicability of the model in the field, foresees the start-up of an experimental phase for the implementation of the project by paediatric cardiology and cardiac surgery centres. From the experimental application of the model, the collection of indications and of the standards defined for the organisation, processes and services that will be useful for the revision of the requirements and subsequent validation by the Section of Paediatric and Adolescent Cardiac Surgery of the Italian Society of Cardiac Surgery and by the Italian Society of Paediatric Cardiology is expected.

The following step, to be hoped for with respect to the validation of the professional accreditation model in the field, is the definition of the rules for managing the accreditation procedure in all of its phases, that is: from the presentation of the request by the interested centres, to the evaluation of the fulfilment of the defined requirements, to the issuing of the accreditation, to the periodic maintenance up to the possible annulment, suspension and/or revocation.

The rules for professional accreditation should be defined in accordance with principles such as:

- impartiality in the technical-operative management of the certification process and thus the uniformity of the treatment for whomsoever presents the certification request;
- independence in the audit activity for the issuing of the certification and thus the absence of conflicts of interest;
- cultural, technical and professional competence of the personnel authorised to do the audit for certification,

with the end result of giving credibility to the process and to guarantee its sustainability even on a state level.

The final goal, the most ambitious, should be the recognition by institutions of the work done within the sphere of the **Baby Heart Project** so that it is taken into account during the national and regional planning of the value of professional accreditation on the developments in paediatric cardiology and cardiac surgery.

In perspective, a positive trend, for emulation, towards the improvement of the service offered by paediatric cardiology and cardiac surgery centres on the whole is expected, to the benefit of the satisfaction of the patient, family members and, more generally, of the interested parties.



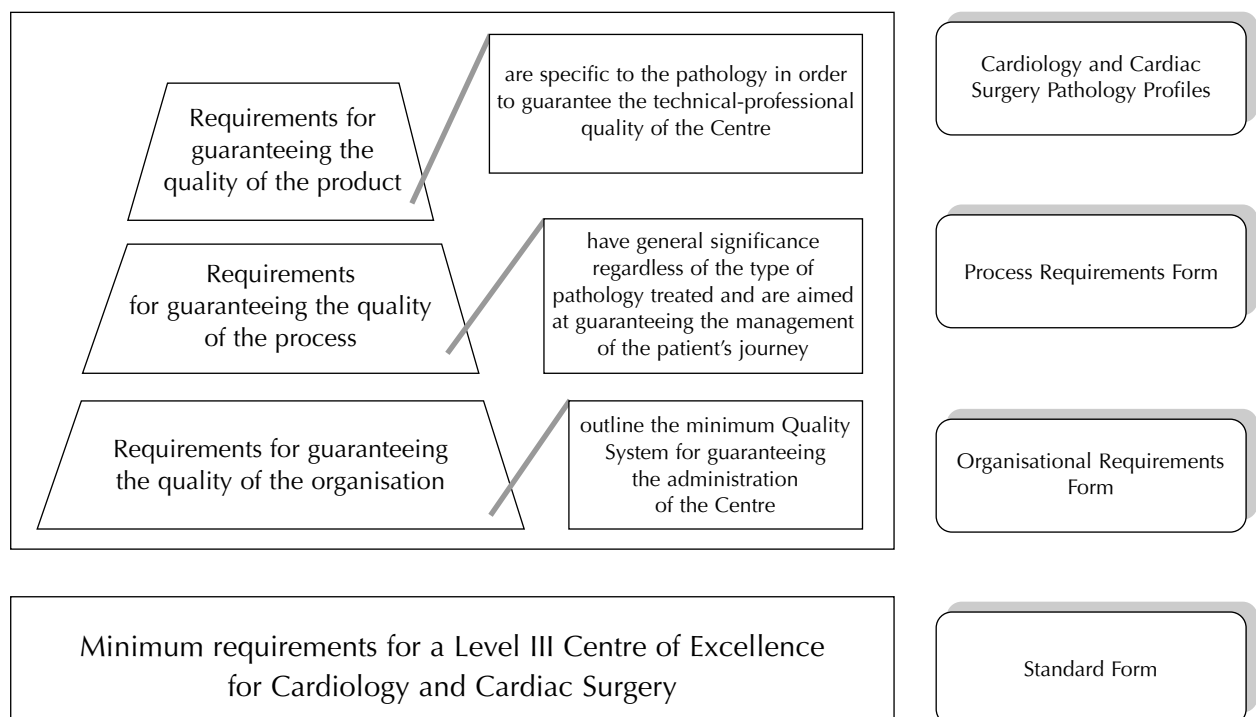
# Appendix 1

## Premise on reading the requirements

The attachments below show the requirements that the Level III Cardiology and Cardiac Surgery Centres which handle paediatric and adolescent patients must demonstrate as having in order to conform to that requested by the Professional Accreditation Model in the sphere of the **Baby Heart Project**.

In addition to the above-mentioned requirements, those referring to a centre that deals with the study and care of adult patients affected by a congenital heart disease were identified.

All of the requirements are structured with the method described in the following table:



The data collection form (pg. 37) used as a reference basis for the definition of the requirements should be placed at the top of this table.

It is necessary to repeat that the requirements are subject to periodic review with the objective of guaranteeing:

- even better exemplification in order to avoid comprehension problems;
- adaptation to the changes in science and professional culture in order to make them even more of a valid reference for our scientific community.

In addition, it is held to be suitable to differentiate regarding the relationship between the requirements laid out by the Model of Professional Accreditation developed in the sphere of the **Baby Heart Project** and other possible requirements that the Paediatric Cardiology and Cardiac Surgery Centres must satisfy with regards to State Accreditation or desire for certification based on the ISO 9001:2000 regulations.

The national landscape is decidedly varied partly due to choices made (or not made) autonomously by the individual regions on the topic of state accreditation, and partly due to the various paths that the healthcare institutions to which the centres belong may have followed the theme of quality administration, management and improvement.

Consequently, some centres may or may not have already developed quality systems, or at least structure organisational models which respond to different regulations.

The effort made in the sphere of the **Baby Heart Project** was that of proposing a collection of requirements that:

- could emerge as a complete model for administering management and technical-professional quality for centres which have not yet faced the structural development of their own quality system;
- could steer towards integration of its management model for centres which have already adopted a quality system (based on regional, corporate prodding or own desire). In these situations, it is assumed that some proposed requirements (with especial reference to those of an organisational and procedural type) may be already satisfied by the existing system.

### Forms contained in Appendix 1

Data collection form . . . . .	p. 37
Standard form . . . . .	p. 53
Organisational requirements form . . . . .	p. 63
Process requirements form . . . . .	p. 77
Product requirements form . . . . .	p. 85
Data collection form for adult congenital heart disease patients . . . . .	p. 101
Standard form for adult congenital heart disease patients . . . . .	p. 107
Product requirements form for adult congenital heart disease patients . . . . .	p. 113

# Data collection form

## Registry

Home institution: .....

**Paediatric Centre** (specify the name of the structure which carries out paediatric cardiology and cardiac surgery activities)

.....  
.....

Structure:                       university hospital                       hospital                       scientific/research institution

Location (address): .....

.....

## User base

(specify % of cardiological admittance)

region .....

outside region .....

## User base

(specify % of cardiac surgery admittance)

region .....

outside region .....

**Data collection form (continued)**

**Organisational layout**

The Centre is part of a department/Macro-structure?  Department (meaning single formally constituted cardiology-cardiac surgery department)  Macrostructure (meaning functional aggregation of UU.OO belonging to the same institution)

Briefly describe the organisational context (ref. organigram)

.....

.....

.....

.....

.....

.....

The Centre is part of a hospital which is exclusively paediatric?  Yes  No

If NO, the hospital has the following services with recognised and formalised paediatric competences even in agreement with other institutions?

	Yes	No	In agreement
Anaesthesia and reanimation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nephrology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neurology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
General Surgery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paediatrics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Level II and III Neonatology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24 hour Hemodynamics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neurosurgery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Genetics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chemistry and microbiology lab	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Radiology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Physiokinetic therapy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The Centre is linked to a birthing point?  Yes  No

(by "linked" meaning the existence of a formalised procedure which describes the responsibility and criteria to manage the transfer of a neonatal heart patient)

The Centre is able to admit cardiological and cardiac surgery emergencies within 24 hours?  Yes  No

## Data Collection Form (continued)

Definition criteria of the volume of surgical activity<sup>(1)</sup>

**Number of patients operated on/year** (no. HDF/year) DRG 103, 104, 105, 108\*, 110, 111, 479

(\* DRG 108 excluding cardiology intervention proceduresa)

	Number	Deceased	% mortality
Newborns (< 30 days)	.....	.....	.....
1 month-1 year	.....	.....	.....
1-18 years	.....	.....	.....
> 18 years (adult congenital heart patients)	.....	.....	.....
Total	.....	.....	.....

**Number of cardiac surgery operations**

(Operator registers)

	Total	< 1 month	< 1 year	between 1 and 18 years
Heart Transplant	.....	.....	.....	.....
Lung Transplant	.....	.....	.....	.....
Open heart surgeries	.....	.....	.....	.....
Closed heart corrective surgeries	.....	.....	.....	.....
Closed heart palliative surgeries	.....	.....	.....	.....
Number of circulatory care	.....	.....	.....	.....
Number of other procedures	.....	.....	.....	.....
Total	.....	.....	.....	.....

Outpatient closures of the arteriosus ductus in premature babies

Percentage of closed heart palliative surgeries of the total closed heart operations

*Total number of cardiac surgeries:* open heart and closed heart operations; circulatory assist, other treatments connected to the treatment of a heart patient (sternal closure, reopening, position of drains, pacemaker implantation, etc.)

*Closed heart:* heart or great vessels surgery without cardio-pulmonary bypass

*Palliative surgery:* systemic-pulmonary binding and shunting surgery

Index of complexity (*Aristotle score*) referring to all cases up to 18 years:

average value/year .....

Index of complexity (*Aristotle score*) exclusively referred to open heart surgeries up to 18 years:

average value/year .....

1. The data for surgical activity are divided from the surgical register but must be registered on the "Congenital Database of the European Association for Cardiothoracic Surgery" to allow for the evaluation of the complexity score and of the quality indicators of the Centre.

**Data Collection Form** (continued)**Criteria for defining the volume of cardiologic activity**

<b>System for service supply</b>	<b>Outpatient and consultancy</b>	<b>Admittance</b>
Number of echocardiograms	.....	.....
Number of foetal echocardiograms	.....	.....
Number of transesophageal echocardiograms	.....	.....
Number of computerised axial tomography tests	.....	.....
Number of Magnetic Nuclear Resonance tests	.....	.....
Number of cardio-pulmonary function studies	.....	.....
Number of Holter ECGs	.....	.....
Number of Holter APBMs	.....	.....
Total number of cardiac catheter insertions	.....	.....
- number of diagnostic catheter insertions	.....	.....
- number of biopsies	.....	.....
- number of intervention catheter insertions	.....	.....
- number of hybrid procedures (foresee the presence of a cardiac surgeon)	.....	.....
Number of electro-physical studies	.....	.....
- number of arrhythmia ablation studies	.....	.....
Number of emergencies (catheter insertion within 24 hours of admittance of the child)	.....	.....

**Data Collection Form** (continued)**Structural and organisational analysis**

Responsibility of stay (centre of cost)	<input type="radio"/> Only Cardiology <input type="radio"/> Cardiology and Cardiac Surgery, separated <input type="radio"/> Cardiology and Cardiac Surgery mixed	
Topography of stay	<input type="radio"/> Single	<input type="radio"/> Separated
Total number of beds (cardiology and cardiac surgery)		
– ward	.....	
– day hospital	.....	
– semi-intensive	.....	
Total number of rooms (excluding semi-intensive)	.....	
Semi-intensive beds	<input type="radio"/> N/A <input type="radio"/> placed in ward <input type="radio"/> another location	
	<b>Yes</b>	<b>No</b>
Is there a waiting room?	<input type="radio"/>	<input type="radio"/>
Is there a lunchroom?	<input type="radio"/>	<input type="radio"/>
Is there an interview room?	<input type="radio"/>	<input type="radio"/>
Is there a meeting room?	<input type="radio"/>	<input type="radio"/>
Is there a playroom?	<input type="radio"/>	<input type="radio"/>
Are the children's wards in common with the adult wards?	<input type="radio"/>	<input type="radio"/>
Is there the possibility of a bed for the parent?	<input type="radio"/>	<input type="radio"/>
Is telemetry available?	<input type="radio"/>	<input type="radio"/>
Number of monitored ward beds (at least ECG – transcutaneous pulsioximeter)	.....	
Number of cardiac surgery operating theatres:		
– dedicated to paediatric cardiac surgery	.....	
– shared with adult cardiac surgery	.....	
– shared with other specialties	.....	
Location of operating theatre	<b>Yes</b>	<b>No</b>
near intensive care (meaning in the same building on the same floor)	<input type="radio"/>	<input type="radio"/>
near the hemodynamic room (meaning in the same building on the same floor)	<input type="radio"/>	<input type="radio"/>

\* Semi-intensive is a structure with centralised, oxygen supply and aspiration monitoring system. The nursing staff present is a ratio of 1:4 in three shifts.

## Data Collection Form (continued)

<b>Equipment and instruments</b>		
<b>Operating theatre equipment</b>	<b>Yes</b>	<b>No</b>
X-ray transparent operating table	<input type="radio"/>	<input type="radio"/>
Electrosurgery	<input type="radio"/>	<input type="radio"/>
Double container aspirator device	<input type="radio"/>	<input type="radio"/>
Lighted source for head lamp	<input type="radio"/>	<input type="radio"/>
Equipment for arrhythmia ablation (even shared with hemodynamics)	<input type="radio"/>	<input type="radio"/>
Video tower for videoscope	<input type="radio"/>	<input type="radio"/>
<b>Instruments for cardio-pulmonary bypass</b>	<b>Yes</b>	<b>No</b>
Heart-lung machine (5 heads + 1 reserve)	<input type="radio"/>	<input type="radio"/>
Hot-cold block + thermal exchange mattress	<input type="radio"/>	<input type="radio"/>
Air-oxygen mixer for gaseous exchanges	<input type="radio"/>	<input type="radio"/>
Blood recovery machine and haemoconcentrators for auto-transfusion	<input type="radio"/>	<input type="radio"/>
Two centrifugal pumps for possible ventricular assistance	<input type="radio"/>	<input type="radio"/>
Online analyser of arterial blood gas	<input type="radio"/>	<input type="radio"/>
<b>Anaesthesia instruments</b>	<b>Yes</b>	<b>No</b>
Inhaled FiO <sub>2</sub>	<input type="radio"/>	<input type="radio"/>
Pressure and volume alarms (visible and audible)	<input type="radio"/>	<input type="radio"/>
Anaesthetic gas supply system (halogenated-nitrous oxide)	<input type="radio"/>	<input type="radio"/>
Double trace module for ECG monitoring	<input type="radio"/>	<input type="radio"/>
Double trace module for blood pressure monitoring	<input type="radio"/>	<input type="radio"/>
Module for non-invasive monitoring of pressure	<input type="radio"/>	<input type="radio"/>
Module for CO <sub>2</sub> end exhalation monitoring	<input type="radio"/>	<input type="radio"/>
Module for transcutaneous pulsioximeter monitoring	<input type="radio"/>	<input type="radio"/>
Module for monitoring 2 temperatures	<input type="radio"/>	<input type="radio"/>
Defibrillator	<input type="radio"/>	<input type="radio"/>
Fibrillator	<input type="radio"/>	<input type="radio"/>
Twin-chamber Pacemaker	<input type="radio"/>	<input type="radio"/>
Echocardiography with paediatric transesophageal probe (even shared with cardiology)	<input type="radio"/>	<input type="radio"/>
Blood gas analysis machine	<input type="radio"/>	<input type="radio"/>
ACT (activated clotting time) machine	<input type="radio"/>	<input type="radio"/>
System for supply and analysis of nitric oxide (even shared with intensive care)	<input type="radio"/>	<input type="radio"/>
Additional active air heating system	<input type="radio"/>	<input type="radio"/>
Cerebral saturation monitor (N.I.R.S.) (even shared with intensive care)	<input type="radio"/>	<input type="radio"/>
Thromboelastography	<input type="radio"/>	<input type="radio"/>

Are part of the operating theatre equipment such as blood fridges, boilers, ice machine, defroster for plasma, balloon pumps.

( continued)

<b>Equipment in hemodynamic room</b>	<b>Yes</b>	<b>No</b>
Hemodynamic with digital imaging acquisition	<input type="radio"/>	<input type="radio"/>
Filmless production on magnetic formats (CD, DVD)	<input type="radio"/>	<input type="radio"/>
Biplane scope	<input type="radio"/>	<input type="radio"/>
Defibrillator in the room	<input type="radio"/>	<input type="radio"/>
Availability in the room of temporary pacemakers and related stimulator electrodes	<input type="radio"/>	<input type="radio"/>
Availability in the room of magnets for asynchronous stimulation of pacemakers	<input type="radio"/>	<input type="radio"/>
Material for Seldinger technique percutaneous injection for paediatric and neonatal patients	<input type="radio"/>	<input type="radio"/>
Availability of equipment for blood gas analysis in the room (not including thermal lamps as accepted equipment)	<input type="radio"/>	<input type="radio"/>
Availability of catheters for atrial septostomy	<input type="radio"/>	<input type="radio"/>
Temperature controlled heating system for patients (si esclude lampada termica come dispositivo ammesso)	<input type="radio"/>	<input type="radio"/>
Disponibilità cateteri per atriosettostomia ( <i>Rashkind</i> )	<input type="radio"/>	<input type="radio"/>
Ventilator and intubation material constantly available in the room	<input type="radio"/>	<input type="radio"/>
Oxygen consumption measuring devices	<input type="radio"/>	<input type="radio"/>
Dedicated transesophageal probes (even shared with operating theatres or echocardiography labs)	<input type="radio"/>	<input type="radio"/>
Dedicated echocardiography	<input type="radio"/>	<input type="radio"/>
Number of pumps for contrast medium injection	.....	.....
Availability of low osmolarity contrast medium (300 ± 50 mosml/kg)	<input type="radio"/>	<input type="radio"/>
Availability of an ACT ( <i>Activated Clotting Time</i> ) measuring device	<input type="radio"/>	<input type="radio"/>
Availability of a nitric oxide nozzle	<input type="radio"/>	<input type="radio"/>
Number of nurses dedicated to the individual procedures	.....	.....
Radiology technician available	<input type="radio"/>	<input type="radio"/>
Hemodynamic room located close to the department, intensive care and operating theatre regarding the centre	<input type="radio"/>	<input type="radio"/>
Room and nursing/technical personnel available 24 hours for emergencies	<input type="radio"/>	<input type="radio"/>
Anaesthetist service available for 100% of the paediatric procedures	<input type="radio"/>	<input type="radio"/>
Computerised management of material stock (catheters, introducers, devices, etc.)	<input type="radio"/>	<input type="radio"/>
Extra stock available, if necessary, even during the procedure	<input type="radio"/>	<input type="radio"/>
Is there a surgical preparation/awakening room available?	<input type="radio"/>	<input type="radio"/>
Average number of elective cases able to be performed during the week (emergencies excluded)	.....	.....

## Data Collection Form (continued)

## Paediatric cardiology-cardiac surgery Intensive Care Unit

<b>Number of beds</b>	.....	
<b>The ICU is located near:</b>	<b>Yes</b>	<b>No</b>
wards	<input type="radio"/>	<input type="radio"/>
cardiac surgery operating theatre	<input type="radio"/>	<input type="radio"/>
hemodynamic room	<input type="radio"/>	<input type="radio"/>
general paediatric intensive care unit	<input type="radio"/>	<input type="radio"/>
Is there a dedicated waiting room?	<input type="radio"/>	<input type="radio"/>
<b>Intensive care is:</b>	<b>Yes</b>	<b>No</b>
autonomous	<input type="radio"/>	<input type="radio"/>
run by a dedicated manager	<input type="radio"/>	<input type="radio"/>
integrated within the general paediatric ICU	<input type="radio"/>	<input type="radio"/>
integrated within the adult cardiac surgery ICU	<input type="radio"/>	<input type="radio"/>
<b>Intensive care is managed by:</b>	<b>Yes</b>	<b>No</b>
anaesthetists	<input type="radio"/>	<input type="radio"/>
cardiac surgeons	<input type="radio"/>	<input type="radio"/>
intensivists	<input type="radio"/>	<input type="radio"/>
cardiologists	<input type="radio"/>	<input type="radio"/>
<b>Intensive care has:</b>	<b>Yes</b>	<b>No</b>
equipped beams for beds	<input type="radio"/>	<input type="radio"/>
blood data monitors including end-tidal CO <sub>2</sub> and registration device	<input type="radio"/>	<input type="radio"/>
volumetric and peristaltic infusion pumps	<input type="radio"/>	<input type="radio"/>
thermal cradle, preferably with scale	<input type="radio"/>	<input type="radio"/>
defibrillator	<input type="radio"/>	<input type="radio"/>
circuit for nitric oxide	<input type="radio"/>	<input type="radio"/>
head or scialytic lamp (even shared with operating theatre)	<input type="radio"/>	<input type="radio"/>
blood gases analyzer	<input type="radio"/>	<input type="radio"/>
patient heating/cooling system	<input type="radio"/>	<input type="radio"/>
external pacemaker	<input type="radio"/>	<input type="radio"/>
ultrafiltration/dialysis machine	<input type="radio"/>	<input type="radio"/>
radiology device	<input type="radio"/>	<input type="radio"/>
brilliance amplifier (even shared)	<input type="radio"/>	<input type="radio"/>
computer	<input type="radio"/>	<input type="radio"/>

**Data Collection Form** (continued)**IT system: hardware**

<b>Network characteristics</b>	<b>Yes</b>	<b>No</b>
non-existent	<input type="radio"/>	<input type="radio"/>
autonomous from centre	<input type="radio"/>	<input type="radio"/>
centralised (hospital institution)	<input type="radio"/>	<input type="radio"/>
wireless	<input type="radio"/>	<input type="radio"/>
other (please specify)	<input type="radio"/>	<input type="radio"/>

---

<b>Number of PCs</b>	<b>Networked</b>	<b>Autonomous</b>
administration area (public wickets, offices, archive)	Yes ( . . . . . )*	Yes ( . . . . . )*
medical offices area (doctor's offices, meeting rooms, library, etc.)	Yes ( . . . . . )*	Yes ( . . . . . )*
surgical area (operating theatre, hemodynamics room)	Yes ( . . . . . )*	Yes ( . . . . . )*
outpatient clinic (examination room, echocardiography, ECO, etc.)	Yes ( . . . . . )*	Yes ( . . . . . )*
intensive care, semi-intensive care (excluding pc already counted in doctor's offices and similar)	Yes ( . . . . . )*	Yes ( . . . . . )*
wards (excluding doctor's offices and nursing stations)	Yes ( . . . . . )*	Yes ( . . . . . )*
nursing stations (ward head, treatment rooms, stockroom, etc.)	Yes ( . . . . . )*	Yes ( . . . . . )*
laptops belonging to institution	Yes ( . . . . . )*	Yes ( . . . . . )*
other accessories (specify type and quantity)	Yes ( . . . . . )*	Yes ( . . . . . )*
video projector	Yes ( . . . . . )*	Yes ( . . . . . )*

\* = specify number.

**Data Collection Form** (continued)**IT system: software****Database used**

- none
- personalised
- pre-packaged
- subscription to national and/or international databases
- hospital's computerised chart

**Regularly archived data****Administrative\*****Reporting\*****Outpatient clinic**

- examinations  Yes  Yes
- EKG  Yes  Yes
- echocardiogram  Yes  Yes
- foetal echocardiogram  Yes  Yes
- ergometry  Yes  Yes
- holter  Yes  Yes
- pacemaker check up  Yes  Yes

**Wards (doctors)****Administrative\*****Reporting\***

- admittance  Yes  Yes
- day-hospital  Yes  Yes
- daily clinical diary  Yes  Yes
- consulting  Yes  Yes
- x-rays  Yes  Yes
- laboratory tests  Yes  Yes
- treatment prescription  Yes  Yes
- discharge letter  Yes  Yes
- final summary  Yes  Yes
- H.D.F.  Yes  Yes

**Wards (nurses)****Administrative\*****Reporting\***

- vital parameters  Yes  Yes
- water balance  Yes  Yes
- test schedule  Yes  Yes
- exams performed  Yes  Yes
- therapy supplied  Yes  Yes
- end of shift turn-over  Yes  Yes

(continued)

<b>Intensive care (doctors)</b>	<b>Administrative*</b>	<b>Reporting*</b>
admittance	<input type="radio"/> Yes	<input type="radio"/> Yes
day-hospital	<input type="radio"/> Yes	<input type="radio"/> Yes
daily clinical diary	<input type="radio"/> Yes	<input type="radio"/> Yes
consulting	<input type="radio"/> Yes	<input type="radio"/> Yes
x-rays	<input type="radio"/> Yes	<input type="radio"/> Yes
laboratory tests	<input type="radio"/> Yes	<input type="radio"/> Yes
treatment prescription	<input type="radio"/> Yes	<input type="radio"/> Yes
discharge letter	<input type="radio"/> Yes	<input type="radio"/> Yes
final summary	<input type="radio"/> Yes	<input type="radio"/> Yes
S.D.O.	<input type="radio"/> Yes	<input type="radio"/> Yes
<hr/>		
<b>Intensive care (nurses)</b>		
vital parameters	<input type="radio"/> Yes	<input type="radio"/> Yes
water balance	<input type="radio"/> Yes	<input type="radio"/> Yes
test schedule	<input type="radio"/> Yes	<input type="radio"/> Yes
exams performed	<input type="radio"/> Yes	<input type="radio"/> Yes
therapy supplied	<input type="radio"/> Yes	<input type="radio"/> Yes
end of shift turn-over	<input type="radio"/> Yes	<input type="radio"/> Yes
<hr/>		
<b>Surgical activities</b>		
surgeries	<input type="radio"/> Yes	<input type="radio"/> Yes
cardio-pulmonary details	<input type="radio"/> Yes	<input type="radio"/> Yes
circulation assistance details	<input type="radio"/> Yes	<input type="radio"/> Yes
cardiac catheter	<input type="radio"/> Yes	<input type="radio"/> Yes
pacemaker insertion and form	<input type="radio"/> Yes	<input type="radio"/> Yes
<hr/>		
<b>Other</b>		
deceased	<input type="radio"/> Yes	<input type="radio"/> Yes
autopsies	<input type="radio"/> Yes	<input type="radio"/> Yes
statistics	<input type="radio"/> Yes	<input type="radio"/> Yes

\* "Administrative" data means the reporting of the event with reference to patient's personal details, "reporting" means the actual writing of the report or clinical report which is given to the patient or filed in the chart

## Data Collection Form (continued)

**Echocardiography Service Equipment**

<b>Number of machines (for paediatric patients)</b>	.....
<b>Number of transducers (for paediatric patients) of which:</b>	.....
10-12 mHz	.....
5-8 mHz	.....
3-4 mHz	.....
Transesophageal probes for adults	.....
Transesophageal probes for paediatric patients	.....
Number of examination rooms	.....
Presence of echocardiography technicians	.....
<b>How are the images filed?</b>	<input type="radio"/> video tape <input type="radio"/> digital disc <input type="radio"/> hard disk <input type="radio"/> on the network
<b>How are the reports created?</b>	<input type="radio"/> word processor <input type="radio"/> reporting software: <input type="radio"/> owned <input type="radio"/> developed in-house
<b>How are reports filed?</b> (more than one answer possible)	<input type="radio"/> documents in file folders <input type="radio"/> digitalisation on local hard disks <input type="radio"/> digitalisation on network <input type="radio"/> in the clinical charts
<b>Available methods of echocardiography:</b>	
2-D / Doppler / CFM	Yes ( . . . . )*    No
Tissue Doppler	Yes ( . . . . )*    No
3-D ECHO in real time	Yes ( . . . . )*    No

*(continued)***Type of tests performed:**

anatomical evaluation (indicates a complete echocardiogram, Doppler and colour flow evaluation)	Yes ( . . . . )*	No
ventricular function evaluation (indicates echocardiography and Doppler evaluation of the systolic and diastolic ventricular function)	Yes ( . . . . )*	No
echocardiogram under stress	Yes ( . . . . )*	No
transesophageal echocardiogram:		
– intra-surgery	Yes ( . . . . )*	No
– in hemodynamics	Yes ( . . . . )*	No
– elsewhere	Yes ( . . . . )*	No
foetal echocardiogram	Yes ( . . . . )*	No
Are tests performed under sedation?	Yes ( . . . . )*	No
Is hemodynamic monitoring possible? (cardiac frequency, transcutaneous pulsioximeter, arterial pressure)	Yes ( . . . . )*	No
Is an external analysis possible for echocardiograms (measurements calculations, etc...)?	Yes ( . . . . )*	No
Is there a station where echocardiograms are evaluated by other doctors?	Yes ( . . . . )*	No

\* = specify number of operational machines working in this manner.

**Data Collection Form** *(continued)***Personnel**

	<b>Number</b> (full time)
Cardiac Surgeon	.....
Cardiologist	.....
Anaesthetist/Intensivists	.....
Paediatrician/Neonatologist	.....
Perfusionists	.....
Ward Head	.....
<hr/>	
<b>Distribution per shift</b>	<b>Number</b> (full time)
ICU nurses	.....
Ward nurses	.....
Nurses per individual outpatient clinic	.....
Operating theatre nurses (for each theatre)	.....
Hemodynamics nurse (for each room)	.....
X-ray technician in hemodynamics	.....
Physiotherapist	.....
Administrative/secretarial personnel	.....
Auxiliary personnel	.....

**Data Collection Form** *(continued)*

**Quality paths**

The structure has already faced or was involved in structured paths regarding:	<b>Yes</b>	<b>No</b>
state accreditation	<input type="radio"/>	<input type="radio"/>
professional accreditation	<input type="radio"/>	<input type="radio"/>
ISO 9000 certification	<input type="radio"/>	<input type="radio"/>
quality Review check	<input type="radio"/>	<input type="radio"/>
total Quality Management	<input type="radio"/>	<input type="radio"/>
clinical audit	<input type="radio"/>	<input type="radio"/>
joint Commission	<input type="radio"/>	<input type="radio"/>
other (please specify) .....		
none .....		
if yes, for how long? .....		

	<b>Yes</b>	<b>No</b>
Has a “quality” manager/referent already been identified in the structure?	<input type="radio"/>	<input type="radio"/>
If yes, please indicate name and qualification(s) .....		

	<b>Yes</b>	<b>No</b>
Does the structure have written procedures or instructions which were drawn up in advance on an institutional, facility or departmental level, regarding specific processes or activities?	<input type="radio"/>	<input type="radio"/>

If yes, please list them here (indicate type of document and title) .....

Date \_\_\_\_\_

Signature \_\_\_\_\_



## Standard form

### Definition of a Level III Centre

Departmental-type structure where paediatric cardiological/cardiac surgery activities are performed (up to 18 years old).

---

### Classification criteria for a Level III Centre

**Centre A:** performs up to 250 surgical procedures and up to 150 intervention procedures with about 400 admittances to intensive care

**Centre B:** performs up to 400 surgical procedures and up to 250 intervention procedures with about 650 admittances to intensive care

---

### Policy

To offer hospitalisation and outpatient services to the beneficiaries of the National Healthcare Service in accordance to that foreseen by current legislation.

To treat patients up to 18 years old

To put the patient at the centre of diagnostic, treatment and care choices

To pursue selectivity of care paths

To favour advanced technologies

To look after scientific research

To favour professional training

To pursue the search for quality of the services offered

To promote and sustain information and awareness policies for prenatal diagnosis

---

**Standard form (continued)****Volume of surgical activity**

- Number of surgeries, up to 18 years of age, on the heart and great vessels with or without cardio-pulmonary bypass excluding : circulatory aid, pacemaker insertion, reopening, drain positioning/differed sternal closure, sternal infections and other minor operations as deduced from the surgical register:
  - **value which guarantees the achievement of quality standards: 250 operations**
  - **minimum standard: 200 operations**
- *Complexity Score* of the operations up to 18 years of age on the heart and great vessels with or without cardio-pulmonary bypass excluding : circulatory aid, pacemaker insertion, reopening, drain positioning/differed sternal closure, sternal infections and other minor operation: > 6
- Number of closed heart operations not greater than 40% of the total heart and great vessel surgeries with cardio-pulmonary bypass
- Relationship between the number of cardio-pulmonary bypass operations performed within the first year of life and the total number of cardio-pulmonary bypass surgeries not less than 50%

---

The data on surgical activity is deduced from the surgical register but must also be registered on the “*Congenital Database*” of the “*European Association for Cardiothoracic Surgery*” in order to permit the evaluation of the complexity score and of the centre quality indicators

**Volume of cardiological activity**

- Number of intervention procedures:
    - **number of intervention procedures in order to guarantee quality standards: 150**
    - **minimum standard: 120**
-

**Standard form** *(continued)***Structural and organisational layout**

- If the Centre is not within an exclusively paediatric hospital, the hospital must have the following services with paediatric competence:
  - anaesthesia and reanimation;
  - 24 hour hemodynamic availability;
  - chemistry and microbiology laboratory;
  - radiology.

---

- The Centre must be linked to a birth point  
(by linked it is meant that there is a formalised procedure that describes the responsibility and criteria for managing the transfer of the neonatal heart patient)
- The Centre must have a single cardiology and cardiac surgery ward

---

- The ward must not be the same one as the adult ward

---

- Ward, operating theatre and intensive care must be adjacent (same building, same floor)

---

- There must be a bed for the parent

---

- There must be beds protected with centralised monitoring (oxygen supply and aspiration system)

---

- The anaesthesia and reanimation service is composed of a complex operative unit for managing the paediatric cardiac surgery operating theatre, hemodynamic/radiology rooms and for managing the departmental on-line (ward + intensive care unit)

---

- The Centre must have:
  - a waiting room;
  - an interview room;
  - a meeting room;
  - a playroom.

---

- Availability of telemetry both in the intensive care unit and in the departmental ward

---

**Standard form (continued)****Operating theatre**

**Centre A:** a dedicated theatre + one available, if necessary, for emergencies

**Centre B:** two dedicated theatres

**Operating theatre equipment**

x-ray transparent operating table  
 electrosurgery  
 double container aspirator device  
 lighted source for head lamp  
 equipment for arrhythmia ablation (even shared with hemodynamics)

**Anaesthesia instruments**

inhaled FiO<sub>2</sub>  
 pressure and volume alarms (visible and audible)  
 anaesthetic gas supply system (halogenated-nitrous oxide)  
 double trace module for ECG monitoring  
 double trace module for blood pressure monitoring  
 module for non-invasive monitoring of pressure  
 module for CO<sub>2</sub> end end-tidal monitoring  
 module for transcutaneous pulsioximeter monitoring  
 module for monitoring 2 temperatures  
 defibrillator  
 fibrillator (even shared)  
 twin-chamber pacemaker  
 echocardiography with paediatric transesophageal probe (even shared with cardiology)  
 blood gas analysis machine (even shared)  
 ACT (*activated clotting time*) device  
 system for supply and analysis of nitric oxide (even shared with intensive care)  
 additional active air heating system  
 cerebral saturation monitor (N.I.R.S.) (anche in condivisione con la terapia intensiva)  
 thromboelastography

**Instruments for cardio-pulmonary bypass**

heart-lung machine (5 heads + 1 reserve)  
 hot-cold block + thermal exchange mattress  
 air-oxygen mixer for gaseous exchanges  
 blood recovery machine and haemoconcentrators for auto-transfusion  
 two centrifugal pumps for possible ventricular assistance  
 online analyser of arterial blood gas

**Surgical complex**

blood fridge  
 boiler  
 ice machine  
 plasma defroster  
 balloon pump

**Standard form (continued)****Hemodynamics room**

**Centre A:** one dedicated room

**Centre B:** one dedicated room

**Equipment that must be available in the hemodynamics room:**

FiO<sub>2</sub> inhalation analysis

automatic respirator with volumetric and pressure alarms (visible and acoustic)

double trace module for ECG monitoring

double trace module for blood pressure monitoring

module for non-invasive monitoring of pressure

module for CO<sub>2</sub> end-tidal monitoring

module for transcutaneous pulsioximeter monitoring

module for monitoring 2 temperatures

defibrillator

hemodynamic with digital imaging acquisition

filmless production on magnetic formats (CD, DVD)

biplane scope

availability in the room of temporary pacemakers and related stimulator electrodes

availability of equipment for blood gas analysis in the room (even shared with the adjacent intensive care operating theatre)

temperature controlled patient heating system

dedicated transesophageal probes (even shared with the operating theatre or echocardiography lab)

echocardiography (even shared)

availability of ACT (*activated clotting time*) measuring (even shared)

availability of nitric oxide nozzle (even shared)

hemodynamic room located very close to the intensive care and operating theatre departments belonging to the centre

room and Nursing/technical staff available 24 hours for emergencies

anaesthesia service available for 100% of the paediatric procedures

existence of a reawakening room or bed dedicated to intensive care

**Standard form** (continued)**Paediatric cardiological-cardiac surgery intensive care unit****Centre A:** 6 beds**Centre B:** 10 beds

The paediatric cardiology-cardiac surgery of the Centre must be located near:

ward

cardiac surgery operating theatre

hemodynamics room

**The intensive care of the Centre must be autonomous and must be managed by a dedicated manager**

<b>Equipment</b>	<b>Centre A</b>	<b>Centre B</b>
equipped bed beam	1/bed	1/bed
blood data monitor with monitoring of end-tidal CO <sub>2</sub> with recording device	1/bed	1/bed
respirator	6	10
volumetric and peristaltic infusion pump	30	50
thermal cradle preferably with scalea	4	6
defibrillator	1	2
nitric oxide circuit	2	3
head or scalytic lamp (even shared with the operating theatre)	1	1
blood gas analyser	1	1
heating/cooling system	1	2
external pacemaker	6	10
ultrafiltration/dialysis equipment	1	2
x-ray equipment	1	1
Brilliance amplifier (even shared)	1	1

**Ward** (the calculation of beds includes possible semi-intensive wards)**Centre A:** 20 beds**Centre B:** 35 beds

**Standard form (continued)****IT system: hardware**

Existence of a corporate IT network

PC connected to network, distributed at least in the following locations:

- wicket/secretary for admittance for outpatients and for all administrative parts;
  - ward (at least in the common room);
  - operating theatre;
  - outpatient clinic;
  - doctors' offices and meeting room;
  - intensive care (at least in reference points);
  - hemodynamics room.
- 

**IT system: software**

Cardiology and cardiac surgery centre database, available 24 hours

Participation in the *European Association for Cardiothoracic Surgery* database

Data effectively and regularly archived:

Outpatient clinic:

- individual outpatient admittance (personal data and collation of each step);
- echocardiogram reports (essential for patient history);
- pacemaker check-up reports (essential for follow-up of functioning).

Ward:

- data of admission and discharge and stay in intensive care;
- individual visits to Day Hospital;
- discharge letter with complete text;
- essential elements of the HDFs.

Operating theatre:

- surgery report with essential data: date, time, type, operators, etc.;
- detailed (and printed) surgery report;
- essential data of the cardio-pulmonary bypass;
- essential data of circulatory aid.

Hemodynamics room:

- cardiac catheter insertions with essential data: date, times, type, operators, etc.;
- cardiac catheter insertion reports (at least description and conclusions);
- highlighting of interventionist catheter insertions;
- pacemaker implantation (with PM characteristics).

General elements:

- data of deaths (with regards to surgeries or other procedures);
  - reference data of possible autopsies;
  - computerised management of stockroom (catheters, introducers, devices, etc.).
-

**Standard form (continued)****Echocardiography service****Laboratory equipment of internal and external patients**

Echocardiography (color, CW, PW)* complete with neonatal, paediatric and adult probe	With reference to outpatient activity** No. devices: one every 10 daily outpatient services (including exams under sedation, TEE and TCD) + one available for intensive care emergencies
Transesophageal probe issued	For each echocardiograph, equipped with probes for neonates (10-12 MHz), paediatric and conventional for adults
Omni-plane transesophageal probe	With reference to possible sharing of the probe with other hemodynamic or operating theatre activities. Minimum standard = 1 Recommended standard = one probe per use excluding for each activity (lab, hemodynamics, theatre)
Omni-plane transesophageal probe for adults	With reference to possible sharing of the probe with other hemodynamic or operating theatre activities. Minimum standard = 1 Recommended standard = one probe per use excluding for each activity (lab, hemodynamics, operating theatre)
Electrocardiogram	Minimum standard = 1
Availability of sedation facilities (chloral hydrate, midazolam, etc.)	Present and monitored
Cardio-respiratory monitor tests under sedation (pulsioximeter)	Minimum standard = 1

\* Tissue-Doppler, echocardiogram-3D considered only in research field.

\*\* Meaning a bi-dimensional/Doppler complete test with issued report.

**Reporting/schedule management**

Computerised management of schedule for external patients	Present
Computerised management of schedule for internal patients	Present
Production of printed report	Within 30 minutes of the end of the test
Archiving:	
– personal data part computerised	Computerised
– complete report	Computerised
– images	On VHS or digital format (network/CD)

**Standard form** (continued)**Personnel****Clinical competence**

Cardiac Surgeon	Performs 120 surgeries/year with cardio-pulmonary bypass and closed heart of which 50% as lead surgeon
Interventionist Cardiologist	Performs 60 interventionist procedures/year
Paediatric Cardio-anaesthetist	In order to acquire the qualification: <ul style="list-style-type: none"> <li>– performs 160 anaesthesia procedures/year (as first or second lead)</li> <li>– 100 presences in Intensive Care</li> </ul> In order to maintain qualification: <ul style="list-style-type: none"> <li>– performs 50 anaesthesia procedures/year (as first or second lead)</li> <li>– 50 presences in Intensive Care</li> </ul>

**Job description**

Paediatric Cardiac Surgeon	Treats paediatric and adolescent congenital heart diseases. Discusses the surgical indications, thus formalising them, with cardiologists and other specialists. Puts the patient on the waiting list. Performs the pre-operative evaluation of the patient and obtains informed consent. Performs the surgical treatment of the patient. Participates in the post-operative treatment of the patient until discharge, also handling the follow-up at a distance.
Paediatric Cardiologist	Handles the diagnosis and treatment of foetal, paediatric and adolescent congenital and acquired heart disease. Discusses the surgical and/or interventionist treatments, thus formalising them, with cardiac surgeons and other specialists. Puts the patient on the cardiological waiting list and obtains informed consent for procedures which require it. Performs medical-intervention treatments. Participates in the post-operative treatment of the patient until discharge and performs follow-ups from a distance.
Paediatric Cardio-anaesthetist	Handles the pre-, intra- and post-operative evaluation and care of paediatric and adolescent congenital and acquired heart disease and anaesthetist aid for hemodynamic investigations and diagnostic aid for images. Discusses the surgical and/or interventionist indications, thus formalising them, with other specialists. Obtains informed consent for the procedures which require it. Participates in the post-operative treatment of the patient until discharge.

**Standard form** (continued)

<b>Personnel</b>	<b>Centre A</b>	<b>Centre B</b>
Cardiac Surgeons	4	7
Cardiologists	8	12
Anaesthetist	12	16
Perfusionists	3	5
Ward Head	4	4
<b>Personnel per shift</b>	<b>Centre A</b>	<b>Centre B</b>
ICU nurses	4+4+4	7+7+7
Ward nurse	4+4+4	6+6+6
Nurses per each outpatient clinic	1+1	1+1
Operating theatre nurses (per room)	4+4	4+4
Hemodynamic nurses (per room)	3+2	3+2
X-ray technician in hemodynamics	2+1	2+1
Physiotherapist	1+1	1+1
Administrative/secretarial personnel	5 (one per sector per settore)	6 (one per sector and one extra for the work load)

- The indicated presence of medical personnel was calculated based on the clinical competence criteria defined above.
- The calculation of nursing staff was made based on the criticality of the patients. Admitting that in Centre A of 6 beds there are two critical patients (care 1:1) and the rest are non-critical (care 1:2) and in Centre B of 10 beds there are 5 critical patients, the hours to cover were counted: hypothesising a shift of 7, there are 49 hours to cover in the morning, the same in the afternoon and 70 at night for a total of 168 hours. The calculation was then multiplied by 365 days (61,320) and divided by 1520, which represents the hours of a unit in a year of work (including holidays, sick days, etc.). This calculation expresses the number of nurses required per shift of 7 (with 0 overtime) which is equal to 40.34. When a reawakening room is present (see Hemodynamics Room), it is necessary to plan for a suitable increase in nursing staff.
- The count of nurses and technicians for hemodynamics took radiology holidays into account (for which an extra unit must be foreseen).
- The presence of anaesthetists also covers on-call in Intensive Care. The On-Call departmental service is outside of this calculation.
- The increase in volume of activity defines an adequate increase in human resources.
- The indicated presence of staff does not include auxiliary personnel.

## Organisational requirements form

### The documentation system

Quality manual	Yes	No	Note
Does the Centre have and update a document (e.g. quality manual) which includes:			
– a description of the Centre and its characteristics?	<input type="radio"/>	<input type="radio"/>	.....
– a brief description of the responsibilities and adopted methods in order to guarantee the satisfaction of the requirements for accreditation of excellence?	<input type="radio"/>	<input type="radio"/>	.....
<b>Documents</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Have criteria for the writing, verification, approval and distribution of organisational and technical/professional documents been established?	<input type="radio"/>	<input type="radio"/>	.....
Are there established criteria for ensuring that documents from external sources are identified and their distribution controlled?	<input type="radio"/>	<input type="radio"/>	.....
<b>Recordings</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Have criteria been established for the identification, archiving, protection, availability, definition of preservation date and procedure for cancelling the recordings?	<input type="radio"/>	<input type="radio"/>	.....
Have criteria been established for the completion, preservation, and archiving of the documents attesting to healthcare activity, e.g. clinical chart, nursing charts, reports etc. ?	<input type="radio"/>	<input type="radio"/>	.....

**Organisational requirements form (continued)****Policy, Objectives, Review**

<b>Policy</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Has the Centre defined its quality policy?	<input type="radio"/>	<input type="radio"/>	.....
The quality policy:			
– is in line with the strategic vision of the organisation?	<input type="radio"/>	<input type="radio"/>	.....
Does it include the following commitments?			
– to offer hospitalisation and outpatient services for beneficiaries of the National Healthcare Service in accordance with current legislation;	<input type="radio"/>	<input type="radio"/>	.....
– to treat patients up to 18 years old;	<input type="radio"/>	<input type="radio"/>	.....
– to place patients at the centre of diagnostic, treatment and care choices;	<input type="radio"/>	<input type="radio"/>	.....
– to follow up the selectivity of the care paths;	<input type="radio"/>	<input type="radio"/>	.....
– to favour advanced technology;	<input type="radio"/>	<input type="radio"/>	.....
– to run scientific research;	<input type="radio"/>	<input type="radio"/>	.....
– to promote professional training and refresher courses;	<input type="radio"/>	<input type="radio"/>	.....
– to encourage research into the quality of the offered services;	<input type="radio"/>	<input type="radio"/>	.....
– to promote and sustain information policies and awareness of prenatal diagnosis	<input type="radio"/>	<input type="radio"/>	.....
<b>Additional requirements for adult patients with congenital heart disease</b>			
In addition to the preceding, does the policy include the following commitments:			
– to treat adult patients with congenital heart disease?	<input type="radio"/>	<input type="radio"/>	.....
– to be a reference institution for the “training” of medical and paramedical personnel in the treatment of adult congenital heart disease patients?	<input type="radio"/>	<input type="radio"/>	.....
– to encourage a gradual transition of the congenital heart disease patient’s treatment from the paediatric cardiologist to the adult patient cardiologist as the patient grows from childhood to adulthood?	<input type="radio"/>	<input type="radio"/>	.....
– to encourage counselling for women with congenital heart disease about pregnancy and contraceptives to promote psycho-social assistance for adult patients with congenital heart disease?	<input type="radio"/>	<input type="radio"/>	.....
– to understand commitments within the centre for promotion, at the various levels, of management quality (organisational efficiency), of technical-professional quality (service quality) and of the quality perceived by the users?	<input type="radio"/>	<input type="radio"/>	.....
– to be consistent with its reality in terms of management and development of the available internal and external resources?	<input type="radio"/>	<input type="radio"/>	.....
– to understand the needs and the expectations of the users and of the interested parties?	<input type="radio"/>	<input type="radio"/>	.....

(continued)

– to be shared within the Centre?	<input type="radio"/>	<input type="radio"/>	.....
– to be effectively communicated within the Centre in order to be effectively understood?	<input type="radio"/>	<input type="radio"/>	.....
– to be periodically reviewed and modified when there are changes in the reference situations and/or in operational conditions?	<input type="radio"/>	<input type="radio"/>	.....
<b>Objectives</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Is the quality policy translated into measurable objectives?	<input type="radio"/>	<input type="radio"/>	.....
Are the objectives established according to the levels of the organisation in order to ensure the contribution of the individual functions to their satisfaction and to allow the Centre to effectively monitor and review the results with regards to the individual responsibilities, resource actions?	<input type="radio"/>	<input type="radio"/>	.....
<b>Review</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Does the Centre periodically perform a comprehensive evaluation of the activities (at least review annually)?	<input type="radio"/>	<input type="radio"/>	.....
Does this evaluation look at information on the organisational efficiency and the effectiveness of the healthcare services such as:			
– the state and the results of the quality objectives, including the budget objectives and the objectives defined at a national, regional and local level?	<input type="radio"/>	<input type="radio"/>	.....
– the return data of the users and interested parties?	<input type="radio"/>	<input type="radio"/>	.....
– the degree of satisfaction with the declared quality standards for the performed services?	<input type="radio"/>	<input type="radio"/>	.....
– the state and results of the process and result indicators which allow the evaluation of the correct application of the guidelines used in support of the activity and the effectiveness of the healthcare services?	<input type="radio"/>	<input type="radio"/>	.....
– the results of the clinical audit?	<input type="radio"/>	<input type="radio"/>	.....
– the state and results of implemented research activities/projects in terms of:			
– number of publications produced	<input type="radio"/>	<input type="radio"/>	.....
– number of impact factor points achieved	<input type="radio"/>	<input type="radio"/>	.....
– the ability of the Centre to attract funds and investments	<input type="radio"/>	<input type="radio"/>	.....
Do the results of the evaluation activity include decisions and actions regarding:			
– the improvement of the efficiency and effectiveness of the Centre Administration System and of their administrative and healthcare processes?	<input type="radio"/>	<input type="radio"/>	.....

*(continued)*

– the improvement of the services with relation to the requirements of the users and the interested parties?	<input type="radio"/>	<input type="radio"/>	.....
– the needs of the resources (technological, structural, but also necessary to the realisation f the training plan and research plan)	<input type="radio"/>	<input type="radio"/>	.....
Is the evaluation activity (review) in line with the budget process as a planning and control tool of the objectives assigned to the Centre and placed in relation to the resources necessary for their achievement?	<input type="radio"/>	<input type="radio"/>	.....

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**Organisational requirements form** *(continued)***Organisation****Responsibility and authority**

	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the responsibilities and authority which are the province of each level defined by an organigram that is coherent with reality ?	<input type="radio"/>	<input type="radio"/>	.....
Is the job description of each personnel category (nursing, technical and administrative) and the reciprocal substitution in case of absence defined?	<input type="radio"/>	<input type="radio"/>	.....
Is the individual job description of the medical professionals defined?	<input type="radio"/>	<input type="radio"/>	.....
Is this information known within the Centre so that the organisational roles are clear in terms of responsibility, authority and reciprocal relationships?	<input type="radio"/>	<input type="radio"/>	.....

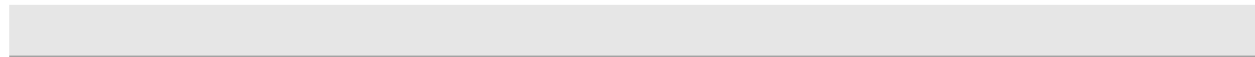
**Organisational requirements form (continued)**

<b>Resources</b>			
<b>Human Resources</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Does the Centre encourage the involvement, motivation and participation of personnel through activities of:			
– awareness, communication, information?	<input type="radio"/>	<input type="radio"/>	.....
– professional training and revision?	<input type="radio"/>	<input type="radio"/>	.....
<b>Internal communication</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Has the Centre defined and implemented an effective and efficient system of communication to make the quality policy, objectives, requirements of the users and interested parties and the achieved results known within the organisation?	<input type="radio"/>	<input type="radio"/>	.....
Is the effectiveness of the communication system ensured through:			
– the analysis of the communication needs linked with the type of healthcare organisation and the characteristics of the services performed?	<input type="radio"/>	<input type="radio"/>	.....
– the definition of the tools, methods and technologies necessary in order to guarantee that the communication is performed in the desired time and manner?	<input type="radio"/>	<input type="radio"/>	.....
– the creation of environmental and human conditions so that communication may be facilitated?	<input type="radio"/>	<input type="radio"/>	.....
Is the creation of environmental and human conditions to facilitate the managerial commitment of the personnel assured through initiatives (course, meeting, etc.) in order to make the personnel aware:			
– of the importance of adopting behaviours coherent with the policy and objectives?	<input type="radio"/>	<input type="radio"/>	.....
– of the significant impact of their activities on the satisfaction of the user?	<input type="radio"/>	<input type="radio"/>	.....
– of the benefits connected to the improvement of services?	<input type="radio"/>	<input type="radio"/>	.....
Do the tools and methods to stimulate the involvement of personnel also include:			
– personnel meetings?	<input type="radio"/>	<input type="radio"/>	.....
– group discussions of clinical cases?	<input type="radio"/>	<input type="radio"/>	.....
– group discussions of criticalities?	<input type="radio"/>	<input type="radio"/>	.....
Is the effectiveness of the communication system periodically evaluated even through the verification of the ability of the Centre to respond appropriately, timely and impartially to the needs expressed by the users? <i>espresso dagli utenti?</i>	<input type="radio"/>	<input type="radio"/>	.....
Are there actions for the ongoing improvement of the communication system?	<input type="radio"/>	<input type="radio"/>	.....

(continued)

<b>Training and research</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Does the Centre have a scientific committee which manages and administrates all of the research and training activities within the organisation?	<input type="radio"/>	<input type="radio"/>	.....
Does the Centre provide for:			
– the determination of the skill needs (education, ability, experience, training) with regards to the assigned role and responsibility?	<input type="radio"/>	<input type="radio"/>	.....
– the supplying of the training necessary for satisfying the identified needs?	<input type="radio"/>	<input type="radio"/>	.....
– the promotion, even through forms of investment allocated according to predefined methods and criteria, of the participation in national and international meetings that are considered relevant?	<input type="radio"/>	<input type="radio"/>	.....
– the evaluation of the effectiveness of the training?	<input type="radio"/>	<input type="radio"/>	.....
– the periodical evaluation of professional performance?	<input type="radio"/>	<input type="radio"/>	.....
– the preservation of relevant appropriate recordings for study, training ability and experience?	<input type="radio"/>	<input type="radio"/>	.....
Has the Centre defined and formalised the definition and implementation of the training plan with a specific procedure (in terms of specifying the manner of definition, formulation and evaluation of training events)?	<input type="radio"/>	<input type="radio"/>	.....
Does the Centre ensure, even through the activity of the scientific committee, the constant and diligent commitment to research?	<input type="radio"/>	<input type="radio"/>	.....
Has the Centre defined and formalised the definition and implementation of the research plan with a specific procedure (in terms of specifying the manner of proposal, definition, formulation and evaluation of research projects)?	<input type="radio"/>	<input type="radio"/>	.....
<b>Technological resources</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Does the Administration ensure the safe, appropriate and economical use of the diagnostic and treatment machines from both a technical and functional point of view?	<input type="radio"/>	<input type="radio"/>	.....
Are the machines appropriately identified and inventoried?	<input type="radio"/>	<input type="radio"/>	.....
Has a plan for the periodic maintenance and calibration of the machines been defined? Does the plan also include checks of functionality and safety as foreseen by regulations?	<input type="radio"/>	<input type="radio"/>	.....
Is the maintenance and calibration plan made known to the various operational levels for the performance of the tasks assigned to the individual staff members?	<input type="radio"/>	<input type="radio"/>	.....
Are the periodic and extraordinary activities of maintenance and calibration suitably registered?	<input type="radio"/>	<input type="radio"/>	.....

(continued)



Does the recorded data permit the formulation of the following information:	Yes	No	Note
– average down-time of a machine?	<input type="radio"/>	<input type="radio"/>	.....
– frequency of malfunction?	<input type="radio"/>	<input type="radio"/>	.....
– type of malfunction?	<input type="radio"/>	<input type="radio"/>	.....
– cost of maintenance?	<input type="radio"/>	<input type="radio"/>	.....

<b>Infrastructures and work environment</b>	Yes	No	Note
Has the Centre defined responsibilities and criteria in order to guarantee the necessary work environment for obtaining conformity to the service requirements and which motivate the personnel to work hard to achieve improvement of the services?	<input type="radio"/>	<input type="radio"/>	.....

**Organisation requirements form (continued)****Planning and supplying of the service**

<b>Planning of the service</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Does the Centre plan and carry out activities of supplying services in controlled conditions in order to:			
– reduce the possibility of clinical and organisational errors to a minimum?	<input type="radio"/>	<input type="radio"/>	.....
– guarantee the achievement of process and result standards in line with the expectations?	<input type="radio"/>	<input type="radio"/>	.....
In particular, does the Centre guarantee:			
– reference to guidelines promoted by Scientific Societies or by groups of experts for good clinical practice?	<input type="radio"/>	<input type="radio"/>	.....
– the use of guidelines and/or internal protocols drawn up and shared with the staff which indicate the manner in which the most frequent or serious clinical events must be managed?	<input type="radio"/>	<input type="radio"/>	.....
– the organisation and use of procedures for the management of clinical, organisational and technological emergencies?	<input type="radio"/>	<input type="radio"/>	.....
– the monitoring and prevention of hospital infections?	<input type="radio"/>	<input type="radio"/>	.....
– the organisation and use of managerial procedures relative to the criticality of the activities?	<input type="radio"/>	<input type="radio"/>	.....
– the availability of operative and pertinent instructions in the workplace?	<input type="radio"/>	<input type="radio"/>	.....
– the use of suitable diagnostic and care devices?	<input type="radio"/>	<input type="radio"/>	.....
– the collection and preservation of recordings that are useful in order to maintain, monitor and improve the quality of diagnostic, therapeutic or care paths?	<input type="radio"/>	<input type="radio"/>	.....
– the clear definition of criteria, procedures and responsibility of the interfaces between various functions (e.g. doctor/nurse/secretary) and/or between the various operations units and support services which concur in the management of the diagnostic, therapeutic and care path?	<input type="radio"/>	<input type="radio"/>	.....
<b>Supplying the service</b>			
See the requirements on the Process requirements form			
<b>Purchasing and storage of consumables</b>			
Has the Centre defined criteria for purchasing and storing consumables?	<input type="radio"/>	<input type="radio"/>	.....
In particular, has the healthcare organisation defined criteria and responsibilities for the management of pharmaceuticals and narcotics with regards to:			
– manner of storage?	<input type="radio"/>	<input type="radio"/>	.....
– manner of preservation?	<input type="radio"/>	<input type="radio"/>	.....
– periodic checks of expiry dates?	<input type="radio"/>	<input type="radio"/>	.....

**Organisational requirements form (continued)****The communication system with the users**

<b>The communication system with the users</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Has the Centre defined and implemented an integrated logic with the internal a communication system, effective manner of communication with the patients and their families and escorts in order to satisfy their expectations and to give them the guarantee of having a clear and known interface which can respond in an effective and timely manner to their needs?	<input type="radio"/>	<input type="radio"/>	.....
Has the Centre defined the criteria for ensuring that all personnel has a suitable communication skill, including knowing the language when appropriate, in order to guarantee effective communication between colleagues and with the patients and their families and escorts throughout all of the phases of the process of supplying the service, that is:			
– booking and reception?	<input type="radio"/>	<input type="radio"/>	.....
– welcome and admittance?	<input type="radio"/>	<input type="radio"/>	.....
– supplying the service?	<input type="radio"/>	<input type="radio"/>	.....
– transfer or discharge?	<input type="radio"/>	<input type="radio"/>	.....
– follow-up?	<input type="radio"/>	<input type="radio"/>	.....
Is the patient adequately informed about their rights and participation throughout all phases of the process of supplying the service?	<input type="radio"/>	<input type="radio"/>	.....
<b>Information during the welcoming and admittance phase</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the responsibilities and criteria of welcoming and admittance of the patient to the Centre defined?	<input type="radio"/>	<input type="radio"/>	.....
Are the responsibilities and criteria defined for collecting patient information in order to identify specific needs in order to favour personalised supply of the service (e.g. religious care, linguistic needs, etc.)?	<input type="radio"/>	<input type="radio"/>	.....
<b>Information during the phase of supplying the service</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the responsibilities and criteria defined for giving correct, clear and exhaustive information to the patient and their families about the diagnosis, treatment of their illness, duration and possible discomforts, irritations and dangers?	<input type="radio"/>	<input type="radio"/>	.....
Are the ways of transferring information about their health and treatment respectful of the rights of the patients with respect to privacy according to the current regulations?	<input type="radio"/>	<input type="radio"/>	.....
Are the responsibilities and criteria defined for the acquisition of informed consent for the various procedures (operation, anaesthesia, transfusion)?	<input type="radio"/>	<input type="radio"/>	.....

(continued)

	<b>Yes</b>	<b>No</b>	<b>Note</b>
Is the consent obtained in written form and signed by the proposing doctor and by at least one parent (for minors) and foresees:			
– Identification of legal guardian and patient	<input type="radio"/>	<input type="radio"/>	.....
– Identification of the doctor who describes the procedure and informs the patient and their family	<input type="radio"/>	<input type="radio"/>	.....
– Description of the procedure			
– Description of potential diagnostic and/or treatment alternatives (cardiologist)	<input type="radio"/>	<input type="radio"/>	.....
– Authorisation for blood product transfusion	<input type="radio"/>	<input type="radio"/>	.....
– Details regarding cardio-pulmonary bypass (cardiac surgeon)	<input type="radio"/>	<input type="radio"/>	.....
– Explanation of the risks according to prearranged categories (anaesthetist), or directly explained to the patient/parents (cardiologist/cardiac surgeon), including life threatening risks	<input type="radio"/>	<input type="radio"/>	.....
– Notification of privacy conditions and the possibility of added and unforeseen (and therefore not illustrated) procedures if the situation requires it in cases of emergency	<input type="radio"/>	<input type="radio"/>	.....
– Signatures of doctor, patient/guardians, possible interpreter, possible witnesses	<input type="radio"/>	<input type="radio"/>	.....
– Illustrated picture of the heart in order to facilitate understanding of the procedure (cardiologist / cardiac surgeon)	<input type="radio"/>	<input type="radio"/>	.....
– Authorisation for the pharmacological use of thyme (cardiac surgeon)	<input type="radio"/>	<input type="radio"/>	.....
Are the patients and their families adequately informed about their responsibilities in case of refusal and/or interruption of the foreseen treatments?	<input type="radio"/>	<input type="radio"/>	.....
<b>The information during the transfer and/or discharge phase</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the responsibilities and criteria defined for the transfer of correct, clear and exhaustive information to the patient and their family and escorts, during the transfer and/or discharge phase?	<input type="radio"/>	<input type="radio"/>	.....
Are the responsibilities and criteria defined for the writing of the letter of discharge?	<input type="radio"/>	<input type="radio"/>	.....
Does the letter of discharge at least contain the following elements:			
– diagnostic picture?	<input type="radio"/>	<input type="radio"/>	.....
– therapeutic suggestions?	<input type="radio"/>	<input type="radio"/>	.....
– follow-up programme?	<input type="radio"/>	<input type="radio"/>	.....
– legible signature of the doctor who treated the patient?	<input type="radio"/>	<input type="radio"/>	.....

(continued)



<b>Information in the follow-up phase</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the responsibilities and criteria defined for the transfer of correct, clear and exhaustive information to the patient and their family during the post-discharge care phase?	<input type="radio"/>	<input type="radio"/>	.....

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**Organisational requirements form (continued)****Measuring, analysis and improvement****Client satisfaction****Yes No Note**

Has the Centre developed and implemented a system to survey the user satisfaction with the healthcare services?

.....

Do the customer satisfaction survey tools used by the healthcare organisation include:

– user complaints?

.....

– satisfaction questionnaires and inquiries?

.....

– the analysis of observed facts?

.....

Does the Centre analyse and use the collected data in order to identify possible areas for improvement in the supplied healthcare services?

**Clinical Audit****Yes No Note**

Does the Centre promote the adoption of systemic procedures of review and self-evaluation by the professionals of the clinical and care practices and of the treatment effectiveness?

.....

**Management of non-conformities, corrective and preventative actions****Yes No Note**

Are the responsibilities and criteria defined for managing problems, non-conformities and undesirable events such as mistakes regarding the prescription/administration of pharmaceuticals, procedural errors, other?

.....

Are the responsibilities and criteria defined for putting into motion actions aimed at avoiding the repetition of the revealed criticalities or preventing their occurrence? (corrective and preventative actions)

.....



## Process requirements form

### Booking

	Yes	No	Note
Are the criteria defined for admittance to the Centre for emergency and elective patients?	<input type="radio"/>	<input type="radio"/>	.....
Are the criteria and the related responsibilities defined for the formulation of the waiting list which take into consideration the necessary information transparency?	<input type="radio"/>	<input type="radio"/>	.....

**Process requirements form** (continued)

<b>Reception</b>			
<b>Reception for emergency patients</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Does reception occur with the coverage of a bed in intensive/semi-intensive care?	<input type="radio"/>	<input type="radio"/>	.....
Is the transport of the patient dependent on the verification of:			
– manner of transport	<input type="radio"/>	<input type="radio"/>	.....
– clinical condition of the patient	<input type="radio"/>	<input type="radio"/>	.....
– time of arrival	<input type="radio"/>	<input type="radio"/>	.....
– type of bed to equip	<input type="radio"/>	<input type="radio"/>	.....
– alert of the cardiologist, cardiac surgeon and anaesthetist	<input type="radio"/>	<input type="radio"/>	.....
Does the transport team supply the receiving doctor with the documentation related to the patient's clinical history and to the conditions of transportation until hospitalisation?	<input type="radio"/>	<input type="radio"/>	.....
<b>Reception of elective patients</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Is the documentation which must accompany the patient at the moment of their entrance/transfer to the Centre defined in order to ensure an effective realisation of the service?	<input type="radio"/>	<input type="radio"/>	.....
Is the reception of the patient preceded by forewarning and does it occur with the consent of the department head?	<input type="radio"/>	<input type="radio"/>	.....
<b>Diagnostic classification</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Have the criteria and responsibilities been established for diagnostic classification, including:			
– the criteria for the collection of anamnestic data	<input type="radio"/>	<input type="radio"/>	.....
– the types of vital parameters to measure as routine and specific to the case	<input type="radio"/>	<input type="radio"/>	.....
– the blood and/or surgical diagnostic procedures	<input type="radio"/>	<input type="radio"/>	.....
– the combined cardiologist-cardiac surgeon evaluation	<input type="radio"/>	<input type="radio"/>	.....
– the completion and management of the clinical-nursing chart	<input type="radio"/>	<input type="radio"/>	.....
Are the criteria and responsibilities defined for the management of interface relationships with healthcare support services for the in-depth diagnostic analysis and/or specialist consultations (doctors, nursing staff, technicians)?	<input type="radio"/>	<input type="radio"/>	.....
<b>Prescription and administration of the treatment</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the criteria and responsibilities defined for the management of the process of prescription and administration of the treatment?	<input type="radio"/>	<input type="radio"/>	.....

(continued)

Are the criteria and responsibilities defined for the management of the process of prescription and administration of blood, blood products and narcotics?	<input type="radio"/>	<input type="radio"/>	.....
Are the prescriptions legible and is it possible to trace them back to their author at any time?	<input type="radio"/>	<input type="radio"/>	.....
Are the criteria and responsibilities defined for the control of the prescriptions with regards to a series of problems such as: allergies, drug interactions, suitability of the dosages, genetic factors that predispose the patient to a greater exposure to the risk of undesirable effects and/or adverse reactions to drugs?	<input type="radio"/>	<input type="radio"/>	.....
<b>Medical and nursing care</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the diagnostic-therapeutic-care protocols for the treatment of the more frequent or serious clinical eventualities available at the Centre?	<input type="radio"/>	<input type="radio"/>	.....
Does the Centre prepare a collection of these documents and does it maintain them up-to-date in order to carry out the more significant technical procedures?	<input type="radio"/>	<input type="radio"/>	.....
Is the personnel informed about the existence of these documents, which must be easily accessible and which must be confirmed and/or updated at least every 3 hours?	<input type="radio"/>	<input type="radio"/>	.....

**Process requirements form (continued)****Pre-operative period**

<b>Management of the surgical list</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the responsibilities and criteria defined for the management of the surgical list?	<input type="radio"/>	<input type="radio"/>	.....
Are the criteria for defining the planning priorities respected, such as:			
– the degree of contamination (placing the dirty or contaminated surgeries or patients with high infection potential at the end of the session)	<input type="radio"/>	<input type="radio"/>	.....
– time commitment (placing the longer lasting surgeries at the beginning of the session)?	<input type="radio"/>	<input type="radio"/>	.....
<b>Anaesthesia preparation</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the rules of shared behaviour defined with regards to the pre-operative examination performance and to the anaesthesiologic evaluation with the classification of the risk stratification criteria?	<input type="radio"/>	<input type="radio"/>	.....
Are these rules defined for the planned surgeries as well as for emergencies?	<input type="radio"/>	<input type="radio"/>	.....
Are the shared behaviour rules defined concerning:			
– the treatment choice	<input type="radio"/>	<input type="radio"/>	.....
– the induction	<input type="radio"/>	<input type="radio"/>	.....
– the monitoring	<input type="radio"/>	<input type="radio"/>	.....
– the reawakening and the recovery of the patient?	<input type="radio"/>	<input type="radio"/>	.....
<b>Management of the anaesthesiologic chart and the surgical register</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the responsibilities and criteria defined for the management of the anaesthesiologic chart and of the surgical register?	<input type="radio"/>	<input type="radio"/>	.....

## Process requirements form (continued)

Intra-operative period			
<b>Entrance into the Operating Theatre</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the transportation procedures to and from the Operating Theatre and the relative responsibilities defined?	<input type="radio"/>	<input type="radio"/>	.....
Are the patient identification procedures on arrival in the Operating Theatre defined?	<input type="radio"/>	<input type="radio"/>	.....
Are the checks that must be made on the patient defined regarding:			
– the correct preparation of the unit for the operation	<input type="radio"/>	<input type="radio"/>	.....
– the laterality of the operation	<input type="radio"/>	<input type="radio"/>	.....
– the positioning of the patient with regards to the type of surgery	<input type="radio"/>	<input type="radio"/>	.....
<b>Operation</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the internal regulations defined which were prepared in collaboration with the staff and which indicate the procedures for the management of the main activities, e.g.:			
– preparation of the surgical instruments and material used for the type of surgery	<input type="radio"/>	<input type="radio"/>	.....
– preparation and contents of the container	<input type="radio"/>	<input type="radio"/>	.....
– count of the surgical instruments and sponges before and after the surgery	<input type="radio"/>	<input type="radio"/>	.....
When held necessary in order to guarantee the standardisation of the activities, were documents prepared regarding:			
– hygienic preparation of the personnel for the surgery	<input type="radio"/>	<input type="radio"/>	.....
– list of the anaesthetist cart material	<input type="radio"/>	<input type="radio"/>	.....
– list of material in the drug locker	<input type="radio"/>	<input type="radio"/>	.....
– list of surgical specialty material	<input type="radio"/>	<input type="radio"/>	.....
– preparation of the material for the specific sterile field for the surgery	<input type="radio"/>	<input type="radio"/>	.....
– positioning of the patient for the type of surgery	<input type="radio"/>	<input type="radio"/>	.....
– antibiotic prophylaxis protocol for the various types of surgeries	<input type="radio"/>	<input type="radio"/>	.....
– list of material and equipment necessary to the transportation of patient to reanimation and intensive care	<input type="radio"/>	<input type="radio"/>	.....
Are the procedures defined for the writing of the surgical report?	<input type="radio"/>	<input type="radio"/>	.....
<b>Reawakening</b>	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the criteria and responsibilities defined for the control of reawakening?	<input type="radio"/>	<input type="radio"/>	.....
Are the criteria and responsibilities defined for the treatment of post-operative pain?	<input type="radio"/>	<input type="radio"/>	.....

**Process requirements form** *(continued)***Post-operative period**

	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the checks to be made defined in relation to the type of surgery?	<input type="radio"/>	<input type="radio"/>	.....
Are the procedures defined for the management of the various surgical drains (monitoring of leaks and criteria for reopening) and of the surgical wounds?	<input type="radio"/>	<input type="radio"/>	.....
Are the protocols defined for the prevention of complications due to immobility (positioning, precocious passive or active immobilisation, postural change in bed, hygiene, bladder catheter if applied)?	<input type="radio"/>	<input type="radio"/>	.....
Are the criteria and responsibilities defined for the transfer of the patient from the Operating Theatre to the ward and/or intensive care?	<input type="radio"/>	<input type="radio"/>	.....
Are the procedures defined for the transmittal of information about the patient from the Operating Theatre to the ward?	<input type="radio"/>	<input type="radio"/>	.....

## Process requirements form (continued)

## Transfer and/or discharge

	Yes	No	Note
Are the criteria and responsibilities defined for the transfer (passage of responsibility) of the patient to another internal or external structure for critical patients with subsequent changes in the admittance procedure?	<input type="radio"/>	<input type="radio"/>	.....
Are the criteria and responsibilities defined for the management of the ordinary discharge of the patient?	<input type="radio"/>	<input type="radio"/>	.....
Are the criteria and responsibilities defined for the discharge process in the various cases:			
– discharge against doctor's orders;	<input type="radio"/>	<input type="radio"/>	.....
– discharge due to death (management of the body);	<input type="radio"/>	<input type="radio"/>	.....
– protected discharge (towards assisted care residence and/or home).	<input type="radio"/>	<input type="radio"/>	.....
Does the Centre, at the time of discharge, supply the patient and doctor in charge of the case with a detailed report in which the following information is found:			
– cardiology anamnestic summary with surgery indication	<input type="radio"/>	<input type="radio"/>	.....
– detailed description of the surgical technique and related procedures;	<input type="radio"/>	<input type="radio"/>	.....
– main intra-operative and post-operative complications in the Intensive Care section such as bleeding, arrhythmia and conduction disorders, low capacity case, need for re-intubation, surgical sepsis, respiratory or renal insufficiency, suspicion of post-operative infection. If temporary prolonged circulatory or ventilation assistance is necessary it is a good idea to specify the reasons, duration and type of system used;	<input type="radio"/>	<input type="radio"/>	.....
– clarification of the clinical conditions or instrument data or lab analyses which did not return to normal or which remain changed, after the the surgery, at the time of discharge;	<input type="radio"/>	<input type="radio"/>	.....
– instructions for the treatment to follow at home, with special emphasis on, in the case where an anticoagulant treatment was adopted, its indications, its dosage and prothrombin time (INR) to maintain and the problems that are linked to that treatment; prescribed secondary prevention measures (hygienic, food and therapeutic) and related suggested checks	<input type="radio"/>	<input type="radio"/>	.....
Is adequate nursing information supplied with care recommendations?	<input type="radio"/>	<input type="radio"/>	.....

**Process requirements form** *(continued)***Follow-up**

	<b>Yes</b>	<b>No</b>	<b>Note</b>
Are the criteria and responsibilities defined for the management of the post-discharge care?	<input type="radio"/>	<input type="radio"/>	.....
Are the cardiologist and cardiac surgeons clearly identified to the family and doctor in charge for the follow-up?	<input type="radio"/>	<input type="radio"/>	.....
Are the clinical controls and instrument blood and non-blood investigations (echocardiogram, transesophageal echocardiogram, holter, lab tests, thorax X-ray, CAT, NMR, NMR-Angiography, biopsy, catheter insertion, intervention catheter insertion, etc.) to be performed defined with respect to the various basic heart diseases?	<input type="radio"/>	<input type="radio"/>	.....

## Product requirements form

In order to define the technical-professional product requirements, the following profiles which identify some quality indicators to monitor aspects which were held to be critical and/or relevant for each pathology were drawn up.

The chosen pathologies were held to be illustrative (due to number, complexity and reproducibility), of paths that are sufficiently standardised but at the same time specific for each age group.

The Baby Heart indicators were identified after much discussion within the team, trying to choose those that are more representative according to the literature. For the surgical pathologies, the data monitored by the *Congenital Database* of the *European Association for Cardio-thoracic Surgery* were also used. Within this database, a section called “Baby Heart National Report” was specially created to allow for the calculation of the standards regarding some of the indicators previously chosen by the team (identified as “Standard National Reports”).

It must be mentioned, finally, that the team, for the calculations of the Baby Heart standard, decided to choose the surgical activity carried out in 2003 in the various Italian centres enrolled in the Database as the reference period, since the data from 2003 was certified during inspections by the specific Commission of the Paediatric Cardiac Surgery Section (the certification permitted the verification of the correspondence between the Database data and that of the operator registers in the individual Centres).

With regards to mortality, reference is made to the hospital mortality rate (deaths that occurred before discharge or within 30 days of the surgery).

### Cardiac-surgery pathologies

Age group	Pathology
< 30 days	<ul style="list-style-type: none"> <li>• Hypoplastic left heart syndrome</li> <li>• Isolated ductus arteriosus coarctation of the aorta</li> <li>• Transposition of the great vessels with intact septum</li> </ul>
1-18 years	<ul style="list-style-type: none"> <li>• Tetralogy of Fallot</li> <li>• Complete atrioventricular septal defect</li> </ul>
1-18 years	<ul style="list-style-type: none"> <li>• Partial atrioventricular septal defect</li> <li>• Sub-aortic fibromuscular stenosis</li> <li>• Total cavo-pulmonary connection</li> <li>• Right ventricular-pulmonary artery conduit substitution</li> </ul>

### Cardiological pathologies

Chronic insufficiency

Paroxysmal Tachycardia

Intervention	<ul style="list-style-type: none"> <li>• critical aortic valve stenosis</li> <li>• pulmonary branch stenosis (angioplasty and/or stent)</li> <li>• re-coarctation (angioplasty and/or stent)</li> </ul>
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## Product requirements form (continued)

## Pathology profile: hypoplastic left heart syndrome: age group – up to 30 days (neonate)

Phase	Indicator	Baby Heart Standard
<b>Perinatal</b>	Neonatologist evaluation	100%
<b>Post-natal</b>		
cardiology service	Preoperative mortality in patients with prenatal diagnosis	≤ 2%
immediate post-operative	Duration of intubation ≤ 10 days	≥ 80%
<b>Clinical course</b>	Post-operative hospitalisation ≤ 30 days	≥ 80%
	Mortality	≤ 35%
<b>Follow-up*</b>	% of patients at <i>follow-up</i> at 1 year	≥ 90%
	Survival rate at 1 year	≥ 50%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Mahle WT, Clancy RR, McGourn SP et al. Impact of prenatal diagnosis on survival and early neurologic morbidity in neonates with the hypoplastic left heart syndrome. *Pediatrics* 2001;107:1277-82.

Stieh J, Fisher G, Scheewe J et al. Impact of preoperative treatment strategies on the early perioperative outcome in neonates with hypoplastic left heart syndrome. *J Thorac Cardiovasc Surg* 2006;131:1122-1129.

Gaynor JW, Mahle WT, Mitchell I et al. Risk factors for mortality after the Norwood procedure. *Eur J Cardiothorac Surg* 2002;22:82-89.

McGuirk SP, Griselli M, Stumper OF et al. Staged surgical management of hypoplastic left heart syndrome: a single institution 12 years experience. *Heart* 2006;92:364-70.

## Product requirements form (continued)

## Pathology profile: Isolated ductus arteriosus coarctation of the aorta: age group – up to 30 days (neonate)

Phase	Indicator	Baby Heart Standard
<b>Perinatal</b>	Aortic arch size evaluation	100%
<b>Post-natal</b>		
cardiological service	Ductus arteriosus evaluation of the systemic circulation	100%
surgery	Correction within the first 7 days of life	100%
immediate post-operative	Instantaneous maximum gradient of doppler	≤ 30 mmHg in 100 % of the cases
<b>Clinical Course</b>	Re-coarctation within 3 months	≤ 20 % of the cases
	Mortality	≤ 3%
<b>Follow-up*</b>	% of patients at 5 years	≥ 70%
	% of repeat surgeries or angioplasty for re-stenosis at 5 years	≤ 30%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Knott-Craig CJ, Elkins RC, Ward KE et al. Neonatal coarctation repair. Influence of technique on late results. *Circulation* 1993;88:198-204.

Conte S, Lacour-Gayet F, Serraf F et al. Surgical management of neonatal coarctation. *J Thorac Cardiovasc Surg* 1995;109:663-675.

Dodge-Khatami A, Backer CL, Mavroudis C. Risk factors for recoarctation and results of reoperation: a 40 years review. *J Card Surg* 2000;15:369-77.

Wright G, Nowak CA, Goldberg CS et al. Extended resection and end-to-end anastomosis for aortic coarctation in infants: results of a tailored surgical approach. *Ann Thorac Surg* 2005;80:1453-59.

Pandey R, Jackson M, Ajab S et al. Subclavian flap repair: review of 339 patients at a median follow-up of fourteen years. *Ann Thorac Surg* 2006;81:1420-28.

## Product requirements form (continued)

## Pathology profile: transposition of the great vessels with intact septum: age group - up to 30 days (neonate)

Phase	Indicator	Baby Heart Standard
<b>Post-natal</b> surgery	Sternal closure in operating theatre	≥ 60%
	Mortality	≤ 7%
	immediate post-operative	Duration of intubation ≤ 5 days
<b>Clinical course</b>	Post-operative hospitalization ≤ 16 days	≥ 90%
<b>Follow-up*</b>	% repeat surgeries at a distance (5 years)	≤ 6%
	Follow-up at 5 years	≥ 80%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Sarris GE, Chatzis AC, Giannopoulos NM et al. The arterial switch operation in Europe for transposition of the great arteries: a multi-institutional study from the European Congenital Heart Surgeons Association. *J Thorac Cardiovasc Surg* 2006;132:633-39.

Dibardino DJ, Allison AE, Waughn WK et al. Current expectations for newborns undergoing the arterial switch procedure. *Ann Surg* 2004;239:588-98.

Qamar ZA, Goldberg CS, Devaney EJ et al. Current risk factors and outcome for the arterial switch operation. *Ann Thorac Surg* 2007;84:871-79.

Wong SH, Finucane K, Kerr et al. Cardiac outcome up to 15 years after the arterial switch operation. *Heart Lung Circ* 2008;17:48-53.

**Product requirements form (continued)****Pathology profile: Tetralogy of Fallot: age group – 1-12 months (baby)**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-natal</b>		
surgical procedure	Primary correction	≥ 80 %
immediate post-operative	Intensive care hospitalisation ≤ 4 days	≥ 80%
<b>Clinical course</b>	Post-operative hospitalisation ≤ 15 days	≥ 90%
	Mortality	≤ 3%
<b>Follow-up*</b>	% of patients at <i>follow-up</i> at 5 years	≥ 80%
	% of repeat surgeries at 5 years	≥ 7%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Pigula FA, Khalil PN, Mayer JE et al. Repair of tetralogy of Fallot in neonates and young infants. *Circulation* 1999;100(suppl II):157-161.

Ooi A, Moorjani N, Baliulis G et al. Medium-term outcome for infant repair in tetralogy of Fallot: indicators for timing of surgery. *Eur J Cardiothorac Surg* 2006;30:917-922.

Bacha EA, Satou GM, Moran AM et al. Long-term results after early repair of tetralogy of Fallot. *J Thorac Cardiovasc Surg* 2001;122:154-161.

Kolcz J, Pizzarro C. Neonatal repair of tetralogy of Fallot results in improved pulmonary artery development without increased need for reintervention. *Eur J Cardiothorac Surg* 2005;28:394-9.

**Product requirements form (continued)****Pathology profile: Complete atrioventricular septal defect: age group 1-12 months (baby)**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-natal</b>		
cardiological service	Complete echocardiography diagnosis (without needing further in-depth studies)	100%
surgical procedure	Correction within the first 6 months of life in patients at the Centre since neonate era	≥ 90%
immediate post-operative	Moderate/severe insufficiency of the left atrioventricular valve	≤ 10%
<b>Clinical course</b>	Mortality	≤ 5%
	AV block total	3%
<b>Follow-up*</b>	Freedom from repeat surgeries at 10 years for insufficiency of the left a-v valve	≥ 80%
	Survival rate at 10 years	≥ 80%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Voci Bibliografiche di riferimento utilizzate per l'elaborazione dei parametri sopra indicati:

Stellin G, Vida VL, Milanese O et al. Surgical treatment of complete A-V canal defects in children before 3 months of age. *Eur J Cardiothorac Surg* 2003;23:187-193.

Cope JT, Fraser GD, Kouretas PC et al. Complete versus partial atrioventricular canal: equal risk in the modern era. *Ann Thorac Surg* 2002;236:514-521.

Lange R, Guenther T, Busch R et al. The presence of Down syndrome is not a risk factor in complete atrioventricular septal defect repair. *J Thorac Cardiovasc Surg* 2007;134:304-310.

Najm HK, Coles JG, Masato E et al. Complete atrioventricular septal defect: results of repair, risk factors and freedom from reoperation. *Circulation* 1997;96(Suppl II):311.-315.

**Product requirements form (continued)****Pathology profile: partial atrioventricular septal defect: age group 1-18 years (child)**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-natal</b>		
cardiological service	Complete echocardiography diagnosis (without needing further in-depth studies)	100%
immediate post-operative	Moderate/severe left atrioventricular insufficiency	≤ 10%
<b>Clinical course</b>	Mortality	≤ 2%
<b>Follow-up*</b>	Freedom from repeat surgeries at 10 years for left A-V valve insufficiency	≥ 80%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

El Nadawi E, Driscoll DJ, Puga FL et al. Operation of partial atrioventricular septal defect: A forty-year review. *J Thorac Cardiovasc Surg* 2000;119:880-889.

Moller JH. Perspectives in pediatric cardiology, Vol 6. Surgery of congenital heart disease. Armonk, N.Y: Futura Publishing, 1998.

Welke KF, Morris CD, King et al. Population-based perspective of long-term outcomes after surgical repair of partial atrioventricular septal defect. *Ann Thorac Surg* 2007;84:624-9.

Najm HK, Williams WG, Chuaranaphong S et al. Primum atrial septal defect on children: early results, risk factors and freedom from reoperation. *Ann Thorac Surg* 1998;66:829-835.

**Product requirements form (continued)****Pathology profile: sub-aortic fibromuscular stenosis: age group - 1-18 years (child)**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-natal</b>		
surgery	Mortality	≤ 2%
immediate post-operative	Permanent total A-V block	≤ 4%
<b>Clinical course</b>	Duration post-operative hospitalisation ≤ 7 days	≥ 80%
<b>Follow-up*</b>	% of patients at follow-up at 5 years	≥ 80%
	Average pressure gradient LV-AO on echo-doppler < 40 mmHg at 5 years	≤ 20 mmHg

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Parry AJ, Silverman NH, FL Hanley. Resection of subaortic stenosis; can a more aggressive approach be justified? *Eur J Cardio-Thorac Surg* 1999; 15: 631-38.

Lampros TD, Cobanoglu A. Discrete subaortic stenosis: an acquired heart disease. *Eur J Cardio-Thorac Surg* 1998; 14: 296-303.

Van Son JAM, Danielson GK, Hagler DJ, Puga FJ. Surgical treatment of discrete and tunnel subaortic stenosis. *Circulation* 1993; 88 part II: 159-169.

Karamlou T, McCrindle BW Prevalence and associated risk factors for intervention in 313 Children with subaortic stenosis. *Ann Thorac Surg* 2007; 84:900.

**Product requirements form (continued)****Pathology profile: total cavo-pulmonary connection: age group - 1-18 years (child)**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-operative</b>	Mortality	≤ 5%
	% disassembly of the TCPC	≤ 2%
<b>Follow-up*</b>	Freedom from repeat surgeries at 10 years (excluding fenestration closure)	≥ 80%
	Survival rate at 10 years	≥ 80%
	Freedom from transplant at 10 years	≥ 80%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Hosein RBM, Clarke AJB, McGuirk et al. Factors influencing early and late outcome following the Fontan procedure in the current era. The two commandments. Eur J Cardiothoracic Surg 2007;31:344-52.

Schreiber C, Horer J, Vogt M et al. Non fenestrated extracardiac total cavopulmonary connection in 132 consecutive patients. Ann Thorac Surg 2007;84:894-9.

Almond CSD, Mayer JE, Thiagarajan RR et al. Outcome after Fontan failure and takedown to an intermediate palliative circulation. Ann Thorac Surg 2007;84:880-7.

Chaudari M, Sturman J, O'Sullivan J et al. Rescue cardiac transplantation for early failure of the Fontan-type circulation in children. J Thorac Cardiovasc Surg 2005;129:416-22.

Bernstein D, Naftel D, Addonizio LJ et al. Outcome of listing for cardiac transplantation for failed Fontan. A multi-institutional study. Circulation 2006;114:273-298.

**Product requirements form (continued)****Pathology profile: right ventricular-pulmonary artery conduit substitution: age group 1-18 years (child)**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-natal</b>		
surgery	Mortality	≤ 3 %
immediate post-operative	Intensive care hospitalisation ≤ to 24 hours	≥ 80%
<b>Clinical course and care</b>	Post-operative hospitalisation ≤ 10 days	≥ 80%
<b>Follow-up*</b>	Freedom from repeat surgeries or angioplasty at 1 year	≥ 90%
	% of patients at follow-up at 5 years	≥ 80%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Tatebe S, Nagakura S, Boyle EM et al. Right ventricle to pulmonary artery reconstruction using a valved homograft. *Circ J* 2003;67:906-12.

Mohammadi S, Belli M, Martinovic I et al. Surgery for right ventricle to pulmonary artery conduit obstruction: risk factors for further reoperation. *Eur J Cardiothorac Surg* 2005;28:217-22.

Bermudez C, Dearani JA, Puga FJ et al. Late results of the peel operation for replacement of failing extracardiac conduits. *Ann Thorac Surg* 2004;77:881-8.

**Product requirements form (continued)****Pathology profile: chronic insufficiency (from altered systolic and/or diastolic ventricular function)**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-natal</b>		
Clinical course and care	Deterioration of hemodynamic and extra cardiac conditions in spite of the treatment	≤ 5%
	Necessity for cardio-respiratory reanimation without mechanical ventilation	≤ 2%
	Hospital mortality in the absence of mechanical support	≤ 10%
	Neurological results	≤ 5%
	Survival with mechanical support	≥ 70%
<b>Follow-up*</b>	% of patients at follow-up at 3 years	≥ 80-90%
	Mortality at 1 year (non-transplanted patients)	≥ 15%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Duncan BW, Bohn DJ, Atz AM et al. Mechanical circulatory support for the treatment of children with acute fulminant myocarditis. *J Thorac Cardiovasc Surg* 2001;122:440-448.

Morrow WR. Cardiomyopathy and Heart Transplantation in children. *Current Opinion in Cardiology* 2000;15:216-223.

Towbin JA, Lowe AM, Colan SD et al. Incidence, causes and outcomes of dilated cardiomyopathy in children. *JAMA* 2006;296:1867-76.

Webber SA. 15 years of pediatric heart transplantation at the University of Pittsburgh: lessons learned and future prospects. *Pediatr Transplant* 1997;1:8-21.

**Product requirements form** (continued)**Pathology profile: paroxysmal tachycardia**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Pre-natal</b>	Diagnosis and management of foetal tachycardia sustained with hydrops	Intra-uterine or neonatal mortality $\leq 15\%$
<b>Post-natal</b> (> 12 months)		
cardiological service	Electro-physical study of patients with reoccurring tachycardia which resists conventional treatment	100 %
<b>Follow-up*</b>	Relapse at 6 months	$\leq 5\%$

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Pongiglione G, Saul JP, Dunningan A, et al. Role of transesophageal pacing in evaluation of palpitations in children and adolescents. *Am J Cardiol* 1988;62:566-570.

Pongiglione G. The role of the pediatric electrophysiologist in the diagnosis and treatment of supraventricular tachydysrhythmias. *Curr Opin Pediatr* 1989;1:124-130.

Campbell RM, Strieper MJ, Frias PA, et al. Survey of current practice of pediatric electrophysiologists for asymptomatic Wolff-Parkinson-White syndrome. *Pediatrics* 2003;111:245-247.

Bevilacqua LM, Berul CI. Advance in pediatric electrophysiology. *Curr Opin Pediatr* 2004;16:494-499.

Drago F, Grutter G, Silveti MS, et al. Atrioventricular nodal reentrant tachycardia in children. *Pediatr Cardiol* 2006;27:454-459.

**Product requirements form (continued)****Pathology profile: critical aortic valve stenosis**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-natal</b>		
immediate result	Reduction of the trans-aortic gradient ≥ 50% or increase in the fraction of left ventricular ejection ≥ 20%	≥ 80%
peri-procedural complications	acute aortic insufficiency 3+/4 Mortality	≤ 20% ≤ 10%
<b>Follow-up*</b>		
	% of patients at 5 years	≥ 70%
	Freedom from moderate-severe aortic insufficiency at 5 years	≥ 65%
	Freedom from repeat surgeries at 5 years	≥ 50%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Balmer C, Beghetti M, Fasnacht M et al. Balloon aortic valvoplasty in pediatric patients: progressive aortic regurgitation is common. *Heart* 2004;90:77-81.  
McElhinney DB, Lock JE, Keane JF et al. Left heart growth, function and reintervention after balloon aortic valvuloplasty for neonatal aortic stenosis. *Circulation* 2005;111:451-458.

## Product requirements form (continued)

Pathology profile: pulmonary branches stenosis (angioplasty and/or stent)		
Phase	Indicator	Baby Heart Standard
Post-natal precedence result immediate	Decrease of right ventricular pressure	Post-procedure right ventricular pressure/aorta post-procedure ratio < 0,6
	Increase treated arterial diameter	Lesion diameter increase $\geq$ 50%
Clinical course and care	Complications	< 7%
	Greater complications	< 3%
Follow-up*	% of patients at follow-up at 5 years	$\geq$ 80%

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Rothman A, Perry JB, Keane JF, Lock JE. Early results and follow-up of balloon angioplasty for branch pulmonary stenosis. J Am Coll Cardiol 1990;15:1109-17.

McMahon CJ, El Said HG, Vincent JA et al. Refinements in the implantation of pulmonary arterial stents: impact on morbidity and mortality of the procedure over the last two decades Cardiol Young 2002;12:445-452.

Rosales AM, Lock JE, Perry SB, Geggel RL. Interventional catheterization management of perioperative peripheral pulmonary stenosis: Balloon angioplasty or endovascular stenting. Cath Cardiovasc Interv 2002;56:272-277.

**Product requirements form (continued)****Pathology profile: aorta re-coarctation (angioplasty and/or stent)**

<b>Phase</b>	<b>Indicator</b>	<b>Baby Heart Standard</b>
<b>Post-natal</b>		
immediate result	Residual peak gradient post-treatment $\leq 20$ mmHg	$\geq 80\%$
	Increase of the diameter of the point of stenosis $\geq 70\%$	$\geq 80\%$
peri-procedural complications	Peripheral vascular complications	$\leq 10\%$
	Dissection and/or aneurism	$\leq 5\%$
	Mortality	$\leq 1\%$
clinical course and care	Hospitalisation $\leq 4$ days	$\geq 90\%$
	<hr/>	
<b>Follow-up*</b>	% of patients at 5 years	$\geq 80\%$
	Freedom from repeat surgeries at 5 years	$\geq 80\%$

\* The data obtained through monitoring performed by another structure was accepted as *follow-up* data.

Bibliographical reference items used for the drawing up of the above-mentioned parameters:

Magee A, Brzezinska-Rajszy G, Qureshi S et al. Stent implantation for aortic coarctation and recoarctation. *Heart* 1999;82:600-606.

Witsenburg M, The SH, Bogers Aj, Hess J Balloon angioplasty for aortic coarctation in children: initial and follow-up results and midterm effect on blood pressure. *British Heart Journal* 1993;70:170-174.

Chessa M, Carrozza M, Butera G et al. Results and mid-long-term follow-up of stent implantation for native and recurrent coarctation of the aorta. *European Heart Journal* 2005;26:2728-2732.



## Data collection form for adult congenital heart disease patients

### Definition

By adult congenital heart disease patient, we are referring to a person with congenital heart disease who is older than 18 years. Included in this are cases with cardio-vascular disease that was acquired during childhood and adolescence (e.g. Kawasaki coronary disease, endocarditis, trauma pathologies, etc.). All of the requested data refers exclusively to this age group.

### Personal data

Home structure: .....

**Paediatric centre** (specify the name of the structure which carries out the paediatric cardiological and cardiac surgery activities)

.....  
.....  
.....

**Data collection form for adult congenital heart disease patients** (continued)**Organisational layout**

Briefly describe the organisational context (ref. organigram):

.....

.....

.....

.....

.....

.....

Does the hospital have the following services dedicated to adult patients:	Yes	No
Anaesthesia and reanimation	<input type="radio"/>	<input type="radio"/>
Nephrology	<input type="radio"/>	<input type="radio"/>
Neurology	<input type="radio"/>	<input type="radio"/>
General surgery	<input type="radio"/>	<input type="radio"/>
Cardiac surgery	<input type="radio"/>	<input type="radio"/>
Thoracic surgery	<input type="radio"/>	<input type="radio"/>
Cardiology	<input type="radio"/>	<input type="radio"/>
24 hour Hemodynamics	<input type="radio"/>	<input type="radio"/>
Neurosurgery	<input type="radio"/>	<input type="radio"/>
Obstetrics and gynaecology	<input type="radio"/>	<input type="radio"/>
Pneumocology	<input type="radio"/>	<input type="radio"/>
Haematology	<input type="radio"/>	<input type="radio"/>
Infectious diseases	<input type="radio"/>	<input type="radio"/>
Psychiatry/Psychology	<input type="radio"/>	<input type="radio"/>
Radiology	<input type="radio"/>	<input type="radio"/>
Nuclear magnetic resonance	<input type="radio"/>	<input type="radio"/>
Physiokinetic therapy	<input type="radio"/>	<input type="radio"/>

Are the following procedures available for adult patients:	Yes	No
Coronary intervention, also for emergencies	<input type="radio"/>	<input type="radio"/>
Electro-physiology (ablation, pacemaker insertion/defibrillator)	<input type="radio"/>	<input type="radio"/>
Non-coronary intervention (trans-septal procedures, aortic endoprosthesis, percutaneous valve implantation)	<input type="radio"/>	<input type="radio"/>
Heart transplant	<input type="radio"/>	<input type="radio"/>
Heart-lung and lung transplant	<input type="radio"/>	<input type="radio"/>

## Data collection form for adult congenital heart patients (continued)

## Definition criteria for the volume of surgical activity

No. patients &gt; 18 years operated on during the years 2005-2006 DRG 103, 104, 105, 108\*, 110, 111, 479

(\* DRG 108 excluding the cardiological intervention procedures)

	Number	Deaths	% mortality
	.....	.....	.....
<b>Number of cardiac surgeries – years 2005-2006</b>			<b>Total</b>
(Operator registers)			
Heart transplant for congenital pathologies			.....
Heart-lung transplant for congenital pathologies			.....
Cardio-pulmonary bypass surgeries			.....
Closed heart surgeries			.....
Number of treatments			.....
Number of other procedures			.....

**Type of surgery**

Septal defects (inter-arterial defect, partial atrioventricular septal defect, partial anomalous pulmonary venous return inter-ventricular defect.)			.....
Post-correction Tetralogy of Fallot state			.....
Left ventricle to pulmonary artery conduit (implant or substitution)			.....
Surgeries on cardiac valve (repair or substitution, primary or repeat surgery, excluding Ross procedure)			.....
Total cavo-pulmonary connection (primary or conversion)			.....
Sub-aortic stenosis correction			.....
Ross technique			.....
Aorta surgeries (Bentall procedure, ascending aorta substitution, aortic arch surgeries, thoracic aorta)			.....
Repeat surgeries			.....

**Definitions**

*Total cardiac surgeries:* cardio-pulmonary bypass or closed heart surgeries; circulatory assistance, other procedures connected to the treatment of a heart disease (sternal closure, reopening, drains, pacemaker, etc.).

*Closed heart:* surgery on the heart or on the great vessels without cardio-pulmonary bypass

*Palliative surgery:* surgeries of systemic-pulmonary binding or shunt.

Euroscore complexity index referred to all cases > 18 years:  
average value/year .....

Complexity index (*Aristotle score*) referred to all cases > 18 years:  
average value/year .....

Complexity index (*Aristotle score*) referred exclusively to cardio-pulmonary bypass CPB > 18 years:  
average value/year .....

**Data collection form for adult congenital heart disease patients (continued)****Definition criteria for the volumes of cardiological activities**

<b>System for service supply</b>	<b>Outpatient and consultancy</b>	<b>Admittance</b>
Number of patients in <i>follow-up</i>	.....	
– admittances 2005-2006		.....
– transesophageal echocardiogram	.....	
– transesophageal echocardiogram in operating theatre		.....
– echo-stress (echo-bike or pharmacological)	.....	.....
– Cardiovascular nuclear magnetic resonance	.....	.....
– vascular-CT	.....	.....
– cardio-pulmonary function study	.....	.....
– Holter ECG	.....	
– Holter ABPM	.....	
– cardiac catheter insertion		.....
<b>Types of hemodynamics</b>		
Number of diagnostic catheter insertions (including electro-physical studies)		<b>Admittance</b>
– biopsies		.....
– intra-arterial occlusion defect/foramen ovale (including Fontan procedure)		.....
– patent ductus arteriosus occlusion		.....
– inter-ventricular occlusion defects (excluding post-infarction)		.....
– angioplasty ± coarctation/re-coarctation stent		.....
– aortic/pulmonary valvuloplasty		.....
– angioplasty ± pulmonary branch stent		.....
– aortic/pulmonary valve implant		.....
– fistulas/collateral embolisation		.....
– arrhythmia ablation		.....
– pacemaker implantation/defibrillator		.....
– coronary intervention		.....
Number of non-coronary emergencies (within 24 hours of admittance or surgery)	.....	.....

**Data collection form for adult congenital heart disease patients (continued)****Structural and organizational analysis**

Those already defined for patients 18 years old or younger are considered valid, integrated with:

<b>Equipment used in operating theatre</b>	<b>Yes</b>	<b>No</b>
Invasive monitoring of cardiac capacity and continuous venous saturation (Vigilance and/or PICCO)	<input type="radio"/>	<input type="radio"/>
Echocardiograph with transesophageal probe for adult patients	<input type="radio"/>	<input type="radio"/>
Equipment for arrhythmia ablation and treatment	<input type="radio"/>	<input type="radio"/>
<hr/>		
<b>Equipment for cardio-pulmonary bypass</b>		
Equipment for the vacuum	<input type="radio"/>	<input type="radio"/>
<hr/>		
<b>Anaesthesia equipment</b>		
Triple trace module for monitoring blood pressure	<input type="radio"/>	<input type="radio"/>
Module for monitoring 2 temperatures	<input type="radio"/>	<input type="radio"/>
Thromboelastography (even shared)	<input type="radio"/>	<input type="radio"/>
<hr/>		
<b>Hemodynamics room equipment</b>		
Transesophageal probes for adults (not shared with echocardiography lab)	<input type="radio"/>	<input type="radio"/>
Dedicated echocardiographer (not shared with echocardiography lab)	<input type="radio"/>	<input type="radio"/>
Availability of complete material for coronary intervention	<input type="radio"/>	<input type="radio"/>
Availability of IVUS intra-coronary	<input type="radio"/>	<input type="radio"/>
Availability of intra-aortic balloon pump	<input type="radio"/>	<input type="radio"/>
Availability of echo-intravascular probe (for ASD/PFO)	<input type="radio"/>	<input type="radio"/>
Possibility of ECMO system in hemodynamics room	<input type="radio"/>	<input type="radio"/>
Anaesthesia service available for selected cases	<input type="radio"/>	<input type="radio"/>
<hr/>		
<b>Cardiology-cardiac surgery Intensive Care Unit (ICU) definition and equipment</b>		
<i>Location of Intensive Care for patients &gt; 18 years</i>		
Paediatric cardiac surgery ICU	<input type="radio"/>	<input type="radio"/>
Adult cardiac surgery ICU separated from paediatric ICU	<input type="radio"/>	<input type="radio"/>
Integrated paediatric-adult cardiac surgery ICU	<input type="radio"/>	<input type="radio"/>
<i>It is managed by:</i>		
Anaesthetists	<input type="radio"/>	<input type="radio"/>
Cardiac surgeons	<input type="radio"/>	<input type="radio"/>
Interventionists	<input type="radio"/>	<input type="radio"/>
Cardiologists	<input type="radio"/>	<input type="radio"/>

*(continued)*

<b>Equipment in Intensive Care integrating the equipment defined for patients 18 years old or younger:</b>	<b>Yes</b>	<b>No</b>
Invasive monitoring of cardiac capacity and continuous venous saturation (Vigilance and/or PICCO)	<input type="radio"/>	<input type="radio"/>
Intra-aortic balloon pump	<input type="radio"/>	<input type="radio"/>

**IT system**

The requisites defined for patients 18 years old or younger are valid

<b>Equipment for echocardiography service</b>	<b>Yes</b>	<b>No</b>
Adult transesophageal probes (not shared)	<input type="radio"/>	<input type="radio"/>
Availability of ventricular function calculation (TDI, etc.)	<input type="radio"/>	<input type="radio"/>
Echocardiography rooms for adults separated from those for paediatrics	<input type="radio"/>	<input type="radio"/>

Date \_\_\_\_\_

Signature \_\_\_\_\_

## Standard form for adult congenital heart disease patients

### Premise

The organisation of a care system for adult congenital heart disease patients represents a challenge for our country. The creation of a centre dedicated to this objective cannot disregard the existing care reality, but it is also evident that some elements, hereinafter, must be present.

Some of these are connected by a more extensive commentary which responds to the logic of spreading cultural knowledge, as widely as possible, in this field in line with the general objectives of the Project.

1. **Beds** dedicated within a ward. The ideal would be to have a dedicated area in order to be able to train the personnel more specifically.
2. **Completeness of the diagnostic procedure:** all of the cardiological diagnostic tools (transthoracic and transeophageal echocardiography, catheter insertion, spiral CT, cardiac NMR, egometry, Holter) should be available.
3. **Presence of paediatric and adult cardiac surgeons.**

■ A study by Stark et al. in 1996 showed that the surgical mortality is much higher in centres with low surgical volume, underlining the very high risk of performing “occasional” surgeries on adults with congenital heart disease.

It is estimated that in the United States more than 20,000 surgeries for congenital heart diseases are performed annually. The immediate result and the *follow-up* resulted as being worse for adult patients not operated on by surgeons with specific training. We do not have reliable data for the Italian situation but it is clear, however, that the concentration of these patients in dedicated centres is convenient both from a medical and a financial point of view. Repeat surgery is frequent in patients with complex congenital heart disease, with a higher total mortality rate in comparison to the first surgery.

Repeat surgery has technical difficulties connected to: adherence (between the heart, the aorta or the conduit and the sternum), little retro-sternal space, loss of anatomical artefacts (above all for the coronary arteries), presence of collateral circles. The harmful effects of previous cardio-pulmonary bypasses, compromised myocardial function conditions and severe cyanosis are conditions which further increase the surgical risk.

Often adult patients refer to a subjective condition of well-being which is linked to the chronic adaptation to their situation. Therefore, it is essential that an accurate pre-operative evaluation is done for these patients (echocardiography, arrhythmologic and anaesthesiologic).

4. **Presence of cardio-anaesthetist**
5. **Intensivists with experience of both the congenital heart disease patient and the adult heart disease patient**
6. **Presence of a arrhythmology service:** all of the diagnostic and intervention procedures should be able to be performed.

■ Arterial and ventricular arrhythmias are an increasing problem in adult congenital heart disease patients. The main causes are: anatomical anomalies of the circulation paths, dilation and progressive fibrosis of the heart chambers, surgical lesions, compromised hemodynamic. Today, ablation, both transcatheter and peri-surgical, and eventually the implantation of defibrillators and pacemakers, is associated with the variously effective pharmacological option.

The modest results obtained (except in a few cases) with the transcatheter ablative technique have made more and more interaction between the surgeon and arrhythmologist necessary in order to be able to

perform procedures during surgeries (above all in patients with Epstein anomalies, Fontan, Senning/Mustard procedures and, in specific cases, of Tetralogy of Fallot post/op). Therefore, it is necessary to develop specific skills even for the arrhythmologist: just thinking of the difficulties that can come up during the implantation of a pacemaker or defibrillator due to the problems connected to the venous access, to the presence of intra-cardiac shunts, to the risk of thromboembolism or only just of the anatomical complexity found in these patients which make the transvenous approach impossible and the epicardial one necessary.

**7. Hemodynamics laboratory:** should be able to perform all of the diagnostic and intervention procedures for both children and adults.

■ The diagnostic usefulness of cardiac catheter insertion was changed by the development of the transthoracic and transaortic echocardiography, by the use of CT, spiral CT and by NMR. Nowadays, the diagnostic use of catheters is limited to the definition of important aspects for the surgical management of the patient such as: evaluation of the coronary arteries, morphologic evaluation of the pulmonary vascularisation, evaluation of pulmonary vascular disease, definition of fistula lesions, functional study of patients who underwent Fontan procedures or other complex heart diseases. These studies may be performed only by professionals who have been specifically trained for this objective. The intervention catheter insertion is currently the field of greater use and development. For lesions such as pulmonary valve stenosis, peripheral stenosis of the branches, re-coarctation of the aorta, arterial-venous fistulas, ostium-secundum type inter-arterial defect, average-broad small and muscular peri-membranous inter-ventricular defects and patent arteriosus ductus, the intervention catheter insertion is universally considered convenient and preferable to surgery. Over the last few years, a noticeable technological acceleration has also been in progress which has allowed for the surpassing of limits that once were considered insurmountable. Among these, remember the transcatheter implantation of valved stents which were useful in patients with unvalved conduits and resulting severe regurgitation.

It would be desirable that the centres with these characteristics were founded in correspondence with centres for the treatment of paediatric congenital heart disease patients. However, in order to rationalize costs and human resources, it would be essential that such centres emerged in a pre-established number and geographic location.

## Definitions

### Adult congenital heart disease patient:

Means a person older than 18 years who is affected by a congenital heart disease, both having undergone surgery and not. Included are cases with cardio-vascular diseases acquired during childhood and adolescence (e.g. Kawasaki coronary disease, endocarditis, trauma pathologies, etc.).

### Level III Centre:

departmental-type structure where cardiological/cardiac surgical activities take place for adult congenital heart disease patients.

### Classification criteria of a Level III Centre:

centre which performs not less than 50 surgical procedures and not less than 80 intervention procedures.

### Policies:

- to offer services, either hospitalisation or outpatient, for beneficiaries of the National Healthcare System according to the current legislation;
- to treat adult patients with congenital heart disease;
- to be a reference institution for the “training” of medical and paramedical personnel for the care of adult patients with congenital heart diseases;
- to encourage the gradual transfer, in the treatment of the congenital heart disease patient who becomes an adolescent and an adult, from the paediatric cardiologist to the adult cardiologist within the institution itself;
- to place the patient at the centre of the diagnostic, treatment and care choices;
- to pursue selectivity of the care paths;
- to favour advanced technologies;
- to encourage scientific research;
- to favour professional training;
- to pursue quality in the offered services;
- to promote and support policies of information and awareness about prenatal diagnosis;
- to favour counselling about pregnancy and contraceptives for women with congenital heart disease;
- to promote psycho-social assistance for congenital heart disease patients

### Volume of surgical activity:

- Number of surgeries with cardio-pulmonary bypass and closed heart in adult patients with congenital heart diseases (excluding: circulation assistance, pacemaker implantation, re-opening, drain positioning, differed sternal closing, mediastinitis and other minor surgeries), as concluded from the surgical registers: 50/year (value which guarantees the attainment of the quality standards.)
- *Complexity Score* for surgeries using cardio-pulmonary bypass and closed heart > 18 years old (excluding: circulation assistance, pacemaker implantation, re-opening, drain positioning, differed sternal closing, mediastinitis and other minor surgeries): >5

**Standard form for adult congenital heart disease patients (continued)****Organisational layout**

A Level III Centre (or of regional reference) which has the qualification for dedicating itself to the diagnosis and treatment of adult congenital heart disease patients must have the following structural requirements:

– **it has a Level III centre for Paediatric Cardiology and Cardiac Surgery**

– **it has the following services dedicated to adults**

(within its structure or in consultancy)\*:

	Yes	No
Anaesthesia and reanimation	<input type="radio"/>	<input type="radio"/>
Nephrology	<input type="radio"/>	<input type="radio"/>
Neurology	<input type="radio"/>	<input type="radio"/>
General Surgery	<input type="radio"/>	<input type="radio"/>
Cardiac Surgery	<input type="radio"/>	<input type="radio"/>
Thoracic Surgery	<input type="radio"/>	<input type="radio"/>
Cardiology	<input type="radio"/>	<input type="radio"/>
24 h hemodynamics	<input type="radio"/>	<input type="radio"/>
Neurosurgery	<input type="radio"/>	<input type="radio"/>
Obstetrics and gynaecology	<input type="radio"/>	<input type="radio"/>
Pneumocology	<input type="radio"/>	<input type="radio"/>
Haematology	<input type="radio"/>	<input type="radio"/>
Infectious diseases	<input type="radio"/>	<input type="radio"/>
Psychiatry/Psychology	<input type="radio"/>	<input type="radio"/>
Counselling outpatient clinic	<input type="radio"/>	<input type="radio"/>
Imaging	<input type="radio"/>	<input type="radio"/>
Physiokinetic Therapy	<input type="radio"/>	<input type="radio"/>

– **it has:**

coronary intervention, also in emergencies

electro physiology (ablations, pacemaker / defibrillator implantation)

non-coronary intervention (trans-septal procedures, aortic endo-prostheses, percutaneous valve implantation)

heart transplant

– **there is a service dedicated to cardio-vascular pathologies**

\* Table 1, pag 1189, Landzberg e Murphy, 32nd Bethesda Conference. Care of the adult with congenital heart disease. JACC 2001, 37(6): 1161-1198.

**Standard form for adult congenital heart disease patients (continued)****Structural and organizational analysis**

Those defined for patients 18 years old or younger are held as valid with the following integrations:

**Personnel***Clinical Competence*

cardiac surgeon	Performs 30 surgeries / year of which at least 50% as lead surgeon
intervention cardiologist	Performs 25 procedures / year of which at least 50% as lead doctor
cardiac-anaesthetist	Must have knowledge of paediatric cardiology and of the morphology and physical-pathology of congenital heart disease patients*

**Job description**

cardiac surgeon	<p>Has gained wide experience in the surgical treatment of congenital and acquired heart diseases before acquiring knowledge of surgery of adults with congenital heart disease with supervisor**.</p> <p>Has the skills of paediatric cardiac surgeon and the skills of the cardiac surgeon for adults.</p> <p>Treats the adult congenital heart diseases; discusses the surgical indications, thus formalising them, with cardiologists and other specialists; places the patient on the waiting list. Performs the pre-operative evaluation of the patient and obtains informed consent; carries out the surgical treatment of the patient. Participates in the post-operative treatment of the patient until discharge, also handling the follow-up at a distance.</p>
cardiologo	<p>Has in-depth knowledge of congenital heart diseases and their management in childhood and adolescence. Has knowledge of general medicine and cardiology in adults or has the opportunity to directly interact with the cardiologists for adults regarding the acquired difficulties.</p> <p>Handles managing the diagnosis and care of the adult congenital heart patient, discussing and formalising the surgical and/or intervention indications. Directly manages the relationships with all of the consultants of the various disciplines; is able to supply counselling about contraception and pregnancy in women with congenital heart disease and to manage the cardio-vascular aspect of the pregnant woman.</p> <p>Is able to manage the transition from adolescence to adulthood of the heart patient, eventually creating or participating in a “transitional” clinic which facilitates the passage.</p> <p>Obtains informed consent for procedures which require it; performs the medical-intervention treatment. Participates in the post-operative treatment of the patient until discharge; performs follow-up at a distance.</p> <p>Interacts with the group psychologists in order to facilitate the management of the psycho-social difficulties of adult congenital heart disease patients.</p>
cardiac anaesthetist	<p>Handles the pre-, intra- and post-operative evaluation and care of congenital and acquired heart disease paediatric and adolescent patients; looks after the anaesthesiologic assistance for hemodynamic investigations and diagnostics for images; discusses the surgical and/or intervention indications, thus formalising them, with other specialists; obtains informed consent for the procedures which require it; participates in the post-operative treatment of the patient until discharge.</p>

In addition to the possibility of supplying medical and surgical assistance for complex heart diseases, the centre dedicated to the treatment of adult congenital heart disease patients should sustain the patients from a psycho-social point of view.

The psychologist should have a minimum knowledge of congenital heart diseases, have taken part in dedicated research-study, and attest to an ongoing activity within the centre dedicated to paediatric and adolescent, as well as to adult, congenital heart diseases.

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\* 32nd Bethesda Conference. Care of the adult with congenital heart disease. JACC 2001, 37(6): 1189.

\*\* 32nd Bethesda Conference. Care of the adult with congenital heart disease. JACC 2001, 37(6): 1166.

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Deanfield J, Tahulow E, Warnes C et al. Management of grown-up congenital heart disease. European Heart Journal 2003, 24; 1035-1084.

## Product requirements form for adult congenital heart disease patients

- Inter-arterial defect
  - Tetralogy of Fallot: untreated or undergone palliation or correction
-

**Product requirements form for adult congenital heart patients** (continued)**Pathology profile: inter-arterial defect**

<b>Indicator</b>	<b>Baby Heart Standard</b>
Surgical mortality	<1%
Percutaneous closure mortality	<1%
Effective percutaneous closure	95%
Post-surgery complications	<3%
Complications after percutaneous closure	< 3.6%
Possibility of associated ablative anti-arrhythmia therapy	100%
Follow-up performed by the Level III Centre or with peripheral network	>95%

Bibliographical references used for the calculation of the abovementioned parameters.

Gatzoulis MA, Redington AN, Somerville J, Shore DF. Should atrial septal defects in adults be closed? *Ann Thorac Surg.* 1996 Feb;61(2):657-9.

Vida VL, Berggren H, Brawn WJ et al. Risk of surgery for congenital heart disease in the adult: a multicentered European study. *Ann Thorac Surg.* 2007 Jan;83(1):161-8.

Padalino MA, Speggorin S, Rizzoli G et al. Midterm results of surgical intervention for congenital heart disease in adults: an Italian multicenter study. *J Thorac Cardiovasc Surg.* 2007 Jul;134(1):106-13, 113.e1-9

Du ZD, Koenig P, Cao QL et al. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults: results of a multicenter nonrandomized trial. *J Am Coll Cardiol.* 2002 Jun 5;39(11):1836-44.

**Product requirements form for adult congenital heart disease patients (continued)****Pathology profile: Tetralogy of Fallot**

<b>Indicator</b>	<b>Baby Heart Standard</b>
Surgical mortality	<7%
Post-surgical complications	8,5%
Hospitalisation < 10 days	>80%
Follow-up performed by the Level III Centre or with peripheral network	>95%
Survival at a distance of 5 years	>95%

Bibliographical references used for the calculation of the abovementioned parameters.

Sadiq A, Shyamkrishnan KG, Theodore S et al. Long term functional assessment after correction of tetralogy of Fallot in adulthood. *Ann Thorac Surg* 2007, 83:1790-5.

Atik FA, Atik E, da Cuhna CR et al. Long term results of correction of tetralogy of Fallot in adulthood. *Eur J Cardio-Thoracic Surgery* 2004, 25:250-255.

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## Appendix 2

### Volume of activity and results of the cardiac surgery and cardiology centres which participated in the *Baby Heart Project*

CARDIAC SURGERY CASE HISTORIES										
		2005			2006			2007		
		Surgeries	Deaths	%	Surgeries	Deaths	%	Surgeries	Deaths	%
0-30 days	CPB	213			225			229		
	CH	225			217			222		
	Tot	438	53	12,1%	442	42	9,5%	451	35	7,8%
30 days-1 year	CPB	498			557			541		
	CH	185			133			141		
	Tot	683	34	5,0%	690	22	3,2%	682	26	3,8%
1 -18 years	CPB	713			727			818		
	CH	115			150			147		
	Tot	828	19	2,3%	877	20	2,3%	965	18	1,9%
TOTAL	CPB	1424			1509			1588		
	CH	525			500			510		
	Tot	1949	106	5,4%	2009	84	4,2%	2098	79	3,8%

CARDIOLOGICAL CASE HISTORIES			
	2005	2006	2007
Diagnostic procedures	937	935	866
Intervention procedures	686	662	706
Total	1623	1597	1572

