

**The Department of Pediatric Cardiac Surgery
AT Univerzitetni Klinični Center
IN Ljubljana, Republic of Slovenia**

Audit Report FOR 2007–2014

July 9, 2015

Audit Committee

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Audit Report Approval by the Commission

Professor Dr. Igor D. Gregoric, <i>President</i>	Date
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Goal of the Report

The goal of the Audit of the Pediatric Cardiac Surgery Services in UKC Ljubljana (Audit) is to analyze and delineate potential insufficiencies in the Department of Pediatric Cardiac Surgery (DPCS) service during the years 2007–2014, focusing specifically on quality of care and surgical outcomes during the year 2012. The findings of the Audit identify the personnel and professional cultural deficiencies responsible for the deterioration of the DPCS service in UKC Ljubljana, and recommend short- and long-term courses for corrective actions.

Abstract

Following the departure of the chief of the Department of Pediatric Cardiac Surgery (DPCS) in 2004, the Univerzitetni Klinični Center (UKC) in Ljubljana, Republic of Slovenia, experienced various challenges in providing surgical services to Slovene children with congenital cardiac diseases. The UKC subsequently entered into an unusual arrangement in which the only available qualified pediatric cardiac surgeon was present to operate only 3–6 days of the month. **This presented numerous problems** in the treatment of pediatric cardiac patients, quality of care for these patients, reoperations, interpersonal DPCS relations, reporting of surgical results in congenital cardiac surgery, and the training of resident Slovene pediatric cardiac surgeons. Service deteriorated sharply, and medical professionals publicized the poor care at the DPCS. This led to public outcry and the formation of the Audit Commission, commissioned by the Medical Chamber of Slovenia at the request of the Ministry of Health of Slovenia and the Government of Slovenia.

Initially charged with reviewing the safety, efficiency, quality of care, and outcomes of pediatric cardiac surgical services for 2012, the Commission arrived in July 2014, extensively reviewed all available data, reports, and databases, and interviewed the personnel at DPCS UKC. It became apparent that the 2012 review alone might not be enough to elaborate on all the questions raised by the commissioning Medical Chamber; therefore, the Commission, in agreement with the Medical Chamber of Slovenia, expanded the audit to include years 2007–2014. After obtaining the database from the data-entering team in Ljubljana and reviewing other previously published official reports regarding the DPCS in Ljubljana, the Commission found frequent discrepancies in the databases that track DPCS surgeries. The Commission asked for additional documents from the UKC leadership and from Dr. Blumauer to clarify these inconsistencies. Numerous requests were made to obtain the supplementary data and information from UKC in Ljubljana during the following months, but the data were either slow in being made available to the Commission or not provided at all.

Despite being unable to provide conclusive findings, the Commission found the following: (1) a small number of surgeries per year at the DPCS in Ljubljana, (2) a lack of reliable data entry into the EACTS registry, and (3) significant deviations from internationally published guidelines and standards of care for pediatric cardiac surgery with questionable surgical outcomes.

Therefore, the Commission concluded that the safety of pediatric cardiac surgical patients at the DPCS in Slovenia had been severely compromised during the years 2007–2014.

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Abbreviations

ASO	Arterial switch operation
AVC	Atrioventricular canal defect
BCPC	Bidirectional cavopulmonary connection
CVS	Cardiovascular surgery
DPCS	Department of Pediatric Cardiac Surgery
DKS	Damus-Kaye-Stansel procedure
EACTS	European Association for Cardio-Thoracic Surgery
EBTCS	European Board of Thoracic and Cardiovascular Surgery
ECMO	Extracorporeal membrane oxygenation
GUCH	Grown-up congenital heart disease
HLHS	Hypoplastic Left Heart Syndrome
ICU	Intensive care unit
LVAD	Left ventricular assist device
PCS	Pediatric cardiac surgery
PHS	Pediatric heart surgeon
PICU	Pediatric intensive care unit
PVR	Pulmonary valve replacement
RACHS	Risk adjustment for congenital heart surgery
RCC	Right Coronary Cusp
STS	American Society of Thoracic Surgeons
TAPVR	Total anomalous pulmonary venous return
THI	Texas Heart Institute
TOF	Tetralogy of Fallot
UKC	University Clinical Center (Univerzitetni Klinični Center)
VSD	Ventricular septal defect

I. Introduction

A. Background

The Republic of Slovenia (Slovenia) is a sovereign European nation that gained independence from former Yugoslavia in 1991. Slovenia is a member of the European Union and has a population of about 2 million people. At no time before or after independence has this country had more than one pediatric cardiac surgery center performing cardiothoracic surgery on children diagnosed with congenital heart defects or disease.

Congenital cardiac disease affects 5–8 children out of every 1,000 live births. Medical advances and the advent of new technologies have significantly decreased the burden of care in many of the simpler cardiac defects. Indeed, many congenital defects can now be managed by cardiac catheterization. However, a large proportion of these defects still require surgical corrections. To standardize the protocols and techniques applied to treat these acute or chronic conditions, professional surgical societies in Europe and USA have developed guidelines and protocols aimed at unifying the level of care and improving the surgical outcomes in these children and adult congenital cardiac patients¹. In this document, these professionals will be referred to as *pediatric cardiac surgeons*.

According to these guidelines, extensive education and skill development is required to reach an adequate level of competence as a pediatric cardiac surgeon. To reflect this adequate level of required training, in 2006 The American Board for Thoracic Surgery established a Congenital Surgical Subspecialty Program. Board Certification is granted to only those pediatric cardiac surgeons who satisfactorily complete all formal training requirements. The eligibility requirements for candidates seeking Board Certification from the Congenital Surgical Subspecialty Program are summarized as follows: *“completion of a regular cardiothoracic surgery residency; during congenital cardiac surgical training the candidates must complete rotations through various departments, including critical care, anesthesia, and the intensive care unit. This enables the candidates to obtain specific and in-depth knowledge on the management of different hemodynamic and respiratory scenarios for patients in intensive care units. In addition to mastering all associated surgical techniques and being familiarized with critical care and anesthesia management of this young patient population, the trainee also gains critical experience in the pre- and post-operative pathophysiologic derailments. The number of cases the trainee is exposed to, especially of more complex and rare pediatric cardiac anomalies seen only in high-volume/ high-quality pediatric cardiac centers, promotes a high level of training, maturity, and expertise of the trainee. The result of this process is a high degree of trainee preparedness to pass the board examination. Most crucially, though, the formal training and skills the trainees acquire enable them to care for these children independently. For the trainee to be considered experienced and receive full credit for the residency, a faculty member must periodically (through entire duration of the training) provide a written evaluation of the candidate.”*

In addition to the candidate's knowledge of theory and proficiency in patient management, the active participation and supervision by the congenital heart surgery faculty is mandatory in preoperative, intraoperative and postoperative care. In Europe, similar developments are, or have been, taking place at the level of the constituent countries; this is currently happening in Germany, the UK and the Netherlands.

After formal training is complete, it is commonly accepted that it takes an additional 3 to 5 years of mentorship under a watchful eye and supervision of a senior surgeon for a young trained pediatric cardiac

¹ Daenen W et al. Optimal structures of a congenital heart surgery department in Europe: by EACTS Congenital Heart Disease Committee 1. Eur J Cardiothor Surg 2003; 24: 343.

surgeon to become a competent, safe surgeon able to function independently and rely on his or her own judgments and decision making in the face of any kind of challenge associated with even the most difficult and complex pediatric cardiac surgical cases. As part of the certification process, at the time of evaluation by the board the trainee must be able to demonstrate the level of training and complexity of cases performed as a primary surgeon (under supervision) or show the number and complexity of operations in which a trainee was involved as a first assistant. As such, it is mandatory for the trainee to keep a detailed case log that is to be presented to the board during this formal review of the candidate's qualifications. These case logs are an integral part of the candidates training and, as such, should be readily available for the mentor or program director of the training institution to review at any time to appropriately evaluate and guide the resident's training. It is the duty of the Chief of Cardiothoracic Services, as well as duty of the program director and trainee's mentor to periodically evaluate and grade the trainee's performance and to share the evaluations with the trainee. There are established international protocols in Europe and the USA as to how these evaluations should be conducted in order to objectively and uniformly educate and train every resident. Collectively, these processes help assure that each trainee is given equal opportunities to learn, participate in surgery and theoretical education, is able to graduate, obtains a certificate of successful training completion, and passes the board exam. Critically, this process also assures a continuity of adequate training and expertise in successive generations of pediatric cardiac surgeons.

The Univerzitetni Klinični Center (UKC) Ljubljana Department of Pediatric Cardiac Surgery (DPCS) in Slovenia was established in the 1960's and became the main pediatric referral center for patients with congenital cardiac anomalies within the former Yugoslavia. The DPCS in Ljubljana has always been a division of the cardiovascular surgery (CVS) department within the hospital. At that time, the UKC served as a main pediatric cardiac surgery center for a population of 20 million. Children referred to the center with cardiac defects received excellent care from a skilled group of doctors and medical staff. During the 1960's and though the 1980's, an average of 250 pediatric cardiac patients a year received medical treatment and surgery at the center. During this time, the team of specialists expanded from cardiac surgeons and pediatricians to incorporate an integrated team of different departments and multidisciplinary staff including pediatric cardiology, pediatric anesthesiology, pediatric cardiac critical care physicians, and pediatric cardiac surgeons. The staff continually received training in highly recognized pediatric centers in Europe and USA and delivered high-quality care (as defined by international standards) for decades.

The very first pediatric cardiac surgeon in Slovenia was a Slovene national who trained outside of Slovenia. Since that time, all the other Slovene pediatric cardiac surgeons at UKC Ljubljana were Slovene nationals who originally completed their training in adult cardiac surgery in Slovenia. These surgeons were then trained in pediatric cardiac surgery at UKC in Ljubljana and obtained additional subspecialty training abroad, mainly in the large centers in Europe and USA. Despite having the Pediatric Cardiac Surgery Center at the UKC in Ljubljana, children with very rare and complex cardiac anomalies were usually sent to large centers in Europe or the USA for definitive surgical corrections performed by the most experienced cardiac surgeons of the time.

B. Deterioration of cardiac surgical services within the DPCS

After Slovenia became an independent European country in 1991, the number of children with congenital cardiac defects who underwent surgery in the UKC Ljubljana DPCS slowly decreased due to diminished referral from neighboring countries.

The DPCS Center in Ljubljana started to show signs of vulnerability at the beginning of the 2000's. At this time two critical events transpired that shaped the future of the pediatric cardiac surgery in Slovenia. First, in 2004, the chief of the pediatric cardiac surgery program became suddenly ill and retired from performing surgical procedures. Complicating his departure, this surgeon was the only trained pediatric surgeon in DPCS at the time. Second, the number of pediatric cardiac operative procedures diminished to fewer than 100 surgeries per year. These two events caused an imminent crisis in the DPCS and suddenly threatened to substantially degrade the quality of care the institution could provide.

As the DPCS at the UKC was the only pediatric cardiac surgical center in Slovenia, the unexpected void caused by the loss of the chief pediatric cardiac surgeon presented the serious problem of how to continue surgical services to Slovene children with congenital cardiac diseases. As a solution to this problem, the administrative leadership of the UKC in Ljubljana (including the Medical Director and the Chief of Cardiac Surgery) with the assistance of the Slovene Ministry of Health, quickly recruited a foreign pediatric cardiac surgeon from Bratislava, **Dr. Sojak**. This surgeon joined the DPCS at the UKC, and pediatric cardiac surgery services continued. During the following three years, the Program stabilized, and most of the pediatric cardiac surgical procedures were performed in Ljubljana. Although there was a plan to eventually train two additional pediatric cardiac surgeons, he remained the only pediatric cardiac surgeon in Ljubljana for the next three years (through October 2007). As backup support, he continued his professional association with his previous institution in Bratislava, Slovakia, where he had completed his training. After being presented at the multidisciplinary conferences in the DPCS Ljubljana, those children needing more complex surgical procedures were sent to Slovakia for surgery.

During the summer of 2007, **Dr. Sojak** started to feel that he was not adequately supported by the institution's administration. The tensions became irreconcilable, and after multiple attempts to resolve the differences between him and the administration, **Dr. Sojak** decided to leave the UKC's pediatric cardiovascular department in October 2007 and pursue his career elsewhere in Europe. Complicating his departure, **Dr. Sojak** was the only pediatric cardiac surgeon within the DPCS at UKC at the time. After his departure, the DPCS in Ljubljana reached a second state of imminent crisis.

Dr. Gersak was the Chief of the DPCS and Head of the Department of Cardiovascular Surgery at the time. **Dr. Gersak** was officially named Chief on February 1, 2006. After **Dr. Sojak's** departure, there were no trained pediatric cardiac surgeons in Slovenia. **Dr. Gersak** informed the governing council of the UKC—administration, medical director, and the chief of the Cardiovascular Surgery Department—of the need to recruit and hire another experienced foreign surgeon to lead DPCS services, perform pediatric cardiac surgery, and train two pediatric cardiac surgeons in the next two years at the UKC in Ljubljana. **Dr. Gersak** informed the governing council that there had been attempts to recruit surgeons from Holland, Austria, Russia, and England, but they were all unsuccessful. As per **Dr. Gersak's** report, **Dr. Mishaly** from Israel was the only surgeon who was willing to operate in Ljubljana on short notice. Therefore, **Dr. Podnar**, the head of pediatric cardiology at UKC at that time and an interventional cardiologist, along with **Dr. Gersak** recommended the hiring of **Dr. Mishaly** in December 2007 to the UKC's governing council for at least two years until the two domestic trainees in pediatric cardiac surgery complete their training (Ref 47, page 2, last paragraph).

Despite the fact that **Dr. Mishaly** would be the only available qualified pediatric cardiac surgeon who could potentially operate on children with congenital cardiac anomalies in Ljubljana, the UKC agreed to a contract stating that **Dr. Mishaly** would perform congenital cardiac operations for only 3-4 visits during the remaining

months of 2007 (Ref 47, page 3, first paragraph, bullet 1), and 3 to 6 days out of the month within the DPCS in Ljubljana for the next few years. During the other 24 to 27 days of the month for two years, the DPCS services were to be covered by the domestic surgical team. Unfortunately, as there were no trained pediatric cardiac surgeons in Slovenia at that time, the service was covered by only two trainees without any staff pediatric cardiac surgeon present in Slovenia. The agreement also stated that within two years **Dr. Mishaly** would train two young residents from Ljubljana to become fully trained pediatric cardiac surgeons (Ref 47, page 4, paragraph 3.1.3 lines 7 and 8; page 5, paragraph 3.1.6 second underscored sentence).

This structure appeared quite unusual and very soon started to trigger numerous concerns from some DPCS staff members regarding the quality and continuity of the services and standard of care for pediatric cardiac patients operated on at UKC Ljubljana.

During the following two years, the goal of training two new residents to become expert pediatric cardiac surgeons was never met (Ref 47, page 2, paragraph 2, bullets 2 and 3; page 5, paragraph 3.1.6 second sentence), and indeed, was doomed to fail from the outset, if only for lack of an adequate number of pediatric cardiac surgeries performed per year at DPCS in Ljubljana. One resident experienced multiple professional problems in the years following his completion of the cardiovascular surgery board exam in Slovenia in 2009 until his departure from the program in December of 2013. The other resident left the country to finish his training and continue his career in Germany as a result of extensive disagreements regarding his training and the direction of the congenital cardiac program in Ljubljana.

With the questionable quality of surgical care for pediatric cardiac patients during **Dr. Mishaly's** prolonged monthly absences from UKC Ljubljana, the concerns within other services also caring for these pediatric cardiac patients in the PCS department began to mount. Additionally, the apprehension among the general public started to escalate when media began to cover the potential substandard of care associated with the new pediatric cardiac surgical arrangements in Slovenia. These concerns widened the communication gap and eroded the trust and working relationships among faculty and staff at UKC Ljubljana from various departments, each charged with providing care to children with congenital cardiac anomalies; some behaviors escalated to being unprofessional. These concerns reached a critical level during the later years of **Dr. Mishaly's tenure**, as stated further in this text.

In response to these concerns, there were several public attempts by the medical and administrative leadership of the UKC to explain to DPCS staff and the public that the DPCS in the UKC was functioning satisfactorily. However, the reality was that a major portion of the physicians involved in the preoperative, postoperative, intensive, and critical care of the pediatric cardiac patients had become increasingly dissatisfied with the quality of surgical and postoperative care the children were receiving at the DPCS within the UKC. Specifically, these medical professionals complained that **Dr. Mishaly** and **Dr. Blumauer** lacked a multidisciplinary approach to pediatric cardiac cases, did not collaborate with other physicians in the decision-making process for surgery, and therefore other physicians were not privy to knowledge about the patients' operating schedules, which often prevented the medical staff from properly preparing these children for surgery.

According to pediatric cardiologist and intensive care physicians, due to the nature of **Dr. Mishaly's** schedule, significant delays to urgent and emergency surgical re-interventions were often incurred. At times, proper surgical treatment was delayed by weeks just waiting for Dr. Mishaly to return. In some cases, this directly affected the medical care of the child in question by unnecessarily prolonging extracorporeal membrane oxygenation (ECMO) or the administration of prostaglandins without proper indication.

Furthermore, according to these testimonies, **Dr. Mishaly** delayed or changed already-planned surgical procedures until his return the following month. These physicians became very uneasy from the standpoint of their moral and ethical obligations and responsibilities to the children in their care and children's parents. They concluded that the safety of the children was compromised due to the lack of a competent, trained senior pediatric cardiac surgeon present daily in the UKC DPCS in Ljubljana. On multiple occasions over a period greater than 5 years, these physicians voiced their concerns to the Medical Director, administrative leadership of the UKC, and the Chief of Cardiovascular Surgery. Their concerns escalated during the last 2 years, until in 2012 an internal review of the pediatric cardiac surgery service was conducted. Despite both their and the Auditor's concerns, the structure and surgical arrangement of the DPCS continued.

The dissatisfaction with the suboptimal arrangement of the pediatric cardiac surgery service and multiple concerns led a large number of physicians to sign a petition to the Slovene's Council for Ethical Medical Conduct. The concerns rose to such an extent that in December 2013, the pediatric critical care physicians sent a letter to the Ethics Commission of the Republic of Slovenia. In this letter, they stated that the pediatric cardiac surgical service had reached such questionable quality that they could no longer ethically collaborate with the DPCS in UKC Ljubljana under its current structure. On December 6, 2013, this letter effectively withdrew their collaboration with the pediatric cardiac surgeons under the present arrangement (Ref 69).

On December 12, 2013, in response to the continued dissatisfaction and the withdrawal of collaboration by the majority of pediatric intensive care physicians and two of the cardiologists with the DPCS, the UKC administrative Leadership, together with the new chief of cardiovascular surgery at the UKC Ljubljana, issued a press release (Ref 71). This press release announced that the pediatric cardiac surgery services in Ljubljana would be indefinitely suspended, and that the children from Slovenia will be transported to Munich, Germany, for the majority of congenital cardiac surgical procedures. Dr. Blumauer's dissatisfaction with his dismissal (Ref 68), the letter of withdrawn support (Ref 69), and other complaints from multiple physicians caring for children with congenital cardiac defects prompted unprecedented action by the Ministry of Health of the Republic of Slovenia and the Slovene Medical Chamber. Facing the worst crisis in pediatric cardiac surgery in Slovenia since the field's conception and the complete fallout between pediatric cardiac surgery and the pediatric cardiology and critical care services, these two agencies together declared that they would commission an External Review Commission to Audit the Department of Pediatric Cardiac Surgery at the University Clinical Center in Ljubljana in order to assess the shortcomings, compliance, and deviations of the department from the international guidelines and standards of care (Ref 72).

An Audit of this nature had never before occurred in the history of the Slovene health system. The Audit was to compare the structure and services of the DPCS to international, evidence-based standards, protocols, and guidelines of the pediatric cardiac surgery associations from Europe and the USA. Its aim was to assess the safety and quality of services rendered to children with congenital cardiac anomalies in Slovenia. The Audit was initially to be limited to the year 2012. Although the Medical Chamber of Slovenia commissioned the Audit to be conducted for only 2012, it became clear that the review required a broader timeframe of analysis of services from 2007 through 2013, a timeline that corresponded with the arrangement of **Dr. Mishaly** operating only 3 days per month in UKC Ljubljana through the termination of his agreement.

II. The Audit Process and External Review Commission

A. Purpose of the Audit

The Audit was commissioned by the Medical Chamber of Slovenia at the request of the Ministry of Health of Slovenia and the Government of Slovenia. The initial goal of the Audit of the Pediatric Cardiac Surgery Service in UKC Ljubljana was to analyze and delineate any potential insufficiencies in the Service during the year 2012. The Audit was also commissioned to review the safety and efficiency of the services rendered to pediatric cardiac surgery patients, to analyze the Service's results, and compare the results to internationally published benchmark data and accepted standards of care during the same year 2012.

Additionally, the goal of the Audit and External Review was to give an objective and unbiased analysis of the facts in safety and quality of care for children with congenital cardiac defects specifically during the year 2012. The agreement was that after obtaining the results of the review, the Commission should be able to provide the commissioning institution - the Medical Chamber of Slovenia - with the outcomes of the analysis for 2012 and provide clear guidance toward the best qualities and practices for the care of children with cardiac defects in Slovenia.

The Commission is very grateful to the administration of the UKC, medical staff, and medical leadership of the UKC and the DPCS for their dedication, time commitment, and seamless organization of the Review and preparation of the Audit during the Commission's members' visit at the UKC in Ljubljana.

However, the Commission is not quite satisfied with the inability of the UKC leadership to provide additional documentation as requested after the audit was completed. Despite the agreement and assurance from the UKC leadership prior to the Commission's members' departure that the documents will be available for review, these key documents were never delivered.

B. Members of the Audit Committee

The Auditing Commission was appointed by the Medical Chamber of Slovenia on the recommendation of the Ministry of Health of the Republic of Slovenia. The Commission included five physicians: three international surgeons and two Slovene pediatric specialists. Each of the members was extensively familiar with the required auditing processes and data reporting.

Both Slovene Auditors are distinguished experts from the ranks of pediatric interventional cardiology and the pediatric cardiac intensive care. They have previously conducted national and international audits and have been associated with the care of pediatric patients for more than 30 years. Their expertise, unbiased reviews, data analysis, integrity, and desire to improve substandard services, mishaps, and insufficient quality have unquestionably been proven on multiple previous occasions and within many previous reports.

The two European physicians are pediatric cardiac surgeons, distinguished professors, and chiefs of their respective departments of pediatric cardiac surgery. They both have extensive clinical and leadership experience in their respective field. However, they are also members and leaders in the Congenital Cardiothoracic Surgery Associations. They both have been involved in the previous audits of various pediatric cardiac programs and are greatly respected in the pediatric cardiac surgery association. They are very familiar with the EACTS database and are readily involved in data analysis of the EACTS data registry.

Dr. Gregoric was commissioned to lead the Auditing Commission by the Slovene Medical Chamber not for his pediatric cardiac surgical background, but predominantly for his understanding of the Slovene language in addition to his knowledge of the Slovene healthcare system. He has been working as a cardiothoracic surgeon for 30 years in the USA and has been involved with the Society of Thoracic Surgery Standards of Care, regulatory requirements, quality control development, FDA research, and auditing processes during his last 15 years in a leadership position.

Professor Dr. Mark Hazekamp

MD, PhD, FEBCTS, registered Congenital CardioThoracic Surgeon (Netherlands Society of CardioThoracic Surgery)

Cardiothoracic and Pediatric Cardiac Surgeon since 1991 and 1993, respectively.

Director of Congenital CardioThoracic Surgery Programs in Leiden University Medical Center, Leiden and in Academic Medical Center, Amsterdam, The Netherlands

Member of Congenital Domain EACTS

Board Member of ECHSA (European Congenital Heart Surgeons Association)

President of the Committee for Congenital CardioThoracic Surgery of the Netherlands Society of CardioThoracic Surgery

Publications: <http://www.ncbi.nlm.nih.gov/pubmed/?term=hazekamp+m>

Professor Dr. Tjark Ebels

High School in NL and USA. College/Medical School: Groningen. Training: General Surgery in Curacao (Netherlands Antilles), Cardiothoracic Surgery in Groningen NL certified 1985. PhD Thesis on Atrioventricular Septal Defect 1989. Chief Cardiothoracic Surgery University Hospital Groningen 1992-2002. Professor Cardiothoracic Surgery 1994. Focus solely on Congenital and Pediatric Cardiothoracic Surgery since 2010.

Organizations

Cardiothoracic Surgery Network

European Association for Cardio-Thoracic Surgery

Netherlands Association for Cardio-Thoracic Surgery

The Society of Thoracic Surgeons

Leadership Bodies

Netherlands Association for Cardio-Thoracic Surgery

Commissie Kinderhartchirurgie

Concilium Cardiopulmonale chirurgie

Publications: <http://www.rug.nl/staff/t.ebels/research/publications.html>

<http://www.ncbi.nlm.nih.gov/pubmed/?term=ebels+t>.

Professor Dr. Metka Derganc

Prof. Metka Derganc, MD, PhD, introduced neonatal intensive care to UKC in 1974, after having finished her internship (Barberton Citizens Hospital, near Cleveland, Ohio) and pediatric residency in the neonatal ICU of Oakland Children's Hospital of Northern California. Later on, she spent several months at a time in the multidisciplinary pediatric ICU in Gothenburgh, Sweden, University College Hospital, UK etc. Between 1989-90 she spent 6 months as a visiting faculty member within the Fulbright Programme at John's Hopkins Medical School and Hospital (PICU), Baltimore, Maryland. She was in charge of multidisciplinary NICU-PICU until 2004, when she was nominated to be the senior counsellor in the PICU and was leading education and research within the Department of Pediatric Surgery and Intensive Care. She helped organize visiting Fulbright professorships of leading pediatric intensivists David Todres, Russel Raphaely (specialized in cardiac intensive care) and Mark Rogers. Although not specifically involved in cardiac postoperative care, she coordinated the surgical and pediatric intensive care, with involvement in the production of protocols for postop cardiac care (with Dr. Sojak and Dr. Kalan), metabolic, infection control, and neurological outcome. In years after 2004, she was engaged by the Leadership of UKC and the Medical Chamber of Slovenia in several audits after unexpected deaths of children, one being non-diagnosed congenital heart disease (with Prof. Robida.). With Prof. Robida, conducted the audit of hypoplastic heart syndrome management at UKC Ljubljana in 2012 (Ref. 153).

Publications: <http://www.ncbi.nlm.nih.gov/pubmed/?term=derganc+m>

www.COBISS.si

Associate Professor Dr. Andrej Robida

Andrej Robida, MD, PhD, FACC (retired), Pediatric Cardiologist (AEPC), Associate Professor of Pediatrics And Public Health.

After the completion of general pediatric training at the University Pediatric Hospital in Ljubljana, Dr. Robida trained in pediatric cardiology in Ljubljana, the Erasmus University Rotterdam, Holland, and the Hospital for Sick Children, London, UK. In Ljubljana, he introduced interventional cardiac catheterization procedures. He was a regular member of the Association for European Pediatric Cardiology (AEPC) and the American College of Cardiology (ACC). In 1990 he left the position as head of the Pediatric Cardiology Department in UKC Ljubljana due to institutional barriers to his efforts to introduce international quality standards to the department. He then served as a consultant and head of pediatric cardiology service within Hamad General Hospital in Qatar, where he had founded a unit for fetal and pediatric echocardiography and introduced interventional catheterization procedures. In 2001, he was invited to the Slovenian Ministry of Health to establish a Department for Quality and Safety to oversee the country's healthcare system. During this time Dr. Robida also served as a co-chair in the European Council (EC) working group for patient safety in the EU. At present, he acts as an expert for patient safety and quality at Technical Assistance and Information Exchange instrument (TAIEX). He is the author of a pediatric cardiology textbook and has authored several papers in international and domestic journals. In recent years he has published several national policy documents and articles regarding patient safety and quality. He is experienced in the audit of patient safety problems and has authored a manual for root cause analysis. He is currently a faculty member within the Department of Medicine in Maribor where he teaches pediatric cardiology and patient safety. He has also introduced a multi-professional curriculum to the faculty of Healthcare Jesenice.

Publications: [http://www.ncbi.nlm.nih.gov/pubmed?term=\(robida%20a\)%20not%20robida%20am](http://www.ncbi.nlm.nih.gov/pubmed?term=(robida%20a)%20not%20robida%20am)
<http://izumbib.izum.si/bibliografije/Y20150704122123-A2103907.html>

Professor Dr. Igor D. Gregoric (President)

MD, FACC, Board-certified in Cardiothoracic surgery, General surgery and certified in Vascular surgery

Chief and Program Director Surgical Division for the Center of Advanced Heart Failure Cardiopulmonary Support and Transplantation Program The University of Texas Health Science Center at Houston-Medical School and Memorial Hermann Hospital - Heart Vascular Institute

Professor of Surgery Department of Cardiothoracic and Vascular Surgery The University of Texas Health Science Center at Houston, and The University of Texas, MD Anderson Cancer Center

Director of Research Center for Advanced Heart Failure at The University of Texas Health Science Center at Houston

Program director: Surgical fellowship in Heart Failure

Prof. Gregoric graduated from Medical school in Ljubljana in 1979. After his internship and military services he served in 1981 for one year as a family practitioner in Kanal near Nova Gorica. He started general surgery residency in Slovenia in 1982 and in 1984 moved to Houston, USA. He served for 8 years as a cardiovascular

surgery fellow in the Texas Heart Institute (THI); among these years he completed 2 years of Vascular fellowship and 2 years of rotations in pediatric cardiac surgery.

In 1992 Dr. Gregoric entered an ACGME accredited residency in general surgery at The University of Texas (UT) in Houston and after the completion of general surgery training in 1996 entered into the ACGME accredited residency in cardiothoracic (CT) surgery at the THI. After finishing the CT surgery training he became a staff surgeon at the Department of Cardiovascular and thoracic surgery at UT in Houston and partial time staff cardiothoracic and vascular surgeon at the THI. He became a full-time staff surgeon at the THI in 2001 when he joined Dr. D. A. Cooley and the Surgical Associates of Texas and became a Clinical Associate Professor of Surgery in the Department of Cardiothoracic and Vascular Surgery at UT in 2007. He continued in that position until 2012 when he moved back to full-time position as a Professor of surgery and a Chief of surgical division at the CAHF at the UT Health Science Center in Houston, Texas.

During the last 15 years Dr. Gregoric has held many leadership positions. He became Associate Chief of Transplant services at THI in 2001 and held that position until his departure in 2012; in 2005 he became a Director for Mechanical Circulatory Support and in 2008 the Director for Center of Mechanical support at THI which he maintained till 2012. During his tenure at THI Dr. Gregoric founded three international meetings, one Medical association for research and education and one outpatient clinic. He was also a director for cardiac transplant fellowship at THI since 2002. After moving to UT he was one of the co-founders of the cardiac transplant and MCS department at Memorial Hermann Hospital and UT in the Center for Advanced Heart failure, which is becoming one of the leading centers in this field in the nation. Additionally upon his arrival, he founded a surgical fellowship in Heart Failure at UT in Houston. He also serves on the Admissions Committee for the ACGME-approved Residency Program for Cardiothoracic surgery at UT M.D. Anderson Cancer Center in Houston Texas.

Dr. Gregoric has authored or coauthored over 200 publications published in peer review journals and has written more than 10 professional book chapters. He also serves as an Editorial Consultant for Texas Heart Institute Journal and is on editorial board for LVAD Journal. He has been involved as a PI or Co-PI in more than 50 IRB and over 20 FDA approved and completed clinical trials in addition to more than 35 IACUC - American Association for Laboratory Animal Science - approved animal studies.

Dr. Gregoric is a member of more than 10 professional societies and Associations and served on multiple professional Committees such as: Transplant Peer Review Committee, LVAD Patient Criteria Team, Operating Room Committee, Cardiovascular Surgery Peer Review Board, Institutional Review Board, Medical Executive Committee, Peripheral Interventional Cardiology Peer Review Board Committee (PRC), Gerson Lehrman – Review/Consultation Committee, At present he is a member of Operative Room surgical Comity, Credentialing Comity, QUAPI (Quality improvement board) for Cardiac Transplant and Mechanical Circulatory support and STS Quality improvement Comity at Memorial Hermann Hospital,

For more information please see his CV (Ref 165).

Publications: <http://www.ncbi.nlm.nih.gov/pubmed/?term=gregoric+i>.

Commission's Mission Statement

Every Audit is slightly different and tailored to specific needs and institutions where it is performed.

It was the Commission's commitment to conduct the Audit and present the report in a professional, honest, and unbiased manner. The results of the Audit will be based on published literature regarding the quality of pediatric cardiac surgery services and common practices regarding similar reviews and recommendations derived from published articles, including (but not limited to):

- 1 World Journal of Pediatric and Congenital Heart Surgery Quality Measures published in 2012
- 2 US National Quality Forum Standards published in 2011
- 3 STS Standards for Pediatric Cardiac Surgery
- 4 Children's' Congenital Cardiac Surgery Standards from England published in 2012
- 5 EACTS Congenital Database Policy
- 6 Aristotle Scores for Evaluation of Pediatric Heart Surgery Results published in EJ CTS in 2006
- 7 Guidelines for Pediatric Cardiovascular Centers from the Journal of Pediatrics from 2002
- 8 Pediatric Cardiology and Heart Surgery Score Cards from 2009 to 2014 in US Hospital Ratings
- 9 Review examples, such as one From Belfast Review for Pediatric Heart Surgery – 2012
- 10 And personal experiences of the Audit Committee conducting similar reviews in the past.

C. Preparations for the Audit

The very first communication from the President of the Medical Chamber of Slovenia was via email in March 2014. Nevertheless, the official agreement between the initial three members of the Commission and the Medical Chamber was on April 1, 2014, at the meeting in the **Dr. Andrej Mozina's** offices in Ljubljana (Ref 1). At this meeting, the members of the Commission were bound to carry out the Audit objectively, in a professional manner, with the highest moral-ethical standards and integrity, and in accordance with the international standards and guidelines.

All three Slovene members of the Commission waived their rights for the honorarium and agreed to perform the Audit pro bono.

The meeting also concluded that **Dr. Mozina** would ask the UKC administration and the physicians at the UKC in Ljubljana to prepare all necessary patients' documentation required for the Audit, that **Dr. Mozina** would prepare the financial analysis required for the Audit, and that there may be a need to expand the audit beyond the year 2012, as requested by Ministry of Health, to include 2007 through 2014 as well. The meeting's minutes specifically outlined: a) that most likely there will be a need for additional international Auditors, who are practicing pediatric cardiac surgeons with great international reputation, and who will add objectivity to the Audit; b) that the auditors will follow the international guidelines, mainly European and those of the United States, for the assessment and evaluation of the program, and the Auditors will strictly adhere to these standards in the final Report. **Dr. Gregoric** was commissioned to provide the American standards, and **Dr. Derganc** was to provide the Committee with the European standards.

In the middle of April 2014, **Dr. Gregoric** informed The Medical Chamber of Slovenia about his discussions with US Joint Commission auditors and the possibility of their staff helping with the Audit in Ljubljana. The preliminary information given by the Joint Commission revealed that it is not customary for the Joint

Commission to conduct international Audits, specifically not if they have to enter the data by themselves. Their staff performs Audits of data already entered to the databases and provides reports about compliance. However, they informed **Dr. Gregoric** that they could potentially aide in locating a group of experts able to conduct the requested audit. Nonetheless, they indicated that it would be very difficult to get their staff to Slovenia within the required timeframe (6 months to one year from the point of that discussion), and their cost would be more than 100,000 USD. This information was presented to **Dr. Mozina** via a telephone conversation that took place approximately three days after it was learned.

In parallel, **Dr. Gregoric** also contacted the Society of Thoracic Surgeons (STS) and their quality assessment department within the Duke Clinical Research Institute (DCRI) at Duke University in North Carolina (Ref81). He inquired about a possible STS Panel going to Slovenia to help perform such an Audit.

Dr. Gregoric informed **Dr. Mozina** and other members of the Audit Commission about his findings in a detailed email (Ref 3) on May 11, 2014. That email stated that discussions with three separate potential international auditors were being explored at that time: 1) the Joint Commission as stated previously, 2) with the STS National Database and DCRI (Ref81), and 3) with the European Board of European Association of Cardio-Thoracic Surgery (EACTS) Congenital Chapter [CCB] in England and Holland. The progress of the discussions as that time was as follows:

- 1) The Joint Commission discussions were moving very slowly due to difficulties establishing appropriate contacts and due to their need to booking 6 months to one year in advance.
- 2) The STS discussions were slightly more promising. However, the leadership of the STS auditors stated that they typically did not conduct audits in this fashion, and the STS would have to assemble a team specifically for work in Slovenia. This appeared to be quite difficult to do. They also informed **Dr. Gregoric** that there is currently no existing body in the US that performs such audits, since the kinds of problems presented to the STS Representative regarding Ljubljana, are extremely rare. The STS was not optimistic about being able to assemble such a team, but stated they would inform the Commission if such a team could be assembled and what their budget needs would be.
- 3) The discussions with CCB in Holland were the most promising and hopeful. It was expected that Slovene Auditing Commission would have their conclusion within a matter of a week or two of the dated email.

In the same email, **Dr. Gregoric** proposed to present a set of finalized options to the Slovene Auditing Commission in the following weeks from which the most optimal choice could be made.

In his email, **Dr. Gregoric** also emphasized that these kinds of Audits – even if conducted in US – need prolonged time for preparation, since it is necessary to prepare the Audit specifically for the individual institution. It was noted that there is no uniform protocol for this kind of inspection. **Dr. Gregoric** outlined that it will be necessary to include the pediatric cardiologists, the pediatric intensivists, pediatric anesthesiologists, and to review the financial part of the pediatric cardiac surgical services in Ljubljana, in addition to reviewing the “leak” of patients to facilities abroad. It was concluded that it would be also necessary to review the mortality of children who had surgery in Ljubljana and abroad in addition to morbidity of these children.

At the end of May 2014, in an email, **Dr. Gregoric** (Ref 4) informed the Medical Chamber of Slovenia that it would be better to use European Auditors for two reasons. First, the Slovene system is closer to the European system. As a result, pediatric cardiac surgical departments usually report data to the European

Database. This central database allows for these departments to be compared to each other. Second, the discussions with US Joint Commission and STS quality assessment department were extremely slow and really not very promising.

In an email dated May 27, 2014, **Dr. Gregoric** outlined in detail what was expected from the Audit at UKC Ljubljana and shared his suggestions with the Commission and the Medical Chamber. Everyone accepted the plan (Ref 5) and agreed that at least two European pediatric cardiac surgeons needed to be identified as potential auditors. During June 2014, there were many emails between the European Pediatric cardiac surgeons and **Dr. Gregoric** to further discuss how to conduct the Audit in Ljubljana (Ref 6). **Dr. Gregoric** was in contact with **Dr. Mark Hazekamp** from Leiden who is on the Board of the European Congenital Heart Surgeons Association and who had accepted the invitation to be a Commission member for the Audit in Ljubljana. It was felt it would be better to have more than one pediatric cardiac surgeon in the Commission to help eliminate bias and promote objectivity. **Dr. Hazekamp** suggested inviting **Dr. Ebels** from Groningen, Holland who had done similar Audits in the past. **Dr. Ebels** was familiar with the process and served on the EACTS Chair Pediatric & Congenital Database Committee. **On the specific question of whether there was any forum in Europe that can conduct the kind of chart reviews, interviews, and data analysis needed in the Audit to be conducted in Slovenia**, the response from the European Experts was, **“Other inquiries in the past (in other European countries) have been made usually on an ad hoc basis, typically by a mix of government agencies and invited professionals. There is not a structured approach towards these audits”** (Ref 5).

During the next few weeks the date for the audit was confirmed. Initially it was suggested by **Drs. Hazekamp and Ebels** to conduct the Audit on September 1, 2014. However, **Dr. Gregoric** recommended to the Commission that the Audit be conducted much sooner due to the very sensitive topic and the anxiety of the Slovene authorities pertaining to the review. Everyone agreed to go forward sooner, and the official Audit date for the pediatric cardiac surgery program in Ljubljana was set for July 12 – 14, 2014. At the time of date confirmation **Drs. Hazekamp and Ebels** also outlined the financial proposal for their honoraria (June 21, 2014), which was accepted by Officials within the Slovene Medical Chamber. (Ref 7).

Within the agenda for the Audit, **Dr. Hazekamp** outlined that, “We need to do 1) a revision of the operations of 2012, 2) interviews with all relevant people and 3) visit the facilities (OR, ward, ICU, PICU maybe NICU and cath. lab). It would be very helpful to have the operative data in the EACTS Congenital Database to be able to analyze them properly. Can you ask the people over there if this has already been done? If not they should probably do this before we arrive. If not we may need more time (after the audit) to analyze these data properly, which in turn means that the results of the audit will arrive later than the medical chamber of Slovenia might wish...” (Ref 8).

On June 24, 2014, in a correspondence between the Members of the Audit Committee, some Committee members already mentioned that even though the pediatric cardiac surgery department was a member of the EACTS since 2007, it appeared that not even one single patient was ever entered to the EACTS database by the pediatric cardiac surgery team in Ljubljana (Ref 9).

On June 26, 2014, **Dr. Radovan Hojs** informed the President of the Medical Chamber and the Audit Committee that everything was set for the Audit visit on July 12-14, and the UKC hospital, medical, and administration leadership had agreed to the requests for the Audit made by the Medical Chamber and the Commission. At that time the UKC indicated that the documentation was ready for Audit and entry into the database, and the personnel would be available for interviews (Ref 10).

On July 1, 2014, **Dr. Mozina** summarized in his email his suggestions to the Commission and to the administration at UKC Ljubljana regarding personnel availability, expanding the Audit to include the data from 2007 through 2014, and to create the list of personnel the Commission desired to interview. To address the comments from some individuals at the UKC regarding potential conflicts of interests of the Commission members and the structure of the Commission selection, he assured the Committee of his unequivocal support and firm agreement to go forward with all five members of the Committee as planned (Ref 11).

The detailed plan for the Audit was outlined on July 7, 2014, in an email to all the Committee members and to the Slovene Medical Chamber President, Dr. Mozina. All members of the Committee agreed with the plan. However, **Dr. Mozina** expressed some concerns regarding the interviews with the patient's parents or families. He was concerned that the situation at the UKC was a very sensitive public topic, and there are some biases both within the media and also the population of Slovenia (Ref 12).

In an email from the Commission President dated July 10, 2014, **Dr. Mozina** was informed of the proposed plan, introduction, and the intended agenda for the July 11, 2014, meeting at UKC in Ljubljana (Ref 13).

Before the official Audit started, on July 11, 2014, **Dr. Blumauer** submitted his list of operations performed during 2012 in addition to their Aristotel score data to the Commission, Dr. Mozina, and to the Administrator of the cardiothoracic surgery department at UKC Ljubljana (Ref 14, 15, 16).

D. Conduction of the Audit

The Commission arrived at the UKC in Ljubljana on July 11, 2014, at 2 pm. They first met with the president of Medical Chamber of Slovenia, Members of the Administrative and Medical leadership of the UKC in Ljubljana, and the Chief of Cardiovascular Surgery department in UKC under whom the pediatric cardiac surgery department is structured. After the introductory greetings and outlines of the Audit were conveyed, several conclusions were drawn.

First, the Audit was to start immediately. Second, the UKC staff was to make available any and all relevant data and documentation required by the Commission. Third, the doctors and other personnel would be made available for interviews as well as assisting or otherwise explaining information necessary for the Commission to conduct the Audit. Fourth, UKC personnel were also to assist in facilitating the availability of patients contact data (e.g. parents of operated children) to the auditors in order for the auditors to call them for the interviews. It was determined then that between 8–10 families would be randomly chosen from the list of all patients (Ref 19).

Immediately upon the conclusion of this meeting, the Commission moved to the cardiovascular surgery conference Suite (UKC 7th floor) and started the formal Audit. The basic components of the Audit consisted of: 1) inquires about documentation and protocols, 2) examinations of compliance and adherence to international standards of care, education, training, skill maintenance, interpersonal and interdepartmental communications, research, etc., 3) chart reviews and data entry to the EACTS Database by **Drs. Ebels and Hazekamp**, and 4) formal interviews.

During the audit, the Commission had the privilege of interviewing the medical leadership of various departments caring for children with congenital cardiac defects at the UKC Ljubljana in addition to the professional staff, nurses, and a wide range of physicians. In addition, the Commission interviewed the parents of the children operated on in the DPCS at the UKC Ljubljana. The families were randomly selected to eliminate any bias. Some members of the UKC administration leadership were also interviewed during the Audit.

To acquire objective data from children operated on at the Center, all of the charts available for the year 2012 were given to and reviewed by the Commission. All immediately needed data were entered into the EACTS Database by the Committee members. The Commission members were assured by the administrative and medical leaders that the charts were complete and were, indeed, representative of all the charts from all the children who underwent congenital cardiac surgery during 2012 at DPCS in Ljubljana.

The **review concluded on July 13, 2014**, however the audit formally concluded on July 14, 2014 with the wrap up meeting. The President of the International Commission showed gratitude and expressed thanks to the UKC administration and physicians for their hospitality and availability. The Auditing Commission was pleased with the assistance and accessibility of the personnel, documentation, and the space provided, in addition to the administrative support given to the Commission that enabled an uninterrupted Audit.

The meeting concluded with the agreement that there is further information needed regarding **Dr. Blumauer's** operative logs and also the number of children sent abroad for operations relating to congenital cardiac defects, specifically during the year 2012. It was furthermore agreed that the UKC administration and the clinicians in conjunction with the medical leadership of the UKC would provide additional information regarding the number of children treated for congenital cardiac defects in Slovenia, their success rates, and the mortality prior to surgical interventions for the year 2012. However, the Commission indicated this same information from the years 2007–2014 should be included, if possible. It was also agreed that **Drs. Weiss and Kalan** would enter the rest of the data into the EACTS Database through mid-September 2014, or its completion. These agreements were outlined in a letter from the President of the Auditing Commission addressed to the President of the Medical Chamber of Slovenia dated July 16, 2014 (Ref 21). In an email dated July 13, 2014, addressed to members of the Commission and **Dr. Mozina, Dr. Gregoric** outlined suggestions for the press release about the Audit (Ref 22).

E. Sequence of Events Following the Audit

By August 19, 2014, neither the Administration nor the medical leadership of UKC Ljubljana had provided any of the information requested by the Commission. In an email dated August 19, 2014, from the President of the Audit Commission to **Dr. Mozina**, a request was made for the assistance of **Dr. Mozina** to help gather this crucial information. Additionally, in this email the President of the Audit Commission informed **Dr. Mozina** about his direct email request to **Dr. Blumauer** for him to provide the Commission with his operative logs. (Ref 23)

In the same correspondence, **Dr. Gregoric** pointed out to **Dr. Mozina** and the members of the Commission that, “It appears to the members of the Audit Commission, that the lack of commitment at the DPCS and UKC that lead to the pediatric Cardiac Surgery turmoil continues even after the audit, and NONE of even the simplest goals asked by the Audit Commission, have been achieved yet. **It is definitely**

important to recognize that, unfortunately, this fact does not really give good prospects for the culture change needed for a new start in developing the successful DPCS center in Ljubljana.” (Ref 24)

On August 20, 2014, **Dr. Mozina** informed the Auditing Committee about his inquiry into the inertia at UKC Ljubljana for providing the additional agreed upon documents and his directive to them about the urgency and importance of these data. He reported that there was a guarantee from the UKC to arrange for these data to be given. (Ref 25)

On August 24, 2014, the president of the Auditing Committee received the answer from **Dr. Blumauer** detailing why he could not provide the requested logs of his operative reports. His explanation was that he is no longer employed at the department for pediatric cardiac surgery at UKC Ljubljana, and for him to obtain these logs he would require a specific permission from the UKC Administration to review the operative reports. In addition, **Dr. Blumauer** provided the Commission with a letter from his lawyer indicating that any and all future correspondence to **Dr. Blumauer** should be routed through his legal representation. (Ref 26, 27)

On September 7, 2014, **Dr. Mozina** sent another request to the UKC’s administration regarding data that were not yet received by the Commission.

Despite the lack of this critical data, the Commission started to write the preliminary report about other aspects of the Audit conducted in the second week of July 2014. A portion of the preliminary report about the structure and adherence of the pediatric cardiac surgery department at UKC in Ljubljana to the international standards was concluded, and it was sent to the members of the Commission on September 17, 2014, to be reviewed and edited (Ref 29).

As per the reports in the Slovene media regarding “delays” with the report of the Commission, the members of the Commission responded that they reserve the right to deliver the final report after all the data are gathered and all analysis and results are completed. This message was conveyed to **Dr. Mozina** in a letter dated September 27, 2014. In the same letter, **Dr. Mozina** was informed that the password to the EACTS database was changed by the staff at UKC in Ljubljana without prior notification (Ref 32). Although they had the right to do so, this action definitely made the work of the Commission more difficult (Ref 30). After escalating the issue to Drs. Weiss and Kalan, this awkward problem was corrected, and the new password was provided to the Commission on September 29, 2014 (Ref 66).

On September 30, 2014, in a press release statement **Dr. Mozina** informed the Slovene media and the public that the International Auditing Commission had not yet received any of the data requested by the Commission, and by that time the Data entry to EACTS was not yet completed (Ref 31).

The following day, all members of the Commission and **Dr. Mozina** agreed to wait for the complete data to be entered from years 2007 to 2014. It was agreed that the report would be finished only after this data was analyzed and the results were finalized. It was also noted that this may take another few months to accomplish. **Dr. Mozina** informed the Commission regarding the protocol to be followed for reporting the data and results and the directive given by the Ministry of Health concerning the release of the Commission’s findings to the public (Ref 36).

III. Results of Audit

A. Structure and Location of the Congenital Pediatric Cardiac Surgery Service in Ljubljana

During the last two decades, the number of congenital cardiac surgical procedures conducted at the DPCS in Ljubljana significantly decreased due to the loss of patient referrals from neighboring states, after former Yugoslavia fragmented into separate countries.

The DPCS is the only Slovene pediatric cardiac surgery, and it is structurally a part of the Cardiovascular Surgery Department at UKC in Ljubljana. However, the surgical theater and the daily activities are based in the Pediatric Hospital, which is part of the adjacent University Clinical Center in Ljubljana. The most modern catheterization laboratory is located in the Pediatric Hospital building and opened along with this building just a few years ago. This lab is in close proximity to the state-of-the-art pediatric intensive care unit that houses 14 ICU beds. The pediatric cardiac operative room is on the same floor next to the intensive care unit, which allows for optimal flow of services for the postoperative care of pediatric cardiac patients.

According to international standards, a pediatric cardiology center caring for congenital cardiac pediatric patients must be staffed by at least one pediatric cardiologist per 500 thousand people served (Ref 86, p. 29, C8). The Center in Ljubljana has one senior interventional cardiologist and one interventional cardiologist in training. In addition, there are two non-interventional trained pediatric cardiologists caring for these children. These three staff cardiologists and one in training barely meet the minimum standard for adequate staffing at UKC Ljubljana.

The critical care unit is well staffed with physicians. These physicians have received appropriate training, they have extensive experience, and the team provides full 24/7 coverage of services in the intensive care unit.

The pediatric cardiac anesthesia unit is understaffed with only one dedicated pediatric cardiac anesthesiologist. However, there are additional pediatric anesthesiologists who provide anesthesia for pediatric congenital operations. The Commission was not privileged to competency information and the level of training for these additional anesthesiologists. Furthermore, the Commission could not establish the patient volume of practice per anesthesiologist or the logistics for the structure of the Anesthesiology department. An official document reported on January 20, 2012, (Ref 47) indicates that for the 6 years spanning from 2007 through 2012, the Pediatric Cardiac Surgery Center in Ljubljana provided an average of less than 100 operations for children with congenital cardiac anomalies per year (23 in 2007, 106 in 2008, 90 in 2009, 150 in 2010, 68 in 2011, and 96 in 2012; Ref 47). Our data analysis confirmed there were less than 100 congenital cardiac surgical procedures performed per year at DPCS in UKC Ljubljana during this time.

The relationship with cardiology and other services caring for these young patients was initially cordial and professional. This professional environment facilitated good teamwork across the various pediatric services. However, because of rising concerns and questions of the quality and safety of surgical services provided by the DPCS raised by a number of critical care and pediatric cardiology physicians, the relationship became strained in recent years. The tensions grew larger and eventually led to the collapse of the pediatric cardiac surgery center followed by cessation of the pediatric cardiac surgical services at UKC in Ljubljana in December 2013.

During the period of 2007-2013, pediatric congenital cardiac surgical services were rendered by only one experienced senior staff surgeon and, most of the time, by one junior surgeon. Unfortunately for the service, the senior staff surgeon spent a mere three days out of every month on the premises of UKC Ljubljana and lived in a different country the rest of the time. During the other 27 days of the month for 2007-2009, all pediatric cardiac surgical services depended on pediatric cardiac surgical trainees. After the trainees acquired their general cardiac surgical board certifications (one in 2009 and the other in 2010), they were still undertrained in regards to more complex pediatric cardiac procedures. For the majority of the month when the senior pediatric cardiac surgeon was away, the entire pediatric cardiac surgical service continued to rely on undertrained pediatric cardiac surgeons who were unable to carry the burden of the most difficult decisions or operations due to their lack of experience. **The leadership at DPCS was aware of this situation and the Commission can only conclude that the UKC and DPCS Leadership was undeniably accepting or allowing this structure to continue.**

Additionally, the documentation at the DPCS at UKC was very scarce. It was sometimes difficult for the Commission to assess the appropriateness of the procedures or even to discover what procedure was actually executed in the operative room. This was specifically due to a substantial lack of documentation and operative reports.

Between 2007 and 2014, the DPCS was affiliated with the Sheba Medical Center in Israel, the parent institution, where the children with congenital cardiac defects that could not be operated on in Slovenia were sent for surgery. Although there was an affiliation agreement between the two centers, the Commission was not able to obtain any written protocols or guidelines describing which patients should go for surgery abroad, nor were there any written protocols or standard operating procedures about who would make such decisions. The Commission was not given any written protocols regarding the criteria for surgical treatments abroad, nor was there a record as to which or how many patients were actually treated in Israel. The Commission concluded that this arrangement made the DPCS at UKC in Ljubljana very vulnerable and prone to inconsistencies and substandard care.

B. Findings regarding personnel, Dr. Mishaly

The agreement between UKC Ljubljana and **Dr. Mishaly** stated that **Dr. Mishaly** was hired for contractual - locum work until such time that he obtained a Slovene medical license. After acquiring the proper licensure he would be given a new contract. **Dr. Mishaly** was initially hired to operate in Ljubljana only 3-6 days per month; for the rest of the month, he was not present in Slovenia at all. In addition, to help **Dr. Mishaly**, **Dr. Gersak** (head of CVS at the time) stated in his proposal to the UKC leadership that there were two residents (**Dr. Blumauer** and **Dr. Vodiskar**) in training for conducting pediatric cardiac surgery (PCS). The initial agreement and contract with **Dr. Mishaly** in 2007 stated these two specific residents would be trained during a period of one to two years and, afterward, would be capable of conducting independent surgical procedures for all congenital cardiac cases. However, in June 2011, four years after the commencement of his service, **Dr. Mishaly** stated in an interview that these residents needed an additional 2-3 years of training before they could be considered trained and independent. That meant the two trainees would complete their training in 2013 or 2014.

During an internal audit in January 2012, it was discovered that **Dr. Mishaly** had yet to obtain a Slovene license and was still performing surgery in UKC Ljubljana on locum authorship contractual basis. A new contract with **Dr. Mishaly** was never signed. The Audit also discovered that because **Dr. Mishaly** had been operating for the previous 5 years in Ljubljana under a locum agreement and without a Slovene medical license, he did not officially accept responsibility for his surgeries at DPCS (Ref 47; page 3; paragraph 2 – bullet 1). Additionally, the review discovered that for the same reason, some surgical procedures performed by **Dr. Mishaly** were entered into the record system under **Dr. Blumauer's** name (paragraph 3.1.1 under Ref 47). Furthermore, during the same audit (signed by the legal representative of the Clinical Center of Ljubljana [UKC], **Mrs. Zeleznik**, on January 20, 2012, Ref 47), it was reported that the administrative director of surgical services at UKC in Ljubljana was not informed about the aforementioned contracts, discussions, and agreements (page 3, paragraph 2 – bullet 2).

In a letter from Dr. Podnar, the head of pediatric cardiology, to the CEO of the UKC in September 2009, major concerns were voiced that addressed the dependence of PCS service on the surgeries performed by **Dr. Mishaly**, the absolute need to have a senior pediatric cardiac surgeon present daily at UKC, and the insufficient and even lack of training the two trainees' under the mentorship of **Dr. Mishaly** were receiving that would facilitate them to independently perform congenital cardiac surgical procedures. Despite these warnings, the factual arrangement between UKC and **Dr. Mishaly** continued without any necessary changes.

In summary, among the other findings, the January 2012 internal Audit of UKC (Ref 47) concluded:

1. There was no established functional residency program with written timeline requirements, case logs, and necessary education with continued evaluation of the resident prior to completion of the training.
2. There was no official contract between UKC and Sheba Medical Center in Israel, and the agreement between the UKC and Dr. Mishaly was only a verbal agreement.
3. During resident training and education, the protocols and guidelines for their rotations and timelines were not followed.

Commission's Comment: **The Commission finds these deficiencies unethical, unsafe, and occasionally even fraudulent by international standards** (i.e., using **Dr. Blumauer's** name for **Dr. Mishaly's** operations). In addition, from the Commission's standpoint and that of international safety and quality standards and guidelines, it is simply impossible for the Commission to comprehend or understand how the arrangement, in which the senior pediatric cardiac surgeon, who is supposed to lead the department and educate the new generation of pediatric cardiac surgeons, can be present on premises in Ljubljana only 3 days per month. **We find this arrangement to be unsafe, unethical, and simply dangerous. It should never have passed any accreditation approval.**

C. Findings regarding personnel, Dr. Vodiskar

1. Basic Training and Education

Dr. Vodiskar started his employment as an intern at UKC in Ljubljana in 2001. During his internship, he rotated through the Departments of Emergency Medicine, Internal Medicine, and Cardiovascular Surgery. After completion of his internship, he became employed as a physician without a residency contract in the Department of Critical Internal Medicine. He was accepted to the residency program at the Cardiovascular Surgery Department in 2004. During this residency, he rotated through the departments of traumatology, abdominal surgery, back to traumatology, anesthesia, plastic surgery, pediatrics, cardiovascular surgery, vascular surgery, thoracic surgery, urology, back to cardiovascular surgery, radiology, back to urology, back to cardiovascular surgery, cardiology, and back to cardiovascular surgery, again, until he finally passed his boards on Feb 26th, 2010. For each of these rotations, the Dr. Vodiskar needed to sign a new contract of residency and employment with every new department. The Commission found this to be the general mechanism by which residencies in this program were handled.

Commission's Comment: Unfortunately, the residency program for cardiovascular surgery in Slovenia is very fragmented. This can be observed by glancing over **Dr. Vodiskar's** rotations. There does not appear to be a firm organized structure to the program, no consistent oversight, and no proper trainee evaluations. There are no written protocols of rotations, required number of surgeries or requirements for gradual rise in difficulty of surgery to give the residents a full scope of training and to add consistency to the program. One of the most disturbing elements of the program is that the resident has to sign new contracts with each new department every time he changes his rotation. The contracts are therefore overlapping, and it is not clear where the resident is actually supposed to report during these periods of contractual overlap. This inefficiency of this system creates a large, unnecessary administrative burden that warrants serious discussions as to how it can be improved. There is a definite need for a complete revision and drastic change of the residency structure.

2. Continued training and education

During 2008-2009, **Dr. Vodiskar** spent a year as a fellow at the Department of Pediatric Cardiac Surgery in Leiden, Holland under the mentorship of **Dr. Hazekamp**. He returned to UKC Ljubljana, and after passing the boards in March 2010, he received an offer from **Dr. Gersak** to continue his training with **Dr. Mishaly** at Sheba Medical Center in Israel. While the preparations for him to move to Israel for a year were taking place, he changed his mind. He substantiated his decision by stating he had second thoughts about the Sheba Medical Center's low number of operative procedures per year. He indicated this hospital performed only 150 congenital cardiac surgeries per year. He suggested he would rather go back to Leiden, where he already knew the staff and where they perform more than 400 surgeries per year. This opportunity would afford him a greater opportunity to learn. He stated that he was not privileged to be a lead surgeon for many of the surgeries conducted in Ljubljana. Despite this explanation, **Dr. Gersak** did not approve his suggestion. Two months later, in May 2010, the Medical Director of Surgical Services offered to help **Dr. Vodiskar** find a fellowship in Europe. **Dr. Vodiskar** again suggested going to Leiden in Holland, a decision with which the Medical Director of Surgery agreed. This was also confirmed by the Medical Director of the UKC, and when the plan was presented to **Dr. Gersak**, he signed the agreement. Unfortunately, the UKC did not provide financial support for this fellowship. **Dr. Vodiskar** applied for financial support to the European PROGRESS program, but his application was not approved. He then notified the Medical Director of

Surgical Services and the Chief of Cardiovascular Surgery (**Dr. Gersak**) that he still did not have financial support for the fellowship. They informed him that the UKC Ljubljana did not have any finances for his continued training. **Dr. Vodiskar** tried again in September of 2011, explained the plan for cooperation with the Leiden Medical Center, but he could not acquire funds from UKC for his fellowship.

For the period of 2007–2011, **Dr. Vodiskar** as a lead surgeon performed no operations in 2007–2009, 18 operations in 2010, and 1 operation in 2011. This makes for a total of 19 surgical procedures in UKC Ljubljana in 5 years as per the report from Ref 47.

(Source: Ref 47 is a legal document from internal UKC Audit provided to the Commission and dated Jan 20th, 2012.)

Commission's Comment: At first glance, UKC in Ljubljana appeared to support **Dr. Vodiskar** when they sent him for a one-year fellowship at Leiden University, the Netherlands, in 2008-2009. However, when there was an opportunity to send **Dr. Vodiskar** to do a fellowship in a foreign center for another year, there was approval from **Dr. Gersak** to send him to Israel at the Sheba Medical Center. However, when **Dr. Vodiskar** expressed the desire to go to Leiden instead of Israel, **Dr. Gersak** unexpectedly denied the opportunity (Ref 47, paragraph 3.2.4, second bullet). It is difficult for the Commission to understand why there was a preference to go to Sheba Medical Center and not to other centers because **Dr. Vodiskar** clearly stated his reasons and rationale for his choice of Leiden. Furthermore, the Commission cannot comprehend that an institution such as UKC cannot allocate adequate funds (less than 50.000 Euro/year) to provide an additional year of training for a desperately needed pediatric cardiac surgeon in a highly reputable institution in Europe. This is especially true in light of the fact that they were spending very high amounts of money to bring a pediatric cardiac surgeon from abroad to operate for only three days a month in the UKC in Ljubljana.

The Commission feels that there was little interest in truly training the residents in a constructive manner and giving them appropriate levels of education. It is inconceivable that a trainee can be sufficiently trained in any surgical science with only 19 operative procedures as a lead surgeon during 5 years of residency. In other more structured programs, the program directors could face serious consequences if they exhibited the behavior that was observed from the program director of Pediatric Cardiac Surgery residency in Ljubljana.

D. Findings regarding personnel, Dr. Blumauer

1. Basic training and education

Dr. Blumauer started his career as a volunteer physician at the department of Cardiology in UKC Ljubljana in May of 1999. He started his internship at the internal clinic of UKC and subsequently moved to the Cardiovascular Surgery Department in April 2000. He became a resident for general/cardiovascular surgery in April 2001 and signed a contract that lasted until April 2007. He should have rotated through different departments like **Dr. Vodiskar** did, but **Dr. Blumauer's** rotations were nonstandard compared to other accredited programs. This might be partially explained by the fact that he obtained a Master of Science degree in parallel to his residency. However, we could not decipher which departments he rotated through during his clinical duties. Despite his contract for residency until 2007, he signed multiple additional contracts of employment and residency from 2001 to 2007: general surgery in 2001; another contract for additional education in 2002; enrollment into the PhD program in May 2002; employment in the Department of Cardiovascular Surgery from 2002 to 2004; and for cardiovascular surgery residency, which was approved by

Medical Chamber of Slovenia from the beginning of 2005 to October 2005. From November 2005 to October 2006, he had a new contract and was employed as a resident/researcher at the Department of Cardiovascular Surgery in UKC Ljubljana. He then received another residency contract from November 2006 to the end of August 2007 from the Department of Cardiovascular Surgery at UKC Ljubljana. His residency was then extended on the request of **Dr. Gersak** (who served as program director for the cardiovascular surgery residency program) to the Medical Chamber of Slovenia; first from September 2007 to the end of 2008 and one more time from January 2009 to February 2009. When **Dr. Blumauer** passed his general cardiac surgery boards in May 2009 (Ref 47, page 13 last paragraph), he received a one-year contract to be a staff surgeon in the Department of Cardiovascular Surgery at UKC in Ljubljana (Ref 47, 3.2.1, next to last bullet, page 5). Subsequently in March 2010, **Dr. Blumauer** was named the Leader of Pediatric Cardiac Surgery at UKC (Ref 47, 3.2.1, last bullet, page 5).

A letter from the 2012 internal Audit underscored that based on the review and chronology of **Dr. Blumauer's** employment history, it is not clear that **Dr. Blumauer** fulfilled the requirements for the prescribed rotations through different departments as required by the Medical Chamber of Slovenia.

(Source: legal document from internal UKC Audit from January 20, 2012, provided to the Commission for review (Ref 47, Paragraph 3.2.1, first sentence, page 6).

Commission's comment: As stated in the Commission's comments above, the residency for cardiac surgery, and specifically for pediatric cardiac surgery in Slovenia, has absolutely no structure. It lacks the basic protocols, continued structured training and education, and basic requirements for the length of time of the residency; clinical preoperative, operative, and critical care competency criteria; written examination; surgical volume; index case distribution; and number requirement of major congenital cases. This lists only the critical deficiencies. It is absolutely unimaginable that a resident can finish a residency program without proper rotations through different departments. It is these rotations that provide the trainee with skills in preoperative evaluation, semi-invasive and invasive investigations, diagnostic imaging, postoperative critical care, organ function testing, and even in renewed knowledge of pathophysiology.

The Commission cannot understand how a resident could be, for two years, in charge of a department of PCS that requires tremendous responsibility and experience and could become the leader of the same department barely eight months after passing the general cardiovascular surgical boards. By international standards of care, the leader of a DPCS should be a surgeon, preferably certified by the European Board of Thoracic and Cardiovascular Surgery (EBTCS), should possess a minimum of 5 years of experience in clinical practice as a qualified congenital cardiac surgeon, should possess the appropriate academic qualifications, and should be entrusted with educational and scientific responsibilities (Ref 82, Paragraph 5.2). The Commission cannot comprehend the decision to name **Dr. Blumauer** the leader of the PCS without possessing any of these minimal qualifications.

2. Continued education and training

Dr. Blumauer was granted a fellowship at Texas Heart Institute (THI) in Houston, Texas, during the six-month period from January 2007 to June 29, 2007. During this fellowship, he gained experience in basic cardiac surgery. However, he did not acquire any experience in pediatric cardiac surgery because pediatric cardiac surgery is not performed at THI. The next year, from March through July 2008, he spent 4 months in Tel Aviv, Israel, where he continued his education. It is not clear what his role was during that rotation. In

2009, he again spent an additional 3 months in Tel Aviv for continued education and another 6 months in Tel Aviv from September 2011 to the end of March 2012.

It appears that **Dr. Blumauer** spent, in total, approximately one year in Israel, where he was apparently involved in pediatric cardiac patient care. However, no written documentation provided to the Commission explained **Dr. Blumauer's** educational experience while he was in Tel Aviv. When he was asked about his experience in Israel during the Commission's audit interview in Ljubljana on July 2014, he stated that he was involved in preoperative assessments and postoperative care of congenital cardiac patients. When asked about participation in surgery, **Dr. Blumauer** responded that he performed 40 to 50 simple surgical procedures, including opening and closing the pediatric cardiac surgical patients, B-T shunts, and cannulation. **Dr. Mishaly** assisted him in procedures such as PDA closure and coarctation repair.

Commission's comment: The UKC Ljubljana supported and was grateful to grant permission for **Dr. Blumauer's** continued education outside his home institution on multiple occasions. The Commission was not privileged to see any documentation of **Dr. Blumauer's** involvement from the hospital in Israel. **Dr. Blumauer** was explicitly asked to produce the case logs of his surgical participations from Sheba Medical Center in Israel during his interview, but he never provided the Commission with any of them. The Commission finds it difficult to understand why these documents could not be provided. No documentation was provided that would otherwise indicate any details of his operative experience during his time at the Sheba Medical Center, despite the fact that this should be fairly easy to do because the numbers are very small.

Additionally, for the Commission to better understand **Dr. Blumauer's** training and education, he was asked to provide case logs of his entire surgical experience during the interview in July 2014 and via email in August 2014 (Ref 23); however, these were never provided. On October 22, 2014, **Dr. Blumauer** finally sent a letter to **Dr. Mozina**, the president of the Slovene Medical Chamber, explaining that since he was not employed at UKC anymore and he did not have access to the DPCS data, he could not supply his operative logs as requested by the Commission (Ref 20).

This fact definitely raises a red flag in the Commission's evaluations of **Dr. Blumauer's** operative experience because the Commission also observed his uneasiness, inertia, and even resistance to providing the surgical case logs whenever he was asked to do so. More critically, the Commission emphasizes that according to the international standards, every resident should keep operative logs of his/her operative experience (Ref 93, page 7, paragraph 3) and every PCS program should submit the data to the international database. Therefore, in Commission's opinion, **Dr. Blumauer**, as a staff surgeon, should have no difficulty submitting his entire surgical case logs for Commission to review if these were kept properly.

3. Surgical experience

Although **Dr. Blumauer** specifically did not keep his entire case log experience, there are now other documents - as of the writing of this report - in addition to the two databases originally available to the Commission during the July Audit's completion, that have also been examined by the Commission to analyze **Dr. Blumauer's** surgical experience.

First is the document from the internal UKC Audit on January 20, 2012 (Ref 47). This document specified that **Dr. Blumauer** independently performed total of 77 pediatric cardiac surgical operations as a lead surgeon during the five year span from 2007 to 2011. He had operated independently on four children during

2007, one child during 2008, eight children during 2009, 63 children during 2010, and one child during 2011. It is also appropriate to add that he was first assistant in 316 pediatric surgical procedures during the same time period.

In contrast, the same document states that **Dr. Vodiskar** was first assistant in 39 pediatric congenital surgical operations and operated on 19 pediatric congenital cardiac patients in the UKC Ljubljana. Clearly, there was a huge disparity in the involvement in operative cases between the two young pediatric cardiac surgical trainees. **Dr. Vodiskar** had the opportunity to operate on 25% of the cases available to the junior staff and an opportunity to participate in 12% of the cases as the first assistant, whereas **Dr. Blumauer** operated on 75% of the available cases and first assisted in 88% of the pediatric cardiac surgery cases.

The second document provides the statistical analysis of the performance of the Department of Pediatric Cardiac Surgery in Ljubljana that was provided personally to the Commission by **Dr. Podnar** (Ref 46). In this document, **Dr. Podnar** analyzed the results in the DPCS from January 1, 2012, to June 6, 2013. According to his statistical analysis and data review, there were 154 operations performed during the stated timeframe at the DPCS in Ljubljana. Of these, 26 operations were not cardiac. Therefore, the analysis was performed on the remaining 128 cardiac surgical operations. Out of these 128 operations, **Dr. Blumauer** independently performed 46 operations (36%) while **Dr. Vodiskar** independently performed 2 operations (2%) for a total of 48 operations independently performed by the resident trainees. The difficulty of these 48 operations was very low: 19 ASD closures, 8 PDA ligations, 6 VSD closures, 6 coarctation repairs, 4 modified B-T shunts, 2 PA bandings, and 3 other procedures not requiring cardiopulmonary bypass. The basic Aristotle score of these 48 procedures was 4.5 on average (low).

Commission's comment: These data could not be verified by the Commission from the original databases, although the report in Ref 47 is the official UKC legal document. The Commission reviewed numerous documents or databases, each with conflicting information regarding the DPCS's actual operative numbers. This lack of congruous data made the task of delineating the facts extremely difficult. **Dr. Blumauer** was explicitly asked during the Auditing interview on July 12, 2014, to provide to the Commission with a case log of his pediatric cardiac surgical operative experience from Ljubljana and Israel. However, he failed to comply with this request. In addition, he received a written request from the Commission again asking him to send the operative logs. He responded with a letter from his lawyer stating that he cannot provide the logs unless he is given full access to the database as he is no longer employed by UKC. It is worth noting that **Dr. Blumauer** was actually the person responsible for entering the operative data into the EA CTS database for 7 years but failed to do so. Had he done so, the data could have been independently analyzed and would have produced unbiased results. If these data had been entered, many problems, inefficiencies, misunderstandings, and poor patient outcomes or complications could almost certainly have been avoided. **Dr. Blumauer's** surgical experience would have been undeniably transparent and unbiased.

However, assuming the data from the two above quoted documents are accurate, with additional data analyses from other databases (Ref 15, Ref 18, Ref 48, Ref 51), they definitely raise two outstanding and deep concerns. The first concern is that the two young surgeons did not have equal opportunity and caseloads made available to them for training purposes. To the Commission, this is of utmost concern because it is the duty of any residency training program to not discriminate between trainees and to provide them with an equal opportunity to learn and to be trained.

This basic rule was clearly not followed in the UKC pediatric cardiac surgery training program. To the Commission's standards this program does not deserve to be called a pediatric cardiac surgery residency.

The second major concern of the Commission is that **Dr. Blumauer**, even as late as the end of 2013 after more than 7 years of training or involvement in pediatric cardiac surgery, is neither capable nor trained to independently perform more complex pediatric cardiac surgical procedures. Additionally, the Commission has major concerns regarding **Dr. Vodiskar's** frustrations with inconsistencies in the DPCS and apparent favoritism. This caused him to resign from the DPCS at UKC Ljubljana and leave the country to pursue his career in Germany.

It is very clear to the Commission that the training for pediatric cardiac surgery in Ljubljana has several major flaws. Not only it does not deserve to be called a residency, but if any pediatric cardiac surgeons are going to be trained there in the future, the program should be first approved and then supervised by the European Residency Committee with all the required standards and protocols firmly emplaced.

E. Summaries of interviews with pertinent personnel

In their pre-Audit communications, the Commission members concluded that it would be necessary to conduct interviews with the physicians at DPCS in Ljubljana, administrative and medical leadership of the UKC, nurses, and additionally, the families of children who underwent cardiac surgical procedures at the DPCS in Ljubljana in 2012. These interviews were essential to get a better understanding of the performance and surgical results of the department, patients' and families' levels of satisfaction, availability of the protocols for standards of care, quality, and specifically to discuss the compliance with the international guidelines and standards of care at the DPCS.

During the Audit in July 2014, members of the Audit Commission conducted the interviews at the Department of Cardiac Surgery conference room and the cardiology and CV surgery classroom on the seventh floor of the UKC in Ljubljana.

The families were randomly selected for interviews to avoid any bias. All the families who were contacted reported for the interviews and were very appreciative to be included in the Audit.

The summaries of the interviews are presented below.

1. Dr. Robert Blumauer, Interviewed July 12, 2014

Surgical experience: **Dr. Blumauer** stated that he resigned from the Department of Pediatric Cardiac Surgery in December 2013 after being told he was no longer a member of the pediatric cardiac surgical team by **Dr. Klokocovnik**, the new chief of CV surgery at the UKC Ljubljana. **Dr. Blumauer** mentioned that **Dr. Mishaly** operated for the last time in Ljubljana in April 2014. We asked **Dr. Blumauer** about his surgical experience as the lead surgeon with eight major standard congenital cardiac surgeries. He explained that during his career, he performed 3-5 Fontan procedures and one arterial switch. He did mention that he had not performed any TF/VSD, Glenn, Norwood, Hypoplastic Aortic Arch, or AV Canal procedures. He stated, however, that he did perform a total of approximately 400 operations with two deaths as the lead surgeon during his 7 year career on the pediatric cardiac surgery team in Ljubljana. Additionally, he said he did perform 40-50 operations under the mentorship of **Dr. Mishaly** during a total of one year spent in Israel.

When he was specifically asked what he exactly did in Tel Aviv, his response indicated that he never performed any major operations. **Dr. Blumauer** believes, however, that he is sufficiently trained and justified his statement by using many examples of operations that he did perform as the primary surgeon (e.g., coarctation repair, PDA ligation, B-T Shunts, and ASD repairs).

When asked about the official DPCS databases or reporting the surgical results data from the DPCS to the EACTS database, **Dr. Blumauer** indicated there were no official yearly reports of pediatric cardiac surgeries conducted by **him or any other member of the pediatric cardiac surgery team from DPCS in Ljubljana**, and no data was sent to the EACTS Congenital Database.

He was asked to provide the case log numbers for his entire surgical experience. These were not available during the interview. He apparently does not have a logbook of his own specific operations. However, he mentioned he sent the database for year 2012 to Dr. Mozina, DPCS administration, and to Dr. Gregoric.

Emergencies: During the 6-7 years when he was involved with the pediatric cardiac surgery program, **Dr. Blumauer** explains that he was on call all the time. The Commission asked him how service was provided and organized in case of emergencies when he was absent from UKC for longer periods of time and while **Dr. Mishaly** was also not in Ljubljana. **Dr. Blumauer** explained that, in case of emergency, **Dr. Mishaly** could come back to Ljubljana in 3 hours when necessary and that **Dr. Vodiskar** was usually in Ljubljana during such times. He further clarified that while waiting for **Dr. Mishaly** to arrive from Israel, the child was placed on ECMO if needed in case of emergency. **Dr. Blumauer** indicated that a private jet was once hired to bring **Dr. Mishaly** back from Tel Aviv. **Dr. Blumauer** does not know who paid for this.

Multidisciplinary conferences: **Dr. Blumauer** explained that before **Dr. Mishaly** came to Ljubljana the conferences were usually conducted once a week prior to surgeries. **Dr. Blumauer** indicated he was present at the meetings most of the time. The most common topic at these meetings was elective procedures. If there was an emergency, they held an ad hoc meeting if time permitted. If the cardiologist disagreed with the planned procedure, they (the surgeons) would review the case again. He told the Commission that the mortality and morbidity sessions always resulted in heated discussion and even shouting.

Interpersonal communications: The relationship with pediatric cardiology was troubled and “very, very bad” and had deteriorated during the last few years. Especially problematic was **Dr. Podnar**. **Dr. Blumauer** complained that he was always portrayed as the bad guy by the media, and all this (according to **Dr. Blumauer**) was probably done by **Dr. Podnar**. **Dr. Blumauer** believes that **Dr. Mishaly’s** being absent for 90% of each month had nothing to do with the turmoil of the DPCS.

Dr. Blumauer reflected that there were many ego-related interpersonal issues, particularly from cardiology. **Dr. Blumauer** gave an example in which there was a refusal from cardiology to do a catheterization diagnostic procedure. As he stated, the problem existed because there was only one interventional cardiology staff physician, but at least two were needed. According to **Dr. Blumauer**, the relationship with the pediatric ICU critical care staff physicians was also troubled. In his view, there were too many PICU doctors and this could complicate things during on-call problems because not all of them had sufficient experience. Belittling comments were also passed between the surgery and cardiology or intensive care staff physicians, according to his submission. He felt there was no dedicated team to take care of postoperative cardiac surgery patients. In his view, the continuity of care was compromised.

Dr. Blumauer’s position in the department: He stated he was not satisfied with his training. He felt he was not trained properly. He stated he did not have enough complex cases, the training was too slow, and during the recent years, he started to feel that his mentor (**Dr. Mishaly**) was not mentoring him properly. He remarked that there were no written rules for his training. When asked why he did not bring this issue to superiors, he stated the he did not have very much support from the cardiovascular service Chief (**Dr. Gersak**) or from the administration. **Dr. Blumauer** reported that **Dr. Gersak** never even came to the pediatric cardiac surgery department to visit. He stated that he informed the leadership of his suggestions regarding issues such as how to improve the DPCS, how to try to get referrals from surrounding countries, how to make the program grow, about the need for a coordinator, etc. He felt he was sometimes exploited and definitely overworked because he always had to be available. As he mentioned, **Dr. Blumauer** was also required to be involved in adult cardiac surgery, taking up 60% of his time. He first observed that the DPCS service was starting to deteriorate in 2009, 2 years after **Dr. Mishaly** started operating in Ljubljana. It was his impression that the other pediatric services involved in the care of congenital pediatric cardiac patients were not supportive of the surgical services. **Dr. Blumauer** believes that **Dr. Podnar** is responsible for the pediatric cardiac surgery

program falling apart. “Dr. Podnar is a 'pusher' and selectively reported postoperative problems and brought these troubles to the media’s attention.”

Data entry: There was no formal registry of operations. Patients’ logs were not submitted to the EACTS Congenital Database, although the leadership of UKC had agreed upon this being standard operating procedure. **Dr. Blumauer** was asked why he did not enter any data to the Database, since this was his responsibility as requested in 2012 by the UKC administration. The Commission interviewers reminded him that in his report to the Ministry of health in January 2013 (Ref 45, page 11, last sentence) he guaranteed that data entry would be started in January 2013.

Dr. Blumauer responded that he had no time for this, he was not paid extra for data entry, and he had too many duties. He stated that he attempted to submit the data in 2012, but at some point the computer “crashed,” and everything was lost. He explained that he tried to enter them again later, after the data entry was requested by the UKC leadership in 2012. At that time everybody agreed that the data should be entered, but the ICU staff member who was designated to enter data with **Dr. Blumauer** “refused” to provide the data. The ICU physician wanted the password, and **Dr. Blumauer** believed the password was only for surgical staff. So, **Dr. Blumauer** refused to provide the password. He did not know that data could be submitted easily and directly to the central database, so this was “unnecessary really.”

Dr. Blumauer concluded his answers about the data entry with the statement that not a single patient’s data were ever entered to EACTS Database by him or any other staff member of the DPCS from Ljubljana before the Commission’s Audit in July 2014.

The current program - Dr. Blumauer’s view: He is very disappointed that he was removed from participating in pediatric cardiac surgery at UKC Ljubljana in December of 2013. He feels he dedicated his entire career to this field, and he believes they had good results. He believes the new leadership destroyed the program and that it is not safe to send the children to Munich. He indicated that at times it could take 5 days to organize the transport for a child transfer from Ljubljana to Munich. He believes that it is extremely expensive to have all the children operated on in Munich. He believes the cost is approximately 5 million Euros per year to have Slovene children operated on in Munich, whereas the cost to have **Dr. Mishaly** run the program in Slovenia was around 150.000 Euros per year. **Dr. Blumauer’s** vision for optimizing the pediatric cardiac surgery program in Ljubljana is to connect UKC to a nearby high-volume center. He said during his training in Tel Aviv he observed this type of setting to work very well.

The team: **Dr. Blumauer** stated that perfusion was never a problem (3 perfusionists), and anesthesia (3 anesthesiologists) was also never a problem. ECMO was entirely in the hands of PICU physicians, and he says that it is a pity that the perfusionists were not involved in it.

Commission’s Impression: **Dr. Blumauer** is very passionate about the pediatric cardiac surgery service in Ljubljana. Without a doubt, he is very disappointed that he was removed from the program. However, it sometimes appears that he is disconnected with the reality of the situation. He never once doubted or questioned why **Dr. Mishaly**, as chief surgeon, would only be available for 3 days per month in Ljubljana. **Dr. Blumauer** believes the surgical results are good. He supported his statement by mentioning the analysis of the data in 2012 given to the Ministry of Health in his report in January 2013. **Dr. Blumauer** maintained that the results are comparable to European standards. Again, there is no database for the Commission to review, audit, or confirm this report.

The Commission has major concerns regarding his case logs and surgical experience. **Dr. Blumauer** believes he is a competent pediatric cardiac surgeon, despite the fact that he has not fulfilled the international criteria for the number of eight major indexed congenital cardiac surgeries he has performed, nor has he had sufficient experience on a necessary amount of difficult and complex cases. He even admits to this fact. He is very nebulous and reluctant to provide accurate surgical numbers, although these would be easy to deliver if appropriate surgical logs were ever kept in the first place. It is obvious that he is rather embarrassed about either the low acuity of cases or the low number of operations he handled as a lead surgeon, in direct contradiction of his statements about his competency.

He should have never been put in a leadership position without appropriate expertise and adequate training. He was overwhelmed by the workload and could not process the enormous amount of responsibility and work that was given to him. Furthermore, he was not self-aware enough to ask for help when needed.

His interpersonal communication skills were not appropriate. He did not try to resolve problems with the other staff physicians. Rather, he took a stance of self-promotion and self-importance instead of being humble and helpful. This led to isolation and team destruction instead of team building and teamwork. He did not possess appropriate leadership qualifications and did not know how to deal with difficult issues when they surfaced.

What the Commission learned from other physicians and nurses it interviewed is that **Dr. Blumauer** lacks appropriate judgment when called upon to make a decision, especially in emergency situations or postoperative decisions for reoperations. It was indicated that **Dr. Blumauer** lacks an understanding of the postoperative urgency for corrective measures in cases of operative complications (such as the instance describe in Patient #3, see above).

Overall, the Commission believes **Dr. Blumauer** was not the right person to lead the Department of Pediatric Cardiac Surgery at UKC in Ljubljana. He did not have the leadership experience or the qualities required for such a demanding and responsible job. He lacks decision-making skills requisite for his level of experience and needs additional structured training in preoperative, operative, and postoperative care of congenital cardiac patients. He needs a true mentor to become a competent and fully-trained pediatric cardiac surgeon. The leadership should have realized this fact long before the problems became so extensive and devastating and should have helped **Dr. Blumauer** by bringing in an experienced senior pediatric cardiac surgeon to lead the team and to be present on a daily basis within the UKC.

It appears that across the entire pediatric cardiac surgery service line, there was an obvious lack of leadership (surgeons, **Dr. Podnar**, PICU staff physicians, management, and directors). The leadership failed to respond to complaints and mortalities and the willingness to change was inadequate or completely nonexistent. The problems were ignored and permitted to persist, and the bizarre situation with **Dr. Mishaly's** contract was unfortunately accepted for many years. Additionally, the administration, the surgical director, and the Chief of Cardiothoracic Surgery ignored the fact that **Dr. Blumauer** was not sufficiently trained. Additionally, it is obvious that nobody helped **Dr. Vodiskar** advance his training after he returned to Ljubljana after a one-year fellowship abroad.

2. Dr. Borut Gersak, Interviewed July 13, 2014

Dr. Gersak started his interview with the statement that nobody in his generation wanted to do pediatric cardiac surgery, not even in 2005 or 2006. He claimed that interpersonal problems within pediatric cardiac surgery existed before 2006 (when he became chief) and were present even in the '90's.

In 2006, **Dr. Vlado Sojak's** hiring as the staff pediatric cardiac surgeon caused some controversy. **Dr. Gersak** stated that the chief of anesthesia was not in favor of employing **Dr. Sojak** "because Dr. Sojak was 'not' a cardiovascular surgeon." He did not have an "official license." The other objection was that he was not doing "all the procedures." **Dr. Gersak** mentioned that apparently, **Dr. Sojak** is a "slow starter even now in Leiden."

Dr. Gersak stated that regardless of some differences, the majority of the staff gave full support to **Dr. Sojak**. However, despite this support, two anesthesiologists left the department because of profound disagreement to appointing **Dr. Sojak** as a pediatric cardiac surgeon. **Dr. Gersak** mentioned that **Dr. Sojak** suddenly quit in October 2007, however he did not elaborate why **Dr. Sojak** left.

Dr. Gersak continued that after **Dr. Sojak's** departure, they were confronted with a large problem that needed an immediate resolution. **Dr. Podnar** asked him to find a pediatric cardiac surgeon and to do so with urgency. **Dr. Gersak** tried to get help from several European centers, and he contacted surgeons in several areas, including Russia and Leiden. He was personally doing some surgeries in Israel and contacted someone in the pediatric department of the hospital to ask if they knew of a pediatric cardiac surgeon. This is how he met **Dr. Mishaly**.

Dr. Mishaly came to Ljubljana and initially did a few cases and started to help build the program. There was no decision to hire him at that time, however. Following these initial visits, **Dr. Podnar** experienced a case in which while he catheterized a child with a previous Norwood procedure he found a complication. This child needed a surgical correction. **Dr. Mishaly** came to Ljubljana and did the surgery. That was when **Dr. Gersak** made a personal decision to hire **Dr. Mishaly**. At the same time he also decided to recruit two residents for pediatric cardiac surgery. It was then when he approached **Drs. Vodiskar and Blumauer** as candidates for residency. At this time he also talked with **Dr. Mishaly** about him training residents and not just operating. The first trainee to start the residency was **Dr. Blumauer**.

Two years after hiring **Dr. Mishaly**, problems started to arise. According to **Dr. Gersak**, the main reasons for these difficulties were the changes in UKC management that led to the rifts between the critical care physicians and surgeons. Perhaps most importantly, the new UKC management began questioning **Dr. Mishaly's** financial arrangement for his services in Ljubljana. **Dr. Gersak** believes he was paid approximately 10.000 Euros a day when he came to operate at the UKC in Ljubljana. It is his firm opinion that the financial arrangement with **Dr. Mishaly** created this enormous problem, but he also believes that this situation may have been used as a vehicle for "pushing some agendas." Pediatric cardiologists, in addition to the CMO of the UKC in Ljubljana at the time, **Dr. Brigita Dernovsek**, complained frequently about the finances spent for **Dr. Mishaly**.

The other major problem was the consistently increasing tensions between **Drs. Vodiskar and Blumauer**. Specifically, tensions rose when **Dr. Blumauer** became the Director of Pediatric Cardiac Surgical Services after finishing his residency and 8 months after passing his boards. **Dr. Gersak** explained that **Drs. Blumauer and Vodiskar** were always fighting, sometimes publicly. He indicated that he (**Dr. Gersak**) unsuccessfully tried to pacify the two young physicians and repeatedly attempted to calm them down. He

even offered to have them go and work elsewhere. However, they were not willing to accept that offer. He is not sure of their reasons behind rejecting this offer but suggests possible personal or financial reasons. **Dr. Gersak** did not elaborate much when he was asked about **Dr. Blumauer's** apparent preferential treatment. He explained that **Dr. Blumauer** was the first resident at the department, and they needed someone to be trained quickly. He denied any favoritism toward **Dr. Blumauer** and justified training the most senior fellow as soon as possible as an attempt to get the program running independently. **Dr. Gersak** never explicitly addressed what he thought was the real underlying issue between these two residents.

During the interview, **Dr. Gersak** revealed that he believes there were three important factors that each contributed to the turmoil. He indicated that although there was never a plan to “do all pediatric cardiac surgery in Ljubljana,” some physicians thought differently. This caused tensions. Second, **Dr. Blumauer** did not have had the character to realize all his limitations. And, lastly, according to **Dr. Gersak**, **Dr. Blumauer** was never able to arrange and implement a multidisciplinary team environment.

The culmination of these issues occurred during the year 2012, when the pediatricians demanded the audit.

Dr. Gersak explained that in 2012, the distractions and disagreements became so comprehensive that he even considered rearranging the structure and “giving” the governance of the pediatric cardiac surgery department to the pediatric cardiology department. He notified the Chief of Pediatric Cardiology (**Dr. Podnar**), the UKC CEO, and the Medical Director. However, his suggestion was refused by management and also by **Dr. Kenda**, the Chief of the Department of Pediatrics. The UKC CEO reportedly asked him if he was trying to destroy the entire structure of the UKC.

The next question asked by the Commission was why they did not bring another surgeon to Ljubljana.

Dr. Gersak explained that they brought in **Dr. Igor Knez**, a pediatric cardiac surgeon, who even started operating at the DPCS in Ljubljana. However, the very first surgery he performed unfortunately had a major complication; therefore they did not pursue hiring him. In 2012, they had entered negotiations with Leiden to provide support. However, he is not sure why the CEO did not proceed with that plan. Additionally, the team from Leiden did not foresee working with **Dr. Mishaly**, although this was a condition voiced by the management.

Dr. Gersak concluded his interview by saying that he believes there was a “cult of personality” surrounding **Dr. Mishaly** that had been created by Slovene public opinion. He believes this issue is “going to be very difficult to correct.” **Dr. Gersak** stated that this situation was certainly not what he intended and that he “has a hard time to see the favorable options out of these difficulties.” He concluded the interview by saying that “he is not an optimist” regarding the outcomes for the department. He does not see a realistic solution for the future because everything has “exploded” at this point.

Commission's comments: It is very clear to the Commission that the DPCS staffing, organization, and personnel hiring were very poorly planned. The structure in the Slovene residency program is much disorganized, and leadership positions are not filled with the best candidates. There may well be a larger problem with the hiring and training system. However, there is also an exhibition of poor judgment in placing incapable individuals in leadership positions. Many problems could have been avoided if the organization and leadership had built the program with more structure and thought and had followed international standards. It would have been much easier to avoid these problems and the deterioration in the quality of pediatric cardiac surgery services by hiring outside advisors, building the program more slowly, and affiliating with a large, reputable pediatric

cardiac surgery center somewhere in Europe and closer to Ljubljana. It would have definitely been better if **Dr. Gersak** and the rest of the leadership would have listened to suggestions and advice presented to them as early as 2006 and 2007. The Auditors could not hide their disappointment in realizing that there is no formal recruitment process when searching for high-quality physician and academic leaders. We learned that there were no formal interviews from within the department or from multidisciplinary services that were done for to fill these leadership positions.

Clearly, another major problem was the discrepancy in payments and financial arrangements with **Dr. Mishaly**, in comparison to those for the regular staff. The department and institution leadership should have anticipated such problems when a surgeon is paid as much in one day as the chief of a department is paid for three months of work. This type of situation inevitably creates animosity, envy, resistance, rebellious behavior, and mostly, a loss of trust and collaboration. This arrangement was definitely not favorably received by some employees when the same administration denied help in arranging to raise Dr. Sojak's compensation.

The Commission is of the sentiment that the leadership was completely detached from the reality of what constitutes solid, factual, corporate faculty arrangements and certainly did not do any market analysis, research, pedigree checkups, or background investigations prior to signing contracts with future employees. Further, these contracts often did not comply with the international standards of care for pediatric cardiac patients.

And last, but not least, **Dr. Gersak** should have understood the implications of such dangerous arrangements that allowed the chief pediatric cardiac surgeon to be present only 3 days a month on the premises of UKC. He should have also been aware of the department's poor training capabilities. Furthermore, **Dr. Gersak** should have comprehended **Dr. Blumauer's** lack of judgment, compromised integrity, and inability for self-critique. He should have not only recommended but also insisted that the structure be completely changed and new physicians be hired. In the Commission's assessment, with respect to pediatric cardiac services, he completely failed as the leader of the Cardiovascular Surgery Department and as a Residency Program Director.

3. **Dr. N. Kosmac**, Anesthesiologist, Interviewed July 12-13, 2014

Dr. N. Kosmac introduced herself as the only trained, dedicated full-time anesthesiologist assigned to the DPCS. There are another two pediatric anesthesiologists who help in pediatric cardiac anesthesia; however, they are not assigned to serve exclusively to pediatric cardiac anesthesiology.

When asked directly about **Dr. Mishaly**. She stated that she respects him as a surgeon and that he was always helpful in the operating room (e.g., helping with insertion of central lines). She felt safe with him and he is technically 100% proficient. He cooperated well with one of the cardiologists.

The Commission was very interested about her perspective of **Dr. Blumauer**. She explained that his interactions with intensive care physicians were not always good; he was "temperamental" but polite outside of the operating room. She believes **Dr. Blumauer** was also inexperienced, technically insufficient, not completely confident, and often afraid of surgeries that were too difficult. She does not believe that **Dr. Blumauer** was a leader, and she has doubts about his competency. The anesthesiologist indicated that when **Dr. Blumauer** was confronted with a difficult case, he did not handle the challenges well. However, he was not willing to ask for help if he could not handle the problem. She believes, however, that **Dr. Blumauer** was

sometimes put into an impossible situation. She felt sorry for him and she believes there were no written protocols for his training and education. She also stated that when **Dr. Mishaly** and **Dr. Blumauer** were in the operating theater together, there were usually no problems.

She believes there were also problems created by the intensive care physicians in that they were sometimes difficult to deal with. They never called anesthesia even when anesthesia physicians could be helpful. The anesthesiologist indicated that there were no problems with the perfusionists (3); they were always available and technically skillful.

Toward the end of her interview, **Dr. N. Kosmac** started to tear up. She stated that it is extremely sad to know that there are no congenital cardiac surgeries now being performed in Ljubljana. She was sad because they all invested so much time, effort, and education into the program, and now it is gone. She indicated that it is difficult for the anesthesiologists to accept the loss of the program because they are also losing access to the technical skills and the knowledge that often helps in taking care of other pediatric surgical patients.

She feels profoundly saddened by all that has happened. She is personally, severely, and deeply hurt with the entire DPCS catastrophe and never wants to work for pediatric cardiac surgery again.

In her opinion, the hospital administration and chiefs are to be blamed for the DPCS disaster because they took too long to resolve this tragedy. Nothing was done for extended periods of time despite numerous warning signs.

Commission's comment: **Dr. N. Kosmac's** demeanor was very pleasant, and the Commission recognized she was truly speaking from her heart. She is genuinely saddened about the loss of the pediatric cardiac surgery program.

Without a question, **Dr. N. Kosmac** is a very dedicated anesthesiologist. She clearly understood the enormity of the negative implications of the poor leadership and management of the program. She understood how these implications could trigger an undesirable, harmful, and adverse domino effect of all other programs involved. Additionally, wrong staffing, bad decisions, and compromised patient care, such as what happened in the Pediatric Cardiac Surgery Department in Ljubljana, affects not only the multiple services working in collaboration with the defective department but also impairs and eliminates the possibility for the physicians and supporting staff to keep or continue their education, training, and skill maintenance. It can affect the entire generation of physicians from those services, and it may completely destroy their careers.

Dr. Kosmac clearly expressed that she did not think **Dr. Blumauer** was a well-trained, competent, and mature pediatric cardiac surgeon. She definitely believes he was not fit to lead the DPCS in Ljubljana.

4. **Dr. B. Kosmac**, Pediatric Cardiologist Trainee, Interviewed July 12-13, 2014

The next interviewee introduced himself as a pediatric cardiologist in training. He has been with the department for 2.5 years and is training to become an interventional pediatric cardiologist.

First, the Commission asked **Dr. B. Kosmac** about the relationship between the pediatric cardiac intensive care physicians and pediatric cardiac surgery staff. He was quite complimentary and believed the collaboration was good, and he did not observe any major disagreements between two services. However, he pointed out that he knows there are pediatric intensive care unit “people not on speaking terms” with others from

different departments that care for pediatric cardiac patients. Furthermore, some critical care physicians are not speaking with him because he once disagreed with them about patient management. The lack of communication is a major problem in the DPCS in his opinion.

He explained that his education in pediatric cardiology started 2.5 years ago. He is learning pediatric echocardiography. He spent 6 months in Munich, where they do approximately 800 pediatric catheterizations a year divided between three specialists. In Munich, he performed approximately 20 interventional and about 30 diagnostic catheterizations under supervision.

According to **Dr. B. Kosmac**, they perform 2–3 pediatric catheterizations a week in Ljubljana. However, he has performed only one catheterization by himself, and he has yet to do any interventional catheterizations.

He is very disappointed in the training he is receiving in Ljubljana because it practically does not exist in an organized manner. For example, the intensive care physicians do not allow the pediatric cardiologist trainees to rotate through the pediatric cardiac intensive care unit where they may be able to learn and extend their training.

There are no written protocols, and no structured program exists as to how the rotations should be organized. He really does not see himself finishing his training in Slovenia. If he finds an opportunity, he intends to leave Slovenia and practice elsewhere.

He spoke highly about his mentor, **Dr. Podnar**, stating he is a good and fair mentor and that the relationship between him and **Dr. Podnar** is good. However, **Dr. B. Kosmac** thinks more than one pediatric cardiologist should be performing the catheterizations in Ljubljana. There are approximately 130 catheterizations per year performed in Slovenia, and he believes there should be a team of cardiologists doing these procedures. He believes **Dr. Podnar** was a good pediatric cardiology department leader while he was the Chief. However, at this point, **Dr. B. Kosmac** does not even know who the leader of the pediatric cardiology department is. In his mind, pediatric cardiology appears considerably disorganized at the moment.

Dr. B. Kosmac believes that a pediatric cardiac surgery program can be built in Ljubljana. He believes the most difficult surgical procedures, such as Norwoods and arterial switches, should be sent to a larger center for the surgery in order to assure a more excellent result. He stated that even routine cases, such as VSD repairs, often had too many complications when conducted in Ljubljana. He articulated that he does not want to be involved in the whole affair; he just wants to be trained as a pediatric cardiology interventionist. Because of the entire situation under investigation, young and promising doctors are thinking about leaving the country, he stated.

However, he expressed his desire to see the surgical program return to Ljubljana.

Commission's comment: Once again, the Commission witnessed the disappointment of a young, enthusiastic, very capable trainee who is in the middle of his residency and already thinking of leaving not only the program he is in but also the country. The lack of leadership, lack of vision, and lack of proper training and mentorship is affecting an entire generation of young physicians, and the unsatisfactory and deficient system currently in place is the driving behind their desire to leave.

If the current leadership continues this program on its current trajectory and does not resolve the profound structural problems of the program, then it will take enormous new financial investments and many years to rebuild the medical community and people's trust in the institution. Without major changes, the ability to

educate a new generation of physicians who will be capable of facing challenges and leading the new department toward excellence will be severely and adversely impacted. It is depressing for the Commission to witness the exodus of young, intelligent, hardworking physicians because of their leaders' apathy and lethargy to retain them.

5. Dr. Tomaz Podnar, Interviewed July 11, 2014

Dr. Podnar introduced himself as the former Chief of Pediatric Cardiology at the UKC in Ljubljana. He served in this role until January 2012. He conducts nearly all interventional pediatric cardiac procedures. **Dr. Podnar** believes he was replaced as head of the department because of his disagreement with the pediatric cardiac surgery program.

He started the interview by giving the members of the Commission a brief history of the Department of Pediatric Cardiac Surgery. In 2007, **Dr. Sojak** departed. In response, the immediate the goal of the Chief of Cardiovascular Surgery (**Dr. Gersak**) and the Department of Pediatric Cardiology - including himself - was to regain pediatric cardiac surgery services at UKC in Ljubljana.

The goal and the agreement with the pediatric cardiac surgery department were to deliver pediatric cardiac surgery services with a surgeon from Israel, who would come to Ljubljana at least twice a month. They were all in favor of hiring **Dr. Mishaly** because it appeared he was the only choice they had at that time. The second goal for hiring **Dr. Mishaly** was that he would teach, educate, and train two young residents from Ljubljana to become pediatric cardiac surgeons by the end of a two-year span (2007-2009). Unfortunately, neither of these two major goals was reached. **Dr. Podnar** stated that he also believes the reason for the failure to achieve these goals was that **Dr. Mishaly** desired to continue operating as the lead surgeon on practically all of the patients over the first two and a half years. **Dr. Podnar** calculated that **Dr. Mishaly** had mentored the young trainees to perform only 5% of operative procedures then. **Dr. Podnar** expressed his feeling that **Dr. Mishaly** never intended to expend enough effort to truly train anyone. **Dr. Podnar**, and the rest of the pediatric cardiologists and critical care physicians, gradually became worried, and recently even convinced, that there may never have been a genuine intention from either **Dr. Gersak** or **Dr. Mishaly** to truly train the residents. **Dr. Podnar** stated that when **Dr. Vodiskar** came back from his one-year fellowship in Leiden, where he was consistently involved in the surgical theater, **Dr. Mishaly** never gave him a chance to advance and upgrade his skill and knowledge. Furthermore, he is certain there was a discrepancy in education these two residents were receiving. Additionally, he firmly believes there was favoritism toward **Dr. Blumauer**. Regardless of the UKC administration's and medical leadership's attempts to portray the training for the two young domestic pediatric cardiac surgeons as adequate, it is **Dr. Podnar's** judgment that both trainees have been undertrained.

Dr. Podnar further explains that all these concerns were brought to the leadership's attention as early as two years after hiring **Dr. Mishaly** by him and by other physicians involved in treating children with the congenital cardiac anomalies. He also indicated the administrative director and CEO of the UKC responded to these warnings stating that the discussions and the corrections had to be dealt with by the DPCS and within medical services.

By 2009, according to **Dr. Podnar**, the statistical analysis already showed that the two young surgeons were not receiving adequate training and operating opportunities. However, regardless of his insufficient expertise and the risk of his incompetency, there was a push from administration for **Dr. Blumauer** to start to operate

independently, regardless of his insufficient expertise. For **Dr. Podnar**, being the Chief of Pediatric Cardiology, this trend was very worrisome because he believed **Dr. Blumauer** was not adequately trained.

Dr. Podnar pointed out other discrepancies and inaccuracies in the pediatric cardiac surgery department. There were no standard multidisciplinary preoperative meetings. For example, there were cases when the patient would already be on the operating table, ready for surgery, and only then would the surgery team for the first time have a brief meeting about that patient. As per **Dr. Podnar**, **Dr. Mishaly** very rarely, if ever, attended conferences before surgery. He would never sign any clinically pertinent document, whatsoever. **Dr. Blumauer** was usually the only representative from the pediatric surgical department to attend the minor understaffed meetings. However, when **Dr. Blumauer** was asked intricate questions and when he needed to elaborate on the strategy for complex surgical cases, he was unable to give appropriate answers because of his lack of proper experience. Consequently, the rest of the team did not get the responses they needed for apt and complete preoperative patient evaluations and treatments.

In 2011, **Dr. Podnar** explains, he realized that on multiple occasions, although he assumed he was sending patients to **Dr. Mishaly** for surgery, he did not know who will be really operating on the patient. Further, he did not have any input into decision making. The decision-making process as to who was going to be the lead surgeon was never transparent according to **Dr. Podnar**. **Dr. Mishaly** was never listed as an attending on any documents. It was then, **Dr. Podnar** stated, that he realized that he was in reality sending the children to **Dr. Blumauer** and not to **Dr. Mishaly** for surgery.

When these irregularities and incomprehensible actions were brought to the attention of the administrative Leadership's two chairmen—**Dr. Gersak** (CV surgery) and **Dr. Kenda**, the Chairman of the Pediatric Medicine Department (under which the Pediatric Cardiology Department structurally falls)—it was decided that **Dr. Mishaly** had to sign every document from that point on. Unfortunately, according to **Dr. Podnar's** statement, nothing ever changed.

Dr. Podnar continued his interview stating that **Dr. Mishaly** was always in a hurry. He would arrive to Ljubljana on Tuesday, operate on Wednesday, Thursday, and maybe Friday, and depart immediately after the last surgery. On multiple occasions, the patient was still on the operating table when **Dr. Mishaly** was already on the airplane according to **Dr. Podnar**.

In **Dr. Podnar's** opinion, **Dr. Mishaly** is not a safe surgeon and he occasionally also questioned his ethics. In case of emergency for example, the staff at the DPCS would have to put a child on ECMO and often be forced to wait on ECMO for 2 weeks or more (patient **E.C.**) while awaiting **Dr. Mishaly's** return to Ljubljana. **Dr. Podnar** stated that this unnecessarily prolonged ECMO application to wait for a surgeon is completely inconsistent with modern standards of care. When further discussing the patient care with **Dr. Podnar**, he explained with discomfort that it was not possible for Pediatric Cardiology or intensive care physicians to send the patient for surgery to a different institution out of Slovenia when **Dr. Mishaly** was not in Ljubljana. He further clarifies that they were instructed either by the chief of the CV surgery or the administration to wait for **Dr. Mishaly** to return to Ljubljana. Since the time was quite often prolonged for 2 to 3 weeks due to **Dr. Mishaly's** extended absence from Ljubljana, in certain cases the pediatric patients would also have to receive prostaglandins for the entire time while awaiting **Dr. Mishaly's** return. As a result, some patients developed necrotizing enterocolitis because of prolonged Prostyn application and subsequent insufficient systemic circulation (1) *(There is an article published about this well-known odd complication by the group from Ljubljana, where the surgery was performed 42 days later).*

Dr. Podnar continued his interview, explaining “Occasionally, there were surgical procedures performed on children that no pediatric cardiologist could explain or understand why the procedure was done or what was the underlying rationale. However, neither **Dr. Mishaly** nor other pediatric cardiac surgeons would take the time to explain the justification to the team or share important information. **Dr. Mishaly** hardly ever stayed longer in Ljubljana, even in instances where a patient might have been unstable.” **Dr. Podnar** stated that there were some strange decisions made by the surgery team occasionally; for example, in cases when a patient needed an urgent reoperation, **Dr. Mishaly** would prefer to put another patient on the operating room table and go on with his scheduled elective surgery prior to the urgent reoperation.

Dr. Podnar further explained that information on the status of the pediatric patients was always given to their families by **Dr. Blumauer** and rarely by **Dr. Mishaly**. There was no unified approach for collaboration with pediatric cardiology or critical care physicians by the surgical team or for giving unified and consistent information to the families to minimize confusion. No formal rounds existed in the ward or the PICU.

Dr. Podnar also spoke about the staff interactions within the intensive care unit. The nurses were always confused by conflicting orders. They often could not determine if they should follow the pediatric surgeons’ orders or comply with directives from the critical care physicians. By the hospital bylaws, the nurses were obligated to follow the critical care physicians’ orders. This, however, created tensions between the surgeons and nursing staff when the orders from surgical team were in conflict with critical care team. **Dr. Blumauer** would commonly be on the phone with **Dr. Mishaly**, and afterwards he would make some diverse decisions followed by giving unusual orders to the nurses. **Dr. Podnar** mentioned that, while overall infrequent, there were heated discussions in the PICU between the surgical team and ICU staff physicians. According to Dr. Podnar, there were also occurrences in which the nurses heard **Dr. Blumauer** belittling the intensive care physicians in front of the patient’s family.

As Dr. Podnar further explained, despite the fact that there was clearly turmoil in the DPCS, **Dr. Gersak**, Chief of the Cardiovascular Surgery Department and the leader to whom DPCS reports, never visited the pediatric clinic or the pediatric intensive care unit and was entirely uninvolved in attempts to immediately resolve these problems. He also seldom attended the multidisciplinary meetings. He never even came to visit the children postoperatively. According to **Dr. Podnar**, **Dr. Gersak** did not demonstrate much interest in being the mediator in the arguments that occurred.

The Commission asked **Dr. Podnar** about the quality assurance meetings. He responded that occasionally, sporadic cases were presented, but this was more periodic and often resulted in no conclusions that may lead to improvement at the end. As stated by Dr. Podnar, there were no organized, routine M&M meetings. There were no written documentation of the meetings, no analyses, and no quality improvement grading at the end. There was no root cause analysis of the outcomes and complications in which the standards of treatment were questioned by team members. As Dr. Podnar stated there were, rather, arguments and accusations between different members of the pediatric cardiac surgery and pediatric cardiac services involved in the care of children. For example, he explains, all patients, no matter their weight, received a 4 mm BT shunt. Often this resulted in “overshunting.” **Dr. Podnar** explained that there were also problems with using the Hancock valves in the RVOT that degenerated very early (within 2-3 years) and no fenestrations in TCPC, even when needed. But even after discussing all these issues during informal M&M sessions, he concluded that there was no improvement to the processes, and no changes were made.

When asked about the research department and pediatric cardiac surgery publications, **Dr. Podnar** replied there were very few, if any.

Another issue **Dr. Podnar** exposed was within the grown-up congenital heart disease (GUCH) service. Although there is a dedicated cardiologist on staff for adult patients with congenital anomalies, the staff has limited surgical experience. **Dr. Mishaly** had good knowledge of these patients; however, there were always postoperative problems where these patients should have been sent for recovery, Dr. Podnar explained. He also elaborated that the patients were routinely sent to the adult ICU postoperatively. However, the nursing and support staff in this unit were not experienced in the postoperative care of GUCH patients. Even teenage cardiac patients were sent to the adult floor after cardiac surgery for postoperative recovery, despite that no adequately trained staff for these patients were there. As per Dr. Podnar, it was difficult to properly care for these patients.

Commission's comment: **Dr. Podnar** was very helpful in understanding the turmoil within the service. The department's insufficient organization and lack of dedication by **Dr. Mishaly** to sufficiently train surgical residents is, to the Commission, simply an unacceptable practice. No multidisciplinary conferences, insufficient and very questionable documentation, the lack of discussion about surgical procedures, and the **lead surgeon's premature departures are such staggering and outstanding irregularities that the service should have been immediately terminated and restructuring performed. The most outrageous delinquencies and the questionable moral and ethical behavior by the surgeons should be seriously investigated.** The Commission stands very firmly on the practice that patient care should never be compromised if a surgeon is out of town or unavailable. The children should have never been put on prolonged ECMO support or prostaglandins only because they were forced to wait for the surgeon's return. Without question, the children should have been sent elsewhere for surgery. These instances bring the surgical staff's moral and ethical principles into direct question. In addition, the nurses should have never been put in the middle of physicians' quarrels and disagreements. The lack of the physicians to appropriately communicate and the outrageous examples of physicians' inappropriate attitude are deplorable. But the most controversial issue about the reports of belittling other professionals, in addition to prioritizing personal issues over patient care, is outrageous and disgraceful behavior. Swift and corrective actions should have been implemented.

The Commission cannot comprehend how the UKC Leadership could have underestimated the importance of pediatric cardiac surgical service quality and turned a blind eye to its collapse. There is no excuse, in the Commission's view, as to why the deeper root causes of the difficulties were not more diligently and thoroughly investigated. Furthermore, that such substandard surgical services were tolerated and allowed to continue when there were clear indicators that drastic change was required and the surgical service needed to be stopped is, for the Commission, completely objectionable.

The Commission's only question is why, despite the numerous warnings delivered to the highest UKC leadership on multiple occasions, were this service's arrangements continued for 7 years prior to finally making drastic changes and terminating the program just recently?

Ref.:

- 1) *Ref: Ups J Med Sci.* 2013 May;118(2):138-42. doi: 10.3109/03009734.2013.778374. Epub 2013 Mar 22. Prolonged prostaglandin E1 therapy in a neonate with pulmonary atresia and ventricular septal defect and the development of antral foveolar hyperplasia and hypertrophic pyloric stenosis.) *Perme T¹, Mali S, Vidmar I, Gvardijančič D, Blumauer R, Mishaly D, Grabnar I, Nemec G, Grosek S.*

6. Dr. Gorazd Kalan, Interviewed July 11-13, 2014

Dr. Kalan is a director of pediatric intensive care unit at UKC in Ljubljana. He started his interview speaking about the state of the service of pediatric cardiac surgery from the moment when **Dr. Mishaly** was hired. Prior to that, **Dr. Sojak** performed all the pediatric cardiac surgical procedures. The only exception was arterial switches. During **Dr. Sojak's** tenure in the DPCS in Ljubljana, from 2004 to 2007, there were approximately 30 pediatric patients sent abroad for surgical corrections.

Dr. Kalan's belief why surgical service did not work well from the very beginning and did not gradually improve is because **Dr. Mishaly** did not have the intention to really train the young residents. In addition, **Dr. Kalan** also believes that **Dr. Blumauer** did not possess the capacity to be trained, and **Dr. Vodiskar** was not given the adequate chance to operate and learn in Ljubljana. Out of 200 surgeries that were performed in the first 2.5 years, only approximately 5% were performed by the trainees under **Dr. Mishaly's** mentorship, with the majority of these performed by **Dr. Blumauer**.

In 2011, the major complaints of the pediatric cardiology and critical care physicians were presented to the highest UKC administration, Dr. Kalan expressed. In these objections, it was stated (among many other grievances) that **Dr. Vodiskar** was given only four operations to perform through the entirety of 2009. In **Dr. Kalan's** mind, there is no doubt there was favoritism toward **Dr. Blumauer**, and there was no intention from Dr. Mishaly to teach anyone.

The Commission questioned **Dr. Kalan** whether he believes there were other undisclosed interests. **Dr. Kalan** mentioned that there were a lot of discussions throughout the UKC about **Dr. Mishaly's** financial arrangement. To investigate this potential irregularity, an internal UKC committee was formed (**Drs. Tonin, Drnovsek and Gersak** and one more person, whose name **Dr. Kalan** could not remember) to investigate this issue. **Dr. Kalan** stated he does not know the findings of this committee. Following this investigation, there was no change in the structure and arrangement in the DPCS in 2011, or thereafter.

One of **Dr. Kalan's** major concerns was that **Dr. Blumauer** was asked to perform duties he was not capable of performing, such as leading the department, making difficult decisions when **Dr. Mishaly** was gone, and performing surgical procedures for which he was not sufficiently trained.

Postoperative care was another major issue in Dr. Kalan's mind. The bylaws of the hospital state that the responsibility of postoperative care in the pediatric ICU is in the domain of pediatric cardiac intensivists. Dr. Kalan explained that "**Dr. Blumauer** always had an issue with this organizational guideline. He would go to patient's parents and blame the critical care physicians if there was a complication." For example, he would say "surgery went great but the intensive care physicians do not want to give 'Lasix...'" This problem existed because **Dr. Gersak**, as Chief of Cardiovascular Surgery (although he never visited the pediatric ICU), backed **Dr. Blumauer** up (in **Dr. Kalan's** opinion). This kind of disgrace finally led to the ethical and moral outrage against **Dr. Blumauer** in December of 2013, the point at which 8 out of 10 intensive care physicians sent the above-mentioned letter to the Slovene Ethics Commission, in which they refused to continue to work with **Dr. Blumauer** as Dr. Kalan explained.

Dr. Kalan further reported that after completing the surgeries, **Dr. Mishaly** never stayed even an extra day in Ljubljana. He operated 2-3 days out of each month in UKC, and then he was gone. If there was a problem after he was gone, the service was usually able to carry out only conservative measures, regardless of whether or not the patient required surgical reexploration or another type of surgery. They were forced to use Novo7, give massive transfusions, and place patients on ECMO in case of emergency. However, it was very difficult

to get a child postoperatively into the OR for reexploration. **Dr. Blumauer** was very hesitant to make this decision. Aside from his inexperience, **Dr. Blumauer** was not confident in decision making in general, according to Dr. Kalan. ECMO survival in children in Ljubljana was 25%, according to **Dr. Kalan**. Nevertheless, ECMO had to be used when the surgeon was not available for definitive surgical correction. **Dr. Kalan** specifically underlined that the ECMO service was actually good, and the nurses were specially trained. He emphasized that during the last 5 years there has been a dedicated ECMO team, and the equipment is excellent. He believes the low survival in their institution is due to poor patient selection due to the lack of availability of the chief surgeon.

In regards to multidisciplinary conferences, **Dr. Kalan** mentioned these meetings were insufficient. Meetings to discuss patients took place only once a week and were sparsely attended. Typically, **Dr. Blumauer**, one intensivist, and very rarely an anesthesiologist would be present. **Dr. Blumauer's** input was usually impractical. Dr. Kalan stated that the surgical team was always in a hurry during these meetings. On multiple occasions, the critical care physicians and the pediatric cardiologists were asked to meet and discuss a specific patient plan when that very child was already on the operating table as per Dr. Kalan. **Dr. Kalan** states there was no attempt from **Dr. Mishaly** to give adequate surgical input to the entire team. In fact, there was really no team approach to the treatment of the pediatric congenital patients as Dr. Kalan explains. For example, the pediatric cardiologists and the intensivists would get a list of patients to be operated on during the three days when **Dr. Mishaly** was in town. However, they were never sure if these children would actually undergo the surgical procedures. The pediatric cardiology service would usually admit the child a day before potential surgery, and **Dr. Blumauer** would get the written consent, but **Dr. Mishaly** would almost never talk to the families. According to **Dr. Kalan**, he discussed an operative plan with the family maybe five times total over the whole duration of his time performing surgeries in Ljubljana.

When asked about quality assurance at the DPCS in Ljubljana, **Dr. Kalan** indicated that once a month, the intensive care physicians had their own discussions about the cardiac patients in the pediatric intensive care unit. The largest quality assurance issue he stated, was that during the 2-3 days when these surgeries were actually performed, 7 to 9 cardiac congenital surgical procedures would be conducted. The large pediatric cardiac surgery volume in this short amount of time overwhelmed the intensive care unit. Furthermore, Dr. Kalan explained, there are 14 beds in the pediatric ICU, which also serve for postoperative care of other pediatric surgical procedures. The relatively large volume of pediatric cardiac procedures in this relatively short time prevented the other pediatric patients from being admitted to the ICU. The problem sometimes became so large that the pediatric patients had to be postoperatively transferred to other cities in Slovenia (Maribor), Dr. Kalan explained. The inability to admit the children to ICU sometimes created a potential safety issue for the children after other types of surgery. This was due to the fact that the exact plan for the nature of the surgery and the number of cardiac congenital operations was hardly ever accurate, if provided at all to the surgical team, Dr. Kalan indicated.

Commission's comment: **Dr. Kalan** gave the Commission an inside point of view detailing the critical care physicians' struggle to manage congenital cardiac surgery patients. They were often frustrated with the lack of a capable senior surgeon present in UKC on a daily basis, the inability to have daily consultations when needed, the favoritism shown toward **Dr. Blumauer**, and **Dr. Blumauer's** lack of experience, judgment and training. This behavior from the pediatric cardiac surgery team from Ljubljana is completely contrary with international standards and recommendations. The UKC Leadership failed to respond to the grievances of

the critical care physicians. This added fuel to the fire for the dissatisfied intensive care physicians. The worst incident for the intensivists was when they became aware that **Dr. Blumauer** was belittling their colleagues in front of the patient's families - a behavior needing serious corrective actions and one in contrast with every ethical and moral physician's standard. Neither **Dr. Mishaly** nor **Dr. Gersak**, as his superiors, acted in compliance with standards when they should have disciplined **Dr. Blumauer** for such behavior. Instead, they backed him up. This again shows a tremendous lack of true leadership in the pediatric cardiac surgery service line, although these inadequacies were pointed out previously. During **Dr. Robida's** previous audit 2 years earlier, which was conducted at the request of the CMO (**Dr. Drnovšek**) regarding a death of a patient with hypoplastic left heart syndrome (HLHS), it was found that no existing institutional bylaws concerning professional behavior existed, nor were there any other rules or regulations regarding appropriateness of medical staff conduct. These documents were requested by Dr. Robida's Commission by the UKC, but they were never presented. In their recommendation at that time, Dr. Robida's Commission specified that the bylaws should be written and instituted. Despite the insistence by this audit that it is absolutely necessary that such bylaws were followed, no changes were made, and nothing happened.

Additionally, **Dr. Mishaly's** early departures, the lack of multidisciplinary rounds or meetings, and no true team approach to care for congenital cardiac surgical patients further worsened the already eroded collaboration between pediatric intensivists and cardiologists on one side and pediatric cardiac surgery on the other, eventually leading to the suspension of surgical services. It is absolutely unacceptable that: 1) children were placed on alternative therapy instead having timely operations; 2) pediatric patients were not allowed to be transferred outside of Slovenia for immediate surgical corrections; and 3) cardiologists or intensivists were forced to wait for **Dr. Mishaly** to return to Slovenia to operate on these children. These breaches in acceptable standards of care should be thoroughly investigated by the Medical Chamber of Slovenia or Ministry of Health. It is not the Commission's responsibility to carry out or recommend any disciplinary action toward those kinds of irregularities, but it is the Commission's view that those who perpetrated such acts should not be left without any disciplinary consequences.

7. **Dr. Brane Gaber**, Interviewed July 11-13, 2014

Dr. Gaber is a senior intensive care specialist who has been practicing in this field for over 30 years. He appeared very concerned for the children with congenital cardiac issues and their outcomes. He started his interview by explaining that in his opinion the entire structure of the DPCS was not functioning properly. In his opinion, the basis of all the problems was the arrangement with **Dr. Mishaly** and his lack of presence within the DPCS 90% of the time. Dr. Gaber explained that during **Dr. Mishaly's** absence, the communication with the surgical team was possible only through **Dr. Blumauer**. Never could **Dr. Mishaly** be directly communicated with. **Dr. Gaber** observed that **Dr. Blumauer's** decisions appeared sometimes strange and against normal practice. Direct contact with **Dr. Mishaly** was requested by PICU physicians but was nevertheless refused by **Dr. Gersak**, **Dr. Gaber** explained. He also believes that **Dr. Blumauer** had insufficient knowledge of pediatric cardiac pathophysiology.

According to Dr. Gaber, there were organizational problems in the DPCS as well, including excessively long waiting times for scheduling surgeries, inadequate seniority on congenital cardiac surgical service, and a lack of a collaborative and team approach. **Dr. Gaber** was also dismayed that children sometimes had to be placed

on ECMO and wait 2 to 3 weeks for **Dr. Mishaly** to return to Ljubljana. Occasionally, waiting time was 3-4 weeks while the child waited on Prostina for an arterial switch operation.

Dr. Gaber stated that these problems were clearly presented to the Medical Director of UKC Ljubljana at the time - **Dr. B. Drnovsek**. An agreement was reached that there would be a change in the surgical services' structure. However, three weeks later, the promise was changed without an explanation. Following this, **Dr. Blumauer** was taken out of the pediatric cardiac surgery program twice and both times was forced back to the same position by the management and even by order of the Minister of Health, according to **Dr. Gaber**. There is an article about the pediatric cardiac surgery program in ISIS (Journal of the Medical Chamber).

Dr. Gaber explained that when the problems with training the young residents were exposed, there was a recommendation to hire **Dr. Weiss**. **Dr. Gersak** at that time explained that no other young surgeon was interested in pediatric cardiac surgery, including **Dr. Weiss**. That information was clearly not accurate. Today, **Dr. Weiss** is actually the only congenital cardiac surgery resident in Ljubljana. He was hired shortly after the fiasco with the entire DPCS services in December 2013.

Dr. Gaber elaborated on the surgical outcomes for congenital pediatric cardiac cases. He believes the results for simple cases were acceptable and **Dr. Mishaly** was a good surgeon. However, in more complex cases, complications occurred too frequently. He also pointed out there were too many Hancock valves used, which he believes is not standard of care. The valves deteriorate extremely quickly, and children have to undergo a reoperation. Another painful issue was handling of cardiac emergencies. **Dr. Gaber** revealed that decisions in emergency situations were postponed for too long by the surgical team if **Dr. Mishaly** was not in Ljubljana. He believed that **Dr. Blumauer** lacked the confidence, skill, and judgment necessary to make the necessary decisions. He was afraid of reoperations and re-interventions, and he was very reluctant to change his opinion. During the 6-year period, this did not improve by much, he stated.

Dr. Gaber talked about the discussions he had with **Dr. Mishaly**. He reported that **Dr. Mishaly** told him that he could rely on **Dr. Blumauer**, but he was practically ordered or forced (by **Dr. Gersak**) to train him. **Dr. Gaber** indicated that **Dr. Mishaly** believed that **Dr. Blumauer** was very dedicated, but he could not train him "how to think." Apparently, **Dr. Mishaly** expressed that **Dr. Blumauer** lacked certain qualities to be a pediatric cardiac surgeon. Nonetheless, **Dr. Mishaly** completely ignored **Dr. Vodiskar**, **Dr. Gaber** concluded.

In **Dr. Gaber's** opinion, there "must be someone with power from higher levels" who is responsible for keeping both **Dr. Mishaly** and **Dr. Blumauer** in their positions. The reason for this can only be imagined.

Commission's comment: It appears at first glance that there were certain unexplained motives from either **Dr. Gersak** or the administration to force **Dr. Blumauer** to be trained as a pediatric cardiac surgeon. When there was a suggestion or an attempt to hire someone else for training (like **Dr. Weiss**) or questions about why **Dr. Vodiskar** was not given equal opportunity to perform surgeries, there was always some sort of excuse or contradictory explanation given. The Commission was not privileged to find the root cause for this behavior, but a thorough investigation should be conducted by appropriate authorities into the motives of the leadership to maintain the status quo, even to the detriment of the UKC. Additionally, the Commission is questioning why the surgeons at DPCS in Ljubljana kept using surgical materials known to deteriorate in less than one year (Hancock valves) instead of more durable ones, contrary to published data on this standard. This deviation from the standard of care may be considered unethical. The Commission finds this

deviation to be unacceptable for most centers since it poses additional risk for early reoperations. **The Commission recommends full investigation into this variance.**

8. Dr. Stefan Grosek, Interviewed July 11-13, 2014

Dr. Grosek is a senior staff intensive care physician with over 30 years of experience. His demeanor suggested he was not really comfortable speaking to the Commission.

Dr. Grosek stated that he got along with the pediatric cardiac surgery team well. He respected **Dr. Mishaly** and was very impressed with his skill. He never heard a bad word from **Dr. Mishaly** or **Dr. Blumauer**, and he never had a bad conflict with the cardiac pediatric surgical team. In his opinion, the major problem was that **Dr. Mishaly** came to Ljubljana only 3 days per month. **Dr. Grosek** believes the attitude and skills of **Dr. Mishaly** are perfect. In the beginning, everybody was happy with **Dr. Mishaly**, he stated. But after some years, the problems started. Unfriendly discussions during the occasional conferences and later confrontations and disagreements in the PICU between **Drs. Mishaly** and **Blumauer** and the PICU staff triggered the destruction of the surgical services in **Dr. Grosek's** view. Additionally, he believes the behavior between two parties during the meetings was not good. **Dr. Grosek** believed that PICU doctors and pediatric cardiologists were damaging the reputation of the surgeons. **Drs. Blumauer** and **Mishaly** always remained polite and never shouted. He admired them for that. He blames his PICU colleagues for never going to the operating room and for having reached their opinions much too rapidly.

Dr. Grosek communicated that disagreements between the intensive care physicians and the pediatric surgeons started to escalate as early as in 2009. There were also some conflicts between **Dr. Sojak** and the pediatric cardiology physicians prior to 2007. **Dr. Grosek** explained there were other pediatric surgeons (not only cardiac) who complained about his colleagues (the intensivists), and those surgeons did not want to work closely or collaborate with the critical care ICU staff physicians “because they do behave badly.” Apparently, there was a letter sent in 2013 and signed by the various pediatric surgical specialists (neuro, trauma, abdominal, urology, etc.) – including **Dr. Blumauer** – against the ICU physician staff. The Commission was never privileged to see this letter, although the Commission requested it from the UKC Medical Director.

Large problems appeared when children needed urgent or emergent reoperation after undergoing a previous cardiac surgery. Apparently, **Dr. Blumauer** was reluctant for children to have a reoperation because he always followed the orders from **Dr. Mishaly**, **Dr. Grosek** stated. This was particularly evident in cases involving oversized Blalock shunts. There were no revisions, patients remained on the ventilator, and sometimes even went into heart failure and died without reoperation.

Dr. Grosek stated at the end that he firmly believes the surgical team should be in charge of the ICU and the role of the critical care staff should be to support the surgeons.

When directly asked about the frequency of surgical procedures and the fact that **Dr. Mishaly** operated in Ljubljana only 3 days per month, he agreed that this was not enough. He did not comment further about this issue.

Commission's comment: The Commission is confident that there are, without any doubt, reasons to believe the behavior of the ICU staff physicians was not the finest, and there were deviations regarding collaboration, communication, and willingness to support the pediatric cardiac surgeons. By the same token, however, the

critical care physicians were frustrated by not having the surgical team readily available to answer their questions, and the majority of the time not being able to help with the management of the most critical and complex congenital cardiac surgical patients. Most critically, they were forced to delay decision making due to the inexperience of the junior pediatric cardiac surgeons. It is the Commission's impression that, in regards to their capability, the critical care physicians did everything in their power to optimize care for the patients. In the opinion of the ICU staff, when the standard of care was compromised, in the majority of these cases it was the result of the surgical cardiac team's actions. As **Dr. Grosek** articulates, the critical care physicians definitely carry part of the blame for not always being collegial to the surgical team. There probably is sufficient cause to bring some innovative management education and behavioral corrective actions to the ICU physicians' staff as well.

9. Dr. Mojca Groselj, Interviewed July 11-13, 2014

Dr. Groselj is one of the senior members of the intensive pediatric critical care team in Ljubljana and is very disturbed by the entire pediatric cardiac surgery situation in Ljubljana.

She started her interview by discussing the interactions between the pediatric cardiology and pediatric intensive care physicians. In her opinion, this interrelationship was good, and there was always collaboration among these two services. She has a very poor opinion of the pediatric cardiac surgeons because they were always unfriendly and arguing. She articulated to the Commission multiple examples to support her statement. In one such example, **Dr. Groselj** was trying to take care of a patient with a pneumothorax and in distress when **Dr. Blumauer** questioned her decisions. He did not take any criticism, even if it was meant to be constructive and well-intended. On one occasion, she explained that she felt very afraid of **Dr. Blumauer** as a result of him yelling at her. She indicated that he was very aggressive, and she was actually afraid he was going to physically attack her.

On another occasion, there was a patient with endocarditis. **Dr. Mishaly** was not in Ljubljana, and **Dr. Blumauer** was in charge. He could not make a decision regarding surgical therapy, and nothing was done for 10 days. **Dr. Blumauer** could not even put a drain into the pleural space properly. She questioned his competency because, in her opinion, he could never make a complex decision.

To emphasize this lack of decision making she recalled an urgent situation involving a patient after a Ross procedure. The patient deteriorated in 12 hours. They took the patient to the catheterization lab and established that he was experiencing an acute myocardial infarction with highly elevated ST changes. The surgical team waited for over 6 hours before finally taking the patient to surgery.

Another occasion involved a patient with hypoplastic left heart syndrome. The surgery team left the child on prostaglandins and did pulmonary artery banding for one month instead of performing the correct operation earlier.

In **Dr. Groselj's** opinion, **Dr. Mishaly** and **Dr. Blumauer** did not always make the right decisions. She witnessed **Dr. Blumauer** arguing in front of the nursing staff.

Commission's comment: Providing the specified actions truly happened, there are no excuses for the described behaviors of the pediatric surgical team. Most disturbing is the fact that they left patients on alternative

therapies and waited for prolonged periods of time instead of performing standard of care procedures. The Commission cannot comprehend the questionable and unacceptable ethical and moral standards used by the congenital pediatric surgical team. **The Commission finds this kind of conduct not only unacceptable but also prohibitive and suggests that it be further investigated by proper authorities.** Although the Commission was not requested to pass judgment, it is the Commission's duty to highlight that if harm was done to the patients due to substandard care, this kind of behavior would lead to punitive actions in most societies.

10. Dr. Silvo Kopriva, Interviewed July 13, 2014

Dr. Kopriva is one of the most experienced and senior members of the intensive pediatric critical care team.

He started his interview with a statement that, in his belief, the pediatric intensive care physicians would not have come to the point of questioning the ethics and morals of the pediatric congenital cardiac surgical team if the administration would have intervened in 2012, when **Dr. Robida** reported his audit results and suggested the needed changes. Unfortunately, **Dr. Robida** was publicly ridiculed for his recommendations by some members of the administration's leadership, **Dr. Kopriva** explained. He also believes the core of the problem was not so much **Dr. Mishaly's** financial arrangements, as it was the lack of willingness for change and restructuring from the highest administration leaders, including the Medical Director of the UKC in Ljubljana and **Dr. Gersak**. According to **Dr. Kopriva** everyone in the pediatric cardiac team was questioning why there was such resistance to change and why there was such a high level of determination to preserve the status quo, despite an abundance of evidence that there was something fundamentally wrong with the structure and the arrangement of the DPCS. **Dr. Kopriva** additionally explained that regardless of the wide array of existing problems, **Dr. Gersak** never visited the pediatric intensive critical care department to show interest or to try to help. This was despite the urgency, requests, and even pleading from the pediatric cardiology and critical care physicians. **Dr. Kopriva** believes **Dr. Gersak** kept the status quo on purpose for his own interests.

When **Dr. Kopriva** spoke about **Dr. Mishaly**, he questioned his decisions, as well. **Dr. Kopriva** spoke of an example of a patient with artificial valve endocarditis. **Dr. Mishaly** informed the cardiology and intensive care team he would arrive to operate in 2 weeks. He did not come for a month to replace the valve! Moreover, he did not allow **Dr. Blumauer** to do the valve replacement, which would have resulted in the surgery being conducted in a more appropriate timeframe. Although **Dr. Blumauer** was trying to portray himself as a competent pediatric cardiac surgeon, **Dr. Kopriva** stated that even **Dr. Mishaly** once made a comment about **Dr. Blumauer's** competence ("how can somebody shred the mitral valve?"). In **Dr. Kopriva's** view, **Dr. Blumauer** lacked the ability to self-critique, and he was often too arrogant. He wanted to get involved and control everything without collaborating and trying to learn, even for complex patients for whom he was not adequately trained. Per **Dr. Kopriva**, he sometimes did not even understand the physiology in detail. He indicated that **Dr. Blumauer** was never a team player.

According to **Dr. Kopriva**, an additional problem on the service was the lack of training the residents were receiving from **Dr. Mishaly**. He agreed to train two residents in two years, but this did not happen. **Dr. Vodiskar** was assigned to assist on the simplest operations but very rarely or almost never was he allowed to be the lead surgeon.

Per Dr. Kopriva, the intensive care physicians were never invited to be involved in preoperative communications with the families or to be present during multidisciplinary rounds.

Dr. Kopriva seriously questions if there were other hidden motives to keep **Dr. Blumauer** in his position as the leader of the Pediatric Cardiac Surgery Department, and he also questions why the administration and the medical leadership would maintain the status quo for 7 years. He believes that there still would have been no changes if the intensive critical care physicians had not finally stopped the unsafe pediatric cardiac surgery practices.

Dr. Kopriva believes the true core of the problem was **Dr. Mishaly's** unavailability and **Dr. Blumauer's** incompetence. There were definitely problems within the cardiology service as well, but those problems were more power struggles than patient management-related. He cannot speculate why there was no earlier restructuring of the pediatric cardiac surgery services.

Commission's comment: It is the Commission's firm belief that the pediatric congenital cardiac services should have been restructured immediately after the first signs of unsafe and substandard practices. The responsibility definitely lies within the highest leadership of the UKC, the UKC Medical Director, and **Dr. Gersak**. **Dr. Blumauer** should have been humble and self-critical enough to realize his limited potential. He should have sought help with situations in which he felt insufficiently trained, and he should have been properly educated abroad before starting to perform the more complex operations. The institution should have given him enough time within a much more structured residency program before they let him undertake the most critical decisions. **Dr. Mishaly** proved to be a very poor mentor. His motives leading to his insufficient training of the residents should have been questioned when it became clear that in two years, the residents practically had not performed any of the complex pediatric cardiac surgeries as lead surgeons. Clearly written guidelines for the standards of residency training detail how many and which operations are required for a resident to graduate. The resident trainees in Ljubljana did not even come close to meeting the benchmarks stipulated by these guidelines.

Regarding **Dr. Blumauer's** behavior as stated by multiple interviewees, on multiple occasions the arrogance, argumentative conduct, inability to recognize his own limitations, and poor decision making are clearly not acceptable traits for a pediatric cardiac surgeon, especially one in a leadership position.

11. ICU Pediatric Nurses: Interviewed July 11-13, 2014

The nurses reported that in transition from the operating room, the standard procedure was that the nurse, anesthesiologist, and **Dr. Mishaly** or **Dr. Blumauer** would usually accompany the patient to the ICU. The transitions were always smooth. The anesthesia nurse reports the details to the ICU nurse while physician talks to the physician on service. There was both verbal and written information on the transfer, including digital information.

There was always 1:1 (or sometimes, if necessary, 3:2) nurses per patient, depending on the postoperative hemodynamic stability of the child. The challenge the nursing staff experienced was that there was seldom a postoperative note written to confirm exactly what was done in the operating room. Half of the time, the

volume was more than seven surgeries in the span of the 2-3 days when **Dr. Mishaly** was operating in Ljubljana.

These large volumes of pediatric cardiac surgical patients over a short 3-day period created problems with bed capacity and PICU nurse staffing. When PICU was overloaded with too many cardiac patients at once, the other pediatric surgical patients had to be redirected to Maribor or to other adult ICU's in the UKC in Ljubljana. Nurses felt this trend was not an example of good practice and was definitely not good for patients or their parents.

In the case of unstable patients, the intensive care physician was present at all times. The coverage was 24/7 for critical care physicians, and staffing was never a problem. The orders were always given by a pediatric critical care physician. If **Dr. Blumauer** wrote an order, the nurses always discussed this order with the intensivist prior to executing the order. This is the policy of the ICU department.

The communication between the nursing staff and the surgeons was always good. There were no issues from the nursing staff toward the surgeons. Communications from surgeons to the family was always outside the ICU. In the ICU, the intensivists communicated with the child's parents or family. At the beginning, the rounds were together with surgical staff and critical care physicians. However, during the later years, the rounds were conducted separately. There was hardly any communication between the surgical team and critical care physicians during the last two years. The nurses explained that **Dr. Blumauer** communicated with parents and nurses well but not with PICU doctors. Occasionally, he would say to PICU physicians and pediatric cardiologists that "they had no idea what they were talking about." Those statements were sometimes overheard by the nurses. However, similar statements "also occurred the other way around" intermittently. Sporadically, there was even shouting heard in the side rooms or in the corridors from both parties. Fortunately, it did not happen in front of the parents or in the PICU itself. The nurses told the doctors that that kind of behavior within the PICU "was not allowed." The tensions between doctors escalated specifically when PICU physicians thought that a child should be taken back to surgery but **Dr. Blumauer** alleged this was not necessary.

On very few occasions, in critical situations, **Dr. Blumauer** and PICU doctors communicated with the parents together.

When the nurses were asked about **Dr. Blumauer's** surgical skill, they all stated that his technical skill was in their opinion, questionable. Sometimes it took him 3 days to decide to take a child for reoperation because of bleeding. During that entire waiting period before reexploration, the nurses had to give blood to the patient. In their opinion, he was not very skillful even in minor procedures like inserting peritoneal dialysis catheters.

The ICU nurses questioned why **Dr. Blumauer** was involved in surgeries approximately 80% of the time despite his indecisiveness and lack of technical skill, while **Dr. Vodiskar** was only involved in 20% of the surgeries. Communication for them was much better with **Dr. Vodiskar**, although **Dr. Vodiskar** was not often in the PICU. **Dr. Mishaly** rarely visited the ICU, and **Dr. Gersak** never stopped there, according to nurses' interviews.

When discussing the Unit and the working environment, all interviewed nurses were very proud to work in the ICU and portrayed a sense of ownership of the department. They were sad that pediatric cardiac surgery is no longer performed there. They all believe they have a very modern department, good visitations for

parents, and good ECMO support. As a result of the cessation of pediatric cardiac surgeries, they are afraid they will lose the nursing skills required to properly care for pediatric cardiac patients.

When asked about the interpersonal communications among physicians, they reported there was a lot of arguing during the last 2.5 years, especially between the critical care physicians and surgeons.

Commission's comment: The pediatric ICU nurses are very dedicated and passionate about their work. They are depressed now because pediatric cardiac surgery has been suddenly terminated after 50 years of strong tradition. The nursing staff was not happy about poor and inadequate planning of pediatric cardiac surgical procedures. The transport of pediatric non-cardiac postsurgical patients to Maribor added an additional unacceptable risk to the children due to the pediatric ICU overload and lack of more evenly spread pediatric cardiac surgeries.

The nurses reported that the lack of communication between the physicians, lack of postoperative reports, and dual orders from critical care physicians and surgeons caused misunderstandings and confusion and resulted in additional safety risks to the pediatric surgical patients that could otherwise be avoided. The multiple arguments between physicians and their condescending behavior do not belong in any highly ranked, prestigious, and noble service. This is especially true for pediatric cardiac surgery services that care for helpless, sick children. The Commission profoundly questions the lenience the highest medical leadership of UKC Ljubljana had toward the patronizing physicians and their immoral activities. The moral and ethical manner of such physicians warrants thorough investigation into their character, capability, and competence and most likely necessitates corrective actions.

12. Families, Interviewed July 11-13, 2014

Multiple families conveyed to the Commission that there were numerous **miscommunications** or even a total lack of communication by the physicians to the patients' relatives for prolonged periods of time. One family reported that when their child was diagnosed with VSD 2 days after birth and the pediatric cardiologist communicated to the parents that the child would need an operation, the pediatric cardiac surgical **service did not explain the exact time** when surgery would take place. It was very stressful for them not knowing where or when the child would be operated upon. This occurred on March 2, 2012. According to the family, at that time, after 5 years of operating in Slovenia, **Dr. Mishaly** had yet to obtain a Slovene license, and at that time **Dr. Blumauer** was no longer part of the PCS program. The child's parents had to wait for 10 days to 2 weeks to receive any further information. At that time, the patient was discharged home, and the family was told they would be called in 1 to 2 weeks to discuss the surgery. They were also told the surgery would be done when the child was 3 months old. When the child reached the age of 3 months, they met with the surgical team and were told the surgery would be in a month. After the month passed, they were notified the surgery was cancelled. They were not informed as to the reason why. However, they were told the surgery would be after another month. The **surgery was postponed several more times** and did not happen until the child was 8 months old. This caused tremendously high level of anxiety among the family members. They were finally relieved when the surgery happened at last and it went well. They appreciated when **Dr. Mishaly** and **Dr. Blumauer** came to talk to them after surgery. They were satisfied with their explanations and once the child was admitted to the ICU postoperatively, they did not have any major problems with the surgical team any longer. The waiting period for surgery for many months was unbearable, however. While the issues with surgical team appeared to be resolved, this family's experience with the ICU was not completely smooth.

The **nurses were not consistent in updating** the family nor did they give them reliable information. For example, one nurse told them they could bring the toys for the child, while another nurse did not allow them to do so. They wanted their child to be restrained out of fear that he would pull out his lines or drains, but the nurses did not want to listen to them. While they were on the ward, the child next to them was very loud. They believe the **nurses did not have any protocols** to handle this specific situation. They believe the quiet children would have been better helped if they were closer together, while the loud ones could be housed at a different location on the ward. At some point, they even observed a **nurse screaming at the child** who was not quiet. In this family's experience, the nurses were either very nice or rude. One family expressed a very negative opinion about the nurses. Another family complained that chest X-rays were not done in the PICU but in the Radiology Department, which is physically far away from the PICU while their child was still ICU-bound and, in their opinion, **the transport to the Radiology for X-Ray was quite risky**.

A different family reported they had a relatively good experience once their child was admitted for surgery at the age of 3 months. They could not understand, however, why they were told the child needed an **emergency operation, and then this surgery did not happen for 3 months**. They thought that was quite strange, and nobody took the time to give them any explanation. This waiting was very stressful and difficult. They were not given any information about the time when **Dr. Mishaly** would arrive to operate in Ljubljana. This stress - awaiting for surgery and not knowing the timing of the operation was very traumatic for the entire family. Once the child was operated on, everything went relatively smoothly. Postoperatively, they did not have any complaints about the nurses or physicians, and the child left the hospital 10 days after surgery. Waiting for surgery and not knowing the date of the operation for almost 3 months was the most difficult and traumatic experience for them.

Another family described that the **lack of communication** and inconsistent or contradictory statements by different doctors were nerve-wracking. They did not know which physician to believe. Additionally, some nurses were not friendly and sometimes made sarcastic remarks. When their child was on the ward, for example, the mother noticed that **therapy was not given** to her child. When she complained and reported this to the nurse, the nurse was unfriendly, argumentative, and tried to convince the mother, without double-checking, that the therapy was given. Another nurse checked the chart and confirmed the treatment was not administered. The first **nurse never apologized**, and the mother believes her child would not have received the treatments if she did not complain. The parents also reported that the nurses were hiding the charts from the families.

Another time, the parents reported **the charts were mixed up**. In one child's chart, it was documented that the child had Down's syndrome, but that information was incorrect and belonged to a different patient.

Commission's comment: In general, the families were satisfied with the care their children received as patients. However, there were sporadic situations in which the nurses were not polite and sometimes even rude. This should not be an acceptable behavior for any program or service.

Additionally, the sometimes contradictory or mixed patient information or chart mix-ups, the lack of communication, and the delay in relaying proper or timely information to the families of the operated children are each not acceptable actions by any standards of care. The evidence of sarcastic and sometimes rude nurses' comments and that of the nurses skipping administering the medication or missing a patient's therapy necessitates serious quality control protocols and corrective actions be implemented. Hiding the medical charts does nothing other than inject uncertainty, suspicion, and mistrust into the patient-physician/hospital relationship. It destroys expectations and hope.

The Commission believes the above described untraditional and bizarre behavioral deviations are, among other reasons, a reflection of the lack of protocols, quality assurance, and leadership at all levels of the organization.

These idiosyncrasies at the DPCS and extensive public media coverage of the physicians' arguments during 2013 and the first half of 2014 made the public very cognizant, however, of how disorganized and deficient the department really had become over the last few years.

Several families' complaints about the DPCS in Ljubljana were circulated in the newspapers and other media. Public awareness of the disorganized scheduling, multiple surgical cancellations, the lack of communication between the physicians and families, the unknown dates for surgery, and thus the families' fear of their child's death before the surgical procedure created a near panic among the parents of these children awaiting surgery. The Commission is cognizant that the Slovene public may not have been completely aware of all the departmental intricacies, and it did not have a comprehension of the majority of the details regarding the substandard care and chaos present in the DPCS to make appropriate judgments of the DPCS in Ljubljana. However, the Commission is taking a firm position that no parent or family should ever experience such uncertainty and anguish waiting for an ill child to undergo an already stressful cardiac surgical operation.

Since the trust of the public in the DPCS was completely lost, the Commission believes that to even consider the possibility of having a new pediatric cardiac surgery service in Ljubljana, the new department structure and commitment from the highest leadership will have to be outlined prior to the restart of the program. All the protocols will need to be presented in writing. Competent and dedicated leaders will have to be recruited by specific committees (as expressed by this Commission in the recommendations chapter). International standards will have to be implemented, and quality assurance must be routinely assessed with punitive actions implemented if the standards are not followed.

The Commission is convinced that only then will there be an opportunity to regain the public trust, respect, and confidence in pediatric cardiac surgery services in Slovenia.

13. Dr. R. Kenda, Chief, Department of Pediatrics, Interviewed July 12, 2014

Dr. Kenda told the Commission that he has been chief of Department of pediatrics since 2009. He said that interpersonal relationships are seriously disturbed within the department of pediatric cardiac surgery. **Dr. Podnar** came to him (possibly in 2009 or 2010) to complain of all the problems with pediatric cardiac surgery. **Dr. Kenda** took this complaint to the hospital board, **Dr. Gersak**, and the Chief of the surgical division. Their answer was that there were no problems and that the pediatric cardiac surgery program was running well according to Dr. Kenda's statement.

Dr. Kenda reports that for a prolonged time until Dr. Blumauer's departure in 2013, there had been no trust between **Dr. Blumauer** and the majority of the pediatric cardiologists and PICU doctors. Complaints about **Dr. Blumauer** were very concerning; his lack of surgical skills, his method of communication, his attempt and tendency to frequently override the PICU doctors' orders, and his hesitation to reoperate on children even when emergently needed.

Dr. Kenda explained that **Dr. Mishaly** once told him that "**Dr. Blumauer** was a lousy surgeon." **Dr. Kenda** suspects that **Dr. Mishaly** nevertheless continued working with **Dr. Blumauer** because he (**Mishaly**) had a

large financial interest in this situation. When **Dr. Vodiskar** came back, he was disfavored in comparison to **Dr. Blumauer**. When cooperation with Leiden was discussed at one of the department meetings in March 2012, it was suddenly and unexpectedly stated by the medical director of UKC that **Dr. Mishaly** would continue working even though the Leiden surgeons had made it abundantly clear that this was against their wishes if they were to start operating in Ljubljana. **Dr. Kenda** stated that the decision to keep **Dr. Mishaly** and continue the program structure as it existed was a total surprise to everyone and probably money driven.

Dr. Kenda had complaints about **Dr. Blumauer** regarding his results and his behavior (toward PICU staff and pediatric cardiologists as well as toward parents). He emphasized **Dr. Blumauer's** behavior as being especially bad when there were disagreements about decisions in the PICU. **Dr. Kenda** pointed out that sometimes **Dr. Blumauer** would come to the parents and make suggestions that they should not listen to PICU doctors but only listen to him because he was the surgeon and knew much better what was happening with the patients.

Dr. Kenda was asked about the structure and who was ultimately responsible for the patients before surgery. He indicated that once the indication was made for surgery, the patient was placed under the supervision of the Department of Surgery (which includes all ICUs and the PICU). However he also explained that the PICU physicians and Pediatric Cardiology did not trust the work of **Dr. Blumauer**. No true attempts at mediation were, however, done until it was too late and the gap between pediatric cardiac surgeons and other physicians was too wide.

Dr. Kenda was asked about his awareness of the surgical results and if he was familiar if the surgical data were being reported by the DPCS to the official pediatric cardiac surgery association database. He stated there was a lack of data all along from 2007 onwards through the present. When the official data report of pediatric cardiac surgery written by **Drs. Blumauer** and **Gersak (Ref 45)** was presented to the Ministry of health at the beginning of 2013, **Drs. Kalan** and **Podnar** profoundly objected and disagreed with the results.

Commission's comment:

Dr. Kenda holds one of the highest leadership positions as the chief and chair of the pediatric department, under which pediatric cardiology falls. After **Dr. Kenda's** interview, it remains unclear to the Commission why the structure of the DPCS and **Dr. Mishaly's** agreements were kept for so long despite clear indications that this arrangement perpetuated unsafe and dangerous conditions within the pediatric cardiac surgery department.

The Commission cannot imagine why the unsafe and flawed pediatric cardiac surgical practices were tolerated by the highest UKC leadership. The leadership was informed on numerous occasions about the questionable technical skill and inexperience of the junior pediatric cardiac surgeon, the lack of availability of the senior pediatric cardiac surgeon at UKC Ljubljana, the lack of proper reporting of surgical results to the international database, and the clearly substandard practices of the pediatric cardiac surgical program over 7 year period. The leadership was also made aware of grave questions regarding the financial motives of the lead surgeon. **It is the Commission's conclusion that the leadership was aware of the faults in question and did not act to correct the situation.**

The Commission did not receive a clear answer from **Dr. Kenda** to its questions as to how he, as the Chief of the pediatric department, could not stop these unsafe practices much earlier in the process and why he and

the rest of the leadership tolerated the aforementioned procedural and structural deficiencies until December 2013.

14. Dr. S. Hojker, UKC Medical Director, Interviewed July 13, 2014

Dr. Hojker's interview was quite short and his answers were quite diminutive. **Dr. Hojker** stated that he has been in the position of the UKC Medical Director only for the last 6 months prior to the interview. As **Dr. Hojker** also stated, he has had no collaborative relationship with any of the involved specialists regarding pediatric heart surgery from 2007 through 2013. He told the Commission he believes that the only possible future solution for continuation of pediatric cardiac surgery in Ljubljana involves an experienced surgeon from a high-volume center coming regularly to Ljubljana in addition to sending difficult cases abroad, especially for the first years.

When asked what he thinks was the main problem for the turmoil in the DPCS in Ljubljana, **Dr. Hojker** said he believes that **Dr. Mishaly** earned way too much for the level of service he provided. He also thinks that it is not good that **Dr. Mishaly** was there for only 3 days/month.

Dr. Hojker explained that after he took office, the mediation at the DPCS had started some months ago with the attempt to resolve the problems at the DPCS in UKC Ljubljana. However, **Drs. Gersak** and **Blumauer** were the only two physicians who refused to take part in these mediations as per **Dr. Hojker's** explanation. All others parties were participating.

When asked about his vision for the future of PCS in Ljubljana, **Dr. Hojker** recommended that a regional center is mandatory for the future of the DPCS. Accordingly, there should be at least 200 surgeries performed in a given year. **Dr. Hojker** mentioned that this will require cooperation with a high-volume center. He felt that the current situation is impossible to resolve because the people involved do not trust each other. He provided additional input that he is aware the protocols are lacking and should be mandatory. **Dr. Hojker** expressed his belief that all patients should be put into the EACTS Congenital Database starting with those from 2007 through all current patients, and that he is investigating why this was not done.

When asked how he plans to build a center of excellence for PCS in Ljubljana, when there have been fewer than 100 congenital cardiac surgeries performed per year in Ljubljana over last 7 years, he did not have a clear answer. He believes, however, that bringing an experienced surgeon to be full-time employed at UKC and eventually train two domestic pediatric cardiac surgeons may be the solution.

Commission's comment:

As the highest medical authority at the UKC in Ljubljana, **Dr. Hojker** also believes that financial issues were one of the motives for the prolonged continuation of the flawed structure of the DPCS in Ljubljana. **The Commission can only hope that the proper authorities were informed about this concern.** It is not the place or intention of the Commission to dictate to the Slovene government or Ministry of Health a proper response to this concern. However, the Commission felt responsible to illuminate this concern.

The Commission finds it to be quite unusual, surprising, and even alarming that **Drs. Gersak** and **Blumauer**, the two key surgeons within the pediatric cardiac surgery department, were the only two physicians who refused mediation when it was offered at UKC.

It appears that Dr. Hojker understands the consequences of the gigantic problem that the cessation of the pediatric cardiac surgery in Ljubljana has created. However, it is the impression of the Commission that he does not possess a clear idea of the structure and the requirements of how to rebuild and sustain a pediatric cardiac surgery center of excellence.

The Commission believes, however, that there is a strong will and desire to bring pediatric cardiac surgery back to Ljubljana and that the leadership of the UKC is opened to international experts' suggestions how to accomplish this enormous task.

F. Chronology of Events leading to the analysis of the EACTS Database

The Commission was informed by **Dr. Weiss** that the data entry to EACTS Database was complete and concluded on October 4, 2014. According to the data entered, there were 593 congenital cardiac operations on 473 patients between the years 2007 and 2014 at the UKC in Ljubljana.

Analysis of these data began immediately after they were received. After a few weeks of analysis, the first results were given to the Commission by **Dr. Ebels** on October 30, 2014. These preliminary data showed a very low number (less than 100) of pediatric cardiac surgeries in Ljubljana per year, and the overall mortality was 4.4. The average case difficulty score (Aristotle) was 6.5 (Ref 33).

Quite quickly it became clear that the results of this analysis would not yield adequate and satisfactory information able to address the concerns of the Ministry of Health of Slovenia due to the very small number of congenital cardiac patients operated in UKC Ljubljana. Therefore, the additional table for required results was constructed and shared among the members of the Committee on November 3, 2014 (Ref 34).

On November 18, 2014, the Commission requested **Dr. Weiss** to provide the additional downloaded file to the Commission. This was delivered by him almost immediately. While analyzing this data over the next few days, the Commission started to notice discrepancies between the data entered to the EACTS database and the data entered to the EACTS by **Drs. Ebels** and **Hazekamp** for year 2012 specifically. These unveiled differences and additional inconsistencies in the entered data raised profound concerns among the Commission's members and exposed the need for a deeper investigation into the database.

After communicating these concerns to **Dr. Weiss**, he then explained to the Commission that:

“We enter the data on two different computers. **Dr. Kalan** entered data into his computer, and I entered data into my computer. When we finished with data entry I exported all patients from my computer and all patients from year 2012 (who we entered together) and imported them into **Dr. Kalan's** computer. After doing that, all patients (**Dr. Kalan's**, mine, and all from year 2012) were in the EACTS database software, which we uploaded to the EACTS server.” (Ref 37.)

Concerned with these data inconsistencies, the Commission felt the need to contact **Dr. Zdzislaw Tobota**, MD, EACTS Congenital Database Coordinator, to seek possible explanations for these discrepancies and how best to analyze them.

Dr. Tobota's response was:

"After the tests we've done yesterday, I confirm that the order of numbering admissions and operations may be caused by data handling as described by **Miha Weiss** and that we cannot draw the conclusions about possible deletions of the operations and admissions based on these numbers. They were not designed for that." (Ref 39.)

These problems identified in the database began to erode the Commission's trust and confidence in the numbers entered by the Ljubljana team; hence, there many explanations were requested from the Ljubljana's UKC's data entry team, thereafter (Ref 35).

During the following few days (November 28-29, 2014), unsatisfied with additional discoveries of data inconsistencies, the members of the Auditing Commission expressed deep concerns regarding the validity of the data they were presented with. This was despite the attempts at clarifications and explanations made by **Dr. Weiss and Dr. Kalan**. The Commission decided to request help from the director of the EACTS Database, **Dr. Bohdan Maruszewski** (Ref 74), in addition to the database software expert, **Dr. Zdzislaw Tobota** (Warsaw), on how to interpret these findings. All these concerns were readily shared with the president of the Medical Chamber of Slovenia, **Dr. Mozina** (Ref 37).

After a few days of investigation into the database problems, and after the Ljubljana team's explanation that the data were entered on multiple computers, it appeared that the resolution of the database problems was reachable, and the explanations by the team at Ljubljana were sincere and credible. **Mr. Tobota** confirmed, "That the order of numbering admissions and operations may have been caused by data handling" as described by the Ljubljana data entry team (Ref 38). These explanations seemed believable. Therefore, the Commission resumed the data analysis (Ref 39).

Upon further data analysis (Ref 44) it became apparent that more problems with the data in the EACTS were imminent. The analysis indicated that even after the entire set of operative data from 2007 through 2014 had been harvested and entered into the EACTS Pediatric Database by the Team in UKC Ljubljana, the validity of this data may, after all, not be credible.

On December 11, 2014, **Dr. Ebels** questioned the information entered about a specific patient that was discharged home, readmitted, and then died on the same day (Ref 40). Though this is possible, it is unlikely. Furthermore, there were additional questions regarding other patients. Incorrect dates were entered, and many questions arose regarding inconsistencies in the data of several patients about what surgeons actually performed the surgery. One of the physicians entering the data indicated in an email that at the time the charts were being entered, frequently many were incomplete (Ref 41).

Furthermore, in additional data analysis **Dr. Ebels** observed in an email dated Dec 14, 2014, "Another issue is that in the database none of the 2012 operations seem to have been performed by **Mishaly**. His code does not appear on any of the operations." Specifically, **Dr. Ebels** recalled the data for patient who he himself had entered into the database during the July 2014 Audit. At that time, **Dr. Mishaly** was indicated as the surgeon for that particular patient. In this new database, this same operation was indicated to have been performed by **Dr. Blumauer**.

Dr. Ebels requested the team in Ljubljana to check the database about these issues because it seemed as if something was very erratic. It appeared particularly odd to him, since during the July 2014 Audit all operative procedures for the year 2012 were entered into the EACTS database by **Drs. Hazekamp and Ebels**. It

would have been very unlikely, that in 2012 all operations were done by the other surgeons and not by **Dr. Mishaly**, as well.

Additionally, going through many documents about pediatric cardiac surgery in Ljubljana during these past 6 months one of the findings was that in the report of internal UKC Ljubljana pediatric cardiac surgery audit from 20th January 2012 (official document of the UKC, paragraph 3.1.1 - Findings) it is clearly stated that “all the surgeries done by **Dr. Mishaly** are entered into the system under the name of **Dr. Blumauer**, since **Dr. Mishaly** does not have the provider number given by the Medical Chamber of Slovenia.”

Therefore, the Commission could not be sure if these surgeries had been sifted apart. Furthermore, this made it difficult if not impossible to actually determine with any accuracy WHO REALLY was the surgeon on any given case.

Moreover, **Dr. Ebels** expressed his concerns that, “It is evident that the data in the database are not consistent. The paradoxical thing is that in particular the 2012 data are improbable, while **Mark and I** entered those personally. This is what I find a very worrying observation. Is it that we never entered **Mishaly** as surgeon? Unlikely. How then can the year 2012 differ so fundamentally from all other years? I don’t remember ever having heard of a doctor **Lakic**, who purportedly did a few dozen operations in 2012, but maybe my memory is failing me. Have you heard about or even talked to a **Dr. Lakic**? In the other years the intermittent presence of **Dr. Mishaly** can clearly be seen, which is in line with what we have been told. Apparently the other doctors also performed operations in his absence. I have not yet analyzed what happened in **Mishaly’s** absence.” (Ref 42.)

With serious doubts and deep concerns about the data entered into the database, the Committee members decided to conduct a conference call between all members of the Audit Commission on December 18, 2014, at 6 p.m. European time (Ref 43). The call took place at the agreed upon time and date. **Dr. Derganc** was unable to participate. After prolonged discussions about the data entry and the validity of the database described above, it was decided that:

- 1) The Commission will finish the report with the information provided. As the information entered into the EACTS database is inconsistent and needs to be verified, it would take a substantial amount of additional time to complete this verification. In addition, the Commission had serious doubts that consistent data can be collected that would enable an objective and accurate analysis, since at least 10% of patient data was missing just from the year 2012 alone. This information was not provided by the UKC for analysis, even though **Dr. Blumauer** had sent them to the UKC administration at the same time he sent it in his email to the Commission and to the Medical Chamber of Slovenia (Ref 14). Since the Slovene Medical Chamber and the Ministry of Health are in need of the report as soon as possible, the decision of the Commission was to complete the report on the basis of the gathered information and the data entered to the EACTS Database by the members of the Commission.
- 2) **Dr. Gregoric** will write the preliminary report and distribute it to the members of the Commission to be reviewed.
- 3) The Interviews section of the report will be summarized, and the actual documentation of the interviews is going to be presented in the Reference section.
- 4) After reviewing the report, the report will be officially edited by the editorial office and redistributed to the Members of the Commission for final approval. Completing the approval process, the Report will be edited into the final version.

- 5) After a final viewing of the report by all the members of the Commission, the report will be signed by all the members and then officially delivered to the Medical Chamber of Slovenia.
- 6) With the delivery of the Report, the Commission's responsibilities to the Slovene's Medical Chamber will be concluded.

During the two and half months since December 18, 2014, additional data from the database (depicted in Ref 48, Ref 15, Ref 18, and Ref 51) were analyzed, and the results were reviewed and compared in conjunction with the information from the Ref 47 and Ref 46.

During a telephone conversation between **Dr. Gregoric and Dr. Ebels** on the February 15, 2015, discussion of the absence of **Dr. Mishaly's** log numbers for year 2012 from the Database (Ref 48) took place. The Commission was convinced that **Dr. Mishaly** had been operating in Ljubljana in 2012 based on evidence the Commission acquired from the Commission's own database information entry and analysis (Ref 18) as well as from all the interviews. When comparing **Dr. Mishaly's** log numbers from the database for 2012 entered by the UKC physicians (Ref 48) with the data entered by the Commission itself (Ref 18), and also comparing this information to **Dr. Blumauer's** database (Ref 15) and **Dr. Tjark Ebels'** database of the major operations performed in Ljubljana in 2012 (Ref 51), **it was clearly evident that Dr. Mishaly** was definitely present and operating in Ljubljana in 2012 and not absent as it appears in database Ref 48. At the conclusion of the telephone conversation it was agreed that **Dr. Ebels** will go back and review the two databases (Ref 48 and Ref 51) once again.

Following an exchange of emails on February 16, 2015, and discussions first between **Drs. Gregoric and Ebels, and then by Dr. Ebels and Dr. Hazekamp**, it became clear that the reason for the discrepancies in the numbers of surgeries performed by different surgeons was that diverse staff coding practices were used by **Drs. Weiss and Kalan**, who originally entered these data on three different computers in Ljubljana. As staff coding was done independently on the different computers, the codes were not congruent. This matter came then to its culmination when these data sets were merged and the staff coding of the recipient data set prevailed over the imported data set (Ref 58). In addition, it was discovered that some patients may have been entered under the year 2001 instead of the correct year, 2011. This would, obviously, skew the data results (Refs 54, 58).

	first_name	last_name	staff_role_r	staff_code	Nieuw veld toevoegen
+	Miha	Weiss	Surgeon	A	
+	David	Mishaly	Surgeon	B	
+	pela	tupnik	Anaesthetist	C	
+	Robert	Blumauer	Surgeon	D	
+	Janez	Vodikar	Surgeon	E	
+	Ivan	Kneevi	Surgeon	F	
+	Toma	Podnar	Referral Cardi	G	
*					

Table A

	A	B	C	D
1	first_name	last_name	staff_role_name	staff_code
2	David	Mishaly	Surgeon	A
3	Robert	Blumauer	Surgeon	B
4	Janez	Vodiskar	Surgeon	C
5	Nikola	Lakic	Surgeon	D
6	Janez	Vodikar	Surgeon	E
7	Ivan	Kneevi	Surgeon	F
8	Toma	Podnar	Referral Cardiologist	G
9				
10				
11				
12				

Table B

Tables A and B represent the “Staff” coding examples from different computers where the data were entered prior to sending them to the EACTS Database (note the different codes for Drs. Mishaly, Blumauer, Weiss, and Vodiskar, who has codes C and E in Table B

Another observation brought back to the Commission’s attention was that at least some of the surgeries performed by **Dr. Mishaly** in Ljubljana during the year 2012 were entered into the system in Ljubljana under the name of Dr. Blumauer, a domestic surgeon. This was probably due to the fact that surgeon coded B was Dr. Mishaly in Dr. Weiss’s computer, while it was Dr. Blumauer in the computer of Dr. Kalan.

As **Dr. Kalan** explained in an email on December 15, 2014, “...your findings on oddities about data for year 2012 are the result of the program, which was run under the guidance of **Prof. Gersak**. In 2012, it became publicly known that **Mishaly** does not have a medical license in Slovenia. Therefore, at the time of license acquisition operations were attributed to **Lakic** and **Blumauer**, although they were done by **Mishaly**...” (Ref 58).

The mortality and morbidity rates at the DPCS in Ljubljana were discussed through the emails as well. It was noted that while the mortality data were entered, adequate morbidity data were not included in the database

(Ref 48). In an email from **Dr. Hazekamp** dated February 16, 2015, he commented on this observation and suggested, again, to write our report with the data - or lack thereof – as they currently exist. “Data on mortality have probably been entered completely into the database. However, as far as I know we have not entered complications into the database. To say the least complication data are not reliable as they are now (as far as I know). This means that we would have to go through all patient files again to guarantee adequate data input” (Ref 75).

G. DATABASES and REPORTS for years 2007–2013 and the Interpretation of Data and Data Inconsistencies

Databases and Reports

The Commission was privileged to view different data results which were previously reported in different Audits or conveyed to the Authorities (Ministry of Health) in previous years prior to the current Commission's Audit in July 2014. These documents were distributed to the Commission by individual physicians. In addition, the Commission was given some data that were collected by individual physicians that had never before been reported. Finally, the last group of Data was collected by the Commission's members themselves, and it was uploaded to the central EACTS Database for year 2012. The larger group of data for the surgeries at the DPCS in Ljubljana from 2007 through 2014 was collected by physicians who are members of the pediatric cardiac surgery service (**Dr. Weiss**) or Pediatric Critical care service in Ljubljana UKC (**Dr. Kalan**) (Ref 48).

Table 1. Data analyzed or reviewed by the Commission.

1	Analysis of data for years 2007–2014 (Databases Ref 48 and 51)
2	UKC report presented to the Ministry of Health of Slovenia in January 2013 (Ref 45)
3	Official Report of the KVK Audit performed by the Internal Audit services at UKC in Ljubljana in 2012 for the period of 2007 through 2011 (Ref 47)
4	Analysis of data entry to EACTS by Drs. Weiss and Kalan (Ref 48)
5	KVK - Dr. Podnar's personal data (Ref 46)
6	Dr. Blumauer's personal database given to the Commission for pediatric cardiac surgeries, Ljubljana 2012 (Ref 15)
7	Analysis of GFM data entry into the EACTS by the Commission (Ref 18)

From the above recorded data it became evident very early on that there are enormous discrepancies among different data sets.

1. Analysis of data for years 2007–2014 from Database entered by Ljubljana team (Databases Ref 48 and 51)

The Data presented to the Commission (the same Data that were uploaded to the EACTS base by **Drs. Kalan and Weiss**) were independently analyzed by two different groups of Commission members to compare the results and the conclusions. This was done to assure objectivity of the outcomes of the data analysis. Both groups came to the same results (presented below).

Database Ref 48: There are **total of 593** procedures listed in the database. However, from 2007 until January 2014, there were **590** congenital cardiac operations performed on **473** patients at the UKC in Ljubljana. Since the Commission was looking into the data only for a period of time from 2007 until the end of 2013, three patients were excluded, one each from 2001, 2006, and 2014. In this database there were **27**

procedures listed during 2007, 98 in 2008, 88 in 2009, 94 in 2010, 96 in 2011, 98 in 2012 and 89 in 2013. (See Figure 1 below.)

Database Ref 51: The separate analysis was done for **major** congenital cardiac operations during the same time period from 2007 until January 2014.

There were **553 major procedures** listed in the database (Ref 51); however, only 550 were done during the period between 2007 and end of 2013. Of **all** 553 listed procedures, **Dr. Mishaly** performed 360, **Dr. Blumauer** 138, **Dr. Vodiskar** 23, **Dr. Lakic** 31, and **Dr. Knezevic** 1. The three patients excluded from Ref 48 (for the exact number of surgeries from 2007 till 2014 as explained above), were left in this analysis, since they do not significantly influence the analysis numbers.

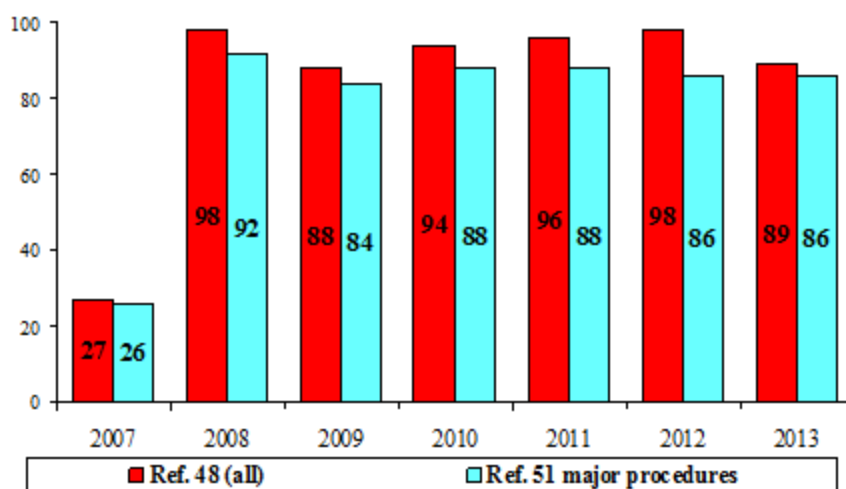


Figure 1. Surgical procedures in 2007–2014. Overall N = 590 and major procedures N = 550.

Figure 1 represents the total number of surgical procedures entered into the database by the Ljubljana’s staff physicians as indicated in Ref 48 from 2007 until end of 2013. The data in Ref 51 were the major procedures extrapolated from the entire Database (Ref 48) by the Commission using the minor/major procedures codes. One procedure listed for year 2001, one for year 2006, and one for year 2014 were not included in above table. **Overall mortality on the 553 major operations was 2.9%, and if calculated to number of patients (16 pts/473 pts), mortality was 3.4% (Ref 51).**

During the year 2012, numbers from the database (Ref 51) show there were 86 major congenital cardiac operations performed. Of these procedures: **Dr. Mishaly** performed 62 (72%); **Dr. Blumauer** 18; **Dr. Vodiskar** 1; **Dr. Lakic** 4; and **Dr. Knezevic** 1. See Figure 19 and Figure 20 in Section III.H.5 and 6, respectively, below (p. 94–95).

The different databases report vastly different numbers of procedures for 2007-2014

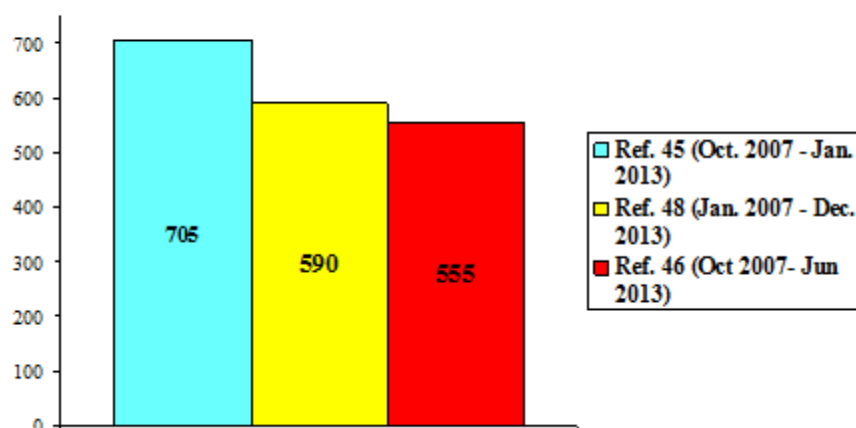


Figure 2. Number of surgical procedures according to different databases during the last 7 years (Ref 45, Ref 48, and Ref 46).

Figure 2 depicts the **inconsistencies among the various data reports or databases for the number** of the congenital cardiac procedures reported to be performed in the UKC Ljubljana during the 7 year period from 2007.

While the numbers reported in Ref 48 and Ref 46 are fairly comparable, it is difficult for the Commission to understand how the **number of surgeries reported in Ref 45 differ by 115 procedures**. Note that Ref 45 reflects the time period from October 2007 through January 2013, and Ref 48 reflects the time period from January 2007 through December 2013; this translates to 115 fewer operations within a time period that was 22 months longer.

The Commission was not privileged to audit the database from which the report with 705 operations was given to Ministry of Health in 2013 (Ref 45). **However, it is inconceivable to the Commission how the authors of the report in Ref 45 arrived at this much higher number of surgical procedures performed at DPCS in Ljubljana.** This also brings into focus the missing 115 operative reports and an unknown number of patients' charts. The conclusion is that none of the figures are reliable and only the EACTS database figure is substantiated by an actual data set.

2. UKC report presented to the Ministry of Health of Slovenia in January 2013 (Ref 45)

Data presented here were given to the Slovene Ministry of Health as the official report of the surgical results at the DPCS in Ljubljana at the beginning of 2013. Unfortunately, only the report was available for the Commission to view. The raw data and the database itself were not available (at least not) for the Audit. The aforementioned report claims that there were **705 pediatric cardiac operations** performed between October 2007 and January 2013 at the DPCS in UKC Ljubljana.

In the summary of this report the authors claim their results are in concordance with the results of the European EACTS benchmark. They report their **overall perioperative mortality** was **2.1%**, and their **perioperative mortality** for the **primary** congenital cardiac surgery was **1.8%**. These results could not be verified by the Commission. The authors of this report **failed to list 1 year mortality** in their Results.

The authors (Drs. Blumauer, Gersak et al.) claim that the majority of the surgical procedures in 2012 at the DPCS in Ljubljana were done by domestic surgeons (77.6%). It does not specify which procedures were actually performed by the domestic surgeons, and it does not indicate the difficulty of those procedures. In addition, they claim that 70.1% of the **primary** procedures done in 2012 were conducted by domestic surgeons. There was **discrepancy of 7.5%** when this value was compared with the UKC report presented to the Ministry of Health of Slovenia in January 2013 (Ref 45, page 8). There is no explanation of who actually performed the indicated discrepant operative procedures. The report also claims that 80% of the congenital cardiac procedures were performed by domestic surgeons in **2013** with only 20 % performed by **Dr. Mishaly**. It is also noteworthy that the text of the same report states that in **2012, 80%** of the surgeries were performed by domestic surgeons (page 7, bullet 5; last sentence), while the data in Ref 45 (Page 8 - Table 5 in the original report, and Table 5 of Figure 6 in this report) clearly indicate this number is **70%**. Note also that the percentage numbers in **Figure 6 do not add up** (out of Ref 45). This clearly highlights major discrepancies within the reported data.

In the same report, the authors acknowledge and commit that they will enter and report all the surgical data to the EACTS Database starting in January 2013 (Ref 45, p. 11, last sentence). **These data were never entered** in the EACTS Database until the Commission's Audit in July 2014.

5. Razvoj domače ekipe

S strani kirurške klinike sta bila v program vključena dva specializanta kardiovaskularne kirurgije, brez izkušenj za samostojno izvajanje operacij. V letu 2008 je bila opravljena prva samostojna operacija pri novorojenčku ter nekaj posegov pri večjih bolnikih z enostavnejšimi napakami. Delež bolnikov, ki jih operira domača ekipa je v letu 2012 znašal 80 odstotkov.

Tabela 4. Delež vseh operacij glede na operaterja v posameznem letu.

Leto	Operater kirurg UKCL	Operater: David Mishaly
	%	%
2008	31,8	68,2
2009	42,2	57,8
2010	50,8	49,2
2011	58,8	41,2
2012	77,6	22,4

Figure 3. Development of the Domestic PCS team in Ljubljana: Percentage of ALL operations by Dr. Mishaly and by the domestic surgical team (Ref 45; page 7 / Table 4).

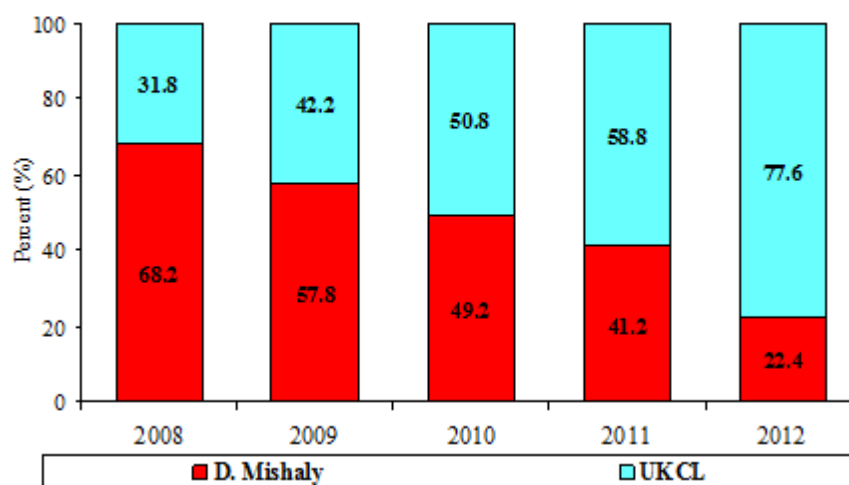


Figure 4. Development of the domestic surgical team. Percent (%) of all procedures 2008–2012 performed by UKCL surgeons and by Dr. Mishaly (Ref 45).

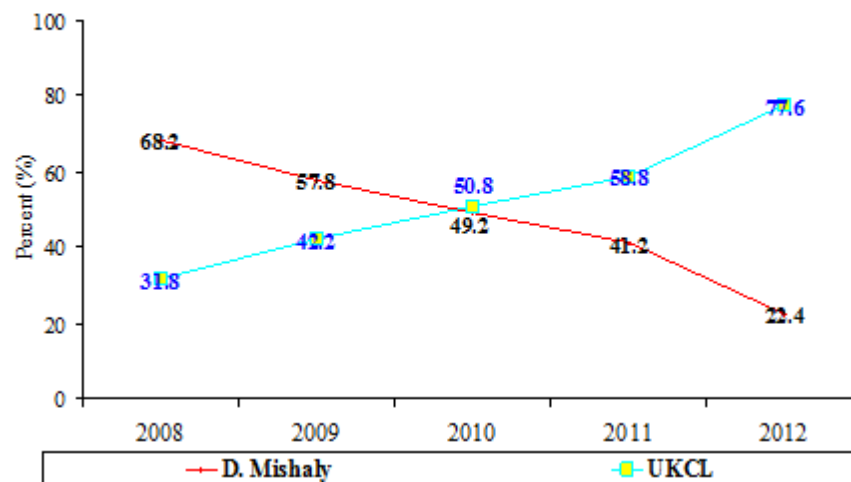


Figure 5. Development of the domestic surgical team. Percent (%) of all procedures 2008–2012 performed by UKCL surgeons and by Dr. Mishaly (Ref 45).

Figures 4 and 5 demonstrate the development of the domestic pediatric cardiac surgical team from Ljubljana. From the year 2008 thru to 2012 the percentage of **ALL** cases reported to be performed by the domestic surgeons increased in proportion to those reported to be performed by **Dr. Mishaly**. These data were officially reported to the Ministry of Health in 2013 (Ref 45).

Tabela 5. Delež **primarnih** operacij glede na operaterja v določenem letu.

Leto	Operater kirurg UKCL	Operater: David Mishaly
	%	%
2008	25,2	68,2
2009	38,3	57,8
2010	47,4	49,2
2011	55,1	41,2
2012	70,1	22,4
2013	80,0	20,0

Graf 1. Razmerje med opravljenimi operacijami s strani kirurga UKCL v primerjavi z dr. Mishaly-jem za vsako leto posebej.

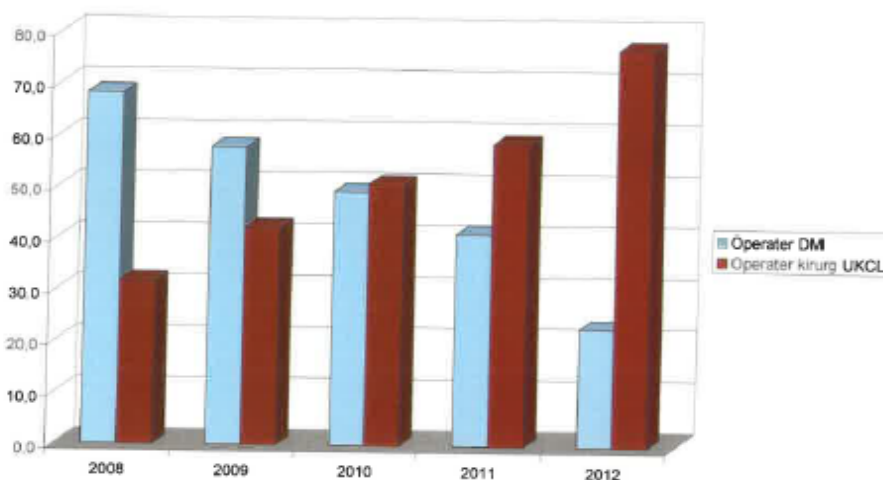


Figure 6. Development of the Domestic PCS team in Ljubljana: Percentage of **PRIMARY** surgical operations by Dr. Mishaly and by the domestic surgical team (Ref 45).

Figure 6 demonstrates the development of the domestic pediatric cardiac surgical team from Ljubljana. From the year 2008 through 2012 as the percentage of **PRIMARY** congenital cardiac surgical cases reported to be performed by the domestic surgeons and by Dr. Mishaly. The numbers in Table 5 of Figure 6 **are not accurate and do not add up to 100%**.

3. Official Report of the KVK Audit performed by the Internal Audit services at UKC in Ljubljana in 2012 for the period of 2007 through 2011 (Ref 47)

V letu 2011 je dr. Mishaly operiral 97% vseh opravljenih posegov, mag. Blumauer 1,5%, Vodiškar 1,5%.

Tabela 2: Pregled števila opravljenih operacij po operaterjih za leta 2007, 2008, 2009, 2010 in 2011

	Operater	1. asistent	2. asistent	Trajanje operacij v urah za operaterja
Mishaly (2007)	19	4	0	51
Blumauer(2007)	4	18	1	6
Vodiškar (2007)	0	1	13	
Ostali (2007)	0	0	4	
Skupaj operacije v 2007	23			57
Mishaly (2008)	105	1	0	311
Blumauer(2008)	1	102	0	2
Vodiškar (2008)	0	3	35	
Ostali (2008)	0	0	49	
Skupaj operacije v 2008	106			313
Mishaly (2009)	82	7	1	260
Blumauer (2009)	8	79	1	23
Vodiškar (2009)	0	1	5	
Ostali (2009)	0	3	64	
Skupaj operacije v 2009	90			283
Mishaly (2010)	64	7	1	224
Blumauer (2010)	63	61	7	131
Vodiškar (2010)	18	24	39	23
Ostali (2010)	5	19	36	11
Skupaj operacije v 2010	150			389
Mishaly (2011)	66	1	0	239
Blumauer (2011)	1	56	8	3
Vodiškar (2011)	1	10	47	1
Ostali (2011)	0	0	5	
Skupaj operacije v 2011	68			243

Vir podatkov: Operacijski listi

Figure 7. Development of the Domestic PCS team in Ljubljana: Number of procedures performed from 2007-2011 by UKCL surgeons and by Dr. Mishaly (Ref 47).

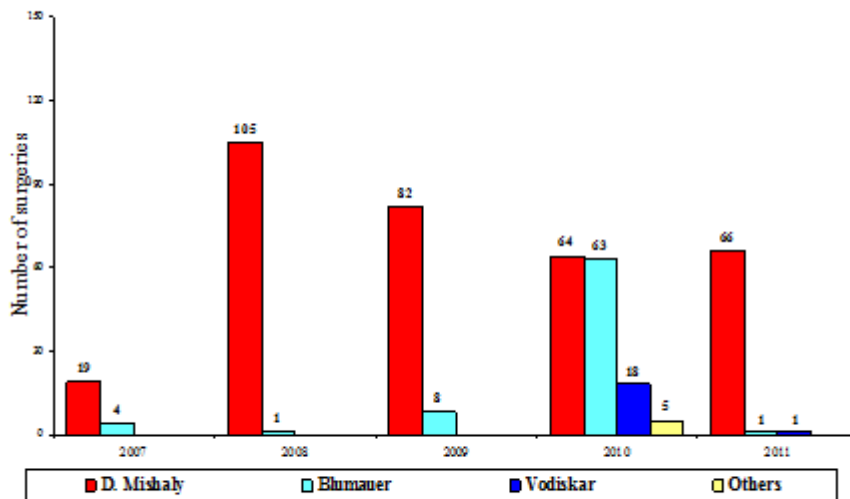


Figure 8. Development of domestic surgical team. Number of procedures performed from 2007–2011 by UKCL surgeons and by Dr. Mishaly (Ref 47).

Figure 8 summarizes the **number** of procedures per year recounted by the individual Pediatric cardiac surgeons in Ljubljana as reported by the Official Internal Audit Report on January 20, 2012 (Figure 7 above; Ref 47).

When comparing the data from **Figures 3, 4, 5, and 6**, (Report to Ministry of Health, Ref 45) with the report of the KVK internal audit at UKC depicted in **Figures 7 and 8** (Ref 47) in conjunction with the Analysis of data from EACTS database in Figure 1 (Ref 48 and 51), it appears that **Dr. Mishaly's** participation as the lead surgeon in DPCS in Ljubljana was **significantly higher** than portrayed in report given to the Ministry of Health by the UKC in 2013 (Ref 45). **See also below, Figures 9, 10, and 11.**

		Total	A	B	C-E	Other	DM %	UKCL %
2007	Ref.48	27	16	5	4	2	59%	41%
2007	Ref.47	23	19	4			83%	17%
2008	Ref.48	98	74	22	2		76%	24%
2008	Ref.47	106	105	1			99%	1%
2009	Ref.48	88	66	22			75%	25%
2009	Ref.47	90	82	8			91%	75%
2010	Ref.48	94	52	35	5	2	55%	45%
2010	Ref.47	150	64	63	18	5	43%	57%
2011	Ref.48	96	46	39	10	1	48%	52%
2011	Ref.47	68	66	1	1		97%	3%
2012	Ref.48	98	0	38	10	50	0%	100%
2013	Ref.48	89	38	51			43%	57%
Total	Ref.48	590	292	212	31	55	49%	51%
Total	Ref.47	438	336	77	19	5	77%	23%

Table. Development of domestic surgical team. Number of procedures 2007–2012 performed by UKCL surgeons and by D. Mishaly (Ref. 48 and Ref. 47) (A=DM; B=RB; C&E=JV)

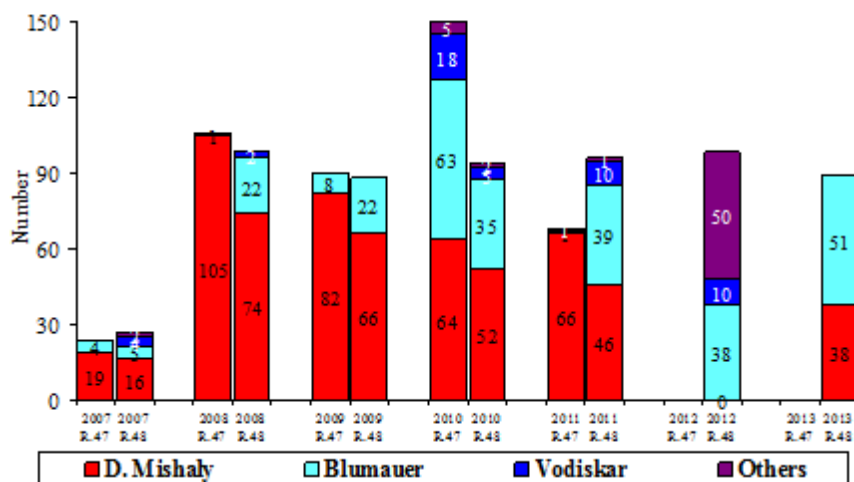


Figure 9. Development of domestic surgical team. Number of procedures from 2007–2013 performed by UKCL surgeons and by Dr. Mishaly (Ref 47 and Ref 48).

Figure 9 relates the total **number of procedures** described in KVK Audit 2012 Report (Ref 47) with the Commission's data analysis from database entered by **Drs. Weiss and Kalan** in October 2014 (Ref 48).

Figure 9 clearly shows discrepancies in the data regarding the number of pediatric cardiac operations performed by each surgeon per year at the UKC in Ljubljana compared to the numbers of operations reported by the UKC team to the Ministry of Health (Ref 45). This data clearly demonstrates the higher numbers of surgeries done by Dr. Mishaly at UKC Ljubljana than were reported by Drs. Gersak and Blumauer in Ref 45. **The Commission's concerns with these inconsistencies trigger multiple questions about the data reporting principles and values at the DPCS in UKC Ljubljana.**

4. Analysis of the EACTS' UKC Ljubljana Database (Ref 48)

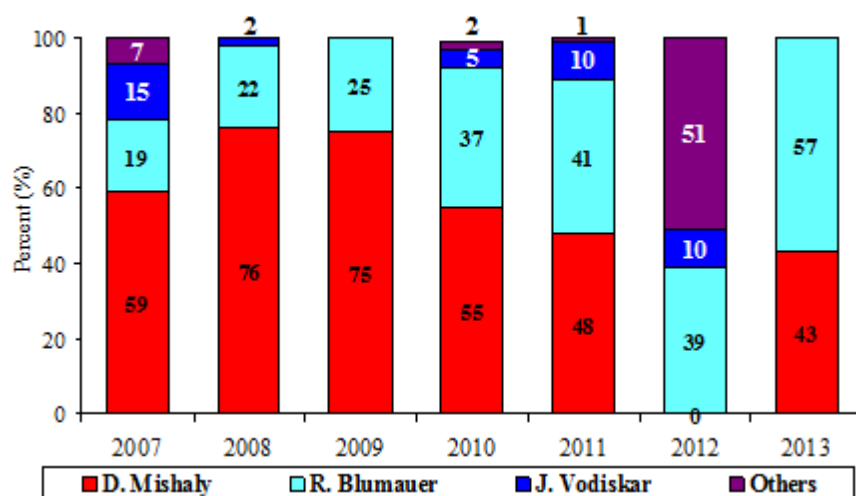


Figure 10. Development of domestic surgical team. Percent (%) of TOTAL procedures between 2007 and 2013 performed by UKCL surgeons and by Dr. Mishaly (Ref 48).

Figure 10 details the **percent** of **total procedures** performed by **Dr. Mishaly** and domestic surgical team as extrapolated by The Commission from the database of **Drs. Weiss and Kalan** sent to EACTS.

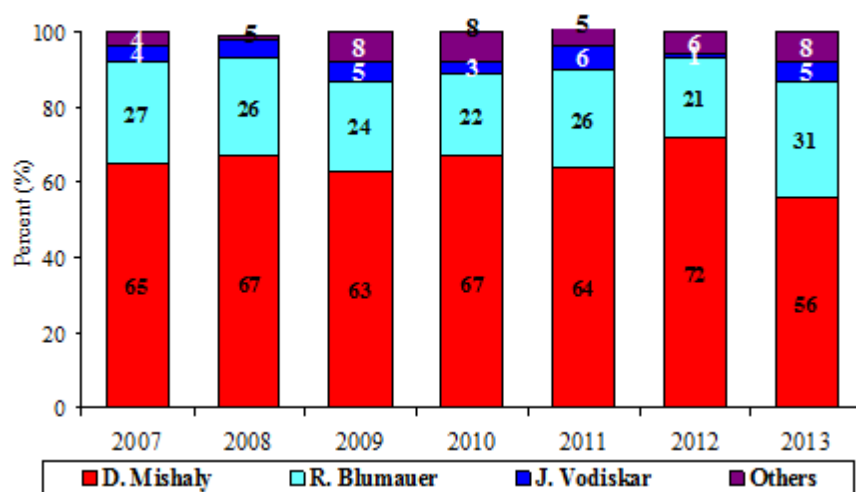


Figure 11. Development of domestic surgical team. Percent (%) of MAJOR procedures between 2007 and 2013 performed by UKCL surgeons and by Dr. Mishaly (Ref 51 – 550 cases).

Figure 11 indicates that **percent** of **major procedures** performed by Dr. Mishaly and domestic surgical team as extrapolated by The Commission from the database of Drs. Weiss and Kalan (Ref 51).

These two figures (Figures 10 and 11) show that the percentage of **major** congenital cardiac operations during the 7-year period in question performed by **Dr. Mishaly** remained fairly **constant** through this

period, while the percent of **total** pediatric cardiac operations performed by **Dr. Mishaly** diminished during the same time interval.

These data also reflect that the number of secondary operations done by domestic surgeons was increasing during this same time period.

5. KVK – Dr. Podnar's personal data (Ref 46)

This report contains the information from the personal database of the pediatric cardiologist, **Dr. Podnar**. He reports there were 555 congenital cardiac operations performed between October 2007 thru May 2013 at the UKC Ljubljana.

Additionally, in the same document he reports and lists by name: **31 deaths** which accounts for **5.6%** overall mortality, **15 neurologic** adverse events (**2.7%**), 32 patients requiring **reintervention (5.8%)**, and 20 patients with **other major complications (3.6%)** among the children operated for congenital cardiac anomalies during the mentioned time span at UKC DPCS in Ljubljana. **This Database and charts were not available to the Commission for verification.**

This report also indicates that 41% of surgeries were performed by **Dr. Mishaly** and 59% were performed by domestic surgeons from January 1, 2012, until June 6, 2013, at the DPCS in Ljubljana (Figure 12).

1. Od 128 operacij, ki so bile napravljene z namenom, da bi bolniku kompletno korigirali ali omilili srčno napako, so deleži po kirurških naslednji:

1. Mishaly	53 op (41%)
2. Blumauer ob asistenci Mishalyja	27 op (21%)
3. Blumauer samostojno	46 op (36%)
4. Vodiškar	2 op (2%)

Dr. Blumauer in dr. Vodiškar sta od 01.01.2012 do 06.06.2013 **samostojno opravila 48 operacij ali 37% vseh operacij, katerih namen je bil kompletno ali paliativno korigiranje srčne napake**

Figure 12. Percentage of the pediatric cardiac surgical operations at UKC performed by individual surgeons from October 2007 until June 6, 2013.

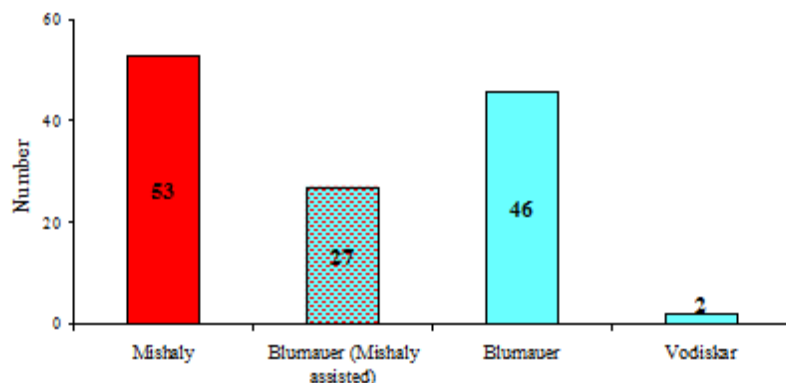


Figure 13. Surgical procedures from 1.1.2012 to 6.6.2013, N=128 (Ref 46).

Figure 13 above represents the total number of congenital cardiac procedures performed at the UKC in Ljubljana by different surgeons during the time span between January 1, 2012, and June 6, 2013 (Ref 46).

1. Operacije, ki sta jih opravila samostojno so bile: (Ref 46)

a. Zaprtje ASD II + sin ven	17 op
b. Zaprtje ASD I	2 op
c. Ligacija PDA	8 op
d. Zaprtje restriktivnega VSD	6 op
e. MBT anastomoza	4 op
f. Koarktacija aorte	6 op
g. Bandaža debla PA	2 op
h. BCPC	1 op
i. Pulm St	1 op
j. Bandaža vej PA	1 op

Figure 14. Types of surgeries performed independently - as a primary surgeon - either by Dr. Blumauer or Dr. Vodiskar (Ref 46).

Figure 14 represents the number of operations (48 of 128 operations, 38%) performed independently by **Drs. Blumauer and Vodiskar** at the DPCS in Ljubljana from January 1, 2012, through June 6, 2013. **Dr. Mishaly** performed 53 of 128 (41%) total operations during the same time (Ref46).

H. Analysis of data from 2012 only

1. Analysis of different databases reflecting volumes of congenital cardiac surgeries performed at DPCS in Ljubljana during the year 2012 only

Each of the three databases reported a different number of procedures performed during 2012 in the UKC Ljubljana. The data entered in the database in Ref 18 were entered by Commission members. Therefore, this database (Ref 18) is the only database that the Commission is absolutely confident that the numbers are entered correctly.

The Commission did not receive any explanation as to why the numbers of patients reported in each database who underwent the congenital cardiac surgery in Ljubljana varied substantially for the same year.

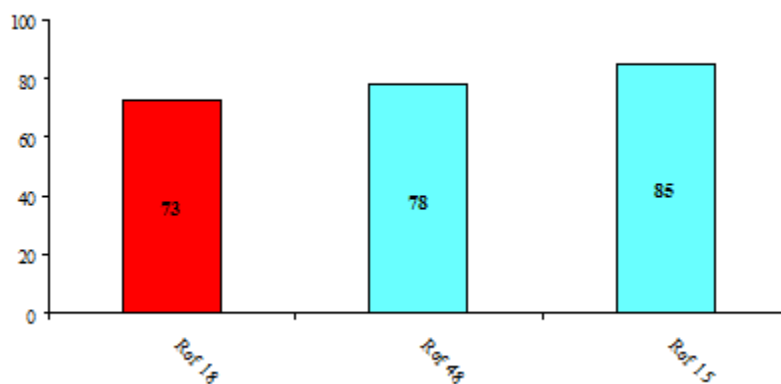


Figure 15. Surgical patient numbers in 2012 (Ref 18, Ref 48, and Ref 15).

Figure 15 demonstrates the discrepant data found in the different databases regarding the total number of patients who underwent congenital cardiac surgery at the UKC in Ljubljana during the year 2012.

The Commission received the charts of 73 patients who, collectively, had 93 surgical procedures during 2012. In Ref 15, 85 patients were reported to have had 141 procedures. A direct comparison of patient names from Ref 18 and Ref 15 revealed that not only were 12 additional patient charts included in Ref 15 that were not in Ref 18 (unavailable for the Commission to review), there were an additional 2 patients included in Ref 18 that did not appear in the database of Ref 15. Therefore, it can be concluded that there are 14 patient charts somehow unaccounted for in either Commission's analysis or Dr. Blumauer's analysis of data (Figure 16).

This discrepancy of charts and patients represents 16% of patients (14/87potential total patients) reported either by **Dr. Blumauer** in Ref 15, or from the charts received by the Commission (Ref 18) for patients who had congenital cardiac surgical procedures at DPCS in Ljubljana during 2012. **Therefore, any conclusion on the bases of these data should be interpreted with caution.**

Additionally, the number of surgeries conducted during 2012 in DPCS Ljubljana was analyzed from the database given to the Commission by **Drs. Weiss and Kalan** (Ref 48). This analysis revealed that this database also contained discrepancies regarding the different number of patients (78) operated during the same time period.

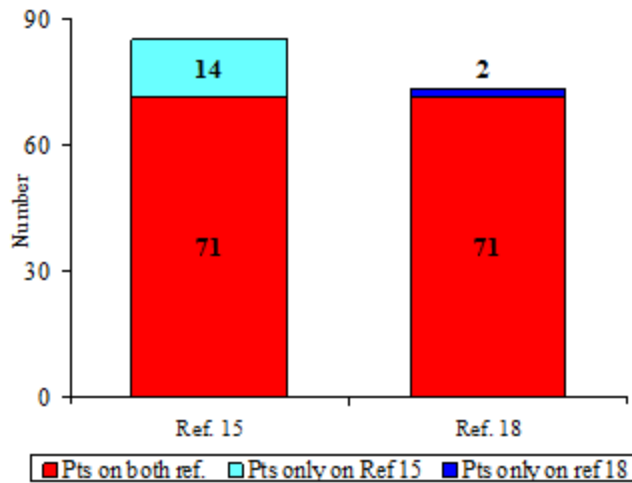


Figure 16. Difference in patients having surgery during 2012 listed in Ref 15 (85 pts; 141 procedures) and 73 patients (93 procedures) whose charts were given to the Commission.

Comments:

When the Commission analyzed the data entered in their Database (Ref 18), it was learned that 4/73 patients died after having surgery in year 2012 (two died perioperatively, and two died later [Ref 64]). However, due to the discrepancy in the numbers and based on the fact that the Commission could not review the 12 patient charts discussed above, it is not possible for the Commission to give any accurate results or conclusions on this analysis. This is emphasized by the fact that as few as 1 or 2 potential patient deaths within these 12 unknown patients could significantly change the results of the mortality analysis.

2. Dr. Blumauer's personal database for pediatric cardiac surgeries performed in the year 2012 (Ref 15)

This Database was given to the Commission by **Dr. Blumauer** himself in an email addressed to **Dr. Gregoric and Dr. Mozina** dated July 11, 2014. According to **Dr. Blumauer's** analysis described in his email (Ref 14 and 20), this database contains: 83 patients who underwent 144 congenital cardiac operations, of which 32 (22%) were performed by **Dr. Mishaly**, 73 (50%) by **Dr. Blumauer**, 29 (20%) by **Dr. Vodiskar**, and 10 by others (Ref 15, column I).

Of the **106 primary** operations as per Dr. Blumauer, **Dr. Mishaly** performed 31 (30%) operations, and UKC domestic surgeons performed 75 (70%); **Dr. Blumauer**, 57; **Dr. Vodiskar**, 15; **Dr. Knezevic**, 2; and **Dr. Ksela**, 1) as described in Dr. Blumauer's email (Ref 20)

When the Commission analyzed the same data (Ref 17) the results were slightly different. The Commission found that **85** patients underwent **141** operations. There were two patients who were admitted in December 2011, but had surgery in January 2012. There were **107** primary operations and **34** secondary surgeries.

As per Commission's analysis of database in Ref 15, **Dr. Mishaly** performed 32 (23%) of all 141 operations, **Dr. Blumauer** performed 73 (52%) operations, and all other surgeons performed 36 (25%) of total operations according to the database.

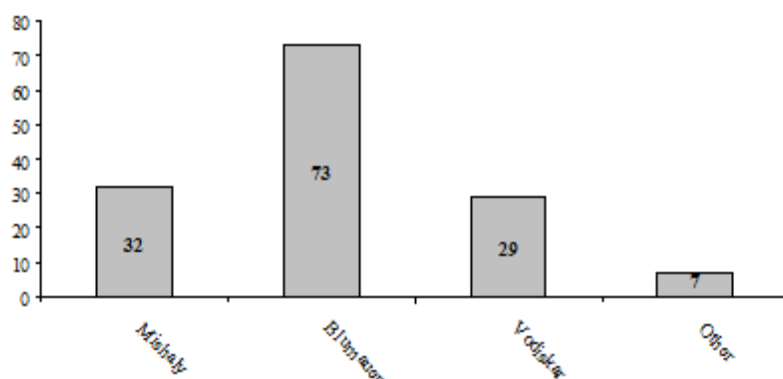


Figure 17. Surgical Procedures in 2012, N=141 (Ref 15).

Figure 17 represents the number of procedures performed by each individual surgeon during 2012 at the DPCS in Ljubljana as provided by **Dr. Blumauer** in Ref 15 and analyzed by the Commission. In this database, he is listed as the primary surgeon in 73 out of 141 operations.

Results of the procedures from database Ref 15:

Table 2. Surgeries performed in 2012 according to the Commission's analysis of Dr. Blumauer's database (Ref 15).

	Procedures	N	B	M	O
1	ASD	13	7	0	6
2	VSD	10	8	2	0
3	TOF	5	2	3	0
4	ASO	6	2	4	0
5	RV-PA Conduit	4	2	2	0
6	BT Shunt	7	3	4	0
7	Ross	3	0	3	0
8	Norwood	2	0	2	0
9	BCPC	2	1	1	0
10	PVR	3	2	1	0
11	DKS	1	0	1	0
12	AV Canal	1	0	1	0
13	Fontan Fenest.	1	0	1	0
14	PA Sten. Rep.	2	0	2	0
15	PA Banding	3	3	0	0
16	Atrial septectomy	1	1	0	0
17	Pericardial Window	3	2	0	1
18	TAPVR	1	1	0	0
19	Resection Subaortic Stenosis	4	1	3	0
20	Ao Coarctation Repair	5	5	0	0
21	AP window	1	1	0	0
22	Cor Triatriatum Rep.	1	0	0	1
23	MV Repair/Replacement	1	1	0	0
24	Hancock Conduit insertion	1	1	0	0
25	Epicardial PM Insertion	1	1	0	0
26	Cardiac Transplant	1	1	0	0
27	PDA Division	1	1	0	0
28	LVAD insertion	2	0	0	2
29	LVAD complication / exploration	8	0	0	8
30	LVAD bleed	1	0	0	1
31	LVAD Exchange	1	0	0	1
32	ECMO insertion	8	6	0	2
33	ECMO Removal	6	3	0	3
34	ECMO Canula Reposition	2	1	0	1
35	ECMO Exchange	3	2	0	1
36	ECMO Canula bleed	1	0	0	1
37	Wound I & D	4	1	0	3
38	Wound VAC Insertion	4	0	0	4

39	Secondary sternal closure	10	9	0	1
40	Iatrogenic Perforation RCC (B)	0	0	0	0
41	Post VSD Bleed / Tamponade (B)	1	1	0	0
42	Bleed post RV-PA Conduit (M)	1	1	0	0
43	Bleed / Tamponade post Ross (M)	1	0	1	0
44	RV Iatrogenic Perforation (B)	1	1	0	0
45	Mediastinal Expl. Post PA Band (B)	1	1	0	0
46	Radial AV fistula complication	2	1	1	0
	TOTAL	141	73	32	36

Table 2 represents the number of different procedures performed at DPCS in Ljubljana by different surgeons during 2012 as per Dr. Blumauer's personal database (Ref 15). N = total number of procedures, B = Dr. Blumauer, M = Dr. Mishaly, O = other surgeons analyzed by Commission.

When **the eight classic Pediatric Congenital Cardiac Benchmark Operations** are listed as the Primary Procedures, they are usually tracked and analyzed to represent the complexity of cases and programs' Surgical Volume for comparison between different institutions. These operations are: VSD, TOF, AVC, ASO, ASO+VSD, Fontan, Truncus Art., and Norwood.

As per the Commission's analysis, **Dr. Blumauer's** database (Ref 15) indicates that during 2012 of the 107 primary procedures performed at UKC Ljubljana, **26 (24%)** met the criteria listed above. The breakdown of these surgeries was: 10 VSD, 5 TOF, 1 AVC, 6 ASO, 0 ASO + VSD, 1 Fontan, 1 DKS, and 2 Norwood procedures.

According to **Dr. Blumauer's** database (Ref 15), **66** patients had 1 operation and **19** patients underwent multiple operations:

- 1 patient had 26 operations
- 1 patient had 6 operations
- 1 patient had 5 operations
- 6 patients had 3 operations
- 10 patients had 2 operations
- **Total: 75 operations**

The 75 operations in these 19 patients account for 53% of all operations. The other 66 patients had a single operation (47% of all operations). A total of 141 operations were performed. In other words, 19 patients (22%) had multiple trips to the operative room, which accounted for more than half of all operations.

By the Commission's analysis of database Ref 15, there were 107 (68%) primary and 34 (32%) secondary surgeries performed. All 34 secondary operations were performed by a member of the domestic pediatric cardiac surgery team: **Dr. Blumauer**, 15; **Dr. Vodiskar**, 14; all other surgeons, 5. (Ref 15)

Secondary procedures were:

• Wound VAC insertion	3
• Sternal closure	10
• Pericardial window	3
• ECMO repositioning	2
• Control of bleeding	11
• I & D	5

There were eight major perioperative complications; (This equals 5.6% if calculated as a percentage of ALL surgeries, 7.5% if calculated as a percentage of primary surgeries, and 12% if calculated as percentage of 66 major surgeries - see numbers 40–46 in Table 2). One major complication is listed in Table 2 under #40 as an Iatrogenic Right Coronary Cusp (RCC) perforation of the aortic valve; however, it is not listed as a separate primary surgery since it occurred during a VSD repair, which is listed in the database under patient #71 as the primary surgical procedure (Ref 15). Four of 10 secondary sternal closures were performed as a consequence of serious perioperative complications requiring emergent chest opening; see Table 2 above).

No survival/mortality data were available in this database.

Due to substantial discrepancies in the data between sources, the interpretation of the Ref 15 data should be treated with caution since several data points are missing from the original database: date of admission, discharge status, and 30 day status. These data are crucial for a record to be complete and eligible for mortality analysis as described in Ref 63, p. 1941, bullet #5, and defined in the same article in paragraphs A, C, D, F, and G). To be able to perform the mortality analysis, there are specific data that are mandatory to be completed in the database, such as admission date, date of surgery, type of operation, primary diagnosis, primary or major procedure, the patient's discharge status (alive or dead), 30 day status, etc.

All the above numbers were calculated from Dr. Blumauer's personal database (Ref 15) and should be interpreted very cautiously.

Additionally, it is quite **disturbing for the Commission to discover that Dr. Blumauer listed himself as a primary surgeon for the pediatric cardiac transplant, since he was not involved in cardiac transplantation in UKC at all.** Furthermore, it is clearly evident by the Commission's review of charts and the data entry into the database Ref 18 that the only pediatric cardiac transplant in 2012 was performed by Dr. Knezevic (see below the Tally of Detailed Surgical procedures based on Ref 18 and Ref 64 Table 3).

3. Analysis of the GFM data entry into EACTS by the Commission (Ref 18)

This database was populated by the members of the Commission during the Audit on July 11-13, 2014, in Ljubljana. **Therefore, for the Commission it is the only authenticated and verified database of all available databases.** Unfortunately for the Commission, it was later discovered that there may have been more patients operated upon in UKC Ljubljana during the year 2012 who were not included in the charts given to the Commission during the Audit in July of 2014. This became evident from the database provided to the Commission by **Dr. Blumauer**, where he lists 85 patients having 141 congenital cardiac operations in Ljubljana UKC during the 2012 (see Section F above). The Commission is very concerned with this discovery

as it appears there were 12 patient charts potentially lost or withheld from the Commission's Review by either the Administration or medical staff during the July 2014 Audit.

	A	B	C	D	E	F	G	H	I	J	K	L
1	GFM	2012 operative death	proportion	95%CL low	95%CL up						Confidence Limit Calculator	
2	N patients	73	2	0.027	0.00475962	0.1044					70	1.03643
3	N admissions	75									90	1.64485
4	N operations	93									95	1.95996
5	N minor	11									n	73
6											p	2
7	N maj neon	14									p'up	0.03424658
8	N maj infant	25	1	0.04							p'lo	0.02054795
9	N maj child	31	1	0.03							CLup 70	0.06391876
10	N maj adult	12									CLlo 70	0.00905636
11	total maj	82	2	0.024							CLup90	0.08908869
12											CLlo90	0.00585734
13											CLup95	0.10438718
14											CLlo95	0.00475962
15												

Figure 18. Summary of the Commission's data analysis for pediatric cardiac surgeries performed at DPCS in Ljubljana during 2012 (Ref 18 GFM 3 under summary in folder - Ref 64).

Figure 18 represents the summary of the analysis of the database for year 2012. There were 93 operations on 73 patients. Two perioperative mortalities account for 2.7% total mortality if calculated per total patients, and 2.4% if calculated as percent (%) of major operations.

The Commission received the charts of 73 patients who had 93 surgical procedures during the year 2012. In Ref 15, 85 patients are listed who collectively underwent 141 procedures. When comparing and cross-populating patient names, the Commission found that beyond the 12 additional patients included in the Database from Ref 15, 2 patient charts were given to the Commission (among the 73 presented) for patients who were not listed in database Ref 15 at all. This discovery suggests a potential discrepancy of 14 patient charts.

The Commission also reviewed in detail 4/73 charts of patients who died after surgery done in 2012, which accounts for 5.5% **overall** mortality calculated on patient's denominator number and 4.3% if calculated to the procedures denominator. (The detailed analysis of these deaths is described further in the text [Section H, bullet 9, page 94]). A difference of 12 charts in the initial review of 73 patients accounts for a **16%** discrepancy in the data when comparing the databases in Ref 15 and Ref 18. **Due to this discrepancy and the lack of potential charts made available to the Audit Commission by the UKC administration during its July 2014 visit, possibly, the mortality and morbidity results could be very skewed.** This clearly can have a large impact on statistical analysis.

Taking all of the above information into account, it is not possible for the Commission to give any definitive conclusion on the surgical morbidity and mortality of the DPCS program in Ljubljana for year 2012. Due to the lack of a complete and accurate number of surgeries performed and the number of patients having these

surgeries at the DPCS in Ljubljana during the year 2012, the Commission must conclude that the current information is potentially inaccurate.

Therefore, with regard to the potential existence of additional 12 patients who underwent congenital cardiac operations in the UKC in Ljubljana, these charts should be located and all data should be verified.

4. Tally of Detailed Surgical procedures based on Ref 18 and Ref 64.

Table 3. Total Operation Procedures performed by the surgeons.

Operation Procedure	Surgeon Code				Total
	Mishaly	Blumauer	Vodiskar	Knezevic	
Aortic stenosis, Subvalvar, Repair, With myectomy for IHSS	1	0	0	0	1
ASD repair, Patch + PAPVC repair	0	1	0	0	1
Hybrid Approach "Stage 1", Application of RPA & LPA bands	0	1	0	0	1
ECMO cannulation	0	1	0	0	1
ASD repair, Primary closure	0	4	0	0	4
Arterial switch operation (ASO)	5	1	0	0	6
ASD repair, Patch	0	3	5	0	8
Coarctation repair, End to end	0	1	0	0	1
Coarctation repair, End to end, Extended	0	4	0	0	4
PDA closure, Surgical	0	1	0	0	1
ASD creation/enlargement	0	1	0	0	1
Pacemaker implantation, Permanent	0	1	0	0	1
Shunt, Systemic to pulmonary, Modified Blalock-Taussig Shunt (MBTS)	2	2	0	0	4
Shunt, Systemic to pulmonary, Other	1	0	0	0	1
PA banding (PAB)	0	1	0	0	1
PA debanding	1	0	0	0	1
Damus-Kaye-Stansel procedure (DKS) (creation of AP anastomosis without arch reconstruction)	1	0	0	0	1
Bidirectional cavopulmonary anastomosis (BDCPA) (bidirectional Glenn)	1	1	0	0	2

Palliation, Other	0	1	0	0	1
Pleural drainage procedure	0	0	1	0	1
VSD repair, Primary closure	0	2	0	0	2
Right/left heart assist device procedure	0	0	0	2	2
Delayed sternal closure	0	5	0	2	7
VSD repair, Patch	3	3	0	0	6
Sternotomy wound drainage	0	1	1	0	2
Cardiac procedure, Other	1	0	0	0	1
AVC (AVSD) repair, Complete (CAVSD)	1	0	0	0	1
TAPVC repair	1	0	0	0	1
TOF repair, Ventriculotomy, Transanular patch	5	1	0	0	6
Unifocalization MAPCA(s)	1	0	0	0	1
RVOT procedure	1	1	0	0	2
PA, reconstruction (plasty), Branch, Peripheral (at or beyond the hilar bifurcation)	1	0	0	0	1
Conduit reoperation	1	0	0	0	1
Valve replacement, Pulmonic (PVR)	1	4	0	0	5
Conduit placement, RV to PA	1	0	0	0	1
Valvuloplasty, Aortic	0	1	1	0	2
Ross procedure	3	0	0	0	3
Aortic stenosis, Subvalvar, Repair	1	1	0	0	2
Valvuloplasty, Mitral	0	1	0	0	1
Norwood procedure	1	1	0	0	2
Transplant, Heart	0	0	0	1	1
Fontan, TCPC, External conduit, Fenestrated	1	0	0	0	1
Total	35	45	8	5	93

Table 3 represents the official data analysis from the EACTS database entered by Commission members using data from Ref 18 and Ref 64 for individual surgeons' involvement and types of the procedures.

There are **eight classic Pediatric Congenital Cardiac Benchmark Operations** usually listed as the Primary Index Cardiac Procedures. These operations are usually tracked to represent, analyze, and compare the Volume and complexity of congenital Pediatric cardiac Surgery **in different institutions**. These operations are: VSD, TOF, AVC, ASO, ASO+VSD, Fontan, Truncus Arteriosus, and Norwood.

According to the Commission's database (Ref 18 and Ref 64), of the 82 major procedures that were performed at UKC Ljubljana during 2012, **25 (31%)** were major procedures that meet the criteria listed above. The breakdown of these surgeries was as follows: 8 VSD, 6 TOF, 1 AVC, 6 ASO, 0 ASO + VSD, 1 Fontan, 1 DKS, and 2 Norwood procedures. Of these 25 operations Dr. Blumauer performed only 8: (VSD 5, TOF 1, ASO 1, and Norwood 1).

It is very interesting that one Norwood operation performed at DPCS is listed under Dr. Blumauer in Table 3. The Commission learned in the staff interviews that Dr. Blumauer had never been trained to do a Norwood operation. Even in the Database (Ref 15) given by Dr. Blumauer himself, it is not indicated that he actually performed a Norwood surgery. Interestingly enough during his interview, Dr. Blumauer never suggested that he had ever performed a Norwood operation. The Commission is suspicious that the surgery was done by Dr. Mishaly and entered into the chart under Dr. Blumauer.

It is these kinds of discrepancies that completely destroy the credibility of the charts' entered information and the documentation at the DPCS in UKC Ljubljana.

Of 93 operations performed during 2012 in UKC Ljubljana, 35 (38%) were performed by Dr. Mishaly, 45 (48%) by Dr. Blumauer, 8 (9%) by Dr. Vodiskar and 5 (5%) by Dr. Knezevic.

Of these 93 operations there were 82 major operations and 11 minor.

Of 82 major operations Dr. Mishaly performed 34 (41%), Blumauer 39 (48%), Vodiskar 6 (7%) and Knezevic 3 (4%).

The minor operations were done By Drs. Mishaly 1, Blumauer 6, Vodiskar 2 and Knezevic 2 (Ref 64 - from original Ref 18 - GFM 3).

5. Percentage of the operative procedures performed by Dr. Mishaly and domestic surgeons at DPCS in Ljubljana during 2012 by different sources

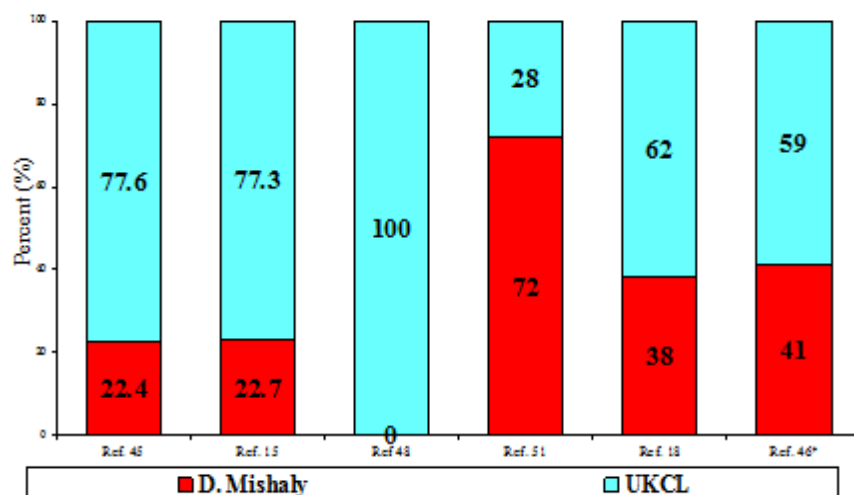


Figure 19. Percent (%) of procedures in 2012 performed by UKCL surgeons and Dr. Mishaly (Ref 45, 15, 48, 51, 18, and 46*). *From January 1, 2012 to June 6, 2013.

Figure 19 depicts the discrepant data regarding the percentages of operative procedures performed by **Dr. Mishaly** compared to the domestic pediatric cardiac surgeons at UKC DPCS in Ljubljana for the year 2012, as described by various databases' authors. When comparing the databases, it is clear that the authors of the Ref 15 and Ref 45 databases indicate that Dr. Mishaly performed a much lower percentage of the total operations in 2012 compared to those performed by the domestic surgeons.

The Ref 48 does not show any procedures performed by Dr. Mishaly during 2012. This mistake has occurred during the merging of the UKC Ljubljana data from three computers which each used different codes for different surgeons. The database assembly computer utilized the code that was entered to the first computer, regardless of whether the code correctly matched the surgeon in the other two computer databases.

Explanations for this occurrence were given to the Commission by Drs. Weiss, Kalan, Ebels and Tobota (Ref 38). The Commission is aware that Dr. Mishaly performed surgeries in 2012 in Ljubljana; therefore the accuracy of the original database sent to the EACTS by Slovene data harvesting team (Ref 48) is questionable due to this particular discovery.

6. Number of operative procedures performed by different surgeons at DPCS in Ljubljana during 2012 from different sources/databases

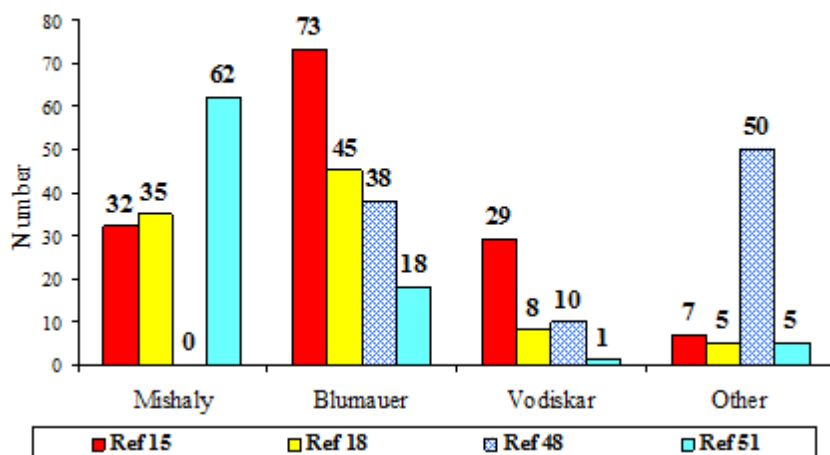


Figure 20. Surgical procedures performed in 2012 as reported by different databases.

Figure 20 reflects significantly different numbers of procedures performed by an individual surgeon during 2012 in UKC Ljubljana. The variance is quite large and data are inconsistent. The data were extracted from databases Ref 15, Ref 18, Ref 48 and Ref 51 as they were presented or given to the Commission.

The zero procedures performed by Dr. Mishaly in the database Ref 48 during 2012 in Ljubljana shown in above diagram is the reflection of the erroneously merged data from three computers which contained data using inconsistent physician's codes. As the data were merged into one file, the database software assigned the operative reports to the surgeon's code from the first computer as explained by the experts from the European EACTS database headquarters (Ref 38 and 60).

As a consequence of the inconsistency in surgical operations data, the analysis and results cannot be interpreted with certainty.

7. Unsuccessful attempts to develop a domestic cardiac surgical team/Dr. Blumauer's surgical experience

Dr. Blumauer's experience as a primary surgeon could be verified from various databases. During the years 2007–2013 the percentage of **primary** congenital cardiac surgical procedures performed by **Dr. Mishaly** remained fairly constant performing approximately 2/3 of all these surgeries (Ref 51 and Figure 11). His percentage of **total** procedures diminished to approximately 1/3 during the last couple of years. The information below explains these observations.

Table 4. Drs. Blumauer's and Mishaly's surgical volumes at DPCS in Ljubljana

Dr. Blumauer's surgical volume /experience	Timeline	Total operations	Blumauer	%	Mishaly	%	Others
Ref 15	2012	141	73	52%	32	23%	29
Ref 18	2012	93	45	48%	35	38%	13
Ref 48 all op.	2012	98	38	39%	0	0%	60
Ref 51 Major op.	2012	86	18	21%	62	72%	6
Ref 51 Major op.	2007 - 2014	553	138	25%	360	65%	55
Ref 48 all op.	2007 - 2014	590	212	36%	294	50%	84
Ref 47	2007 - 2011	437	77	18%	336	77%	24
Ref 46	2012 - 2013	128	73	57%	53	41%	2

Table 4 lists the number of surgical cases **Dr. Blumauer** performed at DPCS in Ljubljana according to different time frames and different databases (see Figures 7, 8, 9, 10, 11, 12, 13, 14, 17, 19, 20, and Tables 2 and 3 for more detailed information). While it is clear he was operating on one third to one half of the patients who underwent congenital cardiac surgery at the UKC Ljubljana, it is also obvious he was performing mostly the secondary and easier types of operations. The majority of primary procedures were still done by **Dr. Mishaly** (See Figure 13).

However, what cannot be clearly extrapolated from any of these Databases is how many procedures were listed under Dr. Blumauer's name and actually performed by Dr. Mishaly. This uncertainty has erupted due to the Commission's discovery that patients operated on by Dr. Mishaly were listed in the reports under Dr. Blumauer's name because Dr. Mishaly had lacked the Slovene medical License, as described in the official legal document from UKC dated January 20, 2012 (Ref 47, paragraph 3.1.1 last sentence). Dr. Mishaly obtained the medical License in Slovenia during the first quarter of 2012, as indicated in official legal Report from UKC titled: Answers and Explanation to the Slovene Corruption Agency' charges, dated November 12, 2012 (Ref 79 page 4, second paragraph).

Additionally, it was very difficult to extrapolate the exact number of operations that Dr. Blumaur carried out during 2012 in Ljubljana due to, as Dr. Ebels put it in his email on 3/09/15, "This is less easy than I thought. Looking at the sheet "operation" after having sorted it according to date_of_surgery I stumble straight away at the period 10-11 January. All 4 procedures have been done by B, but whether or not he was coached by M, is unknown...."

From **Dr. Blumauer's** own database (Ref 15), it can be ascertained that he did **12 primary procedures** during 2012 that are usually reported for Surgical Volume as part of the Eight Pediatric and Congenital Heart Benchmark Operations. From the same database Ref 15, the Commission determined that during the year 2012, **Dr. Blumauer** performed **eight** VSD operations (one had a serious complication of cardiac tamponade and had to be taken back to the operative room), **two** arterial switch operations (he expressed to the Commission during his interview in July 2014 these were his first two ASO operations ever), and **two** repairs of TOF (Table 2). During his entire career from his start as a resident in 2007 through his departure in December 2013 (which he also shared with the Commission during his interview), he never performed an AV

canal repair, ASO + VSD operation, Fontan operation, truncus arteriosus repair, or a Norwood operation which all count as benchmark operations that require a higher level of surgical skill to be performed safely. From other data (see above Ref 46, Ref 15) it is also observed that **Dr. Blumauer** performed only simpler cardiac congenital procedures.

8. Mortality and Morbidity

The morbidity and mortality data could be calculated only from certain databases or reports. Again it is of crucial importance to mention that regardless of attempts to calculate the mortality and morbidity from these databases, all these data still require verification due to the enormous differences in numbers of patients reported by different authors for the same time periods, enormous idiosyncrasies and inconsistencies in data entry, faulty data merging into a single database, and the lack of complete and final patient numbers in these databases.

In his personal database, **Dr. Podnar** reports the names and complications of the children after congenital cardiac surgery. According to his report, there were 555 patients who underwent congenital cardiac surgical procedures between October 2007 and June 2013 at UKC Ljubljana. Among these children, there were 31 deaths (calculated on number of patients 5.5%): 15 children (2.7%) had a significant neurologic event with residual deficit, 32 children required reoperation (5.7%), 7 children (1.2%) had major bleeding episodes with significant blood loss, 10 children suffered from Chilo thorax (1.8%), 6 had mediastinitis (1.0%), and 6 (1.0%) had infective endocarditis (1.0%). These data were given to the Commission. However, there was no raw database available to be reviewed; therefore the data from **Dr. Podnar's** personal database (Ref 46), unfortunately, could not be verified.

Mortality in Database Ref 51.

Of 553 major congenital cardiac procedures performed at UKC Ljubljana according to this database (Ref 51), there were 16 deaths, which accounts for **2.9%** mortality based on the number of procedures calculated according to the standards accepted by the societies in 2016 (Ref 63). See below.

The numbers for mortality associated with individual surgeons was calculated by the Commission from the EACTS database populated by UKC physicians and is listed below (Ref 51). Again, the Commission emphasizes that the accuracy of these data is not verified and cannot be interpreted with complete certainty.

Table 5. Number of major congenital cardiac procedures performed by different surgeons and the overall mortality from database Ref 51.

Surgeons	# major procedures 2007-2014	# mortality	overall mortality %	
Mishaly	360	9	2.5%	1.2% - 4.9%
Blumauer	138	4	2.9%	0.9% - 7.7%
Vodiskar	23	0	0.0%	0.4% - 17.8%
Lakic	31	3	9.7%	2.5% - 26.9%
Kneevi	1	0	0.0%	
total	553	16	2.9%	1.7% - 4.8%

Table 5 represents the data as analyzed by the Commission from the EACTS database Ref 51. (Kneevi is Knezevic.)

Mortality in Report Ref 45

Compared to the UKC Report to the Ministry of Health from 2013 (Ref 45), where the authors claim their overall perioperative mortality to be 2.1% and their perioperative mortality for the primary congenital cardiac surgery to be 1.8% (they informed the ministry of Health to be among the first four institutions with the lowest mortality in Europe), the above data (from Refs 46, 51, 48, and 18) simply do not match. It is also not clear if the reported mortality in Ref 45 was calculated according to the guidelines and standards (Ref 63).

Mortality in Database Ref 18

The Commission also analyzed the mortality data from the data entered into the EACTS Database by Commission members during the audit of July 2014 (Ref 18). There were 73 patients who had congenital cardiac operation at UKC in Ljubljana during 2012 according to this database. Two patients died perioperatively (2.7 %) and two patients died after 30 days. The overall mortality of 4 patients that died following operations in 2012 was 5.5%. (The details of these 4 children that died are described in Section III.H.9 below.)

Table 6. Summary of the Commission's own data analysis for pediatric cardiac surgeries performed at DPCS in Ljubljana during 2012 (Ref 64).

	A	B	C	D	E	F	G	H	I	J	K	L
1	GFM	2012 operative death	proportion	95%CL low	95%CL up						Confidence Limit Calculator	
2	N patients	73	2	0.027	0.00475962	0.1044					70	1.03643
3	N admissions	75									90	1.64485
4	N operations	93									95	1.95996
5	N minor	11									n	73
6											p	2
7	N maj neon	14									p'up	0.03424658
8	N maj infant	25	1	0.04							p'lo	0.02054795
9	N maj child	31	1	0.03							CLup 70	0.06391876
10	N maj adult	12									CLlo 70	0.00905636
11	total maj	82	2	0.024							CLup90	0.08908869
12											CLlo90	0.00585734
13											CLup95	0.10438718
14											CLlo95	0.00475962
15												

Table 6 represents the mortality as calculated by the Commission from their database (Ref 18) according to the joint EACTS-STs society database committee guidelines from 2006 (Ref 63).

This database does not have the surgical procedure complications entered. When the Commission entered the data during the Audit in July 2014, severe time constraints only allowed for mortality and the basic variables and demographics to be entered. It was agreed that the rest of the data would be entered by the domestic team in UKC Ljubljana after the Commission departed.

9. Review of specific cases of mortality from the Commission's reviewed and entered data in the EACTS database Ref 18

The Commission found that 93 operations were performed on 73 children at the UKC in Ljubljana during 2012. There were four deaths out of these 73 patients (5.5%). By the Commission's standards, all four deaths **may have been preventable occurrences**, and according to the Commission's pediatric surgeon case reviews, the management of these patients was compromised. The facts of these four patients are summarized below. Following each case is a summary analysis by the Commission.

Patient #1. A 15-year-old patient was diagnosed with pulmonary atresia with intact ventricular septum (PA/IVS). The patient underwent a fenestrated Fontan operation on November 28, 2012. (No operative report was available.) Massive bleeding occurred at the end of the operation. **Dr. Mishaly** had already departed by air.

Finally, the bleeding was managed, but the patient had been in shock, was sent to the adult ICU, and developed renal failure, SIRS, and pleural effusions (up to 3 liters per day). After 9 days, the patient was transferred to the PICU (as the staff there had more experience with postoperative Fontan patients). The patient recovered and was finally sent to the ward where he continued to have large pleural effusions. During this time, there was discussion about the questionable patency of the fenestration.

Reoperation for the fenestration was performed on January 28, 2013. (No operative report was available). This had no effect on the pleural effusions, which persisted.

The PICU suggested transferring the child to Munich. The Surgeons took the child to Tel Aviv instead. The pleurodesis was done and collaterals were closed. The patient came back to Ljubljana and directly after arrival in the hospital, he suffered a cardiac arrest, had unsuccessful CPR, and died. An autopsy was performed.

Commission's Analysis:

- Complete absence of any operative reports.
- Senior surgeon already in an airplane with the patient still on the operating table, and this was done while the patient experienced severe bleeding.
- It seems that this patient would have benefitted from early Fontan takedown, which is the normal treatment for these problems.
- Why transfer the patient from the adult ICU to PICU? Why was there no consultation of PICU doctors while the patient was in the adult ICU?
- The patient should never have been transported to Tel Aviv; Fontan circulation with important pleural fluid leakage is very volume-dependent, and hydration during a longer air flight is always seriously compromised.
- **Conclusions:** Severe absence of infrastructure, protocols, and operative notes; no cooperation between the ICU's; faulty decision making, totally irresponsible behavior of senior surgeon.

Patient #2. An infant patient born in July 2012 was diagnosed with hypoplastic left heart syndrome (HLHS). On July 25, 2012, the patient underwent surgery for bilateral pulmonary artery banding and received Prostin to keep the duct open. On August 2, 2012, the Rashkind procedure was performed because of a restrictive atrial septal defect. This intervention was not successful. The patient underwent surgical atrio-septectomy on August 4, 2012. A reopening of the sternotomy was conducted on August 5, 2012; sternal closure was performed 4 days later. The patient underwent a Norwood/Sano procedure on September 11, 2012 and was discharged home on October 20, 2012. The patient was readmitted on December 11, 2012 because of a urinary tract infection. ECHO performed on December 13, 2012 showed decreased RV systolic function and a gradient across the Sano shunt of 35-40 mmHg with signs of RV failure. The child was sent urgently to the catheterization lab. Cardiac cath. on December 13, 2012 showed poor RV systolic function and asynchronous contractions. The therapy consisted of Enalapril. On December 18 during a chest X-ray examination, the patient suffered from apnea and went to cardiac arrest. CPR was required, but it was unsuccessful and the patient died.

Commission's Analysis:

- This kind of surgery had never before been performed in UKC in the absence of a senior pediatric cardiac surgeon, as reported by two of the Commission's members in a prior analysis. (Ref 153 p 5; paragraph 5, bullet #2) One of the cardiologists did not agree with the planned temporizing procedure of pulmonary artery banding and the continued infusion of prostaglandins. He believed the Norwood procedure should have been performed. The UKC surgeon's rationale for not operating immediately was the patient's poor initial hemodynamic condition. However, per the

attending cardiologists' opinion at that time, the patient's hemodynamics had significantly improved and the Norwood operation could have been done. Nevertheless, the surgical team proceeded with the original plan despite the objection of the pediatric cardiologist. No attempts were made toward the mediation or resolution of these conflicting opinions. A possible explanation (consistent with the internal auditor's opinion, Ref. 153), could be that since Dr. Mishaly was not accessible and a proper homograft was not available, the standard Norwood procedure could not be performed at the time); however, no attempt was made to proceed with the Norwood operation, and to send the patient for surgery abroad if Dr. Mishaly was not available. Instead a temporizing procedure was performed. **There is no documentation to be found that these alternatives were discussed with the family and that the family was properly notified.**

- It is, however **unimaginable** for the Commission to comprehend **why and how Dr. Mishaly's name appears in the operative report, as he did not participate in the operation on July, 25th 2012.** (Ref 153, page 5, paragraph 5; bullet 4c). The Norwood procedure was, nevertheless conducted by Dr. Mishaly 2 months after the PA banding, because the child could not have been weaned from the respirator and was, however, deconditioned.
- It is unclear what happened at the time of death. No echocardiogram results were available.
- The UKC possesses a detailed audit report on the results of Dr. Robida's Commission for this patient where many failures of the DPCS and the leadership of UKC were already depicted (Refs. 151, 152, 153); however their suggestions were never followed.
- Discharge of pediatric patients to home after a Norwood procedure should always be under the strict surveillance of a home monitoring program. This was absent here.
- **Conclusions:** No protocols and no home monitoring program for Norwood procedure; insufficient reporting of the patient's final days for life. This Commission's analysis concurs with the 2012 Auditor's findings that there were multiple insufficiencies at the DPCS in Ljubljana with regard to decision-making processes, following the established guidelines for safety, and compliance with international standards of care for children with congenital cardiac anomalies (Ref 153).

Patient #3. A premature, low-birth weight (850 g) infant was diagnosed with Tetralogy of Fallot. The patient underwent surgery with a modified Blalock shunt (most likely 4 mm) on April 25, 2012, at 10 weeks of age. The patient, weighing 2600 g, was intubated and remained intubated because the lung flow was too high. The patient was extubated on May 8, 2012. Six hours later that same day (May 8) the patient was reintubated, was in circulatory shock, with lactate up to 19 mmol/L, DIS. The patient was diagnosed with pulmonary overflow because of an overly large shunt. The patient died on May 16, 2012.

Commission's Analysis:

- A shunt of 4 mm is far too large for a baby of 2600 grams.
- Shunt reintervention was not done, even when this was frequently requested by the cardiologists and intensive care physicians.

- **Conclusions:** Wrong surgical decision making at first shunt operation and later when shunt revision was refused; irresponsible behavior of **Drs. Blumauer** and **Mishaly**.

Patient #4. An infant patient born in December 2011 was diagnosed with omphalocele and tetralogy of Fallot. First the patient received abdominal surgery, and later Blalock shunt (dates unknown). On June 19, 2012, the patient underwent surgery for complete repair of the tetralogy of Fallot with the use of a Hancock valved conduit. The patient was readmitted in August 2013 with stenosis of the Hancock conduit. In September 2013, **Dr. Mishaly** indicated that reoperation was necessary. The patient was discharged with night ventilation. The patient was readmitted to the hospital in January 2014 and died.

Commission's Analysis:

- Why use a Hancock conduit in primary TOF repair? This is exceptionally uncommon.
- Reoperation was the only solution, but this was not done for unknown reasons.
- Why was the child not sent abroad for reoperation if it were not possible in Ljubljana?
- **Conclusions:** Faulty surgical decision making, irresponsible behavior of both **Drs. Mishaly and Blumauer**, also shortcomings of pediatric cardiology and PICU staff for not sending this child to another center.

I. Overall Commission's conclusions about the key personnel:

Dr. Mishaly:

Totally irresponsible behavior as a doctor and a surgical supervisor:

- Leaving the country when patients are still on the operating table, in the hands of an inexperienced surgeon, even when patients are not stable
- Leaving patients too long on Prostin or on ECMO waiting for a surgeon
- Not returning for reoperations
- Not responding when PICU staff and pediatric cardiology request early reoperation
- Not reoperating when this was obviously necessary
- Faulty pediatric cardiac surgical decision making
- Not training Dr. Blumauer sufficiently
- Keeping Dr. Blumauer in position even when it was evident that he did not have the talent to become a skilled pediatric cardiac surgeon
- Ignoring Dr. Vodiskar totally
- Insufficient administration (sometimes no operating room reports)
- No leadership

Dr. Mishaly has certainly good surgical skills and human qualities, and there are exceptions where **Dr. Mishaly** has shown better conduct. However, these exceptions do not justify the above-mentioned severe shortcomings.

Dr. Blumauer:

Irresponsible behavior as a doctor:

- Not reoperating when absolutely necessary
- Not listening to and entering in a dialogue with pediatric cardiologists and PICU staff
- Not transferring patients to other centers when necessary
- Arrogant behavior
- Not conducting himself properly as a doctor should (shouting in the PICU)
- Lack of self- criticism and over-estimating his skills (he does not see that after 6 years he still was an inexperienced pediatric cardiac surgeon).

Dr. Blumauer does have some positive qualities, but they do not prevail over these above-mentioned severe shortcomings

Dr. Podnar and some other members of the pediatric cardiology staff:

Lack of tact and sense for mediation:

- Occasionally unfriendly toward the surgeons
- Leaking the problems to the media
- Insufficient willingness to cooperate with surgeons to find a solution for the problems

Some of the PICU staff physicians:

Lack of diplomacy:

- Occasionally antagonistic toward the surgeons
- Lack of willingness to cooperate with surgeons to find a solution for the problems

Dr. Gersak, director of the surgical division, and the rest of hospital management:

No leadership patterns in this situation:

- Responsible for creating a unsafe pediatric cardiac surgical service in which the senior surgeon is present in the program only 10% of the time
- Responsible for keeping this situation unchanged even when serious complaints arose
- Responsible for not answering complaints from the floor staff when the problems were brought to their attention
- Responsible for keeping **Dr. Blumauer** in a leadership position and without supervision even when it became apparent that his skills (technical and human) were significantly lacking
- Responsible for keeping the other colleague (**Dr. Vodiskar**) uninvolved in the program

Commission's preliminary data analysis from the database entered into EACTS by Drs. Weiss and Kalan (Ref 48)

The graph below depicts the number of patients and procedures entered by the Ljubljana team, as is shown on the login page of the EACTS Congenital Database.

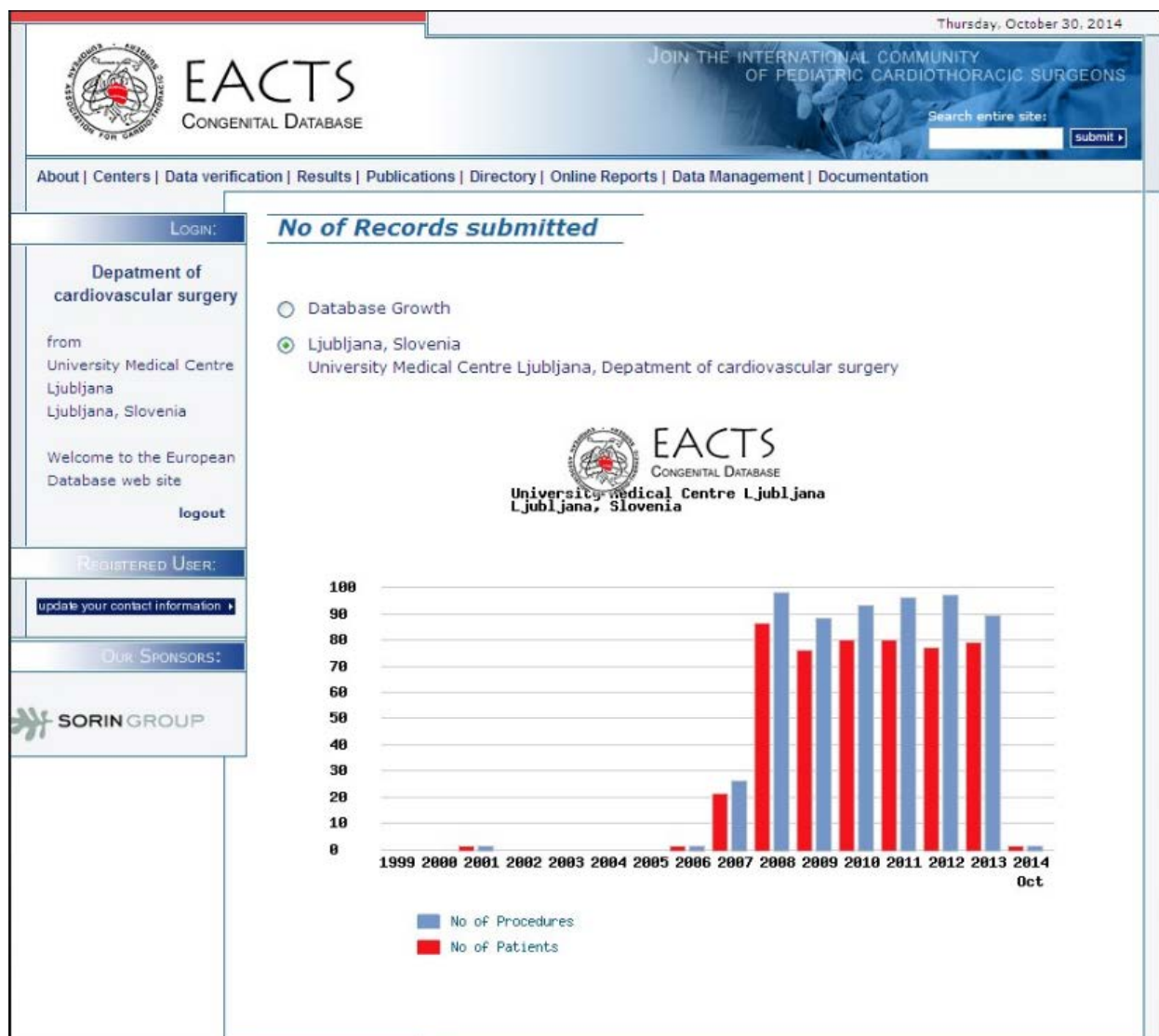


Figure 21. Numbers of procedures and patients reported to the EACTS Congenital Database as of October 30, 2014 (less than 100 per year).

These data clearly show the very low number of pediatric cardiac surgeries per year at UKC Ljubljana (<100 per year).

The diagrams presented below were the Commission's **preliminary** results of the database (Ref 48), which was provided to the Commission by the Ljubljana "data entry" team. The green lines represent the mean values of hospital survival (vertical) and Aristotle Basic Score (horizontal) in Figures 22 and 23, and Total Number of Procedures in Figure 24, from the database content for all EACTS institutions. The red lines and red bubbles represent Ljubljana DPCS and Ljubljana surgeons. (Ref 33)

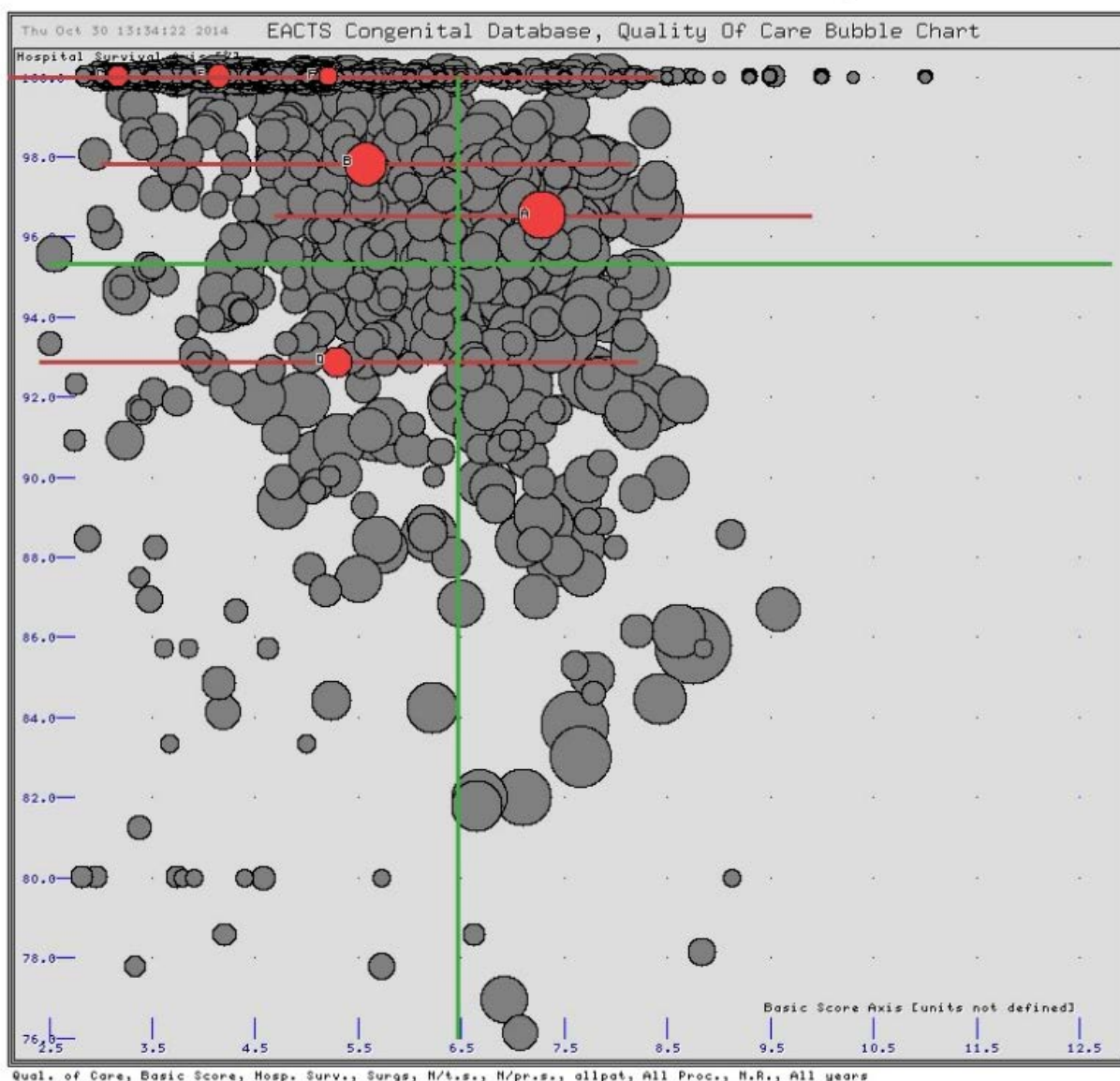


Figure 22. EACTS Congenital Database, Quality of Care Bubble Chart, as of October 30, 2014.

Hospital Survival is shown on the vertical axis, and the Aristotle Basic Score on the horizontal axis. The red bubbles are the Ljubljana surgeons. The diameter of the bubbles depicts the number of procedures. The grey bubbles depict all other surgeons in the database. The period is all years, with all procedures and all patients included.

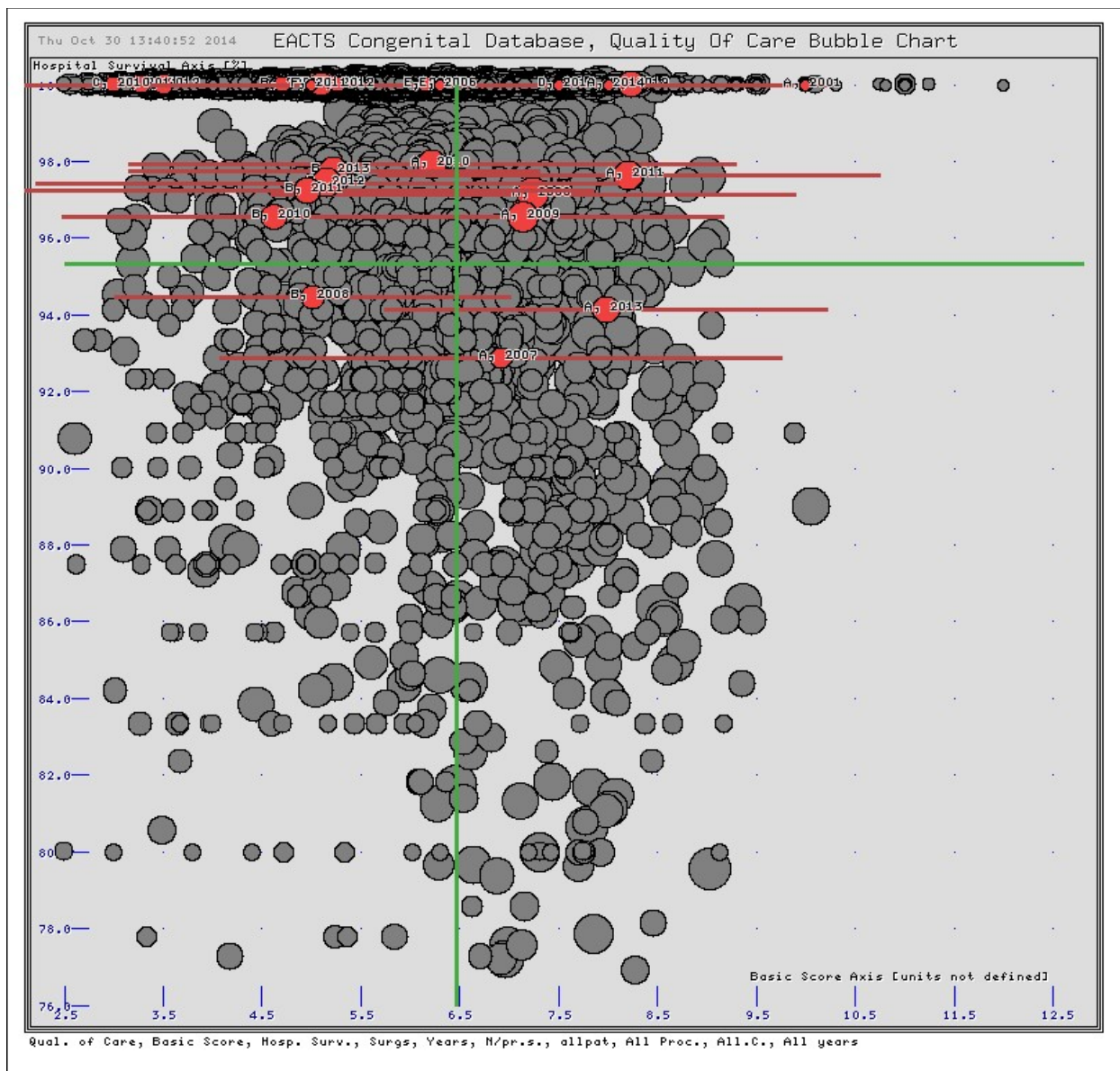


Figure 23. EACTS Congenital Database, Quality of Care Bubble Chart, as of October 30, 2014

Legend as in Figure 22, except that the bubbles have now been split by year.

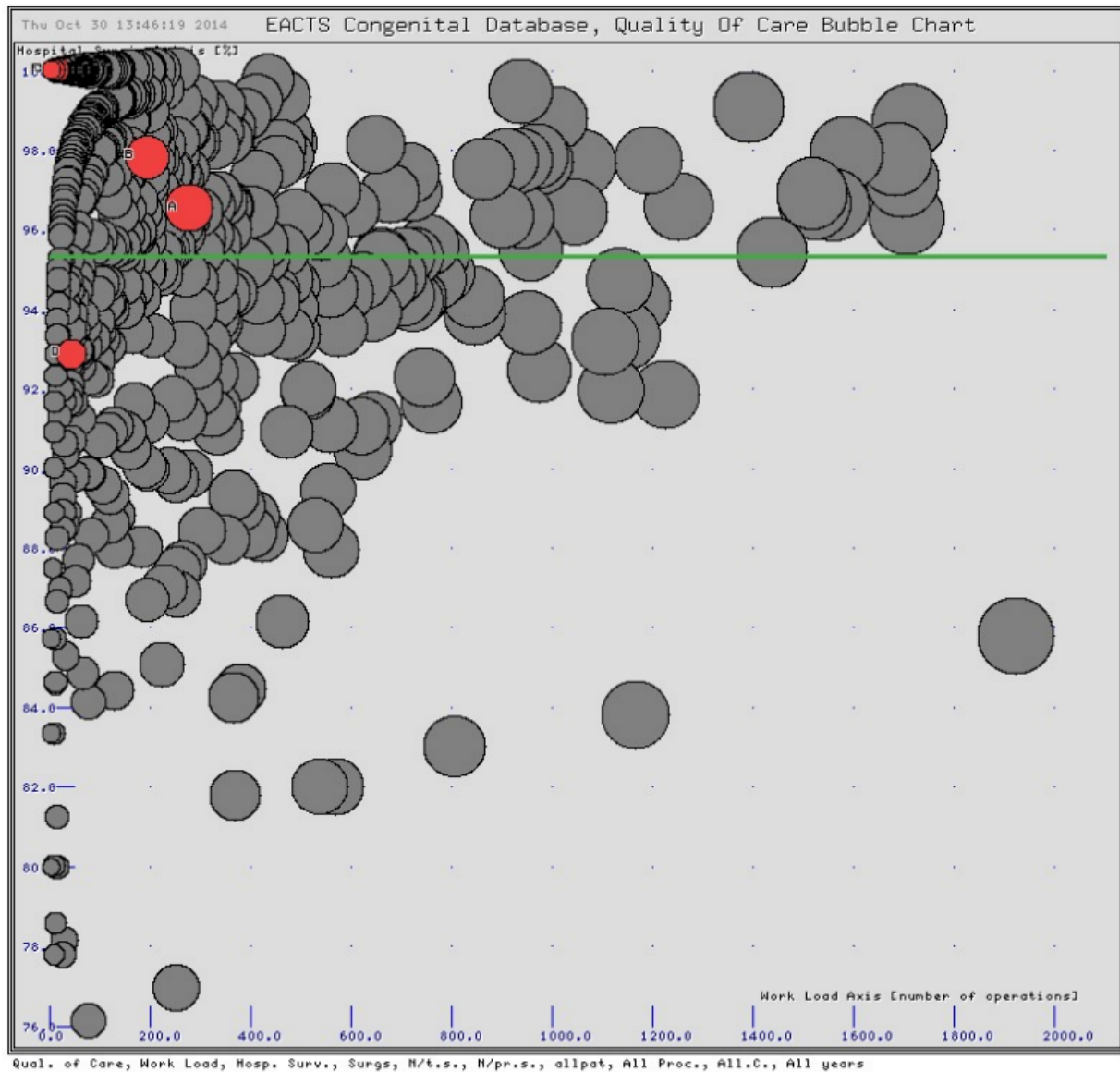


Figure 24. EACTS Congenital Database, Quality of Care Bubble Chart, as of October 30, 2014.

Legend as in Figure 22, except that the horizontal axis now depicts the total number of procedures in the database per surgeon.

The overall mortality was 4.4, the average case difficulty Aristotle score was 6.5, calculated from these charts.

Further interpretation of these charts should be done by EACTS database experts after the verification of data is performed.

Data Relevance

As previously mentioned, the EACTS data (Ref 48) were entered into the database by the physicians in Slovenia from three different computers (Ref 37). This was despite the database headquarters' advice that only a single computer should be used. As Dr. Tobota explained, "What they did with the installation of the software was unusual. It seems that they did not read the on line manual, and of course, did not ask for advice." (Ref 59)

During the data analysis, the Commission discovered that the codes for surgeons were, unfortunately, entered differently on different computers in Ljubljana. While merging the data from three computers to one database prior to sending the data to EACTS central database, Dr. Tobota explained, "When importing data from another PC, the surgeons' codes behave in such a manner that, if in the PC1 the code A is assigned to a surgeon X and in PC2 the code A is assigned to a surgeon Y, when importing data from PC2 to PC1 all operations with the A code will be assigned to a surgeon X (from PC1)."

This coding issue caused enormous problems and resulted in many surgical operations credited to the wrong surgeon in the main EACTS Database from Ljubljana. This was specifically pronounced for the year 2012. For example, during the Audit in July 2014 in Ljubljana, the Commission's own members entered the data into the database and knew there were 35 operative procedures performed by **Dr. Mishaly**. On the contrary, the database submitted by **Drs. Weiss and Kalan** listed no surgeries performed by **Dr. Mishaly** in 2012 in Ljubljana at all.

The Commission also learned that in addition to assigning erroneous codes to different physicians when merging the data from three computers, another, maybe far larger problem was unveiled. The problem was that some of the surgical procedures were intentionally entered under different surgeon's name!

In an email to one of the Committee members from **Dr. Kalan** dated December 15, 2014, he describes: "findings on oddities about data for year 2012 are the result of the program, which was run under the guidance of **Prof. Gersak**. In 2012, it became publicly known that **Dr. Mishaly** does not have a medical license in Slovenia. Therefore, at the time of license acquisition operations were attributed to **DR. Lakic** and **Dr. Blumauer**, although they were done by **Dr. Mishaly**. **Dr. Lakic** is the heart surgeon for adults. In 2012, he was ranked as the coordinator of congenital heart surgery program. **Dr. Lakic** has never operated on children with HLHS, truncus arteriosus, TOF, VSD etc. Nor has **Dr. Blumauer** ever done any Ross operation. From the data collected, it is evident that this has happened for a while in the year 2012." (Ref 58)

Once all these idiosyncrasies were discovered, it became impossible for the Commission to trust the available data. The Commission attempted to make some sense from all the databases and presents these databases for comparisons. It is absolutely clear though, that to get uncompromised and definitive results, the data in the EACTS database will without any doubt have to be verified.

J. Conclusion on analysis of the available data

1. Data entry into international databases

No data entry was ever performed at the DPCS until after the Commission's Audit, nor were reliable registries kept of the patients and procedures performed at DPCS in Ljubljana.

2. Data discrepancies

There are significant discrepancies and inconsistencies between different databases and documents available to Commission for the year 2012 and for the entire seven years of surgical services (from 2007 through 2014) for congenital cardiac surgery at UKC Ljubljana. These discrepancies range from the number of patients, the number of surgical procedures, as well as the surgeons who performed these procedures. These discrepancies remain when comparing all databases Commission has received.

During the July 2014 audit, the Commission received the charts of only 73 patients operated at UKC DPCS during year 2012 with the assurance that this number constituted all the patients operated upon in that year (Ref 18). The Commission discovered that there should be 12 additional charts for the same time period (based on **Dr. Blumauer's** personal patients' database, Ref 15) for the Commission to review during the Audit in July 2014. The Commission also discovered there were 2 patients charts of the 73 patients provided to the Commission in July 2012, that were not in Dr. Blumauer's database. What, finally, was the correct number of procedures in the year 2012 remains a mystery?

Additionally, the number of patients operated at DPCS in Ljubljana during the 2007 through 2014 was substantially different depending on the database examined. While the numbers from two databases are somewhat consistent (Ref 48 with 590 patients and Ref 46 with 555 patients), it is unclear to the Commission how 115 additional procedures are listed in the UKC report database (Ref 45) for a reporting period of almost 2 fewer years, that are not listed in the other two databases. This is a major divergence.

This discrepancy leads to the logical conclusion that a substantial amount of documentation (>15%) overall, and particularly for the year 2012, is either displaced, missing, or misrepresented. This may significantly affect the results of the data analysis. Therefore, **it is absolutely mandatory to launch an investigation into where the rest of the charts are and how to address the data verification**, and what a reliable source is in Ljubljana for basic numbers, such as an operative logs - either electronic or on paper.

3. Development of Domestic surgical team:

Based on the available data, the Commission concludes that the October 2007 goal to develop a domestic surgical team was not reached by the end of year 2014.

Evidence to support this conclusion was consistent in all data and documents made available to the Commission, including the data given to the Slovene Ministry of Health (Ref 45). In that official document, the authors claim that only 22.4% of PRIMARY congenital cardiac surgical procedures at UKC Ljubljana were performed by **Dr. Mishaly** in 2012 and 70.1% of PRIMARY operations were performed by domestic surgeons (Figure 6 above). These numbers **do not add up** and could not be confirmed by the Commission's Audit in July 2014 because no database for Ref 45 was available.

On the contrary, while the UKC report (Ref 45) shows only 22.4% of ALL operations done by **Dr. Mishaly** in 2012 (Figure 3), the data from the Commission's database entry (Ref 18) clearly demonstrates that **Dr. Mishaly** was the surgeon in 38% of ALL surgical procedures and 41% of MAJOR congenital cardiac procedures in Ljubljana in 2012. Additionally, **Dr. Podnar's** database showed **Dr. Mishaly** as a surgeon in 41% of cases for the time period comprising all of 2012 and half of 2013. Furthermore, the EACTS database of primary procedures (Ref 51), for year 2012 only, reported **Dr. Mishaly** to be primary surgeon in 72% of MAJOR surgical procedures (Table 4).

The same analysis of the EACTS database (Ref 51) showed **Dr. Mishaly** to have consistently performed roughly **two thirds of the primary procedures** (Figure 11) through the 7 years of his partial tenure at DPCS in Ljubljana. This data **directly contradicts** the UKC report from 2013 (Ref 45).

As per the Commission's analysis, no substantial change in number of primary procedures performed by the domestic team has occurred during the 7-year period while Dr. Mishaly operated in Ljubljana.

4. Verification of the data is absolutely needed to make any meaningful conclusions.

Data verification **will require an outside independent agency (such as EACTS)** to review all charts from 2007 through 2014, which will entail a significant amount of time. Unfortunately, the Commission does not have presently the luxury of time to go back and correct the flaws in the Database entered imprecisely by the UKC physicians. The decision of when to complete this verification, who should perform it, and to what extent it will be carried out will be the domain of Ministry of Health and the government of Slovenia.

5. Morbidity and mortality

The UKC report Ref 45 depicts the perioperative mortality at the DPCS was consistent if not better than European average (1.8% for primary operations as described in Ref 45, page 12, paragraph 4) during 2007 through 2013). The Commission was provided with no database to analyze and to support this claim. In the analysis of data entered into the EACTS by Commission for year 2012, the perioperative mortality was 2.4 (2 deaths for 82 major operations) and overall mortality for 2012 was 4.9% (4 deaths for 82 major operations), and the hospital mortality for the entire population of patients from 2007 through 2014, calculated based on 553 major operations was 2.9%. The 1.8% mortality reported by the UKC Ljubljana group could not be

verified, and the Commission did not have the information available to assess if this number was calculated in accordance with the standards reported in Annals of Thoracic Surgery in 2006 (Ref 63). The mortality calculated by the Commission **from the database** (Ref 48) is 2.9; however, based on the discrepancies between referenced databases, inaccurate data entry and physician's code assignments and merging data from three computers to one database, no definite or reliable conclusion about overall mortality and morbidity can be made.

The Commission would like to acknowledge and underscore again, however, that the database provided to them by **Dr. Kalan and Weiss** contained multiple errors. Therefore the reliability of the data in this database was questionable. Consequently, it is imperative that these calculated numbers are verified prior to reaching any definitive conclusions.

IV. Conclusions of the Audit

A. Summary

After completion of the Audit, the Commission came to the realization that the department it was reviewing could, at best, be considered a small pediatric congenital cardiac surgery service designed to care for Slovenian children with congenital cardiac defects. The word “Program” then is way overstated in the opinion of the Commission.

Considering the evidence and testimonies detailed in this report, it is difficult for the Commission to give an optimistic review of the DPCS at this time. The Commission is equally doubtful regarding the prospects for developing a new viable pediatric congenital heart surgery program in UKC Ljubljana in the next few years.

The Commission believes that for the minimum of the next 5 years, the children of Slovenia who require congenital cardiac surgery would be better served by being referred to an outside facility. The only viable resolution to this problem and to restore the congenital cardiac surgery to Ljubljana, in the Commission’s view, would be for the UKC to recruit at least two new, experienced surgeons who could, in a year or two, build a center that would completely comply with all international standards of care for congenital cardiac surgical patients, including performing at least 250 surgical operations a year. Knowing the market and the trends in pediatric cardiac surgery in Slovenia and in the region, it is difficult for the Commission to believe such a task is possible in such a short period of time.

The Commission’s inquiry revealed that the structure of the pediatric cardiac surgery service was nontraditional, to say the least, and that the surgical service was not viable, was unsafe, and could barely qualify as a “program.” The Commission discovered that most of the time during 2012 (90% of the days each month) the DPCS did not have a competent, experienced, senior pediatric cardiac surgeon present or available on the premises of the UKC in Ljubljana. The functional arrangement of pediatric cardiac surgery services from 2007 to 2013 was not sustainable, nor was it compatible with any international standards for pediatric cardiac surgery. For the first 2 years of this time period from 2007 when Dr. Mishaly’s services started, surgical care relied solely on two general cardiovascular surgery trainees who worked partially in the department of pediatric cardiac surgery when Dr. Mishaly was absent. The rest of the time these two trainees worked in the department of general adult cardiovascular surgery. Even after both trainees passed their general cardiac surgical boards in 2009 and 2010 respectively, it was commonly known they were not adequately trained in pediatric cardiac surgery and were unable to independently perform complex pediatric cardiac procedures. Surgical procedures were conducted without the supervision of a trained senior pediatric cardiac surgeon approximately 90% of the time. Nevertheless, this structure with the senior pediatric cardiac surgeon present in Ljubljana and Slovenia only 3 days per month continued for 7 years. The Commission learned that the UKC leadership finally changed the structure of the DPCS on December 12, 2013.

From the interviews, the databases’ case logs, and from analysis of the complexity of cases performed by Drs. Blumauer and Vodiskar, the Commission concluded the domestic pediatric cardiac surgeons were not adequately trained to perform the most complex pediatric cardiac surgical procedures independently. In most European countries, it takes an additional 2-3 years after passing the board exams in general cardiothoracic surgery for a surgical candidate to be trained as a pediatric cardiac surgeon. On top of this, it takes an additional 3-5 years for this surgeon to become an experienced, competent, mature congenital cardiac surgeon, one who is able to independently and safely operate on children. This time is also required in order

for this surgeon to integrate as a productive member of a multidisciplinary team of physicians successfully caring for these very sick children who often present as very complex cases. The Commission was not presented with any credible suggestions that there is such a candidate currently in Slovenia who can become an independent and competent pediatric cardiac surgeon before the end of this decade.

An audit specifically of surgical procedures performed in the DPCS during 2012 revealed that only 93 surgical procedures on 73 children with cardiac anomalies were performed. This small number of surgeries performed and their outcomes do not meet the international standard criteria for good quality of care. Although it was not the primary goal of the Commission to review the results of pediatric cardiac surgical procedures performed in the UKC Ljubljana outside of the year 2012, the Commission and the Medical Chamber of Slovenia, together with UKC administration, agreed that the data from 2007 to 2014 should become available to the Commission to expand their review. Analyzing and auditing the results only for 2012 would not arm the Commission with adequate data to make any substantial conclusions due to the small number of patients who underwent operations. It is important to note, however, that in the time period of 2007 to 2014 there were, on average, less than 100 congenital cardiac surgeries performed per year in Ljubljana. This, again, is not in accordance with the international measures and standards needed to provide safety and a high quality of services to children with congenital cardiac anomalies. Further, this is not consistent with evidence-based best practices and policies.

The Commission is unsure why the UKC leadership decided to continue congenital cardiac surgical services after becoming aware of the substandard of care at the DPCS as early as 2009. Evidence of this knowledge can be found in the form of multiple written concerns addressed to the leadership from both pediatric cardiology and critical care physicians.

Moreover, the Commission is greatly concerned by the finding there were no congenital surgical data ever entered into the EACTS registry database despite the pediatric surgeons' agreement and confirmation that this guideline would be followed. Had these data been entered, the substandard surgical results for congenital cardiac surgery in Ljubljana would have been discovered much sooner.

These two major findings — the small number of operations and the lack of data entry into the EACTS registry at DPCS — along with additional observations demonstrating deviations by DPCS from the internationally published guidelines and standards of care for pediatric cardiac surgery have led the Commission to conclude that the safety of children requiring pediatric cardiac surgery in Slovenia under the structure of the DPCS between the years 2007 and 2014 was severely compromised.

The Commission acknowledges that, at this time, **adequate security and a safe environment in which to continue pediatric cardiac surgery in Ljubljana do not exist.** The Commission also recognizes that the children who need surgical correction for congenital cardiac anomalies at present are better served at an outside institution affiliated with the UKC Ljubljana, one with an organized program that performs a high volume of pediatric cardiac surgery and has demonstrated good results.

The Commission is aware that the Audit was initially instructed to review only the results for the year 2012. However, after initiation of this review, it became immediately apparent that the problems and turmoil of the pediatric cardiac surgery program in Ljubljana started over 10 years ago, and these problems clearly grew worse over the last decade. This deterioration of service led to the public outrage and questioning of the quality, decision making, and surgical services for the children in the DPCS specifically during the last few

years. The inability of the medical and administrative leadership to resolve the internal conflicts within the congenital cardiac surgery service and to verify its quality eventually led to the complete collapse of the DPCS in December 2013, 6 months prior to the Commission's Audit. Ultimately, the result of this collapse is that now Slovenian children with congenital cardiac abnormalities must now be sent to a foreign country to have cardiac surgery safely performed.

We, the Commission, wish to underscore that our mission was to evaluate the compliance of the DPCS at UKC in Ljubljana with international standards or guidelines for services rendered in the year 2012. We leave it to the Slovene government, medical leadership, and other authorities to exercise their responsibilities and power in their response to the Report of this Commission. The strategy to develop a new Slovenian center of excellence for the treatment of children with congenital cardiac diseases or dissolve these services entirely will rely upon the decision of the Government and Ministry of Health of Slovenia.

The Commission does wish to emphasize that it found many individual elements of the service and care of children with congenital cardiac defects at the UKC in Ljubljana to be good, and some were excellent. There are many very dedicated individuals and teams with considerable experience that desire to have nothing but excellent care delivered to these children being treated within the UKC.

B. Specific Topics of Analysis

1. Personnel

Below are a brief summary of the findings of the Commission regarding the pertinent personnel.

a. Dr. Mishaly

The Commission found the behavior of **Dr. Mishaly** as both a surgeon and a surgical supervisor to be totally irresponsible. Below is a summary of the evidence revealed during the Commission's inquiry to that support this conclusion:

- **Dr. Mishaly** would often leave the country while patients he had just operated on were still on the operating table. As a result, he was not involved in nor did he demonstrate concern for the stabilization of this patients postoperatively.
- The Commission found several instances in which **Dr. Mishaly** would leave patients on ECMO or Prostin for long periods of time prior to his arrival at Ljubljana. These treatments are completely substandard and are not at all in line with international guidelines.
- **Dr. Mishaly** as a leader failed to respond to the requests of the PICU and Pediatric Cardiology staff for an early reoperation in distressed patients. He also failed to respond to Dr. Blumauer and was not readily available to be directly consulted when outside of Slovenia.
- **Dr. Mishaly** was unwilling to reoperate or to instruct Dr. Blumauer to reoperate even when this was deemed medically necessary by other physicians involved in pediatric patient care.
- The Commission found fault with his pediatric cardiac surgical decision making.
- **Dr. Mishaly** failed to properly train **Dr. Blumauer**.

- **Dr. Mishaly** kept **Dr. Blumauer** in his position as a pediatric cardiac surgeon even when it was evident that **Dr. Blumauer** did not possess the necessary skills to hold this position.
- **Dr. Mishaly** completely ignored the training needs of **Dr. Vodiskar**.
- **Dr. Mishaly** was an insufficient administrator, often times documenting no operating room reports.
- **Dr. Mishaly** demonstrated extremely poor leadership skills as chief surgeon.

Dr. Mishaly certainly has good surgical skills and human qualities, and there are exceptions where he demonstrated better professional conduct. However, these traits do not justify the above-mentioned severe shortcomings.

b. Dr. Blumauer

The Commission found **Dr. Blumauer** to behave irresponsibly as a doctor and medical profession. Below is a summary of the evidence revealed during the Commission's inquiry to that support this conclusion.

- **Dr. Blumauer** was not willing to reoperate on children even when deemed absolutely medically necessary by the other experienced physicians involved in pediatric patient care.
- **Dr. Blumauer** showed consistent disregard for the opinions of the cardiologist and PICU staff.
- **Dr. Blumauer** was unwilling to transfer patients to other medical centers when a transfer was medically necessary.
- **Dr. Blumauer** consistently demonstrated arrogant behavior to staff and other medical professionals.
- **Dr. Blumauer** routinely did not conduct comport himself as a doctor with highest moral and ethical standards toward other medical personnel (i.e. shouting in the PICU).
- **Dr. Blumauer** lacked the ability to self-critique. After 6 years of being undertrained and repeated demonstrations of his inability to successfully perform even simple or routine pediatric cardiac surgical procedures, he still views himself as being a competent pediatric cardiac surgeon.

Dr. Blumauer does have some positive qualities, but they do not prevail over these above-mentioned severe shortcomings

c. Dr. Podnar and other members of the pediatric cardiology staff

The Commission found **Dr. Podnar** lacking some leadership qualities. The other members of the pediatric cardiology staff who reported to him, also occasionally lacked the tactful skills and management qualities to avoid unnecessary confrontations with the other physicians caring for congenital cardiac patients. Below is a summary of the evidence revealed during the Commission's inquiry to that support this conclusion:

- **Dr. Podnar** and his staff were found to be occasionally unfriendly toward the surgical staff.
- **Dr. Podnar** disclosed internal departmental problems to the media.
- **Dr. Podnar** and his staff demonstrated an insufficient preparedness to find solutions to the problems that were presented.

d. PICU staff physicians

The Commission found that some members of the PICU staff physicians occasionally lacked the diplomatic or tactful skills required to conduct themselves as medical professionals. Below is a summary of the evidence revealed during the Commission's inquiry to that support this conclusion:

- Some members of the PICU staff were occasionally antagonistic and unfriendly toward the surgical staff.
- Some members of the PICU staff lacked the willingness to find a solution to these interpersonal problems.

e. Dr. Gersak, director of surgery, and the top administrative hospital management of the UKC

The Commission found that **Dr. Gersak** and the UKC leadership team lacked the leadership skills necessary to negotiate and resolve the escalating situation described in this report. Below is a summary of the evidence revealed during the Commission's inquiry to that support this conclusion:

- The UKC leadership was responsible for creating an unsafe pediatric cardiac surgical service in which the senior surgeon was present in the program only 10% of the time.
- The same leadership was responsible for maintaining this situation even after serious complaints and questions of compromised quality arose.
- Peer reviews and necessary protocols were not in place.
- The UKC leadership allowed many gaps and unsafe practices in patient care to exist because relevant policies and standards were mostly nonexistent.
- The UKC medical and administrative leadership is responsible for not responding to the complaints of the floor staff when problems within the DPCS were brought to their direct attention.
- The administrative and medical leadership, including Dr. Gersak, is responsible for keeping **Dr. Blumauer** in a leadership position and without supervision, even after it became clear that his skills (both technical and human) were significantly lacking.
- The UKC leadership is responsible for limiting the training opportunities and seriously jeopardizing the career development of the second surgical resident, **Dr. Vodiskar**.
- The UKC leadership failed to respond to the recommendations of previous internal audits. The UKC Ljubljana misled the public and Ministry of Health regarding what it declared to be safe and excellent pediatric cardiac surgery service results.

Despite multiple warning signs, the UKC medical and administrative leadership did not appropriately react to the constant flow of information signaling causes for concern. The leaders with close responsibility for ensuring a safe and excellent standard of care failed to appreciate the enormity of the problem, responded inappropriately, and downplayed the significance of the warnings. The culture was unfortunately one of self-promotion rather than critical analysis and transparency. The UKC leadership turned a blind eye toward the all too frequent concerns that were unveiled even before this present audit. Unfortunately, mediocrity was tolerated, and the interests of some groups prevailed over the safe and high-quality care of patients.

The Commission was presented with evidence that the highest level of UKC management did not react with any vigor to pursue changes in the Pediatric Cardiac Surgery Department despite the warnings and concerns

they had been informed about. In addition, the UKC of Ljubljana lacked a sufficient sense of collective responsibility or engagement to ensure that the highest quality of care was delivered at every level of pediatric cardiac service. The management and the cardiac surgery leadership had no culture of listening to patients' families. There were inadequate processes for dealing with complaints.

The radical change was finally forced on the UKC medical and administrative leadership when pediatric critical care physicians and pediatric cardiologists send an unprecedented letter to the Slovene Ethics Commission in December 2013 and refused any further collaboration with the DPCS in Ljubljana. These physicians stated that their ethics and moral integrity did not allow them to send the children to a cardiac surgical procedures service with a severely compromised program and outcomes.

2. Pediatric Cardiac Surgery and Its Integration with the Institution's Priorities at UKC in Ljubljana

The Commission concluded that the UKC in Ljubljana did not possess a clear knowledge and vision of how strategically important the pediatric cardiac surgery services were for the UKC and for Slovenia. However, after DPCS interdisciplinary relations spun out of control and the public became outraged with the conduct of services at the DPCS, the urgency to make changes reached not only the leadership of the UKC Ljubljana, but also extended all the way to the Ministry of Health, the Prime Minister of Slovenia, and the entire Slovene government. The problem became so large that there were daily accusations and finger-pointing among various members of the Center explaining different reasons, opinions, and causes for the collapse of pediatric cardiac surgery. The situation was further exacerbated by some unresolved conflicts within the department of pediatric cardiology itself and within the department of pediatric intensive care.

For many years prior to the service's collapse, there were numerous warnings, reports, and letters written by pediatric critical care and cardiology physicians to the medical leadership and the hospital's highest administration. These documents detailed the deficiencies and insufficiencies of the DPCS. They also outlined specific potential safety issues and dangers to the children with congenital cardiac anomalies undergoing cardiac surgical procedures within the DPCS. Despite these efforts that extended over a 5-year period, there was no substantial change in the structure of the congenital cardiac surgery services during that time period. The conflict between the surgical and other services grew deeper and eventually led to pediatric services writing a letter to the Ethics Committee of Slovenia stating that they refused to send children to surgery or to collaborate with the surgical team at DPCS unless there is a senior pediatric cardiac surgeon present in the UKC daily. The cardiology and critical care physicians clearly believed the problem of not having an experienced pediatric cardiac surgeon available on a daily basis clearly compromised the safety of the children. This was the main substance of concern raised in the letter to the highest Slovene Ethics Committee.

It appears to the Audit Commission that there was not a real grasp of the magnitude of the problem by the medical and administrative leadership of the UKC. The general public may not have ever become aware of the compromised care given to these children had the pediatric critical care physicians and pediatric cardiologists not addressed these unacceptable results to the UKC leadership on multiple occasions. The Commission finds the pediatric cardiac surgery and its integration within the institution's priorities at UKC in Ljubljana to be **unacceptable**.

a. Data entry into international registry

Although the Slovene DPCS has been registered with EA CTS since 2007, the surgical data from DPCS in Ljubljana were never entered to the EA CTS registry by the physicians or any other staff of the DPCS. This occurred despite the fact that this data entry was officially requested by the administrative and medical leadership and agreed upon by the surgical team. Once the data for year 2012 were entered to the official EA CTS database by the members of the Commission, the data analysis results were in sharp contrast to the surgical results officially presented to the Ministry of Health in January 2013 by the pediatric cardiac surgical team.

The pediatric cardiac surgery service's data analysis, reported in January 2013 (Ref 45) for 2012, showed DPCS services to be excellent and in accordance with international standards. Our Audit Commission was never given the aforementioned data to audit, and a proper review of this analysis cannot be completed. Therefore, the Commission is unable to directly comment on the accuracy and authenticity of this 2013 report. However, the Pediatric Cardiology Department provided the data on 555 patients treated between 2007 and 2012. Patient's names and descriptions of their complications along with the names of the children that died during that time were all included. The data within these patients' records support the cardiologist's deep concerns of substandard care at the DPCS. The Commission understands, however, that these data need to be properly statistically analyzed and cannot confirm their accuracy.

There was an agreement between the Medical Chamber of Slovenia, Audit Commission, and the leadership of the UKC in Ljubljana that the entire dataset from 2007 through the time of the Audit should be entered into the EA CTS registry. Although this was agreed to be completed by mid-September, these data were not fully entered and completed until October 4, 2014. The Commission discovered, however, that the data entry was completely compromised by merging the data from three computers to one database by the team in Ljubljana. During this process, the codes for the surgeons were not uniformly assigned, which resulted in the complete loss of evidence for Dr. Mishaly's surgical involvement during 2012. Additionally, the Commission became aware that some of the procedures Dr. Mishaly performed during 2012 were assigned to Dr. Blumauer or other surgeons at the DPCS in Ljubljana because Dr. Mishaly had not yet obtained the Slovene medical License. Therefore, the detailed surgical experience for each individual surgeon and their results could not be interpreted accurately.

The Commission finds the data entry into international registry from UKC in Ljubljana to be, by any standard, unacceptable.

b. Current service delivery

After the letter from critical care MDs and pediatric cardiology MDs to the Slovene Ethics Committee, the pediatric cardiac surgery service ceased to exist in Slovenia in December 2013. This was a necessary measure to ensure the safety of congenital cardiac patients. The current arrangement of sending the children to Munich for their cardiac surgical procedures has temporarily resolved the UKC's problem of pediatric cardiac surgery and put to rest the Slovene public outrage. However, this is not an optimal long-term solution.

There are some serious concerns outlined by the Commission regarding the handling of new cases of pediatric emergency. There were currently no trained pediatric cardiac surgeons in Ljubljana or anywhere in Slovenia who could safely perform pediatric ECMO placement at the time of the Commission's Audit. The Commission became aware that in emergencies, cardiac surgeons caring for adult patients have attempted to

place emergent ECMO in pediatric cardiac patients. However, the adult cardiac surgeons lack the proper training on pediatric cannulations and ECMO placement. Furthermore, they have minimal, if any, experience in pediatric ECMO management. The new trainee in pediatric cardiac surgery at this time has only recently completed his cardiac surgery boards, and he has only just begun his pediatric cardiac training. His experience with pediatric ECMO can only be considered to be at the beginner level at best.

The new arrangement with the Munich pediatric cardiac surgery service is not without problems. First, from Ljubljana, Munich can only be reached after 4-6 hours by ground or 1 hour by air. These times do not include the additional time necessary to stabilize the patient, to secure a team and the patient for transport, and to coordinate such transportation. Additionally, this arrangement is not suitable for the patients who are too unstable hemodynamically to tolerate transport.

Second, there are issues pertaining to the agreement between UKC Ljubljana and Munich. The Commission learned that currently, the agreement only stipulates bringing children to the Munich for surgery. There is no firm arrangement between the UKC administration, the medical leadership supported by the Ministry of Health, the government of Slovenia, and the Munich Clinical Center administration to eventually station pediatric cardiac surgeons from Munich in Ljubljana on a rotational basis and be truly affiliated as a franchise of the center of excellence in Munich. This arrangement would enable the Slovene pediatric cardiac surgeons to be proficiently trained within proper training programs with access to large case volumes and critical care experience for congenital cardiac surgical patients. This potential arrangement would also enable the DPCS personnel in UKC Ljubljana to maintain their medical skills, rotate on a yearly basis to their parent institution in Munich, where they could gain experience and become true extensions and integrated components of the Munich center. There are examples of such arrangements in other countries. In addition, such an arrangement would also support the pediatric interventional cardiology service with adequate patient volumes and help maintain the skills, education, and research projects within that department. In addition this would enable the young physicians to be properly trained, educated, and graduate as young congenital interventional cardiology residents with excellent skills.

The Commission finds the current delivery of pediatric cardiac surgical services for Slovenia to be only **partially acceptable**.

c. Response to previous audits and warnings

There were numerous warning letters of concern and outcries from pediatric cardiologists and pediatric critical care physicians about the inadequacy and underperformance of pediatric cardiac surgery. There were letters of concern regarding a junior surgeon's postoperative patient management skills. This junior surgeon was left practically unsupervised a majority of the time (90%), due to the experienced, mature pediatric cardiac surgeon not being present in Slovenia. The Audit Commission was presented with reports, audits, and letters of concern regarding the inadequacy of the junior pediatric cardiac surgeon's surgical training and experience. These documents also addressed his, sometimes, counterproductive and out-of-protocol decision making and lack of proper consultation of critical care physicians. This was despite the fact that hospital policies stipulate that critical care physicians are in charge of postoperative patients. In addition, the Committee learned about a junior surgeon's direct orders to the nursing staff and his demands that his orders be implemented contrary to the critical care physician's orders. This placed the nursing staff in uncomfortable situations and eroded their ability to perform their duties and compromised their integrity.

These letters of complaint were addressed to the medical director of the UKC, the highest UKC administration, the Chief of the Pediatric Clinic, and the Chief of Cardiovascular Surgery, under which the DPCS structurally belongs. Over a 5-year period, despite these multiple concerns, the surgeons attempted to convince the leadership and the public that there were no problems in the department, that the structure worked, and that the results were very good. A report to the Ministry of Health in January 2013 detailing the pediatric cardiac surgical results from 2007–2012 demonstrated that the surgical performance to have “acceptable mortality and comparable results to the leading centers in Europe and abroad. “ Although the other services involved in pediatric cardiac care were very doubtful of these results, there was no internal audit to verify the validity of data presented to the Ministry of Health. Despite the outrage and concerns, the UKC leadership, on the suggestion of the Cardiovascular Surgery Chief, agreed to continue the arrangement with the locum surgeon operating merely 3 days out of the months.

During this time (2012), there was also an outside official review and audit regarding a questionable postoperative death of a child operated on for a congenital cardiac anomaly. The report outlined the idiosyncrasies and inadequacies of the substandard performance of the pediatric cardiac surgical team. This report gave some recommendations regarding what and how to change the structure of the service at that time. These suggestions were ignored. Importantly, in an unfortunate event, the UKC Ljubljana then publicly declared that the Auditors who reviewed this death were incapable of auditing that event, regardless of whether or not the auditors were fully qualified and had internationally honorable reputations. This again demonstrates that the UKC leadership consistently disregarded the continual problem of compromised quality and safety of pediatric cardiac surgery at the UKC Ljubljana.

The outrage about the quality of care at the DPCS in Ljubljana and indication of possible corruption in the DPCS and UKC went so far that some individuals were investigated by the government agency for possible corruption charges in October 2012. All the findings about potential corruption were denied in a letter by the UKC CEO dated November 12, 2012 (Ref 79).

It was not until the cardiovascular leadership changed and the letter written by the cardiology and critical care physicians of the UKC expressing the questionable standard of care by the pediatric surgical department was presented to the Slovene Ethics Committee that the necessary structural changes were finally addressed. By then, the enormous problems of the pediatric cardiac surgical department had grown to unimaginable proportions. This forced the physicians and administrative leadership to hold multiple press conferences and media appearances to help calm the outraged and concerned Slovene public.

The Commission finds the response to previous audits and warnings by the UKC in Ljubljana to be **unacceptable**.

d. Future arrangements

The Commission realizes that most countries and governments wish to retain pediatric cardiac surgery services within their borders, and Slovenia is no exception.

However, many obstacles need to be overcome before such an arrangement can be accomplished in Slovenia. The continued collaboration with Commissioners or other experts and the willingness and desire to have such a center of excellence are a prerequisite to start building this kind of very specialized and delicate service. There was such considerable damage sustained by the pediatric cardiac surgery services in Slovenia by DPCS

that there has been a complete loss of trust not only between the services and physicians but also of the general public. The creation and structure of a new pediatric cardiac surgical service must be exclusively based on international guidelines and standards of care. This process must be supported by the medical and administrative leadership along with the Ministry of Health and Medical Chamber of Slovenia.

The new structure for DPCS in Slovenia will have to establish written protocols, adequate staffing with unquestionable expertise and education, transparent accounting, quality control and verification of compliance, risk stratification, reciprocal voluntary audits, individualized surgical results, routine data entry to the EA CTS registry, and all other policies and procedures associated with a center of excellence.

Thus far, the Commission has been presented with only a glimpse of such a vision. However, the Commission is aware that it is currently too soon after last year's collapse of the DPCS to reorganize and put together a sound plan for the future. The present discussions are within the preliminary stages of planning and are aimed at creating the optimal solution for pediatric cardiac surgery in Slovenia. There is plenty of desire and motivation among some physicians to bring congenital surgery back to UKC as soon as possible. However, the beginning of discussions regarding how to build such a program has not yet been reported.

The Commission finds the future plans for arrangements and structure of DPCS within the UKC in Ljubljana to be presently poor.

e. Written protocols and quality of care for pediatric cardiac surgery in Ljubljana

Every program taking care of children with congenital cardiac anomalies, including surgical corrections, should have written protocols for preoperative assessment, intraoperative care, and postoperative therapies and treatments for pediatric patients. These protocols should outline the pathways between services taking care of these children, communication between clinicians, communications between physicians and parents or entire families, as well as communications between clinicians and younger or older children. The protocols should be developed and agreed upon by local referring surgeons, pediatric cardiologists, pediatricians, children's cardiac specialist nurses, clinical psychologists, and patient groups. There should be specific written protocols about the surgical share of care. These should include protocols for operative services, personnel, education and trainings, pathways to the operating room, standardized transition to the intensive care unit, protocols for pediatric ECMO (who can start ECMO and how ECMO is initiated), and protocols for pediatric transplantation and mechanical assist support.

When searching and asking for written protocols at the DPCS in the UKC in Ljubljana, the Commission was unable to obtain any relevant documentation. The protocols should have been established to avoid mistakes, to facilitate repetitive optimal and efficient pathways of patient care, to avoid or minimize learning curves, and, most importantly, to avoid complications and mortality.

The Commission has learned there are actually serious deviations from international standards of care, especially in interpersonal physician communications. The Commission found strong evidence of a lack of patient care-related discussions between some clinicians and other staff members of the team.

Furthermore, the Commission was told that there were no protocols in accordance with international standards for the training of new pediatric surgeons. There were no guidelines in place specifying the numbers of specific types of operations to be completed and the time frame in which this has to be accomplished. No protocols or documentation existed between 2007 and 2014 regarding any of the

following: interventional cardiology mentorship and training; multidisciplinary conferences; the growth and increased referral base necessary to reach internationally established numbers for compliance; optimization of the service for child safety; the minimal number of experienced pediatric surgeons present daily in the department; and collaborations with an established center.

The Commission realizes that even if some protocols exist or are available, they must be scarce and remain mostly ignored. The Committee observed a substantial deficiency of compliance with international standards of care for children with congenital cardiac anomalies.

The Commission finds the written protocols and quality within the UKC in Ljubljana to be unacceptable.

f. Quality of Care

The Commission is very concerned that the level of care delivered at the DPCS in UKC in Ljubljana did not meet the international standards of care for children with cardiac defects and UKC failed to deliver adequate care to these children.

The Commission was presented with information indicating that there are elements of substandard care delivery at every level of pediatric cardiac care in the DPCS including evaluation, preoperative, intraoperative, and postoperative care delivery. Although there are many extremely dedicated members of the team who desire nothing but the best for their patients, there are significant gaps in the system that prevent excellence (as measured by international standards) from being achieved.

It is inconceivable to the Commission that the evaluation of a potentially critical pediatric cardiac patient may be delayed because an ultrasound-trained cardiologist is not present in the hospital during the weekend. More importantly, the Commission learned that the staff is reluctant to call the cardiologist from home to come and evaluate the patient during such times. The Commission was informed that there are no explicit written policies to guide the staff about the calling of pediatric cardiologists after hours or on weekends. Therefore, cases may present in which the infant and mother must be hospitalized for an entire weekend, even though this may be completely unnecessary and avoided in cases where the echocardiogram shows no abnormality.

It is inconceivable that there are no routine multidisciplinary preoperative conferences held with all services' representatives present to discuss operative plans in detail. When these conferences were held at the DPCS (albeit rarely), the inexperienced junior surgeon was left as the sole surgeon to deliberate on the most complex cardiac surgical procedures and plans. This was counterproductive in many instances.

The Commission also received reports that patients had been left in the operating room with the junior surgeon while the participating senior surgeon had already traveled out of town with evident disregard for any potential patient complication. The Commission holds the very strong opinion that it is not ethical to leave the patient in the operating room and leave town prior to bringing the patient to the intensive care unit, establishing patient stability, and ensuring there are no complications or that any complications can be satisfactorily dealt with by the remaining surgical team.

The Commission also learned that some DPCS team members reportedly slandered and were unfairly or falsely accusing their coworkers. Not only would this be morally and ethically unacceptable, but these actions might even be subject to Slovenian legal investigation.

These are just a few examples of the deviations from the standards of excellence for quality care that were uncovered by the Commission. These are representative examples of the unacceptable quality of care of the pediatric cardiac services in Ljubljana.

The Commission finds the quality of care at the UKC in Ljubljana to be **unacceptable**.

3. Quality Measures for Congenital and Pediatric Cardiac Surgery (Ref 85)

1. Participation in a National Database for Pediatric and Congenital Heart Surgery
2. Multidisciplinary rounds involving multiple members of the healthcare team
3. Availability of Institutional Pediatric ECLS (Extracorporeal Life Support) Program
4. Surgical volume for Pediatric and Congenital Heart Surgery: Total Programmatic Volume and Programmatic Volume Stratified by the Five STS-EACTS Mortality Categories
5. Surgical Volume for Eight Pediatric and Congenital Heart Benchmark Operations
6. Multidisciplinary preoperative planning conference to plan pediatric and congenital heart surgery operations
7. Regularly Scheduled Quality Assurance and Quality Improvement Cardiac Care Conference, to occur no less frequently than once every two months
8. Availability of intraoperative transesophageal echocardiography (TEE) and epicardial echocardiography
9. Timing of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients
10. Selection of Appropriate Prophylactic Antibiotics for Pediatric and Congenital Cardiac Surgery Patients
11. Use of an expanded pre-procedural and post-procedural “time-out”
12. Occurrence of new postoperative renal failure requiring dialysis
13. Occurrence of new postoperative neurological deficit persisting at discharge
14. Occurrence of arrhythmia necessitating permanent pacemaker insertion
15. Occurrence of paralyzed diaphragm (possible phrenic nerve injury)
16. Occurrence of need for postoperative mechanical circulatory support (IABP, VAD, ECMO, or CPS)
17. Occurrence of unplanned reoperation and/or unplanned interventional cardiovascular catheterization procedure
18. Operative Mortality Stratified by the Five STS-EACTS Mortality Categories
19. Operative Mortality for Eight Benchmark Operations
20. Index Cardiac Operations Free of Mortality and Major Complication
21. Operative Survivors Free of Major Complication

C. Summary of Commission's findings when compared to international guidelines and standards for surgical care of children with congenital cardiac anomalies

The chart below represents the summary of the Commission's findings.

The first column is a brief description of standard of care. The second column describes the narrative explanation how this standard of care should be implemented. In the third column there are specific expectations that should have been implemented at DPCS in Ljubljana. The fourth column describes the Commission's actual findings and concerns. The last column represents the Commission's grade regarding the compliance and Quality assessment.

Legend:

	Definition	
	Unacceptable	No adherence to the standards of care
	Poor	Limited evidence to adherence to the guidelines and standards of care provided
	Acceptable	Confirmation of adequate adherence provided, however some discrepancies exist
	Good	Evidence of implementation of standards of care is good, some minor variance present
	Excellent	Compliance with the standards is exceptional

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
1 S1	Participation in a systematic multi-institutional database (registry) for cardiac surgery	Participation in at least one multi-center, standardized data collection and feedback program that provides regularly scheduled reports of the individual center's data relative to national multicenter aggregates and uses process and outcome measures.	There were multiple requests from 2007 to participate in EACTS pediatric database. It was finally agreed and accepted that the data would be continuously entered starting no later than January 2013 (Ref 45).	Not a single entry of data was ever made into the EACTS database until the Audit. Commission members entered the data for 2012.	Despite multiple requests and agreements, the designated and responsible members of the DPCS failed to follow the recommendations.	Unacceptable (1)
2 P1 A27	Participation in preoperative multidisciplinary conference involving cardiology, cardiac surgery, anesthesia, and critical care to plan surgical cases	Occurrence of weekly multidisciplinary meeting involving multiple members of the healthcare team, with recommended participation including but not limited to: cardiac surgery, cardiology, critical care, anesthesiology, primary caregivers, family, nurses, pharmacist, and respiratory therapist.	Written protocols and registry of attendance and activities for weekly conferences to carefully plan patient care with physicians, chief ICU head nurse, social worker, and the lead surgeon should be present. Multidisciplinary conference should be pathway driven (assessment post-op care...etc.)	Routine weekly conferences occurred very rarely; the lead surgeon has not been attending these conferences most of the time; anesthesia physicians were rarely present in these meetings, very poor communication among physicians.	From the interviews there was little if any evidence that the pediatric cases were properly discussed prior to surgery among all the pediatric team members. In absence of the lead surgeon it was difficult for cardiology and ICU specialists to get proper answers. The Commission was not given any written documentation as evidence of multidisciplinary meetings.	Unacceptable (1)
3 S2	Multidisciplinary rounds involving cardiology, anesthesia, cardiac surgery, and critical care	Occurrence of daily multidisciplinary rounds on pediatric and congenital cardiac surgery patients involving multiple members of the healthcare team, with recommended participation including but not limited to: cardiac surgery, cardiology, critical care, primary caregiver, family, nurses, pharmacist, and respiratory therapist. Involvement of the family is encouraged.	The DPCS was expected to have daily multidisciplinary rounds with anesthesia, pediatric surgery, critical care physicians and nurses where care and plan for each individual patient is discussed. The Commission expected to find the written protocols to assure quality measures including daily rounds.	There was limited evidence that there was even an attempt to conduct daily multidisciplinary rounds. There was evidence that some physicians were not even talking or communicating with each other.	The Commission did not get the feeling that there was an outreach to organize this format of rounding. The Commission was very concerned with this deviation of standards, since there should be regular communications between the surgical team, cardiology and critical care team to avoid any complications, delayed procedures and to perform surgical interventions in timely fashion. In addition the Critical care team and cardiology sometimes were not informed in detail about the finished surgical procedure.	Unacceptable (1)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
4 P2	Regularly Scheduled peer review Quality Assurance and Quality Improvement Cardiac Care Conference	Occurrence of a regularly scheduled (no less frequently than once every two months) Quality Assurance and Quality Improvement Cardiac Care Conference to discuss care provided to patients who have undergone pediatric and congenital cardiac surgery operations, including reporting and discussion of all major complications and mortalities, and discussion of opportunities for improvement. A "Quality Assurance and Quality Improvement Conference" is also known as a "Mortality and Morbidity Conference" (M and M Conference).	Optimal compliance would have been to have the occurrence of a regularly scheduled Quality Assurance and Quality Improvement Cardiac Care Conference at least once per month to discuss complications and how to improve the services, since the program lead surgeon was not present daily.	There was no evidence or assurance presented to the Committee that this quality-measure conference ever occurred. No written reports or confirmation were given by UKC.	Members of the Commission were not presented with any written documentation about the protocols for the quality assurance conference. There was no confirmation during the interviews that the framework or plan to conduct such a conference even existed.	Unacceptable (1)
5 P3	Availability of intraoperative transesophageal echocardiography (TEE)	Availability of intraoperative transesophageal echocardiography (TEE) and appropriate physician and sonographer support for pediatric and congenital cardiac operations. Epicardial echocardiography should be readily available for those patients in whom TEE is contraindicated or less informative. Availability means presence and availability of equipment and staff.	Intraoperative TEE availability 24/7, including staff.	Most of the time the intraoperative TEE was available.	The Commission members were warned that on some occasions there was the refusal of the staff to provide the ECHO surveillance in the operating room. Although it appears that TEE is readily available intraoperatively, the Commission raises serious concern regarding the possibility of staff refusing to conduct the intraoperative TEE. This could pose severe compromise to the treatment of children where ECHO is needed to make intraoperative surgical decisions.	Poor (2)
6 S3	Availability of institutional pediatric ECLS (ExtraCorporeal Life Support) Program	Availability of an institutional pediatric Extracorporeal Life Support (ECLS) Program for pediatric and congenital cardiac surgery patients. Measure is satisfied by availability of ECMO equipment and support	Written protocols and audits of compliance, quality measures and reports, Periodic analysis of results (mortality and morbidity), participation in the national or	The Commission was provided with evidence that ECMO was readily used. However, there were not sufficient collaborations among different specialties in	Although the ECMO is available and readily used, the Commission was not privileged to see the written protocols, the standards for staff credentialing and certification. There were no databases for ECMO presented to the	Poor (2)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
		staff, but applies as well to Ventricular Assist Devices (including extracorporeal, paracorporeal, and implantable devices).	international Data registry, availability of properly trained and certified personnel who can safely administer ECMO therapy, (credentialing protocols, familiarity with cannulation), availability for other assist devices and properly credentialed personnel.	management of patients on ECMO. No quality measure written reports were presented to the Commission. Occasionally prolonged support was unnecessarily implemented. No implantable assist devices for children were readily available.	Commission. There was limited evidence about the clinical interdisciplinary relationship in managing ECMO patients. The Commission has serious concerns about the suggestions that occasionally the children were placed on prolonged ECMO support since the senior surgeon was not available. Results: as per Critical care MDs, only 25% survival!	
7 S5	Surgical Volume for Eight Pediatric and Congenital Heart Benchmark Operations	These 8 Eight Benchmark Pediatric and Congenital Heart Operations are tracked when they are the Primary Procedure of an Index Cardiac Operation (VSD, TOF, AVC, ASO, ASO+VSD, Fontan, Truncus Art., Norwood).	Sufficient volume of these procedures per year is required for a center to be considered capable of operating on the most difficult and complex pediatric cardiac procedures with acceptable results (Ref 100).	Very small volumes of these procedures performed in DPCS in Ljubljana per year (in 2012, only 25 such procedures).	Although Dr. Mishaly is capable of performing 8 benchmark operations with acceptable results since he operates in another center as well, the rest of the DPCS physicians and supporting staff do not have enough exposure to the sufficient volume of these surgeries to achieve or maintain the required skill.	Unacceptable (1)
8 S4 C6	Surgical volume for Pediatric and Congenital Heart Surgery	Each pediatric surgical center should perform at least 400 pediatric surgical procedures each year (GB), 250 (EU) equally distributed between 4 (GB); 2-3 (EU) congenital cardiac surgeons to avoid occasional practice.	To comply with European stands DPCS UKC should, optimally, have at least 200 – 250 pediatric cardiac surgical procedures distributed between 2 -3 pediatric staff cardiac surgeons. Data should be submitted to EA CTS. The service must provide enough staff to provide a full 24 hour emergency service within legally compliant routs.	There were 93 operations on 73 children at DPCS in 2012 by the Commission's database. The center was insufficiently staffed with one senior surgeon available only 3 days a month and a junior pediatric cardiac surgeon inadequately trained to undertake and perform the most complex congenital cardiac operations.	The Commission was extremely concerned about the arrangement of surgical staffing at the DPCS in Ljubljana. Not that the service did not meet the criteria and standards, in addition was not able to deliver a full 24 hour emergency service with a senior fully-trained pediatric cardiac surgeon. The DPCS in Ljubljana did not meet the standard for the minimum caseload. Data submitted to EA CTS for the period 2007–2014 show fewer than 100 operations per year for all 7 years.	Unacceptable (1)
9 P4	Timing of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients	Measure is satisfied for each cardiac operation, when there is documentation that the patient has received prophylactic antibiotics within the hour immediately preceding surgical incision (two	Written protocols and audit of compliance.	Antibiotics delivered appropriately, however some discrepancies of opinion between surgery and critical care physicians about duration and	The Commission recognizes the fact that the antibiotics are tailored for each individual patient, however there should be a consensus among the physicians caring for the patient adjusted to the	Acceptable (3)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
		hours if receiving Vancomycin).		occasionally types of antibiotics.	characteristics of antibiotic sensitivity of individual institutions.	
10 P6	Use of an expanded pre-procedural and post-procedural "time-out"	Measure is satisfied for each cardiac operation when there is documentation of performance and completion of an expanded pre-procedural and post-procedural "time-out" (A Cardiac Operation is defined as an operation or operation type "CPB" or "No CPB Cardiovascular");).	Written protocols and evidence of compliance.	No written protocols were provided to the Commission for this measure. During the interviews there were no disclosures of conducting time-out prior and upon completion of surgery.	The timeout is designed to avoid possible complications, surgical site misallocations, to assure that every team member understands and agrees with the surgical procedure, to assure that antibiotics are given in timely fashion... No Timeout conducted, no written protocols, no documentation of timeout given.	Unacceptable (1)
11 O1	Occurrence of new post-operative renal failure requiring dialysis	For each surgical admission (Index Cardiac Operation) code whether the complication occurred during the time interval beginning at admission to operating room and ending 30 days post-operatively or at the time of hospital discharge, whichever is longer.	Written protocols and evidence of compliance. Database reporting.	No relevant data were reported regarding renal failure in any verifiable database.	This and other variances in compliance again demonstrate the unsafe and dangerous practice for children at the DPCS in Ljubljana.	Unacceptable (1)
12 O2	Occurrence of new post-operative neurological deficit persisting at discharge	For each surgical admission (Index Cardiac Operation) code whether the complication occurred during the time interval beginning at admission to operating room and ending 30 days post-operatively or at the time of hospital discharge, whichever is longer.	Written protocols and evidence of compliance. Database reporting.	No relevant protocols for evaluating the major adverse events or data were reported regarding neurologic events at the DPCS in Ljubljana. Only one report (Ref 46) suggested a 2.7 stroke rate, however it could not be verified by the Commission.	Yet another variance of compliance reflecting the unsafe and dangerous practice for children at the DPCS in Ljubljana. The true stroke rate or percentage of neurologic deficit for children undergoing pediatric cardiac surgery in Ljubljana is not reported and not known.	Unacceptable (1)
13 O3	Occurrence of arrhythmia necessitating permanent pacemaker insertion	For each surgical admission (Index Cardiac Operation) code whether the complication occurred during the time interval beginning at admission to operating room and ending 30 days post-operatively or at the time of hospital	Written protocols and evidence of compliance. Database reporting.	No relevant protocols for evaluating the major adverse events or data were reported regarding arrhythmias.	This adverse event or complication is completely unknown for DPCS in Ljubljana.	Unacceptable (1)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
		discharge, whichever is longer.				
14 O4	Occurrence of paralyzed diaphragm (possible phrenic nerve injury)	For each surgical admission (Index Cardiac Operation) code whether the complication occurred during the time interval beginning at admission to operating room and ending 30 days post-operatively or at the time of hospital discharge, whichever is longer.	Written protocols and evidence of compliance. Database reporting.	No relevant protocols for evaluating the major adverse events or data were reported regarding diaphragm paralysis.	This adverse event or complication is completely unknown for DPCS in Ljubljana.	Unacceptable (1)
15 O5	Occurrence of need for postoperative mechanical circulatory support (IABP, VAD, ECMO, or CPS)	This complication should be coded even in the situation where the patient had preoperative mechanical circulatory support if the patient has mechanical circulatory support postoperatively at any time until 30 days postoperatively or the time of hospital discharge, whichever is longer.	Written protocols and evidence of compliance. Database reporting.	Some data was reported regarding the ECMO or MCS at the DPCS in Ljubljana. There was no structure outline, specific database documenting ECMO need and analysis, or data reporting received from DPCS in Ljubljana.	Some data regarding ECMO were reported; however the indications and complications are poorly defined and documented.	Poor (2)
16 O6	Occurrence of unplanned reoperation and/or unplanned interventional cardiovascular catheterization procedure	This measure counts all patients who require any additional unplanned cardiac or non-cardiac operation and/or interventional cardiovascular catheterization procedure occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention.	Written protocols and evidence of compliance. Database reporting.	No relevant protocols for evaluating the major adverse events or data were reported regarding unplanned re-interventions after surgery.	There were at least 4 unplanned emergent chest reopening procedures and additional 6 major complications according to one database (Ref 15). However these data were not properly reported and could not be verified. According to another data report there were 32 reoperations of 555 congenital surgical procedures (5.7%). These data could also not be verified by Commission.	Unacceptable (1)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
17 O7	Operative Mortality Stratified by the Five STS- EACTS Mortality Categories	Operative mortality stratified by the five STS-EACTS Mortality Categories, a multi-institutional validated complexity stratification tool See J Thorac Cardiovasc Surg 2009;138:1139-1153 O'Brien et al. An empirically based tool for analyzing mortality associated with congenital heart surgery. Table 1, pp 1140-1146. and Ref 163	Written protocols and evidence of compliance. Database reporting.	No reported mortality regarding the stratified 5 operative categories.	No accurate mortality rates could be extrapolated or analyzed from any database. The data inconsistency and inaccurate data entry deprived the Commission of any relevant conclusions for mortality.	Unacceptable (1)
18 O8	Operative Mortality for Eight Benchmark Operations	These 8 Eight Benchmark Pediatric and Congenital Heart Operations are tracked when they are the Primary Procedure of an Index Cardiac Operation. (These 8 Eight Benchmark Pediatric and Congenital Heart Operations are listed and described in this table in Measure Number 7 , S-5.)	Written protocols and evidence of compliance. Database reporting.	Data entry errors, inconsistencies with data merging, transfers and surgeon codes prevented the Commission from reporting any accurate or relevant mortality.	The Commission was unable to analyze or report accurate mortality for any of the databases. In 2012 there were 2 perioperative and 4 total deaths on 73 operated patients. However this number is relevant only to number of 93 operations (Ref 18) the Commission was privileged to review from given charts. After the Commission's departure in July 2014 it became apparent that during the same year 2012 there may be an additional 12 patient charts missing (Ref 15). The mortality from databases (Ref 48 and 51) could not be verified.	Unacceptable (1)
19 5.2 (Ref 91)	Facility structure Surgical leadership	Institutional structure CHS units of high specialization in dealing with the 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). This Head of Department should be entrusted with educational and	Evidence of compliance and structure.	The DPCS is housed in the most modern facility with the most modern equipment. The Commission learned there was an inexperienced head of the DPCS who lacked proper qualifications. The leadership of DPCS was very fragmented. The surgeon in charge did not possess credentialing of 5 years' clinical practice as a board-	The Commission was stunned to learn that from academic administrative and surgical leadership, a junior pediatric heart surgeon (PHS) was put in charge of an entire structure of the center. Clearly this junior PHS was not capable of organizing and leading complexity of the service and not possessing adequate experience or training as a surgeon or the leader to be competent or capable of making difficult strategic or clinical decisions.	Facility structure Excellent (5)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
		scientific responsibilities, and should possess a minimum experience of 5 years clinical practice as a qualified CHS surgeon. He/she should preferably possess academic qualifications. Such a unit 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.		certified Congenital heart surgeon. The department was integral part of adult cardiac surgery.		Surgical leadership Unacceptable (1)
20 C 3 C 9	Supporting staff Nursing	Each pediatric cardiac cardiology center will provide nursing support with specific skills and additional training in pediatric care geared toward the unique requirements for different elements needed to care for children with cardiac congenital anomalies.	Evidence of compliance.	The nursing care for the patients was good. Very dedicated nursing team, however disconnected when the need arose to give information to the child's family, sometimes lacked availability to the families.	The Commission found sufficient evidence that the nursing care is in compliance with standards of care and routine continuing education in the majority of cases. The Commission gained reports from families that nurses' communications to the families were not always friendly and were sometimes sloppy and argumentative.	Acceptable (3)
21 5.3.7 (Ref 91)	Pediatric hospital	Dedicated beds within a larger cardiac ICU should be pooled geographically in order to guarantee expertise from the pediatric medical and paramedical staff. The nurse/patient ratio in this ICU should be 1/1 full-time equivalent for difficult patients and 0.5/1 for simpler patients.	Evidence of compliance and structure.	DPCS is equipped with state-of-the-art 14 bed ICU. Very dedicated and caring nursing team. Commission did not observe any deviations in the ICU structure or equipment.	There is evidence of compliance with standards of care and a good grasp of needs and requirements for service excellence and care delivery.	Excellent (5)
22 5.3.4 (Ref 91)	Pediatric cardiac critical care Physicians	A very specialized team of intensivists with proper credentialing and certification to take care of the most complex and critical pre and postoperative pediatric patients with congenital cardiac anomalies.	Evidence of certification of training and level of clinical experience. The ICU staff should include a medical director who should have fellowship training, experience, and	Copies of documentation of training not readily available. However, team is very experienced, well organized with 24/7 in-house coverage. Medical director has a good	The Commission learned of some discrepancies and different opinions within the ICU team about standards of care by the surgical team. The medical director of Intensive care unit was not respected by the junior cardiac surgeon. The particular	Pediatric Intensive care MDs Good (4)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
			specific expertise in the postoperative care of pediatric heart patients.	grasp of the problems that existed from 2007 through 2013 with surgical care and the lack of senior staff surgeon.	multidisciplinary approach to pediatric cardiac patients care was not optimal.	Interpersonal relationships Poor (2)
23 A 20 C 8	Pediatric cardiology	The children's cardiology will provide all of the noninvasive services (EKG, chest X-Rays, tele monitoring, exercise testing, ECHO). The staff has to be appropriately trained and credentialed. Each Specialist Surgical Center must be staffed by a minimum of 1 consultant pediatric cardiologist per half million population served.	Evidence of compliance and certificate of training and credentialing.	The Commission learned of some direct complaints about pediatric general cardiology. There were complaints from the family members about no availability to the families, especially over the weekends by cardiology staff and regarding no ECHO staff in the departments over the weekends. Only on home call, for emergencies.	Although in general there were good reports about pediatric cardiology, the Commission is concerned that children have to wait in the hospital for 2-3 days over the weekend to get ECHO until Monday or Tuesday instead of being discharged if ECHO was available. Also concerning were the complaints that some on-call physicians are not family friendly and not readily available to the families to give patient's condition updates. There are sufficient cardiologists for the Slovene population of 2 million people.	Acceptable (3)
24 (Ref 88, p 545)	Pediatric interventional cardiology	A board-certified pediatric interventional cardiologist should direct the pediatric catheterization laboratory, should gather data prospectively to document quality of care, and should lead M + M. Catheterization-related mortality rates much less than 1% are achievable, and major complications less than 3% are also attainable. Another study showed that fewer than 4% of transcatheter interventional procedures should require surgical intervention.	Compliance with standards, guidelines and evidence of certification should be available.	The Commission was not privileged to the results of cardiology service since this was not the focus of the Audit. There is only one interventional senior pediatric cardiologist. One interventional cardiologist trainee is also part of the team. Trainee does not have enough interventions per year, although trained in Munich for 6 months.	The Commission's concern is that there may potentially be a gap in interventions when the senior staff is absent. Another concern there is to slow educational process for young trainee and there are no written protocols and timetables for mentorship of fellows. There were, occasionally, some complaints about lack of availability of cardiac interventional cardiology. However, in general there were no major complaints about their dedication and the quality of service provided to the children by interventional cardiology service.	Acceptable (3)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
25 C 16 5.3.3 (Ref 91)	Pediatric cardiac anesthesia and perfusion	A specialized team of anesthetists 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 theater contribute to a favorable outcome. Proper training and certification needed.	Certificate of training and evidence of compliance.	Only one pediatric cardiac surgery dedicated anesthesiologist. There are two additional pediatric anesthesiologists providing cardiac pediatric anesthesia. There are adequate number of trained pediatric perfusionists familiar with ECMO.	The Commission is concerned there may be a potential problem if the chief trained pediatric anesthesiologist is absent for a prolonged time. Difficult call schedule, especially during condensed 3 days of surgeries if there are reoperations or other complications. The small number of surgeries posed the risk of occasional practice without good possibility for skill maintenance.	Acceptable (3)
26 5.2 (Ref 91)	Pediatric cardiac surgical leadership	Head of Department should be entrusted with educational and scientific responsibilities, should possess academic qualifications and should provide leadership in clinical network. This includes managing and developing referral, care, transfer protocols, policies and procedures and lead effective multidisciplinary team working	Evidence of compliance and credentialing.	No convincing evidence of true leadership. At DPCS, the chief of CT surgery who was in charge never visited DPCS-even in crisis. The pediatric surgical department was led by inexperienced, insufficiently trained junior surgeon. The senior surgeon did not have input into structure and daily activities, since he was present only 3 days a month in the department.	The Commission was privileged to the information that the junior surgeon did not possess the adequate knowledge how to lead such an organization. His interpersonal skills did not include the elements and qualities of a level 5 leader. There was no effective interdisciplinary communication. The senior locum surgeon was only operating 3 days/month and the Commission did not receive information or evidence of the senior surgeon's desire to build a true DPCS center and train and educate the residents or the staff of the center.	Unacceptable (1)
27 4.2 (Ref 91)	Pediatric cardiac 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	Evidence of adequate training, certification and compliance.	The senior pediatric locum cardiac surgeon at DPCS in Ljubljana is an established surgeon in a center with 350 pediatric cardiac surgical procedures per year. Possesses a foreign license and received Slovene license in 2012. Experienced in operating complex congenital pediatric and GUCH cases. The Commission was	The Commission believes this element is the crucial component of the Collapse of the DPCS in Ljubljana. Although the senior experienced surgeon operated on complex cases and the junior on the less difficult ones, the inexperience, pressure in decision making, insufficient training and unavailability of the senior surgeon for the mentorship and support 90 % of the time, led to wider gap between ICU staff, Critical care	Unacceptable (1)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
		surgical field of a congenital heart surgeon includes all corrective, palliative and minimal invasive procedures of the heart, pericardium and great vessels.		not privileged to obtain his personal results. The junior cardiac surgeon in charge of DPCS did not provide the specific operative log numbers or results of his operations either during training or from operating as a primary surgeon. The 2nd trainee of the DPCS did not operate sufficiently and was not included in making various decisions, therefore he left the DPCS and the country.	Physicians on one side and surgery service on the other. Due to frustration and major concerns of pediatric cardiology and critical care physicians about the safety of the operated children the service finally collapsed.	
28 6.0 (Ref 91)	The surgeons' workload and volume	The surgeon carries the main responsibility for the outcome and thus for the inner organization, surgical treatment and peri-operative care. From experience, most congenital heart surgeons should perform around 125 operations a year. In order to guarantee a responsible surgeon the optimal working conditions around the clock - all year, 2-3 fully qualified surgeons should be employed in any DPCS.	Evidence of compliance and written protocols. Presence of at least two fully-trained surgeons. A surgeon should perform a bare minimum of three surgical procedures per week. Considering 42 weeks' annual activity, the total surgical output for a surgeon is 126 operations.	Insufficient volume of surgeries per year. For junior pediatric cardiac surgeon it was impossible to gain adequate experience in management and surgical skill and expertise. Inadequate constructive communication between the service for postoperative care of children.	The Commission is extremely concerned about the lack of understanding and the lack of response from leadership about warnings and reports of sustainability of the DPCS under previous arrangement (under review). There was no attempt to change the structure, although it was clearly evident that the safety of children was compromised and surgical volumes were insufficient. This eventually led to complete collapse of the DPCS, loss of trust from multidisciplinary physicians, committees, and families and eroded public opinion.	Unacceptable (1)
29 4.4 (Ref 91)	Multidisciplinary team work	The surgical treatment of children with CHD implies an excellent partnership with a team of pediatric cardiologists. The strength of this partnership is a general vector to optimize the quality of any CHS unit. It should be permanently maintained through	Expectation is to have a collaboration between all disciplines of the team caring for congenital cardiac patient; anesthesiologists, intensive care doctors, neonatologists, pediatric	The Commission was left with the impression that there was poor collaboration between the DPCS team members, especially between pediatric cardiac surgeons and intensive care physicians, and between pediatric	The Commission realizes that the Center's quality, continuing learning, motivation, moral and working enthusiasm depend on healthy working environment, sense of belonging to the team or center, camaraderie which eventually leads to great success and excellence. However, there was little	Poor (2)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
		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.	cardiologists and interventional cardiologists, pediatricians, surgeons perfusionists, scrub nurses, ICU and ward nurses, administrators, etc.	cardiac surgeons and interventional cardiology. This poor collaboration is exemplified by certain physicians who are no longer on speaking terms.	evidence observed of this requirement at DPCS. This observation leads to Commission's concern about children's safety intraoperatively and postoperatively due to inconsistencies of surgical communications with other team members.	
30 7.0 (Ref 91)	GUCH (grown-up congenital heart disease) surgical patients	Large cardiac surgery centers also specialize in taking care of adult patients who were operated on for congenital cardiac defects as children or who require surgery as adults. This patient population requires a specialized adult cardiologist and cardiac surgeon trained in congenital and postoperative care of adult cardiac patients with congenital cardiac defects.	Expectation of training, certificate and familiarity with these subpopulation of patients.	The Commission was given explanations about the pathways of following these adults at DPCS. There is a specialized cardiologist trained for care of these patients in Ljubljana. However, there is no adult cardiac surgeon trained for GUCH patients at <u>DPCS in Ljubljana</u> . There is also evidence and desire to improve and train the cardiology staff and nursing staff for this capacity.	Concern of the Commission is that there is insufficient experience for taking care of GUCH patients due to low annual volume. In 2012 there were 18 such patients operated in the clinical center of Ljubljana. The Commission also learned these patients are postoperatively placed on the adult patient ward where the nurses may not be adequately trained for GUCH patients care. The Commission expressed the need to improve these services in the future.	Acceptable (3)
31 8.0 (Ref 91)	Evaluation of quality of care and M + M	Every department should perform internal and occasional external surveillance for quality control. For pediatric cardiac surgery, the gold standard is reporting the data routinely to the EA CTS registry database. In addition, the centers should have routine M + M conferences to analyze and discuss constructively the reasons for mortality and complications, to identify the root causes, and to avoid repeating mistakes or process deviations in the future.	To have written protocols and evidence of conducting such meetings and quality reviews. There should be written reports of such analysis and root cause reviews. The European Cardiovascular and Thoracic Surgery Institute of Accreditation (ECTSIA) certifies the pediatric cardiac surgery centers and the center cannot be accredited without this quality measure.	The Commission did not find any evidence of the DPCS conducting these audits, reviews, or meetings. It is the Commission's assumption therefore, that DPCS in Ljubljana was not accredited by ECTSIA. There was no evidence provided to the Commission regarding accreditation.	The Commission is very concerned about the lack of such conferences and quality control. This may be another crucial insufficiency that most likely led to the collapse of the Center. The Commission is also concerned that there were no plans for having these routine quality of care audits in the future. Lack of results, analysis and quality control poses serious danger and safety risk for pediatric patients.	Unacceptable (1)

# Ref	Standard of Care Criteria	Standard of care Description/explanat ion	Expected measures at UKC DPCS	DPCS compliance / deviations	Commission Concerns	Quality Analysis rank/grade
32 9.2 (Ref 91)	Education and surgical training	Special training in CHS in order to qualify for independent position needs in Europe a minimum duration of 3 years in addition to completion of residency in general as well as cardiothoracic and possibly vascular surgery. During the training in CHS, a comprehensive knowledge of the entire field of CHS must be offered to the trainee. Surgical trainees who specialize in CHS with the aim of qualifying as an EBTCS approved surgeon should have had their specialized education in units recognized and authorized for training in CHS.	Compliance with standards and requirements for board eligibility. Evidence of written protocols and programs for training and resident rotations.	There were two trainees at UKC in Ljubljana designated for pediatric cardiac surgery starting in 2007. There is existing evidence there was not equal opportunity given to both trainees over same period of time. There was not a single written protocol detailing the requirements of the program for trainees, their rotations through different departments, and modalities of routine knowledge evaluations and surgical expertise gained. This led to departure of one of trainees from the center and out of the country. The other trainee completed his cardiac surgery boards in 2009. There is no evidence as of how many surgery cases he performed. The Commission officially asked for this information, but did not get the data. The senior surgeon had adequate experience and surgical training, however complete lack of leadership and mentorship.	The Commission has serious concerns about qualifications and training of the junior surgeon. The lack of operative logs, avoidance of providing this information, especially the knowledge of the numbers of exposures and actual performance of complex surgeries under organized mentorship, lack of intention to educate and form an independent, confident, safe and mature pediatric cardiac surgeon by the senior pediatric cardiac surgeon, leads the Commission to the conclusion there was no real intention to complete the junior surgeon's training and graduate him. There are documents proving serious lack of critical decision making ability and maturity about timing of the operative procedures, especially in urgent or emergent situations. Inertia to deliver the case logs to the Commission despite multiple requests mirrors the fear of uncovering the inadequacies and insufficiencies of the training, mentorship, and proper education. There is no documentation regarding the quality of organized training received while the trainee was for 1 year abroad.	Unacceptable (1)
33 10.0 (Ref 91)	Research programs	Every active pediatric cardiac surgical unit should be involved in research activities and participate in national and international meetings. Very active research consists of interactions with basic	Participation in research activities is essential for growth and contribution to the field of medicine.	Although the Commission did not focus specifically on the research, there is evidence in the form of a few publications that there was some	The Commission was not privileged to abundant information about research activities in the DPCS at UKC in Ljubljana. The few publications speak of some activity in research and retrograde chart	Acceptable (3)

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		scientific departments, provides opportunities for clinical studies, and preclinical laboratory testing and studies.		activity in the research and publications from DPCS.	reviews.	

Legend: S = Ref 85; P = Ref 85; O = Ref 85; A, = Ref 86.

D. Conclusion summary

During the past few years, the families and broader public in Slovenia experienced a lack of homogeneous, high-quality care of children with congenital cardiac anomalies in Ljubljana. In addition there was disorganization of the services within the DPCS of UKC in Ljubljana and high tensions existed with several interpersonal relationships among various members of the team.

The collaboration between all services caring for children with congenital cardiac anomalies is crucial for the excellence of care. The lack of collaboration among different departments was clear; however, this extended into the personnel manning these individual departments. The Commission discovered that in some instances the collaboration between staff physicians at the DPCS in Ljubljana did not even exist or it was severely eroded. These problems originated in the beliefs of pediatric cardiology and pediatric critical care physicians that the pediatric cardiac surgical services were providing unsafe practices and care to the children with congenital cardiac anomalies. One of the major causes of these feelings was the unavailability of an experienced staff pediatric cardiac surgeon on the premises of UKC 90% of the time. The contract between the senior surgeon and UKC Ljubljana agreed to have this expert surgeon operating in Ljubljana 3 days out of the month. When he was not present in Ljubljana, the entire service was led by an inexperienced trainee from 2007 through 2009 and continued afterwards until 2013 to be headed by the same insufficiently trained and inexperienced young surgeon. In addition, it became apparent that this individual did not possess adequate surgical skill and expertise to provide safe and adequate care to congenital cardiac patients while the senior pediatric cardiac surgeon was abroad.

In addition to these causes of dissatisfaction for cardiology and intensive care physicians was the fact that there was no real attempt by the experienced cardiac pediatric surgeon to mentor and train the junior surgeons. The excuse was that there were an inadequate number of potential surgical cases to be given to the young surgeons for mentoring.

A minimum number of 250 operations per year has been published and is accepted to be adequate for complying with standards of care in place to assure good quality and safety for congenital cardiac surgery patients. Unfortunately, the pediatric cardiac surgical services in the UKC in Ljubljana did not meet this minimum standard for surgical caseloads and averaged less than 100 surgeries per year from 2007–2014.

To maintain the skillset required to be a proficient and safe pediatric cardiac surgeon, a surgeon should perform over 100 surgical procedures per year. This guideline and standard for adequate surgical numbers was not met in DPCS in Ljubljana by the junior cardiac surgeon. The senior surgeon operates in his own institution outside of Slovenia and is performing more than 125 pediatric cardiac surgical procedures per year, thereby superseding this criterion.

The failure to meet these standards was reported to the administration on multiple occasions. The Commission has deep and serious concerns that the safety of some children may have been compromised due to lack of compliance with these standards of care. This lack of compliance continued even after previous internal review warnings took place two years ago, and a previous internal audit revealed serious deficiencies in the DPCS at UKC in Ljubljana.

Even though these insufficiencies were made abundantly clear for many years, the UKC leadership only stopped the unsafe practices of the surgical team and ceased the pediatric cardiac surgery services in UKC

Ljubljana after a letter, written to the Slovene Ethics Commission in December 2013, suspended support to pediatric cardiac surgeons by collaborating physicians.

The current affiliation (as at the time of the Audit) with the Munich pediatric congenital cardiac surgery center is a better and safer solution for these Slovene children at present. However, the Commission does not believe that this is an optimal long-term solution. It does not provide 24/7 surgical coverage in case of emergencies; there is at least a 4–6 hour travel gap, and no trained pediatric cardiac surgeon is available in case of emergency or if a patient is hemodynamically unstable and ineligible for transport.

The discussions about alternative attempts to bring another pediatric cardiac surgeon to Ljubljana, or to collaborate or affiliate with another Pediatric cardiac center outside of Slovenia are still in early stages of negotiations at the time of the Audit.

The Commission is further concerned that, if the pediatric cardiac surgery services cease to exist in Ljubljana for a prolonged period of time, the pediatric interventional cardiology department will not realistically be able to meet the international safety standards required. The Committee recognizes that the current pediatric interventional cardiologist at the UKC is very skillful and experienced. He clearly cares for the children with the congenital cardiac anomalies. This is evident from multiple letters written to the administration and to the medical leadership of UKC where he expressed his deep concerns about the quality and safety of surgical department.

However, the Commission learned that he is the only senior interventional cardiologist currently available for the entire center. With only one senior staff interventional cardiologist on the service, it is not realistic to be able to deliver 24/7 uninterrupted patient care in compliance with the international standards. Since interventional cardiology requires a surgical backup, and there is no pediatric cardiac congenital surgery service now at UKC Ljubljana, the Commission's conclusion is that not only does staffing not meet the standard of practice criterion, but safety standards may be compromised without the surgical availability. *If the congenital cardiac surgery cannot be reinstituted in the DPCS at UKC Ljubljana, the interventional cardiology may require cessation of its services, as well.* In a similar fashion, the expertise of pediatric intensive care physicians, anesthesiologists, etc., will be affected because the care of pediatric cardiac patients makes it possible for them to maintain their diagnostic and treatment skills for patients with cardiac failure. These skills are required to care for other pediatric patients in shock. It is, therefore, absolutely essential that a viable and excellent pediatric cardiac surgery service be reestablished at the UKC in Ljubljana, else the UKC risks losing other accredited departments.

V. Recommendations of the Commission

The Commission's Perspective of Danger/Liability of Noncompliance with Standards of Care

Different departments involved in treating children with congenital cardiac anomalies depend on highly trained and qualified professional experts of different services delivering excellent care for each individual patient. The main component of such care is the teamwork approach, professional behavior, trust and excellent communication across the team members of different departments. The isolation, inconsistencies and unorthodox arrangement of surgical services in DPCS in UKC Ljubljana clearly limited the growth and continued skill development of other Service team members and compromised the safety and delivery of standards of care to the children with congenital cardiac defects.

It appears that the leadership at UKC Ljubljana placed the emphasis and importance only on the services requiring technical skills; however, the non-technical skills, collaboration, teamwork training, protocols (specifically for patient safety), and quality assurance of healthcare professionals at the DPCS were completely ignored.

Does the pediatric cardiac surgery have a future in UKC in Ljubljana?

It is definitely possible to construct a new center to provide excellent care for children with the congenital cardiac anomalies in Ljubljana. However, it will require significant efforts to build a pediatric cardiac center able to meet and comply with international standards and provide excellent delivery of patient care for these children. It will, for certain, not be possible to arrange it under the same structure and configuration that existed from 2007 through December 2013. It was this structure that underlined the compromised patient care that was followed by tremendous public outrage.

The future

The specifics that will govern how the congenital cardiac surgical services will be organized in Slovenia and where they will be implemented in the future is the privilege, responsibility, and obligation of the Ministry of Health and the government of Slovenia. How these services are actually performed and structured will most likely be the responsibility of the Medical Chamber of Slovenia in accordance with the medical and administrative leadership of UKC in Ljubljana. This may even involve the oversight by another institution. It is not the role of the Commission to make these decisions. However, the Commission has discussed the possible options for the future of congenital cardiac surgery in Slovenia, and these options are detailed below.

Options for the future

Option 1) Continue with the previous arrangement with a surgeon performing surgery only a few days a month, while the rest of the time the service is dependent on a junior surgeon or a resident. (Since this option has already proven to cause complete turmoil, it should be obvious that this type of arrangement is never to be repeated again.)

Option 2) Status quo – no pediatric cardiac surgery in Ljubljana and send all the surgery to Munich, Germany.

Option 3) Affiliation with a different outside pediatric cardiac center in a similar fashion as with Munich

Option 4) Bring a surgeon from outside and mirror the services from 2004 through 2007

Option 5) Develop pediatric cardiac surgery in Ljubljana under completely different arrangement, with adequate surgical volume and stable structure.

Details of Option 1) This option mimics the dysfunctional arrangement the UKC had with **Dr. Mishaly** in which a locum experienced surgeon operates only 3 days out of the month. This option is not acceptable and listed only as a reminder what should NOT be done. Because this arrangement has led to complete collapse of the pediatric congenital surgical services in Ljubljana, the Commission cannot support even the assumption of this idea and configuration of the service.

Details of Option 2) Continue with the current status quo with the arrangement with Munich. This is a good temporary solution for children in need for surgical corrections of cardiac congenital anomalies. The Commission's concern with this arrangement is the distance the children need to travel for surgical services. Although Munich is 4-6 hours away by ambulance and 1 hour away by air, the distance still possesses a certain risk for patients needing emergent care. No doubt, the services in Munich are excellent and have a highly respected international reputation. However, the Commission can foresee some potential shortcomings and problems with this kind of arrangement. Particularly:

- There exists a potential to disrupt the family quality of life and family dynamics if the length of stay for the pediatric patient is prolonged.
- High expense and cost for the family.
- High economic expense for Slovenia's health care system.
- Problems with schooling and teaching for the children due to a different national language. This is especially the case if the length of stay is prolonged out of medical necessity.
- The current arrangement does not include a surgeon to be stationed in Ljubljana. No Slovene surgeon is fundamentally trained or on staff in Munich.
- With a nonexistent pediatric cardiac surgery service in Ljubljana, the question arises as to where the children would be sent for interventional cardiology procedures, since this service will inevitably cease in the UKC, as well.
- There is no ECMO trained and experienced pediatric surgeon in Ljubljana in case ECMO is needed in emergencies.
- The Commission was not privileged to hear any solid explanations or to see any written protocols between Munich and UKC Ljubljana that outline in detail the steps of collaboration and affiliation with the Munich center. These documents are necessary to assure that the current arrangement is well planned. The Commission has the following concerns regarding sending all children for surgery to Munich: 1) relying on Munich may unintentionally compromise the readiness and response capabilities of medical staff in Slovenia should emergent cases arise; 2) there is only a superficial, but no firm commitment from both sides regarding how young cardiac surgeons from Slovenia will be trained in Munich; 3) there are no current arrangements to have a staff surgeon from Munich perform congenital cardiac surgery in Slovenia for a prolonged

period of time. The additional benefit of a senior cardiac surgeon from Munich operating in Slovenia would, without a doubt, be to provide necessary mentorship to Slovene junior pediatric cardiac surgeons after their training is completed. With this arrangement the non-interventional cardiology would continue with the services in Ljubljana, however the interventional cardiology would return to the pediatric department only upon return of the surgical services.

Details of Option 3) Affiliating the UKC with the pediatric surgery center for cardiac anomalies in Padua, or some other city, is very similar to the arrangement currently made with Munich. The only advantage to affiliating with a hospital center in Padua may be that Padua is slightly closer than Munich. However, the discussions with other hospital centers are still preliminary. Unless this new arrangement is substantially different from the current one with Munich, all the concerns listed above in “Option 2” still exist. The Commission does not recommend this option.

Details of Option 4) Hire a surgeon from the outside and mirror the services that existed in the UKC DPSC from 2004 through 2007. While this option is viable, it is far from ideal. This option has been actively pursued by the UKC. At one time, the UKC recruited a surgeon from Serbia, but this surgeon could not obtain a medical license in Slovenia. The Commission has further concerns about this potential arrangement. There was a suggestion that this surgeon was not completely trained for surgery in the most complex cases. With this in mind, this option could only work if the surgeon is on the premises in Ljubljana and this surgeon remains affiliated and collaborates with a large parent institution. There is no realistic evidence to believe this arrangement would comply with international standards to provide safe services unless the number of cardiac surgeries per year is more than 250, and the infrastructure completely follows international standards and guidelines. The Commission does not recommend this option unless there is the potential to have two or more experienced cardiac surgeons recruited and hired at the same time.

Details of Option 5) The optimal option This option assumes the successful completion of the arrangement with a Munich staff surgeon present for at least 5 years in Slovenia and that 2-3 Slovene pediatric cardiac surgeons will become well trained over the next 3 years. Once these surgeons are fully trained, two other stipulations must be met: 1) Pediatric interventional cardiology must add one or two more staff physicians, and 2) pediatric cardiac anesthesia must expand their service to at least three dedicated anesthesiologists. Only then should the pediatric cardiac surgical services move back to Ljubljana.

Meanwhile, the structure of the new center must be changed, and the infrastructure planning and funding allocation must be developed to support training new surgeons. The new center has to have unconditional support of the Ministry of Health, insurance companies, and institution’s administration and medical leadership.

The new center may have a standalone independent configuration, where all the different subspecialties (pediatric cardiac surgery, pediatric cardiac critical care, pediatric cardiac anesthesia, pediatric cardiology, etc.) caring for population of patients with congenital cardiac anomalies join in the collaboration under the structure of one Center. The leadership of this center would be placed under a single Chief, who is usually - but not necessarily - the chief pediatric cardiac surgeon. The Chief would be responsible for the overall quality of the program, inpatient and outpatient care, the education and training of the entire staff, interdisciplinary collaborations, volume of the center, referral base and growth of the center, moral of the personnel, research, certification and recertification, financial accountability, and other administrative tasks.

This structure is common for larger centers with higher volumes of surgical procedures. These centers would be useful as a model.

The other option is to have the pediatric cardiac surgery services as a sub-discipline of the Department of Cardiovascular Surgery. This service would then collaborate in a tight, close arrangement with the other services caring for children with congenital cardiac anomalies. This configuration is definitely more vulnerable to risks of developing a fractionated services and communications, since it does not have a common and unified structure of governance.

Regardless of the pediatric cardiac service structure, if there is a sincere desire for UKC to develop a new modern center of excellence for treatment of children with congenital cardiac anomalies, there will have to be an unconditional, firm pledge from the government to build such a center with a clearly delineated yearly budget and financial structure for the intermediate 5 years. The government must also commit to continued long-term support. In addition the UKC administrative and medical leadership must commit to execute such a plan and continue it for more than 10 years.

The new leaders, physicians, and staff will have to demonstrate the interdisciplinary communication and collaboration and must unconditionally comply with the international standards of care for pediatric cardiac surgery, pediatric intensive care, and pediatric cardiology. The new center must strive for excellence in these and all services rendered to children. To achieve this goal there will have to be advanced quality assurance systems in place, and the results and activities of the new center must be presented to the broader scientific community. There must be written protocols, stated goals for the next 5 and 10 years' of service operations, written expectations, plans for systematic staff and patient recruitments, marketing, and networking for referrals from larger geographical areas outside of Slovenia. There must be written clearly stated goals necessary for academic promotions, education, and continued training (including non-technical skills) in addition to goals for research and publications.

The new center must be affiliated with a large reputable center where high-risk and complex cases are sent. In return, the parent institution has to provide continued training and education for staff from Ljubljana. There will have to be both 5- and 10-year financial, medical, and business plans in place aimed at facilitating the center's growth to care for at least 250 surgical patients per year.

If these goals are not achieved, the pediatric cardiac surgery center in Slovenia may not be able to return or restart. Most importantly, without meeting or exceeding these goals the new center cannot be sustained.

Final Comments

Regardless of the specific path chosen to rebuild the DPCS at UKC, important guiding principles must be adhered to and general pitfalls must be avoided. To develop a new pediatric center of excellence there should be a change in institute's current understanding of the following:

- I. **Culture:** The demise of the DPCS at UKC was, perhaps, largely due to the widespread culture of denial, lack of openness to criticism, lack of consideration for patients' complaints, defensiveness, secrecy, acceptance of mediocrity, self-declared excellence, and the failure to put the patient first in everything that is done. The patient must be the first priority. As such, the new culture should include:

- Zero tolerance for substandard care and noncompliance. Rigorous policing of international standards of excellence, openness, and transparency should be commonplace.
- A commitment to common ethical and moral values throughout the system by all.
- Readily accessible written protocols and fundamental standards² and means of compliance.
- Accountability.
- Information and results that are accessible to all, allowing effective comparison of performance by individuals, services, and organizations.
- Professional behavior at all levels and service in accordance with clearly stated standards.
- A displacement of a culture of fear with a culture of openness, candidness, honesty, and transparency.
- Training and continuing professional development for all healthcare professionals not only in technical skills but also in non-technical knowledge and skills.

II. **Leadership:** The requirements for the highest-level leadership positions should change and should be clearly stated. A common code of ethics and standards of conduct for senior level healthcare leaders and managers should be produced at the regulatory level in consultation with all stakeholders, including patients. The principles appearing in those ethics and standards should apply to all staff, and it is the responsibility of employers to ensure that they are honored.

- The highest level of leadership and middle management personnel should provide proper documentation of their qualifications. If they prove to be unfit for the positions they occupy, there should be a mechanism in place for these leaders to be replaced. Every position should have a written job description and clear expectations that go with it. There should be standards and written protocols for employee performance and evaluations on a yearly basis. The test of fitness should include a requirement to comply with a prescribed code of conduct. Serious noncompliance with these standards and codes should be grounds for termination.
- Organizations and their leaders must be honest, transparent, and truthful when making statements to regulators. They must not mislead any parties. Public statements must be considerate, candid, and truthful. If there is even trace of evidence that they are misleading, this should be punishable by law.

III. **Information:** Information about the performance and outcomes of the service provided must always be made available. It is a duty of healthcare professionals to report results and to collaborate in the provision of such information. The public should be able to compare relative local performance to international standards of care. Therefore, access to the necessary information needs to be open, honest, transparent, and comply with appropriate standards.

- Transparency and patient safety would be greatly enhanced by the introduction of a user-friendly electronic patient record systems and reporting the data to the international registries.

IV. **Non-technical skills for leadership and healthcare professionals:** Competencies in non-technical skills are sine qua non for efficient, efficacious, patient-centered care and patient safety. Recommendations for training:

² This applies not only to hospital accreditation standards but especially to specialty standards, in this case to standards of pediatric cardiology, pediatric cardiac surgery, and pediatric cardiac intensive care.

- Essential tools for quality improvement, such as process designed protocols, measurement and analysis of data, models for improvement, and improvements in microsystems
- Basic discussions of patient safety in quality assurance (M&M) conferences (including errors, near-miss, root cause analysis, learning from errors, human factors, patient involvement, disruptive behavior, prevention of adverse events due to errors, a systemic approach vs. blaming, and building reliable systems)
- Patient-centered care
- Teamwork and improvements in interpersonal and interdisciplinary communications

V. **Stability of the pediatric cardiac services:** It is of utmost importance that before a certain proposal for any major structural change to the system of pediatric cardiac service is accepted, an impact and risk assessment should be undertaken, and the future stability of the services should be envisioned.

VI. References and Documentation

- Ref 1 – Letter about the meeting of the Commission with the President of the Medical Chamber of Slovenia, dated April 1, 2014 (Zapisnik komisije za nadzor-otroška kardiokir 1.4.2014).
- Ref 2 – Email from Dr. Ebel, dated December 16, 2014.
- Ref 3 – Emails about audit discussions with the STS and the Joint Commission, dated April 16-May 11, 2014.
- Ref 4 – Emails containing a proposal to include auditors from Europe, dated May 28, 2014.
- Ref 5 – Emails containing a detailed outline for the audit, dated May 27-31, 2014.
- Ref 6 – Emails from Dr. Hazekamp confirming his participation and accepting the position as a member of the Auditing Commission, dated May 10-June 23, 2014.
- Ref 7 – Emails confirming the audit dates, dated June 12-23, 2014.
- Ref 8 – Emails from Dr. Hazekamp with suggestions for the proposed agenda for the audit, dated June 24, 2014.
- Ref 9 – Emails stating that no data from the DPCS were ever sent to the EACTS Database, dated June 24, 2014.
- Ref 10 – Emails from Dr. Hojs (Medical Chamber of Slovenia) regarding the details of the audit requirements, dated June 26, 2014.
- Ref 11 – Emails from Dr. Mozina agreeing to all the requests of the Commission with regard to the planning and details of the audit, dated July 1, 2014.
- Ref 12 – Email containing Dr. Gregoric's audit outline, dated July 7-8, 2014.
- Ref 13 – Purpose of the audit.
- Ref 14 – Email from Dr. Blumauer with comments regarding inconsistencies in the numbers of the patients and his patient database for year 2012, dated July 11, 2014.
- Ref 15 – Database of Dr. Blumauer listing patients operated on in 2012 at the DPCS in Ljubljana.
- Ref 16 – File from Dr. Blumauer providing the Aristotle basic score nomenclature.
- Ref 17A – Database outlining the final number (141) of patients for the year 2012, as calculated from Dr. Blumauer's database.
- Ref 17 – 2012 patient database of Dr. Blumauer that was analyzed by the Commission.
- Ref 18 – GFM database of patients operated on in DPCS Ljubljana during 2012, entered into the EACTS Database by Commission members from charts given to the Commission during the July 2014 audit.
- Ref 19 – Meeting minutes of the July 2014 audit.

- Ref 20 – Letters from Dr. Blumauer to Dr. Mozina and Dr. Gregoric.
- Ref 21 – Letter from Dr. Gregoric to Dr. Mozina, requesting assistance in obtaining more data from UKC Ljubljana.
- Ref 22 – Brief review description sent from Dr. Gregoric to Dr. Mozina for press release, dated July 13, 2014.
- Ref 23 – Email request from Dr. Gregoric to Dr. Blumauer to provide specific data regarding his operative experience, dated August 19, 2014.
- Ref 24 – Email from Dr. Gregoric requesting Dr. Mozina to provide additional documents and information that were agreed upon between the Commission and the leadership of University Clinical Center (UKC), Ljubljana during the July 2014 audit, dated August 19, 2014.
- Ref 25 – Email from Dr. Mozina, requesting the UKC (Prof. Hojker, Dr. Blumauer, Dr. Kalan) to provide the additional data, as requested by Dr. Gregoric and mentioning he has their commitment to make all the information available, dated August 20, 2014.
- Ref 26 – Reply from Dr. Blumauer to Dr. Gregoric stating why he cannot supply the data he was asked to provide, dated August 22, 2014.
- Ref 27 – Letter from Dr. Blumauer’s attorney, Mr. Pitako, to the UKC legal office regarding the requested information and data from Dr. Blumauer, with a request to channel all future correspondence with Dr. Blumauer through Mr. Pitako’s office, dated August 12, 2014.
- Ref 28 – Email from Dr. Mozina, requesting the same missing information from the CEO of UKC as described in Ref 25, dated September 7, 2014.
- Ref 29 – First draft of the report sent by Dr. Gregoric to the members of the Commission via email, dated September 17, 2014.
- Ref 30 – Letter and email to Dr. Mozina regarding pressure from TV reporters about the timeline of the Commission’s report, dated September 27, 2014, in addition to the commencement of the difficulties and Commission’s concerns regarding a password change and the 2007–2014 data collection by the team from Ljubljana.
- Ref 31 – Press release from the Medical Chamber of Slovenia, dated September 30, 2014.
- Ref 32 – Email from Dr. Ebels to the Director of the EACTS Database with profound concerns regarding the password changes without notification to the Commission, and email from Dr. Gregoric to Dr. Weiss in Ljubljana voicing the same concerns, dated September 19, 2014.
- Ref 33 – Tjark’s first attempt to analyze the data on October 30, 2014.
- Ref 34 – Email from Dr. Gregoric requesting a more detailed data analysis and additional results, in addition to sharing the information about attempts in Ljubljana to discredit the audit authority of the Commission, dated November 3, 2014.
- Ref 35 – Email from Dr. Ebel voicing additional concerns about the validity and accuracy of data entry to the EACTS database by the team in Ljubljana, dated November 28, 2014.

- Ref 36 – Email from Dr. Mozina regarding the press release describing the audit and the requests from the Ministry of Health, dated November 2, 2014.
- Ref 37 – Document describing further concerns of the Commission and Dr. Mozina about the validity and accuracy of the data harvested and entered by the Ljubljana team into the EACTS database.
- Ref 38 – Email from Dr. Tobota attempting to explain the problem with the UKC Ljubljana data entry into the EACTS Database, dated December 7, 2014.
- Ref 39 – Email listing possible explanations for the database inaccuracy, dated December 8, 2014.
- Ref 40 – Email from Dr. Ebels containing further questions about the patient being discharged, readmitted, and dying on the same day, dated December 11th, 2014.
- Ref 41 – Email from Dr. Kalan containing further explanation regarding the database confusions by Dr. Kalan and additional concerns of the Commission, dated December 13, 2014.
- Ref 42 – Email dated outlining the decision taken by the Commission during the conference call on how to proceed with the report because of profound concerns regarding the database, December 14, 2014.
- Ref 43 – Email containing the Commission’s conference call confirmation, dated December 16, 2014.
- Ref 44 – Additional Graphs provided by Dr. Ebels analyzed from the existing EACTS UKC Ljubljana database, dated December 13, 2014.
- Ref 45 – Official report from DPCS UKC Ljubljana (Drs. Blumauer, Gersak, and Pleskovic) on five years of surgical care for children with congenital cardiac anomalies.
- Ref 46 – Personal database of Dr. Podnar for outcomes of children with congenital cardiac anomalies who underwent surgery at UKC Ljubljana DPCS from 2007 until June 2013.
- Ref 47 – Final UKC internal audit report regarding financial support for the pediatric cardiac surgical program; official document signed by UKC legal representative Mrs. Silva Zeleznik, dated January 20, 2012.
- Ref 48 – Preliminary data analysis from the available EACTS database for Ljubljana pediatric cardiac surgery.
- Ref 49 – List of patients from the databases of Dr. Weiss and Kalan (Ref 48) for the number of patients in 2012 only.
- Ref 50 – List of all 593 surgeries (data entries by Drs. Weiss and Kalan to the EACTS database) reflecting no surgeries for Dr. Mishaly through 2012 (inaccurate data).
- Ref 51 – Draft results by Dr. Ebels from the available EACTS database for pediatric cardiac surgery in Ljubljana from 2007 until 2014.
- Ref 52 – Patient mortality (16 patients) from 593 surgeries on 473 patients.
- Ref 53 – Highlighted in database - Dr. Mishaly is not listed as a surgeon in 2012 in the EACTS Database (Ref 48), as entered by Drs. Weiss and Kalan by October 4, 2014.

- Ref 54 – Email from Dr. Ebels explaining the database inconsistencies, the codes of different surgeons, and data loss during database merger, dated February 15, 2015.
- Ref 55 – Data analysis, and graphs with tables, by Dr. Gregoric.
- Ref 56 – Data table representations by Dr. Gregoric.
- Ref 57 – Outlined number of surgeons for the year 2012 from the EACTS database of Drs. Weiss and Kalan: Dr. Mishaly is not listed as a surgeon in 2012 according to this database.
- Ref 58 – Email exchanges in the Commission attempting to explain the EACTS Ljubljana DPCS database inaccuracies and data confusion, in addition to the realization that morbidity was never entered to the database, dated February 16, 2015.
- Ref 59 – Emails between Drs. Ebels and Tobota about the coding of surgeons and the data loss in the EACTS Database of Drs. Weiss and Kalan, dated February 16, 2015.
- Ref 60 – Emails from Dr. Ebels regarding further inquiry into the log files for different surgeons to Dr. Tobota in Poland, dated February 17, 2015.
- Ref 61 – Diagrams from different data for the DPCS results in Ljubljana.
- Ref 62 – First draft of Ljubljana data comparison, parallel to References 15 and 18.
- Ref 62A – Ljubljana updated data comparison, parallel to References 15 and 18.
- Ref 63 – Journal article: What is operative mortality? Defining death in a surgical registry database: a report of the STS Congenital Database Taskforce and the Joint EACTS-STS Congenital Database Committee. Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T Jr, Walters HL 3rd, Kurosawa H, Stellan G, Ebels T, Elliott MJ; STS Congenital Database Taskforce; Joint EACTS-STS Congenital Database Committee. *Ann Thorac Surg.* 2006 May; 81(5):1937-41.
- Ref 64 – Newest corrected datasheet from Dr. Ebels, dated March 2, 2015.
- Ref 65 – Spreadsheet with data in parallel for Ref 15, clarifying the 145 vs. 141 surgeries for the year 2012.
- Ref 66 – Email resolution regarding the password changes by Dr. Weiss, dated September 29, 2014.
- Ref 67 – Review of the Pediatric Congenital Cardiac Service, Belfast Health, and Social Care Trust – July 2012.
- Ref 68 – Chronology of events as described by Dr. Blumauer to Dr. Gregoric in a letter sent via email, dated July 11, 2014.
- Ref 69 – Copy of original letter to the Slovene Ethics Committee by the Pediatric Cardiologists and Intensive care Physicians, alleging unethical conduct by the DPCS in Ljubljana, dated December 6, 2013.
- Ref 70 – Letter from the Slovene Medicine Ethics Committee in response to the letter of complaint received in December 2013, dated March 12, 2014.

- Ref 71 – Report in the “DELO” newspaper regarding the letter of complaint by pediatric cardiologists and intensivists to the Slovene Medicine Ethics Committee, in which they declare withdrawn support of DPCS in Ljubljana due to the unethical conduct of pediatric cardiac surgical services.
- Ref 71A – Bylaws of Slovene’s Health Care Services, dated June 23, 2006.
- Ref 72 – Press release interview by Dr. Mozina, in the newspaper “DELO” regarding the Official Audit of the DPCS in Ljubljana and the comments regarding the letter to the Slovene Ethics Committee, dated December 13, 2013.
- Ref 73 – Response of Mr. Zitnik (the father of one of the operated children at DPCS in Ljubljana) in the newspaper “DELO” to the media coverage of the pediatric cardiac surgical services at UKC in Ljubljana, dated January 11, 2014.
- Ref 74 – Email from Dr. Ebels consulting with Dr. Bohdan Maruszewski (the president of EACTS Database Center) on allowing a Slovene national report, despite the fact that there is only one center in Slovenia, dated October 30, 2014.
- Ref 75 – Email from Dr. Hazekamp, regarding the entered data for mortality but not for morbidity, dated February 16, 2015.
- Ref 76 – Example of report overview for Adult Cardiac Surgery from the Duke Clinical Research Institute - STS - Data Analysis Center.
- Ref 77 – Email from Dr. Ebels about the data inconsistency and explaining why is it impossible to perform any analysis of Dr. Blumauer’s surgeries from the database populated by Drs. Weiss and Kalan, dated March 9, 2015.
- Ref 78 – Dr. Podnar’s data demographics as displayed in the Association for European Pediatric and Congenital Cardiology, dated March 2015.
- Ref 79 – Response from UKC, signed by Mr. Simon Vrhunec, to the Slovene’s Commission for prevention of Corruption, dated November 12, 2012 (copy of official Letter).
- Ref 80 – Slovene’s National TV interview of a mother of a child treated in DPCS in Ljubljana, titled “Why was Pika not operated on”, dated June 11, 2014.
- Ref 81 – STS National Database (STS) and Duke Clinical Research Institute (DCRI) Contacts.
- Ref 82 – Journal article: Pediatric cardiac surgery: The effect of hospital and surgeon volume on in-hospital mortality. Hannan EL, Racz M, Kavey R-E, Quaegebeur JM, Williams R. *Pediatrics* 1998 June; 963-969, and other references associated with the topic of pediatric cardiac surgery.
- Ref 83 – Journal article: Reevaluation of the volume-outcome relationship for pediatric cardiac surgery. Gauvreau K. *Circulation*. 2007 May; 115(20): 2599-601.
- Ref 84 – Journal article: A reflection on the performance of pediatric cardiac surgery in the State of São Paulo. Caneo LF, Jatene MB, Yatsuda N, Gomes WJ. *Rev Bras Cir Cardiovasc*. 2012 Jul-Sep; 27(3): 457-62.

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- Ref 86 – Service Standards of the Children’s Congenital Cardiac Services in England; updated by the NHS in February 2011.
- Ref 87 – Journal articles referencing the Aristotle Score 2:
- Stratification of complexity: the Risk Adjustment for Congenital Heart Surgery-1 method and the Aristotle Complexity Score--past, present, and future. Jacobs ML, Jacobs JP, Jenkins KJ, Gauvreau K, Clarke DR, Lacour-Gayet F. *Cardiol Young*. 2008 Dec; 18 Suppl 2:163-8.
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- Ref 88 – Journal article: Guidelines for pediatric cardiovascular centers. Section on Cardiology and Cardiac Surgery; American Academy of Pediatrics. *Pediatrics*. 2002 Mar; 109(3):544-9.
- Ref 89 – UKC Information release regarding media coverage of Internal Audit Report of pediatric cardiac surgical services in Ljubljana signed by Professor A. Pleskovic on July 11, 2013.
- Ref 90 – Mortality and volume of cases in paediatric cardiac surgery: retrospective study based on routinely collected data. Spiegelhalter DJ. *BMJ*. 2002 Feb 2;324(7332):261-3.
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- Ref 92 – National Voluntary Consensus Standards for Pediatric & Congenital Cardiac Surgery, National Quality Forum, May 2, 2011.
- Ref 93 – The American Board of Thoracic Surgery: Booklet Information for Congenital Heart Surgery Subspecialty Certification, 2012.
- Ref 94 – Quality Improvement in Pediatric Cardiology: An overview of National Initiatives; Children’s Hospital Cleveland Clinic, December 5, 2008.

- Ref 95 – Journal article: Initial application in the EACTS and STS Congenital Heart Surgery Databases of an empirically derived methodology of complexity adjustment to evaluate surgical case mix and results. Jacobs JP, Jacobs ML, Maruszewski B, Lacour-Gayet FG, Tchervenkov CI, Tobota Z, Stellin G, Kurosawa H, Murakami A, Gaynor JW, Pasquali SK, Clarke DR, Austin EH 3rd, Mavroudis C. *Eur J Cardiothorac Surg.* 2012 Nov; 42(5):775-9; discussion 779-80. doi: 10.1093/ejcts/ezs026. Epub 2012 Jun 14.
- Ref 96 – STS/NQF Quality Indicators for Pediatric and Congenital Cardiac Surgery.
- Ref 97 – Duke Clinical Research Institute, The STS Data Warehouse - The Harvest overview.
- Ref 98 – 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; 2011.
- Ref 99 – Journal article: Association of Center Volume With Mortality and Complications in Pediatric Heart Surgery. Pasquali SK, Li JS, Burstein DS, Sheng S, O'Brien SM, Jacobs ML, Jaquiss RDB, Peterson ED, Gaynor JW, and Jacobs JP. *Pediatrics* 2012 Feb.129:2.
- Ref 100 – Journal article: Variation in Outcomes for Benchmark Operations: An analysis of the STS Congenital Heart Surgery Database Jacobs, JP, O'Brien, SM, Pasquali, SK, Jacobs, ML, Lacour-Gayet, FG, Tchervenkov, CI, Austin, EH, Pizarro, C, Pourmoghadam, KK, Scholl, FG, Welke, KF, and Mavroudis, C. *Ann Thorac Surg.* 2011 December; 92(6): 2184–2192.
- Ref 101 – An empirically based tool for analyzing mortality associated with congenital heart surgery. O'Brien SM, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro C, Welke KF, Maruszewski B, Tobota Z, Miller WJ, Hamilton L, Peterson ED, Mavroudis C, Edwards FH. *J Thor Cardiovasc Surg.* 138(5): 1139.
- Ref 102 – Pika's fight for life – Press conference by the mother of the patient, on June 11, 2014.
- Ref 103 – UKC Ljubljana annual professional report, 2010.
- Ref 104 – Email containing Dr. Ebels' summary of the audit, dated December 16, 2014.
- Ref 105 – History of Department of Pediatrics - UKC Ljubljana.
- Ref 106 – ACC/AHA 2008 Guidelines for the management of adults with congenital heart disease: Executive summary. A report of the American College of Cardiology/American Heart Association. Task force on practice guidelines (writing committee to develop guidelines for the management of adults with congenital heart disease); Warnes CA, Williams RG, Bashore TM, Child JS, Connolly HM, Dearani JA, del Nido P, Fasules JW, Graham TP, Hijazi ZM, Hunt SA, King ME, Landzberg MJ, Miner PD, Radford MJ, Walsh EP, Webb GD. *Circulation.* 2008; 118:2395-2451.
- Ref 108 – Newspaper report of pediatric cardiologist Dr. Podnar discussing correspondence between pediatric cardiac surgeons and unveiling the substandard results of DPCS in Ljubljana, dated January 22, 2012.

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- Ref 115 – National Adult Cardiac Surgery Audit; NICOR: National Institute For Cardiovascular Outcomes Research; Annual Report 2010–2011.
- Ref 116 – Letter from Dr. Kalan to Dr. Gersak recommending the formation a multidisciplinary team for the care of congenital cardiac pediatric patients, dated December 5, 2007.
- Ref 117 – Complaints from pediatric cardiac intensive care physicians regarding Dr. Blumauer’s care of patients, dated October 8, 2008.
- Ref 118 – Summary of the discussions between Drs. Kalan, Blumauer, and Primožic, regarding pediatric cardiac surgical services, dated May 14, 2009.
- Ref 119 – Summary by Dr. Kalan of the discussion between Pediatric Cardiac Surgery services and Pediatric cardiac intensive care physicians regarding delineation of patient care, dated November 11, 2009.
- Ref 120 – Letter from Dr. Kalan to Dr. Gersak about pediatric intensive care physicians observing questionable therapeutic decisions by Dr. Blumauer with potential consequential complications for the patients with suggestions for solutions, dated 2009.
- Ref 121 – Letter from Dr. Kalan (as the chief of pediatric intensive care physicians) to Dr. Mishaly, outlining the lack of collaboration between pediatric cardiac surgeons and intensivists, and Dr. Blumauer’s inexperience, and expressing serious concerns for the future of this program, dated Summer 2010.
- Ref 122 – Letter from Dr. Kalan (chief pediatric intensive care physician) to Mr. Vrhunec (CEO of UKC), expressing deep concerns about the pediatric cardiac surgery program in Ljubljana, delays in operations, broken promises of UKC medical leadership, breaches of contract, Dr. Blumauer’s lack of leadership and experience, and, in his opinion, deliberate attempts to remove Dr. Podnar, dated January 25, 2012.
- Ref 123 – Letter from Dr. Kenda (chair of Department of Pediatrics at UKC Ljubljana), outlining the conclusions of the meeting between Pediatric Cardiology, pediatric intensive care physicians, and Pediatrics, dated February 9, 2012.
- Ref 124 – Notes and minutes containing the conclusions and agreements of the urgent meeting called by Dr. Kenda (Chair of Department of Pediatrics) and Dr. Pleskovic (Chair of Surgical Services) to correct the substandard services at DPCS in Ljubljana; in attendance, Drs. Kenda, Kozelj, Gersak, Klokocovnik, Podnar, Vidmar, Kalan and Vesel, held on March 1, 2012.
- Ref 125 – Minutes and conclusions of the meeting between UKC CMO Dr. Drnovsek and the pediatric intensivists regarding the continuation of the program for pediatric cardiac surgery after the resignation of Dr. Blumauer, held on April 18, 2012.
- Ref 126 – Minutes and conclusions of the meeting between CMO Dr. Drnovsek, Dr. Blumauer, and the representatives of the Pediatric Intensive Care Unit regarding the organization of DPCS and Dr. Blumauer’s return to pediatric cardiac surgery, held on April 20, 2012.

- Ref 127 – Letter from Dr. Skofljanec (Assistant Director of the Pediatric Intensive Care department), to the UKC CEO Dr. Drnovsek, explaining the situation in the Pediatric Intensive Care Unit at UKC Ljubljana and dismissing Dr. Blumauer's accusations, dated January 2013.
- Ref 128 – Letter from Dr. Kalan to Dr. Pleskovic explaining and apologizing for his inappropriate behavior, dated March 22, 2013.
- Ref 129 – Dr. Blumauer's reference for his contribution to the literature in the booklet, titled 'Critically ill and injured child', November 2011.
- Ref 130 – Journal article: Hidden incision for better cosmetics result in congenital and pediatric cardiac surgery Mishaly R, Blumauer S, Prisman. From the book: Minimally invasive technologies and nano systems for diagnosis and therapies.
- Ref 131 – Response to the article in Medical Chamber journal "Syndrome of vulnerable system: how an institution becomes excellent", dated December 2013.
- Ref 132 – Report by Dr, Blumauer about the treatment of the patient KK with congenital cardiac anomaly who died, dated June 26, 2012.
- Ref 133 – Journal article: Kirursko zdravljenj transpozicije velikih arterij; r. Blumauer B. Gersak D. Mishaly D; Pediatric Surgery Book; October 2013.
- Ref 134 – The Ross procedure: a good alternative for selected patients. Mishaly D, Blumauer R, Gersak B. Lectures: Aortic valve, 2011.Excerpt from the lecture notes.
- Ref 135 – Closure of patent ductus arteriosus; Dr. Lilijana Kornhauser Cerar, Ljubljana; January 6, 2014.
- Ref 136 – Report with complaints from Dr. Skofljanec to her Chief about the substandard treatment and, in her judgment, inappropriate decisions and surgeries for 3 children with eventual mortality; and her ethical dilemma about Dr. Blumauer's professional conduct and inappropriate decision making, dated July 2012.
- Ref 137 – Copies of multiple letters to administration obtained from media reporters.
- Ref 138 – Dr. Podnar's letter to the CMO Dr. Drnovsek, expressing his deep concerns about the inappropriate utilization of pulmonary Hancock grafts, which are known to have a very high failure rate, at the DPCS in Ljubljana, dated June 12, 2012.
- Ref 139 – Letter from Dr. Podnar to Dr. Arnez with plans and concerns about the DPCS in Ljubljana, dated August 4, 2004.
- Ref 140 – Follow-up report of the financial review of the pediatric cardiac surgery program in Ljubljana from Internal UKC Auditors, signed by Mrs. Zeleznik, director of UKC Internal Auditing Services, dated March 5, 2012.

- Ref 141 – Report of discussions in an interdisciplinary meeting about the DPCS in Ljubljana, signed by Drs. Kenda, Pleskovic, Kozelj, Gersak, Klokocovnik, Podnar, Vidmar, Kalan, and Vesel, stating the conclusion to continue pediatric cardiac surgical services in the same manner as before with Dr. Vodiskar performing simple surgical procedures following Dr. Blumauer's resignation, and describing the proposed formation of a committee to coordinate the activities at DPCS as well as the decision to send all complex cases abroad for surgery, dated March 1, 2012.
- Ref 142 – Letter from Dr. Gersak to the UKC CEO Dr. Vrhunec recommending the reinstatement of Dr. Mishaly as the pediatric cardiac surgeon for DPCS in Ljubljana and outlining the collaborative contract between Sheba Medical Center and DPCS UKC Ljubljana, dated December 12, 2011.
- Ref 143 – Letter from Mr. Vrhunec to the Department of Pediatrics describing the lengthy waiting time for pediatric cardiac surgery and the services remaining reliant on Dr. Mishaly only. Mentioned are the binge cardiac surgical treatments at DPCS in Ljubljana and the need for a permanent senior pediatric cardiac surgeon at DPCS, dated September 15, 2009.
- Ref 144 – Email copy of a letter from Dr. Podnar to the medical and administrative leadership of UKC Ljubljana complaining that despite the decision from January 31st, 2012 to conduct an internal audit about the DPCS, and additionally the agreement on June 13th, 2012 to audit substandard biological valve utilization, neither had been initiated in 9 months. The letter expresses his deep concerns regarding the death of the pediatric patient ZL, which the auditors believe was contributed to by inappropriate decisions with regard to surgical services. In the same letter, Dr. Podnar and Dr. Vesel express their decision to resign from the pediatric cardiac surgical program due to profound ethical dilemmas and additional concerns, dated September 7th, 2012.
- Ref 145 – Letter from Slovene's Medical Ethic Commission signed by its president Prof. Dr. Trontelj J. to the CEO and CMO of UKC in Ljubljana, regarding the Pediatric cardiac surgery department substandard services, dated November 11, 2013.
- Ref 146 – Report from the meeting between Drs. Podnar, Kenda, and Gersak where they agreed about the planning for the pediatric cardiac surgery schedule and the notification of the surgeon who will do the surgery.
- Ref 147 – ACHA Research Symposium II: Quality measurement and quality improvement for adult congenital heart disease. Jenkins K; Children's Hospital Boston, April 25, 2009.
- Ref 148 – Article: The impact of intensive care unit structure on post-operative outcomes following congenital heart surgery: analysis of a multi-institutional database. Burstein DS, Sheng S, O'Brien SM, Rossi AF, Jacobs JP, Checchia PA, Wernovsky G, Welke KF, Peterson ED, Li JS, Jacobs ML, Pasquali SK. American Heart Association Scientific Sessions, November 15, 2010.
- Ref 149 – Joint Commission International Consulting; Consultation Profile for HOSPITALS - Proposal for UKC Ljubljana Audit.

- Ref 150 – Joint Commission International Consulting; Consultation Profile for HOSPITALS - Template.
- Ref 151 – Pathology/Autopsy report of KVK program for Plazovnik Gašper
- Ref 152 – Recommendations algorithm from Dr. Robida's Commission Audit during 2012 - Drevesni diagrami PG
- Ref 153 – Official report and analysis of cause of death of patient P.G. and analysis of safety issues at DPCS in Ljubljana/Internal audit - poročilo o PG s HLHS na UKCL, dated September 17, 2012.
- Ref 154 – Explanation in response to Dr. Ebel's question regarding where the databases are, for Refs. 45 and 46
- Ref 155 – For a surgeon it is not easy when changes are made – Blumauer 1-16-2014 interview
- Ref 156 – <http://www.rtv slo.si/zdravje/novice/misali-mislim-da-niti-v-najboljsih-bolnisnicah-nimajo-takoznizke-smrtnosti/367764>. (Dr. Mishaly's interview 6-17-2015)
- Ref 157 – <http://www.texaschildrens.org/About-Us/Quality-Measures/> (measures TCH).
- Ref 158 – Congenital cardiac surgery outcomes at TCH, 2014.
- Ref 159 – Psychological pressure in media - Blumauer and Insurance company discussion Video - <http://www.24ur.com/novice/slovenija/zavarovalnica-ne-vrne-28-tisocakov-starsileona-odpeljali-v-tujino-tam-ga-je-operiral-kar-slovenec.html>
- Ref 160 – Ranking institutions. Spiegelhalter D. J Thorac Cardiovasc Surg. 2003 May;125(5):1171-3.
- Ref 161 – Risk adjustment in analysis of surgery for congenital heart disease; J. Shuhaiber; J Thorac Cardiovasc Surg. 2003 May; 125(5):1171
- Ref 162 – RACHS (Risk adjustment) articles.
- Ref 163 – Article: Consensus-based method for risk adjustment for surgery in CHD; Jenkins KJ, Gauvreau K, Newburger JW, Spray TL, Moller JH, Iezzoni LI.; J Thorac Cardiovasc Surg. 2002 Jan;123(1):110-8. Review.
- Ref 164 – Slovene guidelines for PGE usage in newborns, Mojca Groselj; Zdrav.Vestnik 2012; 81: 91–7.
- Ref 165 – Dr. Gregoric's CV.