

**OPTIMAL STRUCTURE  
OF  
A CONGENITAL HEART SURGERY DEPARTMENT OF IN EUROPE**

**W. Daenen, F. Lacour-Gayet, B. Maruszewski, L. Hamilton, S. Daebritz, H. Lindberg,  
R. di Donato, J. Comas, J. Monro and T. Aberg**

Addresses for correspondence:

- Willem Daenen. MD,  
University Hospital Gasthuisberg,  
Herestraat 49,  
B-3000 Leuven, Belgium
- The EACTS Congenital Heart Surgery Committee  
<http://www.ctsnet.org/committee/eacts/183/roster>

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## **Executive Summary.**

This document presents a professional view of the optimal organization of Congenital Heart Surgery (CHS) in Europe. It has been approved by the Congenital Heart Surgery Committee of the European Association of Cardio-Thoracic Surgery (EACTS) and the European Congenital Heart Surgeon Association (ECHSA). These societies represent the majority of European pediatric cardiac surgeons in Europe.

Current facilities and arrangements for the care of patients with congenital heart diseases are of variable quality throughout Europe. Experience, workload and resources can sometimes be below an adequate level.

A structure is foreseen with some large CHS units of high specialization, covering the full spectrum of minor and major surgical procedures such as neonatal surgery, complex repairs, transplantation, and cardiac assist devices. These larger units would also possess research facilities and cater for advanced educational needs within the specialty. They would have an advanced quality assurance system and make their activities and results known to the scientific community. There would also be smaller units of more standard care who most often do not have the full range of activities mentioned above but who would also participate in the same quality assurance system as the larger units.

In an optimal structure, the overall surgical activity should be over 250 patients operated per year. This represents a draining area of approximately 4 to 6 million inhabitants, depending on the birth rate and on the number of foreign patients.

In both types of units the organization should be orientated around patient needs and besides adequate physical and personnel resources, encompass such features as: quality control, data collection in a European Registry, risk stratification, reciprocal voluntary audits, individualized surgical results, collaboration in clinical research, continued education and re-certification.

The developments suggested in this document will have to be handled differently by each European nation and may take several years to implement as medical policies vary within each country. It should provide useful information and guidance to national governments, regional authorities and health care organizations.

The outlined measures are expected to result not only in an improved quality of patient care but also in an improved cost-efficiency of CHS throughout Europe.

**Introduction.**

Congenital Heart Surgery (CHS) is a sub-discipline of cardiac surgery, treating children, born with a high-risk heart defect. The main developments over the last 20 years have been to treat the patients at an earlier age paired with improved surgical methods and deeper understanding of the physiology of the premature, neonatal and early childhood age. The results measured as both short term and long term survival have improved considerably. (1,2).

CHS developed within heart surgery departments. A trend during later years has been to organize this subspeciality either in conjunction with large adult heart surgery units, rarely as stand-alone units or co-organized with pediatric cardiology in pediatric hospitals or heart centers.

The developments suggested in this document will have to be handled differently by each European nation and may take several years to implement as health care management varies within each country. However, the patient's needs are similar in all countries and it would seem intuitively correct to orientate service delivery around the needs of the patient. Therefore it seems obvious that there is a need for guidelines for pediatric cardiology and treatment (3).

The authors believe that the measures described can be applied in the majority of the European nations and that they are useful to achieve optimal results and improve the quality of care in CHS. Furthermore, we believe that cost-efficiency as measured by cost per added year of life will be improved. We also believe that the most important changes we may currently undertake in order to improve the outcome for these patients are organizational. The medical development is important and may also be improved upon by the organizational changes proposed in the document.

## I. Methodology in preparing the manuscript.

The congenital heart Committee of the European Association for Cardio-Thoracic Surgeons (EACTS), was asked by the EACTS Council to prepare a document defining the optimal structures of CHS, in order to improve the quality of care in this specialty in Europe. The EACTS is representative of the majority of the cardiac surgeons specialized in CHS, in Europe.

The document was prepared by the Congenital Heart Surgery Committee of the EACTS (Table 1) and obtained the agreement of the European Congenital Heart Surgeons Foundation (ECHSF) (Table 2). These are the only structures representing this specialty at the European level.

In order to obtain a general consensus for the document, a survey of the pertinent literature was performed and some of the salient references are given at the end of the document.

A working group met at the EACTS Council meeting in Umea in June 2001, where some major trends were outlined. It was decided to define the requirements of an optimal structure of CHS Unit and not *the minimal requirements*, as no consensus could be obtained on the minimal activity.

The document, in various stages of its development was discussed several times at the EACTS Council, at the EACTS Congenital Committee, at the ECHSF and was also presented at the Public Congenital Committee Meeting held in Lisbon in September 2001. It has been posted on the Internet at the EACTS HomePage for all cardiac surgeons to read and reflect upon for more than 6 months. It has been commented on by all the authors and modified accordingly by the three senior authors.

## II. The Congenital Heart Surgery Specialty

### *Definition*

CHS encompasses the factual knowledge, technical skill and judgment required to diagnose accurately and to manage surgically congenital heart defects. CHS requires in-depth knowledge of physiology, diagnostic imaging, organ function testing, semi-invasive and invasive investigation, preoperative evaluation, postoperative care, critical care, ECMO (Extracorporeal membrane oxygenation), mechanical assist systems and surgical techniques

of repair, palliation and transplantation. A main feature is the necessity of an interdisciplinary approach together with interventional pediatric cardiologists and cardiac anaesthetists.

#### *Surgical expertise*

Congenital heart surgeons are qualified to manage simple and complex surgical lesions from infancy to adult age. This includes interpretation of examination, surgical indication, an optimal updated intra-operative expertise, management of potential postoperative complications, as well as controlling cardio-pulmonary bypass and ECMO. In essence, the surgical field of a congenital heart surgeon includes all corrective, palliative and minimally invasive procedures of the heart, pericardium and great vessels. Sometimes congenital and other diseases of the lung, trachea, mediastinum, oesophagus and diaphragm in infancy and childhood are included in the local practice and/or also treated by thoracic surgeons and/or general pediatric surgeons. They are not alluded to in other parts of this document.

#### *Wide Spectrum of Pathology*

Congenital Heart Diseases (CHD) represents a very wide spectrum of complexity, both from anatomical as well as from a physiological point of view. The recent studies conducted on the risk stratification themes (4) allow definition of surgical procedures that can be described in simple, average, difficult, complex and salvage. This will bring some order in the presentation of results achieved and may also offer some guide as to organization. If the simple and average surgery can be performed by most cardiac surgeons with some training in CHS, it is different for the more complex procedures that must be handled by a complete specialized team to allow optimal results.

The age distribution of the patients is wide with two important extreme groups: the neonates (including prematures) and the adult congenital patients. The increasing number of adolescents and adult patients needing surgery requires organization of appropriate structures in the future.

#### *Teamwork*

The surgical treatment of children with CHD, implies an excellent partnership with a team of pediatric cardiology. The strength of this partnership is a general vector to optimize the quality of any CHS unit. It should be permanently maintained through mutual human and professional respect, and through optimal transverse

structures. Many modern centers are organized on official common structures with cardiologists; whenever this link is not officially established, an optimal relationship is mandatory.

CHS requires the participation of many different disciplines and professionals: surgeons, anesthesiologists, intensive care doctors, pediatricians, neonatologists, perfusionists, scrub nurses, ICU and ward nurses, administrators, etc. The quality, the unity and the motivation of all the actors in the team are crucial aspects for the success of the surgical program.

### **III. Structure of a CHS unit**

#### *General principles*

To ensure optimal patient care and education of the members of the team, CHS needs to be performed within the logistical and economical framework of units. The structure of these units should be designed to allow:

- patient care and treatment at the level of accepted standards.
- education of surgical trainees in the field of CHS according to valid criteria.
- continuous development and research in the field of CHS.

To meet these demands a certain organizational background and a number of optimal requirements are necessary, depending on the individual level of standard or high specialization (vide infra).

#### *Institutional status*

CHS units of high specialization and dealing with the whole spectrum of congenital heart disease should be within a university setting or within a private center of a comparable scientific level. The unit should be headed by a surgeon certified by the European Board of Thoracic and Cardiovascular Surgery (EBTCS), or an equivalent body recognized by the EBTCS. This Head of Department should be entrusted with educational and scientific responsibilities, and should possess a minimum experience of five years clinical practice as a qualified CHS surgeon. He/she should preferably possess academic qualifications. These units can either be a totally independent department or an independent unit attached to an adult cardiac surgery structure. It may also be organized within a children's hospital together with pediatric cardiology.

Smaller units of more standard care will most often not be able to offer the full range of activities mentioned above. We have not been able to define the minimal requirements for a smaller CHS unit. Cardiac centers dealing with any aspect of congenital heart diseases should have the infrastructure as regards quality as outlined above and should collect information in order to present pertinent outcome data. Results should be comparable to large centers.

#### Institutional resources

##### 1. Surgeons

The members of the team around the child with congenital heart disease are all of major importance. However, the surgeon carries the main responsibility for the outcome and thus for the inner organization, surgical treatment and peri-operative care. By experience, a congenital heart surgeon performs around 125 operations a year. The labour laws in various countries make different demands on work schedule, on-call schedule, holidays, continued education and other causes for absence. In order to guarantee a responsible surgeon around the clock all year, three fully qualified surgeons should be employed in many countries, increasing the theoretical output of those units to 375 operations. By these considerations, an absolute minimum for a full time surgeon is 125 operations per year. Having junior surgeons in advanced training or getting help from adjacent structures, such as an adult heart surgery unit or collaboration across several units may modify this rule.

##### 2. Operating Rooms

The number of fully equipped operating theatres within a CHS unit may be calculated on the basis of 1 operating room per 250 major cardiac procedures per year. A fully equipped operating theatre includes standard equipment for video-assisted surgery. One additional operating theatre should be available for emergencies.

##### 3. Intra-operative team

For complex procedures, three surgeons are often preferred and sometimes necessary, the third one being a trainee.

A specialized team of anaesthetists devoted to CHS is of paramount importance as well as a specialized team of perfusionists. Furthermore, it has been shown that the organization, knowledge and dedication of all personnel in the operating theatre contribute to a favourable outcome.

### 3. Pediatric Cardiac Intensive Care Unit

CHS units should have access to a dedicated pediatric cardiac ICU, preferably independent financially and scientifically. Dedicated beds within a larger cardiac ICU should be pooled geographically in order to guarantee expertise from the pediatric medical and paramedical staff. A specialized unit including variably pediatric cardiologists, neonatologists, pediatric intensivists and pediatric anesthesiologists will, in close cooperation with the congenital surgeons, take care of the patient after the operation. The average number of beds required, depending on the complexity, is 6-8 per 250 cardiac patients per year. The nurse/patient ratio in this ICU should be 1/1 full time equivalent for difficult patients and 0.5/1 for simple patients. In addition, 2 to 4 intermediate beds equipped with monitoring and telemetry are desirable, either in the ICU or on the ward.

The on-call schedule for the intensive care with presence around the clock is a major burden for any CHS unit. It is variably staffed by intensivists, anesthesiologists, junior surgeons and pediatric cardiologists, according to local custom.

### 4. Pediatric Ward Care

Pediatric surgical patients before and after surgery and ICU stay are hospitalized in a dedicated pediatric/neonatal ward with full supporting paramedical staff including dedicated physiotherapists. Optimally, there should be 10-12 beds per 250 patients per year. One wound treatment room should be available on every ward. Rooming-in facilities allowing the permanent presence of the mother or another member of the family should be available. A psychologist consultant is useful. It is necessary to cater for the needs not only of the patients, but also of the parents. Rehabilitation facilities for children should be available.

### 5. Outpatients

There should be sufficient facilities for outpatient visits and at the same visit access to echocardiography, electrocardiography and radiology. These visits are often supervised by the pediatric cardiologists.

### 6. Institutional Facilities

CHS units must have access to on-site support facilities. Minimum facilities must include:

- Department of General Pediatrics with all diagnostic and therapeutic facilities;
- Department of Pediatric Cardiology with all diagnostic and therapeutic facilities;
- Unit of Cardiac Pathology

Depending on the spectrum of pathology, centers should also have access to:

- Department of Neonatology with all diagnostic and therapeutic facilities;
- Department of Adult Cardiology and Electrophysiology with all diagnostic and therapeutic facilities;
- An adult cardiologist specialized in congenital heart disease;
- Perfusionists with special experience in ECMO and mechanical assist devices;
- Specialized laboratories relevant to subspecialty work such as transplant immunology, virology, etc...

#### **IV Optimal surgical activity.**

Recent publications have shown a convincing relationship between number of patients treated at an institution and a lower mortality (a crude expression for quality) (5,6) This relationship is also true for Congenital Heart Surgery (7-11). There are examples of highly successful changes in the organization of Congenital Heart Surgery for instance in Sweden (12). We believe that in the structuring of the Health Services of the nations, as recently published in the United Kingdom for pediatric cardiac surgery (13), due consideration should be taken to such knowledge in order to increase the quality of the service towards the patient.

However, there are no data in the scientific literature of an exact cut-off point between what is a too small, adequate or optimal case load and indeed it seems impossible to ensure such points as so much of medical service is dependent on the local culture and circumstances. The figures given here are the results of much discussion between ourselves. They must be taken as informed guidelines and not as the absolute truth. They also have to be interpreted in the light of the particular nation's health system, working regulations etc.

- The optimal overall activity should be over 250 patients operated per year (Vide infra)
- The optimal activity in neonatal and infant surgery should be over 100 infants operated per year.
- Complex corrections on adolescents / adults should be performed by surgeons who are well educated and experienced in this field.
- Heart and/or heart-lung transplantation should be performed in centers with ample experience in organ transplantation

- A CHS unit requires the presence of at least 2 fully trained surgeons. It is usually recognized that a surgeon needs to perform a minimum of 3 surgical procedures per week (a bare minimum). Considering a 42 weeks activity, the total surgical activity for a surgeon is 126 operations. Two surgeons will need 250 operations, three surgeons will need 375.
- The individualized approach (surgery vs interventional procedure) for every complex anomaly has to be discussed and agreed.

The optimal minimal number of over 250 patients per year covers approximately a population of 4 to 6 millions inhabitants, depending on the birth rate (Table 3). This number possibly creates problems in nations less than 8 millions inhabitants. European nations with a population less than 8 millions (see Table 3) could find their own optimal solution including considering merging their activity to reach an optimal number. This was the solution recently adopted between Slovakia and Slovenia who merged their activity for complex patients (EJCTS article in press).

European Countries with strong regional structures should consider organizing supra-regional structures for small and challenging specialties like CHS.

Finally, the aim of a medical activity is not size but quality. For the planner, size is one of the ways of ensuring quality. However, units of suboptimal size may produce brilliant results as a result of individual devotion and organizational and surgical skills. A cautious health service would not interfere with such units. The absolute proviso, however, must be that the unit adheres to the same quality assurance systems as the larger units and that adequate measures are taken to provide good service around the clock and around the year.

## **V. Grown Up Congenital Heart Surgery (GUCH)**

The success of cardiac surgery in infants and children with CHD has led to an increasing population of adult patients who were operated upon for a congenital heart lesion but have residual problems. It seems that in the

coming decades, the majority of patients with CHD will be adults and not children (14). These patients require to be followed by adult cardiologists specialized in GUCH. Expertise in electro-physiology and access to magnetic resonance imaging (MRI) seem particularly needed. These patients may require reoperations that can sometimes be quite challenging. Many CHS units are today developed in Children's Hospitals, where the treatment of these adult or adolescent patients is difficult. A good collaboration with a department of adult cardiac surgery and an adult congenital cardiologist is mandatory to allow a dedicated surgeon to take optimal care of these adult patients (15).

Larger centers with facilities for congenital and for adult cardiac surgery are in a good position to treat these patients.

## VI. Evaluation of quality of care

The evaluation of quality of care is a new duty of our clinical practice.

- Quality surveillance is expected in every CHS unit. In order to do this, there must be a computerized documentation of all procedures performed together with a listing of all major adverse events. Results should be analyzed on a regular basis. All units should report to a central registry
- The database designed to evaluate quality is a "Registry", defined (16) as including a limited number of essential data on all the patients operated in a CHS unit. The EACTS along with the ECHSF has created a European registry for CHS: the EACTS Pediatric Database (17). This allows, among other things, comparing results at the European level, following the International Nomenclature for CHS established by the STS and the EACTS (18,19).
- However, a complexity stratification of the procedures performed is also needed to be able to compare the results according to the complexity of the pathology treated (4). A complexity score is currently being developed (20) through an international collaboration of pediatric cardiac surgeons from the European and US societies in the subject (EACTS, STS, ECHSF and CHSS), that will allow a precise stratification of complexity.

- The quality surveillance system will offer the possibilities of self-evaluation, self-improvement as well as allow comparisons over time and –lastly- between departments, both for a given period and for a given pathology. The ultimate goal is to be able to speed up the development of even better operating methods by collaboration between departments.
- Regular analysis of the causes of mortality and morbidity and evaluation of long term follow-up should be performed within the entire surgical team with close cooperation with the cardiologists.
- Both small and large CHS departments are expected to participate in this quality control.
- A European Cardiothoracic Surgery Institute of Accreditation (ECSIA) is being created. In order for a unit to be accredited, several features will be asked for, among other things to possess a registry, to report from this registry and to make analyses as outlined above. Non-profit reimbursement for the costs of these processes will have to be charged to each unit. The initiators of this document anticipate that each hospital will wish to participate in these quality surveillance features by paying relevant charges. We also expect that the necessary infrastructure for quality surveillance (i.e. computers, computer programs and technical assistance) will be provided.

## **VII. Education and surgical training**

### *Education*

There should be in-house facilities for education with adequate provision of meeting and lecture rooms and access to medical libraries, databases, e-mail and internet. Teaching lectures in cardiology, pathology, surgery and physiology should be organized.

Continuous post-graduate education and access to important national and international meetings should be ensured for the major actors of the team and financed.

An optimal CHS unit should be recognized as a training center, validating the training program of the future specialists.

### *Surgical training*

Surgical trainees who specialize in CHS with the aim of qualifying as an EBTC approved surgeon will have had their specialized education in units recognized and authorised for training in CHS according to the rules in each country.

Special training in CHS in order to qualify for independent positions needs a minimum duration of 3 years.

Experience of general as well as cardiac and vascular surgery is recommended.

During the training in CHS, a comprehensive knowledge of the entire field of CHS must be offered to the trainee.

Surgical trainees should have good access to surgical research.

## **VIII. Research Programs**

Research projects are essential in an optimal CHS unit as the development of CHS surgery is currently very active. Regular collaboration in national and international scientific meetings and journals is a sign of an active unit. In order to do that, appropriate surgical research facilities and staff should be provided.

Basic science research in physiology, immunology, molecular biology, genetics, Heart-lung machine, etc... can be performed in association with other research laboratories in the hospital.

The possibility for the individual surgeon of pursuing a more research oriented career should be open via the Faculty of Medicine.

## **IX. Re-certification of CHS surgeons and units**

Congenital heart *surgeons* approved by the EBTC need to re-certify every 8 years. Criteria for re-certification include evidence of their ongoing work in the field of CHS together with records of their operative practice

within the period of time since their last certification. The responsible body will be the European Board of Thoracic and Cardiovascular surgeons.

Congenital heart surgery *units* officially acknowledged by the certification process, need to undergo re-certification according to the rules of the certification process. The responsible body will be The European Cardio-thoracic Institute of Accreditation (ECSIA).

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**Table 1. EACTS Congenital Heart Surgery, Business Committee**

Comas	Juan	Hospital Universitario "12 de Octubre"	Madrid	Spain
Daebritz	Sabine	Ludwig-Maximilians-University	Munich	Germany
Daenen	Willem	Gasthuisberg Universitair Ziekenhuis	Leuven	Belgium
Di Donato	Roberto	Ospedale Pediatrico Bambino Gesu	Rome	Italy
Hamilton	Leslie	Freeman Hospital	Newcastle	UK
Lacour-Gayet	Francois	University Hospital Hamburg-Eppendorf	Hamburg	Germany
Lindberg	Harald	The National Hospital	Oslo	Norway
Maruszewski	Bohdan	Memorial Hospital	Warsaw	Poland

**Table 2. European Congenital Heart Surgeons Foundation (ECHSF) Members**

Berggren	Hakan	Queen Silvia's Hospital for Children and Adol.	Goteborg	Sweden
Brawn	William	Birmingham Children's Hospital	Birmingham	UK
Cicek	Sertac	Acibadem Carousel Hastanesi	Istanbul	Turkey
Carrel	Thierry	University Hospital Bern	Bern	Switzerland
Comas	Juan	Hospital Universitario "12 de Octubre"	Madrid	Spain
Corno	Antonio	Universite de Lausanne	Lausanne	Switzerland
Crupi	Giancarlo	Ospedali Riuniti	Bergamo	Italy
Daenen	Willem	Gasthuisberg Universitair Ziekenhuis	Leuven	Belgium
Di Carlo	Duccio	Ospedale Pediatrico Bambino Gesu	Rome	Italy
Di Donato	Roberto	Ospedale Pediatrico Bambino Gesu	Rome	Italy
Ebels	Tjark	Academisch Ziekenhuis Groningen	Groningen	Netherlands
Elliott	Martin	The Great Ormond Street Hospital for Children	London	UK
Fragata	Jose	Hospital de Santa Marta	Miraflores-Alges	Portugal
Hraska	Victor	Children's Hospital	Bratislava	Slovakia
Kiraly	Laszlo	National Institute of Cardiology	Budapest	Hungary
Ilyin	Vladimir	Bakulev Center of Cardiovascular Surgery	Moscow	Russia
Lacour-Gayet	Francois	University Hospital Hamburg-Eppendorf	Hamburg	Germany
Lindberg	Harald	The National Hospital	Oslo	Norway
Maruszewski	Bohdan	Memorial Hospital	Warsaw	Poland
Pozzi	Marco	Royal Liverpool Children's Hospital Alder Hey	Liverpool	UK
Rubay	Jean	Universite Catholique de Louvain	Bruxelles	Belgium
Sarris	George	Onasis cardiac Surgery	Athens	Greece
Sairanen	Heikki	University Hospital of Helsinki	Helsinki	Finland
Stellin	Giovanni	University of Padova	Padova	Italy
Urban	Andreas	Deutsches Kinderherzzentrum	St. Augustin	Germany
Von Doorn	Carin	Yorkshire Heart Centre	Leeds	UK
Wood	Alfred	Mater Misericordiae Hospital	Dublin	Ireland
Ziemer	Gerhard	Eberhard Karls University Tübingen	Tübingen	Germany

**Table 3. European Population and birth rate.**

	Population	Birth rate %	Births / Y	New surgical pts Births x 0.4%	EJCTS 98 (21). European CHS activity, year 1995
Russia	145.470.197	0,94	1.367.420	5470	
Germany	83.029.536	0,92	763.872	3055	5741
United Kingdom	59.647.790	1,15	685.950	2744	4286
France	59.551.227	1,21	720.570	2882	3720
Italy	57.679.825	0,90	519.118	2076	
Ukraine	48.760.474	0,93	453.472	1814	
Spain	40.037.995	0,93	372.353	1489	1759
Poland	38.633.912	1,02	394.066	1576	2926
Romania	22.364.022	1,08	241.531	966	
Netherlands	15.981.472	1,19	190.180	761	1082
Yugoslavia	10.677.290	1,26	134.534	538	
Greece	10.623.835	0,98	104.114	416	188
Belarus	10.350.194	0,96	99.362	397	
Czech Republik	10.264.212	0,91	93.404	374	694
Belgium	10.258.762	1,07	109.769	439	709
Hungary	10.106.017	1,32	133.399	534	564
Portugal	10.066.253	1,15	115.762	463	658
Sweden	8.875.053	0,99	87.863	351	681
Austria	8.150.835	0,97	79.063	316	483
Bulgaria	7.707.495	0,81	62.431	250	312
Switzerland	7.283.274	1,01	73.561	294	608
Slovakia	5.414.937	1,01	54.691	219	
Denmark	5.352.815	1,20	64.234	257	393
Finland	5.175.783	1,07	55.381	222	437
Georgia	4.989.285	1,12	55.880	224	
Norway	4.503.440	1,26	56.743	227	313
Moldova	4.431.570	1,34	59.383	238	
Croatia	4.334.142	1,28	55.477	222	
Bosnia	3.922.205	1,29	50.596	202	
Ireland	3.840.838	1,46	56.076	224	237
Lithuania	3.610.535	1,00	36.105	144	
Albania	3.510.483	1,90	66.699	267	
Armenia	3.336.100	1,15	38.365	153	
Latvia	2.385.231	0,80	19.082	76	
Macedonia	2.046.209	1,35	27.624	110	
Slovenia	1.930.132	0,93	17.950	72	
Estonia	1.423.316	1,34	19.072	76	
Luxemburg	442.972	1,23	5.449	22	
Malta	394.583	1,28	5.051	20	
Iceland	277.906	1,46	4.057	16	
Jersey	89.361	1,13	1.010	4	
Isle of Man	73.489	1,16	852	3	
Guernsey	64.342	0,99	637	3	
Faroe Islands	45.661	1,36	621	2	
Liechtenstein	32.528	1,15	374	1	
Monaco	31.842	0,97	309	1	
Gibraltar	27.649	1,12	310	1	

**Legends to tables and Figure.**

Table 1: no legend

Table 2: no legend

Table 3:

The source of this information is the Central Intelligence Agency website

(<http://www.cia.gov/cia/publications/factbook/> )

The last column represents the European activity in CHS in 1995, published by Jim Monro (20)

The column “ New Surgical Patients. 0.4% x Births” represent an *evaluation* from the authors of the number of new surgical patients seen in each country, according to a percentage of births. This number is usually inferior to the number observed because of reoperations and “imported” patients.