December 2023

SHIRGH CRITIC

# 'Change Is The Only Constant' Heraclitus

Critical Care Research is founded on 'change' and in this Newsletter we'll look at how technology impacts everything we do. As we strive for people-centered care

during research, we rely more on 'Big Data' to help make clinical connections we've never noticed before for our patients. This has supported extensive advances in areas such as Genomics. Basing research decisions on accurate data enables robust study outcomes post trial. Of course, this in turn, informs future studies.



Take a look at the article on TRAITS on page 5 to see how technology will be used to personalise treatments and modify them during the trial.

# Stall On The Mall—RIE



We had a lot of fun and met lots of great people when we had our stall on the mall on Wednesday 13th December.

Research nurses from Oncology joined us and together there was lots of research experience to draw from.

Everyone passing the stall could find out how randomisation within a trial works. A very handy device, that looked suspiciously like a bingo machine, was used to give people the experience of randomising themselves to one of two tubs of sweeties!

There was information on our Patient and Public Involvement Group, on SHARE, the research register and lots of goodies from the trials and studies.

We'll keep you posted when we do this again so you can come and say hello!

# Inside this issue:

| 'Change Is The Only Constant'                          | 1 | Technology Is Crucial To Research          | 4 |
|--|---|--|---|
| Maggie's Master-piece!                                 | 1 | The TRAITS Of Research                     | 5 |
| T-POT: Ushering In a New Era In<br>Neuro-Critical Care | 2 | Big DATA And How We Use It                 | 6 |
| Informed Consent For ICU Research                      | 3 | Acronym Buster; Six Studies; Get In Touch! | 7 |

Critical Care—Critical Research

# T-POT: Ushering In A New Era In Neuro-Critical Care

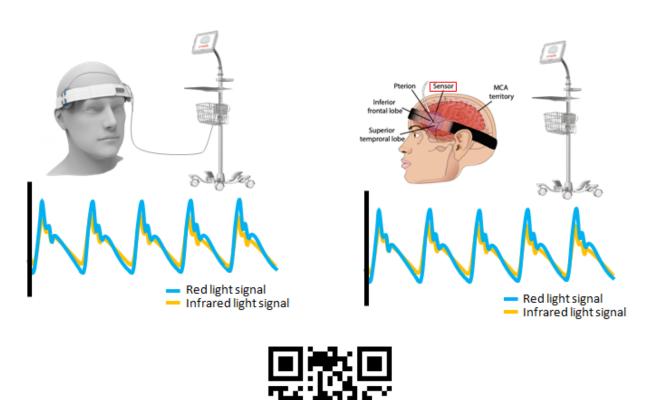
### Transcutaneous Pulse OximeTry Brain Monitoring Study

Our new neurological study **T-POT** involves a novel technology — developed by Melbourne-based company, Cyban Pty Ltd. The brain pulse monitor provides bilateral, non-invasive, continuous intracranial pressure (ICP), and percentage tissue oxygen saturation (StO2 %) information. This novel multimodal monitor uses a modified pulse oximetry approach, distinct from traditional cerebral oximeters, to derive a StO2 % estimation, and changes in the waveform shape estimate ICP.

The technology will assess the accuracy and reliability of our non-invasive brain pulse monitor against the current gold-standard invasive brain oxygen monitor in patients with severe traumatic brain injury.

The continued refinement of the StO2 and ICP algorithms promises major improvements in patient outcomes through earlier detection and treatment of brain hypoxia. Plus, this simpler and safer approach would allow monitoring to be part of the routine care of all patients at risk of brain injury, in all areas of acute hospital and emergency care.

We're really eager to move along with T-POT and help our critically ill patients. Keep an eye out in future issues to see how we're getting on...



Scan here to find out more about T-POT

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Page 2 ECCRG RESEARCH NEWS

# Informed Consent for ICU Research

Informed consent for Research in the Intensive Care Unit has always been challenging due to the patient group it serves, as some lack capacity to make decisions. Research is crucial in many areas of healthcare, but invaluable within the field of critical care. Offering best care to each patient requires; evidence-based practice, individual clinical expertise and patient choice

During Dr Annemarie Docherty's recent forum entitled "ICU Research and Consent: A Forum for the Future", discussions were sparked about the process of informed consent in ICU. This is a complex issue which involves vulnerable patients who are unable to fully understand the information given. It is crucial that we hold patient well-being and safety at its core. Professor Tim Walsh opened the forum with the types of research and how each type employs different regulations for obtaining informed consent.

Article by
Mia Amamio
Critical Care
Research Team



Dr Annemarie Docherty, Honorary Consultant in Critical Care

There are still many ideas to be discussed and opinions to be debated, but this forum has been an important catalyst. The forum was attended by Critical Care Consultants, Critical Care Research Nurses, the Research Ethics Committee, the Public Patient Involvement Group and representatives from the EMERGE team, all of whom agreed that Critical Care should be advertised to a greater extent and reach a wider audience. This reach will create a platform that can be used to enhance the process of informed consent in Critical Care to benefit the patients, the staff and healthcare as a whole.

The Forum was expertly captured in this illustration by Tess, Graphic Designer  $\dots \rightarrow$ 



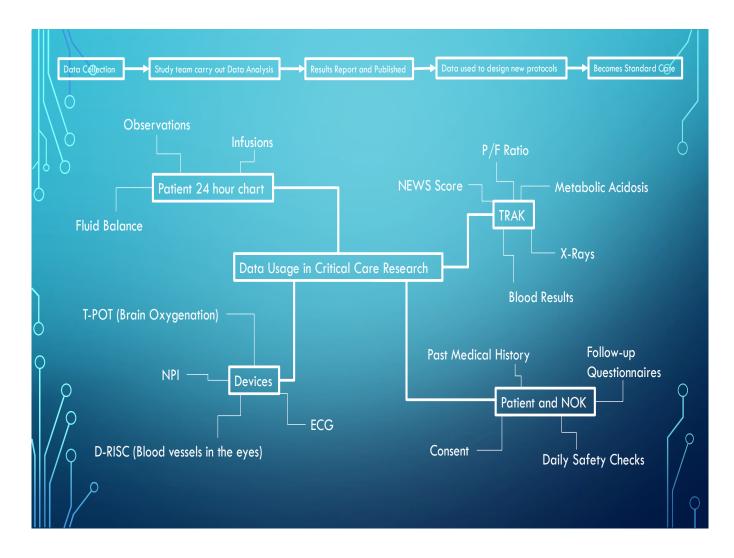
The Panel

The focus of the forum was the Critical Care Futures Project, which was presented by Dr Catherine Montgomery. This is a public engagement initiative that involves a range of professional and public ICU stakeholders in dialogue about the boundaries between research and care. The project made use of a design research tool called 'cultural probes'. This is used to explore alternative processes and is a creative space for progressive thinking towards critical care research.



Page 3 ECCRG RESEARCH NEWS

# **Technology Is Crucial To Research**



### ... And here's why!

Data is a huge part of research, understanding critical illness and developing practice. This data is analysed by the study teams and statistic experts, so we can better understand different patient groups and how best we can care for them.

If it's written on a chart, monitored on a ventilator, results reported on TRAK or even waveforms on a novel device - we probably collect it!

Scott Simpson - Critical Care Research Team

If you head to page 6, you'll discover what the future for Big Data in the clinical field could look like — read Dr Annemarie Docherty's article 'Big Data and how we use it'

Page 4 ECCRG RESEARCH NEWS

# The TRAITS Of Research...



TRAITS is the first precision medicine trial of critically ill patients in the UK and will be starting in our critical care very soon! Traits is different from a traditional randomised study (see table below) and is classed as a platform and adaptive trial.

TRAITS will enable time critical precision medicine to be used in critically ill patients presenting to intensive care units (ICUs). It will use novel and efficient clinical trial design that can test multiple interventions matched to the individual patient biological features.

Treatable traits are defined as 'measurable biological abnormalities, that are determinants of clinical outcomes (e.g., organ dysfunction or death), and are modifiable with interventions'. The concept is that such treatable traits in critically ill adults can be found in different

**Chief Investigator** Dr Manu Shankar-Hari **Principal Investigator** Dr David Griffiths

| Randomised control trial   | Platform Trial   | Adaptive Trial   |
|--|--|--|
| Tests multiple interventions/drugs.  | Lots of different interventions<br>can be tested at once in differ-<br>ent groups rather than one inter-<br>vention in one patient group | Trial can be changed as data is emerging   |
| Traits uses randomisation but is not a traditional randomised controlled trial | Results can be checked as the study goes along rather than waiting until the end   | If data shows an intervention is not as effective this can be changed and a new intervention added |

# LYMP-RESP TRAIT

**Budesonide** – Inhaled 1mg twice daily for seven days

**Baricitinib** – Oral 4mg a day for up to fourteen days or ICU discharge

- defined as PaO2/FiO2 ratio <40kpa whilst receiving non-invasive ventilation (including high flow nasal cannula) or invasive mechanical ventilation for 6 hours or longer.
- lymphocyte count 1.2x10^9/L.

# **ENDO-SHOCK TRAIT**

Imatinib - Oral 800mg loading dose 400mg a day for 9 days

**Standard Care** 

- Provision of consent
  - Respiratory dysfunction is respiratory support with either
- Lymphopenia defined as

Various inclusion and exclusion criteria guide who can be recruited into the Traits arms. The research team will look at every patient and work alongside medical and nursing staff to aid recruitment.





- Provision of consent
- Presence of **shock**: defined as hypotension requiring vasopressor therapy to maintain mean blood pressure 65 mm Hg or greater and having a blood lactate level greater than 2 mmol/L after adequate initial fluid resuscitation.
- Evidence of **inflammation**: defined as C-reactive protein (CRP) 50mg/L or more OR neutrophil count >=12x109 /L.

Find out how we get on when the TRAITS study opens in the next issue

Issue 3 Page 5 In hospitals all around the world, a huge amount of information is collected every year about patients and their health. However, very little of this information is used right away to help doctors make decisions about how to treat their patients. In the UK, only a small number of research studies use this information.

My vision is to use this collected information to learn more about how to improve healthcare. I want to do this by working closely with the hospitals and using the information they already have, instead of collecting new data. This way, we can help more patients and make healthcare better for everyone

Intensive Care Unit (ICU) is the perfect place to start as it is where the sickest patients are treated. In the ICU, there are many machines and devices that measure different things about the patients, like their heart rate and breathing. But right now, research studies only use the information from these machines every once in a while, maybe once an hour. I want to change that and use the information in real-time to help doctors make decisions faster and more accurately.

Have a look at Scott Simpson's infographic on how the Critical Care Research Team interact with technology on a daily basis page 4

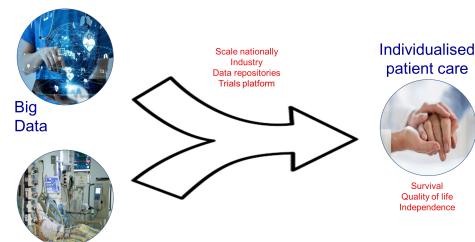
I also want to find a way to predict when a patient might have a heart attack and prevent it from happening. Right now, doctors can miss heart attacks in the ICU because the signs are different from what we expect, and the tests we use are not done very often. I want to see if we can use information from the monitor at the patient's bedside so we can catch heart attacks earlier and save lives.

Another important thing I want to study is how people with different health conditions react to treatments. Sometimes, a treatment that works for one person can be harmful to another person. For example, giving extra fluids to some patients might help them, but for others, it could make their heart condition worse. I want to understand these differences and make sure that each treatment we give is safe and effective for each patient.

To do all of this, I will work with other experts, like engineers and computer scientists, and use big sets of data from patients in different hospitals. I will create special tools that can analyse the data and help doctors make better decisions. I want to try these tools in real hospitals to see if they can really help patients.

By doing all of this, I believe we can make healthcare better and save lives. I want to make sure that

all patients, no matter their condition, get the best care possible. I hope that this work will inspire others to do more research and make hospitals even better in the future



Issue 3 Page 6



# Wishing All Of Our Readers And Contributors A Very Merry Christmas And

# A Happy Healthy New Year



### **Acronym Buster!**

Six More Studies For You To Peruse!

### **Get In Touch!**

API – Associate Principal Investigator

CI - Chief Investigator

CRF - Clinical Research Facility

Or Case Report Form

GCP — Good Clinical Practice

PerLR – Personal Legal Representative

PI—Principal Investigator

PIS - Patient Information Sheet

PPI – Patient and Public Involvement

ProLR – Professional Legal Representa-

REC – Research Ethics committee

Need to know anything else? Drop us an email!

### **Six Studies:**

**ARDSNeut:** Investigating the biosynethic properties of ARDS neutrophils

**T-POT**: Transcutaneous Pulse OximeTry Brain Monitoring Study (UK)

MOSAICC: Multicentre evaluation Of Sodium bicarbonate in Acute kidney Injury in Critical Care

LicuiD: Liquid biopsy In the Critically Unwell wIth acute Disease

**SIGNET**: **S**tatins for **i**mproving or**g**an outcome in transplantation

**BIS TBI:** The use of **Bis**pectral Index monitoring to assess depth of sedation in patients with TBI

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