THE WINSTON CHURCHILL MEMORIAL TRUST OF AUSTRALIA
Report by Brenda Button
2014 Churchill Fellow

The Sir William Kilpatrick Churchill Fellowship

Extra corporeal membrane oxygenation (ECMO) as a bridge to lung transplant: airway clearance physiotherapy and early mobilization in Belgium, Germany, France, the USA and Canada

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This report has been prepared with due care and diligence. The report provides commentary on and makes recommendations for the use of certain techniques and various medical devices. These recommendations are of a general nature. Since all persons and their medical situations are unique and different, my suggestions should not be followed unless they are also recommended by suitably qualified and experienced professional advisors, carers or therapists with specialized knowledge of and responsibility for the specific patient in question.

I also warrant that my Final Report is original and does not, to the best of my knowledge, infringe the copyright of any person, or contain anything which is, or the incorporation of which into the Final Report is, actionable for defamation, a breach of any privacy law or obligation, breach of confidence, contempt of court, passing-off or contravention of any other private right or of any law.

Signed: Brenda Button
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Introduction
Cystic fibrosis, the most common lethal inherited disease in Australia, affects more than 3,000 Australians. Over the past twenty-five years I have worked as a physiotherapist with people with cystic fibrosis from infancy (diagnosed with newborn screening) through to old age. Survival has improved markedly over this time with advances in many aspects of treatment. When severe lung disease progresses to respiratory failure, lung transplantation is the final treatment option for survival. Extracorporeal membrane oxygenation (ECMO) is the new frontier for bridging patients to lung transplant if they become critically ill before donor lungs become available. Development of this life supportive treatment has advanced significantly in Europe and North America over the past decade and research related to its successful use has been published. The Sir William Kilpatrick Churchill Fellowship provided the opportunity to travel to centres in Belgium, Germany, France, the USA and Canada. This afforded the opportunity to learn about new airway clearance techniques and devices and early mobilization and physical exercise at international centres with extensive experience in cutting edge treatments and managing patients on awake ECMO.

I would like to thank the Winston Churchill Memorial Trust for awarding me the Sir William Kilpatrick Churchill Fellowship. It is an incredible privilege to be a Churchill Fellow and to learn from international experts in the field. I hope this report will give something in return to physiotherapists working in this field, providing insight and knowledge about the range of different treatment options and equipment available in different countries to treat patients on ECMO safely, effectively and confidently.

I am deeply grateful to Professors John Wilson and Robyn O’Hehir for
supporting me in the process of applying for a Winston Churchill Fellowship. Professor Greg Snell was extremely generous with information and contact details of clinicians at a number of centres that I wished to visit. Professor Graeme MacLaren went out of his way to personally contact a number of his extremely busy colleagues who are leaders in this field of interest in Europe and North America and who were so generous with their time and expertise. I am indebted to Winston Churchill Fellows Professor Anne Holland and Associate Professor Bronwyn Levvey for mentoring me through the process of applying for and preparing to undertake this Fellowship. Physiotherapists Kate Hayes and Dr Carol Hodgson from the Alfred Hospital generously shared their knowledge and expertise and mentored me in this relatively new field of treatment for patients with cystic fibrosis who require ECMO for acute respiratory failure and bridging to lung transplant. My colleagues in the Physiotherapy Department at the Alfred under the leadership of Mr Jim Sayer all supported me so generously in covering my clinical and administrative workload for the two months that I was overseas undertaking this Fellowship. Special thanks to Lisa Wilson, Ben Tarrant, Rochelle Philp, Janet Bondarenko, Lou Fuller and Scott Bradley.

I am extremely grateful to all the experts who welcomed me into their institutions and allowed me to spend time observing the management of patients, attend ward rounds and team meetings, answer questions and impart their extensive clinical and research knowledge and experiences in Belgium, Germany, France, the USA and Canada. The generosity with which these busy people gave of their time and expertise was overwhelming. The patients at all of these institutions were extremely gracious and generous in allowing me to observe them during procedures and physiotherapy treatments; they answered my questions and taught me so much about the patient experience of a number of new airway clearance techniques and
items of exercise equipment and general treatment while on ECMO.

Special thanks to my husband, Andrew, who has shared my vision for increased knowledge and expertise in the physiotherapy management of critically ill patients waiting for lung transplants and who continues to support me in my work with patients with cystic fibrosis. It was wonderful having you share part of my Fellowship trip with me. Your support and assistance with travel plans and logistics are much appreciated.

I dedicate this report to the six courageous women with cystic fibrosis who taught me so much about the patient’s experience of being treated with ECMO. Their tenacity, determination, resilience, openness and willingness to share their thoughts, feelings and questions about this challenging experience motivated me to apply for this Fellowship and undertake this journey of discovery.
Executive Summary
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The Sir William Kilpatrick Churchill Fellowship

Extra corporeal membrane oxygenation (ECMO) as a bridge to lung transplant: airway clearance physiotherapy and early mobilization in Belgium, Germany, France, the USA and Canada

ECMO is the new frontier of life supportive treatment for critically ill patients with lung disease waiting for a lung transplant. Patients who require ECMO to keep them alive while waiting for donor lungs require daily physiotherapy in the intensive care unit to remove infected pulmonary secretions and maintain muscle mass, strength and optimal physical condition. This is to provide the best chance of surviving the wait followed by the complex transplantation surgery and post-operative recovery. I visited centres that have internationally recognized expertise providing state of the art physiotherapy to patients with end stage lung disease. Further, I investigated the use of ECMO as a survival bridge for patients waiting for lung transplantation. My Churchill Fellowship included research at the following institutions:

The University Hospital, Brussels, Belgium – a leading physiotherapy program in the use of Intrapulmonary Percussive Ventilation (IPV) as a potential new form of airway clearance physiotherapy for patients with end stage lung disease and excessive mucus production including while being treated with ECMO. Other techniques researched at this centre were Positive Airway Pressure using the Ez-PAP® device and the Oscillating PEP device the AerobiKa®. This centre is also well known for its research into the management of gastro-oesophageal reflux.

The University Hospital Gasthuisberg, Leuven, Belgium – a large university hospital with a published track record in impedance monitoring to measure acid, non-acid, weakly acid and alkaline gastro-oesophageal reflux in patients with cystic fibrosis; as well as interpretation of results and treatment.
**The Medizinische Hochschule Hannover (MHH), Germany** – a major university teaching hospital with an internationally recognized ECMO service.

**La Hôpital de la Pitié Salpêtrière, Paris, France** – a leading international unit with published outcomes of the successful treatment of patients together with research into the long term quality of life after treatment with ECMO.

**La Hôpital Foch, Mount Valerian, Suresnes, Paris, France** – a major French medical institution using awake ECMO as a bridge to lung transplant.

**Duke University Hospital, 2300 Erwin Road, Durham, North Carolina** - a major regional health care centre with an international reputation in the management of critically ill patients on awake ECMO awaiting lung transplantation; a significant research record on the impact and treatment of gastro-oesophageal reflux in this patient population.

**New York – Presbyterian, The University Hospital of Columbia & Cornell Universities** – a leading international centre providing awake ECMO, specializing in the early mobilization of patients bridging to lung transplant.

**Toronto General Hospital, Toronto, Canada** – an international leader in treating patients with awake ECMO specializing in early mobilization.

**Use of ECMO in the clinical setting: a patient’s perspective**

ECMO in awake and physically active critically ill patients is a successful treatment strategy to keep them alive while donor organs become available for lung transplantation. Some reports suggest that this form of treatment is still experimental and until large randomized controlled trials have been undertaken to evaluate safety and efficacy, this form of treatment should not be considered standard of care.

While ECMO is reserved as a treatment of last resort after all other evidence based treatment options have failed, there is a growing belief that it may be a more successful option if used at a time when the patient still has some physical reserve and while other organs are still functioning well.

**Cannulation – configurations that allow ambulation**

Many different configurations of ECMO cannulation were seen at the centres.
visited during the Churchill Fellowship. There were regional preferences depending on objectives of treatment, individual patient requirements, the environment that cannulation took place in and local experience. If it was intended that patients were to be awake while on ECMO participating in early mobilization and active participation in treatment, all the centres visited preferred cannulation in the upper body and/or cervical region. The general opinion was that femoral cannulation should not be used if the patient was to engage in standing, walking or sitting upright with 90 degrees flexion at the hips. The risk of occluding blood flow through the cannula in upright sitting and the development of thrombosis was thought to be too great.

**Airway Clearance Techniques used by patients on awake ECMO**

A variety of different airway clearance techniques and devices were used at the centres visited. The techniques selected varied from centre to centre and there was no consensus as to which were best for patients while on awake ECMO. These techniques included:

- Positive expiratory pressure (PEP); oscillating PEP, and positive airway pressure therapies;
- Devices that promoted inspiratory and expiratory respiratory muscle training;
- Techniques that increased lung volumes and ameliorated atelectasis and segmental collapse;
- Methods that elicited shear forces in the airways to loosen tenacious sputum and enhance muco-ciliary clearance;
- Manual techniques that assisted in increased expiratory airflow and mechanical chest wall oscillation;
- Adjunctive inhaled and instilled mucolytic agents;
- Suction of airway secretions via tracheostomy site or the nasopharynx;
- Walking as airway clearance to increase lung volumes and mobilize secretions.

**Early mobilization – physical exercise while on ECMO**

Each centre visited had a positive culture of early mobilization in the ICU
setting and while treated with awake ECMO. For those not strong enough to stand up and walk, bed exercises (passive, assisted and active) and while sitting in a chair were assisted and encouraged. Many different forms of enabling equipment allowed for assisted early mobilization:

- Beds or trolleys that converted into a standing frame (tilt table), chair or wheel chair (one particular chair manufactured in Germany had an optional sturdy supportive wrap around tray that allowed a deconditioned patient with weak core and back extensor muscles) to sit out of bed for periods of time including during meal times;

- Standing frames to allow the severely deconditioned patient to stand upright with a number of supportive straps, promote exercise of the anti-gravity muscles of the legs and experience the benefit of increased basal ventilation and lung expansion;

- Walking frames for patient support with rails, platforms, hooks, bars, wheels and a seat to allow the patient to sit down during the walk; drains, drips, monitoring equipment and oxygen bottles able to be attached so that the patient can be assisted by one or two health professionals during regular walking;

- Portable treadmill that can easily be brought to patient’s bedside allowing him/her to swing legs over the side of the bed then step onto the treadmill positioned at right angles to the bed, with hand rails for support during walking;

- Battery power for ECMO machines, ventilators, oxygen and nitric oxide inhalation equipment and drips to enable patients to walk away from the bedside out of the room to an outside or viewing area for exercise and the psychological benefits of a change in environment.

**Gastro-oesophageal reflux (GOR) management**

The opportunity to observe the clinical application, analysis and interpretation of impedance pH oesophageal monitoring was achieved. Management of GOR in patients with chronic lung disease and after lung transplant varied between centres. Views relating to measurement of GOR and treatments including pharmacological, surgical and lifestyle changes provide new approaches to be considered in the future.

**The team approach to management of patients on ECMO and different treatments and procedures**
All centres acknowledged the importance of the multi-disciplinary team in the management of patients awake on ECMO. The composition of teams varied between centres with different challenges and priorities.

- Use of tracheostomies, mechanical ventilation and non-invasive ventilation varied between centres;

- Nutritional approaches varied from tube feeding, parenteral nutrition and independent eating sitting out of bed at mealtimes eating normal food;

- Bronchoscopies carried out in awake patients with local anaesthetic and minimal or no sedation was observed at three centres. Patients appeared to place great trust in the practitioner carrying out the procedure and became engaged in observing the process on the video screen with real time explanation of the anatomical features observed;

- Quality improvement initiatives were varied and numerous including innovative pressure injury and falls prevention strategies; ways to decrease the incidence of nosocomial infections; and the use of the prone position (‘proning’) to improve ventilation. ‘Proning’ remains challenging with the potential for improving outcomes in selected patients with the objective of preventing the need for treatment with ECMO;

- Published research consists of mostly case series or observational studies. A number of future research topics emerge as future considerations including multi centre randomized controlled trials.
Winston Churchill fellowship Programme

1-13th June, 2015  Belgium
Brussels University Hospital
Dr Filip Van Ginderdeuren, Sylvie Vanlaethem
Dr Bruno Hauser, Marianne Borremans,
Isobel Ooms, Professor Anne Malfroot

Leuven University Hospital
Professor Christine De Boeck, Dr Ans Pauwels,
Myriam Vreys, Trudy Havermans

Brussels
38th European Cystic Fibrosis Conference
8-13th June, 2015

15-20th June, 2015  Hannover, Germany
Hannover University Hospital
Dr Christine Fegbeutel, Jens Oerding,
Dr Mark Greer, Professor Jens Gottlieb,
Dr Annette Sauer, Jon Horn

22nd June – 6th July, 2015  Paris, France
La Pitie Salpêtrière Hospital
Professor Alain Combes

International Congress on ECMO & short-term circulatory/respiratory support
Palais des Congres, Paris, France
25-26th June, 2015

Hôpital Foch, Paris
Dr Elise Cuquemelle, Professor Charles Cert,
Eric Horvat, Adrian Morales

8-10th July, 2015  Duke University Hospital, Durham, NC, USA
Professor Ira Cheifetz, Virginia Wills, Desiree Bonadonna,
Professor Neil McIntyre, Dr Kevin Watt, Dr Craig Rackley, Dr Christoph P. Hornic,
Dr Raquel Bartz, Dr George Orfori-Amanfo,
Janice Thalman, Heather Harrison, Kenneth Gold, Jennifer Edelschick, Tamara
Klintoworth-Kirk, Dr Alice Gray

13-17th July, 2015  New York Presbyterian Hospital, USA
Professor Dan Brodie, Susan Tanzi Pfeifer, Patrick Ryan, Patricia Rychcik, Tom Benson, Alissa Kolins, Dave Zemmel, Lori Buck, Denise Zakula, Dr Ellen Goldberg, Abigail Zemelman, Dr Darryl Abrams, Allyson Klein

20-22nd July, 2015  Toronto General Hospital, Toronto, Canada
Dr Eddy Fan, Annemarie Bourgeois, Theresa Torres, Liz Gordon.
ECMO as life support: limited knowledge about physiotherapy treatment for patients with suppurative lung disease in Australia

Introduction
In Australia, many patients suffer from chronic lung disease such as cystic fibrosis (CF). There are more than 3,000 people with the most common Caucasian inherited life limiting disease of CF in Australia who are managed nationally by 27 multidisciplinary CF clinics. The hallmark of CF consists of excessive viscous mucus production in all the exocrine glands of the body. The airways become impacted with plugs of mucus and are exposed to repeated cycles of airway infection and inflammation leading to a progressive decline in lung function eventually ending in respiratory failure.

The four corners of treatment include medical, physical (physiotherapy), nutritional and psychological. Medical treatments include pharmacological therapies such as antibiotics, antifungal and anti-inflammatory agents together with management of the complications that arise from this multi-organ disease. Physiotherapy consists of airway clearance therapy, adjunctive inhaled mucolytic agents and preservation of normal physical function and rehabilitation when required. This is achieved through physical activity and exercise together with management of musculoskeletal problems that cause pain and postural changes. Nutritional support is provided to optimize absorption of nutrients and maintenance of an ideal body weight and muscle mass. Psychosocial support is provided for psychological anxiety and distress that develop as lung function declines and patients become more physically debilitated. Members of a multi-disciplinary team provide this complex care.

With years of repeated infections, and gradual but relentless lung function decline, lung transplantation becomes the final treatment option. Patients are assessed for transplant and if appropriate are placed on a waiting list. In Victoria, Australia the average waiting time from listing to lung transplantation is nine months. Some patients will receive lungs in a shorter time while others may wait for two years or longer. While on the waiting list patients sometimes physically decompensate and become critically ill and if donor lungs do not become available within a short time
they will not survive. Extra corporeal membrane oxygenation (ECMO) has become the new frontier of life support extending survival as a bridge to lung transplantation. Patients with other types of chronic lung disease such as bronchiectasis, chronic obstructive pulmonary disease, pulmonary hypertension and interstitial lung disease may also require ECMO as a bridge to lung transplant.

Acute respiratory distress syndrome (ARDS) is another life threatening condition that can occur in healthy members of the public with severe attacks of influenza or other surgical or medical conditions that cause sudden lung decompensation. They may require rescue with specialized treatment in the intensive care unit including ECMO which in these previously healthy individuals is usually used as a bridge to recovery.

The first reported successful use of ECMO was in 1972. Clinical research to justify the use of this previously cumbersome and invasive treatment has advanced intermittently over the decades in Europe and North America. Between 1980 and 2000 there was limited use of ECMO as a bridge to transplant due to poor outcomes reported in various prospective studies. Advancements in technology such as heparin-coated circuits, centrifugal pumps and new innovations in oxygenators made ECMO a more viable form of treatment with successful outcomes. Important clinical trials including the CESAR trial published in 2006 together with the H1N1 influenza outbreak around the world in 2009 resulted in further knowledge, advancements in technology and greater institutional experience. This was followed by the development and introduction of a dual lumen single ECMO cannula (Avalon®) that has revolutionized lung bypass with this form of treatment.

The H1N1 influenza outbreak in 2009 resulted in many deaths and during this time ECMO advanced significantly to provide a bridge to recovery. ECMO was used in numerous units around the world where clinicians developed experience in a critical mass of patients required to achieve expertise and improved survival and clinical outcomes. Using modern day ECMO it is now possible to support patients for days to months while injured tissues heal as in acute respiratory distress syndrome (ARDS) or donor organs become available for lung transplantation.
**How does ECMO work?**
ECMO involves gas exchange and oxygenation of blood outside the body and can provide complete or partial support of the lungs and/or heart for patients who, without this treatment, are not likely to survive (Lindstrom, Pellegrino & Butt 2009). An ECMO system consists of two single cannulas, or one double lumen cannula to take venous blood from the body and to return oxygenated blood to the arterial circulation for oxygenation of all the tissues of the body. Outside the body the blood circulates through a pump and a gas exchange device with a membrane that removes carbon dioxide and oxygenates the blood. A temperature control device either heats or cools the blood and maintains it at an optimal temperature in the circuit (Lindstrom, Pellegrino & Butt 2009). In the case of respiratory failure in patients with advanced chronic lung diseases such as cystic fibrosis the ECMO system acts as a lung bypass machine. This provides continuous support to the patient in an intensive care setting by a highly trained team of health professionals in order to oxygenate and support vital tissues and keep the patient alive as a bridge to lung transplantation.

Complications can occur while on ECMO. Bleeding from different parts of the body such as nose and lungs can occur as patients are treated with the blood thinning drug heparin to prevent blood clotting while circulating through the ECMO machines. Clotting of blood in the circuit can occur which may require the ECMO circuit to be changed. Recirculation, the mixing of venous and arterial blood in the circuit, can occur if the two cannulas or the double lumen single cannula are not positioned correctly. This can compromise the patient’s condition requiring medical intervention such as repositioning of the cannula. Recirculation can also limit the ability of the patient to be physically active.

Until relatively recently patients treated with ECMO have been sedated and paralyzed lying in bed in the intensive care unit, breathing with the assistance of a mechanical ventilator, feeding via a tube into the stomach and unable to participate in physical activity. If patients are sedated and immobilized for a number of days or weeks they quickly lose muscle mass, strength, bone density and generally become physically
weak and debilitated and outcomes after lung transplant are very poor (Fan et al 2009).

In recent years ‘awake ECMO’ has been developed where patients are intubated in the operating theatre for the surgical insertion of the ECMO cannulas and, once stable, sedated patients are woken up and taken off the ventilator and allowed to breathe independently. They spend the time on ECMO waiting for a lung transplant awake, alert and able to participate in physiotherapy to clear airway mucus and carry out physical exercise to preserve muscle mass and strength. Awake ECMO has led to better outcomes after lung transplantation than traditional sedation and mechanical ventilation (Fuehner, Kuehn, Hadem et al 2012). Little rigorous scientific research has been published in peer reviewed journals or presented at national or international conferences about the use of airway clearance physiotherapy and physical exercise while patients are on awake ECMO. Published articles and conference presentations have been mostly based on descriptions of local experiences in case reports and relatively small case series.

Dual lumen single Avalon® cannula – diagram with permission from Professor Vincent Pellegrino, The Alfred Hospital, Melbourne.
In Melbourne, at the Alfred Hospital, we have an extensive experience treating patients with veno-arterial ECMO supporting cardiac function and veno-venous ECMO with patients with ARDS providing a form of lung bypass while the lungs heal bridging patients to recovery. We treated our first patient with cystic fibrosis with veno-venous ECMO using the recently developed dual lumen single Avalon® cannula in 2010 that allowed the patient to be awake and active. Since then we have treated a small number of patients with cystic fibrosis using this technology to bridge to lung transplantation. We had little information to guide us in the physiotherapy treatment. Therefore we relied on clinical reasoning based on our local knowledge and experience for the treatment of patients with significant lung infections and respiratory failure and applied this to patients on awake ECMO. When patients are immobilized and treated in recumbent positions for prolonged periods of time lung volumes are reduced resulting in atelectasis and stasis of lung secretions and infection. In keeping with state of the art modern airway clearance therapy to increase resting lung volumes and improve lung clearance, use of the following techniques were employed with this series of patients: positive expiratory pressure (PEP) therapy, oscillating PEP therapy, the Active Cycle of Breathing Technique, the Forced Expiration Technique, targeted positioning to improve ventilation and non-invasive ventilation combined with airway clearance therapy. Adjunctive inhaled mucolytic agents such as dornase alpha and saline (normal saline or hypertonic saline) were used to break up and rehydrate thick dehydrated mucus respectively. We assisted the patients in safe physical activity respecting the requirements of the ECMO cannula, circuit and pump. This included bed exercises for feet, ankles and lower limbs, sitting with legs over the side of the bed with feet on the floor; standing in a tilt table, standing beside the bed supported by two physiotherapists or with patient’s forearms supported by a walking frame; marching on the spot; and sitting in a chair doing active leg exercises. Sometimes these exercises and activities appeared to interfere with ECMO functions and flows. The longer the patients were on ECMO the more problems were experienced with flows during physiotherapy. This limited physical activity significantly.

Many patients with end stage lung disease suffer from significant gastroesophageal reflux and regurgitation of stomach contents during physiotherapy and coughing as
well as while lying down. This results not only in discomfort but possibly the worsening of lung disease. Current medical pharmacological treatment and lifestyle changes are not always effective in treating this condition.

**Aims of the Winston Churchill Fellowship**

The aims of this fellowship were to visit eight centres in Europe and North America to achieve the following:

- Investigate treatment of patients using awake ECMO at large international centres with extensive experience and successful outcomes which have been published in scientific peer reviewed journals;
- Explore the different types of airway clearance techniques used in five different countries as well as learn new techniques not currently used in Australia that recruit underventilated lung regions, increase resting lung volumes and enhance mucus clearance;
- Research the prescription and application of physical exercise together with the equipment to enable this for patients on awake ECMO to maintain muscle mass, strength and physical condition;
- Gain insight into the patient's perspective of the experience and quality of life during and after awake ECMO relative to airway clearance and physical activity;
- Examine state of the art diagnosis and management of gastro-oesophageal reflux in patients with chronic lung disease at centres where research has been carried out and published in recent years;

**References**

1. Cystic Fibrosis Standards of Care, Australia; Scott C. Bell and Philip J. Robinson Steering Committee Co-Chairs, Dominic A. Fitzgerald Editor 2008 Thoracic Society of Australia Website.


The Universitair Ziekenhuis, Brussels, Belgium

Overview
The Universitair Ziekenhuis (UZ), Brussels is a large university hospital treating adults in all specialties of medicine. The Adult Cystic Fibrosis Unit manages around 100 adults and the Paediatric Unit approximately 80 children. A number of different teams of physiotherapists provide therapy to patients across this large campus. Thirty-five physiotherapists make up 25 full time equivalents. They are all required to do a straight seven-day stint once or twice per year. During this week they are on call 24 hours per day while also working fulltime during their usual daytime shifts. Patients who are expected to deteriorate overnight without treatment are prioritized on an overnight treatment list. Patients with cystic fibrosis often fall into this category. Patients requiring lung transplantation attend the Erasmus Hospital in Brussels as no lung transplants are carried out at the Universitair Ziekenhuis. The UZ Brussels has for decades been a leader in innovative physiotherapy treatment techniques as well as research into the effects of physiotherapy and different positions on gastro-oesophageal reflux.

Aims of visit to the Universitair Ziekenhuis, Brussels (UZ Brussels)
1. Investigate the equipment, rationale for use and application of Intrapulmonary Percussive Ventilation (IPV) and Positive Airway Pressure using the Ez-PAP device combined with Assisted Autogenic Drainage (AAD) as new airway clearance techniques to use with patients in acute respiratory failure with sputum retention in Australia.
2. Research the use of impedance monitoring to diagnose gastro-oesophageal reflux (GOR) together with this institutions treatment approaches to GOR.

Airway clearance techniques used at the UZ Brussel
Physiotherapists in Belgium are well known for two physiotherapy techniques that have been extensively used over many years. These include Intrapulmonary Percussive Ventilation (IPV) and Autogenic Drainage (AD). When patients require manual assistance with AD (such as infants, small children and very unwell patients)
then manual assistance in the form of Assisted Autogenic Drainage is provided (AAD). More recently they have used the Ez-PAP system in selected patients.

**Intrapulmonary Percussive Ventilation (IPV)**

IPV is used to treat patients with obstructive and/or restrictive, acute or chronic respiratory diseases with retained pulmonary secretions. IPV delivers a continuous pulsatile flow superimposed on the patient's breathing pattern during inspiration and expiration. The percussions are subtidal volumes of gas delivered to the patient with low pressure and an adjustable high rate, through an open breathing circuit called The Phasitron®. This is a pressure flow converter that transforms small volumes of gas at high pressure and low flow into larger volumes of gas at low pressure and high flow. The waveform generated by the Phasitron® depends on device characteristics including the selected work pressure and frequency and the patient characteristics such as thoraco-pulmonary compliance and pulmonary resistance. The open breathing circuit is based on the venturi effect.
Theoretical Effects of IPV

IPV is believed to improve mucociliary clearance via recruitment of pulmonary territories and increased lung volumes utilizing collateral channels. This results in the decrease of preferential airway ventilation and more homogeneous ventilation. Air gets behind mucus and pushes it in a cephalad direction towards the mouth. These processes lead to an improvement in gas exchange and removal of secretions using directed controlled coughing or suctioning in patients unable to follow instructions. Humidification and use of mucolytic agents such as saline and hypertonic saline are combined with treatment to optimize muco-ciliary clearance. IPV is believed to have a positive effect on the three circulations, namely, bronchial, pulmonary and lymphatic.
Autogenic drainage (AD) combined with IPV

Autogenic drainage is an airway clearance technique developed in Belgium over the past four decades by Mr Jean Chevaillier. AD is a technique that can be used independently by trained patients as a stand-alone technique or combined with positive expiratory pressure therapies and mucolytic agents. The aims of AD are to generate the highest expiratory airflow through all generations of bronchi without causing dynamic collapse. This increased airflow through the airways results in erosion of the adherent mucus off the airway wall utilizing shear forces and promoting muco-ciliary clearance. The technique can be used in upright or horizontal positions. In the hospital setting physiotherapists can manually assist patients of all ages providing a technique called Assisted Autogenic Drainage (AAD). The physiotherapist places one hand on either side of the chest and provides proprioceptive guidance and controlled pressure during expiration encouraging the patient to exhale towards residual volume. Mr Filip Van Ginderdeuren, the host of my Winston Churchill Fellowship visit is an expert in this technique. He and his colleagues often use AAD in combination with IPV to optimize airway clearance.
The Metaneb System® has recently become available to patients in Australia and other parts of the world. This availability corresponded with my return from training in the use of IPV during my Churchill Fellowship. The knowledge gained during the Fellowship has allowed me to use this airway clearance treatment technique with selected patients developing expertise and experience which is sought after by physiotherapists in Australia and New Zealand. The Metaneb System® runs off an approved high pressure 50 psi gas oxygen source. It provides a CPEP (constant positive airway pressure) mode resulting in positive expiratory pressure during expiration as the patient exhales against the continuous flow (0-30 cmH2O pressure). It also provides a CHFO (constant high frequency oscillation) mode that allows the selection of a lower oscillation frequency of 170 or a higher frequency of 230 RPM. Humidification and/or mucolytic agents are combined with treatment attaching into the circuit as seen in the accompanying figure above.

**Treatment with Positive Airway Pressure using the Ez-PAP® device**

Used in spontaneously breathing patients the Ez-PAP® hand held device provides a constant flow of air with or without added oxygen which can be altered according to each patient’s needs. Ez-PAP® unloads inspiratory muscle work and increases lung expansion during inspiration and results in a positive expiratory pressure (PEP) during expiration promoting increased lung volumes and airway clearance therapy.
This technique assists in preventing or ameliorating lung complications in selected patients. Ez-PAP® can be used with a mouthpiece or closely fitting mask forming a seal in actively participating patients or those who require assisted treatment. It can also be used by patients with a tracheostomy using a company provided connector. Ez-PAP® is attached to oxygen and/or air outlets to provide increased airflow during the complete respiratory cycle. During inspiration alveolar recruitment is promoted. The PEP generated during expiration against the positive airflow allows air to move via collateral channels and get air behind secretions in the peripheral airways moving them upstream towards the mouth for expectoration.

The amount of inspiratory airflow provided is individualized to patient need and comfort. The FiO2 is selected according to each individual patient's requirements. A manometer is used to measure the inspiratory and expiratory pressures. Ez-PAP® can be combined with Assisted Autogenic Drainage for airway clearance therapy. Starting with a low flow rate (around 5 litres) titrate the flow up towards 8 to 10 to 12 litres (L) finding the level that is comfortable and well tolerated by the patient and that is likely to achieve the desired treatment effect. This usually is achieved at positive expiratory pressures of 10-20cmH2O. It is recommended that maximum flow should not exceed 15L in order to prevent barotrauma to the airways. Humidification and mucolytic agents such as saline or hypertonic saline can be included in the circuit with a nebuliser and T-piece attachment between the patient interface and the device. The device is cleaned using institution approved cleaning protocols.

Figure 1: Mask interface
Indications, precautions and contra-indications for IPV and Ez-PAP®

Indications:
Patients with obstructive and restrictive conditions resulting in low lung volumes and sputum retention will benefit from IPV and the Ez-PAP® systems. These techniques can be used across all ages with and without patient cooperation:

- Treatment of peripheral obstructions and ventilation problems of restrictive and/or obstructive diseases, independent of age and patient cooperation;
- Treatment of persistent atelectasis / lung collapse resistant to usual physiotherapy techniques such as deep breathing exercises, positive expiratory pressure therapy or physical activity such as walking.

Precautions / contra-indications

- Unable to tolerate treatment – increases the work of breathing
- Increased intracranial pressure
- Hemodynamic instability
- Acute sinusitis
• Recent facial, oral, skull surgery, trauma
• Epistaxis
• Oesophageal surgery
• Active haemoptysis
• Untreated pneumothorax
• Oesophageal surgery / varices
• Risk of pneumothorax
• Presence of large bullae on radiological images

Use of IPV in the Neonatal Intensive Care Unit (NICU)
Four neonates, gestational age 28-32 weeks, were observed receiving treatment with IPV and suction in the Neonatal Intensive Care Unit at the UZ, Brussels. The physiotherapist supported the infant’s head during IPV to avoid head shaking injuries. IPV was applied with a small infant facemask. Infants appeared to relax during treatment and are reported to sometimes stop breathing spontaneously during IPV. Infant oxygen saturations were observed to increase during the treatment. Infants were monitored with transcutaneous pCO2 monitors. At the end of treatment the physiotherapist sometimes needed to stimulate the infant to start breathing spontaneously again. IPV equipment was rinsed under running water, sprayed with alcohol and left to dry. For infection control all physiotherapists wore gowns, gloves and masks when treating all patients. The nursery had noise monitoring equipment. When noise levels were too high an illuminated green ear on the wall became red and staff were alerted to reduce the volume of noise in the nursery. All infants’ cots were covered with heavy cloth covers for darkness, warmth and quiet. According to the treating physiotherapist the Research Ethics Committee has not supported a randomized controlled trial of IPV versus no treatment in this unit as IPV has become accepted as the standard of care. A new unit is being built with a central nurses’ station with monitors screening images from each room. Infant single rooms fan out from the nurses’ station. A corridor around the perimeter of the circular ward will allow parents entry to their infant’s single room with a security card.

Case studies of IPV used with different patients on the wards
Case 1:
A teenage boy with neurofibroma and post-surgical complications including a chest infection requiring 30% inspired fraction of oxygen was observed. His breathing was supported with non-invasive ventilation using bi-level positive airway pressure with inspiratory pressures of 24 and expiratory pressures of 7. His airway clearance therapy consisted of IPV with two gas drivers, one with 100% oxygen and the other with air. The frequency generated during treatment ranged between 240-280 cycles per minute (~4Hz) with 8cmH2O pressure. The IPV treatment was provided with a facemask interface. IPV was combined in cycles with manually assisted autogenic drainage and intermittent huffing and coughing and sputum clearance. His daily dosage of physiotherapy was three treatments with a duration of around thirty minutes per session.

Case 2:

An adult who had received a kidney transplant 16 years previously with a right middle lobe pneumonia. IPV was provided with a frequency of 300 cycles per minute combined with 10 mls of hypertonic saline via the nebulizer cup. The physiotherapist increased the flow gradually starting at zero until the patient’s diaphragm vibrated or moved at a comfortable level. During the treatment the patient’s heart rate remained in the 60s, oxygen saturations were between 95-100% and the respiratory rate was between 16-22. Cycles of IPV were combined with assisted autogenic drainage and coughing. Barotrauma is avoided by limiting the inspiratory flow. IPV is used to recruit alveoli and is believed to induce ‘counterflow’ in the airway resulting in air moving in both directions causing shear forces to mobilize secretions. If the flow rate is too high the patient resists or ‘fights’ against it and paradoxical breathing movements are seen. Hypertonic saline 6% is nebulized to rehydrate the airway surface liquid layer to promote muco-ciliary clearance. Assisted autogenic drainage is combined with IPV resulting in an effective and productive cough.

Case 3:

A school aged boy with a tracheo-oesophageal fistula, oesophageal atresia and gastro-oesophageal reflux disease (GORD). The patient observed during treatment continues to experience recurrent chest infections following a Nissen fundoplication the previous year. He was treated with IPV with a frequency of 270 cycles per minute and positive expiratory pressures of 8-10cmH2O. A trial of dornase alpha was being
carried out for viscous secretions. IPV was combined with assisted autogenic drainage.

**Case 4:**

**An infant with CF requiring an inguinal hernia repair the following day.** His usual physiotherapy consisted of AAD while bouncing on his mother’s lap at home. A pre-surgical treatment was observed. This consisted of IPV combined with bouncing and AAD on a peanut shaped Fit Ball. The infant was very relaxed and tolerated treatment surprisingly well.

**Case 5:**

**A 55 year old lady with diabetes and a recent leg amputation** transferred from a regional hospital with neurological impairment and unable to participate in treatment was observed. She was being treated for a chest infection. Treatment consisted of IPV (using a tracheostomy interface) with nebulized normal saline combined with assisted autogenic drainage. Intermittent suction was performed via a tracheostomy tube inserted in the regional hospital.

**Case 6:**

**An 84 year old gentleman with multiple fractures** fell down the stairs two days previously and sustained a fractured cervical and thoracic spine, manubrium sternum and multiple fractured ribs together with a cerebral haemorrhage. He had an unstable chest with paradoxical breathing movements. Treatment consisted of IPV and careful and gentle assisted autogenic drainage.

**Case 7:**

**A 60 year old lady with aorta valve surgery via a sternotomy** required chest physiotherapy to recruit alveoli and prevent complications. Treatment consisted of use of the Ez-PAP device to recruit alveoli and increase lung volumes together with assisted autogenic drainage to enhance mucociliary clearance. The patient used a sternal support with a band around the back and a handle each side of the anterior chest. To support her sternotomy during coughing and minimize pain she grabbed the handles each side of the chest and pulled them together during coughing. She had clear breath sounds and a non-productive cough. This treatment was used to prevent post-operative lung problems.
Monitoring, diagnosis and treatment of gastro-oesophageal reflux

Professor Yvan Vandenplas, Head of the Gastroenterology Department, has been a leader in research in gastro-oesophageal reflux (GOR) in infants and children for more than 40 years. He developed reference values for interpreting pH monitoring in infants and children. He published a landmark study on the effects of postural drainage with 30 degrees head down tilt on gastroesophageal function in the early 1990s. This study was carried out in children from infancy to 5 years of age including those with cystic fibrosis; other chronic lung diseases; and SIDS siblings as controls. He demonstrated a significant increase in episodes of GOR when in 30 degrees head down positions in all groups of subjects, those with lung diseases as well as controls. In meeting and talking with him one realizes the extent of his influence and the contribution he has made in this area of medicine. He continues to be a world leader in gastroenterology and is highly sought after as a speaker at international conferences.

Dr Bruno Hauser, is the Chief Gastroenterologist at the Universitair Ziekenhuis, Brussels. Gastro-oesophageal reflux is a major problem in patients with chronic lung disease including cystic fibrosis. He reports that non-acid, weakly acid and alkaline gastro-oesophageal reflux all potentially lead to major lung problems. The more recently developed technique of impedance monitoring has made diagnosis of non-acid, weakly acid and alkaline reflux possible. This technique has been used extensively at this unit for a number of years. Bile (alkaline) reflux is now recognized as a major factor in worsening lung disease. Proton pump inhibitors are used for treatment and may decrease symptoms. This group has not found a correlation between acid reflux and delayed gastric emptying. However, they have found a correlation between alkaline reflux and delayed gastric emptying.

Impedance monitoring procedure
Calibration of the pH probe is undertaken prior to placement in a solution with a pH of 4 for 10 minutes followed by calibration with a pH of 7. A card is placed in the reader attached to the computer. Patient details are recorded. The protocol is selected (07 for tall children; S1 for small children). These measurements are based on the child's height with 75-80cm being a shorter probe and >80 cm a longer probe.
The calibrated probe is inserted into the oesophagus of the infant or child lying supine. Infants are held still by one nurse while the pH monitoring nurse inserts the probe into one of the nares and stimulates the infant to swallow by blowing in the infants face. During the swallow the probe is quickly inserted into the stomach (pH reading <4). It is then withdrawn to a position above the lower oesophageal sphincter. Fluoroscopy is used to check the position of the probe and if necessary adjustments are made. Parents and mature patients are instructed to keep a 24 hour food and activity diary and are asked to press the event buttons for symptoms and activities such as cough, meals, upright and supine positions. Probes are designed for single patient use. The probes are not discarded in case of equipment failure allowing the study to be repeated without extra cost. Each probe costs €150 and patients are required to pay €50 each.

**Summary of visit to The Universitair Ziekenhuis, Brussels**

During the time at the Universitair Ziekenhuis the objective to investigate the airway clearance techniques (including equipment, rationale and use) of IPV and Ez-PAP combined with assisted autogenic drainage as new airway clearance techniques was achieved. Observing four different highly specialized physiotherapists treating adults, children, infants and neonates on the wards, in the intensive care unit and high dependency units was highly instructive. They generously shared their knowledge and answered many questions related to these treatments. This experience will form the basis for the introduction of these new techniques for critically ill patients in acute respiratory failure as a rescue airway clearance therapy in an attempt to avoid admission to ICU and the potential need for ECMO. For those who require awake ECMO these techniques show great promise as a highly effective but more passive (less tiring) treatment from a patient perspective. An objective trial of IPV and Ez-PAP with patients with end stage lung disease without and with ECMO in the ICU is warranted. Feedback from patients will be crucial in this evaluation.

Observation of the procedure of impedance monitoring to measure non-acid, weakly acid and alkaline reflux together with discussion about state of the art interpretation of results and treatment of gastro-oesophageal reflux with these medical authorities
in Brussels gives new impetus and inspiration to carry out further research into this
important topic of gastro-oesophageal reflux and its impact on lung disease.

Acknowledgements

Mr Filip Van Ginderdeuren kindly organised the visit to the Universitair Ziekenhuis,
Brussels. He and his colleagues Sylvie Vanlaethem, Marianne Borremans and
Isabel Ooms were extremely generous with their time and expertise is providing
theoretical information and practical demonstrations of the use of IPV, Ez-PAP® and
assisted autogenic drainage across a range of age and different pathologies. These
experiences pave the way for the use of these treatment techniques with patients in
Australia.

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Gastro-oesophageal reflux and aspiration of gastric contents in adult patients with
Universitair Ziekenhuis (UZ), Leuven, Belgium

Overview
The University Hospital Leuven is a vast hospital complex treating all disciplines of medicine across all age groups. The University of Leuven is in an adjoining building facilitating clinical research. The Gastroenterology Department is famous for its research into the diagnosis, interpretation and treatment of gastro-oesophageal reflux (GOR) in patients with cystic fibrosis before and after lung transplantation. This group has reported associations between GOR and decline in lung function before and after lung transplantation. Dr Ans Pauwels is an expert in research in GOR using pH-impedance monitoring. She completed her PhD titled ‘The Role of Gastroesophageal Reflux in Cystic Fibrosis’ in 2012. Her thesis included the following topics: ‘methods to monitor acid and non-acid reflux and duodeno-gastroesophageal reflux; gastric emptying; high resolution manometry impedance; methods for evaluation of aspiration; inflammatory markers in the lungs; prevalence of different types of reflux – the Leuven experience; failure of the anti-reflux barrier at the oesophago-gastric junction; lower oesophageal sphincter function; the prevalence of aspiration in CF; the effect of reflux/aspiration on lung disease; effect of gastric juice on IL-8 production by CF primary bronchial epithelial cells; pathophysiological mechanisms of reflux related respiratory disorders; hypersensitivity of the cough reflex and therapeutic options for GOR in CF’.

Aims of the Churchill visit to UZ Leuven
1. To meet with Dr Ans Pauwels and receive instruction on the measurement of duodeno-gastroesophageal reflux (DGER) and gastro-oesophageal reflux (GOR) and the interpretation of results using pH-impedance monitoring and high resolution manometry;
2. To learn about the effects of non-acid, weakly acid and alkaline GOR on lung disease and their relationship to gastric emptying;
3. To investigate the mechanisms of cough and its relationship to GOR.

Duodeno-gastroesophageal reflux and gastro-oesophageal reflux
Duodeno-gastroesophageal reflux (DGER) is now recognized as a major factor in people with gastro-oesophageal reflux (GOR) after lung transplantation. For some
patients GOR is a pre-transplant co-morbidity that continues on after transplant. This can be exacerbated by damage to the vagus nerve during the transplant surgery. For others GOR is a new co-morbidity brought on by vagus nerve damage during the surgery. DGER is associated with Barrett’s oesophagus and adenocarcinoma. DGER results in bilirubin (bile) refluxing into the stomach and then into the oesophagus. Bile acids have been identified in saliva and sputum in half of patients with cystic fibrosis studied at this institution. Acid reflux is defined as an event of GOR with a pH of <4 for 4 seconds. Weakly acid reflux is defined as an event of GOR with a pH of 4-7 for 4 seconds. Alkaline reflux is defined as an event of GOR with a pH of >7 for 4 seconds.

**pH-impedance monitoring and the Bilitec System to measure bile reflux**

Impedance monitoring is a relatively recently developed technology of measurement of the passage of a bolus of gastro-oesophageal reflux up the oesophagus. It records the volume and height of the refluxate via multiple visible antimony filled pockets along the impedance probe while it is positioned in the oesophagus. pH-impedance monitoring records the pH between 1, 4 and 7 and therefore estimates how much acid, weakly acid, non-acid and alkaline reflux occurs during the measurement period.
usually over 24 hours. The Bilitec System measures oesophageal bilirubin absorbance >0.14nm for >10 seconds during episodes of bile reflux into the oesophagus. A combination of pH-impedance monitoring and the Bilitec system allows for the measurement of bile reflux. This is achieved with the two probes joined together with small pieces of Parafilm tape. The combined probes are inserted into the oesophagus and both record different information during the 24 or 48 hour study. This combined measurement provides more information on bile reflux, its proximal spread and bolus exposure. The higher the proximal spread and the larger the bolus exposure the more likely that pulmonary aspiration is occurring. Pathological DGER occurs when the fractional reflux time (FRT) is >4.2% for >10 seconds. In the Leuven study, 18/32 (65%) of patients with CF studied had silent alkaline (bile) GER; 5/14 (35%) had DGER as well as increased GOR (acid); increased bolus exposure; an increased number of reflux episodes and increased proximal spread of the refluxate.

**Delayed gastric emptying**
Measurement of gastric emptying occurs by ingestion of a radiolabeled meal after a period of fasting followed by measurement of the time taken for the meal to move out of the stomach. The definition of delayed gastric emptying (DGE) is half of the meal (t ½) taking longer than 75 minutes to leave the stomach. In a further study DGE was measured in 11/33 (33%) patients at UZ, Leuven. No correlation of DGE with acid GOR was found, however there was a positive correlation of DGE with total bile exposure, namely alkaline reflux pH >8 found in duodeno-gastro-oesophageal reflux.

**High resolution manometry and impedance monitoring**
High Resolution Manometry provides colourful graphic images of oesophageal peristalsis and movement of swallowed water through the oesophagus, either in graphs or in a colour contour plot. This enables measurement of transient lower oesophageal sphincter relaxations (TSLERS), which are relaxations of the lower oesophageal sphincter not triggered by swallowing. Due to the impedance channels incorporated on the probe gas and liquid refluxate can be measured. Identification of cough on the trace is possible even if the patient forgets to press the event button. This form of measurement can help identify whether cough occurred before or after an episode of GOR and therefore helps establish whether cough is a cause or consequence of GOR. Pressure flow analysis
includes impedance monitoring together with manometry. Dilated intercellular spaces are seen microscopically in gastro-oesophageal reflux disease (GORD). This may offer a way to look at neural innervation as a possible explanation for silent GOR. Bile acids are difficult to assay in saliva. The Hart protocol may be used to analyze bile acids in sputum. This checks for bile acid / pepsin in sputum. The Leuven group believe bile acids are too diluted for accurate assessment in bronco-alveolar lavage.

Period off proton pump inhibitors (PPIs) required before pH monitoring
Ten days off PPIs is the standard protocol at this institution prior to pH-impedance monitoring. Ideally, 14 days is the preferred time off PPIs before pH-impedance monitoring, however, seven days in the minimum time off PPIs before monitoring for GOR at Leuven.

Acid pocket
An acid pocket is an unbuffered reservoir of acid that floats on top of the gastric contents in the stomach. With a hiatus hernia, the acid pocket moves above the diaphragm and increases acid GOR and the risk of aspiration especially when patients
lie down during physiotherapy and sleep.

**Treatment for gastro-oesophageal reflux & research at Leuven**

Lifestyle modifications are amongst the most important treatment modalities used by the Leuven group. Late dinners should be avoided with two to three hours between eating and lying down. The head of the bed should be raised for lying down and sleeping. Proton pump inhibitors are prescribed. Research at UZ, Leuven showed that PPIs may not prevent aspiration and may even result, paradoxically, in increasing the inflammatory effect in the airways through aspiration of a changed milieu of liquid refluxing up into the oesophagus from the stomach. Baclofen, a GABA<sub>B</sub> receptor antagonist has been shown to decrease TSLERS and thereby decreases reflux. Furthermore baclofen reduces duodeno-gastroesophageal reflux and it is likely it decreases bile acid aspiration. Because of the side effects of baclofen, such as nausea and sedation, it is not well tolerated by patients and its use is limited. Different prokinetic agents such as metoclopramide, cisapride and domperidone can improve oesophageal motility and accelerate gastric emptying. Macrolide antibiotics such as erythromycin and azithromycin (AZM) have been reported to have prokinetic effects and have been proposed for treatment of gastro-oesophageal reflux especially in cystic fibrosis. AZM is often used after lung transplant because of its immunomodulatory effects. The Leuven group studied the effects of AZM on post lung transplant patients and found they had significantly less reflux and less bile acid aspiration. Anti-reflux surgery is often the treatment of choice. They propose that earlier reflux surgery may be the most appropriate treatment.

**Multi-centre study: UZ Brussels and UZ Leuven (Blondeau and colleagues 2008)**

Investigators with an interest in gastro-oesophageal reflux in patients with cystic fibrosis before and after lung transplant at these two centres in Belgium undertook the following study. Thirty-three CF patients (19 men) with a mean age of 29 (18–55) years from the two Belgian centres participated. Of these 10 were post lung transplant patients. They all underwent pH-impedance monitoring for detection of acid (pH<4) and weakly acid (pH 4–7) GOR. Gastro-oesophageal reflux was monitored using ambulatory impedance–pH metry which comprised six electrode pairs to measure intraluminal impedance and two antimony pH sensors. The proximal pH sensor was positioned 5 cm above the lower-oesophageal sphincter, the distal pH sensor in the
stomach and the impedance channels were positioned 3, 5, 7, 9, 15 and 17 cm above the lower oesophageal sphincter (LOS). Patients also underwent 24h manometry to register cough. A separate thin (2.7 mm external diameter) manometric catheter with two solid-state pressure sensors (15 cm apart) (Unisensor, Attikon, Switzerland) was positioned so that one pressure channel was located in the oesophageal body (5 cm above LOS) and the other in the stomach. The pH-impedance and manometric catheters were connected to a single ambulatory device containing the respective amplifiers (Sleuth, Sandhill Scientific). Simultaneous pH-impedance manometric recordings were obtained in 16/23 non-transplanted patients. In 16 patients cough was objectively recorded with oesophageal manometry, and the symptom association probability (SAP) was calculated. Saliva and bronchoalveolar lavage fluid were tested for bile acids. The results showed that twenty-eight patients had increased gastro-oesophageal reflux (21 acid, 5 weakly acidic and 2 acid+ weakly acidic) and 10 had a positive SAP index for reflux followed by cough. GOR parameters were similar in non-transplanted and post-lung transplant patients with CF. The sequence of reflux followed by cough was significantly more common than cough followed by reflux. Sixteen of 38 patients had bile acids in saliva and six out of ten had bile acids in their bronchoalveolar lavage fluid. This was almost exclusively observed in patients with homogeneous DF508 genotype. Only 12 out of 28 with increased GOR and 9 out of 22 with bile acids in saliva or bronchoalveolar lavage fluid (BALF) had typical reflux symptoms. There was a positive correlation (r = 0.53, p = 0.03) between oesophageal acid exposure and cough. SAP-positive patients for reflux followed by cough had lower lung function than SAP-negative patients. They concluded that increased GOR is prevalent in CF and not secondary to cough. Acid GOR is common, but weakly acidic GOR may also occur. CF patients have a high risk of aspiration and reflux seems to be associated with more cough and poorer lung function. Outcome studies with intense anti-reflux therapy are needed to confirm the deleterious role of reflux in CF progression and the effects of treatment.

The reasons why CF patients have increased bile acids in saliva and BALF remain to be elucidated. A study by Hallberg et al in Sweden in 2004 showed increased duodeno-gastric reflux in CF. In this Belgian study, bile acids were found in saliva and BALF of CF patients with the DF508 homozygous genotype. This finding suggests that
this genotype is associated with abnormal intestinal motility that may favour duodeno-gastric reflux and increase the bile acids concentration in the stomach. Furthermore, increased duodeno-gastric reflux with bicarbonate may have a neutralizing effect on gastric contents which may explain the decreased gastric acid exposure observed in their patients who are homozygous for the DF508 mutation. Further studies on gastric secretion and distribution of gastric contents in CF are needed to test this hypothesis.

**Study investigating GOR with pH-impedance monitoring and the relationship with delayed gastric emptying (Ans Pauwels and colleagues 2011)**

This prospective study was performed in a total of 53 patients with CF with a mean age of 28 years; range 18–58, 25 were male. All were recruited at the CF out-patient clinic of the University Hospital Gasthuisberg, Leuven. Reflux monitoring alone or together with gastric emptying studies were performed. Duodeno-gastroesophageal reflux was monitored simultaneously with pH-impedance monitoring using the Bilitec 2000 system (Synetics Medical, Stockholm, Sweden). Impedance monitoring and gastric emptying were also measured. The main findings of their study were, (1) gastric emptying is delayed in approximately one third of CF adults, (2) 67% of CF adults have increased GOR, predominantly acid reflux, (3) 35% of CF patients have increased ‘acidic’ DGER and this seems to be related to high volume reflux, (4) there is a positive correlation between rate of gastric emptying and the severity of DGER.

**Summary of visit to the UZ, Leuven**

This visit resulted in significantly increased knowledge, understanding and ability to interpret results of the relatively recently developed technology of pH-impedance monitoring for the measurement of acid, weakly acid, non-acid and alkaline gastro-oesophageal reflux. The meeting with Dr Ans Pauwels, an expert in the measurement and interpretation of DGER and GOR using pH-impedance monitoring, the Bilitec system and manometry shed much light on these complex investigations and their interpretation. New insights were gained into the relationship between cough and GOR. In terms of treatment options this visit reaffirms the importance of educating patients about lifestyle modifications that are likely to decrease the symptoms and the impact of gastro-oesophageal reflux on lung health. A number of alternative medical treatment options were discussed that may be useful for patients at the
Acknowledgments

Professor Christine De Boeck, Professor Lieven Dupont, physiotherapist Myriam Vreys and psychologist Trudy Havermans made my visit to this highly regarded centre possible. I was invited to present our Melbourne physiotherapy approach to management of patients with CF together with some of our key research findings at their regular Grand Round. Further, I had the opportunity of attending a CF Team meeting in Flemish which was interesting given my background and ability to talk Afrikaans, a dialect of Flemish. I was afforded the opportunity to meet interesting patients who agreed to allow me to observe them while receiving physiotherapy treatments.

Dr Ans Pauwels graciously met with me to share her extensive knowledge of the use of state of the art tools for measurement of gastro-oesophageal reflux. Her instruction on the interpretation of impedance monitoring has given me the confidence to undertake further research in this important field. There continues to be a paucity of knowledge and a lack of effective treatment in gastro-oesophageal reflux and chronic lung disease. She and I hope to undertake collaborative research studies in the future. I am grateful to her for giving me a copy of her PhD thesis, which is an excellent record of her research and a useful clinical and research resource.

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Medizinische Hochschule Hannover (MHH), Germany

Background
The Hannover Medical School, founded in 1965, is one of the world’s leading university medical centres. Research and patient care set national and international standards at this institution. They attribute their success to interdisciplinary collaboration both within MHH and with extramural scientific institutions attracting significant grant funding. They are also part of an excellent regional medical network. The number of beds at MHH in 2015 numbered 1518. Multiple buildings on the campus interconnect with weatherproof passages. All aspects of medicine are represented at MHH. The cardio-thoracic department includes the cardiothoracic ICU and the posttransplant unit, and the respiratory division includes the respiratory ICU as well as the adult cystic fibrosis service. The paediatric respirologists take care of the paediatric CF service. The adult cystic fibrosis unit manages around 200 patients and the paediatric CF unit approximately 180 children. They are seen in separate clinics in the same building by different medical teams. The transplant unit is also located in this complex. MHH is a major internationally recognized lung transplant unit. Around 150 of the 300 lung transplants carried out over the whole of Germany occurred at MHH in the past year.

Aims of the Churchill visit to MHH
1. Research the use of ECMO at this institution with a large published experience;
2. Investigate the types of airway clearance therapy used with respiratory and ECMO patients with lung secretion problems;
3. Explore early mobilization for respiratory patients and those on ECMO together with the different types of equipment used to enable safe and effective physical exercise.

Cystic fibrosis and lung transplantation services at MHH
Patients are managed by general medical practitioners in their local regions with good communication and shared care arrangements with the MHH lung transplant unit. This management plan occurs both before and after lung transplant by way of
scheduled reviews. Assessment occurs with all necessary tests done at the local hospital or medical facility. When patients come to the transplant clinic appointments all the tests and information previously performed are reviewed. Cystic fibrosis and lung transplant patients all wear masks whenever they attend outpatient clinics as part of universal infection control practice. When asked how they felt about wearing masks in the hospital patients reported that they valued wearing masks as it gave them a sense of control in protecting themselves against cross infection. The MHH strives to have patients’ BMI range between 17-25 pre lung transplant for optimal outcomes.

Telemedicine and telephone calls are frequently used for remote management of patients. After lung transplantation patients are treated in the MHH transplant ward of the cardi-thoracic department for two to four weeks. They are then discharged to a rehabilitation centre, ‘Bads Fallingeostel’, a one-hour drive from Hannover, for three weeks intensive rehabilitation. The head of rehabilitation specialist attends weekly ward rounds to meet the patients and discuss individual requirements with the medical team before they are discharged to the rehabilitation facility.

The German Government funds rehabilitation for the general population for three to four weeks every two years to optimize national health, fitness and well-being. If people feel they need more rehabilitation, they pay privately for the extra service. Initially, after lung transplantation, patients attend the MHH post lung transplant clinic three monthly. These extend to six monthly once their post lung transplant condition stabilizes and medications are optimized. Prescriptions are filled by local general practitioners and by medical staff at small local hospitals. The transplant ward of the cardiothoracic department at MHH has twenty beds.

**Lung Allocation Score**

The Lung Allocation Score (LAS) is used in Germany to prioritize patients on the waiting list for lung transplant. The score ranges from 0-100 (100 indicating the most urgent priority). Most patients are transplanted when their scores reach between 45-50. The allocation of lungs in Germany is centrally monitored to ensure fair allocation of organs. Documentation of all aspects of assessment, calculation of the lung
allocation score and justification for all decisions is regularly completed for each patient. Random assessors who arrive unannounced to monitor adherence to the system audit these documents and the program. MHH has recently been audited for compliance.

**Awake ECMO at MHH**

Awake ECMO has been used as a treatment modality to bridge patients to recovery or to lung transplant for a number of years at this institution. The following research was undertaken to evaluate patient outcomes.

**Awake ECMO versus mechanical ventilation as a bridge to lung transplant** (Fuehner et al, 2012).

In 2012 MHH described ECMO in awake and spontaneously breathing patients as a novel bridging strategy toward lung transplantation. They carried out a retrospective single centre intention-to-treat analysis of consecutive lung transplant candidates with terminal respiratory or cardiopulmonary failure receiving awake ECMO support between 2008-2011. The outcomes were compared to a historical control group of patients with conventional mechanical ventilation treated between 2006-2011.

Sixty patients were included in the study; 26 in the awake ECMO group and 34 in the mechanical ventilation group. The groups were of similar ages ranging from 18 to 62 years. Ten (29%) in the mechanical ventilation group and 5 (19%) in the awake ECMO group had cystic fibrosis (CF). The patients who received VV ECMO all had either CF or bronchiolitis obliterans. Nineteen (78%) of the intended awake ECMO group remained unventilated up until transplantation. The duration of ECMO support or mechanical ventilation was comparable with the awake ECMO group treated for a median of nine days (range 1 to 45) and the mechanical ventilation group 15 days (range 1 to 71). Six (23%) in the awake ECMO group and 10 (29%) in the mechanical ventilation group died before a donor organ was available. Survival at six months after lung transplant was 80% in the awake ECMO group versus 50% in the mechanical ventilation group (p=0.02). Patients in the awake ECMO group required significantly shorter postoperative mechanical ventilation (p=0.04) and showed a trend towards shorter postoperative hospital stay (p=0.06). The main benefits of awake ECMO were avoiding the complications that accompany intubation,
anaesthesia and prolonged mechanical ventilation. Mechanical ventilation may induce pulmonary and systemic inflammation as well as muscle atrophy and difficulty with weaning from prolonged ventilation post lung transplantation. After intubation patients are susceptible to infections leading to multi-organ failure (a leading cause of death in the MV group before and after lung transplantation). In contrast patients on awake ECMO are able to eat and drink and participate in active physiotherapy and physical exercise and be in better physical condition for transplantation. Nonetheless, numerous complications were experienced in this awake ECMO group some of which were catastrophic. Air embolism during insertion of the VV ECMO cannula, a power failure of an ECMO circuit, serious bleeding, life threatening infections and hypoxemic cardiac arrest during the exchange of the oxygenator membrane. Therefore it is recommended that awake ECMO should only be used in experienced centres when all non-invasive treatment options have been exhausted. They concluded that until more data becomes available this form of treatment should be considered as investigational and should not be considered as standard of care (Fuehner et al, 2012).

**Types of ECMO used at MHH**

The following types of ECMO are used at MHH: (1) VV ECMO in awake patients using the double lumen single Novalung Twinport cannula which is used as an alternative to the Avalon cannula. This cannula is used to enable patients to sit out of bed, stand and walk; (2) VV ECMO with femoral and jugular cannulas. Other combinations are used in individual patients with particular needs. In the MHH experience there is less risk of infection at the cervical insertion site than the femoral; (3) VA ECMO with both cannulas at the femoral site on one side. A small arterial subsidiary line is inserted into the arterial circulation of the leg (taken from the arterial cannula to provide antegrade blood flow to that leg) to prevent complications of leg ischaemia; (4) VA ECMO with arterial cannulas either in the femoral or in the subclavian arteries; (5) Central VA ECMO is used when this form of treatment is expected for a prolonged period of time. A central cannula to the jugular and a cannula to the arterial subclavian are tunneled along the chest wall and inserted from below and firmly stitched in place. This method is more secure and if the cannula remains in situ for a period of time granulation tissue further secures the cannula. This method of cannulation allows the patient to be awake, sitting out of bed and walking to preserve
muscle mass and physical strength and condition.

**Awake bronchoscopy, bronchoalveolar lavage (BAL) and biopsies at MHH**
After lung transplantation, bronchoscopy, BAL and biopsies are regularly undertaken. Patients are well educated and prepared prior to the procedure, usually carried out without additional sedation. They are told there will be no discomfort as there is no sensory nerve supply to the transplanted lungs. Also they will not have to go through the post-sedation period of restricted movement while the drugs are metabolized which many patients object to especially when they come in as outpatients for the procedure.

Patients are required to fast for at least 6 hours prior to bronchoscopy. BALs are preferably carried out in the morning so no breakfast is eaten on the day of the procedure. The local anaesthetic agent xylocaine is gargled and sprayed in the oropharynx and on the vocal cords. The bronchoscope is inserted via a mouthpiece. A number of patients were observed in the lung transplant bronchoscopy suite and in the Cardiothoracic ICU undergoing bronchoscopy awake without sedation.

Surprisingly, all patients observed tolerated the procedure remarkably well. They remained calm without any coughing or appearance of distress. Trust and confidence in the medical staff was evident. Patients were able to observe the procedure on the video screen next to the bed with the doctor giving a real time commentary about the anatomical structures and process. Patients appeared to be fascinated by the images on the screen. Resting heart rate did not increase in the patients observed providing further evidence that the procedure was well tolerated. Nurses commented that this is the method of choice because there is no recovery area for sedated patients. This lack of space has been a great motivator for awake BAL. Patients were restricted from eating for at least two hours after the procedure till the local anaesthetic wore off.

**Airway clearance therapy at MHH**
A number of different airway clearance techniques and devices were observed at MHH.

**Positive expiratory pressure (PEP) using the Pari-PEP® device**
Positive expiratory pressure (PEP) therapy promotes airway clearance and decreases mucus plugging via the physiological actions of collateral ventilation and temporarily
increasing FRC via recruitment of alveoli over 10-15 consecutive sealed system breaths that form each cycle. This process allows air to build up behind secretions in the distal airways moving them upstream towards the mouth. Each individual patient is prescribed a number of cycles per treatment depending on the particular problems experienced. This treatment can be provided with a mask or mouthpiece.

PEP therapy using the Pari-PEP® device (Pari Germany) is widely used throughout MHH for airway clearance therapy in patients with increased pulmonary secretions and low lung volumes after surgery and during periods of decreased physical activity. The device consists of a one-way valve, a series of eight apertures ranging in size from 1.5 to 5 mm. These form the resistors that provide the positive expiratory pressure (PEP) during expiration. The one-way valve with the resistors is placed over the body of the device which is attached to a solid mouthpiece. During inspiration with the mouth sealed around the mouthpiece (with optional nose clips to prevent air escaping through the naso-pharynx) air moves in via the one-way valve. Expiration occurs through the individually selected resistor (usually from the range of 2 to 3.5mm) generating a backpressure of 10 to 20 cmH2O during the middle part of expiration. The patient breathes in (slightly larger than a tidal volume breath) and out with a slightly active breath against the resistance of the device aiming for 10-15 consecutive breaths during each cycle, keeping the lips sealed, aiming to temporarily increase FRC during the cycle by progressively recruiting more alveoli with each expiration. These cycles are interspersed with forced expirations and coughing. All patients on day one post lung transplant at MHH are provided with a Pari-PEP® (mouthpiece) device. Patients are taught to routinely carry out PEP three times per day with repeated cycles of PEP breathing, huffing and coughing as required individually. Post lung transplant the aim is to recruit alveoli, increase lung volumes and prevent atelectasis and clear secretions regularly each day while patients are relatively sedentary recovering in bed. PEP assists with optimizing mucociliary clearance when patients have abnormal secretions. Breathing against the PEP resistance is also used to exercise the expiratory muscles. Patients are taught to use this device independently with physiotherapists monitoring clinical status and adherence to treatment.
Oscillating PEP using the Cornet® device
Oscillating PEP is used to vibrate the airway wall, loosen adherent secretions, decrease the viscosity of mucus and promote airway clearance. The oscillatory PEP device, the Cornet®, is used as an airway clearance device for patients with chronic lung disease and excessive secretions. Post-operatively it is used to recruit alveoli, increase lung volumes and optimize mucociliary clearance. It consists of a firm horn shaped outer case with an internal soft rubber tube, mouthpiece and cap over the distal end. When blowing out through the Cornet® the rubber vibrates in the outer tube making a loud rumbling noise. An oscillating positive pressure is developed with an average backpressure of around 10 to 20 cmH2O. Blowing through the device results in vibration of the airways, splinting them open with positive pressure. This promotes lung recruitment, increased lung volumes and loosening and removal of secretions. Post lung transplant at MHH the Cornet® is prescribed every 1-2 hours to recruit alveoli, increase lung volumes and prevent atelectasis and consolidation. Breathing against the oscillating positive expiratory pressure is also used to exercise respiratory muscles. All patients are routinely provided with a Cornet® in the cardiothoracic ICU at MHH to use frequently and independently throughout the day. Rubber inner tubes are for single patient use, while the outer case can be sterilized and re-used. Individual rubber tubes cost around 1 Euro each.

Use of PEP and Oscillating PEP immediately post-lung transplantation
In some units around the world PEP and oscillating PEP devices are not used or are contra-indicated immediately post-lung transplant (or until healing of anastomoses has been visualized on bronchoscopy) because of concern about compromise to healing or the risk of causing air leaks. The rationale for the early use of PEP and oscillating PEP devices at MHH is that patients are ventilated at higher pressures prior to extubation after lung transplantation and pressures generated during coughing are significantly higher (up to 200 cmH2O), a post-operative requirement post lung transplantation. MHH has not experienced problems with the early use of these techniques post lung transplantation.

Triflo Incentive Spirometer use at MHH
The Triflo Incentive Spirometer® is a device to motivate deep breathing combined with inspiratory pauses to increase lung volumes via the physiological actions of
collateral ventilation and interdependence. This device consists of a clear plastic three-chambered body with a lightweight ball in each chamber. The patient is taught to hold the device upright and inhale slowly and deeply lifting the balls to the top of the chamber and holding them there for 2 to 3 seconds. They repeat this activity 3 to 10 times every hour independently. This device is also provided to each patient in the cardiothoracic ICU and post lung transplant at MHH to be used along side the Cornet® every one to two hours during the day. Patients report that they are happy to carry out this program of PEP, oscillating PEP and deep breathing via the inspirometer to recruit alveoli, exercise respiratory muscles and prevent complications such as hypostatic pneumonia as part of their treatment at MHH. This three-pronged approach to physiotherapy in this ICU is routine. Medical staff believe it contributes significantly to their excellent outcomes post lung transplant minimizing post-operative complications such as atelectasis and its consequences.
Positive Airway Pressure using the Ez-PAP® device utilizing gas flow

The positive airway pressure device, Ez-PAP®, promotes increased lung volumes with a continuous airflow and pressure provided by oxygen/air from the ICU wall outlets. During inspiration the continuous airflow and pressure generated promotes increased lung volumes. During expiration against the continuous airflow a positive expiratory pressure is generated promoting collateral ventilation and a build up of air behind secretions in the small airways. This action results in movement of secretions upstream towards the mouth and an increase in resting lung volumes. This treatment is administered by a respiratory therapist to patients who have developed significant atelectasis or segmental or lobar collapse. The author observed the successful use of this technique in a 60 year old patient who had experienced thoracic surgery four days previously. He developed a right lower lobe collapse clearly seen as a white out on chest radiograph on the day he was due to be discharged to the post-operative ward. Ez-PAP® with a 12 litre flow of oxygen (providing approximately 10 cmH2O pressure) was commenced and prescribed twice daily for the patient until resolution of the lobar collapse. For illustration of Ez-PAP® see chapter on visit to the UZ Belgium.

Cough Assist Device

The “Vivisol” Cough Assist Device (DIMA Italia, Pegaso Home Care Services) was on trial for use with patients on the cardiothoracic wards at MHH. This is an airway clearance device for patients with sputum retention and a weak cough. The cough assist device increases inspiratory lung volumes with positive pressure during inspiration and assists with sputum removal using a negative pressure during expiration. A previously healthy patient in his 30s with multi-organ failure previously intubated and ventilated for two weeks was observed being treated with this device by a respiratory therapist. The patient had developed a right vocal cord palsy which had resulted in an inability to cough effectively. During the treatment the patient was supported in supine 45 degrees head up. The cough assist machine was applied by the respiratory therapist with a well sealed mask interface. Cycles of assisted inspiration with positive pressures of +40cmH2O and negative pressures of -40cmH2O during expiration were applied during 10 consecutive breaths. Following each cycle the patient was manually assisted to cough and expectorate mobilized secretions. Six repetitions of these cycles were applied during each of four airway
clearance sessions per day between 7am and 6pm. This device assisted the patient with a right vocal cord palsy and consequent weak cough to clear airway secretions effectively. It should be noted that this patient had previously healthy lungs and concern about the potential for barotrauma was less than it would be in a patient with chronic lung disease when such high inspiratory pressures would likely be contra-indicated.

**Contraindications** for using the Cough Assist Device in cardiothoracic patients of MHH would be persistent bronchopleural fistula, lobectomy and dehiscence of the anastomosis after lung transplantation.

**Staffing for airway clearance therapy at MHH**
Physiotherapists (PT) and respiratory therapists (RT) work during daytime hours. The RTs have two shifts with the early shift from 7am-3pm; and the later shift from 10am to 6pm. There is no overnight service. If patients require airway clearance therapy overnight the pulmonologist on call is called in to do a therapeutic bronchoscopy.

**Physical exercise at MHH**
A number of items of equipment and supplies were observed being used to enable safe early mobilization in the cardiothoracic ICU and on some wards at MHH. Many of these are manufactured in Germany.

**Standing device to carry out strengthening exercises**
A standing device to assist patients get up and be supported on a standing plate with straps around the knees, sacrum and feet is used on the cardiothoracic ICU at MHH. This equipment is used for assisting deconditioned patients up into supported standing for general exercise. A sturdy attached tray table shaped with a cut out space for the abdomen at waist height allows the patient to stand and move a little from side to side and forwards and backwards to strengthen muscles and improve balance and co-ordination. The system allows strengthening of the lower limbs, core and anti-gravity muscles. The patient also benefits from the pulmonary and whole body effects of standing upright. A 60 year old gentleman who had recently had a cardiac stent inserted and who was weak and deconditioned but ready to go to the ward was observed exercising in this assisted standing system positioned next to his bed.
**Exercise bike for use while lying supine in bed**

A computer operated exercise bike (Motomed, Germany) was observed by a patient on the cardiothoracic ICU lying in bed with feet and lower legs supported in leg rests designed to allow the patient to carry out passive, assisted or fully active cycling while in a recumbent position. A combination of part active and part assisted exercise can also be achieved. The bike is wheeled into a position at the end of the bed with the patient supported supine 45 degrees head up. The feet and calves are supported in padded leggings and stirrups and secured with velcro straps. The patient observed cycled for 21 minutes of which fourteen were active and seven were assisted. The patient accomplished 2 km of cycling and expressed a great sense of achievement and was motivated by the ability to measure her cycling distance which was increasing each day.
Exercise bike with arm ergometer for patient sitting in a chair
A portable exercise bike with an arm ergometer (Motomed, Germany) electrically powered with inbuilt computer can be is positioned next to the patient’s bed and is used on the transplant ward to strengthen the thoracic muscles. The patient sits in a chair with the bike in front. The feet are strapped onto the pedal and the hands grip the handles of the arm ergometer. The resistance to pedaling is set according to the individual’s ability. The gentleman observed was in his 50s post transplant. He was prescribed 50 minutes of arm and leg pedaling with level 4 resistance. Initially he was only able to pedal on level 1 for 10 minutes and has steadily built up time and resistance. He looked forward to this session every day. Being able to measure his achievements and gradually progress his time and resistance was motivating and encouraging to him.

Equipment for mobilizing patients from bed to standing and sitting
The Samarit Roll Board (Australia) is a silver plastic covered rectangular foam based slide sheet used to transfer a person from bed to another surface in a supine or half seated position. The mat is about 80cm wide and 180 cm long and folds in half with a loop for space efficient storage on a hook when not in use. The Mobilizer Medior (Germany) transformable equipment has a number of possible configurations: bed with head-rest and support, tilt-table and chair with wheels and optional securely fastened meals tray. Two health professionals transfer the patient from the hospital bed to the Mobilizer Medior bed. Patients are encouraged to sit up out of bed in this chair and eat their meals. If their trunk muscles are weak the chair and tray table securely support the patient in upright sitting similar to an infant’s high chair. If the patient’s neck needs supporting in lying, sitting or standing there is a firm padded neck support that can be adjusted to each patient’s particular needs.
Rotorest bed to change position of bedbound patients

This highly engineered and expensive Rotorest bed (San Antonio, Texas, USA) supports the patient in such a way that he/she can safely be moved side to side and up and down to change the gravitational forces on bedbound patients. The patient is supported with shaped pads under the arms to hold the upper body in position and a V shaped pad between the abducted legs with each leg supported in a padded channel to hold the lower body in position. These pads essentially maintain the patient in a safe supported position during movement. Belts add an extra layer of support to the patient while the bed changes position. The Rotorest bed starts rotating up to 30 degrees side to side gradually increasing up to 62 degrees where the patient is almost fully in side lying. The head of the bed can also be elevated to 45-50 degrees. The bed achieves the desired angle of tilt and then maintains that position for the time set for individual patients depending on their pathophysiology and particular needs. The aims of placing acutely ill or bedbound patients in the Rotorest bed are first to avoid pressure areas; and second to provide the benefits of changes in regional ventilation brought about by changes in position relative to gravity. The patient observed during the visit was being treated with VA ECMO after two bouts of cardiac surgery. He developed respiratory insufficiency with prolonged sedation and immobilization. Both ECMO cannulas were inserted in the right femoral vessels.
**Special tape to secure the ECMO cannula**

A special tape, Fixier-Set Hydrocolloid ‘Secutape’ (Switzerland) is used to secure the femoral ECMO cannula to the thigh of the patient. The tape has two parts, an upper layer that wraps around the cannula or chest tube, and a lower layer that adheres to the limb or chest wall in the case of a chest drain. The secure upper layer with velcro fastenings can be loosened to make adjustments while the lower layer remains securely in place.

**Non-slip socks for getting patients up into standing and walking**

On admission all patients are issued with double tread socks or slippers with non slip strips to prevent slipping and falls when up and walking in the hospital.

(Medline REF MDTEDBTRDXL).
Protection of lower limbs while patients are on extended bed rest

All foot and ankle joints are mobilized by the physiotherapist daily if active movements are not possible. The patella is mobilized side to side and up and down. Passive knee and hip movements are carried out as long as there is no femoral cannula in situ. Feet are supported at >90 degrees with a pillow or rolled up towel to prevent contractures developing during prolonged bed rest with the ankle flexed ≤ 90 degrees. These contractures significantly reduce function during rehabilitation. In sedated and de-conditioned patients legs are supported in the neutral position in order to avoid external rotation of lower limbs and peroneal nerve injuries at the knee.

Summary of visit to Medizinische Hochschule Hannover, Germany

The four days spent in this large highly regarded German medical centre afforded the experience of observing a number of different patients being treated with VV and VA ECMO with a variety of cannula placements. As there were no awake ECMO patients treated during the visit a number of substitute videos were viewed of MHH patients walking with awake VV and VA ECMO. A number of procedures and activities observed provided great learning opportunities including: awake bronchoscopy; insertion of a percutaneous tracheostomy; a sedated and ventilated patient on VA ECMO being rotated side to side on a Rotorest bed for pressure area prevention and whole body gravitational benefits; a severely debilitated patient get up safely supported in a standing frame to begin rehabilitation; a patient using an exercise bike
lying in bed; a patient using an exercise bike with arm pedals while sitting in a chair
beside the bed; a bed able to be modified into a standing frame/tilt table/wheel
chair/chair with securely attached tray for meals out of bed for patients with weak
trunk muscles; use of the cough assist device; the Cornet and Ez-PAP devices used for
airway clearance therapy and increasing resting lung volumes. The wide range of
airway clearance techniques and devices enabling mobility and ambulation together
with their application by experienced respiratory and physiotherapists are believed
to contribute to excellent outcomes at this ECMO unit. The friendly and welcoming
multi-disciplinary team is highly experienced and offered a high standard of teaching
both theoretical and practical. Many new ideas about alternative ways of treating
patients were observed and will be considered for future use in clinical practice in
Australia.

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Tobias Welte, Axel Haverich, Marius M. Hoeper, and Gregor Warnecke.
Extracorporeal Membrane Oxygenation in Awake Patients as Bridge to Lung

Motomed Movement Therapy including bikes:
https://www.google.com/search?site=&tbm=isch&source=hp&biw=1280&bih=665&q=motomed+movement+therapy&oq=Motomed&gs_l=img.1.5.0l9j0i30.6130.7798.0.13319.7.0.0.0.165.689.5j2.7.0....0...1ac.1.64.img..0.7.689.sl_AshGDz0.
3.Samarit Roll Board for moving patients from bed to mobilizing bed.
4. Bed/tilt table/wheel chair/supported meals chair for weak patients.
https://www.google.com/search?site=&tbm=isch&source=hp&biw=1280&bih=665&q=Mobilizer+Medior&oq=Mobilizer+Medior&gs_l=img.3...1424.9558.0.11544.16.15.0.1.0.242.1540.5j71.13.0....0...1ac.1.64.img..4.12.1461.z8sAh1Hqeyo.
5. Rotorest bed for altering the patient’s position.
6. ‘Secutape’, TechniMed AG, Switzerland; info@secutape.ch; Telephone 0041/71 844 49 20; Germany Telephone: Area code 02941/79892

7. Double tread non-slip slippers/socks.

8. Cornet airway clearance device.
La Hôpital de la Pitié Salpêtrière
13th Arrondissement, Paris, France

Overview
The Salpêtrière was originally a gunpowder factory ('salpêtre' being a constituent of gunpowder), but was converted to a dumping ground for the poor of Paris. It served as a prison for prostitutes, and a holding place for the mentally disabled, criminally insane, epileptics, and the poor; it was also notable for its population of rats. In 1656, Louis XIV charged the architect Libéral Bruant to build a hospital on the location of the factory, founding the Hospice de la Salpêtrière. The building was expanded in 1684. By the eve of the Revolution, it had become the world's largest hospital, with a capacity of 10,000 patients plus 300 prisoners, largely prostitutes swept from the streets of Paris. In the first half of the 19th century, the first humanitarian reforms in the treatment of the violently insane were initiated here by Philippe Pinel, friend of the Encyclopédistes; his sculptural monument stands before the main entrance in Place Marie-Curie, Boulevard de L'Hôpital. Later, when Dr. Jean-Martin Charcot took over the department, the Salpêtrière became known as a psychiatric centre. Charcot is often credited as the founder of modern neurology. His teaching activities on the Salpêtrière's wards helped to elucidate the natural history and pathophysiology of many human illnesses including neurosyphilis, epilepsy, and stroke. Students came from all over Europe to listen to Charcot's lectures. Among them was a young Sigmund Freud. The Hôpital de la Pitié, founded about 1612, was moved next to the Salpêtrière in 1911 and fused with it in 1964 to form the Groupe Hospitalier Pitié-Salpêtrière. The Pitié-Salpêtrière is now a general teaching hospital with departments focusing on most major medical specialities (Wikipedia Website).

Aims of visit to La Hôpital de la Pitié Salpêtrière
1. Experience the use of ECMO at this highly regarded French institution in patients requiring lung and heart bypass;

2. Research the types of airway clearance therapy used with patients on ECMO;

3. Investigate physical exercise for patients while on ECMO.
**ECMO at La Hôpital de la Pitié Salpêtrière**

The ECMO Unit at this hospital is one of the largest and most established internationally and has published a number of studies undertaken here. This ICU treating patients on ECMO is located on the 1st Floor of the Department of Cardiothoracics. There are three 6 bed ICU Units namely Units 1, 2, 3. There is a 6 bed step down unit adjacent to the ICU on same floor. The same nurses, doctors and physiotherapists staff the ICU and step down unit.

‘La Pitie’ is a tertiary centre where patients are transferred from other surrounding hospitals requiring or already on ECMO. Cardiac transplantation is carried out at ‘La Pitie’ but not lung transplantation. These are carried out at other centres in Paris. Patients are often discharged back to their home units once out of ICU and the step down unit. Sixty nurses, sixteen doctors (eight of whom are interns) and two physiotherapists manage patients in this ICU unit.

**Types of ECMO observed at La Hôpital de la Pitié Salpêtrière**

VA and VV using cannulation in the following combinations: femoral / femoral; femoral / IJV; femoral / femoral / aorta (for additional circulatory support); SVC and IVC via cervical lines; Avalon Double Lumen cannula – IJV; Quadruple ECMO – cannula into each chamber of the heart.

Some patients on ECMO were sedated while others were awake participating in physical activity. One patient had an Impella device to unload his right ventricle and after a number of days decompensated and was placed on ECMO.

**Venovenous ECMO at La Hôpital de la Pitié Salpêtrière** (Combes et al 2012).

In a retrospective study of 1900 patients admitted to this unit between 2008-2011 sixty-three (36 men) received venovenous (VV) ECMO for severe respiratory failure including ARDS caused by H1N1 influenza and other causes. Their mean age was 41.4±15.7 years. Mean duration of VV-ECMO support, mechanical ventilation and ICU stay were 22.6±23.5, 28.7±26.4 and 29.8±26.7 days respectively. In ICU mortality rate was 40%. Patients with H1N1 ARDS had a lower mortality than others 18% vs 50%, p=0.01. Significant haemorrhage occurred in 45% of patients, in particular haemothoraces (13%) and ENT bleeding (14%). In this ICU patient population treated over a three year period VV-ECMO was able to rescue >60% of patients with
respiratory failure refractory to conventional treatments. (Combes and colleagues, 2012).

**Long-term outcomes and quality of life of patients supported by ECMO for cardiogenic shock** (Combes et al 2008).

Dr Alain Combes and colleagues have described the use of ECMO in cardiac and respiratory conditions as an effective technique to provide emergency mechanical pulmonary and circulatory assistance to patients with cardiogenic shock and acute respiratory distress syndrome (ARDS) refractory to conventional medical therapies. Sequelae and health-related QOL were evaluated for the 28 long-term survivors (median follow-up, 11 months) of patients supported by ECMO for cardiogenic shock using the SF-36 questionnaire. Compared to French age- and sex-matched normal controls, ECMO patients had significantly lower mean scores for role-physical, general health, and social functioning and mean physical composite scores, reflecting persistent problems with work or other daily activities because of poor health and frequent interferences with social activities. Conversely, they considered their mental health and vitality satisfactory and did not complain of severe pain limiting their daily activities. Among the 21 patients treated with femoral ECMO four reported persistent problems at the cannula-insertion site (lymphocele, late wound healing); one required surgical repair of a femoral artery aneurysm; and nine had symptoms related to crural nerve injury (skin numbness and/or paraesthesia) which tended to lessen over time. Higher SF-36 scores were obtained for patients with longer follow-up suggesting time-dependent improvement in HRQL. Previous studies have indicated that this patient population carries very high risks of severe brain damage and multiple organ failure, even when adequate blood flow is ultimately restored and hypothermia for brain protection is rapidly applied. The association of female sex with ECMO failure in this study is intriguing despite it being in agreement with other studies showing poorer outcomes for women after cardiac or cardiac-surgical procedures or treated for infection, particularly hospital-acquired pneumonia. Further, emergency initiation of ECMO with severe ARDS or cardiogenic shock also led to poorer outcomes previously. In this La Pitié study women were on average smaller and thinner than men, yet only female sex was retained in the multi-variate model predicting ICU death. Whether anatomical and/hormonal pathophysiological factors account for this difference is speculative. However, women's smaller femoral
vein and artery diameters leading to sub-optimal cardiac decompression and lower flow delivery by the pump may ultimately affect their prognosis (Combes et al 2008).

**Airway clearance therapy at La Hôpital de la Pitié Salpêtrière**

**Broncho-alveolar Lavage**

Medical treatment to clear airways is in the form of broncho-alveolar lavage (BAL), including after hours when no physiotherapy service is available. Awake bronchoscopy is carried out if patients are not sedated with ECMO or mechanical ventilation. If patients are sedated on ECMO or ventilation then short acting sedation is used (around 15 minutes). On admission, BAL is frequently undertaken to obtain sputum specimens for cultures in their laboratory on the ECMO unit. If an organism is identified then the appropriate intravenous antibiotic is started. If nothing is identified then they wait for the next day’s results with extended testing by the hospital laboratory.

**French Bronchial Drainage Technique**

The French Bronchial Drainage airway clearance technique is carried out by physiotherapists. This involves a series of maximum inspiration followed by a fast maximum expiration down towards residual volume with the physiotherapist providing active verbal encouragement and manual assistance. The physiotherapist provides chest compression using two hands, one placed on the upper chest and the other over the abdomen squeezing them together during expiration encouraging fast expiration down towards residual volume. If there are two treating physiotherapists working together then four hands are used. Patients are then encouraged to expectorate and assisted with suctioning if required.

**Bottle Positive Expiratory Pressure (BPEP) therapy**

Bottle Positive Expiratory Pressure (BPEP) therapy is used with a 250ml bottle with a 10 cm column of water and a short length of large gauge suction tubing. Maximum inspiration is followed by maximum expiration against the 10cm column of water pressure all the way down towards residual volume.

**The Triflow Incentive Spirometer®**

The Triflow Incentive Spirometer® is used with the patient instructed to take a slow deep maximum inspiration drawing the three balls up and holding them in the
upward position for a number of seconds. Sometimes the Triflow® is used upside down with the patient carrying out a fast expiration to get as many balls up in the spirometer after a maximal inspiration. A series of breaths in and out as described make up a treatment session to increase lung volumes, decrease atelectasis and assist in airway clearance. For illustration see previous chapter on the visit to the University Hospital in Hannover (MHH), Germany.

**Coughing and suction**

Patients are encouraged to cough spontaneously into the mouth then remove secretions either with paper towel or oropharyngeal suction. Nasopharyngeal cough stimulation and suction is used with awake ECMO patients when required.

**Physical exercise for patients on ECMO**

This unit actively encourages all awake patients with suitable ECMO cannulation to get up and mobilize as is individually appropriate. They do not usually stand or walk patients with femoral cannulas. They have done so in the past, but believe it is risky and are not convinced that the benefits outweigh the risks.

**Mobilizing patients on ECMO**

Patients sit out of bed and walk when the Avalon Double Lumen Single Cannula is used or when cannulas are placed in the cervical region. Stable patients able to sit upright are taken in a wheel chair to sit outside. With femoral cannulas patients are sometimes allowed to partially sit up in their bed modified into a reclining chair conformation with hip flexion >90 degrees.

Physiotherapists perform passive / assisted / active bed exercises for limbs without lines or cannulas. No shoulder movements are allowed with the Impella device inserted at the axilla. Once out of the ICU and in the step down unit patients receive individualized rehabilitation after which they are referred to local rehabilitation centres in their home region. The main items of exercise equipment observed were cycling on exercise bikes and walking with assist devices such as walking frames.

**Case studies of patients on ECMO at La Hôpital de la Pitié Salpêtrière**

During the visit a number of patients on VV ECMO and VA ECMO (five sedated and five awake) were observed during treatment. These cases provided real life examples of the different challenges and the individualized physical treatments required for
patients on ECMO. Four of the cases are described.

Case 1:
A 70 year old gentleman was recently treated with VA ECMO for a cardiac condition, initially intubated and ventilated. He had a tracheostomy, was awake and able to eat and cough spontaneously. He had epistaxis from anti-coagulation requiring nose plugs. His airway clearance therapy included the French Bronchial Drainage and manual chest compression described previously. Following spontaneous coughing suction was applied via his tracheostomy.

Case 2:
A 75 year old gentleman with asthma and H. Influenza in cardiogenic shock was initially intubated and sedated then placed on awake VA ECMO and extubated. His twice daily airway clearance therapy consisted of French Bronchial Drainage, BPEP and incentive spirometry using the Triflow®. Following improvement in his condition he was decannulated. The future plan was to sit out of bed for prolonged periods and carry out a progressive physical exercises program in sitting and begin assisted standing. The patient would start walking as soon as he was strong enough to do this safely and effectively.

Case 3:
A 37 year old gentleman with asthma and allergies suffering from a cardiomyopathy since 2009, diabetes, dialysis for renal failure, obesity, and a duodenal ulcer was observed. He was supported by a Heart Mate VAD as well as awake VA ECMO, an IJV (arterial) and femoral (venous) cannula. He had a moist cough and was seen in bed, in supine supported 30 degrees head up, in the morning and afternoon for physiotherapy. This included French Bronchial Drainage, BPEP, exhalation via an upside down Triflo®, naso-pharyngeal stimulation and suction which resulted in effective coughing and oropharyngeal suction of excessive secretions. Because of his femoral cannula he was not allowed to sit upright or stand out of bed.

Case 4:
A 64 year old gentleman with cardiac insufficiency and a stent, with an Impella device inserted via the right axilla to unload and augment left ventricular function, was
observed. He had a cannula for dialysis in his left femoral vein. He was treated with physiotherapy in the morning with the French Bronchial Drainage and BPEP followed by passive and assisted exercises for his left arm and legs. The right lower arm was exercised but not the shoulder because of the Impella device. He decompensated in the afternoon and VA ECMO was initiated.

**La Hôpital de la Pitié Salpêtrière Mobile Cardiac Assistance Unit**

This unit was created in 2008 for highly unstable patients. This unit travels rapidly to other Paris area hospitals with a portable ECMO system and connects patients before multi-organ failure occurs.

**Current management and the future of ECMO - Dr Alain Combes**

In the ICU at Hôpital de la Pitié the average time on ECMO ranges from a week to around a month. The longest time on ECMO was six months. This resulted in a poor outcome when the patient died. Common complications include infections, thrombus sequelae, haemoptysis and bleeding complications from anti-coagulation. Thrombus formation is more of a problem in circuits after ~2 weeks necessitating circuit changes. Nutritional support following ICU protocols is strongly encouraged with referral to dietitians as required. Their aim is to get patients eating a normal diet as quickly as possible. Sometimes semi-sitting with a femoral cannula to optimize respiratory function is allowed as long as the angle at the hip is more than 90 degrees. This occurs in the patient’s bed modified to a chair configuration. Patients do not get out of bed with a femoral cannula.

When cervical cannulas are used patients are allowed to stand and walk if well and strong enough and not obese. Cycling is used once patients are discharged to the step down unit. Placing patients prone, ‘proning’ is sometimes used to try and prevent the need for ECMO and has occasionally been used with patients treated with ECMO. However, it is important to be selective in patient pathology. Those with increased lung secretions and localized atelectasis may find this position beneficial. ‘Proning’ has been found to be particularly useful with bibasal lower lobe collapse with radiologically normal upper lobes. ‘Proning’ with ECMO is not often used in this unit as there is little evidence for its usefulness compared with the complexity and risk. Based on clinical assessment of patients, QOL is reasonable around six months after ECMO however some continue to have anxiety and depression longer term. Cognitive
function has not been measured at this unit.

**Looking into the crystal ball:** ambulatory ECMO for lung bypass (along the same lines as the use of currently available ventricular assistance devices) is believed to be a possibility in the next 10 years. Thereafter it is hoped that ambulatory artificial lungs will be a reality. Indwelling cardiac assist device development is progressing very fast because of better quality long lasting batteries and component parts being developed in the car industry. This will have a positive flow on effect in the development of ‘pulmonary assist devices’.

**Summary of visit to La Hôpital de la Pitié Salpêtrière**
Many different forms of awake VV and VA ECMO were experienced during this fellowship. A number of patients treated with ECMO for pulmonary and cardiac problems requiring VV and VA ECMO were observed. Some were awake and participating in active treatment while others were immobilized in bed with sedation and treated passively. Treatment of patients with Impella and Ventricular Assist Devices were also seen. Attendance at ward rounds and ICU team meetings was educational and gave a further perspective on the complexity of managing these acutely unwell patients who without this life supportive treatment were unlikely to survive.

Many of the patients with complex conditions required airway clearance physiotherapy and physical exercise. The two treating physiotherapists were generous in sharing their theoretical and practical knowledge of the French approach to airway clearance and exercise used with patients during the Churchill Fellowship. The French airway clearance technique used offered new insights into the way regions approach the same pathophysiological problems in different ways. Observation of the use of newer technologies such as the Impella device together with discussions with the medical staff provided an in depth insight into cutting edge practice at this historic and iconic institution.

**Acknowledgements**
Grateful thanks to Professor Alain Combes for generously allowing me to spend four days in this highly regarded unit in Paris with one of the longest and largest
experiences of VV and VA ECMO. Gratitude is also extended to the other friendly medical and physiotherapy staff namely Elisa Marin and Hugo Abgrall who made me welcome and who shared their knowledge and expertise with generosity.

References

1. History of La Hôpital de la Pitié Salpêtrière: https://en.wikipedia.org/wiki/Pitié-Salpêtrière_Hospital


Hôpital Foch, Mount Valerian, Suresnes, France

Overview
The Hôpital Foch is located just outside the western boundary of the 16th Arrondissement, in Paris. The hospital was established after World War I (1932-1937) on the initiative of an eminent group of French and American figures in charge of reorganizing the American Red Cross and redistributing large donations to Europe. Between 1940-1943 it was requisitioned by the French military health services, later occupied by the German health services, then taken over by welfare services starting in 1944. The Hôpital Foch is currently managed by a nonprofit association established by the Fondation Foch together with the Département des Hauts-de-Seine and the City Hall of Suresnes. With 600 beds and 262,000 consultations and almost 47,000 hospitalizations in 2013, Hôpital Foch is one of the largest hospitals in the Paris region.

The 30 bed ICU is for various acutely ill patients with acute and chronic lung disease pre- and post lung transplant, stroke, brain trauma, septic shock and post operative (mainly thoracic and neuro surgery). Fourteen beds are dedicated to the most acutely unwell patients (including intubated and ECMO patients). Eight beds are dedicated to neuro and other patients (who may have tracheostomies and may be ventilated). A further eight beds are dedicated to respiratory patients with tracheostomies and / or ventilated. There is also a step down unit, a pre-ward unit and a respiratory ward. The four units form a square on the same floor.

Approximately fifty percent of patients admitted have CF and the other 50% is made up of COPD, pulmonary hypertension and other lung diseases, all post lung transplant.

The Hôpital Foch has a large CF centre with around 300 patients where lung transplantation occurs when patients reach end stage lung disease. High emergency listing was started in France in 2007 for patients with CF, pulmonary fibrosis and pulmonary hypertension. This initiative is to ensure that patients with these lung diseases are given priority when they become critically ill to receive donor lungs.
Prior to 2007 these patient groups experienced an unacceptably high mortality rate while on the lung transplant list. In 2013, sixty-five lung transplants were carried out at Hôpital Foch.

**Aims of the Churchill visit to Hôpital Foch**

1. Investigate awake VV ECMO at this large institution which carries out lung transplants for patients with chronic lung disease including cystic fibrosis;
2. Research their methods of airway clearance therapy for patients on ECMO;
3. Establish what enabling exercise equipment is used to successfully mobilize patients while on ECMO and after lung transplant.

**ECMO at Hôpital Foch**

ECMO has different uses in lung transplantation: bridge to transplant and bridge to recovery. The double lumen, singular Avalon® cannula inserted in the cervical region is the one of choice for awake and physically active patients at this centre. Sometimes other configurations including cervical and femoral cannulas are used if ECMO is planned for short term use as for example after lung transplant where patients may only require support for a few days. During the Churchill visit the author was able to view a change of cannulas in the operating room. A young man in his 20s with CF had undergone a double lung transplant two weeks previously. He had experienced cardiac and lung complications during the surgery necessitating VA ECMO with both cannulas inserted in his right femoral region and a right cervical central line inserted for renal dialysis. In the post-operative two weeks cardiac function had improved. However he still required ECMO for lung support. He returned to the operating room to change his ECMO from VA to VV. This visit to the operating room highlighted the complexity of ECMO and the number of highly trained professionals required to carry out this life saving procedure safely and effectively.

**Use of the Avalon® cannula in patients with CF at Hôpital Foch** (Sage et al 2015)

At a the International ECMO Conference in Paris in June 2015 (attended by the author), the transplant surgeon Doctor Sage from the Hôpital Foch presented the results of a large case series of CF patients who were successfully treated with awake ECMO as a bridge to lung transplant. In this retrospective study of 16 patients with CF (10 females) from 2010 – 2014 treated with awake ECMO with the Avalon® dual lumen cannula the median time from listing to lung transplant was 4 (1-9) days; the
median time on mechanical ventilation after lung transplant was 3 (0-14) days and the median length of stay in ICU after lung transplant was 7 (2-34) days and discharge from hospital after lung transplant was 27 (17-106) days. (Sage, Lecoste et al manuscript submitted to Journal of Heart and Lung Transplant).

Doctor Cerf (Head of the ICU) commented that he believed the success of the awake ECMO program, using the Avalon® cannula at Hôpital Foch, was as a result of the surgical procedure carried out in the operating room where the cannula is firmly stitched in place to avoid problems when the patient moves around. Further, the emergency listing in France guarantees a short time on ECMO. This avoids prolonged cannulation time that inevitably results in an increase in problems with ECMO flows, thrombus formation, bleeding, organ failure and other complications. These problems can also result in an inability to be physically active which in turn leads to further complications such as deep vein thrombus, loss of muscle mass and general deconditioning further compromising post lung transplant outcomes.

**ECMO used as a bridge to lung transplantation in France** (La Farge et al 2013). ECMO is increasingly used as a bridge to lung transplantation. Data concerning this approach and outcomes remain limited. A retrospective review of medical records of all patients in France who received ECMO as a bridge to lung transplant was undertaken from 2007-2011. All hospitals that carried out lung transplantation and used ECMO participated in this study. These were located in Paris, Toulouse, Strasbourg, St Herblain, Lyon, Marseille, Grenoble and St. Denis. Included were 36 patients from 11 centres including cystic fibrosis (CF) 20 (56%), pulmonary fibrosis 11 (30%), and other diagnoses 5 (14%). Venovenous ECMO was used for 27 (75%) patients and venoarterial ECMO for 9 (25%). The mean follow-up time was 17 months. Thirty (83%) patients were bridged to lung transplant. Twenty-seven (75%) patients survived the lung transplant procedure and 20 (56%) were discharged from hospital. From ECMO initiation, 2 year survival rates were 50.4% overall, 71% for CF, 27% for pulmonary fibrosis and 20 % for other patients. After lung transplant 2-year survival rates were 60.5% overall, with CF 71%, pulmonary fibrosis 43% and 33% other patients (p=0.04) respectively. This French study confirmed that ECMO can be used as a bridge to lung transplant in critically ill patients. Survival differed by
underlying respiratory disease. CF had a significantly better long-term survival rate than the other two lung disease groups (p=0.001) (La Farge et al 2013).

**Airway clearance therapy at La Hôpital Foch**

Airway clearance techniques used at this centre are similar to the previous hospital visit in Paris. The techniques of broncho-alveolar lavage carried out by medical staff and French Bronchial Drainage combined with manual assistance provided by the physiotherapists are the mainstays of airway clearance therapy at this hospital.

**Case studies of patients observed during visit to La Hôpital Foch**

**Case study 1:**

A 25 year old woman with cystic fibrosis who weighed 50kgs with a BMI of 22 underwent a double lung transplant with left and right thoracotomies the day prior to the hospital visit. The patient remained intubated, and was awake and calm. The ICU doctor explained the need to do a bronchoscopy to view the anastomoses and determine if she was ready for extubation. The patient was told transplanted lungs have no sensation and therefore no pain or distress would be experienced during the procedure. Local anaesthetic, xylocaine, was instilled into the tube. An oropharyngeal airway was introduced to guide the bronchoscope into the airway. The patient was able to observe the procedure on the video screen with the doctor providing real time commentary throughout. The patient tolerated the bronchoscopy well, there was no coughing or distress and from her expression it was obvious that she found the procedure interesting to watch on the video screen. This likely acted as a distraction from any potential distress or anxiety. A small amount of ischaemia was seen on the left main bronchus while the right anastomosis looked healthy. A large amount of secretions was suctioned from the airways. After removal of the bronchoscope and endotracheal tube she coughed vigorously and expectorated a large amount of creamy yellow secretions.

**Non-invasive ventilation (NIV) combined with French Bronchial Drainage and manual techniques**

The patient described above received non-invasive ventilation (NIV) for two hours on and two hours off for the following 24 hours with pressures of 13/5 and an FiO2 of 0.35. When off NIV she had 2 litres of oxygen via nasal prongs at rest, during airway
clearance therapy and while walking. This kept her oxygen saturations at around 96%.

The airway clearance therapy undertaken while on NIV consisted of French Bronchial Drainage and manual compression. The physiotherapist placed one hand over the patient’s central abdomen and one on the central upper chest. The patient was encouraged to inhale deeply towards inspiratory reserve volume with NIV. This was followed by exhalation all the way out towards residual volume through an open glottis with the physiotherapist vigorously encouraging the patient while applying manual compression. The patient complained of pain and asked for less pressure. She was then instructed to cough against the positive airway pressure generated through the NIV mask. This was followed by expectoration of old blood stained secretions. This routine was repeated until the airways were deemed to be clear.

Case study 2:
A lady in her 50s with CF was 3 weeks post double lung transplant still ventilated via a percutaneous tracheostomy requiring 30% of oxygen. Her contused donor lung was slowly recovering. She had increased secretions and was receiving French Bronchial Drainage with physiotherapist assisted manual compression as described previously. Installation of 4 mls of normal saline resulted in a slightly productive cough and suction of mobilized secretions. She continued to experience thoracic back pain from the double thoracotomy at the time of lung transplantation and transcutaneous electric nerve stimulation (TENS) with 4 electrodes was applied intermittently for pain relief.

Early mobilization for patients at Hôpital Foch
The patient (case study 1) previously described had two chest drains and one peripheral subcutaneous drain each side following double lung transplantation. She had an epidural inserted at the time of the lung transplant for pain relief and drip lines with intravenous antibiotics and equipment. A portable oxygen cylinder and an oximeter needed to be transported as well. All of these attachments were placed on a French purpose built walking frame (Fiche Deamborghini-HG). The sturdy frame has three sides (front, left and right) for holding onto and attaching equipment. It has hooks for holding IV bags. There is a plate for holding monitoring equipment at the front and a seat that is lowered behind the patient in case the patient needs to sit
down and rest during the walk. If the patient was unable to walk back to bed she could be wheeled sitting on the seat of the frame. The patient was assisted up into standing and walked the full square of the Unit, 200 metres, without needing to rest. This purpose built walking frame is also used by patients treated with awake ECMO to enable standing and walking. The pre-requisites for walking with ECMO are: a duel lumen Avalon cannula in the internal jugular vein in situ, the patient able to sit on the edge of the bed, stand and march on the spot. At least three persons are required for walking safely on ECMO: the physiotherapist who manages the patient, a nurse who holds the ECMO cannula and a perfusionist who manages the ECMO machine.
Fluoroscopy for visualization of diaphragm movement and biopsies

A middle-aged male patient post lung transplant was observed having video guided fluoroscopy to observe diaphragmatic movement. If one diaphragm is not working then biopsies are taken from that side to avoid risk of pneumothorax to the lung with the working diaphragm. Frequent surveillance bronchoscopies are carried out in the ICU every few days then weekly and then less frequently as clinically indicated.

Summary of visit to Hôpital Foch

The emergency lung transplant listing in France reduces the waiting time for organ procurement in the case of critically ill patients and those on ECMO optimizing survival and long term outcomes. Greater insights into French physiotherapy techniques were gained. Manual compression with French Bronchial Drainage can be uncomfortable if too much pressure is applied over the abdomen. The physiotherapist commented that evaluation of the technique in rigorous scientific studies was warranted. Awake bronchoscopy is well tolerated by selected patients when real time commentary is provided which appears to distract patients from becoming anxious or distressed during the procedure. The ICU has a culture of encouraging physical activity and walking to preserve muscle mass and prevent deconditioning to ensure optimal outcomes pre- and post-lung transplantation, whether ventilated, on ECMO or breathing spontaneously.

The unique, practical French purpose built walking frame allows the activity of walking to be safely and efficiently undertaken by a minimum number of professionals. Walking with ECMO usually requires three professionals. Many lessons were learned about the use of ECMO and the management of patients before and after lung transplantation. A strong culture of getting patients up and mobilizing them as soon as it is safe to do so was evident.

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as those waiting for, or who recently underwent lung transplantation.

References


Duke University Hospital, North Carolina, USA
Duke Hospital 2300 Erwin Road, Durham, North Carolina

Overview
In 1924 an endowment of $40 million from James B. Duke, ‘The Duke Endowment’, was given to transform Durham’s Trinity College into Duke University. This was followed a year later by an additional bequest to establish the Duke School of Medicine, Duke School of Nursing and Duke Hospital with the goal of improving health care in the Carolinas and nationwide. Construction was completed and Duke University Hospital was established in 1930 and medical students began classes. Within five years Duke was ranked among the top 25% of medical schools in the country. In 1980 the new $94.5 million, 616-bed Duke Hospital opened bringing the total number of patient beds to more than 1,000. In 1998 Duke University Hospital System (DUHS) was officially created when it established partnerships with Durham Regional Hospital, Raleigh Community Hospital and other regional health care providers. DUHS includes three hospitals, ambulatory care and surgery clinics, primary care medical practice clinics, home health services, hospice services, physician practice affiliations and other related facilities and services. This information on the origins and establishment of Duke University Hospital was seen on an educational video screen at the entrance of the hospital to inform the public of its history and establishment.

Aims of Churchill visit to Duke University Hospital (Duke)
1. Research the use of awake ECMO and its management at Duke;
2. Investigate the different types of airway clearance, physical exercise and enabling equipment used to keep patients in optimal physical condition while waiting for a lung transplant;
3. Discuss the research and management of gastroesophageal reflux (GER) before and after lung transplant carried out at Duke University Hospital.

ECMO at Duke
Duke carries out ECMO as a bridge to recovery or to lung transplantation in four
different intensive care units. These include the paediatric ICU (PICU) that manages patients with respiratory conditions from birth to adulthood (especially if these patients have been treated for paediatric conditions); the paediatric cardiac ICU (PCICU) where infants and children with congenital cardiac conditions are treated into adulthood; the adult Medical ICU (MICU) a unit which developed ECMO capabilities following the H1N1 epidemic in 2009 - 2010 which resulted in very large numbers of adult admissions to Duke with fulminant respiratory failure. Until that time all ECMO was provided to patients across the lifespan with respiratory, cardiac and post-surgical problems in the PICU under the direction of Dr Ira Cheifetz, the sponsor of this Churchill Fellowship. ECMO (both VV and VA) is also extensively utilized in the adult cardiothoracic surgical intensive care unit.

The Duke MICU has been in existence for many years and started offering ECMO in 2010. The number of patients placed on VV ECMO each year has increased. This includes patients with ARDS who require a period of 'lung bypass' while lung recovery occurs and those with end stage cystic fibrosis and other respiratory conditions waiting for lung transplantation. The total number of ECMO treatments at Duke University Hospital between 2010 and 2014 was around 100 per year. In 2014 there were 75VA and 25 VV ECMO treatments undertaken. In 2015 up to the time of the Churchill visit in early July 50 VA and 50 VV ECMO lung bypasses had already been carried out.

Approximately five to ten patients with CF per year have required ECMO as a bridge to lung transplant over the past five years. Patients requiring ECMO as a bridge to lung transplant in recent years have come predominantly from surrounding cystic fibrosis units as opposed to the Duke CF Unit. On any given month there may be zero to one to five patients with CF on ECMO. The introduction of the Lung Allocation Score (LAS) has resulted in patients at the Duke CF Centre receiving lung transplantation in a much shorter time than previously with the allocation of a very high LAS once they reach the stage of severe lung disease and respiratory failure. As a consequence not many CF patients managed at the Duke CF Unit have required ECMO. Most CF patients requiring lung transplantation at Duke are in their 20-40s. Most CF patients on ECMO bridging to lung transplantation patients are in their 20s.
At Duke 70-120 lung transplants and around 75 heart transplants are carried out each year. At the time of the Churchill visit the oldest patient to have had a lung transplant at Duke was 79 years old, at the time of listing. To be transplant listed the patients’ BMI should be between 17 and 28 (there are exceptions if patients are transferred from other centres already intubated or on ECMO outside this range). Patients should also have two caregivers. They can be family members or friends. The second caregiver is a back up in case the first is unable to assist the patient. The patient must be able to walk at least 1000 feet (305 metres) to qualify for transplant listing and be up and walking twice a day while waiting for lung transplantation, however lesser distances may be acceptable in otherwise good candidates on ECMO. Past experience has resulted in very poor outcomes in patients who are ventilated and on ECMO and who are unable to walk. Heart-lung, kidney, kidney-lung, liver, liver-lung and intestinal transplants are also carried out at Duke.

Outcomes for patients with ARDS treated with ‘bridge to recovery’ ECMO are excellent with the majority making a full recovery often regaining 60-70% of their previous lung function 6-12 months after being weaned from ECMO. At Duke VV ECMO is managed by respiratory therapists (RTs) with each RT looking after up to 4 patients on ECMO at a time. Perfusionists manage patients on VA ECMO at Duke.

**Type of ECMO cannulation at Duke**

Ambulatory VV ECMO is provided with the Avalon® dual lumen cannula described previously for early mobility and physical activity. Use of the Avalon® cannula in infants can lead to a perforated RA or RV with blind insertions. Therefore fluoroscopy is used during ECMO insertion at Duke. Insertion of the Avalon® cannula at Duke is percutaneous using a needle followed by guide wires that increase in size dilating the blood vessel until the optimal cannula size is achieved. Two stitches are inserted and left untied outside the site under the dressing so that when the patient is decannulated, the two stitches are pulled together quickly, tied and the incision closed. The average time on ECMO with an Avalon® cannula is 10-14 days usually as a bridge to lung transplant.

VA ECMO via the internal jugular vein (IJV) and carotid vessels is used for neonates. VV-VA ECMO using a ‘ChestMO’ developed by Dr Mani Daneshmand comprises a venous cannula inserted via a small 3-5cm anterior thoracotomy into the right
atrium; arterial cannulation occurs via a bridge to the ascending aorta. This configuration allows for arm exercises and walking (unpublished information provided during the Churchill visit). Axillary cannulation is not a preferred option as patients then cannot use the Swedish walking frame. This in turn limits getting up and walking. Patients have developed brachial plexus lesions from this form of cannulation. Femoral cannulas are avoided if possible because patients are then not allowed to sit upright, stand or walk. Ambulation is a very high priority at Duke.

Sizes of cannulas used at Duke include French 13,16, 19, 20, 23, 27, 31. The longer they are the more they decrease flow dynamics. Sizes 19 and 23 are sometimes used in small adults and teens with CF. Sizes 13 and 16 are used for infants and size 19 for one to 10 year olds. Most adults require a size 31 with short women needing a size 27. A wider diameter catheter on the venous side is needed to draw venous blood than on the arterial side where the cannula is required to push oxygenated blood through the circulatory system. With VV ECMO minimal flow for optimal oxygen saturation is around 70% of projected cardiac output in litres per minute. Assessment with pulse oximetry is used to assist in avoiding too much mixing and recirculation. Lower rpms in the ECMO pump lead to less damage to blood cells. Hypovolaemia leads to collapse of the right atrium.

The Maquet ECMO pump is the most commonly used pump. It is a reliable compact and simple pump. With patients with ARDS the average time on ECMO at Duke is seven to ten or more days. Once the patient shows improvement, ECMO tends to be used for one to two days longer then weaned. Outcomes with ARDS six to 12 months after weaning ECMO have been variable. Patients usually experience a full recovery often regaining 60-70 of their previous lung function. Patients who are not used to the sensations of dyspnoea are often intolerant of awake ECMO and may need to be sedated. They may be ventilated via a percutaneous tracheostomy. Patients with CF and other chronic lung diseases usually tolerate dyspnoea well as they have acclimatized to the sensation over a prolonged period of time and are therefore highly suited to awake ECMO. The Avalon® cannula is the one of choice as it allows patients to be awake and walking while they wait for lung transplant. The average
cost of an ECMO circuit is around US $40,000 and an Avalon® cannula around US $2,000.

**ECMO Procedure at Duke**

In the adult unit ECMO is usually set up in the operating room by cardiothoracic surgeons. Patients also have a percutaneous-tracheostomy and a percutaneous endoscopic gastrostomy/jejunum (G/J) tube inserted under the one general anaesthetic. These three procedures take approximately two hours to complete. The G (gastric tube) is for the delivery of medications directly into the stomach and the J (jejunostomy) tube is positioned in the jejunum for feeds. Some patients with VA ECMO without lung problems do not have a percutaneous-tracheostomy if it is anticipated that the ECMO duration will be short.

In the paediatric unit ECMO is inserted in a sterile field in the PICU ward. Children often have a percutaneous-tracheostomy inserted prior to the start of ambulation. The rationale for early tracheostomy is the ability to provide quick access to ventilation in case of an emergency with the ECMO cannulas during ambulation. Nutrition occurs via a nasogastric or naso-jejenum feeding tube as well as by mouth depending on the medical team’s preference and the patient’s ability.

**Ventricular Assist Devices (VADS) at Duke**

Around 100 patients at Duke receive ventricular assist devices (VADs) each year. Five to 15 are in hospital at a given time being set up with VADs. Two thirds of patients are destination therapy VADS with some in their 80s.

**Airway clearance for awake ECMO patients at Duke**

Physiotherapy for patients on ECMO consists of lung recruitment for atelectasis, airway clearance therapy and adjunctive inhaled mucolytic agents for increased or retained pulmonary secretions. Most patients with advanced lung disease in acute respiratory failure who require lung support have VV awake ECMO using the Avalon® dual lumen cannula at Duke. Because it is inserted in the internal jugular vein it allows the patient to sit, stand and walk while waiting for lung transplant preserving muscle mass and avoiding deconditioning. A variety of different airway clearance techniques are used at Duke.
**Vibrating beds and Intrapulmonary Percussive Ventilation (IPV)**
Some of the beds used in the ICU are able to vibrate while patients are lying in them supine or 30 degrees head up. The vibratory effect is believed to loosen secretions and promote mucociliary clearance. The rationale for this form of treatment is extrapolated from studies undertaken with high frequency chest wall oscillation therapy. Intrapulmonary percussive ventilation (IPV) is used at Duke and can be delivered by various manufactured devices including the Hillrom Metaneb® system. The rationale, treatment and evidence for IPV has been described previously in Chapter 2 during the visit to the Universiteit Zieckenhuis in Brussels.

**PEP and oscillating PEP devices**
Oscillating positive expiratory pressure therapy using the Acapella® and Flutter® devices are frequently used at Duke. PEP therapy using the Pari PEP® device and bottle PEP using a bottle with a column of water and tubing are also used for airway clearance therapy.

**Manual techniques of percussion and vibrations and the cough assist device**
Manual techniques of percussion and vibrations are infrequently used at Duke. The cough assist device is occasionally used with end stage CF and patients with neuromuscular disease. A facemask interface is used with +40 during inspiration and -40 during expiration. Three to four cycles are carried out followed by a rest. These sets are repeated until secretions have moved to the upper airways then patients huff, cough, throat clear or have suction applied to eliminate the secretions from the lungs. Care needs to be taken with patients with large bullae as an inspiratory pressure of +40cmH2O may result in barotrauma with the potential for pneumothorax.

**Incentive spirometers**
Incentive spirometers (previously described) are routinely supplied to patients at Duke for respiratory muscle strengthening and maintenance together with recruitment of alveoli and increasing lung volumes while on awake ECMO.

**Intermittent mechanical ventilation, BAL and airway suction**
Most of the time the majority of patients on ECMO are ventilated. This is based on the Duke experience that patients tend to become air hungry on oxygen via nasal prongs.
They have found that high flow nasal prongs do not always provide enough support for respiratory patients with acute respiratory failure while on ECMO, however, some with chronic respiratory or cardiac failure manage well with this form of oxygen support. Patients also receive intermittent ventilation for alveolar recruitment, mobilization of secretions and prevention of lung complications. This is combined with tracheal suction. Bronchoalveolar lavage and suction are sometimes used for airway clearance therapy via the percutaneous tracheostomy. NIV is not generally used with awake ECMO patients at Duke.

**Inhaled mucolytic therapies**

Adjunctive inhalational therapy includes mucolytic agents such as nebulized saline, hypertonic saline or dornase alpha. If the patient is treated with mechanical ventilation combined with inhalational therapy the Aerogen® ICU nebulizer system is used in line.

**Physical exercise and walking patients while on ECMO**

Walking is the highest priority for these patients during physiotherapy sessions using exercise as airway clearance therapy as well as for preservation of muscle mass and prevention of deconditioning. The aim is for two walks per day of at least 1000 feet (305 metres). If patients are already deconditioned then passive, assisted, active and resisted bed exercises are used to prepare them for sitting, standing and walking.

The number of health professionals required to walk a patient depends on whether the patient is on a ventilator at the time or not. Five to seven professionals are required to walk a patient with ECMO who is also on a ventilator. If the patient on ECMO is breathing spontaneously then five to six professionals are usually required. For short walks within the ICU unit, 4 health professionals may be adequate. The team walking the patient with ECMO always includes the patient’s nurse together with a selection of the following: the physical therapist with or without an assistant, the respiratory therapist, the occupational therapist, the perfusionist and the doctor on the unit. Each person has a role. One looks after the cannula holding it steady during the walk (Coban, self adhesive tape, is used for securing the ECMO cannula); one manages the ventilator and oxygen support; one looks after the intravenous
therapy lines; one to two professionals support the patient on either side; one pushes the ECMO equipment and one brings the wheelchair behind in case the patient needs to sit down or be wheeled back to bed.

To get the patient up into sitting then standing the bed is electrically transformed into an upright chair with an inflatable back cushion that pushes the patient forwards towards the edge of the chair. The patient is assisted by the physical therapist into standing and onto a sturdy supportive Swedish walking frame. It can take 10 minutes to prepare for the walk. The first stand out of bed can be challenging for the patient. The physical therapist assists the patient up into standing while stabilizing the patient at the knees. The six-minute walk test is used as an objective measure to monitor the patient’s progress. Cycling with a pair of pedals is used when the patient is able to sit out of bed in a chair and peddle.

**Evaluation of pre-transplant physical rehabilitation** (Rehder et al 2013). Dr Cheifetz’ group with Dr Rehder as first author and their colleagues at Duke carried out a study to investigate the importance of maintenance of muscle strength and mobility before lung transplantation (Rehder et al 2013). They tested the hypothesis that pre-transplant deconditioning has a significant impact on outcomes for patients after lung transplant, and is likely a major contributor to increased mortality in lung transplant recipients who were critically ill and physically deconditioned pre-transplant. They described a retrospective case series of patients bridged to lung transplant with ECMO at Duke and examined the potential impact of active rehabilitation and ambulation during pre-transplant ECMO.

Pre-transplant ECMO patients who received active rehabilitation and ambulation were compared to those patients who were bridged with ECMO but did not receive pre-transplant rehabilitation. Nine consecutive subjects between April 2007 and May 2012 were identified for inclusion in the review. One-year survival for all subjects was 100%, with one subject alive at 4 months post-transplant. The 5 subjects participating in pre-transplant rehabilitation had significantly shorter mean post-transplant mechanical ventilation (4 days versus 34 days, p = .01), ICU stay (11 days versus 45 days, p = .01), and hospital stay (26 days versus 80 days, p = .01). No subject who participated in active rehabilitation had post-transplant myopathy, compared to 3 of 4 subjects who did not participate in pre-transplant rehabilitation.
on ECMO. They concluded that bridging selected critically ill patients to transplant with ECMO is a viable treatment option, and active participation in physical therapy, including ambulation, may provide a more rapid post-transplantation recovery. They concluded that this innovative strategy requires further study to fully evaluate potential benefits and risks (Rehder et al 2013).

**Management of gastro-oesophageal reflux (GOR) pre- and post-lung transplant**

Discussion about the Duke experience of the measurement and management of GOR occurred with Dr Alice Gray, the Head of the Duke Adult Cystic Fibrosis Service. Duke has a strong research track record in GOR research around the time of lung transplant. This research has resulted in the development of the following clinical guidelines at this centre.

Twenty-four hour pH monitoring or a pH-impedance study (off anti-secretory therapy), high-resolution oesophageal manometry and an upper GI series are carried out as part of the work up pre-lung transplant. If patients are diagnosed with GOR pre-lung transplant and are deemed well enough to undergo surgery then fundoplication is carried out pre-lung transplant. If surgery is thought to be too high risk in the lead up to lung transplant then it is scheduled about a month after lung transplantation during the rehabilitation phase. If the 24hour pH monitoring study is normal pre-lung transplant then it is repeated post-lung transplant, as GOR sometimes becomes a problem after the surgery with damage to the vagus nerve during the surgical procedure. If this test is positive then a fundoplication is carried out once the patient has recovered from the initial transplant surgery approximately four to six weeks after lung transplant.

Before fundoplication three investigations need to have been carried out including barium swallow; pH-impedance study or twenty-four hour pH monitoring off anti-secretory therapy; and oesophageal manometry. If the patient had an abnormal study diagnosing GOR pre-transplant then a repeat study is not required prior to fundoplication post-lung transplant. If suboptimal oesophageal peristalsis is found with manometry then a 270degree (Toupet) wrap is carried out. If manometry is normal then a 360degree (Nissen) wrap is the chosen surgical approach.
Treatment of GOR at Duke University Hospital
Lifestyle changes are regarded as highly important in managing GOR. Elevating the head of the bed for sleeping and avoiding head down positions or activities are recommended. Avoiding reflux promoting foods and allowing enough time for digestion of meals before lying down. These are combined with pharmacological treatments including proton pump inhibitors and ranitidine. Fundoplication is aggressively undertaken at Duke as it is recognized as the most successful way of treating GOR and preventing consequent pulmonary compromise after lung transplantation.

Summary of visit to Duke University Hospital
The Duke ECMO program has world-class outcomes that are based on strict criteria for listing for lung transplantation and a unique approach to treatment. This includes ECMO cannulation in the operating room together with placement of a percutaneous tracheostomy for ventilation and airway secretion removal and placement of percutaneous GJ tubes for medication and intensive feeding. Preservation of muscle mass with optimal nutrition and physical exercise including walking to preserve muscle strength, prevent general de-conditioning and assist with airway clearance are regarded as keys to good outcomes before and after lung transplantation. Regular physical exercise is a high priority assisted by a large team of well-trained professionals to ensure safe delivery of treatment whether passive, assisted or active and individualized to each patient. The active management of GOR based on their research findings with early fundoplication to prevent this from being one of the causes of the development of broncho-obliterans syndrome (BOS) post lung transplant is a further management strategy that ensures the best outcomes for patients undergoing lung transplant at Duke.

Acknowledgements
Ms Virginia Wills, co-ordinator of Churchill Fellowship visit, went above and beyond expectations to organize the comprehensive program of meetings and observation opportunities. The following scheduled meetings with the wider Duke medical team provided new knowledge and insight into what makes this program at Duke so
successful. These highly experienced and dedicated health professionals gave generously of their time and expertise and included Professor Ira Cheifetz (Chief Medical Officer Children’s Services) who sponsored the Churchill visit; Dr Kevin Watt MD in the PICU Unit, Dr Craig Rackley MD and Assistant Professor of Medicine, Dr Christoph P. Hornik MD and Assistant Professor of Pediatrics in the PICU, Dr Raquel Bartz MD and Assistant Professor of Anesthesiology and Medicine, Dr George Ofori-Amanfo MD and Attending in the PCICU, Professor Neil MacIntyre, Professor of Medicine and Dr Alice Gray MD and Medical Director of the Adult Cystic Fibrosis Program. Dr Gray highlighted the active management of GOR at Duke.

Ms Desiree Bonadonna, perfusionist and Clinical Manager, ECMO Services provided a wealth of knowledge regarding ECMO equipment, cannulation, retrieval of patients on ECMO from other sites and many details about the use of ECMO at Duke. Ms Janice Thalman, Director of Respiratory Care Services gave valuable insight into the training, expertise and ongoing certification process that respiratory therapists undertake to manage many of the respiratory treatments, ventilation and ECMO equipment and procedures at Duke. Heather Harrison RN, Nurse Manager of Operations, in the PICU provided information about her role and nursing practices and services in the PICU. Ms Tamara Klintoworth-Kirk, physical therapist and Clinical Services Coordinator, Mr Kenneth Gould, adult physical therapist and Ms Jennifer Edelschick, paediatric physical therapist provided knowledge, practical demonstrations and insight into the physical therapy treatments and equipment used to treat patients at Duke.

Duke is well staffed with highly enthusiastic health professionals who are dedicated to achieving the goal of safely ‘walking while waiting’ the title of a review paper recently published by this unit and having an aggressive approach to treatment at each step of the way.

References


New York – Presbyterian (NYP): The University Hospital of Columbia & Cornell Universities
Milstein Hospital Boulevard, 177 Fort Washington Avenue, New York

Overview
The earliest roots of the hospital go back to nineteenth century Manhattan. Around that time the medical community’s latest breakthrough was the discovery of x-ray. The hospital started in 1892 as a haven for unmarried mothers in a humble house on East 123rd Street in Manhattan. The Salvation Army operated the Rescue Home for Women. The facility was one of the Salvation Army’s first installations in the United States. During World War 1 the facility opened a free medical service for the dependents of enlisted men. After the war the name of the facility was changed to the Booth Memorial Hospital. It relocated twice before being established permanently in Flushing, Queens. For nearly 60 years the facility operated on East 15th Street. The move to Queens was spurred by the baby boom in the 1950s. The Salvation Army became aware of the shortage of local general hospital facilities in the farmland communities east of the East River, Queens, which was supporting a rapidly growing population.

The new hospital was built on the site where the hospital resides today. It opened to great fanfare in 1957 with 210 beds, 45 bassinets and a 35-bed unit, the Williams Residence, designed for elderly patients. By the early 1990s the Salvation Army decided to hand over management of acute care hospitals across the USA so that it could concentrate on other charitable endeavours. In 1992 the hospital became an affiliate of the New York Hospital-Cornell Medical Centre and the following year was renamed the New York Medical Centre of Queens. Subsequently while retaining this name legally, for ease of use it was shortened to New York-Presbyterian/Queens, after in 1997, the New York Hospital and The Presbyterian Hospital merged creating the New York Presbyterian Hospital Care Network. The hospital system is now one of the largest healthcare systems in the USA. It has grown to become a 535-bed acute care hospital with more than 30,000 patients treated annually and more that 160,000 outpatient visits each year. (History of NYP, Queens on the website nyhq.org)
Aims of visit to NYP

1. Observe the ECMO management and early mobilization program provided by physical therapists and the wider multi-disciplinary team;
2. Research the equipment that enables safe and effective physical activity;
3. Experience the wider physical therapy and rehabilitation program at NYP.

ECMO at NYP

Professor Dale Needham of Johns Hopkins University did early work on the clinical effects of early mobilization in one of the OACIS (Outcomes After Critical Illness and Surgery) studies. This was compared to traditional treatment with sedation and bedrest. This study demonstrated a significant decrease in length of stay in the ICU when patients were awake and up and moving early on in their ICU admission. The introduction of ‘Obamacare’ in the USA led to the HERCULES Project in 2011 whose objective it was to reduce cost in hospitals across the USA in order to afford the universal health care program. Professor Dan Brodie presented to the hospital administration the initiative to decrease sedation, wake patients up and carry out early mobilization in the ICU units under his direction together with the data supporting shorter lengths of stay in the ICU as shown by the OACIS study. The projected savings on decreased hospital bed days would outstrip the cost of employing an extra 1.5 EFT of key staff to enable this initiative.

Increased staff would include a physical therapist dedicated to the project as well as a part time occupational and speech therapist. This funding proposal was successful and the change in practice was enthusiastically adopted by the entire team of health professionals in the ICUs at NYP. Any resistance to this change in management amongst the ICU healthcare team (who were accustomed to treating sedated patients lying in bed) was quickly dispelled with strong leadership from Professor Brodie and his team. This led to a rapid change in the culture of patient management in the ICU setting at NYP. Initially, regular planning meetings were held to develop new protocols and guidelines and to train staff in new early mobilization practices. The New York Presbyterian Medical Intensive Care Unit (MICU) consists of MICU A and MICU B, each with 12 beds. MICU A cares for critically ill patients some who require mechanical ventilation with or without ECMO. MICU B treats patients
requiring intensive care but not treated with ECMO. Professor Dan Brodie leads the early mobilization program at the 13 intensive care units that make up the Columbia and Cornell University Hospital.

**Types of ECMO cannulas used at NYP**

For VV ECMO, the Avalon Elite® Bi-caval Dual Lumen Catheter by Maquet, Germany is used which allows for ambulation. Sometimes VV ECMO is set up using the superior vena cava (SVC) at the cervical site and the inferior vena cava (IVC) at the femoral site. This set up poses a greater risk with walking with a cannula in the femoral region and is not the preferred option if the objective is to get the patient up and walking.

VA ECMO with the modified Avalon Elite® Bi-caval Dual Lumen Catheter is used creatively returning arterial blood from the right ventricle (RV) to the left ventricle (LV) and allows ambulation. VA ECMO with a cannula in the internal jugular vein (IJV) in the cervical region and one in the subclavian artery via a small anterior chest incision near the breast also allows ambulation. Sometimes when patients are rescued outside of NYP intensive care units under challenging conditions cervical and femoral cannulation is used. This procedure is not preferred as early physical activity is more challenging.

**ECMO Procedure at NYP**

A thoracic surgeon sets up ECMO in the operating room at NYP. Once patients recover from the general anesthetic and are medically stable and able to breathe independently they are extubated from mechanical ventilation. This occurs as early as possible. If patients require ongoing mechanical ventilation or suction of airway secretions then a percutaneous tracheostomy is performed so that early physical therapy and mobilization can occur. Patients are able to walk supported with a portable battery powered ventilator. As required, supplemental oxygen is provided with high or low flow nasal prongs and humidification.

**Number of patients treated in recent years and patient outcomes**

The ECMO program grew rapidly with the H1N1 influenza epidemic in 2009. Approximately 100 patients per year are treated with ECMO at NYP. More patients are treated with VV ECMO than VA ECMO. A study was recently carried out evaluating 57 patients treated with ECMO at NYP by Professor Brodie and colleagues.
Seventy-two percent of patients were treated with VV ECMO with 42% of those patients having cystic fibrosis. The mean time on ECMO was 13 (standard deviation 10.6) days with the longest 55 days. The one-year survival after ECMO as a bridge to lung transplant in this study was 87.5% of patients. (Dan Brodie, unpublished data).

**Transporting patients on ECMO the NYP Experience**

NYP is a specialist center that carries out ECMO transports from surrounding hospitals including overseas. Extracorporeal life support technology has gained acceptance as a salvage mode for patients in respiratory or cardiac failure. Patients who are sick enough to require ECMO support are often too unstable to transport to a hospital with ECMO capabilities. To date, 150 ECMO transports have successfully been undertaken at NYP. A retrospective study from 2008 to 2014 examined the outcomes of the first 100 patients transported on ECMO. Data were collected retrospectively from their hospital’s electronic medical record from the time their institution began an ECMO transport program in 2008. Patient outcomes are reported through April 2, 2014. In the initial phase transport involved only highly selected patients for short distances. With experience they refined their intake and evaluation process. They also consolidated care for ECMO patients with two Intensive Care Units and developed a dedicated ECMO intensivist position. As the service has matured, patient selection has become more inclusive and they have extended their capabilities to include interstate and international transport. All 100 patients were successfully placed on ECMO and transported to NYP. Seventy-nine patients were placed on VV ECMO, 19 on VA ECMO and 2 on veno-venous arterial ECMO. The median transport distance was 16 miles and ranged from 2.5 to 7,084 miles. The group highlights the progressive development of an ECMO transport team and the manner in which it provides reliable transport. They conclude that ECMO transport can be performed safely and reliably with excellent outcomes with a dedicated team that maintains stringent adherence to well-designed management protocols.

Intensive care doctors, nurse practitioners, intensive care nurses, physical and respiratory therapists, perfusionists, an occupational therapist, a speech therapist, a psychologist and a social worker make up the ECMO multi-disciplinary team.
**Airway clearance therapy for patients on ECMO at NYP**

High frequency chest wall oscillation (The Vest) is occasionally used. The vest band is more frequently used than the full vest because of lines and cannulas. Occasionally the manual technique of percussion is used. Physical exercise and walking are believed to be the best forms of airway clearance in this unit. When patients are on ventilators or have a percutaneous tracheostomy and have increased airway secretions they are suctioned as necessary.

**Early physical exercise and mobilization program at NYP**

There are restrictions on movements and physical activities depending on ECMO cannula sites. With cervical cannulation avoid moving the cannula at the site. The cannula is secured with a sturdy cotton headband with velcro fasteners. No patients have their heads shaved for cervical cannulas. With a subclavian cannula avoid shoulder movements on the cannula side. If the patient has a femoral cannula avoid hip flexion, abduction, sitting upright, standing or walking. Physical exercise includes active, assisted or passive bed exercises given by the physical therapist depending on the patient's ability and level of participation; standing, sitting out of bed for periods of time each day; cycling while lying in bed or sitting in a chair; walking on a treadmill beside the patient's bed; walking outside the ICU room to the bridge to enjoy the view.

**Walking a patient on a treadmill while on ECMO: equipment, staff and method**

This is a case study of a 35 year old woman listed for lung transplant for pulmonary hypertension. This case represents the typical care provided to patients on awake ECMO at NYP. This includes the staffing and equipment required to carry out early mobilization safely and effectively.

**Preparing the patient to walk on the portable treadmill next to the bed**

The patient remains attached to all drips and monitoring devices while walking on the treadmill. Appropriate levels of oxygen and nitrous oxide (if necessary) are supplied via high flow nasal prongs and humidification. The plan is to ambulate on a portable treadmill next to bed and then sit out of bed for several hours depending on the patient's clinical state and capabilities. The well-nourished patient observed was highly motivated and keen to participate in the activity. She viewed walking as a way to stay strong physically and mentally so that she remained in the best shape possible
while she waited for a lung transplant. The patient was instructed to keep her right arm relaxed with no pushing or pulling during the activity as she had a haematoma in a previous subclavian cannula site.

**The Portable Treadmill**

The newly acquired portable ‘GaitKeeper Mini’ treadmill was used for the first time with this motivated patient. This treadmill is compact, durable, folds up and is light enough to be carried or wheeled by one physical therapist. It has a sturdy adjustable and removable frame that firmly clips onto the base of the treadmill providing protective handrails around the front and sides while the patient is walking. The handrails can be raised or lowered to suit the height of the patient. A portable handheld measurement device records time, speed and distance walked. The treadmill set up costs around US$3,000.
Procedure for walking patient on the treadmill beside the bed

The treadmill was placed on the floor at right angles close to the patient’s bed. The aim was to assist the patient to sit up over the side of the bed with the bed height adjusted so that her feet touched the treadmill. Five highly trained health professionals were required to assist during this exercise session. These included the dedicated ECMO physical therapist who co-ordinated and led the activity; the perfusionist who managed the right cervical ECMO cannula; the respiratory therapist who managed the oxygen and nitrous oxygen equipment and intravenous (IV) lines; the nurse practitioner who managed the ECMO machines and monitored vital signs; and the physical therapy assistant who assisted the physical therapist in getting the patient up safely. The patient was assisted to sit on the edge of bed. The bed height was adjusted so that her feet were flat on the treadmill. The physical therapist instructed the patient to lean forwards and to use her legs to stand up while the perfusionist carefully supported the cannula to avoid movement. The physical therapist and assistant, each side of the patient, assisted her in getting up into standing on the treadmill holding onto the sides of the frame with her left hand and her right hand resting on the frame avoiding active movement because of the haematoma in her right shoulder region.

The treadmill speed was started at 0.5mph and slowly increased over 5-7 minutes to 1.0 then 1.5 mph. When her heart rate increased from 90 (before standing up) to 145 bpm the speed was decreased to 1.0mph (145 was the upper limit heart rate allowed for this patient, with the aim of <140 bpm). The patient walked continuously for 20 minutes and reported that she felt great. This was followed by a 5 minute cool down at 0.5 mph before stopping. She was assisted to sit down on the bed while the treadmill was wheeled away. The patient was again assisted into standing and then asked to perform assisted squats beside the chair (2 sets of 10 repetitions). She then carried out heel raises (2 sets of 10 repetitions) before being assisted to sit down in the chair. She sat out of bed for four hours before being assisted back into bed. The session of walking and leg exercises took 45 minutes from getting up to sitting in the chair. The patient expressed that she enjoyed the session and felt a great sense of achievement. The activity was labour intensive with five highly trained and experienced professionals involved for close to an hour including preparation time.
Walking outside the room and a six minute walk Test (6MWT) on ECMO

The following day the patient was to walk outside the room carrying out a 6MWT down the corridor to the bridge to enjoy the views. Six highly trained health professionals were required to achieve this. All the monitoring equipment was attached to the walking frame. Intravenous bags were hung on hooks on the walking frame. The ECMO machine was made portable by the perfusionist to be battery operated during the walk. The high flow nasal prongs generating a flow of 35 liters per minute and FiO2 of 0.4 plus nitrous oxide (NO) were made portable by the respiratory therapist. The oxygen was disconnected from the wall outlet and connected to a full cylinder and the NO machine was made portable. It took ten minutes to prepare all the equipment and to change over from electricity to battery power. The patient walked on the same settings of oxygen and nitrous oxide as resting in bed.

The patient was assisted into sitting on the edge of the bed, instructed to lean forward and assisted by the physical therapist and physical therapy assistant to stand up as previously described. The physical therapist co-ordinated and led the activity supporting the patient on one side; a nurse supported the patient walking on the other side; a perfusionist managed the right cervical ECMO cannula avoiding movement; a respiratory therapist took control of the oxygen and nitrous oxide equipment and IV lines. A nurse practitioner managed and pushed the portable ECMO machines and monitored the patient’s response to exercise. She changed settings to optimize the patient’s oxygenation while walking, verbally communicating with the perfusionist. The physical therapy assistant pushed a wheelchair next to the walking group in case the patient became tired, vital signs deteriorated and the activity needed to be stopped or the patient was too tired to walk back from the bridge. The sweep gas was increased at the beginning of the walk and ECMO flows increased. For the 6MWT the patient was instructed to cover as much ground in 6 minutes as possible leading the pace of the group. If she needed to sit down then the 6MWT would be terminated. If she just needed a short standing rest, she could continue walking when she felt able. The physical therapist timed the test and communicated instructions to the patient and the team during the walk.
The 6MWT started once the group was outside the room and continued all the way to the bridge with the patient leading the pace. The patient walked continuously without stopping. Six minutes was up when she arrived at the bridge. She volunteered that she felt great. Once on the bridge she sat down in a wheelchair with assistance for a rest and to enjoy the view of uptown and downtown New York. When the patient was asked which gave more enjoyment the treadmill beside the bed or walking to the bridge she reported walking to the bridge. The reason she gave was that she liked getting out of her room, the feeling of fresh air and a greater sense of space and indeed the view. After a rest of about ten minutes she walked back to the room with the group walking in the same order at a similar pace. The group walked into the room backwards so that all the equipment arrived back in the same place as before walking. The patient, assisted, walked slowly and carefully backwards until she sensed the chair behind her, sat down using her left hand to lower herself onto the chair and enjoyed a rest. All the equipment was reattached to power outlets and the patient again reported feeling great. She walked 560 feet (170 meters) during the 6MWT and the same distance on the way back to her room. In total she walked 1120 feet (340 meters) out of her room and back. The whole activity took an hour with six experienced professionals each taking on an important role. She had 6 further sessions before transplant, 4 were on the treadmill, one walking in the hall and on the day of the lung transplant transferred to the chair and sat out of bed. Just before transplant she was only able to walk 5 minutes on the treadmill. After the Churchill visit she had more sessions walking on the treadmill than out of her room mainly because of staffing limitations and the difficulty getting out of her very small room with all the equipment and staff needed to walk safely as described previously.

To make the activity safe and effective an important set of rules needs to be obeyed by the team. These include everyone having a specific role that they were trained for and they all need full focus and attention. There should be no distractions. For safe walking on ECMO there needs to be one leader who co-ordinates the procedure and communicates instructions. The leader is often the physical therapist.

The patient was transplanted 8 days after the Churchill visit and was on ECMO for 5 days post lung transplantation because of respiratory failure (a tracheostomy was
inserted). She was managed in the Cardiothoracic ICU post lung transplant where she was treated for 26 days. From there she was discharged to the ward where she received rehab for 13 days and then was discharged home. This case study illustrates well the post operative course many patients experience post ECMO and lung transplantation.

Outcomes of Early Mobilization of ECMO Patients at NYP

All ECMO patients are exposed to early mobilization in the MICU at NYP. Some will be as a bridge to recovery and others as a bridge to lung transplant. A pediatric program has also been established but fewer children require ECMO than adults. An evaluation of length of stay in hospital from admission to discharge home was calculated after the early mobilization program started. Prior to commencement, based on earlier experiences in the unit, it was predicted they would decrease the number of annual ICU bed days by 843 annually. They exceeded their target and ended up reducing the predicted number of bed days by 1195 days. This decrease in length of stay has been sustained over time. (Information provided by Patricia Rychik, Patient Care Director).

Physical activity for patients not yet ready to mobilize out of bed
Passive/assisted/active bed exercises
If patients are not ready to get out of bed and stand independently, the physical therapist carries out passive stretches and passive, assisted or resisted exercises for legs and arms that have not ECMO restrictions. Bed exercises include hip abduction & adduction and quadriceps exercises over the physical therapist’s forearm avoiding hip flexion if an ECMO cannula is in a femoral site. If the patient is too weak for the former, static quadriceps exercises are carried out instead. Dorsi- and plantar flexion are prescribed for feet and ankles. Arm and hand exercises are supervised. These exercises are done before or after cycling on an exercise bike in bed with an hour’s rest between activities.

**Bicycle Exercises**

The MOTOmed Viva 2 Portable Exercise Bike for legs and/or arms is used at NYP. This bike can be set up to use while patients are lying in bed, or sitting out of bed in a chair or wheel chair. Patients, when able, have this portable exercise bike set up at the base of the bed. Their legs are placed in stirrup like feet supports secured with Velcro straps. This exercise bike senses the patient’s effort (or inability to move independently) and is able to provide assistance to get the legs pedaling. The aim it to get the deconditioned patient partly active cycling over a 15 minute period increasing the time cycling independently as able. The physical therapist encourages the patient to actively cycle during the session. A read out on the computerized bike monitor summarizes the amount of active versus assisted cycling achieved by the patient at each session. Over time the patient is able to do more active cycling. This information is provided to encourage the patient about progress over time. The patient then rests in bed for an hour followed by bed exercises (active, assisted or passive exercises) and then is hoisted out of bed to sit in chair. The bike can also be set up for arm strengthening.

**Sitting out of bed in a chair using a portable hoist**

An “Easy Lift” hoist is used to safely assist patients out of bed into an armchair beside the bed. An “Easy Lift” hoist sling made out of thick fabric is placed beneath the patient by the physical therapist and assistant. The lower two wide fabric sling pieces are criss-crossed right to left and left to right onto the front two metal hoist hooks above the patient. The loops behind the patient are hooked on the posterior hoist hooks to form a safe, comfortable and supported seat. The patient is slowly lifted and
swung over the chair next to the bed and slowly lowered and positioned with a pillow behind the back and neck. The fabric sling is left beneath the patient for use when hoisted back to bed in 2 hours time.

**Physical therapy early rehabilitation program after discharge from ICU**

Once discharged from the ICU, patients are treated in the early rehabilitation ward and attend the large circular gym on the 7th Floor with spectacular views over the Hudson River and Washington Bridge. There they receive up to three hours a day of rehabilitation consisting of physical therapy, occupational and speech therapy. The three hours comprise at least one hour of physical therapy. The program is tailored to each patient as needs change with improvement in physical condition. The gym is equipped with treadmills, bikes, arm and leg ergometers. An innovative "Shuttle mini press" for leg strengthening and joint mobilization, each leg exercising one at a time, has a moving plate that allows for leg abduction, adduction, flexion and extension exercises, core and stabilizing exercise. NASA is reported to have had this equipment developed for use in their physical conditioning program. The "Moveo" leg press with a plate can be attached to a plinth in the gym or a bed on the ward. The lower section can be removed and patients lying supine can push the foot-plate for leg flexion and extension strengthening exercises.

**Role of the speech pathologist in the ICU at NYP**

When patients have been ventilated, inactive and bedbound unable to exercise for a protracted period, not only does the body become weak and debilitated and lose muscle mass, but also muscles used for eating, swallowing and breathing. A large gentleman who had been on ECMO and ventilated for a number of weeks and for medical reasons was not able to get up and exercise was referred for an assessment of swallowing by the speech pathologist. He had been able to sit up over the side of the bed with help from the physical therapist to do some assisted and active legs exercises that morning in preparation for future standing and walking. He had been tube fed with naso-gastric feeds while on ECMO and after weaning until the current time. The medical team questioned whether he was safe to swallow and whether he had gastro-oesophageal reflux. He was referred for video guided flexible fibreoptic endoscopic evaluation of swallowing (FEES).
**Video guided flexible fibreoptic endoscopic evaluation of swallowing (FEES)**

The speech pathologist planned to trial five different food types with different consistencies coloured with green food dye for visualization during FEES. These were ice, water, nectar consistency thickened juice, honey textured thickened juice and graham cracker biscuits. Three areas make up the glottis: the epiglottis, the false vocal folds and the true vocal folds with the trachea seen beyond the vocal folds. The fibrescope was passed via the patients nare. ‘Cobblestoning’ indicating areas of irritation and inflammation as well as redness was seen around the glottal region, the likely cause was gastro-oesophageal reflux (GOR). The patient was tested swallowing green ice and water. Both of these were seen on the video screen aspirating around false and true vocal folds. Some of the green substance arrived at the vocal folds before the patient swallowed. Some upward bubbling of the green stained liquid confirmed GOR was occurring. The patient was able to swallow the thickened green nectar textured juice and chew and swallow the green graham cracker satisfactorily. The speech pathologist recommended to the medical team that the patient should have nectar textured thickened foods such as pureed foods, thickened soups, thickened iced tea, juice and milk but was not safe to have water or coffee at that time. He was encouraged to suck on ice to strengthen his swallowing muscles. All eating was to be done in upright sitting to optimize safe swallowing.

**Role of the Occupational Therapist (OT) in the ICU and with ECMO Patients**

The OT employs a number of strategies to assist patients with orientation to day, time and place. Each patient had a calendar on the wall beneath the mounted TV screen. Days were marked off. A digital clock with time (am /pm) and date was also mounted on the wall below the TV. Assistance with activities of daily living such as feeding and eating, using special utensils, face washing and wiping, tooth and hair brushing and general grooming all form part of the OT’s role at NYP. Arm and foot pedals are provided to selected patients for leg exercises sitting in a chair and arm exercises by placing the pedals on the meal table. These exercises are supplementary to exercises done with the physical therapist. One OT is employed to every 3 PTs on the NYP ICU team. Once patients are discharged from the ICU to the rehabilitation ward they have an intensive program with the OT. The OT Gym has a simulated supermarket with
realistic looking and correctly weighted products to take patients ‘shopping’ in preparation for discharge home and back to a normal life. These include fruit and vegetables, ice cream in a pretend refrigerator and other foodstuffs commonly seen in home grocery cupboards. The floor in the gym has curbs, steps and uneven surfaces, a Taxi car to get in and out of and a bedroom with en suite bathroom to practice making the bed, getting in and out of bed and bath, shower and toilet. There is a dining and recreation room for patients to use. Selected patients are encouraged to get dressed and have breakfast together also providing an opportunity for socialization. Infection control guidelines are strictly practised. There is a pool table for recreational use and a computer for patients to access the internet and check emails and stay in touch with family and friends while in hospital.

**Use of the prone position ‘proning’ in the ICU at NYP**

The prone position recently termed ‘proning’ has been used for over 40 years in patients with acute respiratory distress syndrome (ARDS).

**Evidence for use of the prone position**

As recently as 2010 researchers have shown that proning can improve oxygenation in patients with ARDS. Previously RCTs have failed to demonstrate that prone positioning improves outcomes with ARDS overall (Gattinoni et al 2010). However, in 2013 the large multi-centre randomized controlled PROSEVA trial of 466 patients with severe ARDS (P:F <150) showed significantly improved mortality when prone positioning was applied compared with standard supine positioning (Guerin et al 2013). Notably these patients underwent prone positioning sessions of at least 16 hours and all patients were receiving low tidal volume (TV) ventilation. The 28 day mortality was 16% in the prone group compared to 32.8% in the supine group. Additionally the incidence of complications did not differ significantly between groups except for the incidence of cardiac arrests which was higher in the supine group. These results were further supported by a large meta-analysis of over 2100 patients of whom over 1000 received prone positioning. Proning was associated with significantly reduced ARDS mortality in the low tidal volume era of artificial ventilation (Beitler et al 2013).
**Why would proning work?**
Repositioning from supine to the prone position alleviates lung compression from mediastinal and abdominal structures. The prone position redistributes lung oedema to less perfused areas enhancing oxygenation. It potentially reduces injurious transpulmonary pressures. In addition prone positioning facilitates clearance of lung secretions and reduces the incidence of ventilatory-associated pneumonia (Walkley et al 2012).

**Proning and adverse events**
Adverse events in a prolonged prone position can include pressure ulcers, endotracheal obstruction and accidental catheter or tube dislodgement (Sud et al 2010). The PROSEVA trial demonstrated that while proned patients live longer; they are at greater risk for pressure ulcers on the face and anterior thorax. Thus great care must be taken in the positioning and re-positioning of these patients (Guerin et al 2013; Girard et al 2013).

**What sort of patients may benefit from proning?**
ARDS is sometimes termed “double pneumonia”, “shock lung”, or “post traumatic lung”. ARDS is an acute, severe, often fatal inflammatory disease of the lung characterized by the sudden onset of pulmonary oedema and respiratory failure. This usually occurs in the setting of other acute medical conditions resulting from local (such as pneumonia) or distant (as in multiple trauma) injury (Matthay et al 2012). There are more than 140,000 cases of ARDS in the USA annually. It is associated with a high mortality rate. Using the Berlin definition of ARDS the severity is based on the degree of hypoxaemia as measured by PaO2/FiO2 (P:F) ratio (Brodie & Bachetta 2011).

- Mild ARDS; P:F 201-300
- Moderate ARDS; P:F 101-200
- Severe ARDS: P:F <100

The mortality rates for mild, moderate, and severe ARDS are estimated to be 27%, 32% & 45% respectively (Walkley 2012).

**Use of proning and its relation to ECMO**
Clinicians who use proning as a treatment for critically ill patients in the ICU report that they use it as a treatment in carefully selected patients at a time when they are
trying to avoid the next step, ECMO. Recently, at the International ECMO Conference in Paris in June, 2015 the Marseille Group presented their positive outcomes and practical application of proning patients with ARDS on veno-venous ECMO (Guervilly et al, Minerva Anesthesiol 2014). They believe the prone position and ECMO are complementary. It is recommended that a critically patient with P:F <50 who has had lung protective strategies including the prone position for at least three hours should be considered for ECMO.

**Using the prone position: the NYP experience**

Since 2013 in pursuit of excellence in practice NYP has used proning with selected sedated and mechanically ventilated patients. In the past products such as the Rotoprone bed have been considered for use, however, they failed to meet the occupational health and safety standards expected. Therefore NYP set about developing their own equipment and protocol to allow the safe application of proning suitable patients such as those with ARDS. The program is based on that developed at Toronto General Hospital. Since 2013 the MICU staff at NYP has worked with Sundance Enterprises to develop a device to help prone patients safely in a controlled structured manner. Further aims were to reduce the risk of pressure ulcers in patients and decrease the risk of injury to staff.

After several workshops and brainstorming sessions they came up with an adaptation of their existing Tortoise© product which was originally designed to reposition patients while supine. With some additional components the Tortoise Prone© is a manual positioning device that allows for safe controlled turning, easy positioning and full visualization of the patient while lying prone. Since December 2014 they have proned more than 5 selected patients without adverse events resulting from the process or equipment. The teamwork and time taken to successfully apply proning is significant but found to be worthwhile in terms of overall patient benefit. Further, in this early MICU proning experience the majority of patients lived on to survive their bout of severe ARDS and did not require salvage ECMO therapy. NYP regards this as a very important management modality to add to their range of treatment techniques to manage patients with severe ARDS. An
The proning protocol in sedated ventilated patients at NYP
The aims of proning carefully selected patients in acute respiratory failure at NYP are to optimize ventilation, promote early recovery and avoid the need for ECMO. In order to successfully and safely achieve this, and ensure that patients are not at risk of further adverse events, ventilation parameters, pressors and level of sedation need to be optimal. The biggest risks during the procedure are: extubation resulting in death; losing an access line for essential medication; and pressure ulcers on anterior surfaces while positioned prone for prolonged periods. Staff must be protected in the awkward movement of heavy patients from back injuries in particular. The product NYP have developed is back friendly to all staff, including those who are tall and strong as well as staff who are petite. The Tortoise Prone© is made of slippery black material with air pockets throughout. The activity requires one long (body length) and one shorter (half body length) Tortoise material sheet, the Tortoise Prone©, with numerous handles down both sides corresponding with edges of the bed.

One nurse at the top of the bed readies all the lines before turning. The shorter Tortoise slide sheet is tucked in under the patient by rolling from side to side (as with sheet changing) and is positioned flat and even under the patient’s torso. Two people (usually nurse or doctor) stand on the side the patient is going to be moved towards. A nurse stands on the opposite side. The patient's lower arm is tucked under and behind the buttocks. This should not be an arm with an arterial line). The sedated patient is pulled towards the 2 health professionals and rolled up onto the side with the hand tucked under the buttocks. The four cardiac leads are removed from the anterior chest and are quickly attached to the posterior chest. All bedding and Tortoises© are smoothed out under the patient. The nurse standing at the head of the bed manages the patient’s ventilator attachments and other lines while the patient’s body is slowly, and in a controlled manner, turned and lowered in the prone position. The patient’s head is placed on one side on one of the small purpose built pillows to prevent pressure injuries to the head and face. The arm the patient’s head is facing is placed in the “swimmer’s” position with the arm flexed up near head. The other arm
is positioned at the patient’s side and the feet are placed over another purpose built cushion to prevent pressure areas. The lines and ventilator attachments are repositioned and secured. All bedding is smoothed avoiding wrinkles and pressure points.

Patients are usually placed prone for around 18 hours (16-20) at a time. This time period has been shown to be the most clinically beneficial. The timing of proning is determined around shifts and medical rounds when patients are expected to be in the supine position for assessment and visualization. Medical rounds usually occur between 8am and midday. Patients are turned back to supine in time for medical rounds. Therefore proning is usually carried out in the afternoons and requires adequate staff on duty. Turning patients to prone or back to supine takes at least 4 nurses (or doctors, medical trainees or other suitably trained health professionals) around 10 minutes. The most experienced nurse co-ordinates and leads the activity giving instructions during the procedure. Like walking the patient, the team needs to be well trained with each person looking after one aspect of the activity and equipment. They all need to understand their role and remain focused during the activity. To prone a patient safely takes prior education and co-ordinated team work. The experience at NYP has demonstrated that patients with single organ failure such as ARDS have done particularly well with this intervention making a successful recovery and avoiding the need for ECMO.

**The future of proning and ECMO – NYP experience**

NYP continues to gain experience in patient choice and management using this technique in carefully selected patients. It is anticipated that in the future proning will be combined with ECMO in carefully selected patients as an additional complementary therapy for critically ill patients in order to promote lung healing and weaning from ECMO used as a bridge to recovery. Observation during the Churchill Fellowship visit of two sedated patients being positioned from supine to prone and prone to supine was highly educational and gave great insight into the team training, co-ordination and skill required to carry out this activity safely for patients and ICU staff.
Innovative quality improvement initiatives in the ICU at NYP

NYP is a leader in innovative practice in terms of professional practices and equipment used to achieve excellent patient outcomes. The following initiatives are examples.

**Nurse Practitioner (NP) Extended Scope of Practice**
The 12-bed MICU A Unit where ECMO patients are treated is run by nurse practitioners with an Attending Fellow supervising the program. There are 7 to 9 NPs on each night shift and 12 during the daytime. They work up to 12 hour staggered shifts with scheduled overlapping hand-over rounds. The Rapid Response Team always has 1 NP and a triage fellow together with a triage attending (consultant). Procedures that are carried out by NPs include insertion of central and arterial lines, lumbar punctures and spinal taps, insertion of renal dialysis catheters, paracentesis – tapping pleural spaces, intubations in some circumstances, ordering of CT scans, assisting physical therapists in walking ECMO patients, talking with families, referring patients to the palliative care team when appropriate, as well as other regular nursing duties. They work 12 shifts per month over 3-4 days a week. They have 7 days off every few weeks and can organize to be away for periods of time, because of flexibility with shifts, and still remain full time employees. The rationale for this NP led ward is that specialized nurses develop expertise in many of the routine procedures required by ECMO patients and they provide continuity of care. There is high job satisfaction among NPs because of the work practices as well as flexibility of days on and off duty and retention rates are therefore high.

**Training of monthly rotating medical house staff**
MICU B is a 12 bed ICU ward where all types of ICU patients other than ECMO patients are treated. The rotating house staff (residents) are in training to carry out all the medical procedures mentioned in the previous section. The attending fellow, who can bill for 100% of cost of services, while nurse practitioners can bill for 85% of scheduled fees, provides supervision and practical training.

**Patient toilet plumbed and stored in a cupboard in ICU rooms**
A regular porcelain toilet is plumbed into the floor of the built in cupboard in each patient’s room. When required by patients it is rotated out of the cupboard still remaining attached to the central plumbing of the hospital. Once used it can be
flushed and then rotated back into the cupboard. This provides quality care for patients as no patient likes using a bedpan or a commode. This also motivates patients to get out of bed and be active. This initiative was the idea of a previous patient in the ICU with engineering skills who assisted in designing, funding and implementing this project. It is also a time efficient quality improvement for nurses reducing the number of bedpans that need to be emptied and cleaned each day.

**Other support services to the ICU**
The ICU has an active nutritional program to preserve muscle mass and prevent patients losing physical condition while in the ICU.

Psychology referrals for anxiety, depression and post traumatic distress syndrome are made as required. NYP actively avoids sedation whenever possible as they believe that some of these drugs may lead to anxiety and/or depression in patients after recovery from their treatment in ICU.

**The projected future of ECMO envisaged by clinicians at NYP**
Current research and development is aiming for a destination device for lung bypass. Experts believe an external and portable ‘artificial lung’ is likely to be developed in less than 10 years. They expect Extra Corporeal CO2 Removal (ECCO2R) devices to continue to evolve and be developed and their use to increase significantly over ECMO. ECCO2R devices are easier to insert, less complicated than ECMO and may be able to be offered by community hospitals. Future treatment and equipment will be more like lung ‘dialysis’. Potential uses may be for moderate ARDS, acute COPD exacerbations with hypercapnia and respiratory failure, and status asthmaticus as an alternative to intubation and ventilation.

**Summary of the early mobilization program at NYP**
Strong medical and nursing leadership form an integrated and cohesive team. They actively support highly enthusiastic allied health professionals including physical therapists, occupational therapists, speech therapists and psychosocial practitioners. As a multi-disciplinary team they aim to achieve early mobilization in the MICU whether on ECMO, mechanical ventilation or while receiving early rehabilitation while still very ill and clinically unstable. Physical therapists have been supported with additional staff and expensive and highly innovative and useful ‘enabling’
equipment such as the compact portable treadmill and sophisticated exercise bike both able to be used at the bedside. The 6MWT is commonly used as an outcome measure in the MICU as observed with three critically ill patients while on the Churchill Fellowship. The senior medical staff, under the direction of Professor Dan Brodie, together with the nursing and multi-disciplinary allied health team, provide an inspirational early mobilization service to patients with cutting edge medical technology such as ECMO at NYP. Their enthusiasm and support for the early mobilization initiative has influenced a culture change in the ICU setting worldwide where patients are traditionally sedated, passive and unable to participate in their care. Safety is a top priority at every stage of each activity and is often discussed in the team setting.

The teamwork that is evident (with each member of the multi-disciplinary team working together to achieve a common goal of improving long term outcomes with early mobilization) is exemplary and inspirational. Getting patients up and walking contributes to airway clearance and physical conditioning. It is labour and time intensive and each member of the team strives to achieve safe practice. They demonstrate a passion for their work and display a sense of achievement and work satisfaction. Each person is extremely encouraging of patients’ efforts, which in turn motivates patients and staff in a positive feedback loop. This information taken as a whole provides evidence of the positive early mobilization culture that exists across the team at NYP. This Churchill visit has resulted in the acquisition of new knowledge about early mobilization of patients and cutting edge enabling equipment that will lead to advances in practice with awake ECMO patients in Australia.

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ECMO at Toronto General Hospital, Toronto, Canada
10th Floor, Munk Building, Toronto General Hospital, 585 University Avenue, PMB 11-123, Toronto, Canada

Overview
University Health Network (UHN) is one of Canada’s largest acute care, academic and research institutions. UHN consists of four hospitals including Toronto General Hospital (TGH), Toronto Western Hospital, Toronto Rehabilitation Institute and Princess Margaret Cancer Centre. This network operates approximately 1200 beds with an annual operating budget of over a billion dollars. Primary funding for healthcare at UHN comes from the Ontario Ministry of Health and Long Term Care. Other funding for research and education comes from grants and donations from their Foundations. The board that governs UHN includes members of the community, the hospitals and the University of Toronto. The vision of UHN is to achieve global impact. Their purpose statement is that they are a caring, creative and accountable academic hospital, transforming health care for their patients, their community and the world.

St Michaels Hospital (affiliated with Toronto University) is the Cystic Fibrosis Service that cares for adults with CF in Toronto and environs. CF is the most common fatal genetic disorder affecting Canadian children and adults. The median age at which patients die in Canada 2012 is 32 years up from 22 years in 1990. Lung transplantation has improved the longevity of patients with CF remarkably since the introduction of this life saving treatment. Lung transplants do not cure people of CF as the defective gene is found in all cells of the body except in the newly transplanted lungs. A recent Canadian transplant outcome paper including 580 patients who received lung transplants between 1988 and 2012 found the one-, five- and 10-year survival to be 88, 67 and 50 percent respectively. As a result of lung transplant Canadians with CF are living almost 20 years longer than they did 20 years ago. The median survival age was 50.9 years in 2013, up from 31.9 years in 1990. Dr. Stephenson who reported on this research said there are few therapies that can impact survival as dramatically as lung transplantation, which along with advances in
CF treatment in many fields of healthcare has likely contributed to the increasing survival in Canadians with CF. (Information from St Michael’s Hospital web page).

**Aims of visit to TGH**
1. Observe the ECMO management and early mobilization program provided by physical therapists and the wider multi-disciplinary team;
2. Research the equipment that enables safe and effective physical activity;
3. Experience the wider physical therapy and rehabilitation program at TGH.

**ECMO in Toronto at TGH**
In the past one to three patients were treated with extracorporeal lung support (ECLS) per year in Toronto. They were sedated in bed, tube fed, breathed with the assistance of a ventilator and unresponsive. Physical rehabilitation began after the removal of ECLS weeks to months later. Patients were in a significantly weakened and debilitated state.

**Consequences of prolonged bedrest** (Fan et al 2013).
Remaining inactive in bed for long periods leads to bedsores and venous thrombosis. All muscles of the body atrophy and patients can develop profound ICU acquired weakness. This can lead to poor long-term outcomes in terms of physical function and reduced quality of life. Dr Eddy Fan and colleagues recently published early findings of their two-year follow-up of adult patients who received ECMO during their ICU stay at TGH. This prospective multi-centre trial, ‘Towards RECOVER’ conducted in Canada evaluated the outcomes of patients with an average age of 37 years (75% were women) at three, six, twelve and twenty-four months after being treated with ECMO while ventilated for seven or more days. Of the 12 patients studied five were bridged to lung transplant, two died in the ICU while the others recovered after a period of healing on ECMO. Muscle strength, physical function and six minute walking distance were measured at each time point and improved over time. Among hospital survivors, 2 patients were discharged home, 4 were discharged to rehabilitation facilities and 2 were discharged to chronic care facilities. Preliminary data from this small study of patients suggests that early muscle weakness and physical disability resulted in persistent impairment up to 12 months after ICU discharge with improvement over time. These losses in muscle strength and physical function likely
contribute to the need for costly (in financial terms as well as quality of life for patient and care givers) ongoing rehabilitation and complex care in the majority of ECMO survivors (Fan et al 2013).

**The present day management of patients on ECMO at TGH**
Knowledge about the deleterious effects of sedation and prolonged inactivity has resulted in changed treatment strategies. The 24 bed Intensive Care Unit with a 12 bed step down unit is the site where early mobilization and the management of patients on ECMO for Toronto and environs occurs today. The Lung Transplant Unit is located in the same building. Currently there are on average three to five patients on ECMO any given week at TGH with one or two participating in active rehabilitation. Some are awake, liberated from mechanical ventilation, eating proper food, cycling, walking on a treadmill or along the hallway and sitting up in a chair for two to six hours per day.

**Types of Extra Corporeal Lung Support in Toronto**
Veno-venous (VV) ECMO using the Avalon® Cannula is the preferred method as it allows patients to get up, sit for periods of time and walk. The Avalon® dual lumen cannula is inserted in the internal jugular vein (IJV) where it is firmly stitched and the cannula is supported against the side of the neck and head with an adjustable sturdy cotton headband with velcro self adhesive tape. Veno-arterial (VA) ECMO is provided with a variety of combinations of cannulation sites depending on the needs of the individual patient. These include: central site, an open chest procedure where cannulas are attached to the heart chambers via an incision in the chest; a subclavian site below the clavicle is sometimes used in which case no shoulder flexion or abduction is allowed; femoral vessels are sometimes used in which case sitting up, standing and walking are not permitted.

**ECMO procedure and ventilation of patients at Toronto General Hospital**
Patients are placed on ECMO in the operating room under general anaesthetic and are placed on mechanical ventilation for the procedure. They usually return to the ICU intubated and ventilated. Once stable after initiation of ECMO they are extubated, often the next day. Sometimes a percutaneous tracheostomy is performed if the patient requires ongoing ventilation or has increased lung secretions requiring removal with suctioning. Approximately 50% of patients require tracheostomies with
supplemental oxygen or remain on a ventilator while being bridged to lung transplantation. Non invasive ventilation (NIV) via a mask and machine is sometimes used once off the ventilator and if requiring further respiratory support while on ECMO. High flow nasal prongs with flows of up to 60 liters per minute and up to 100% oxygen are sometimes used to provide ventilatory support. Some patients only require low flow oxygen with nasal prongs while on ECMO. The ECMO team at TGH consists of intensive care doctors, perfusionists, respiratory and physical therapists, psychosocial professionals and nutritionists.

**Airway clearance therapy for patients on ECMO at TGH**

Physical therapists use exercise as an effective airway clearance technique in patients who are able to get up and walk at TGH. Sometimes the inhaled mucolytic agent dornase alfa is administered by the respiratory therapist to break up thick mucus. If patients require inhaled antibiotics after airway clearance they are given in line with the ventilator via the endotracheal or tracheostomy tube by the respiratory therapist. The main forms of airway clearance are suctioning by nursing, physical or respiratory therapy staff or broncho-alveolar lavage carried out by the medical staff.

**Early mobility for ICU patients at Toronto General Hospital**

The circumstances of the patients’ admissions, their general medical condition, state of consciousness, physical condition, capability, activity tolerance and ability to participate in physical exercise will determine how suitable they are for early mobility. The treating team will determine if and when each patient is ready for mobilizing. If patients are on awake ECMO, the following factors will determine readiness or suitability for early mobilization: the effectiveness of the ECMO support; whether there is any bleeding; and the overall goals of treatment.

The following criteria are considered when making the decision about each patient’s readiness to participate in early mobilization. (Information provided by Vincent Lo, Physical Therapist, Toronto General Hospital website).

- The patient is awake, obeys commands and has adequate strength;
- Cardiac stability with a heart rate between 50 – 140 beats per minute;
- No serious arrhythmias or myocardial infarction in the past 24 hours with Troponin levels trending down;
- Hemodynamic stability with systolic blood pressure 80-180 mmHg and mean arterial (MAP) >65 mmHg;
- Low dose inotropes with a stable trend;
- No significant bleeding in the past 24 hours (with Plt >20, INR <3);
- No high fevers, temperature <39°Celsius;
- Respiratory stability with the patient on or off a ventilator:
  - resting FiO2 <80-90% (with room to increase if necessary)
  - pO2 > 60 mmHg
  - pCO2 < 80 mmHg
  - pH > 7.25
  - Respiratory rate < 40 breaths per minute
- Other factors that may affect mobilizing the patient are anxiety, delirium, nausea and vomiting.

**Specific ECMO variables related to mobilizing patients**
- ECMO Flow 0 – 5 liters per minute (10 exceptional)
- Gas Sweep 0 – 10 liters per minute (CO2 elimination)
- Active clotting time (ACT) levels 160 -180 seconds
- Trend of patient’s condition over past 12 – 24 hours.

**Procedure for Mobilizing the Patient**
Permission: Vincent Lo, Physical Therapist, TGH for protocols and guidelines given by Ms Annemarie Bourgeois (physical therapist) who provided information and practical clinical instruction during my Churchill Fellowship.

The team should carefully plan getting the patient up and out of bed. There should always be contingency arrangements should things not work out as expected. The room should be set up for the activity. All lines, cannulas and tubes should be prepared to avoid any tugging or inappropriate movement during the activity. Each team member should have a designated role. A medical doctor should be on standby to assist if necessary. The perfusionist manages the ECMO circuit and cannulas, the ECMO trained nurse manages the intravenous poles, lines, bed and chair, and assists the patient as required. The physical therapist manages and supports the patient during the activity and co-ordinates the implementation of the activity.
The degree of mobilization is tailored to each patient’s physical condition. Bed controls should be used to assist the patient into an optimal position to move the legs and sit over the side of the bed with legs dangling on the floor. The physical therapist assists the patient up into standing and supports the patient while marching on the spot. If necessary the patient is supported with a walking frame. After walking, the patient is transferred to a chair to sit out of bed for a varying period of time aiming for two to six hours.

**Procedure for Walking on the Treadmill**

A larger team of four health professionals will need to be assembled for this activity with a medical doctor on standby. The perfusionist manages the ECMO cannulas and machines; the nurse looks after the intravenous lines and poles; the physical therapist co-ordinates the activity and supports the patient on one side; an assistant (physical therapy assistant or nurse) may be required to support the patient on the other side if extra support if needed. The standard sized treadmill is wheeled into the patient’s room and positioned close to and at right angles to the bed. The ECMO machinery is positioned beside the head of the bed and to the side of the treadmill. The patient is assisted into sitting as described in the previous paragraph and dangles the legs over the side of the bed. The bed height is adjusted so that the patient’s feet are flat on the treadmill. The physical therapist (and assistant if required) assist the patient into standing. Holding onto the rails of the treadmill the patient starts walking at a slow pace of around 1 to 1.5 miles per hour, and if able gradually increases the speed. The monitors provide information about the patient’s physiological response. This will assist in deciding on the speed and duration of the walk. This varies from patient to patient. The aim is to walk for as long as the patient can tolerate within acceptable guidelines in order to maintain physical condition and muscle mass. At the end of the treadmill walk the patient will back up towards the bed with assistance on both sides and sits down on the edge of the bed. Once the treadmill has been wheeled away from the bed and replaced with a chair, the patient can transfer to the chair and sit out of bed for two to six hours. Alternatively if the patient is fatigued, is assisted back into bed with the bed positioned more upright in a chair like formation for optimization of ventilation to the bases of the lungs.
Procedure for walking in the corridor to a window with a view at TGH
The preparation and procedure is the same as walking on a treadmill except two more staff are needed to assist with wheeling the ECMO machine and managing the settings, and pushing a wheelchair behind the patient in case the patient fatigues and needs to sit down for a rest along the way or needs to be transported back to bed. The perfusionist holds the ECMO cannula steady as the patient walks and is therefore not able to manage the machine and change settings and flows if required. A suitably qualified person manages the battery powered ECMO equipment. Sometimes the patient still requires a ventilator while on awake ECMO. In this case a respiratory therapist will take care of a portable battery operated ventilator. Alternatively, the physical therapist walks behind and to the side of the patient supported on a three-sided padded walking frame. The physical therapist supports the patient under the arms and sometimes manually bags the patient with the elbow resting on the walking frame during the walk providing ventilatory support.

Bicycle exercise
A portable cycle ergometer with foot pedals or a Baltimore bicycle is placed at the end of bed with a video screen with motivating programs to make cycling more interesting.

Patients unable to be mobilized out of bed
Some patients are not ready to get up because of complex medical or surgical problems and may need to be sedated for a period of time. In this case the physical therapist will carry out passive movements to keep joints mobile and prevent shortening of muscles and contractures which will make getting up and walking more difficult at a later date. If patients are awake and on a ventilator patients are assisted and encouraged to do active and sometimes resisted exercises in bed including feet, ankles, legs, hands, arms and shoulders as appropriate depending on the site of the ECMO cannulas. If patients are able to sit in a chair but not able to transfer with assistance, a ceiling hoist with chair shaped sling is used to move the patient to a chair and back to bed after a period of sitting upright in a chair.

Quality improvement initiatives at TGH
TGH is a leader in innovative quality improvement initiatives to decrease the incidence of hospital acquired complications.
Number of patients treated with ECMO in recent years

In 2014 eighty patients were treated with ECMO. From January to July, 2015 fifty-five patients have been treated with ECMO. Two-thirds of the patients were supported with VV ECMO and one-third with VA ECMO. Approximately 10-20 patients with cystic fibrosis are supported annually with VV ECMO as a bridge to lung transplantation with an average time on ECMO around three weeks (personal communication Dr Eddy Fan).

Pressure injury prevention at TGH

A nurse-led wound round inspecting patients’ pressure sites occurs each week. The senior nurse records standardized information obtained during the round at each patient’s bedside. Information is captured on a purpose developed data collection system on an iPad. The information is analyzed, collated and graphical reports are generated for regular reviews of outcomes made available to the treating team. This wound round also forms an informal individualized educational opportunity for nursing staff managing patients at the bedside. This was deemed to be one of the major benefits of the round as it afforded the opportunity to assess local knowledge and provide an individualized opportunity for focused education.

A variety of self-adhesive soft silicone bordered foam dressings are used to absorb pressure and prevent sores. The fit for purpose shapes and sizes are made to prevent pressure injuries to any vulnerable parts of the body including the sacrum, heels and elbows. The dressings can be peeled back for daily inspections of skin and re-applied for a varying number of days (The Mepilex Border Dressing (Molnlycke Healthcare, Goteborg, Sweden).

Hospital acquired pneumonia prevention strategy at TGH

‘The Q-Care Oral Cleansing and Suction System’ for innovative oral and suction hygiene has reduced the incidence of hospital acquired pneumonia to zero since its introduction at TGH in recent years. Each patient is provided with a care package on admission. The system consists of a covered Yankauer mouth cleaning suction system (patients are able to use these independently if awake); two suction toothbrush packages with antiplaque solution applied each time teeth are brushed; four oral
swab packages with Perox-A-Mint® solution for mouth hygiene; and two oropharyngeal suction catheter packages.

**Nutritional support while in the ICU and on ECMO**

Nutrition is considered to be extremely important in terms of maintaining patients’ muscle mass, general body strength and the ability to be physically active. At each ward round steps are taken to optimize each patient’s nutritional state. Feeding with total parenteral nutrition (TPN) provided intravenously is often prescribed. Evidence reported from two large randomized controlled trials demonstrates that it is as good as enteral feeds via a tube inserted via the nose into the stomach. Many patients are on enteral or parenteral feeds until able to eat themselves. Patients are encouraged to eat independently as soon as their respiratory status allows. Speech therapy swallow assessments after periods on ventilation and/or tracheostomy are undertaken to assess whether patients can safely swallow. Overnight and at week-ends medical staff start enteral / parenteral feeds according to their standard protocol and then nutritionists optimize feeds and nutrition on week days.

**Future developments at TGH**

Toronto General Hospital is the site selected to pilot experimental and developing technology in the field of artificial lungs. The NovaLung – an artificial ‘lung’ using equipment outside the body that removes carbon dioxide is currently being evaluated at TGH. The Hemolung – a new experimental carbon dioxide removing machine similar to the NovaLung is also being developed and trialed at TGH.

**Summary of early mobilization program at TGH**

TGH is well known for its strong medical leadership working closely with the multi-disciplinary health care team. The ECMO program with early mobilization at TGH is well developed, has scientific evidence to justify early cessation of sedation regardless of whether patients are still on ventilators or breathing independently. The cultural shift away from keeping ICU patients sedated in bed while they recover (with or without ECMO) is impressive.
A strong cohesive team works together in an informed, well-organized way to ensure that the early mobilization of patients is safe and effective. Medical doctors with different levels of experience and training, perfusionists, therapists, nurses and pharmacists attend early morning patient rounds evaluating each patient’s suitability for physical activity that day. Excellent communication exists with the highly qualified, enthusiastic and flexible physical therapy team who carry out active treatment appropriate to each patient’s daily physical needs.

The objectives of physiotherapy include clearing lung secretions, avoiding deconditioning, contractures of joints and loss of muscle mass and weakness together with playing a part in the prevention of pressure injuries. An active nursing led team care for the patients around the clock and prevent the iatrogenic effects of ICU admissions including prevention of pressure sores and the development of hospital acquired pneumonia. Dedicated attention to nutrition from the time of admission to the ICU using the most appropriate feeding regime as well as encouraging patients to eat themselves as soon as it is safe and they are able.

Weakness becomes more pronounced with prolonged bed rest resulting in prolonged rehabilitation times and institutional care. All of these take a toll on the patient and family and other care givers in terms of quality of life. The earlier patients start exercising and are able to get up and walk the better. Further research is needed to evaluate the long-term outcomes of patients on ECMO and early mobilization from physical, psycho-social, quality of life and health economics points of view. In order to achieve adequate patient numbers this may best be done via multi-centre trials with standardized protocols. The overall experience at TGH concludes that patients on extra corporeal lung support can be mobilized safely.

**Acknowledgements**

Grateful thanks to Dr Eddy Fan, ICU head, who organized the Churchill visit and has played a vital role in establishing the successful early mobilization program while on ECMO in Canada. Ms Anne-Marie Bourgeois (Physical Therapist) shared her knowledge and expertise and allowed the Churchill Fellow to shadow her during
patient treatments. Mr Vincent Lo (Lead Physical Therapist) was away during the Churchill visit. He generously provided protocols and guidelines relating to early mobilization at TGH via Anne-Marie Bourgeoise who was standing in for him while he was away. Ms Theresa Torres (Physical Therapist) provided a perspective on patients after lung transplant. Ms Liz Gordon (Nurse Manager) provided information on the development of the early mobilization program. The TGH team as a whole were very friendly and generous with sharing their time and knowledge for which the author is indebted.

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Patient’s experience of awake ECMO as a bridge to lung transplant

“Here is the memory I have of being on ECMO. There is a lot missing from my memory. What I’ve given you is just pulled from my diary timeline so if there is anything else you wish to know please ask and I’ll try my best.

Saturday 5th: At 11pm I underwent the ECMO procedure. My portacath was also removed during the same operation - not sure why this was except that both the ECMO and portacath were on the same side of my neck/chest.

Sunday 6th – I was extubated mid-morning. I remained on ECMO and BiPAP. No idea what the weird, hot tubes were that were wrapped around my neck. But discovered too that my hair had been shaved (not very happy about that!) so the ECMO tubes could be taped to my head.

Monday 7th to 12th – Ongoing ECMO and increasing use of BiPAP with continued physiotherapy. At this point physiotherapy was BPEP and managing normal breathing as the breathlessness I experienced was extreme. I often felt like I was choking and would never get my breath back. This made me panic and the symptoms worse. I remember needing to have my partner present to hold my hand and assure me I would be OK before I would agree to do a physio session because I was so scared of the breathlessness and his presence calmed me.

Not being able to move my head or sit forward because of the ECMO tubes protruding from my neck was a severe frustration that I remember. Most of the time I just wanted to turn onto my side but the instant I tried I heard nurses were calling at me to stop and hands were grabbing my head still. The blood circulating in the tubes also felt hot and that heat radiated over my whole body. I remember continually begging my sister or partner to rub my chest and legs with cold washers to cool me off.

The physiotherapist would come in the mornings when I often felt the most out of it, then again mid-afternoon and finally for a third time in the evening. I am not sure anyone really understood the effort and struggle it was for me to simply catch my breath after each cough. When I had a physiotherapist who seemed to lack confidence in treating me
with all the ECMO equipment I felt extremely anxious and panicky and really dreaded that treatment time.

The nights were extremely scary. I struggled particularly when I had a coughing fit and needed help to remove the BiPAP mask and spit before I choked on my own sputum. My sputum was so voluminous and thick (the likes I'd never seen before) that it literally clogged my throat.

I was also made to get out of bed and sit in the chair after being put on ECMO and those were some of the hardest times I have EVER dealt with. Feeling so weak and dopey I was barely able to stand and only with assistance. Just trying to stay conscious in a chair and hold my head up for 20 minutes was extremely fatiguing and when returning to the bed I would instantly sleep from exhaustion. Being on ECMO during physio was a pain - the physio would enter the room and tell me 'We are going to get you up now' but it would be half an hour before the 'appropriate team' - those who were trained in ECMO (a farce really, because all that meant was being able to hold my head still) arrived! This was extremely frustrating. I am not sure of what I thought was happening exactly except wishing it would all end, feeling not strong enough to keep fighting, and being shit scared of everything that was happening. Sunday the 13th – lungs were found! “

**Suggestions for physiotherapists managing patients on ECMO**

- All physiotherapy staff should be adequately trained and have the ability to provide treatment in a confident manner to avoid increasing patient's anxiety and fear during treatment.

- Enough time for recovery between episodes of cough, dyspnoea and muscle fatigue must be allowed to avoid undue discomfort and exhaustion during physiotherapy sessions. Treatment times cannot be rushed. A hand held fan should be considered to assist in ameliorating dyspnoea after coughing and activity. Cool face washers and a free standing fan during physiotherapy should be considered if patients report discomfort because of the sensation of being over heated.

- Treatment techniques that are energy and time efficient should be considered. Intrapulmonary Percussive Ventilation (IPV) using the Metaneb® and positive airway pressure using the Ez-PAP® may have merit as future appropriate airway
clearance techniques. IPV is given in combination with nebulised mucolytic agents including normal saline and hypertonic saline which will rehydrate the airway surface liquid and enhance mucociliary clearance. The effects of the percussive ventilation on ECMO flows and cannula position are yet to be determined. Mucolytic agents can also be combined with Ez-PAP® treatments.

- Inhaled mucolytic and muco-active agents should be used to decrease the viscosity of sputum by breaking up the DNA fibres (dornase alpha); and rehydrating the airway surface liquid (hypertonic / isotonic saline, inhaled mannitol).

- Active coughing should be minimized and only occur when secretions have reached the upper airways and assistance should be given with expectoration and sputum removal ensuring minimal movement of the ECMO cannula.

- Appropriate staff should be organised before telling patients that they are to be mobilised. This is to avoid a perception of a long frustrating wait during which anxiety is increased with anticipation of what is reported as an extremely challenging activity.

Acknowledgements

This account of the experience of being awake and active while on ECMO was written with courage, honesty and insight providing important information for the treating physiotherapy team to consider when developing treatment guidelines. For this we are extremely grateful.
Conclusions following the Churchill Fellowship Experience

The inestimable value of having undertaken this research sponsored by the Winston Churchill Fellowship was to have experienced the physiotherapy management of patients treated with end stage chronic suppurative lung disease and while on ECMO at eight large and highly regarded international centres in five countries in Europe and North America. This has led to the acquisition of a significant body of knowledge and practical experience in the physiotherapy management of patients. The range of the boundaries of what is regarded as safe and effective treatment of patients at different international centres have been experienced. Observing the treatment of patients in diverse cultures and languages added to the richness of the experience. Having varying degrees of language skills in Afrikaans (a Dutch regional dialect similar to Flemish spoken in Belgium), German and French were invaluable during ward rounds, team meetings and professional interactions with clinicians and patients during the Fellowship without which the experience would have been less rich and informative.

Experience of ambulatory ECMO at internationally recognized centres

There are many different ways to cannulate patients being treated with ECMO. In general, cannulas in the upper body and cervical region allow patients to be treated awake and more physically active. Patients are able to get up, sit out of bed for prolonged periods of time, walk and enjoy meals sitting in a chair. This paradigm shift away from heavy sedation while patients are bed bound on life support in the Intensive Care Unit has led to the preservation of whole body muscle mass and optimal physical condition while lungs heal or donor organs become available. The ability to exercise the muscles of eating and swallowing by eating proper food as opposed to being tube fed while sedated in bed further promotes better physical condition. Together these measures have resulted in reports of faster recovery during the rehabilitation phase shortening the length of time in hospital and the disruption to the normal life of the patient and family reducing costs at many levels to the individual and the community. The most widely used cannula for awake VV ECMO was the Avalon® dual lumen cannula inserted and secured in the internal jugular vein in the cervical region. Numerous other configurations of upper body or cervical cannulation were observed allowing patients to be upright and active. There was general agreement at the centres visited that walking with cannulas in the femoral
region was probably not worth the risk. Patients with femoral cannulas usually end up mostly being treated in bed.

**Airway clearance therapy to enhance mucus clearance while on ECMO**

One of the components of physiotherapy for patients with chronic suppurative lung disease in respiratory failure and while on treatment with ECMO is airway clearance therapy. This is to assist in the recruitment of atelectatic lung units and the mobilization and removal of thick, tenacious, muco-purulent sputum. Failure to do this may lead to segmental or lobar collapse, consolidation, mucus plugging and life threatening sepsis. Numerous modern evidence based airway clearance techniques are available internationally for use by patients with the problem of excess daily sputum production and retained secretions. The Churchill Fellowship provided the opportunity to investigate the range of different airway clearance techniques used at international ECMO centres and to learn techniques used in Europe not currently available in Australia.

Techniques observed include the following.

**Positive expiratory pressure (PEP) and oscillating PEP (OscPEP) therapies**

Numerous techniques that employ positive expiratory pressure (PEP) to get air behind secretions in the small airways and to move them proximally for removal are available. The use of PEP and OscPEP is indicated for patients with excessive lung secretions in the absence of pneumothorax, air leaks, frank haemoptysis, pulmonary emboli (before therapeutic with anti-coagulants) and cardiovascular instability. PEP is always combined with individually tailored forced expirations and coughing to expectorate sputum. In Belgium PEP is achieved with Intrapulmonary percussive ventilation (IPV) and increased positive airway pressure (PAP) using the Ez-PAP® device. Both of these techniques use increased airflow during inspiration and expiration provided with compressed air and/or oxygen entraining room air via a venturi device. The Pari PEP device (manufactured in Germany) is used widely in Belgium, Germany and North America. Oscillating PEP is generated using the Flutter®, Acapella®, AerobiKA®, Cornet® and Bottle PEP (BPEP) devices respectively. BPEP is provided using a bottle with a column of water and tubing to generate the positive expiratory pressure during exhalation. PEP and OscPEP therapies have an evidence base in patients with chronic suppurative lung disease such as cystic fibrosis and bronchiectasis, but they have not been evaluated for safety, efficacy and
acceptability in patients treated on ECMO.

**Airway suction via tracheostomy or broncho-alveolar lavage**

At centres where tracheostomies are frequently used, ACT is carried out with airway suction. Secretions are able to be suctioned from the large airways. However, in conditions such as CF and bronchiectasis, muco-purulent secretions are often retained in the peripheral airways beyond the reach of suction apparatus. Life-threatening sepsis may begin in these small mucus plugged airways.

**French Bronchial Drainage**

This technique employs increased lung volumes combined with increased expiratory flow via an open glottis. Manual techniques are provided by therapists encouraging exhalation towards residual volume. This technique is based on Belgian autogenic drainage (AD) and when manual assistance is given is called assisted autogenic drainage (AAD). There are no data evaluating this technique in patients on ECMO.

**Forced expirations (huffing) and coughing**

Many ACTs include intermittent forced expirations (huffing) and coughing. Some patients develop habitual paroxysms of coughing that result in high intra-thoracic pressures and decreased venous return. These effects on ECMO flows and function are unknown.

**Walking exercise as airway clearance therapy**

Physiotherapists and patients observe and report the benefits of walking to mobilize secretions with expectoration of sputum during and at the end of a walking session. Therapists at all centres expressed belief in walking to achieve airway clearance therapy. Walking also provides many other benefits such as maintenance of muscle mass and strength; improved circulation and mood and prevention of musculoskeletal pain resulting from too much time recumbent and inactive in bed. However, many would argue that walking is not sufficient as a stand-alone airway clearance technique. Randomized controlled trials are warranted to compare walking as airway clearance therapy compared to other formal evidence based techniques. This will help determine which techniques offer the greatest safety, efficacy and patient acceptability.

**New techniques to be introduced to Australia following Churchill visits**

Three new airway clearance techniques offer great promise for acutely unwell patients with excessive mucopurulent secretions including patients on ECMO and will be introduced to Australia following the Churchill Fellowship visits. These include: intra-
pulmonary percussive ventilation (IPV) using the newly available Metaneb® system, and positive airway pressure during inspiration and expiration using the Ez-PAP® device. IPV and Ez-PAP® have the advantage of being able to be used with different interfaces including mouthpiece, facemask and tracheostomy attachments. These treatments can be administered to the patient passively or involve active participation. Humidification and inhalation of mucolytic agents to rehydrate the airway surface liquid such as isotonic and hypertonic saline can be combined with these treatments. The AerobiKa® oscillating PEP device was highlighted during a poster session at the European Cystic Fibrosis Conference. Ten follow up samples to trial with patients in Melbourne were sent from a supplier in London at the end of the Churchill Fellowship. A local supplier in Australia made them available at the end of 2015 which has added another device to our treatment repertoire in Australia. Currently there are no data evaluating the safety or efficacy of these techniques in patients with end stage lung disease or while on ECMO.

**Early mobilization**

As recent research at centres visited during the Churchill Fellowship has demonstrated, patients should ideally not be sedated but instead should be awake, comfortable, co-operative and willing to work with health professionals while they bridge to recovery or lung transplantation while treated on ECMO. When the aims are to get patients cycling, sitting upright in a chair for varying periods of time each day, standing and walking with assistance while on ECMO, cannulas should be positioned in the upper body rather than in the femoral region. Individualized early mobilization although still regarded as experimental by some is practised as the standard of care at many of the international centres visited.

Patients who begin ECMO treatment deconditioned and in a weakened physical state will require rehabilitative passive, assisted and active bed exercises until they are strong enough to sit over the side of the bed, and stand with assistance. Patients who have been physically active up to the time of treatment on ECMO will more likely be able to sit on the edge of the bed with feet on the floor; sit out in a chair for a number of hours each day; practise active leg exercises while sitting and in supported standing; and walking on a treadmill or out of the room. A qualified and well trained team of health professionals is required for co-ordinated and safe mobilization. The prescription and dosage of physical exercise varies between centres and to date the optimal amount of exercise and walking is
not known. From studies of sedation and prolonged bedrest in ventilated respiratory patients inactivity has been shown to have a profoundly negative effect on rehabilitation and longer term quality of life. Studies promoting early and intensive mobilization and physical activity in other conditions such as stroke and acute exacerbations of COPD, have shown that too much exercise may not be beneficial. We hypothesize that too little and too much exercise may not be optimal in patients being treated with ambulatory ECMO and that the optimal amount is yet to be determined.

**Exercise equipment to facilitate mobilization on ECMO**

Many different types of enabling equipment were observed being used while patients were mobilizing on ECMO. The following stood out as particularly innovative and useful: an electronic standing frame that assists debilitated patients into standing then supports them while they exercise leg, trunk and core stabilizing muscles; a trolley that can be transformed into a tilt table, chair, wheel chair and meals chair that offers patients many options to be mobilized from totally passive to fully active in lying, sitting and standing; a computerized exercise bike highly suitable for use in the ICU setting as it is portable and designed for patients with a range of capabilities from minimal muscle strength to high level functioning, lying in bed or sitting in a chair which can also be combined with an arm ergometer; transformer beds that can tilt from side to side, up and down and are able to transform into chairs with varying angles and additional functions such as an inflatable cushion that can push the patient forward to assist with standing; a number of different walking frames that allow all the equipment attached to the patient (drips, drains, indwelling tubes, oxygen and monitoring equipment) to be attached to the frame as well as a seat upon which the patient can rest; an innovative portable, small, sturdy, durable, affordable, light, fold up treadmill reportedly developed for NASA that can be stored against a wall or in a corner and carried or wheeled from bed to bed.

**Patient and physiotherapist factors during treatments while on ECMO**

This new frontier of life saving treatment is particularly challenging for patients and physiotherapists. There is little known about the patient’s experience of airway clearance and early mobilization while on ECMO or of physiotherapists’ experiences of treating patients while awake and expected to be up and active while on ECMO. Patient feedback relating to physiotherapy while on ECMO suggest that airway clearance therapy and physical exercise can be tiring, uncomfortable, anxiety provoking and lead to extreme
dyspnoea and muscle fatigue. Treating patients while on ECMO can be daunting and stressful for physiotherapists, especially those with little experience in this area of medicine as treatment is complex and life threatening complications can occur. Patients, not surprisingly, find treatment given by underconfident and inexperienced physiotherapists particularly stressful.

There is little published information on the ‘hands on’ physiotherapy management of awake patients with chronic suppurative lung disease on ECMO in the clinical setting. It is intended that this Churchill Fellowship experience will provide physiotherapists with a broad view of the management of patients on ECMO including the international account of what is possible and how to achieve this safely. It will also enable the development of local clinical guidelines and future design of research protocols for the physiotherapy management of patients with chronic suppurative lung diseases bridged to lung transplant with ECMO.

**Well-trained multi-disciplinary teams**

This modern approach to ECMO with awake and active patients relies on the support of suitably qualified and educated clinicians. They need to know how to deliver safe and effective treatment to patients while on ECMO. Multi-disciplinary teams are made up of highly trained doctors, nurses, perfusionists, physio-, physical-, respiratory-, occupational- and speech therapists together with psycho-social practitioners. Depending on the activity and staff available at the time, teams are selected with each member responsible for managing a particular piece of equipment or part of the activity. The leader is often the one supporting the patient physically and who issues instructions to the group. Each member is expected to concentrate fully on their part of the activity without distractions to ensure that the activity is carried out safely and effectively.

**Gastro-oesophageal reflux in end stage lung disease**

The management of gastro-oesophageal reflux remains challenging in patients with chronic lung disease. Newer measurement techniques such as pH-impedance monitoring are able to diagnose non-acid, weakly acid and alkaline reflux, all of which may negatively impact on lung function. The experiences of measurement and management of GOR in Belgium and at Duke University Hospital, North Carolina, USA re-affirms the importance of actively diagnosing and treating this condition. This Churchill Fellowship has
highlighted the need to carry out further research in this area and has provided new skills in interpretation of impedance monitoring.

**Future physiotherapy research**

Much of the published research carried out in patients on ECMO consists of retrospective reviews of patient records and reports of relatively small case series. There are no randomized controlled trials comparing different airway clearance and physical exercise treatments. There is a paucity of prospective studies of quality of life and physical function over a longer time period. What is optimal in terms of treatment selection and dosage is yet to be determined. What is too little or too much is currently not known and the “sweet spot” amount is yet to be determined. This is a fast moving field of research and development. There is a strong need for robust randomized controlled trials to be undertaken to establish best practice. To achieve adequate sample sizes in a relatively short time period before practices change will likely require a multi-centre approach. This strategy will hopefully result in evidence based optimally effective airway clearance therapy and physical exercise most acceptable to patients with fewest complications that assists in successful bridging to lung transplant.

**The benefits experienced as a result of the Churchill Fellowship**

The Churchill Fellowship has allowed me to visit eight hospitals in five countries, all leaders in their field. These centres of excellence with large patient numbers and published clinical outcomes have informed practice via published retrospective reviews and evaluations of case series. I have had the privilege of learning first hand about the different airway clearance and early mobilization techniques used with respiratory patients with end stage lung disease and while on ECMO as practiced in different countries and cultures. This knowledge has not been available in the published physiotherapy literature. It is intended that this indepth Winston Churchill Fellowship report will help to inform the practice of physiotherapists beginning work in this relatively new field of health care. Further that it will provide insight into the relevant aspects of physiotherapy for awake and ambulant patients with end stage suppurative respiratory conditions treated on ECMO while they bridge to lung transplantation.

**Disseminating the findings of my fellowship**

The information summarized in this report will be disseminated at local and national
conferences, seminars and professional development opportunities within the
physiotherapy, allied health and medical interest groups in Australia. This knowledge will
also be incorporated in national courses given in Australia. Clinical protocols will be
prepared for clinicians treating this patient population at our centre which will be
available for wider dissemination. It is intended that these findings will inform gaps in
physiotherapy knowledge and help formulate future research into the best ways of
providing safe and effective physiotherapy to patients with endstage supplicative
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**Recommendations**

Experience of physiotherapy in end stage lung disease in Belgium, Germany, France, the USA and Canada show that ECMO is an invasive treatment that is costly in terms of human discomfort and use of resources and should only be used when conventional treatment fails. Well-trained and co-ordinated teams of qualified health professionals are needed to support each patient while receiving physiotherapy while on ECMO. Patients with chronic lung disease and sputum retention require intensive and effective airway clearance therapy while on ECMO to assist in the removal of muco-purulent lung secretions to avoid life threatening sepsis. Active treatment to prevent loss of joint mobility, muscle mass and strength should be instituted as early as possible after the commencement of ECMO including strengthening bed exercises (passive, assisted and active), sitting up over the edge of the bed or in a chair, leg exercises in standing and walking. Maintenance of muscle mass and strength are essential to ensure optimal outcomes during the post-operative recovery including the return to full physical function and good quality of life after lung transplant. To provide optimal physiotherapy management of patients with end stage chronic lung disease treated with awake and ambulant ECMO the following are required:

1. A well-trained multi-disciplinary team comprising doctors, nurses, and perfusionists who are available to assist physiotherapists managing the ECMO cannulas and other equipment while the patient receives airway clearance therapy, physical exercise and early mobilization and walking so that this physical treatment is safe and effective;

2. A well-trained safe, confident and effective physiotherapy treatment team with adequate staffing seven days a week to treat patients on ECMO. The selected treatment should consider patient expectations, fears and anxiety surrounding treatment. All physiotherapists should be adequately trained and supported to enable patients to feel confident and have trust in the therapist’s ability to deliver safe and effective treatment;

3. A selection of appropriate airway clearance techniques should be available from which to choose the optimal treatment regimen for each patient. These include
devices that provide the patient with positive expiratory pressure (PEP) and Oscillating PEP therapies that are practical and able to be used in upright and recumbent positions.

4. Purchase of an Intra-pulmonary percussive ventilation (IPV) system utilising the Metaneb® device and disposable patient circuits as well as Ez-PAP® devices to provide airway clearance therapy to carefully selected acutely ill patients with end stage lung disease to clear muco-purulent lung secretions comfortably and effectively without causing undue fatigue. In the first instance to treat acute exacerbations of conditions such as cystic fibrosis in the attempt to prevent the need for ECMO as a bridge to lung transplant. When ECMO becomes necessary then IPV should be available as an assisted physiotherapy technique to prevent sepsis while patients are being bridged to lung transplant;

5. Evaluate the safety and effectiveness of PEP and Oscillating PEP devices, IPV using the Metaneb® system and Ez-PAP® devices using outcome measures to estimate the safety and effectiveness of lung recruitment, basal expansion and sputum clearance in acutely ill patients who spend a significant time recumbent in between more active physiotherapy sessions; assess patient response to the experience of this treatment including comfort, energy expenditure, fatigue generated and acceptability; determine staff response to training requirements, confidence in treating patients and perceptions of effectiveness and staff satisfaction with using PEP, Oscillating PEP, IPV and Ez-PAP® devices;

6. Have available or purchase exercise enabling equipment to assist with early mobilization including a tilt table to prepare patients for standing upright if they have been in bed for a prolonged period of time; a portable exercise bike that can be used by patients lying in bed or sitting in a chair; a compact, light, affordable, space efficient and portable treadmill that can be carried or wheeled between patients to facilitate safe early walking at the bedside while remaining attached to all life supportive equipment;

7. Develop clinical guidelines for physiotherapists treating respiratory patients on ECMO about exercise prescription and dosage required to safely and effectively maintain whole body muscle mass and strength while on ECMO including bed
exercises, sitting, standing and walking. Development of clinical guidelines should involve input from medical, nursing and other allied health professionals including experienced ICU physiotherapists;

8. Formulate evaluation tools to quantify exercise prescription establishing the optimal treatments and dosage together with post ECMO measurements of patients’ quality of life while on ECMO and in the year following transplantation.

9. Disseminate the clinical physiotherapy information gathered during the visits to eight international hospitals regarded as leaders in the field of management of patients with chronic end stage lung disease treated and with ambulant and awake ECMO at the following dissemination opportunities in Australia and beyond: The Bi-ennial Australia and New Zealand Cystic Fibrosis Conference in Sydney, August 2015 (completed); the Tasmania Annual Statewide Training Day for Respiratory Disease, Hobart, 21st November (completed); the Alfred Physiotherapy Department Professional Development Program, 16th December, 2015 (completed); The AIRMED Department of the Alfred Grand Round 23rd February, 2016 (completed); the Modern Airway Clearance Course, Melbourne 15th -16th April, 2016 (completed); The European Cystic Fibrosis Conference, Basle, Switzerland 7th – 11th June, 2016; Modern Airway Clearance Course, Wollongong, NSW 3rd August, 2016 ANZICS Conference October 2016; The North American Cystic Fibrosis Conference, Orlando, Florida, October, 2016; The Advanced Airway Clearance Course, 18th, 19th November 2016 in Perth, WA and 25th -26th November 2016 in Melbourne, Victoria.