Surgery of congenital heart anomalies in countries with limited financial resources

George E. Sarris, MD
Athens Heart Surgery Institute
Mitera Children’s Hospital-Hygeia Group

9th Annual Meeting of the Euro-Asian Bridge
Abundant resources
Limited resources
Selected per capita income data
(in US $)

- Norway 57,000
- US 48,000
- Germany 39,000
- UK 36,000
- EU 32,000
- Spain, Italy 32,000
- Portugal 25,000
- Poland 21,000
- Turkey 16,000
- Bulgaria 14,600
- Serbia 12,000
- Iran 11,470
- Albania 8,900
- Ukraine 7,200
- Jordan 6,000
- Armenia 5,800
- Iraq 3,890
- India 3,650

World Bank, 2011
Why is congenital heart surgery a special case?

- The needs for Congenital Heart Surgery are large, especially in developing countries
- Financial resources are limited, especially in “developing” countries
- Congenital Heart Surgery is expensive
Why is congenital heart surgery (CHS) more expensive?

- Patient pathophysiology is generally highly variable (many rare entities), and treatment generally not as suitable for economies of scale, or, “assembly line” standardization.
- Highly individualized care is more expensive
- Effective CHS is a multidisciplinary effort
CHD – some background facts

- The most common birth defect
- The most common cause of death in the first year of life
- Incidence held to be 8 per thousand live births
- 130 million births yearly worldwide
- More than 1,000,000 new cases CHD yearly
- Significant geographic variation in incidence
  - of CHD overall
  - of subtypes of CHD
The Challenge of Congenital Heart Disease Worldwide: Epidemiologic and Demographic Facts

Pierre-Luc Bernier, Ada Stefanescu, Gordan Samoukovic and Christo I. Tchervenkov

Seminars in Thoracic and Cardiovascular Surgery: Pediatric Cardiac Surgery Annual
Volume 13, Issue 1, Pages 26-34 (2010)
DOI: 10.1053/j.pcsu.2010.02.005
Distribution of Incidence of CHD across 29 studies
Incidence of CHD worldwide: variability by country
Incidence of CHD worldwide: variability by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Sample Size</th>
<th>Years</th>
<th>Incidence Per 1,000</th>
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<tr>
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Incidence of CHD worldwide: variability by income group

<table>
<thead>
<tr>
<th>Country</th>
<th>Incidence Per 1,000</th>
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<tbody>
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<td>Low Income</td>
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<td>Dharan, Nepal</td>
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<td>Lower-Middle Income</td>
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<tr>
<td>New Delhi, India</td>
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<tr>
<td>New Delhi, India</td>
<td>4.2</td>
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<tr>
<td>Higher-Middle Income</td>
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<tr>
<td>Anatolia, Turkey</td>
<td>7.7</td>
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<td>Columbia</td>
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<td>Brazil</td>
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<tr>
<td>High Income</td>
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<td>Bohemia, Czech Republic</td>
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<td>United Kingdom</td>
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<td>Navarra, Spain</td>
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<td>12.3</td>
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<tr>
<td>Central/Eastern France</td>
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<td>Tyrol, Austria</td>
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<tr>
<td>Canada</td>
<td>10.4</td>
</tr>
</tbody>
</table>

Distribution of the incidence of VSD

As a percentage of total CHD
Variability in the incidence of Tetralogy of Fallot
Let's not forget: acquired heart disease in children

- estimated burden of chronic rheumatic heart disease in children and young adults: 30 million
  - 90,000 deaths annually
- estimated burden of Chaga's disease in Latin - South America: 10 million, 30% develop cardiomyopathy
  - 13,000 deaths annually
Lets not forget:
An escalating problem: adults with CHD

- CHD diagnosed during adulthood, requiring surgical repair
- Adults with CHD known since childhood, now requiring operation or reoperation(s)
- The number of adults with CHD (GUCH) estimated to have exceeded that of children with CHD in many western countries
Availability of treatment of CHD around the world

2007-2009 World Society for Pediatric Heart Surgery Manpower Survey:

large disparity in ratio of congenital heart surgeons/population:

– North America-Europe : 1: 3.5 million
– South America: 1: 6.5 million
– Asia: 1:25 million
– Africa: 1:38 million
Pediatric and congenital heart disease: the challenges for each country

• Each country must determine its true needs, in terms of both
  – total number
  – specific types of CHD

• Goal is to allocate enough resources to provide adequate care in order to minimize mortality of CHD
What is the mortality of CHD?

• Mortality data must be interpreted in context of regionally available care
  – major reported mortality differences:
    • 3 to 20% in the industrialized world
    • 20-40% in underdeveloped countries, may approach natural history where care is essentially unavailable
  – differences in socioeconomic groups (black vs white in USA CDC study)
Factors affecting mortality of CHD

• prenatal diagnosis of serious disorders and pregnancy terminations
• early diagnosis and referral to tertiary centers of serious CHD
  – N.B. larger number of less severe diagnoses may “artificially” lower mortality rates, without actual improvement in the care of those afflicted
• improvements in diagnosis and medical and surgical care
What are the necessary resources? (components of cost)

- **Material infrastructure**
  - Hospital facilities
    - Congenital unit
    - Supporting units
  - Equipment
- **Human resources**
  - Adequately trained specialists (doctors, nurses, technicians)
  - Other supporting subspecialty service
- **Running costs**
  - Salaries
  - Equipment maintenance and renewal
  - Supplies (disposables, medications)
  - Consultants and supportive services fees
money is not the only issue!

• Satisfactory national economic parameters and absence of satisfactory CHS programs can coexist!

• While CHS is expensive, and adequate funding is crucial, poorly organized care can waste precious resources:
  – complications are very expensive!
Building two CHS units in Greece
Our experience

Greece – summary of data

- Population: 10 million
- Per capita income: **26,892 $**
- Member of the European Union since 1981
- In Euro – zone since 2001
- Assumed annual incidence of CHD: 0.8/1000 live births = estimated 800 new cases /year
- Estimated need for 500-600 operations /year
- Up until 1997, only one unit (public children’s hospital)
  - 100-150 cases/yr
  - **Large un-met need**

Selected per capita income data
(*US $*, *World Bank, 2011*)

- Norway 57,000
- US 48,000
- Germany 39,000
- UK 36,000
- EU 32,000
- Spain, Italy 32,000
- Portugal 25,000
- Poland 21,000
- Turkey 16,000
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- Serbia 12,000
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- Albania 8,900
- Ukraine 7,200
- Jordan 6,000
- Armenia 5,800
- Iraq 3,890
- India 3,650
Dearani et al: Improving Pediatric Cardiac Surgical Care in Developing Countries: Matching Resources to Needs.

Seminars in Thoracic and Cardiovascular Surgery: Pediatric Cardiac Surgery Annual

Volume 13, Issue 1, Pages 35-43, 2010

Figure 1 A patient-centered multidisciplinary, integrated team approach to the cardiac care of children.
Basic principle: cooperation for a common goal
Checklist

• **Institutional support**

• **Volume goal**: initial minimum 150 cases /yr, potential to increase

• **Integrated multidisciplinary approach for diagnosis and treatment**
  – Diagnosis: pediatric cardiologists and related specialists
  – Congenital cardiac surgery
  – Congenital cardiac anesthesia and perfusion
  – interventional cardiology
  – specialized nursing
  – other allied health (blood bank, pharmacy, subspecialties, social work and organizational support)

• **Pediatric Cardiac Intensive Care**
  – preoperative evaluation and optimization
  – postoperative care

• **Provisions for outpatient follow-up**

• **Quality Assessment Program**
  – Morbidity and Mortality Assessment
  – Data collection and verification
  – Assessment of mortality for groups of patients with appropriate risk stratification methods (RACHS-1, Aristotle Basic Complexity Levels and Score- ABC score, STAT score)

• **Utilization of clinical material and experience** for contributions to professional societies, national and international databases, and national and international journals.
Optimal Structure of a Congenital Heart Surgery Department in Europe by EACTS Congenital Heart Disease Committee

Chairmen:
W. Daenen*, F. Lacour-Gayet, T. Aberg

With contributions from:
The two units:
Both organized utilizing same principles and policies

- **Onassis pediatric cardiac unit**
  - 1997: Building a congenital unit in the context of an *established adult cardiac hospital* in the public domain
    - No general pediatric infrastructure
    - No pediatric subspecialties
    - No maternity facilities
  - 1997-2007 unit run by our group, 200-250 cases / year
  - After 2007, continues to operate to date

- **Mitera Children’s and Hygeia Hospital Pediatric and Congenital Cardiac Unit:**
  - 2007: Building a congenital unit in the context of an *established general pediatric and maternity hospital* without any cardiac care infrastructure in the private domain
  - 2007-now: 200-250 cases/year
Material infrastructure
Hospital facilities & equipment

- Dedicated cath lab
- Dedicated OR
- Dedicated pediatric cardiac ICU (8-10 beds)
- Specialized pediatric cardiac ward (18 beds)
- Outpatient clinic, ER and minor procedure room
Hygeia Polis:
Maternity – pediatric – adult hospital group
congenital unit established 2007
Our core team and process

- 3 pediatric cardiologists
- 4 surgeons (senior/juniors)
- 2 anesthesiologists
- 1 perfusionist
- 3 OR nurses
- 4 ICU nurses
- 2 cath lab nurses, 1 technician
- 1 administrative secretary

- Shared responsibility for patient care
- Training of additional personnel
- Communication
- Uniform patient care /management protocols
- Regular patient care conference and complications review
- Participation in quality of care process aiming to continuing improvement
- Academic endeavors
cooperation
Emphasis on uniform patient management protocols, communication and close cooperation to avoid complications

Potential complications in pediatric cardiac surgery: not a little fish!
Surgical safety checklist


EACTS guidelines for the use of patient safety checklists

Stephen C. Clark, Joel Dunning, Ottavio R. Alfieri, Stefano Elia, Leslie R. Hamilton, A. Pieter Kappetein, Ulf Lockowandt, George E. Sarris and Philippe H. Kolh, on behalf of the Clinical Guidelines Committee of the European Association for Cardio-Thoracic Surgery

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### CONGENITAL HEART SURGERY SAFETY CHECKLIST

**SIGN IN**
Before Induction of Anaesthesia

- [ ] **IDENTITY CONFIRMED**
  - Identity, site and procedure confirmed
- [ ] **SITE MARKED** (or not applicable)
- [ ] **HEIGHT, WEIGHT & B CHECKED**
- [ ] **INFORMED CONSENT OBTAINED**
- [ ] **WARD PREPARATION COMPLETE**
  - (Shaving, shower/hair removal, glycaemic control, blood)
- [ ] **MRA/AISSA STATUS KNOWN**
- [ ] **ANESTHESIA MACHINE, MONITORING & MEDICATION CHECKS**
- [ ] **Perfusion regime & prescriptions agreed, Pulse Oximeter, Warming strategy**
- [ ] **PLAN FOR INTRAVENOUS ACCESS**
- [ ] **KNOWLEDGE ALLERGIES?** Yes/No
- [ ] **DIFFICULT AIRWAY/INSPIRATION RISK?**
  - Yes/Inotropic available/No
- [ ] **RISK OF EXCESSIVE BLOOD LOSS?**
  - Yes/No
  - If yes preparations and plan agreed
- [ ] **PROCEDURE BRIEFING WITH ANAESTHESIA TEAM COMPLETE**
- [ ] **SPECIAL EQUIPMENT IDENTIFIED**

---

**TIME OUT**
Before start of Surgery

- [ ] **TEAM MEMBERS INTRODUCED**
  - (Name & role)
- [ ] **PATIENT & PROCEDURE CONFIRMED**
  - Surgeon, Anaesthetist and Registered Practitioner verbally confirm procedure, site and position
  - Surgical incision/area agreed
- [ ] **THEATRE TEAM BRIEFING COMPLETE**
  - Critical or unexpected events planned for
  - Special equipment requirements ready
- [ ] **INSTRUMENT STERILITY CONFIRMED**
- [ ] **THEME & PROPHYLAXIS**
  - Yes/Not applicable
- [ ] **EQUIPMENT/GROUNDS CONCERNS IDENTIFIED**
  - Durability and pressure points protected
- [ ] **PERFUSIONIST CHECKS & BRIEFING COMPLETE**
  - Myocardial protection strategy agreed
  - Cannulation sites, temperature, ultraltration
- [ ] **SURGICAL SITE INFECTION BUNDLE GIVEN**
  - Prophylactic iv antibiotics, patient warming, hair removal, glycaemic control
- [ ] **IMAGING DISPLAYED B/OR REVIEWED**

---

**SIGN OUT**
Before patient leaves theatre

- [ ] **INSTRUMENTS, SHARPS & SWAB CHECKED**
  - Counted and confirmed as correct
- [ ] **DEBRIEFING PERFORMED**
  - Equipment or procedural problems identified and addressed
- [ ] **OPERATION NOTE DONE**
  - Concerns for recovery/post operative care discussed & recorded
  - Packing box meal & thermowax checked
- [ ] **ICU & DRUG CHARTS CHECKED**
  - Correct and filed

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Checklist signed, complete and correct: ___________________________  Date: ___________________
New procedures introduced in Greece

- **Neonatal open cardiac repairs**
  - Arterial switch operation for simple and complex TGA
  - Repair of TAPVC
  - Sutureless repair PVO
  - Truncus arteriosus
  - Ross-Konno operation
  - ALCAPA reimplantation repair
  - Norwood operation (classic, RV to PA conduit, hybrid)
- **Transatrial / transpulmonary repair of TOF**
- **Homograft use** for R and L cardiac reconstruction
- **The Contegra conduit** for RVOT reconstruction
- **Complex pediatric valve repairs** (mitral, aortic), including Ebstein malformation repairs
- **Single ventricle management to the modified extracardiac Fontan operation**
- **Complete systematic program of surgery for adult CHD**
- **Mechanical circulatory support (VAD, ECMO)**
Transposition of the great arteries
Introduced the arterial switch operation
in Greece in 1997
Multi-institutional study of the European Congenital Heart Surgeons Association

The arterial switch operation in Europe for transposition of the great arteries: A multi-institutional study from the European Congenital Heart Surgeons Association

George E. Sarris, MD, Andrew C. Chatzis, MD, Nicolas M. Giannopoulos, MD, George Kirvassilis, MD, Hakan Berggren, MD, Mark Hazekamp, MD, Thierry Carrel, MD, Juan V. Comas, MD, Duccio Di Carlo, MD, Willem Daenen, MD, Tjark Ebels, MD, Josè Fragata, MD, Victor Hraska, MD, Vladimir Ilyin, MD, Harald L. Lindberg, MD, Dominique Metras, MD, Marco Pozzi, MD, Jean Rubay, MD, Heikki Sairanen, MD, Giovanni Stellin, MD, Andreas Urban, MD, Carin Van Doorn, MD, and Gerhard Ziemer, MD, on behalf of the European Congenital Heart Surgeons Association
Tetralogy of Fallot: Introduced complete transatrial –transpulmonary repair in Greece in 1997
Preservation of right ventricular structure and function following transatrial-transpulmonary repair of tetralogy of Fallot

Panagiotis G. Sfyridis, George V. Kirvassilis, John K. Papagiannis, Dimosthenis P. Avramidis, Constantine G. Ieromonachos, Prodromos N. Zarapopoulos and George E. Sarris

Figure 2: Kaplan Meier curve showing freedom from pulmonary valve replacement.
Introduced the bovine valved jugular vein xenograft conduit (VENPRO®, Contegra®) for pulmonary valve replacement in 1998 in Greece
Conduit function

Estimate of conduit stenosis

![Figure 4. Mean transpulmonary gradient (TPG) in the early post-operative period (POST/OP) and at follow up (F/U).]

Estimate of valve insufficiency

![Figure 5. Degree of conduit valve insufficiency in the early post-operative period and at follow up.]

G. E. Sarris, MD
Kaplan Meier estimate of cumulative reoperation-free survival rate

Figure 3. Kaplan-Meier estimation of cumulative reoperation-free survival rate.

G. E. Sarris, MD
Introduced complete interdisciplinary program for the management of patients with single ventricle

- Introduction of staged approach to the Fontan circulation
- Introduction of the extracardiac Fontan operation
The Fontan Procedure in Greece: Early Surgical Results and Excellent Mid-Term Outcome

Panagiotis G. Sfyridis\textsuperscript{1}, Irene D. Lytrivi\textsuperscript{2}, Dimosthenis P. Avramidis\textsuperscript{2}, Prodromos N. Zavaropoulos\textsuperscript{1}, George V. Kirvassilis\textsuperscript{3}, John K. Papagiannis\textsuperscript{2}, George E. Sarris\textsuperscript{1}

\textsuperscript{1}Department of Pediatric and Congenital Cardiac Surgery, \textsuperscript{2}Department of Pediatric Cardiology, \textsuperscript{3}Department of Pediatric Cardiac Anesthesia, Mitera Children’s Hospital, Athens, Greece

Bidirectional Glenn

Extracardiac Fontan
Tertiary referral center for rare or complex defects
Valve repair for Ebstein anomaly from infancy to adulthood
Results of surgery for Ebstein anomaly: A multicenter study from the European Congenital Heart Surgeons Association

George E. Sarris, MD,a Nikos M. Giannopoulos, MD,a Alexander J. Tsoutsinos, MD,a Andreas K. Chatzis, MD,a George Kirvassilis, MD,a William J. Brawn, MD,b Juan V. Comas, MD,c Antonio F. Corno, MD,d Duccio Di Carlo, MD,e José Fragata, MD,f Victor Hraska, MD,g Jeffrey P. Jacobs, MD,h Sofia Krupianko, MD,i Heikki Sairanen, MD,i Giovanni Stellin, MD,k Andreas Urban, MD,l and Gerhard Ziemer, MD,m on behalf of the European Congenital Heart Surgeons Association
ALCAPA: Repair with reimplantation techniques to transfer LCA originating from non-facing sinus

Repair of ALCAPA from non facing sinus. Syridis et al, in press

G. E. Sarris, MD
Organized team approach for management of adults with CHD

State of the Art

Cardiac Surgery in Adults with Congenital Heart Disease: An Emerging Challenge

GEORGE E. SARIS
Department of Pediatric and Congenital Heart Surgery, Onassis Cardiac Surgery Center, Athens, Greece

Clinical Research

Successful Surgical Correction of Congenital Heart Disease in Adults: Seven Years’ Experience

ANDREW C. CHATZIS, NICOLAOS M. GIANNOPULOS, ALEXANDROS I. TSOUISINOS, GRIGORIOS CHRYSSOSTOMIDIS, CHRYSSA PANAGIOTOU, PRODROMOS ZAVAROPOULOS, GEORGE KIRVASILIS, GEORGE E. SARIS
Department of Pediatric and Congenital Heart Surgery, Onassis Cardiac Surgery Center, Athens, Greece
Mid-term results following surgical treatment of congenital cardiac malformations in adults

A C. Chatzis, NM. Giannopoulos, M Milonakis, CA. Contrafouris, A Tsoutsinos, T Kolettis, C Panagiotou, P Zavaropoulos, P Maraki, T Koussi, J Sofianidou, GV. Kirvassilis and GE. Sarris

Cardiology in the Young, Volume 18, Issue 05, Oct 2008, pp 461-466

- Sept 1997-Dec 2006, **N=335 adults with CHD**
- 167 ASD’s, remaining cover spectrum of CHD
- Age 18-72, mean 35±14 yrs, 54% symptomatic
- 12.5% redo
- Early mortality 0.6%
- Late mortality 0.6%
- Resolution or significant relief of symptoms
Introduction of ECMO

1997

Extracorporeal membrane oxygenation circulatory support after cardiac surgery.

Transplantation Proceedings, Volume 36, Issue 6, Pages 1763 - 1765 A. G. Sarris et al

G. E. Sarris, MD
‘Eternal ECMO’: The challenge of prolonged post-cardiotomy extracorporeal membrane oxygenation

George Sarris
Mitera Children’s Hospital and Hygeia Hospital, Athens, Greece

Extracorporeal Membrane Oxygenation (ECMO) is the most readily available and widely used mode of postoperative mechanical cardiopulmonary support in pediatric cardiac surgery. Yet, the relatively prompt development of major complications limits its usefulness to short-term support, so it is typically used as a bridge to either recovery or to initiation of ventricular assist device support.

However, over the last few years, many improvements in technology and techniques, increased awareness of potential complications, meticulous preventive and supportive individualized patient management entailing development of specific patient—care protocols in the context of a specialized team approach have all resulted in increased duration of effective patient support, thereby maximizing the patient’s chance of survival.

Important technological developments have included:

a) The introduction of coated circuits including oxygenators, heat exchangers, tubing and cannulas (“tip-to-tip” coating) in order to minimize the systemic inflammatory response and the need for high levels of anticoagulation.

b) The shift from centrifugal pumps to axial magnetically levitated pumps that have minimized hemolysis and its serious complications, especially kidney failure.

c) The shift from flat sheet silicone membrane to hollow fiber oxygenators.

d) The development of in-line monitoring equipment for oxygen saturation, blood gases and electrolyte measurement, and for assessment of cerebral and peripheral organ oxygenation.

e) The development of methodology to easily monitor heparin levels and platelet function as well as to monitor coagulation factors has been invaluable for optimal anticoagulation management.

Important developments in patient management have included:

a) Increased awareness of the need to institute ECMO early and promptly, and the organization of rapid ECMO deployment systems and teams.

b) The development of strategies to monitor for, diagnose early and adequately treat subtle but lethally deficient tissue malperfusion.

c) Application of strategies to minimize bleeding and its complications.

d) Increased awareness of the need to aggressively look for and correct undiagnosed or residual lesions that may preclude recovery. Transesophageal echocardiography as well as other imaging diagnostic procedures, both noninvasive (computed tomography) and invasive (cardiac catheterization and angiography) can be performed safely under ECMO. Reparative cardiac operations can also be performed under ECMO support, utilizing a period of conversion to conventional cardiopulmonary bypass if “open” procedures are needed.

e) Aggressive management of tissue edema (peritoneal dialysis and in-line ultrafiltration), which can seriously impair organ function.

f) Efficient control of renal failure (employment of continuous hemodialysis)

g) The development of strict patient infection prevention and treatment protocols.

h) Intensive nutritional support, enteral whenever possible, is key during prolonged support.

i) Specific protocols but also an individualized approach to determine the degree of recovery and achieve safe weaning at the earliest possible time.

All aspects of care of the ECMO patient require a coordinated multidisciplinary team approach and dedicated meticulous care by surgeons, cardiologists, intensivists, anesthesiologists, perfusionists, and nurses while systematic communication with the family regarding the realistic prospects for recovery is essential.

Our presentation pertained the case of an infant with functional single ventricle who required postoperative cardiopulmonary support with ECMO. Although the patient’s late recovery, employment of many of technological and methodological improvements alluded to above did allow us to provide effective and, by ECMO standards, late prolonged support (144 days).

ECMO support can be severely taxing to the technical, human and psychological especially if more than one patients are supported simultaneously. A team approach incorporating many of the recent advances outlined above can facilitate facing such challenges efficiently, optimizing chances to support our patients effectively for longer periods of time and to maximize the probability for their survival.
ECMO

• All who drink of this treatment recover within a short time, except in those who do not.

Therefore, it fails only in incurable cases

-Galen
“Science tells us what we can do; Guidelines what we should do; & Registries what we are actually doing.”
Congenital Heart Disease
Meaningful Multi-institutional Outcomes Analysis

Requirements

1) Common Language = Nomenclature
2) Mechanism of Data Collection (Database - Registry)
3) Mechanism of Evaluating Case Complexity
4) Mechanism to Verify Data Validity and Accuracy
5) Collaboration Between Subspecialties
6) Longitudinal Follow-Up
7) Quality Improvement
Two traditional methodologies for Complexity Adjustment

1) Risk Adjustment in Congenital Heart Surgery-1 (RACHS-1)

2) Aristotle Complexity Score
   - Aristotle Basic Complexity Score (ABC Score)
   - Aristotle Comprehensive Complexity Score

RACHS risk categories

**RACHS-1**
- ASD
- PDA > 30d
- Coarct>30d
- PAPVC

**RACHS-2**
- Coarct<30d
- Vascular rings
- SubAS
- RVOT procedures
- VSD
- PAVC
- TOF
- TAPVC>30d
- Glenn

**RACHS-3**
- PAB
- shunt
- AVR
- Ross
- MV repair/replacement
- TV repair/replacement
- Ebstein>30d
- LCAPA
- RV to PA conduit
- DORV
- TrAVC, CAVC
- TOF-PA
- Coarct-VSD
- ASO
- Atrial switch
- Intracardiac tumor
- Fontan
RACHS risk categories

RACHS-4
• Aortic valvotomy <30d
• TAPVC<30d
• Konno
• ASO-VSD
• ASO-subPS
• 2\textsuperscript{nd} stage ASO
• TGA-VSD-PS (Rastelli)
• Truncus
• Interrupted or hypoplastic arch + VSD
• Unifocalization for TOF-PA

RACHS-5
• Neonatal Ebstein repair
• Truncus interrupted arch

RACHS-6
• Norwood
• DSK

<table>
<thead>
<tr>
<th>RACHS-1 Level</th>
<th>% Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.6</td>
</tr>
<tr>
<td>2</td>
<td>1.4</td>
</tr>
<tr>
<td>3</td>
<td>4.1</td>
</tr>
<tr>
<td>4</td>
<td>8.7</td>
</tr>
<tr>
<td>5 &amp; 6</td>
<td>20.2</td>
</tr>
</tbody>
</table>

STS 2006 Congenital Database
45,635 cases
From Subjective Probability to Objective Data

STAT Mortality Score

The Society of Thoracic Surgeons - European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Score

and

STAT Mortality Categories

The Society of Thoracic Surgeons - European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Categories

STAT Mortality Score and Categories

- Developed based on analysis of
- 77,294 operations entered in the STS Congenital Heart Surgery Databases and the EACTS Congenital Heart Surgery Database
  - EACTS = 33,360 operations
  - STS = 43,934 patients
- Operations were sorted by increasing risk and grouped into 5 categories that were designed to
  1. minimize within-category variation and
  2. maximize between-category variation
### Method of Modeling Procedures

<table>
<thead>
<tr>
<th>Model without patient covariates</th>
<th>Model with patient covariates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STS-EACTS Congenital Heart Surgery Mortality Score (2009)</strong></td>
<td>C = 0.787</td>
</tr>
<tr>
<td><strong>STS-EACTS Congenital Heart Surgery Mortality Categories (2009)</strong></td>
<td>C = 0.778</td>
</tr>
<tr>
<td><strong>RACHS-1 Categories</strong></td>
<td>C = 0.745</td>
</tr>
<tr>
<td><strong>Aristotle Basic Complexity Score</strong></td>
<td>C = 0.687</td>
</tr>
</tbody>
</table>

Congenital Heart Disease
Meaningful Multi-institutional Outcomes Analysis

Requirements

1) Common Language = Nomenclature
2) Mechanism of Data Collection (Database - Registry)
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4) Mechanism to Verify Data Validity and Accuracy
5) Collaboration Between Subspecialties
6) Longitudinal Follow-Up
7) Quality Improvement
Data Verification

1. Intrinsic Data Verification
2. Site Visits
3. Verification with External Data Set (SSDMF)

EACTS Congenital Database Data Verification

Data Verification Certificate

This is to certify that:
Department of Pediatric and Congenital Heart Surgery
(Chairman: George E. Sarris, MD, PhD),
Mitera Children's and Hygeia Hospitals
- Hygeia Group, and Athens Heart Surgery

Successfully underwent verification of the data of operations performed in year 2008 according to the Source Data Verification Protocol of the EACTS Congenital Database on May 17-20th, 2009.

Database Coordinator
Zdzislaw Tobota, MD

Database Director
Bohdan Maruszewski MD, PhD
Prof. of Cardiothoracic Surgery

www.eactscongenitaldb.org

Data Verification Certificate

This is to certify that:
Department of Pediatric and Congenital Heart Surgery,
Mitera Children's and Hygeia Hospitals, Hygeia Group and Athens Heart Surgery Institute - Chief Surgeon George Sarris

Successfully underwent verification of the data of operations performed in year 2010 according to the Source Data Verification Protocol of the EACTS Congenital Database on June 27th, 2011.

Database Coordinator
Zdzislaw Tobota, MD

Database Director
Bohdan Maruszewski MD, PhD
Prof. of Cardiothoracic Surgery

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Bohdan Maruszewski MD, PhD
Prof. of Cardiothoracic Surgery

www.eactscongenitaldb.org
Risk stratified mortality

By basic score

By EACTS-STS stat score
«Gold standard report»

Best 5 team results for TOF repair by (%) mortality

N=2305 patients
overall OM=2.82%

G. E. Sarris, MD
## Results for 8 Benchmark Operations – Discharge Mortality

18,375 index operations at 74 centers

<table>
<thead>
<tr>
<th>Operation</th>
<th>Aggregate</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>VSD repair</td>
<td>0.6%</td>
<td>(0%–5.1%)</td>
</tr>
<tr>
<td>TOF repair</td>
<td>1.1%</td>
<td>(0%–16.7%)</td>
</tr>
<tr>
<td>AVC repair</td>
<td>2.2%</td>
<td>(0%–20%)</td>
</tr>
<tr>
<td>ASO</td>
<td>2.9%</td>
<td>(0%–50%)</td>
</tr>
<tr>
<td>ASO + VSD</td>
<td>7.0%</td>
<td>(0%–100%)</td>
</tr>
<tr>
<td>Fontan</td>
<td>1.3%</td>
<td>(0%–9.1%)</td>
</tr>
<tr>
<td>Truncus repair</td>
<td>10.9%</td>
<td>(0%–100%)</td>
</tr>
<tr>
<td>Norwood</td>
<td>19.3%</td>
<td>(2.9%–100%)</td>
</tr>
</tbody>
</table>

Beyond mortality towards improving quality

How can we measure and monitor quality?
5 Structure Measures
6 Process Measures
10 Outcome Measures

5 Structure Measures

- Participation in a National Database for Pediatric and Congenital Heart Surgery
- Multidisciplinary rounds involving multiple members of the healthcare team
- Availability of Institutional Pediatric ECLS (Extracorporeal Life Support) Program
- Surgical volume for Pediatric and Congenital Heart Surgery: Total Program Volume and also Program Volume Stratified by the Five STS-EACTS Mortality Categories
- Surgical Volume for Eight Pediatric and Congenital Heart Benchmark Operations
  - 1. VSD Repair
  - 2. TOF Repair
  - 3. Complete AV Canal Repair
  - 4. Arterial Switch
  - 5. Arterial Switch + VSD repair
  - 6. Fontan
  - 7. Truncus Repair
  - 8. Norwood
6 Process Measures

- Multidisciplinary **preoperative planning conference** to plan pediatric and congenital heart surgery operations
- Regularly Scheduled **Quality Assurance and Quality Improvement Cardiac Care Conference**, to occur no less frequently than once every two months
- Availability of **intraoperative transesophageal echocardiography (TEE)** and epicardial echocardiography
- **Timing of Antibiotic Administration** for Pediatric and Congenital Cardiac Surgery Patients
- Selection of **Appropriate Prophylactic Antibiotics and Weight-Appropriate Dosage** for Pediatric and Congenital Cardiac Surgery Patients
- Use of an **expanded pre-procedural and post-procedural “time-out”**
Surgical safety checklist

EACTS guidelines for the use of patient safety checklists

Stephen C. Clark, Joel Dunning, Ottavio R. Alfieri, Stefano Elia, Leslie R. Hamilton, A. Pieter Kappetein, Ulf Lockowandt, George E. Sarris and Philippe H. Kolh, on behalf of the Clinical Guidelines Committee of the European Association for Cardio-Thoracic Surgery

CONGENITAL HEART SURGERY SAFETY CHECKLIST

SIGN IN
Before Induction of Anaesthesia

- IDENTITY CONFIRMED
  - Identity, site and procedure confirmed
- SITE MARKED (or not applicable)
- HEIGHT, WEIGHT & AB CHECKED
- INFORMED CONSENT OBTAINED
- WARD PREPARATION COMPLETE
  - (Shoatle, shower/hair removal, glycemia control, blood)
- MESA/MISSA STATUS KNOWN
  - Fistulae – Yes/No
- ANAESTHESIA MACHINE, MONITORING & MEDICATION CHECKS
  - Perfusion regime, prescriptions agreed, Pulse Oximeter, Warming strategy
- PLAN FOR INTRAVENOUS ACCESS
- KNOWN ALLERGIES? Yes/No
- DIFFICULT AIRWAY/INSPIRATION RISK?
  - Yes/report not available/No
- RISK OF EXCESSIVE BLOOD LOSS?
  - Yes/No
  - If yes, preparations and plan agreed
- PROCEDURE BRIEFING WITH ANAESTHESIA TEAM COMPLETE
- SPECIAL EQUIPMENT IDENTIFIED

TIME OUT
Before start of Surgery

- TEAM MEMBERS INTRODUCED
  - (Name & role)
- PATIENT & PROCEDURE CONFIRMED
  - Surgeon, Anesthetist and Registered Practitioner verbally confirm procedure, site and position
- Surgical resection/accord/signed
- THEATRE TEAM BRIEFING COMPLETE
  - Critical or unexpected events planned for
  - Special equipment requirements needs
- INSTRUMENT STERILITY CONFIRMED
  - Yes/Not applicable
- EQUIPMENT/STAFFING CONCERNS IDENTIFIED
  - Orthodoxy and pressure points protected
- PERFUSIONIST CHECKS & BRIEFING COMPLETE
  - Myocardial protection strategy agreed
  - Cannulation lines, temperature ultrafiltration
- SURGICAL SITE INFECTION BUNDLE GIVEN
  - Prophylactic IV antibiotics, patient warming, hair removal, glycemia control
- IMAGING DISPLAYED B/OR REVIEWED

SIGN OUT
Before patient leaves theatre

- INSTRUMENTS, SHARPS & SWAB CONFIRMED AS CORRECT
- DERRIEFING PERFORMED
  - Equipment or procedural problems identified and addressed
- OPERATION NOTE DONE
- CONCERNS FOR RECOVERY/POST OPERATIVE CARE DISCUSSED & RECORDED
  - Paci box mode & thresholds checked
- ICU & DRUG CHARTS CHECKED CORRECT AND FILED

Checklist signed, complete and correct: _____________________________ Date: _______________
## 11 Outcome Measures

1. New post-operative **renal failure** requiring dialysis
2. New post-operative **neurological deficit** persisting at discharge
3. Arrhythmia necessitating **permanent pacemaker** insertion
4. **Paralyzed diaphragm** (possible phrenic nerve injury)
5. Need for **Postoperative mechanical circulatory support** (IABP, VAD, ECMO, or CPS)
6. **Unplanned reoperation** and/or interventional cardiovascular catheterization procedure
7. **Operative Mortality Stratified** by the Five STS-EACTS Mortality Levels
8. **Operative Mortality for Eight Benchmark Operations**
9. **Index Cardiac Operations Free of Mortality and Major Complication**
10. Operative **Survivors Free of Major Complication**
Traditional “Quality Assurance”: A focus on the tail

Frequency

Quality

better

worse

QA threshold (standard)

`acceptable` quality

`unacceptable` quality

Courtesy of Robert Beekman, MD
Focus on the Tail to Assure Quality

... assumes that, if serious failures (the tail) are eliminated, what remains is somehow excellent....

Eliminating the lower 5% does little to affect overall system quality

Courtesy of Robert Beekman, MD
To Truly Improve Quality
the System Must…….

1) Eliminate unnecessary variation*
   (e.g. standardize processes)

2) Achieve & document continuous improvement
   (in care processes & outcomes)

True Quality Improvement

Before

After

Moves the Mean
AND
Reduces Unnecessary
Variation

better worse

better worse

Courtesy of Robert Beekman, MD
Continuing improvement resources

• Participation in scientific societies and meetings
  – EACTS
  – ECHSA
  – WSCTS
  – Euro-Asian Bridge
  – Regional societies - meetings

• Collaboration with other societies
  – AEPC

• “Twinning” programs suggested as a method to gradually transfer knowledge from more experienced to less experienced centers
Hearts for Life across the World

WORLD SOCIETY FOR PEDIATRIC AND CONGENITAL HEART SURGERY

Every child born anywhere in the world with a congenital heart defect should have access to appropriate medical and surgical care!
Teach, create vision, recruit and enlist the best

CROSSROADS: WHERE MEDICINE AND THE HUMANITIES MEET

AN INVITATION TO THE MEDICAL STUDENTS OF THE WORLD TO JOIN THE GLOBAL COALITION TO IMPROVE CARE FOR CHILDREN AND ADULTS WITH CONGENITAL HEART DISEASE ACROSS THE WORLD

Pierre-Luc Bernier¹, Noritaka Ota², Christo I. Tchervenkov¹*, Jeffrey P. Jacobs³, Giovanni Stellin⁴, Hiromi Kurosawa⁵, Constantine Mavroudis⁶, Sertac Cicek⁷, Zohair Al-Halees⁸, Martin Elliott⁹, Marcelo Jatene¹⁰, Richard A. Jonas¹¹, Rob Kinsley¹², Christian Kreutzer¹³, Juan Leon-Wyss¹⁴, Jinfen Liu¹⁵, Bohdan Maruszewski¹⁶, Graham Nunn¹⁷, Samuel Ramirez-Marroquin¹⁸, Nestor Sandoval¹⁹, Shunji Sano²⁰, George Sarris²¹, Rajesh Sharma²², Thomas Spray²³, Ross Ungerleider²⁴, Hervé Yangni-Angate²⁵, Gerhard Ziemer²⁶
THE BOTTOM LINE
How much does it cost?

Hospital charges (Euros) vs case complexity (RACHS-1)
Impediments to development of successful CHS programs

- Deficient organization of general health care infrastructure
- Inadequate general educational and training infrastructure
- **lack of government and/or institutional support to organize care for CHD**
  - Lack of vision
  - Lack of skills
  - Lack of incentives
  - Lack of resources
  - Lack of action plan
Managing Complex Change: Diagnostic Approach

How to effect change:
(Data from Ambrose D. 1987; Managing Complex Change. Pittsburgh: TheEnterprise Grp Ltd.)
conclusion

• Message from our experience in Greece: **matching resources to needs:**
  – emphasis on team work and organizational discipline may allow optimization of use of limited resources and may permit the development of excellent CHS programs without the level of funding available for most congenital units in affluent countries of North America and Western Europe.
Thank you