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# Cost-Effectiveness Analysis: Small Country Pediatric Cardiac Surgery Program Development

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#### Keywords

Pediatric Cardiac surgery, Cost-Effectiveness analysis, Outsourcing Healthcare

# Abstract

**Objectives:** The cost-effectiveness of sending children abroad for treatment of their congenital heart disease (CHD) in small population countries versus developing a local program should be carefully considered. From the purely economic viewpoint, we investigated, the cost-effectiveness of developing such program in a small Eastern-European country.

**Methods:** Calculated costs during different stages in developing a program in North Macedonia were obtained from the Ministry of Health. All patients diagnosed and surgically treated between 2010 and 2017 were included in three distinctive periods.

2010-2012 - Outsourcing (All patients sent abroad for surgical treatment)

2013-2016 - *Foundational* (Program development with assistance from a global charity organization)

2017 - *Tutelage Period* (Semi-Independent program)

Cost-Effectiveness is provided in US\$ per Disability Adjusted Life Years (DALY) a unit of health value.

**Results:** Between January 2010 and December 2017, 384 patients diagnosed with CHD underwent surgical treatment at government expense. The breakdown was: 125, 204, and 55 patients in each period.

The cost-effectiveness of the intervention was \$315, \$297, and \$251 per DALY averted, respectively.

**Conclusions:** Surgical treatment of patients born with CHD is a highly cost-effective intervention, irrespective of the approach taken. Even after accounting for the initial capital investment costs, developing a local pediatric cardiac surgery program seems to be slightly more cost-effective than outsourcing.

# Introduction

With a documented rate for CHD of 7,669 new cases per million live births<sup>1</sup> and a daily global birth rate of 353,000 live births<sup>2</sup>, we could estimate a global incidence of nearly 980,000 new CHD patients born every year. Most of these patients are born in low- and middle-income countries (LMIC), lacking the most basic infrastructure to deal with the diagnosis of CHD, let alone its surgical treatment<sup>3,4,5</sup>.

Some LMIC, with sufficient funding for a public health system capable of providing primary and secondary healthcare, may lack the systematic approach, equipment, or the knowledge to deal with the complexities of CHD diagnosis and treatment safely. Instead, they may resort to some form of outsourcing of cardiac services to reduce their infant mortality rate.

When resources are lacking, the cost-effectiveness of alternative management strategies should be carefully considered to secure an equitable allocation of the limited public health system resources. We investigated the cost-effectiveness comparison between different CHD management strategies implemented by the public health system of North Macedonia.

# **Methods**

An Institutional Review Board waiver was granted for this study by the IRB Committee of the University of Tennessee.

Every patient diagnosed with CHD and surgically treated with funding provided by the Republic of North Macedonia Ministry of Public Health between January 2010 and December 2017 was included in the study.

Data obtained from the Ministry of Health of North Macedonia database was used to account for the patients diagnosed and treated and to calculate total expenditures during the period. Patients were divided into three groups, according to the strategy used.

# 2010-2012 - Outsourcing period

All patients were sent abroad (Sofia, Bulgaria) for surgical treatment

### 2013-2016 - Foundational period

In-country program development with help from a specialized global charity organization utilizing existing University hospital facilities and reassigned local personal

# 2017 - The Tutelage Period

A semi-independent program with its own local human resources and the monthly assistance from a small group of specialized professionals from Belgrade, Serbia.

### Costs

During the *Outsourcing Period*, the referral of patients abroad was based on a capitation system (fixed payment per patient treated independently of diagnostic complexity and including up to 20-day hospital admission). The treating hospital billed extra charges incurred beyond the 20-days capitation period on a case-by-case basis. Neither the costs beyond the 20-day capitation for the handful of complex cases that required it nor the transportation and lodging costs for the patient and companion family member were available, therefore are not included in our calculations.

The Foundational Period costs included: Capital equipment, disposable materials, selected medications, administrative service fees, and travel and lodging expenses for a large team of foreign specialists sent by an established foundation (The William Novick Global Cardiac Alliance) specialized in this type of program support and development.

During the *Tutelage Period*, the costs included limited capital equipment, disposables, medications, service fees, and lodging expenses for a smaller team of specialized professionals from Belgrade, Serbia.

All costs are presented in 2018 US Dollars and with a 3% discounting

# **Cost-Effectiveness Calculations**

Cost-Effectiveness of the interventions was expressed in 2018 US Dollars per DALY averted and it was calculated on a patient-by-patient case by applying a formula used for different congenital heart defects in a previous publication by the authors.<sup>6</sup> Once the individual cost-effectiveness of surgical treatment for each patient in each period was calculated, it was then averaged among all patients treated within a period. Mortalities during each period, with their negative effect on the DALYs averted, were properly discounted.

#### Results

Between January 2010 and December 2017, 384 patients diagnosed with CHD underwent surgical treatment for their congenital heart disease at the expense of the North Macedonia Ministry of Health. The breakdown was: 125 patients treated during *Outsourcing* (2010-2012), 204 during *Foundational (2013-2016)*, and 55 patients during the first year of the *Tutelage period* (2017). Mortality between 2013-2017 was 8%. Mortality during the *Outsourcing* period was never reported back to the Ministry of Health therefore a standard mortality of 5% was used in the calculations for that period.

Total global costs were: \$1,826,791; \$2,813,112 and \$639,812 for each period, while costs per patient operated were \$14,614, \$13,789 and \$11,632 respectively.

Using our previously published average of 46.3 DALYs averted per patient operated<sup>6</sup>, the cost-effectiveness for the different management strategies was estimated to be \$315, \$297, and

\$251 per DALY averted during each corresponding period. Itemized costs for each period can be found in **Table 1**, and the surgical case mix by risk category is presented in **Table 2**.

During the Foundational period, the charity in charge of program development realized nineteen trips a 2-week duration each, adding up to 38 weeks of in-country presence. The median size of the international team of specialists participating on each trip was 15 members (range 12-19) and included surgeon, perfusionist, scrub nurse, intensive care specialists, nurses, anesthesiologist, respiratory technician, cardiologist and nurse practitioner or nurse educator. The costs of airfare and lodging for each team member, as well as the charity administrative fee charges, were included in the estimates.

During the *Tutelage Period*, the surgical visiting team (one week per month) was significantly smaller (7-8 members) consisting of a senior surgeon, cardiologist, anesthesiologist, perfusionist, an intensive care specialist and two critical care nurses. All team members were from Tirshova Hospital with a 30-year-old program and experienced in all aspects of congenital heart disease management. The visiting team during this period traveled only 400 kilometers, allowing for minimal travel expenses while providing close collaboration, consistency, and continuity of care.

Table 1. Costs per period, costs per patient, and costs per DALY Averted										
Period	Capitation	Capital Equipment	Disposable Materials /Meds	Service Fees	Travel /Lodge	Total	Patients operated	Cost per patient treated	Cost per DALY Averted (Averaged 46.3 DALY/patient)	
Outsourcing (2010-12)	\$1,826,791					\$1,826,791	125	\$14,614	\$315/per DALY Averted	
Foundational (2013-16)		\$664,874 <sup>△</sup>	\$938,832	\$680,000	\$610,406	\$2,813,112	204	\$13,789	\$297/per DALY Averted	
Tutelage (2017)		\$126,101 <sup>.</sup>	\$311,000	\$178,000	\$24,711	\$639,812	55	\$11,632	\$251/per DALY Averted	

All costs in 2018 dollars and at 3% discounting

△ Includes: Bedside Monitors; Cardiopulmonary Bypass Machine; New X-Ray System; ACT Machine; Temporary Pacemakers; Surgical Instruments (2 sets); Pediatric Cardio-probe for ultrasound machine.

· Includes: Syringe pumps; Ultrasound equipment.

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RACHS-1 (Risk Adjusted Congenital Heart Surgery) <sup>7</sup>								
RACHS-1	Outsourcing	Foundational	Tutelage					
Risk 1	23	37	10					
Risk 2	59	96	26					
Risk 3	34	55	15					
Risk 4	9	14	4					
Not RACHS case	0	1	0					
Adult Congenital	0	1	0					
	125	204	55					

 Table 2. Number of patients in each risk adjusted categories between January 2010 and December 2017

 RACHS-1 (Risk Adjusted Congenital Heart Surgery)<sup>7</sup>

Not RACHS-1 classifiable patients and adult congenital patients were included in order to accurately calculate the costsper-surgery but excluded from the DALYs averted calculations

#### **Discussion**

Most published cost-effectiveness analyses related to cardiac surgery are circumscribed to answering very specific questions, such as the cost-effectiveness of using a particular device<sup>7</sup> or to compare alternative ways of performing a procedure<sup>8</sup>.

We are unaware of a published study investigating the cost-effectiveness of opening a sustainable pediatric cardiac surgery program.

Outsourcing may take different formats.<sup>7</sup> Health authorities may choose to send complex patients for treatment to an outsourced public or private healthcare center abroad (contracting-out), or they may decide to redirect those patients towards a specialist provider in the private sector within country borders (contracting-in).

Outsourcing may be of a mixed format, by exploiting idle capacity in public health facilities while hiring the know-how abroad (NGO or specialized charity) for organizational, clinical and educational tasks. This alternative form of "in-country outsourcing" may be favored when local specialists are unavailable, but there is a strong interest in treating complex patients within the country, near their families and social support network.

Contracting-out is not a new concept, and its use is not limited to LMICs. Some of the earliest adopters of contracting-out were western health systems, and its implementation goes beyond clinical interventions (e.g., food services, materials management, pharmacy services, and others)<sup>8</sup>

Contracting-out healthcare services from government to non-state providers in LMIC may improve the delivery of a particular service,<sup>9,10</sup> and in some cases, it may represent the only available option for the delivery of primary care, as is the case in so-called "fragile states."<sup>11</sup>

Contracting-out of health services has been documented across several European Union countries (Ireland, UK, Norway, Netherlands, Germany, Denmark)<sup>12</sup>, New Zealand<sup>13</sup> and more specifically regarding cardiac surgical services at the Canada - USA border.<sup>14,15</sup>

The contracting-out of primary care services to foreign charities is a simple alternative solution with good results in many LMIC. <sup>16,17</sup>

In this case, the development of a de novo service for pediatric cardiac surgery at a stateowned hospital was driven by local stakeholders interested in providing higher complexity services within the capital, with the hope of a lesser emotional toll on the families of the patients and the goal of reducing healthcare expenses in some critical areas. An element not found in the literature, and certainly not a factor during the decision-making process, at least in this case, is the unexpected benefit associated with the "spill-over" effect of the development of pediatric cardiac surgery program over other areas of the hospital. Several clinical and support services are likely to be positively influenced in their care delivery from working in proximity to a new tertiary specialty. Not much has been published in this respect, and an accurate quantification of hospital wide benefits of developing a pediatric cardiac surgery program is long overdue.

#### **Current status**

Nine years after the inaugural development trip, program's status is as follows. While the program has been moved from the public University hospital into a private hospital, it continues to provide free cardiac surgery care for all children born in North Macedonia and their families. The capitation payment continues as it was, adjusted for the cost of living. Most patients diagnosed with congenital heart disease at birth are managed by this program, with a total volume of between 100-120 cases a year, including hybrid management of hypoplastic left heart syndrome with mortality similar to that of other Eastern European countries. The program does not treat patients in need of a heart transplant yet.

#### Conclusions

The decision between outsourcing and developing expensive health services in a small country is always difficult and subjected to the willingness to pay by the public health authorities. We attempted in this study to present a clear view of the costs-effectiveness options to facilitate an informed decision by other countries in a similar situation.

All three management strategies proved to be highly cost-effective. Despite the significant initial capital costs, the development of a pediatric cardiac surgery program seems to become a more cost-effective intervention by the fourth year.

#### **Potential Shortcomings of this Study**

Arguably, a potential critique of our study would be the absence of patient's clinical data (diagnosis, age, weight, etc.) following the argument that by not knowing such critical information, no equivalent comparison between the cost for each period could be drawn.

The logic behind such reasoning would be

correct in a Fee-for-Service type of healthcare system, but under a Capitation system such as the one described here, where every surgery is paid a global fee regardless of the diagnosis, risk stratification, age and outcome, we believe the absence of specific clinical data, becomes practically irrelevant.

The intention of this manuscript was to study the political decision process and the economic analysis behind the decision as to whether developing a pediatric cardiac surgery program from scratch in this small country would be beneficial. There are no clinical implications meant to be drawn from our study.

As with most cost-effectiveness analysis, several assumptions were made. For instance, the calculated averted DALYs for the cohort of patients in each period were averaged among all the patients regardless of diagnosis or operation. Otherwise, the DALYs averted per patient would vary significantly between simple and highly complex diagnoses. The purpose of this paper was not to speculate whether some surgeries are more cost-effective than others but whether having a program is more cost-effective than not having one.

During our calculations of the DALYs averted, we decided to avoid using age-weighting and health discounting, understanding that if applied, both principles would lessen our cost-effectiveness results. We based our decision on published opinions underscoring the highly controversial nature of these adjustment tools in calculating DALYs.<sup>18,19</sup> The concept of age-weighting seems, from a purely ethical position, debatable given the fact our interventions were specifically targeted towards the least "productive" members of society, neonates, and children.

While we used discounting at 3% per year on the costs of the intervention, we refrained from using discounting in DALYs calculation since we believe "unlike money, health cannot be invested to produce future gains".<sup>20</sup>

The exclusive use of Cost-Effectiveness thresholds to decide allocations of public health resources can be contentious and may induce public debate.<sup>21</sup> The mere definition of what

constitutes cost-effectiveness in LMIC<sup>22</sup> is not enough to guide public health policy and, a few non-economic factors may have to be taken into consideration. For instance, the unmeasurable benefits of family closeness and know-how transfer should also play a meaningful role in these decisions.

Our situation in North Macedonia was unique. During the Foundational and Tutelage periods, all needed vacant positions to eventually provide the services autonomously were pulled from existing hospital staff and re-trained, consequently lowering costs. We do realize that to create an entirely independently functioning pediatric cardiac surgical unit, all of these positions would need to be filled permanently, thereby affecting the final financial cost. However, given the actual salary costs in North Macedonia at the time of the intervention, the high cost-effectiveness of the intervention would not have been greatly affected by including new personal costs.

Finally, a case could be constructed favoring outsourcing services to a foreign regional program, increasing its volume while maintaining or even improving their morbidity and mortality. While the idea of regionalization of pediatric cardiac surgery programs argues in favor of reaching a minimum volume of cases per hospital and per surgeon at which mortality would be theoretically lower, <sup>23</sup> the many positive effects of developing an in-country solution, including but not limited to the family-social ones should not be overlooked.

An understandable concern about the decision-making process is, why not use a team like the one used during the Tutelage period throughout the entire development, hence augmenting savings.

Starting the first pediatric cardiac surgery program in a country with no history of pediatric cardiac surgery in the public sector and no history of neonatal cardiac surgery at all (and no public adult cardiac surgery program for that matter either) is a complex process. From training the human resources in every aspect of the specialty to the decisions on equipment purchasing or clinical space modifications and functionality, everything had to be planned de novo. While onetime teams coming into a country to do cardiac surgery are easily found, few alternatives exist to develop a de novo program. Our organization specializes in such endeavors. Once the program, the equipment, and the human resources were in place, the clinical spaces were functioning, and most importantly, the know-how became routine, it was much easier for the political decision makers to find a less expensive alternative. Lastly, there is the question of Service Fees. When developing a program at a location where no human resources are available and training of these resources is paramount, we normally resort to bringing a full line of specialists on every trip (surgeon, anesthesiologist, intensive care specialist, perfusionist, respiratory technician, critical care nurse practitioner and several nurses).

With that in mind, and while we welcome volunteers to participate in our program development trips, our organization counts on several staff members who are salaried and work full time traveling and participating in the care of our patients and the systematic training of the local specialists. As an organization dedicated to developing sustainable pediatric cardiac surgery programs, we cannot afford to have vacant positions when arriving at a site. Our ongoing commitments and frequent concomitant trips make relying exclusively on volunteers unreliable.

#### Funding source: None

#### **Conflict of Interest: None**

#### **Key Points**

- The treatment of children born with CHD in small countries lacking cardiac surgery services presents a social, economic, and health policy challenge.
- Surgical treatment of these patients is highly cost-effective, regardless of the approach.
- The decision to develop a sustainable in-country program seems to be slightly more cost-effective than outsourcing health services.

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