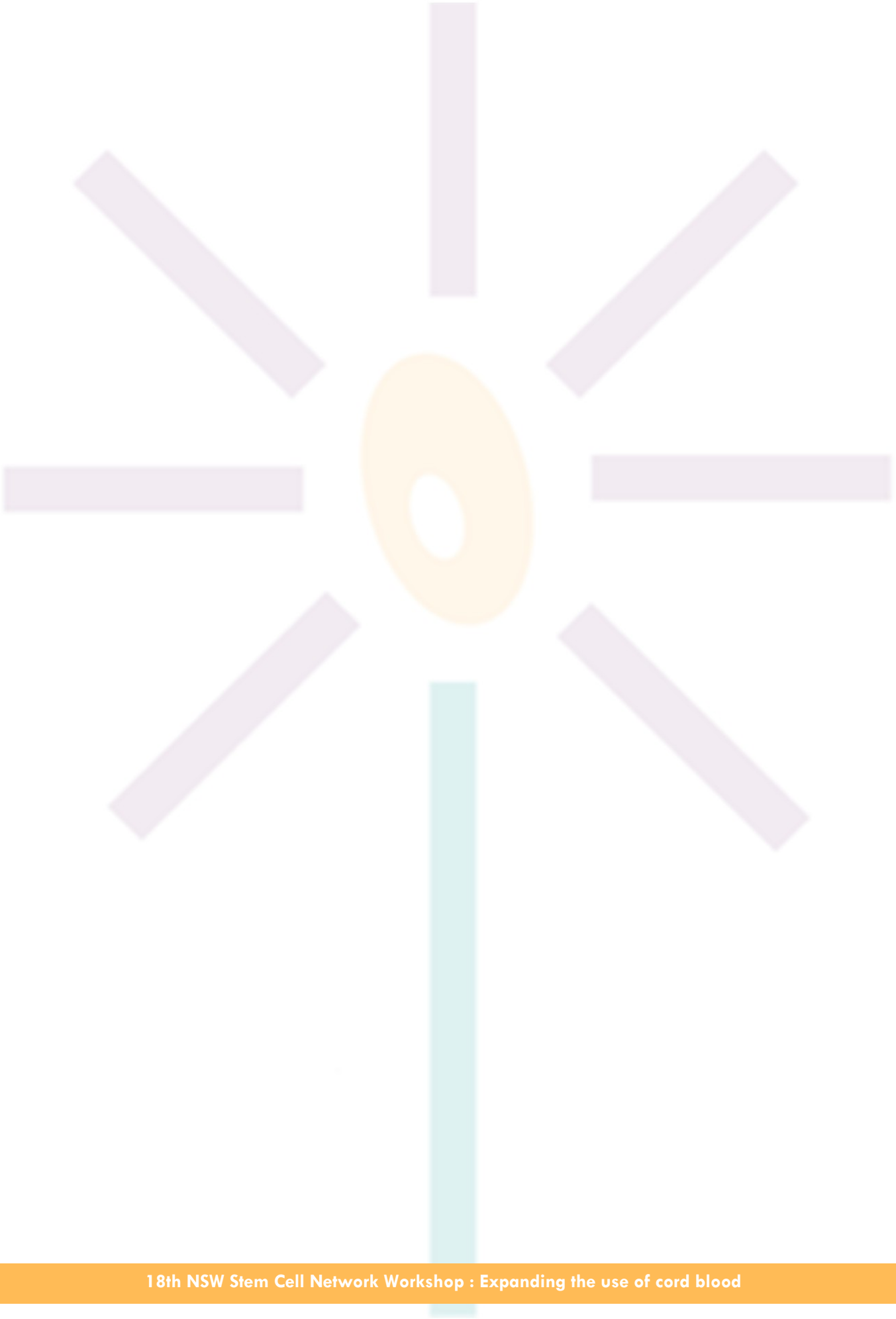
18th NSW Stem Cell Network Workshop

Expanding the use of cord blood

Darlington Centre
City Rd, Sydney.
Tuesday, May 21st, 2013

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WELCOME

Welcome to the 18th Workshop of the NSW Stem Cell Network.

As with the past two workshops of the Network, the current Workshop is devoted to a specific theme, namely cord blood and its novel application to non-blood diseases.

Since the 1990s, cord blood has been used for treatment of a diverse number of haematopoietic disorders, however more recently therapies for a wide variety of diseases are being investigated, including those of an autoimmune nature, such as type 1 diabetes, and those due to chronic inflammation, such as irritable bowel syndrome. In this Workshop we aim to present the most up to date account of progress in the application of cord blood to non-haempoeitic disorders, including clues of mechanism of possible therapeutic effects.

You will hear first of the tricky situation in the ownership and consent of collecting cord blood. Whose body does the blood belong to? Mum or baby? This will be followed by the arguments, not only around the mother's decision as to whether to bank publicly or privately, but also towards the use of publicly donated blood to be used in clinical trials for non-proven applications. Next we learn a little more about the banking of cord blood and the cellular diversity contained within this therapeutic cocktail.

Then we head full steam into the research. After an introduction into the immune and inflammatory regulatory properties of cord blood we aim for the clinics. In contrast to the large number of 'stem cell' clinics around the world offering cord blood stem cell treatments based on anecdotal benefits, it seems that randomised controlled clinical trials exist or are commencing only for type 1 diabetes, cerebral palsy and heart defects. Today you will hear from Australia's pioneering researchers in these fields who in collaboration with the Australian public and private cord banks are involved in such trials.

It is hoped that from the Workshop we will all be better informed about what stage research is up to with novel cord blood therapies and how in Australia we can contribute to progressing clinical trials for therapeutic benefit. It is also hoped that information exchange between the stem cell and disease specific fields will lead to a greater understanding of the issues and usefulness of novel cord blood technologies.

The NSW Stem Cell Network aims to bring the community together in a greater understanding of perspectives and desires. We hope that you enjoy the workshop and invite you to expand your network.

Heather Main
Manager
NSW Stem Cell Network

Bernie Tuch
Director

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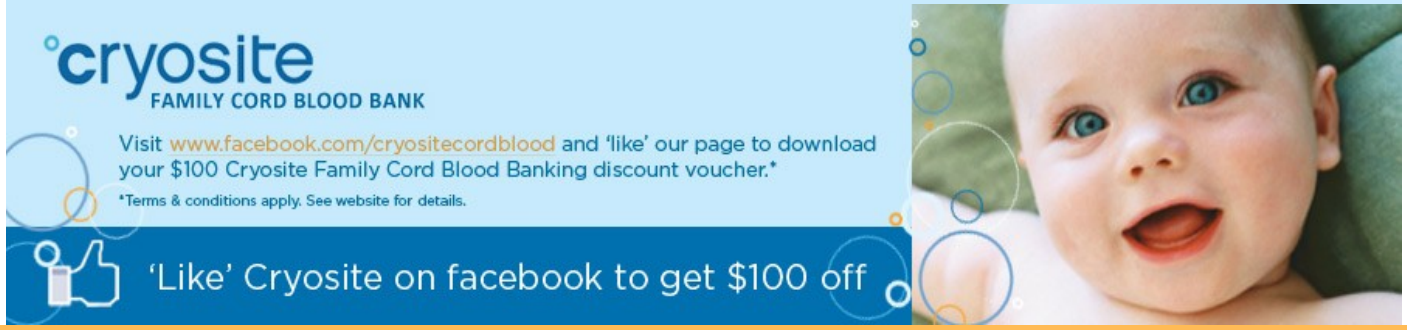

Program

9:00am	Registration opens / Light Refreshment/Research posters mounted
9:30am	**Welcome -** Dr Bernie Tuch, Director of NSW Stem Cell Network **Opening Address – Craig Cormick – Corporate Communications - CSIRO** Public perception of stem cell treatments
Session 1 Chair:	**Cord blood in society today** **CHAIR: Dr Pamela Clark – Director of Sydney Cord Blood Bank**
9:40am	**Prof. Cameron Stewart – Sydney Law School, University of Sydney** Who owns and controls cord blood? : Legal and regulatory issues in cord blood**.**
10:05am	**A/Prof. Ian Kerridge – Centre for Values, Ethics & Law in Medicine, University of Sydney** Social and ethical aspects of the therapeutic use of cord blood outside the blood system**.**
10:30am	Morning tea
10:50am	**Dr Ngaire Elwood – BMDI Cord Blood Bank, Melbourne** Public cord blood banking and the current therapeutic uses of cord blood
11:15am	**A/Prof. Mark Kirkland – Cell Care** Cellular diversity of cord blood and possible therapeutic mechanisms.
11:40am	Lunch / Poster Session
Session 2 Chair:	**Clinical trials past and future** **CHAIR: Dr Janet Macpherson – Royal Prince Alfred Hospital**
12:40pm	**A/Prof. Simon Barry – Children's Research Centre, University of Adelaide** Towards cell therapy for autoimmune disease and transplantation with cord blood derived regulatory T cells
1:05pm	**A/Prof. Maria Craig – Children's Hospital at Westmead** Cord blood– a new approach to prevention of type 1 diabetes?
1:30pm	Afternoon tea
1:50pm	**Dr Salvatore Pepe - Murdoch Children's Research Institute** Autologous Cord Blood Stem Cells for Hypoplastic Left Heart Syndrome
2:15pm	**Prof. Euan Wallace – Monash Institute of Medical Research, Melbourne** Cerebral palsy: towards prevention and treatment with cord blood.
2:40pm	**Judges** (Dr Pamela Clark, Dr Ngaire Elwood and Dr Robyn Rodwell) **announce poster session winners during refreshments**

Public Perception of Stem Cells

Dr Craig Cormick - Corporate Communications—CSIRO

Public perceptions of science can have a major impact on research, particularly where the science is new, uncertain or contested. Research into stem cells is an area that certainly falls into this category and public support for stem cell research is an area that is likely to have implications for the future therapeutic applications of stem cells. Thus, there is a need to understand how the public perceives the legal, social and ethical implications of stem cell research as well as how they understand the science of stem cells.

Dr Craig Cormick is an award-winning Canberra author and science communicator. As a science communicator, he is a regular commentator on public attitudes towards emerging technologies in the media and at conferences in Australia and internationally. He is widely published on drivers of public attitudes towards biotechnology and is a regular commentator in the media and at industry and research conferences, both in Australia and overseas, on causes of public concern towards applications of biotechnology.

Who owns and controls cord blood? : Legal and regulatory issues in cord blood.

Professor Cameron Stewart—Sydney Law School

The transformation of umbilical cord blood (UCB) from being a waste product to being a valuable source of stem cells has led to the emergence of significant legal, ethical and social issues. In this talk I examine the legal issues that have emerged or are emerging, namely, those of characterisation, consent, the interplay of public and private services, and the importance of applying property concepts to the cord blood banking industry.

Professor Cameron Stewart is Pro Dean and Director of the Centre for Health Governance, Law and Ethics at Sydney Law School and Associate Professor at the Centre for Values, Ethics and the Law in Medicine, Sydney Medical School. He has degrees in economics, law and jurisprudence. He has worked in the Supreme Court of New South Wales and has practiced commercial law at Phillips Fox Lawyers. Cameron has worked on a number of projects for NSW Health, the NSW Guardianship Tribunal, the Office of Public Guardian and Alzheimer's Australia. His current projects include studies on umbilical cord blood banking, direct to consumer advertising, guardianship law and consent to high risk medical procedures.

Social and ethical aspects of the use of cord blood for non-blood diseases

Associate Professor Ian Kerridge—Centre for Values, Ethics and Law in Medicine

Associate Professor Ian Kerridge is Director in Bioethics at the Centre for Values, Ethics and Law in Medicine at the University of Sydney and Staff Haematologist/Bone Marrow Transplant physician at Royal North Shore Hospital, Sydney. He is author of over 150 papers in peer-reviewed journals and five textbooks of ethics, most recently *Ethics and Law for the Health Professions* (Federation Press 2013). He is a member of the Australian Health Ethics Committee (AHEC), Chair of the Australian Bone Marrow Donor Registry Research Committee and a member of the NSW Health Department's Clinical Ethics Advisory Panel. His current research interests in ethics include the philosophy of medicine, stem cells, drug policy, end-of-life care, synthetic genomes, public health and organ donation.

Public cord blood banking and the current therapeutic uses for cord blood

Dr Ngaire Elwood—BMDI Cord Blood Bank, Melbourne.

The BMDI Cord Blood Bank is one of three public cord blood banks in Australia, which together with the Sydney and Queensland Cord Blood Banks, form the AusCord network of public cord blood banks. The AusCord banks work closely with the Australian Bone Marrow Donor Registry to source and provide cord blood for patients here and around the world requiring a bone marrow transplant for the treatment of malignant and non-malignant life-threatening illnesses.

The AusCord banks operate with federal and state government funding, along with philanthropic support. All three banks, and their associated cord blood collection centres, are licensed by the Therapeutic Goods Administration and hold international accreditation by the Foundation for the Accreditation of Cellular Therapies (FACT). Cord blood donors are recruited by the banks to altruistically donate cord blood for storage and use by unrelated recipients. Together the AusCord Cord Blood Banks have more than 25,000 cord blood units stored in their inventory and listed on the international search registries, readily available for patients. In February 2012 AusCord released the 1,000th cord blood unit.

There are many quality and regulatory requirements surrounding the release of cord blood for clinical use. The potential use of cord blood for regenerative therapies and other clinical trials raises many new challenges and considerations for the public cord blood banks.

Dr Ngaire Elwood is the Director of the BMDI Cord Blood Bank (CBB) in Melbourne. With a PhD from the Walter & Eliza Hall Institute, Ngaire has held research positions in Melbourne, London and USA. She returned to the Murdoch Children's Research Institute (MCRI) in 2001 to establish the Leukaemia / Stem Cell Research Lab. In 2007 Ngaire became the Director of the BMDI CBB, one of three public cord blood banks in Australia, which form the AusCord network. The BMDI CBB has released more than 400 CB units for unrelated bone marrow transplants for treatment of malignant and non-malignant disease. Ngaire heads the Cord Blood Stem Cell Research Group at MCRI and has worked for more than 25 years in the field of haematopoietic stem cells, cord blood and leukaemia.

Cellular diversity of cord blood and possible therapeutic mechanisms

Associate Professor Mark Kirkland - Cell Care

Umbilical cord blood (UCB) is a rich source of many different types of stem cells, some in clinical use, others under investigation, and some controversial. In addition, UCB contains immune cells (regulatory T-cells, dendritic cells) with unique properties.

While many types of differentiated cells have been derived from UCB, including haemopoietic, neural, myogenic, hepatic and islet cells the current therapeutic potential of UCB seems to be based in its ability to dampen inflammation, modulate immune responses and recruit endogenous repair mechanisms rather then the capacity to replace damage tissue. Studies of UCB in animal models of neurological damage have repeatedly demonstrated efficacy in terms of repair, but with little or no evidence of direct contribution or persistence of UCB cells. Similar results are now emerging in clinical studies in humans. Similarly, a UCB-derived mesenchymal stem cell product recently approved in South Korea for the treatment of osteoarthritis has demonstrated clinical efficacy through the indirect mechanism of inducing endogenous cartilage repair. These studies reinforce the growing paradigm of cell therapeutics as complex “medicinals”, whose efficacy derives from the production of a range of factors (growth factors, chemokines and others), rather than as intrinsically reparative and regenerative agents.

Associate Professor Mark Kirkland has more than 25 years research experience in the field of haemopoietic stem cell biology and holds an Associate Professorship at the Institute for Fronteir Materials, Deakin University. Former Medical Director of Research for the Australian Red Cross Blood Service in Victoria, he is the Chief Scientific Officer of Cytomatrix Pty Ltd, a biotechnology company specialising in novel technologies for the growth and expansion of human adult stem cells and is Director of the private cord blood bank Cell Care Australia Pty. Ltd.

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Poster Presentations

POSTERS WILL BE MANNED DURING THE LUNCH BREAK.

ONCE YOU HAVE YOUR SANDWICHES PLEASE TAKE A MOMENT TO CHECK OUT THE RESEARCH OF OUR REGISTRANTS.

1) Adam Johnston—*How does the Common Law Look at (a) the Body and (b) Property as it Might Relate to the Body or Body Parts, Cells or Cellular Information?*

2) Simon Jones—*Modulating the kynurenine pathway to promote stem cell repair in multiple sclerosis*

3) Janet Macpherson—*Building a good manufacturing practice (GMP) facility within the public healthcare system*

4) Jessica Martin—*Quality of cord blood units and post transplant recipient outcomes at the SCBB—an update*

5) Phillip Johnson—*Ensuring the Quality of Cord Blood Units Released for Transplant by the Queensland Cord Blood Bank at the Mater*

Towards cell therapy for autoimmune disease and transplantation with cord blood derived regulatory T cells

Associate Professor Simon Barry—Children's Research Centre, University of Adelaide

Autoimmune disease is the result of imbalance in the immune system being ready to react to pathogens, while maintaining tolerance to harmless challenges such as food and body tissues. There is increasing evidence that defects in Regulatory T cell function (the police of the immune system) leads to a wide number of disease including Type 1 diabetes and multiple Sclerosis, where failure to regulate the immune system allows inappropriate destruction of tissues. We have spent the last 5 years studying genes essential to Treg function (eg. FOXP3) in diseased and non-diseased human cohorts using state of the art gene discovery tools to identify and then confirm a functional role for key genes in Treg function.

The clinical application of regulatory T cells is significantly hampered by the limited cell numbers that can be obtained from either cord or adult blood. Attempts to expand these purified Treg *ex vivo* have shown much promise, and we are attempting cord and adult blood Treg cell expansion on a clinical scale . An alternative approach is to generate large numbers of T cells *de novo* from cord stem cells since these cells have the capacity to differentiate into all cells of the haemopoietic system. We have established an *ex vivo* differentiation assay that can expand cord blood stem cells and induce their differentiation along the lymphoid pathway. We are now poised to test these Treg in clinical trials, and this forms part of a new CRC for Cell therapy manufacturing.

Associate Professor Simon Barry is the leader of the Autoimmune Diseases Stream at the Children's Research Centre of the University of Adelaide. A/Prof. Barry is concerned with the basis of immunological defects that cause autoimmune diseases such as type 1 diabetes, multiple sclerosis and inflammatory bowel disease. His research focusses on the behaviour of regulatory T cells (the policemen of the immune system) and the genes that drive their formation and function. Simon is currently chief hospital scientist at the Women and Children's Health Network, Adelaide, Associate Professor in the Department of Paediatrics at the University of Adelaide and head of the Molecular Immunology Laboratory at the Women and Children's Health Research Institute.

Cord blood– a new approach to prevention of type 1 diabetes?

Associate Professor Maria Craig—Children's Hospital at Westmead

Regulatory T cells (Treg) have an important role in maintaining immune homeostasis and prevention of autoimmune disease. Mutations in the transcription factor forkhead box P3 (FOXP3) result in Immune dysregulation, polyendocrinopathy, enteropathy, X-linked (IPEX) syndrome. Deficiencies and/or dysfunction of CD4+CD25+Tregs are observed in people with autoimmune diseases, including Type 1 Diabetes (T1D). Umbilical cord blood (CB), a rich source of functionally potent Tregs, reversed T1D in NOD mice, accompanied by reduced inflammatory infiltration within the islets. Co-culture of lymphocytes with CB from individuals with long standing T1D reversed autoimmunity, increased Tregs and led to regeneration β cells and improved glycaemic control. However, no studies in humans have examined whether CB can prevent T1D.

We are currently undertaking a pilot trial to investigate the effects of infusion of autologous CB on progression to T1D in children with multiple islet autoantibodies. Our primary hypothesis is that infusion of autologous CB will restore immune tolerance in children with islet autoimmunity and delay or prevent the progression to T1D. We plan to screen approx. 800 children with a first degree relative with T1D, who have CB stored. Those with multiple autoantibodies will be staged and offered infusion of CB. The study is being conducted at the Children's Hospital at Westmead and funded by Cell Care, Australia.

Associate Professor Maria Craig is a Paediatric Endocrinologist at the Children's Hospital at Westmead and St George Hospital, and a NHMRC Practitioner fellow (University of Sydney). Her major research focus is childhood diabetes, including the epidemiology and viral aetiology of the disease. She is the chief investigator on the CoRD (Cord blood reinfusion to prevent type 1 Diabetes) study, a world first study at the Children's Hospital at Westmead, using autologous cord blood to prevent type 1 diabetes in at risk children. Maria is lead investigator for NSW on the ENDIA (Environmental Determinants of Islet Autoimmunity), principal investigator on the APEG-JDRF clinical research network longitudinal diabetes database, chair of the steering board for VIDIS and scientific co-ordinator of the APPES Society Fellows' School.

Autologous Cord Blood Stem Cells for Hypoplastic Left Heart Syndrome

Dr Salvatore Pepe - Murdoch Children's Research Institute, Melbourne

Hypoplastic Left Heart Syndrome (HLHS) is an extremely severe and complex congenital heart disorder requiring the first of three operations within 2-3 days from birth. One published study has reported the clinical use of autologous *whole* cord blood transfusion during cardiopulmonary bypass to supported surgical repair of complex congenital heart anomalies in the neonate *(Fedevych et al., Eur J Cardio-thoracic Surg, 2011)*.

We demonstrate improvement in right ventricle systolic and diastolic function a month after surgery following direct injection of isolated human cord blood stem cells in a neonatal sheep model of right ventricular pressure loading and failure (pulmonary artery banding) . The beneficial effect did not appear to involve the integration of stem cells into the myocardium but augmentation of ventricular mass critical for avoiding right heart failure. We have now completed a safety study of human cord blood stem cell delivery in a neonatal HLHS lamb model. The efficiency and safety of our new cell delivery protocol with a clinical grade stem cell preparation was validated for acute recovery of contractile and respiratory function and weaning from cardiopulmonary bypass support without adverse events or organ injury. Extensive localization and tracking of human cord blood stem cells in myocardium, other major organs and circulating venous and arterial blood have been performed. We are now preparing to demonstrate the feasibility of autologous cord blood stem cells directly in HLHS neonates.

Dr Salvatore Pepe's research has centred on myocardial and mitochondrial function, including cellular regulatory signalling in survival mechanisms, adaptive remodelling after post-ischaemic injury and in the progression of heart failure. His work has involved molecular, cellular, isolated organ and animal studies, as well as human studies and clinical trials. In 2008 he was invited to move his laboratory to the Heart Research Group at the Murdoch Childrens Research Institute, Royal Children's Hospital, Melbourne, to focus research on myocardial developmental and congenital heart disorders, paediatric cardiac surgical complications and clinical translation of new therapies.

Cerebral palsy: towards prevention and treatment with cord blood.

Professor Euan Wallace, Monash Institute of Medical Research, Melbourne

While umbilical cord blood was first collected and stored as a therapy for diverse haematological disorders it has become abundantly apparent that it is a rich source of "stem cells" that have tissue regenerative and reparative properties. As discussed by other speakers in the Workshop, much of these properties relate to T cells, and more specifically regulatory T cell – so called Treg cells, and the ability of these cells to manipulate the host immune response to injury. This recognition has led to the application of cord blood cells to diseases with immune cell origins that far removed from blood disorders, such as type 1 diabetes and multiple sclerosis.

There is perhaps a no more exciting application of cord blood than to the prevention and treatment of cerebral palsy (CP). The thought of being able to collect, store, and re-infuse a child's own cord blood as a treatment for CP is most enticing. It has been known for some time that cord blood has the ability to reduce brain injury following stroke but, partly due to a lack of suitable models of injury, there has been less evidence for a role in other brain injuries, particularly CP. Indeed, at a recent Cerebral Palsy Summit organized by the Cerebral Palsy Foundation and held in San Francisco in late 2011, one major funding organization stated that it would be difficult to justify funding clinical trials of cord blood for the treatment or prevention of CP because of a lack of either a plausible biological mechanism or supportive data from experimental studies.

In a little over 12 months all that has changed. This year has the seen the publication of a South Korean clinical trial of cord blood re-infusion for the treatment of CP with very promising results. Those results will be discussed in some detail as a backdrop to likely mechanisms of action. Further, we have several large animal (sheep) models of developmental brain injury to which we are now applying cord blood re-infusion. Some of the data from that work will be presented.

I will argue that there are now sufficient pilot clinical and experimental data to justify two large-scale Australian cord blood trials in CP: one for the treatment of children with CP and one for the prevention of CP in children at high risk. How such trials might operate will be discussed.

Professor Euan Wallace is the Director of The Ritchie Centre and the Carl Wood Chair of Obstetrics and Gynaecology at Monash University. As Director of the Ritchie Centre, he has brought together research groups in fetal and neonatal physiology, women's health and stem cell biology to create a research centre focused on women and infant health. His own research group focuses on basic and clinical aspects of pregnancy, including fetal development. He has an established research program in neuroprotection with a view to the development of novel therapies for the prevention and treatment of developmental brain injury, such as occurs in cerebral palsy. In particular, the group is pioneering the use of cord blood and amniotic stem cells as therapies for fetal hypoxic-ischaemic brain trauma arising during pregnancy and birth.

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