

## Grounds for challenging the decision of the JCPCT on the 4<sup>TH</sup> of July

### Summary arguments:

**1) Clinical risk of transferring the respiratory ECMO service to Birmingham Children's Hospital.** Closing the service in Leicester and opening a new service in Birmingham has a national impact with implications upon the capacity of the ECMO service and the quality of that service during the transition phase which may need to last for an unrealistic duration. A safe transition, if possible at all, is likely to be extremely expensive.  
*See appendix 1 (p2-18) below*

**2) Lack of recognition of the sustainability of PICU in the Midlands.** The impact on PICU services in both the East and West Midlands has not been adequately assessed to account for the change in capacity.  
*See appendix 2 (p19-23) below*

### Some recommendations on a Compromise Way Forward:

- **ECMO move considered by an independent panel of ECMO experts (national and international)**
- **Option AB reconsidered with boundaries moved to ensure 400-500 cases in each of 8 centres. Adult Congenital Heart Disease numbers included making it easier, some allowance made for transferable skills (and therefore practice and experience) required for centres that do ECMO/VAD/Tracheal, i.e. they should count towards case load in some way.**

## **Appendix 1: Clinical risk of transferring the respiratory ECMO service to Birmingham Children's Hospital.**

There has not been an adequate consultation on the question of whether ECMO can be moved safely

There has not been a Health Impact Assessment concerning the movement of ECMO, Mott Macdonald were asked to concentrate on cardiac surgery and were not asked to consider movement of ECMO (Kerry Schofield, Mott Macdonald personal communication 24/7/12)

There has been no engagement with the ECMO community in the UK or internationally regarding the safety and advisability of moving the childrens ECMO service

International experts have written expressing their misgivings about the potential relocation of this service

### **BACKGROUND**

#### **What is ECMO?**

Extracorporeal Membrane Oxygenation uses highly modified cardiopulmonary bypass technology to provide prolonged support of respiratory, cardiac or cardio-respiratory function to patients with severe but potentially reversible disease.

#### **• Who needs ECMO?**

Babies, children and adults who are continuing to deteriorate and are therefore at high risk of death despite maximal conventional intensive care.

ECMO can be used to support patients with a wide range of diagnoses such as babies with meconium aspiration syndrome or diaphragmatic hernia, children with low cardiac output after heart surgery and adults with H1N1 pneumonia.

#### **• What is the survival rate?**

Survival rates vary depending on age and diagnosis but must be interpreted in the light of the survival rate without ECMO. For instance about 50% of children who need cardiac ECMO support survive (**60% in Leicester**), but most of these would die without ECMO.

Survival rate for Meconium Aspiration Syndrome in newborn babies is close to 100% with ECMO.

**A baby died of MAS in the south of England last week as the local ECMO unit was full.**

#### **• What is the Evidence that ECMO works?**

- UK Collaborative Neonatal ECMO Trial, Run by David Field (Professor of Neonatology University of Leicester). *Lancet*, 1996; 348:75-83. NNT=3 (number needed to treat, equivalent to 1 extra survivor for every 3 patients treated)

- CESAR, adult ECMO trial, Run by Giles Peek (Consultant in cardiothoracic surgery and ECMO, East Midlands Congenital Heart Centre, Leicester). *Lancet* 2009;374:1351-1363. NNT =6
- Referral to an Extracorporeal Membrane Oxygenation Center and Mortality Among Patients With Severe 2009 Influenza A (H1N1). Noah MA, **Peek GJ**, Finney SJ, et al *JAMA* 2011 ;306(15) :1659-1668. <http://doi:10.1001/jama.2011.1471>. A collaborative study between Leicester and the other UK adult centres, odds ratio for increased survival 0.5 (this means an increased chance of survival of half as much again when the patient is treated in an ECMO unit rather than a conventional intensive care unit)

These studies are not just selected studies from Leicester, these are the *only* studies. There are no randomised controlled trials or case control studies in cardiac or paediatric respiratory ECMO because they are even harder to do,

- **ELSO**

Extracorporeal Life Support Organization, established in 1989 at the University of Michigan, <http://www.elsonet.org/> is an INTERNATIONAL ORGANISATION, representing 160 ECMO Centres across the world.

- **Mission statement:** To provide support to institutions delivering extracorporeal life support through continuing education, guidelines development, original research, publications and maintenance of a comprehensive registry of patient data.

- ***The guiding principles of ELSO are:***

*Innovation:* Seeking to identify and promote advances for the application of extracorporeal therapies.

*Expertise:* Bringing together world leaders in the care of critically ill patients for collaboration to advance quality of care through education and publication.

*Clinical support:* Maintaining a comprehensive registry of data to assist in reducing morbidity and improving survival of patients requiring extracorporeal therapies.

*Community:* Fostering communication and collaboration among professionals who apply advanced technologies in the treatment of refractory organ failure.

- **Giles Peek is only UK ECMO Dr on ELSO steering committee, as well as Chair of Euro ELSO Steering committee**  
<http://www.elsonet.org/index.php/centers/euroelso.html>
- **The ELSO steering committee has written to highlight the danger of closing the ECMO service in Leicester**
- **ELSO was not consulted during the Safe and Sustainable Review Process.**

- **ECMO TEAM**

ECMO requires a large multidisciplinary team with additional specific skills and training compared to either a “normal” PICU or childrens heart surgery unit. This team includes, ECMO doctors, surgeons, intensivists, cardiologists, radiologists, perfusionists, laboratory staff and most importantly **the ECMO specialist nurse**.

This person is central to the safe and effective delivery of ECMO, they are experienced intensive care nurses who have completed additional training in ECMO. They are responsible for the ECMO circuit as well as the patient.

**Leicester has built up a team of over 80 ECMO specialists. The majority of these are women and second wage earner in their households, therefore their expertise is not transferable.**

- **Leicester ECMO Capacity**

Leicester has one of the largest units in the world with one of the longest experiences, having started in 1989. It is the only unit in the UK which can treat all age groups, this was important during the H1N1 pandemic as Leicester was able to flex their service to treat up to 10 adults simultaneously whilst training the other adult centres and coordinating the national service by triaging all the patients and providing the majority of the patient transport.

The “normal” capacity in Leicester is 4-6 patients, these could be of any age or condition mix depending on clinical need (i.e. babies, children or adults, respiratory or cardiac). **The demand for ECMO in babies and children seems to be increasing alarmingly at current referral rates Leicester will treat approximately 100 babies and children with respiratory ECMO support this year.**

**This accounts for approximately 80% of the current Neonatal and Paediatric activity in ENGLAND and WALES**, often taking patients from the catchment area of Great Ormond Street and Newcastle as they have very limited capacity due to the collocated heart failure, transplantation and VAD services. Leicester also admits patients from other countries such as Scotland, Sweden, Finland and Ireland.

- **Mobile ECMO**

**Leicester is the only unit in England and Wales to provide mobile ECMO for babies and children.** This is where the ECMO team travels to the referring hospital and places the patient on ECMO prior to transferring back to base, as high frequency oscillation and nitric oxide use increase around the country mobile ECMO becomes increasingly necessary and expected by referring physicians. It is obviously more challenging providing this service than a “normal” ECMO service and requires many years of experience to do this safely in babies and children, mobile ECMO in adults is relatively straightforward in comparison.

- **Comparison with other Nationally commissioned ECMO services in England and Wales**

	<b>Max simultaneous patients</b>	<b>Mobile ECMO</b>	<b>CDH repair on ECMO</b>	<b>large child capability</b>	<b>Single Care-Giver</b>
Leicester	10	yes	yes	yes	Yes
GOS	3	no	no	yes	No: 2 carers*
Freeman	2	no	no	no	No: 2 Carers*

\* SINGLE CARE GIVER: This is where the ECMO specialist nurse cares for the patient and the ECMO circuit, a ratio of 1:1. Hitherto a 2:1 staffing ratio has been used with an ECMO specialist nurse and a non-specialist nurse for each patient. Obviously single care giver represents an enormous improvement in cost efficiency. It is the standard of care being adopted in the best centres worldwide and requires a mature programme to be done safely.

- **Leicester ECMO Outcome Data**

Data from the Paediatric Intensive Care Audit Network (PICANet) supports the quality of the ECMO service in Leicester. Over the ten years 2002-2012, 1447 children and infants received ECMO support in the UK, 466 at Glenfield Hospital, 981 in other centres, including the three other nationally commissioned centres. **The crude mortality rate in Leicester was 20%, but in other centres was over 50% higher, at 34%.**

***If the national mortality rate had applied in Leicester, 62 more children would have died.*** It is important to remember that the national mortality rate includes the other nationally commissioned centres. Even if a newly established centre operates at the national average, the data presented supports the view that there would be an increase in mortality.

There is no validated risk prediction model for ECMO, but applying the one used for UK PICU (the Paediatric Index of Mortality score), the difference in mortality is maintained even when severity of illness is taken into account. The data does not support the notion that Leicester's mortality is better because the children referred for ECMO in Leicester are not as sick as elsewhere.

**Further data from the international registry, ELSO, supports the good outcomes in Leicester. In the period from 2002-2012, 12,069 children and infants received respiratory ECMO support in ELSO registered centres, 435 at Glenfield Hospital. The crude mortality rate in Leicester was 19%, but in other centres was over 75% higher, at 35%.**

*Both of these independent, validated data sources point to the high quality of ECMO care given at Leicester, and bring in to focus the dangers to our patients of closing the ECMO service.*

PICANet is an audit database recording details of the treatment of all critically ill children in paediatric intensive care units (PICUs). PICANet is endorsed by the Paediatric Intensive Care Society, and funding is provided by the Healthcare Quality Improvement Partnership (HQIP). PICANet is internationally recognised as a robust and impartial data source.

The Extracorporeal Life Support Organization (ELSO) is an international consortium of health care professionals and scientists who are dedicated to the development and evaluation of novel therapies for support of failing organ systems. Membership consists of over 160 ECMO centres from around the world.

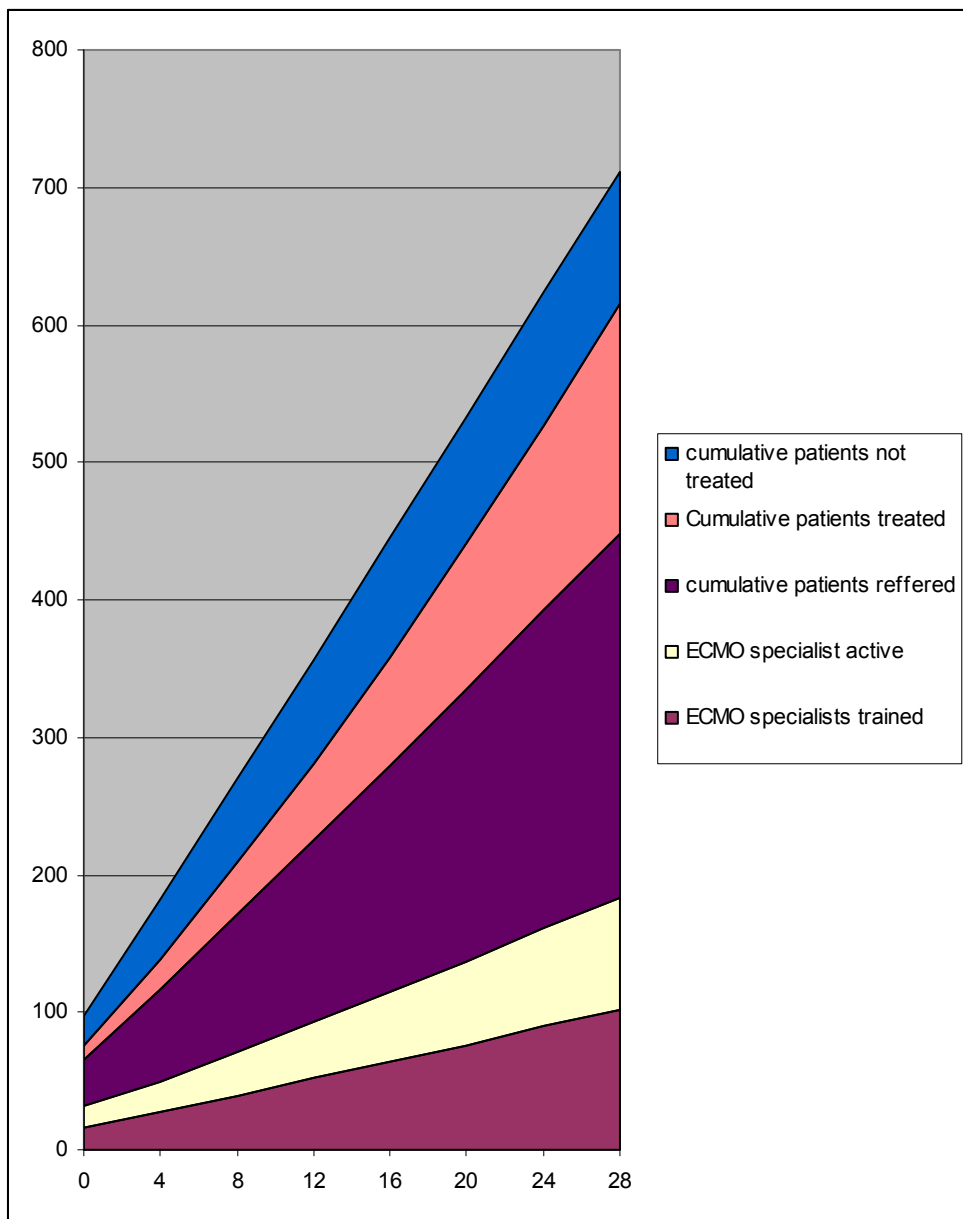
- **How long would it take to replicate the volume and capability of the Leicester neonatal and paediatric ECMO service?**

Based on a number of assumptions:

- Quality in the new centre (i.e. survival) is exactly the same as the current service in Leicester.
- There are infinite monetary resources available to build the necessary additional intensive care beds, redesign the road system in the centre of Birmingham to make BCH accessible to Sea King Helicopters, and double the size of the perfusion department (none of this has been planned as yet).
- Change management can be effectively applied to ensure Leicester medical experts can influence care at BCH. (This has yet to be discussed with any of the clinicians involved).
- There is an infinite supply of suitably experienced PICU nurses willing to train as ECMO specialists to allow three ECMO courses per year with 12 specialists on each course, and all attendees on the course are successful in passing. (This is unlikely)
- Only 10% of ECMO specialists will be off on maternity leave at any one time.
- Only 10% of ECMO specialists leave each year.
- That specialists are prepared to work a mix of full and part time shifts.
- That specialists can learn to do mobile ECMO much more quickly than occurred in Leicester

This table and the graph below gives a breakdown of ECMO treatment capacity at BCH given all of the assumptions above. The patients not treated (97) in total are likely to have a very high mortality rate according to the published literature.

Month	ECMO specialists trained	ECMO specialist active	ECMO beds	cumulative patients referred	Cumulative patients treated	cumulative patients not treated
0	16	16	2	33	11	22
4	28	22	2	66	22	44
8	40	32	3	99	39	60
12	52	41	3	132	56	76
16	64	51	4	165	78	87
20	76	61	5	198	106	92
24	90	72	5	231	134	97
28	102	82	6	264	167	97



- **The ECMO question was not given the same consideration as the question of moving cardiac surgical services:**
  - Only 1 ECMO expert on the panel, whose advice was not followed
  - No UK ECMO experts on the panel
  - No representation from ELSO on the panel despite representations of other professional societies such as SCTS and BCCA
  - No innovation points given for ECMO despite clear evidence of transferable skills and interdependence of ECMO and Cardiac Surgery.
- **The decision to close the Leicester ECMO unit and open a new unit at BCH has been widely condemned by the international ECMO community including Dr Kenneth Palmer who was the only ECMO adviser to the Safe and Sustainable Panel. The conclusion of the panel was that:**

**‘The OPTIMUM is to maintain NATIONALLY COMMISSIONED SERVICES such as ECMO in their CURRENT LOCATION’ PAGE 149, SAFE AND SUSTAINABLE REVIEW DOCUMENT**

Following publication of the decision to adopt option B on the 4<sup>th</sup> of July Dr Palmer wrote the following letter:

**From:** Kenneth Palmér [mailto:kenneth.palmer@karolinska.se]  
**Sent:** 07 July 2012 07:30  
**To:** lansleya@parliament.uk  
**Subject:** Safe and Sustainable ECMO

Dear Sir

It has come to my knowledge that the Safe and Sustainable has recommended that the ECMO treatment for newborn and children should be moved from Leicester to Birmingham. I was the international expert for ECMO treatment and my opinion about moving one unit to another place is the same as totally closing down and rebuilt from zero in the new place. That is Not Easy and it does not even work. You will take over 20 years of experience from one of the world's absolute best ECMO units and throw it away and then to rebuilt it in another place and probably it will take at least 5 years to have some kind of quality and probably 20 years to come back to top quality if it's ever possible.

ECMO has to have one extremely dedicated person who is responsible at the far end to be sure that the quality and sustainable is on track. Everything is depending on that person, otherwise the mortality rate will go up on comparable patients. **The survival rate is 10-20% higher on comparable cases in Stockholm and Leicester depending on the experience and dedication these units has developed over 20 years.** There is not many ECMO units in England today that can take care of the newborn and children, just Great Ormond street who is mainly running post cardiac ECMO and Newcastle (also mostly cardiac ECMO) both units is lacking beds all the time.

**The number of newborn and children who needs ECMO is about 100 per year in Leicester with means if the survival rate goes down 10% during 5 years' time there is about 50 children who is depending on these decision.**

I opposing sharply if my name is used for transferring the ECMO unit from Leicester to Birmingham. **I have been very clear about that you cannot**



**move a unit you can just destroy it and rebuilt with many years of decreasing survival rate and increasing morbidity.**

With best regard

The international expert

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The international professional society of ECMO practitioners (the Extracorporeal Life Support Organization, ELSO) was also deeply concerned about the planned closure of the Leicester ECMO unit. Prominent members of the ELSO steering committee were moved to write the following letters to Mr Lansley in order to express their concerns:

An open letter to Mr. Andrew Tinsley, CBE, MP

Secretary of State for Health

Dear Mr. Tinsley,

We are writing as concerned members of an international group of extracorporeal membrane oxygenation (ECMO) physician leaders committed to providing this lifesaving care to patients failing other conventional therapies. We are united in our dismay at the proposed move of ECMO services from the Glenfield program in Leicester elsewhere. While not citizens of the UK, we are citizens of the greater ECMO community, and we desire to offer our experienced observation: that movement of an established unit such as that at Glenfield in the manner described will have profound negative consequences on the outcomes of patients needing ECMO in that region.

The use of extracorporeal devices like ECMO, developed in great part through the work of Dr. Bob Bartlett, has been responsible for saving tens of thousands of lives of children and adults who would not otherwise have hope. One critical component of providing this treatment is that ECMO is, in Dr. Bartlett's words, a team sport. Providing ECMO requires a small village of physicians, surgeons, nurses, perfusionists, respiratory therapists, blood bankers, and multiple other vital cogs in care. The institutional memory and expertise inherent in the team cannot be quantified. It's clear however, that the Glenfield team exemplifies the results of this expertise. The Glenfield program is clearly and objectively recognized as one of the finest ECMO programs in the world. The outcomes there did not come by accident, but by years of pulling a team together, and developing shared experience, equipment and gestalt of care. Its program director, Mr. Giles Peek, led the groundbreaking study demonstrating benefit of ECMO for adults with respiratory failure unresponsive to traditional therapy. In addition to his leadership roles with ELSO, he recently co-chaired the inaugural European ELSO conference in Rome.

We the undersigned are physician members of the Extracorporeal Life Support Organization Steering Committee with particular expertise and experience in the care of newborns and children requiring ECMO for survival. Infants and children are those for whom ECMO has been best demonstrated to impact outcomes. Thus they are at the greatest risk for impact from breaking apart an ECMO center, and this is of key import to us as pediatric-based specialists. As you have heard about the multiple risks of making this move of the ECMO program, we will only add a few other pediatric-related ones:

Pediatric cases need mobile transport more often now due to increased uses of alternative ventilators (like the high frequency oscillators-HFOV) that make it nearly impossible move a patient. Glenfield offers the only mobile ECMO program in the country

Children need Children's®

which allows them to travel to the patient at the outlying hospital, place on ECMO safely there, and then transport safely back to the home base where the ultimate ECMO care presides.

- Glenfield is the one team in the country with the expertise to safely perform delicate repair of congenital diaphragmatic hernia (a rare life threatening birth defect) on ECMO. This approach may be critical to best outcomes.
- ECMO specialist nurses with pediatric training are exceedingly difficult to find. These specialists at Glenfield would be unable to move as they are primarily women and not likely the main wage earners in their family. The result would be starting from near scratch in training in a new location, an expensive proposition sure to impact care.

We are concerned to hear that the decision on movement appears to have been rapidly decided, with less than 2 weeks from announcement to signoff. We understand that the advice of the only ECMO expert on the Safe and Sustainable panel, Dr. Kenneth Palmer, was also not heeded. We are disappointed as the community of ECMO experts that more extensive consultation was not requested. We would all have been glad to have offered experience, and we all remain willing to do so. As participants in healthcare around the world, we all do understand the realities of costs, the growing pressures and the needs to consolidate and minimize duplication, and the primary aim of Safe and Sustainable, to provide a stable future for pediatric cardiac surgery in England and Wales. If the aim of the review is to ensure excellence in the future provision of surgery why has the panel recommended a mediocre solution for ECMO in babies and children? We humbly suggest, to borrow a phrase, that the move is quite literally throwing the baby out with the bathwater. This move, although well-intended, is one clearly likely to produce results that will have a human toll in increased deaths. As concerned citizens of the ECMO world, we implore you to take the time to weigh the impact of this move on the care that we know you desire for Britons.

Respectfully Submitted,

James D. Fortenberry MD, FCCM, FAAP  
Pediatrician in Chief  
Children's Healthcare of Atlanta  
Chair, ECMO Leadership Council  
Professor of Pediatric Critical Care  
Emory University School of Medicine  
Atlanta, GA USA

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Children's Hospital of Philadelphia Newborn Care  
Medical Director, Chester County Hospital Neonatology  
Chair, ELSO Logistics and Education Committee  
Associate Professor of Pediatrics  
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Thomas V Brogan, MD  
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Associate Medical Director Extracorporeal Life Support Services  
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Columbia University Medical Center  
New York-Presbyterian Hospital - Columbia New York, NY USA

Fortenberry, James  
**Sent:** Friday, July 06, 2012 10:57 PM  
**To:** 'lansleya@parliament.uk'  
**Cc:** Fortenberry, James  
**Subject:** ECMO and the Glenfield programme

[lansleya@parliament.uk](mailto:lansleya@parliament.uk)

Department of Health  
Richmond House  
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London  
SW1A 2NS

Dear Mr. Lansley,

As Chair of the ECMO Leadership Council for Children's Healthcare of Atlanta, a Professor of Pediatric Critical Care at Emory University School of Medicine and a member of the International Steering Committee of the Extracorporeal Life Support Organization, I am writing to respectfully request your reconsideration of the potential move of the Glenfield ECMO program to Birmingham. As a leader at one of the largest ECMO programs in the US, **the impact on care of attempting to move our program *in toto* to another center location would be devastating. ECMO is not merely the equipment, but the incredible collective expertise and institutional memory of its entire team (and ECMO indeed takes a village) of physicians, nurses, therapists, pump specialists, pharmacists, biomedical engineers, and administrators among many others. Building both the expertise and infrastructure for such a specialized programme is an exhaustive effort that takes a minimum of 5 years to create an effective, quality enterprise.**

**Glenfield fields one of the finest ECMO programs in the world, and was the source of the recent CESAR trial, a landmark study that helped sort out the benefits of adult ECMO. One of the key takeaways was that regionalization to a premier center with demonstrated experience in ECMO delivery is critical.** To attempt to rapidly recreate that expertise in another location would seem a task likely to generate at least initial mediocrity and at worst endanger lives. Given the relatively small overall volumes of ECMO relative to other high volume services, such a move seems penny wise and pound foolish.

As a noncitizen of the UK, but as a citizen of the ECMO world, **I humbly offer my voice as an ECMO expert in seeking your reconsideration to allow the Glenfield ECMO programme to continue its excellence in saving the lives of neonates, children and adults in the UK and Europe.**

Sincerely,

Jim Fortenberry MD

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Delivered: Electronically and by Certified Mail

July 17, 2014

Andrew Lansley  
Secretary of State for Health  
Department of Health  
Richmond House  
79 Whitehall  
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Dear Mr. Lansley:

I have been following your decision to consolidate the United Kingdom Pediatric Cardiac Surgical Programs with interest. As the chairman of the Extracorporeal Life Support Organization (ELSO) Logistics and Education Committee, I respectfully would like to share my experience in assisting and developing multiple ECMO programs and to reflect upon how these experiences may provide insights into your decision. **Since the publishing of Mr. Peek's groundbreaking article on the use of ECMO in adult respiratory failure, ELSO has been called upon to assist multiple institutions develop ECMO programs.** I have organized ECMO training programs that have instructed hospital staff members from more than 50 centers world-wide. Personally, I have been involved in building an ECMO program in Hawaii, and currently I am in the process of expanding a cardiac and critical care ECMO program for the state of Delaware in the US.

I believe that history offers remarkable insight into what is required to build a successful ECMO program. As you may be aware, in the 1970s the United States National Institutes of Health (NIH) sanctioned a large multicenter study looking at ECMO therapy in adult respiratory failure (1). This study was terminated due to the high rate of complications and mortality associated in the ECMO treatment arm. However, when the article was critically reviewed with current medical standards, it is clear that the study design was flawed due to its recruitment of study centers that lacked the necessary experience to safely administer this complicated technology to its most critically ill patients. Without the careful consideration of factors outside the technical aspects of the procedure, such as, multidisciplinary team dynamics,

institutional expertise outside of the ICU, and the importance of shared experience among the surgeons and critical care physicians, these programs were unable to implement this lifesaving technology. The failure of the NIH ECMO study was not due to the procedure itself but due to the lack of education and preparedness of the staff instituting the technology.

**After years of assisting centers establish their ECMO programs, I have found the best programs emerge when the ECMO team function and skill sets mature. It is very simple to institute a didactic educational program and to teach the practical procedures with high fidelity simulation. However this is not even half the battle, successful translation of this knowledge to the patient's bedside only occurs with time as teambuilding skills are mastered, something the NIH Principal Investigators failed to consider. When I was leading the Hawaii ECMO program, we found that we required years of patient care, endless case reviews, constant continuing education and simulation training, to achieve the quality benchmarks necessary to receive the designation as an ELSO ECMO Center for Excellence. As I develop my second ECMO program in the US, my timeline for education and team building is measured in years, not months. The institution's ability to accept surgically and medically complex patients for ECMO support is planned in incremental steps to account for institutional maturity. Just as a child's developmental maturity cannot be accelerated, an ECMO program's growth and success, hence maturity, comes with time and experience.**

**The United Kingdom is fortunate to have one of the world's outstanding ECMO and Pediatric Cardiac Centers under the direction of Mr. Peek. A critical component to the success of the Glenfield Cardiac Surgery program is the team's access to a seasoned ECMO program. This one fact allows Glenfield's most complex and challenging pediatric and neonatal cardiac surgical patients to achieve their excellent clinical outcomes. If the Glenfield cardiac surgical and ECMO program is transferred to another institution, the new center will not replicate Glenfield's outcomes since the ECMO program will no longer have access to the established multidisciplinary team proficiency and institutional memories. I fear that your decision to consolidate the Cardiac Surgical programs without recognizing the importance of institutional experience will impact the United Kingdom's ability to remain a leader in Pediatric ECMO care.**

Respectfully yours,

Mark T Ogino, MD, FAAP  
Children's Hospital of Philadelphia Newborn Care  
Medical Director, Chester County Hospital Neonatology  
Chair, ELSO Logistics and Education Committee  
Associate Professor of Pediatrics  
Perelman School of Medicine, University of Pennsylvania  
Philadelphia, PA, USA

Cc: Mr Simon Burns

**Extracorporeal Membrane Oxygenation in Severe Acute Respiratory Failure: A Randomized Prospective Study.** Warren M. Zapol, MD, Michael T. Snider, MD, PhD, J. Donald Hill, MD, et al. *JAMA*. 1979;242(20):2193-2196. doi:10.1001/jama.1979.03300200023016

**Mr  
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Regensburg, 9 July 2012

Dear Sir,

please allow me to contact you as ECMO (extracorporeal membrane oxygenation) specialist from Regensburg University Medical Center, which is a supra-regional center in Germany with more than 100 adult ECMO runs per year. We have started extracorporeal respiratory support in 1996. My friend Giles Peek, Consultant in Cardiothoracic Surgery and ECMO, Glenfield Hospital, Leicester, informed me recently, that it is intended to close down the children's heart surgery service and ECMO service for children in Glenfield Hospital. This comes as a surprise to other ECMO centers in Europe.

As is well known to you, Glenfield Hospital has won an excellent reputation for their expertise in pediatric and adult ECMO treatment and is deemed to be one of the world's leading centers. The knowledge and experience of the staff in Glenfield probably is unmirrored in Europe and the US. To my knowledge, Glenfield treats the largest number of patients with severe cardiac and respiratory failure with ECMO world wide.

ECMO is only used in the most severely sick patients with a high probability of death. Consequently, the use of ECMO demands a specialized training and a longstanding experience with patients and devices. Survival very much depends on competence. The necessary knowledge can not be gained within some months, and centers with less expertise certainly will experience a



higher mortality. Therefore, in the interest of best patient care the decision to close down the most experienced center of the UK is difficult to comprehend for somebody from abroad.

Certainly, it is not my field of responsibility and I lack the necessary in-side information to question the advices of the JCPCT. Nevertheless, let me ask you to take these considerations into account before closing one of your best health care services,

Yours sincerely

Dr. Thomas Müller  
Consultant of Intensive Care Medicine and Pneumology  
ECMO Co-director  
University Medical Center Regensburg  
Germany

## **Appendix 2: Lack of recognition of the sustainability of PICU in the Midlands**

- **The committee made a decision that sees BCH increasing its cardiac surgery from 555 cases currently to 611 cases under option B. Can the committee make assurances that despite their documented difficulties in staffing and managing current referrals that BCH will be able to make these new demands being placed on them (what are their plans)?**

Almost every week, Birmingham Children's Hospital's are referring patients to other centres area because they are full. A number of patients who have been transferred from hospitals in Warwickshire to North Staffordshire hospital for intensive care because BCH PICU is full, necessitating an additional journey of almost 40 miles for these very sick children. Finally, the waiting list for children's cardiac surgery has increased over this year, and currently stands at around 100 cases. It is clear that the existing bed provision is unable to cope with the demands currently placed on it. A significant proportion of BCH expansion will be taken up accommodating its current workload.

- **How does the committee see the knock on effect of services, in particular PICU, being managed within the "unsuccessful hospitals"? What support, financial or otherwise will be available?**

The S&S review team stated (p165 of the business case) that Southampton, going to ~500 non cardiac PICU patients, would be affected because:

- the ability of smaller PICUs to maintain retrieval services would be affected
- the impact of a PICU's ability to continue to recruit and retain high calibre staff over time would be reduced
- smaller PICUs may be less equipped to act as training units, with a particular impact on anaesthetic training.

But that Leicester (page 101 of the business case) going to ~400 non cardiac PICU patients, would not be affected because:

- 'The city of Leicester does not face unique challenges in responding to reduced PICU activity'.
- 'The figures put forward by Glenfield Hospital itself for the expected number of non-cardiac and non-ECMO admissions to the PICU at the Leicester Royal Infirmary (421 admissions a year) would meet the requirements for a viable Level-3 PICU'.

The briefing documents attached may help, but clearly the same standards have not been applied in this instance.

PICU in Leicester is at our Childrens Hospital and East Midlands Congenital Heart Centre and they function as one unit, with one consultant body rotating between the two providing separate on-site cover as well as ongoing nursing rotations. Our results are reported in the national database PICAnet as one service. Closure of the Glenfield will lead to a 65% reduction in PIC activity in this service and therefore would potentially make the service at the Children's Hospital un-viable. This has not been considered as part of the process. Conversely only a 29% loss of the Southampton PICU service was deemed non viable by the review team.

- **Letter from Andrew Coe representing concerned paediatric consultants in the West Midlands**

Dear Mr Lansley

I attach the combined response that went from all the paediatric medical consultants working in Coventry & Warwickshire during the consultation process.

Interestingly the 2 PCTs sent responses without any reference to any its senior clinicians, which I am afraid reflects much of the NHS consultation processes over its history.

We felt our arguments to support option A were, are remain valid

I have personally been involved directly in re-configuration of acute and specialist childrens health services in the midlands over a 15 year period, and have been an external "expert" on service reviews in various parts of the UK

So the basis and argument for the cardiac review I most definitely support

However may I ask you to please read the summary on page 2/3 why the closure of cardiac surgery at Leicester and relocation of all surgical services to Birmingham will have an unmanageable impact on many if not all of the specialist and core services of Birmingham Childrens Hospital.

I do hope even at this late stage you will consider listening to what we believe are compelling reasons for maintaining cardiac services at Leicester

Andrew Coe

Consultant Paediatrician

25<sup>th</sup> June 2011

**Safe and Sustainable - Review of Children's Congenital Heart Disease Services in England – 1 March 2011 – 1 July 2011**

Dear Sirs/Madame,

This is a collated response from **the paediatric consultant body of Coventry & Warwickshire (C & W)**. They work across the three trusts of University Hospitals Coventry & Warwickshire UHCW), Coventry, George Eliot Hospital (GEH), Nuneaton and South Warwickshire Foundation Trust (SWFT), Warwick and the Partnership Trust (PT) (Coventry Community Children's Services).

We are aware that the Arden Cluster has submitted a view (supporting option B). This was drafted **without** any consultation with any of the senior paediatric clinical staff of Coventry & Warwickshire.

UHCW have submitted a view that was drafted by the children's clinical director supporting option A. He based his recommendation following discussion with UHCW clinicians.

We believe that this response from all the C & W clinicians who directly access cardiac services every day, may add clear additional arguments that will help inform and support your decisions.

Individual consultants of C & W may wish to emphasise more emphatically or less emphatically some of the points included. However, cardiac services are accessed by all paediatricians (acute and community) and neonatologists, and we hope therefore this provides a balanced cardiac surgery, over view of what the C & W families would need from a future children's cardiac service that also needs to serve not just the midlands but all of England and Wales.

This consultation document ***Safe and Sustainable***, is unanimously welcomed to meet the ***call for change*** for Children's Cardiac surgery, as detailed by Professor Sir Bruce Keogh. This not only includes a reduction of the current 11 cardiac surgery units to 6 or 7 but the development of cardiac services networks to *coordinate and strengthen existing local assessment units and develop more outreach support* is welcomed, as this principle has been championed for cardiac and other specialist childrens services in Coventry & Warwickshire for many years.

Factors that contribute to the "*too difficult box*" are the unintended consequences on other services to which the review addresses (section 6). Our response is predominated by those concerns along with the potential to threaten capacity for cardiac and other specialist services for children living in the midlands.

We note that ***Option A has been evaluated as having the least impact on other nationally commissioned services.***

We believe option A will also have the **least detrimental impact on our local district** based services against a back drop of possible acute in patient service configuration changes for children over the medium to long term.

We believe that Option A will have the least detrimental impact on the well developed and functioning interactions and inter-relationships across a raft of specialist clinical networks between C & W and Birmingham Children's Hospital Foundation Trust (BCHFT) and University Hospitals Leicester (UHL)

## Summary

1. The predominant tertiary services axis for Coventry & Warwickshire has been with BCHFT, but with important interactions with some specific tertiary services at University Hospitals Leicester (UHL) which include Glenfield Hospital (GUHL).
2. PICU sustainability at GUHL and Leicester Royal Infirmary (LRI) will depend in the medium to long term on both cardiac services and ECMO (at GUHL)
3. ECMO services for both the seasonal demands and for PPHN (persistent pulmonary hypertension of the newborn) delivered at GUHL will help protect BCHFT from the significant demand on its PICU for other specialty services
4. Loss of paediatric ECMO at GUHL may affect sustainability of adult ECMO services in the long term
5. Destabilisation of PICU services at UHL will have un-intended consequences on a number of tertiary service specialties provided for East Midlands and beyond, some of which C & W use, and currently assist the existing precarious capacity in other tertiary specialist services
6. Further anticipated developments and configuration of acute paediatric service delivery across all of the country, in the foreseeable future, may further place demands on PICU capacity and related dependant tertiary services
7. The established (C & W with BCHFT) cardiac network arrangements must be fully supported (through robust commissioning) or if.....
8. GUHL is confirmed as a specialist cardiac service, GUHL and the resulting cardiac network for its population must achieve comparable scoring against the criteria as the other cardiac centre units (such as Southampton). GUHL current position/score is not acceptable in some of the criteria
9. Risks for option B are judged as being uncertain at this stage in achieving adequate numbers of operative episodes (<400/year) for both Bristol and Southampton. Bristol is stated as the centre that will continue to serve South Wales, which infers that Bristol will have to remain as a cardiac surgical centre
10. Option B significantly increases travel time (6.2% versus 3.6% option A) which whilst would not effect C & W families, is a significant burden for the remainder of the population served by BCHFT in option B.
11. We would propose that the M40 corridor could result in some flows towards BCHFT. We are not clear that this is considered in this document. Therefore BCHFT activity could be greater than calculated for Option A

12. Option B we predict will significantly challenge capacity in the midlands in directly and indirectly related tertiary services and in district general acute paediatric services
13. Option B will significantly challenge the necessary and anticipated imminent developments of other tertiary and supra-regional services (eg neurosurgery, plastics, maxillo-facial etc) by BCHFT.
  
14. Commissioning support for the cardiac networks must fully support (including realistic resource) the transition to final configuration in a planned fashion and to time.
  
15. BCHFT can be expected to continue to be a significant provider of general paediatric acute services for Birmingham, and therefore affected by seasonal demands.
16. Glenfield (cardiac services) and Leicester Royal Infirmary (children's and neonatal services) are on distant sites from each other which is not ideal
17. BCHFT and Birmingham Women's Hospital (regional level 3 + neonatal unit and perinatal centre) are on distant sites. This is not ideal.
  
18. There seems no reasonable argument to bring paediatric cardiac transplant services to BCHFT

## **Conclusion**

Our preference is for a 2 cardiac surgical centre service (BCHFT and GUHL - option A) for the midlands but with a midlands cardiac services network operating as a cohesive integrated service provided from 2 cardiac surgical sites. Together they will be able to provide that safe and sustainable service (akin to the 2 centres being proposed for London) that will be more adept at providing adequate capacity for high quality cardiac surgical services for many years to come. This will ensure a sustainable but smaller range of other tertiary services in the midlands provided at UHL, will minimally adversely affect other functioning specialist clinical networks, and not jeopardise BCHFT present and more importantly its future role as a leading national children's hospital across other vital specialties. BCHFT role, as the acute children's hospital for the population of Birmingham should not be compromised by option A but may be by option B.