



Cardiff Research Forum Newsletter

June 2018

Edition 3

"COLLABORATING TO ACHIEVE BIGGER THINGS"

IN THIS EDITION

Cardiff Research Forum and the Research Community is open to all disciplines of research staff from across South East Wales with the aim to bring together likeminded people to share their research experience & practice, and to build on the existing networks of support.

The Forum is held 3-4 times a year, providing a platform for all to share research news and updates, exciting new projects, information about research support, grants and funding streams and an opportunity to network and meet new people.

On 20th May 2018 we celebrated International Clinical Trials Day, the anniversary of the first recorded Clinical Trial, and hosted a week of research related events across Cardiff. This was a brilliant week of events to highlight the importance of research and clinical trials in the NHS today.

The Critical Care Research Team presented a lunchtime seminar on deferred consent in emergency research, and the Cardiology Research Team presented their recent research and service improvement projects. On 16 May, Cardiff and Vale UHB Midwives hosted the Research Forum, and we were joined by HealthWise Wales who shared information about their Wales wide research project.

On Friday 18 May 2018 The Clinical Research Facility held an open afternoon, while Velindre Clinical Trials Unit had a daily spot in the outpatients' department speaking to patients about clinical trials running in Velindre Cancer Centre.

A huge thank you to all those involved in making it a success. Please get in touch if you would like to be involved in future events at:

zoe.boult@wales.nhs.uk

Research Updates

Find out about our first clinical research and development student spoke placement, new Research Training Documents, and an update on training needs analysis workshops over the summer

In the News

The NHS at 70, looking back at Wales' rich history of Research with Health and Care Research Wales

Research awareness week

If you couldn't attend, you haven't missed out. Find all the presentations from the week in this edition

An Exciting New Opportunity

Find out about how to get involved in the launch of the All Wales Cancer Nurses and Allied Health Professional Research Network on 05 September 2018

Dates for your diary

Upcoming Forums and Events

Clinical Research & Development Student Placement Launched

Zoe Boulton, Senior Nurse Research Education & Training

I started working with Cardiff University and the Haematology Research Team early last year to set up the first Clinical Research and Development student placement in the Health Board. We wanted to make this a worthwhile experience for students that would introduce them not only to the roles of staff working in research, but also show them the behind the scenes processes that clinical trials follow in the NHS. We linked the pilot placement to a hub based in the Haematology directorate, and offered nursing students an opportunity to apply for a spoke week with us during this hub.

To support the placement, we developed a workbook with practice

based activities for students to complete before and during the placement, and a reflective exercise during the week to explore how the placement and new knowledge of clinical trials would influence their future practice.

This model of student placement is a template that can be adapted and used to support spoke placements in other specialties and disciplines. Please get in touch for more information about the student pack and teaching sessions if you are interested in taking this forward in your area.

Student Feedback

"..it was a very interesting placement... I met many very knowledgeable and motivated nurses and feel that I have met my spoke objectives"

"I would recommend this placement to students interested in research as you can see what a research nurses role involves, patient care and contact, coordinating research and own workload, adhering to protocols..."

"...as witnessed this week... in future I will try to maintain good professional working relationships with other healthcare providers...in order to ensure patients can utilize different services seamlessly"

"...good to see different people's job roles and appreciate what people do and how things work together in clinical trials"

"I really enjoyed the pharmacy visit... a very different experience"

"...a great mix of theory and practice observations overall"

"Everyone was really welcoming and happy to answer questions"

Activity 2:
Phases of clinical trials

Have a look at two protocols that the research nurse is working on and try and find out the phase of the clinical trial. Discuss with the research team what the trial is investigating, and what it may involve for patients.

Phase	Aim	Note
First In Man / Phase 0	Safety and action in humans	Phase 0 trials are the first small doses of the study drug (pharmacodynamics) and to the drugs (pharmacokinetics), the trial looks at the metabolism, and removal of drug, and the drug's interaction with the body, to confirm that the expected.
Phase 1	Safety, dose and action in humans	Testing within a small group to evaluate safety, determine dose, and begin to identify



Timetable

Monday	Tuesday	Wednesday	Thursday	Friday
AM	AM	AM	AM	AM
Induction & Teaching Clinical Research Facility	Clinical Research Facility	Haematology Research Team	Haemophilia Research Team: Research Documentation	Laboratory Visit
PM	PM	PM	PM	PM
Teaching & workbook	Clinical Research Facility *placement workbook	Haematology Research Team *placement workbook	14:00 SMPU clinical trials pharmacy visit	Workbook sign off & reflection

Shift Time: 08:00 – 16:00 Monday to Friday

*If there is time for self-directed learning here, please use this to complete the activities in your placement workbook

Clinical Research & Development Student Placement pack



RD Student Pack V2.0 18/06/2019



Research Training Updates

A new Research Induction and Training File has been adapted for use for research staff in Cardiff and Vale UHB. This is based on the template used by Health and Care Research Wales, and aims to streamline the induction, information and training that research staff receive across the organisation. Contents include an induction workbook for new staff to support their first 4 weeks in post, up to date information about Cardiff & Vale UHB, Health and Care Research Wales, and the UK clinical research network; as well as competency documents for informed consent and laboratory skills. The template documents have

been disseminated and SOP guidance for use will be in place over the coming months.

Linked to this piece of work I am in the process of looking at the best way to deliver training, for new and existing research staff. I have been working closely with the Paediatric research team to deliver in house training in the Children and Young Adults Research Unit (CYARU), and with the Clinical Research Facility to support safe administration of novel agents. I'm exploring whether training is more effective when delivered on the job and in small easy to manage sessions, rather than staff having to attend half or full day workshops away from their

work base. I'd be really interested to hear how you manage this where you are.

This also goes hand in hand with the work I am doing as part of a training needs analysis across the organisation over the next few months. TNA workshops will be held for staff during the summer where you will have the opportunity to get involved in shaping your development by working on role specific competencies, career pathways and bespoke training for your area.

As with all tools and resources produced, these are available to the wider research community to adapt

and use, they are not just restricted for use in Cardiff and Vale.



An example of questions being asked as part of the research training needs analysis

Please get in touch for more details:
zoe.boult@wales.nhs.uk

Wales' Rich Heritage of Research Excellence

23 May 2018

As a miner's lamp makes its way around Wales to mark the 70th anniversary of the NHS, we reflect on a pioneering study of Welsh miners' lung disease from that time that changed the face of public health forever and lives on through our national project for better health, HealthWise Wales.

Blackened lungs

Back when the NHS was established in 1948, more than 700,000 men worked gruelling, dirty and dangerous shifts in Britain's coal mines. Over 22,000 struggled with the lung disease pneumoconiosis, or 'black lung', with 85% of those living and working in South Wales. It was this disease that Archie Cochrane, a doctor at Llandough Hospital in Penarth, tackled head-on with an ambitious study of entire mining communities in the Rhondda Fach and Aberdare valleys.

On a scale never seen before, chest x-rays and detailed health surveys were performed to see whether a particularly crippling form of lung disease, progressive massive fibrosis, was caused by a combination of black lung and tuberculosis. They found out much more than that, linking coal dust with a range of disabilities and ill health amongst these communities.

An astonishing 95% of the community some 25,000 people, agreed to take part thanks to the highly organised, intensive work of a field team of medics, nurses and disabled miners using ground-breaking methods. The remarkable level of participation and wealth of detailed data collected demonstrated the feasibility of such an approach, launching a new era of public health research and



#TeamResearch

#NHS70

earning Cochrane the mantle 'the father of evidence-based medicine'.

Those remarkable men of Caerphilly

In the late 1960's, Cochrane's work investigating whether aspirin could prevent heart disease, inspired his colleague Professor Peter Elwood to study how lifestyle habits affect chronic disease and health. Tracking the lifestyle habits of 2,500 middle aged men from Caerphilly South Wales since 1979, the Caerphilly Cohort study became and remains one of the most important health studies ever conducted.

Information about how our environment influences risk of chronic diseases like heart disease, diabetes and obesity, is entirely dependent on the dedication and commitment of the men taking part. These 2,500 men of Caerphilly have for 19 years continuously given their time and data to help us better understand health.

The study's greatest success is the rock-solid evidence of the cumulative benefits of healthy habits for people's health. Although now common knowledge, this study this was the first to show that not smoking, having low alcohol intake, maintaining a healthy weight, having a balanced diet and exercising regularly dramatically lowered peoples' risk of

conditions like diabetes, cancer, heart disease and dementia.

The next 70 years

This research has had a huge influence globally, providing a reference point for other and future research, including Wales' national project to better understand and improve our health and care for the next 70 years, HealthWise Wales. Funded by Health and Care Research Wales and true to Archie Cochrane's vision and approach, HealthWise Wales is the largest research study of its kind ever in Wales.

Launched in 2015, information collected will be used to better prevent and treat long-term health conditions, such as heart disease, diabetes and dementia. The study aims to build an in-depth picture of the health of the nation, giving the data for the evidence-based medicine of the future. For more information please visit: www.healthwisewales.gov.wales

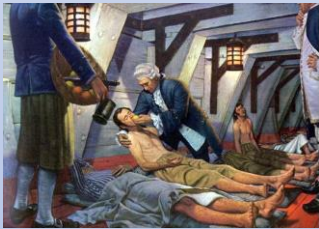
(this article was used with permission of Health & Care Research Wales. For the full article please visit <https://www.healthandcareresearch.gov.wales/news/wales-rich-heritage-of-research-excellence/>)



Research Awareness Week

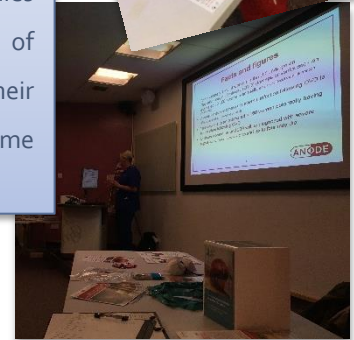
20 May 2018 marked 271 years since the start of the first clinical trial on board HMS Salisbury. James Lind took 12 men with scurvy, divided them into six pairs and experimented with different remedies.

The two men treated with citrus fruits made an impressive recovery and James Lind was credited with organising the first clinical trial in 1747. Clinical trials have developed a great deal since then and thousands of people have taken part in life changing research. In Cardiff we celebrated the week leading up to International Clinical Trials Day with several events to highlight research today.



Velindre Cancer Centre Clinical Trials Team were raising awareness of clinical trials with patients in the busy outpatients' department

The Research Forum was hosted by Midwives Judith Cutter, Anouk Ridgeway and Professor Julia Sanders. Special guests HealthWise Wales brought along lots of information about their research (and of course, some freebies...)



The Hematology Clinical Research Group got in the spirit via social media, and had a visit from Cardiff and Vale CEO, Len Richards



The Clinical Research Facility Open Day was supported by Cardiff University CTR and Cancer Research UK. A big thank you to everyone who came along to meet the team.

A pint of Science was a sell out in O'Neil's Pub in Cardiff, arranged by Cancer Research UK



Getting to the Heart of Research: Introducing the Cardiothoracic Team



The Cardiothoracic Research Team is based in the Sir Geraint Evans building and are responsible for recruiting to and delivery of Cardiology clinical trials.

Background and Development

For the past 20 years, two research staff have worked to deliver clinical trials independently within the Cardiothoracic Directorate. Under the management of Helen Dyer, in 2015 the basis of a growing research team was established. The team have supported a steady increase in clinical trial activity from 4 to 20 trials, and an increase in their commercial trial income from £40,000 to £113,000 in the last two years.

In 2018 further improvements in trial activity have been supported by the

appointment of a data manager, releasing nursing time to efficiently recruit, follow up patients and deliver high quality data. By developing a cohesive research team, a robust governance framework was implemented.

Improving Services & Engagement

Over the last 12 months there have been a significant number of service improvements achieved by the team resulting in an impact on the service, the patient follow up experience, and patient safety. The team have established different ways of working to maximize efficiency, integrating the research with the patient's pathway.

Engagement with the multidisciplinary team has been improved by the introduction of drop in teaching sessions to raise awareness of research activity. Contributions toward poster presentations at research forums,

and the development and delivery of a research teaching module for the Cardiothoracic course has raised the profile of the team, and a successful research open day was held in the Sir Geraint Evans building to share their experiences and achievements.

Future Plans

The team have recently gained access to a daily research clinic on PMS and are hoping to use this to pilot a method of identifying research patients admitted to the UHW. This could potentially have a significant impact on patient care and safety, improving timelines for reporting Serious Adverse Events. Helen and the team are very enthusiastic about sharing their innovations with other research teams within the Health Board and intend to report back their findings following this pilot.

For more information please contact Helen Dyer
helen.dyer2@wales.nhs.uk

Helen Dyer and the Team extend thanks to the R&D Office, Health & Care Research Wales and the Cardiothoracic Directorate for their continued support.

Emergency Deferred Consent in Critical Care Research

Jade Cole & Dr Matt Morgan

What is Emergency Deferred Consent?

The process of enrolling patients into clinical research studies involving critically ill or unconscious patients prior to obtaining informed consent from the patient.

Why do we need it?

Most critically ill patients are either unconscious or too unwell to engage in the process of having a clinical trial described to them. This means they are unable to make an informed decision on whether they would like to participate in the trial.

As the patients are so unwell, treatments and therapies need to be given rapidly meaning there is also very little time to discuss participation with the patients' relatives or legal representatives who are often already distressed and overwhelmed. The patient may not have any relatives, or those relatives may not be able to get to the hospital. Consequently, there is very little opportunity for using the standard process for seeking 'informed consent' to

participate in clinical research which is used elsewhere in medicine.

Only one in ten current critical care treatments are based on the best quality evidence, partially due to the challenges of conducting research in emergency situations with patients who are so unwell. We know that the only way to ensure we are delivering the best possible standard of care is through research which identifies not only new treatments and therapies, but also examines which current treatments are beneficial and which are harmful.

If we are to improve survival rates and outcomes for our critically ill patients' it is vital that we give them the same opportunities to participate in clinical research as they would have with any other area of medicine where participation in research is actively sought out and encouraged. Improving the care of critically ill patients' through research is simply not possible without the use of an emergency deferred consent model

How does it work?

It is a carefully regulated process with considerable oversight and input from an independent professional ethics committee and members of the public. The need for an emergency deferred consent model must be completely

justified by the researchers, and formal plans for ensuring that the patients' wishes are respected are at all times of paramount importance during this process.

Discussion with the patients' relatives or legal representatives takes place at the earliest appropriate opportunity to determine what the patients' wishes would be and if it is believed that they would want to continue to participate. The option to withdraw from the research is always provided with assurances that this will be without prejudice and that the patient's ongoing care will not be affected.

Most importantly, the process of seeking formal informed consent from the patient as soon as it is appropriate is central to the whole process and this is explained and reiterated consistently. When patients have been very unwell, it can be some time before it is appropriate to discuss their participation in a research study with them and so it must be understood by all parties that ongoing and continued efforts will be made to allow the patient to give their informed consent to continue to participate.



For more information please contact the Critical Care Research Team: jade.cole@wales.nhs.uk





What is ANODE?

ANODE is a randomised controlled trial of prophylactic Antibiotics to investigate the prevention of infection following Operative vaginal DELivery.

Infection and sepsis is a recognised and significant complication following delivery operative vaginal delivery. UHW is one of 28 maternity units across the UK taking part in this randomised, blinded, placebo-controlled trial run by the NPEU and is funded by the National Institute for Health Research.

The Aims and Objectives

The main aim will be to test the effectiveness of a single intravenous dose of co-amoxiclav against a placebo in reducing the incidence of infection following an operative vaginal delivery in women at 36+0 weeks or greater gestation.

The trial target is to recruit 3,424 women in the UK and this is close to being achieved. UHW is currently the

fourth in the league table for recruitment.

The primary objectives of the trial are to compare the incidence of confirmed or suspected maternal infection in the first 6 weeks after operative vaginal delivery amongst women who have been randomised to receive prophylactic antibiotic versus placebo.

The secondary objectives are to investigate the effect of the intervention on various short-term maternal outcomes, including severe sepsis, perineal wound infection/pain, hospital admission and general maternal health.

Progress So Far

UHW has 6000 births a year; recruitment commenced from September 2016 and to date has recruited 223

women. Activity based funding to the Health Board from ANODE now stands at £379,100.

We have achieved this by being delivery suite based and having had experience of intrapartum trials.

Over 120 staff have been trained to recruit for ANODE, for which the Health Board and Health & Care Research Wales accepted study specific GCP. We not only aim to recruit successfully but to produce quality research.



New research grant for establishing the safety of waterbirths

20 April 2018

Mother and new born baby Professor Julia Sanders has been awarded £900,000 to lead a study exploring the safety of waterbirth for mothers and babies.



Over the past couple of decades giving birth in water has become increasingly popular in the UK. Many women now use a birth pool during labour for pain relief, and some, perhaps up to 60,000 women a year in the UK, choose to remain in the pool for the birth of their baby.

Many professionals and parents have strong opinions on waterbirth. Some are great advocates, who promote the benefits of waterbirth, whilst others remain concerned that women who give birth in water may be exposing themselves or their baby to additional unnecessary risks.

Julia Sanders, Professor of Clinical Nursing and Midwifery, who works jointly between the School of Healthcare Sciences, Cardiff University and Cardiff & Vale University Health Board said: "Most maternity units in the UK now offer waterbirth as an option to women, but to date there have not been studies large enough to show whether waterbirth is as safe for mothers and

babies as using a pool for pain relief during labour, but then getting out of the pool before birth.

The POOL study plans to answer this important question about the safety of waterbirths. The study will include data from births during the six year period 2015-2020 in around 30 NHS maternity units, and compare the outcomes from 15,000 waterbirths with 15,000 births that took place out of water.

Cardiff based Consultant Midwife Abi Holmes, one of the grant's co-applicants explained: "It is important this study is conducted without disturbing women in labour or just after birth, for this reason the study will use information collected as part of each woman's maternity record stored at hospitals in computerised systems. For babies that need specialist care after birth, the study will also use data held by the National Neonatal Research Database.

The Royal College of Midwives Professor of Midwifery, Billie Hunter, who will lead the area of the study exploring why some maternity units have higher rates of waterbirths than others said: "Having a baby is always a special time and parents want information to make the best choices for themselves and their baby.

This important study brings together leaders in midwifery, obstetrics, neonatology, and together with staff from Cardiff University's Centre for Trials Research, and the NCT who represent parents, we will produce new information on waterbirth so future parents can be better informed on their birth options."

The study is being funded by the NIHR HTA, project 16/149/01 - The POOL Study.

For more information please
contact sandersj3@cf.ac.uk
or poolstudy@cardiff.ac.uk

Maternity research paper wins top prize



Professor Julia Sanders with Professor Peter Brocklehurst and colleagues at the BMJ awards

Julia Sanders, Professor of Clinical Nursing and Midwifery, School of Healthcare Sciences, Cardiff University and Cardiff & Vale University Health Board, was a member of the BUMPES Epidural and Position Trial Collaborative Group who were recently awarded the 2018 BMJ UK Research Paper of The Year.

The paper, published in The BMJ last October, described the results of the BUMPES trial which investigated whether the position a first-time mother with a low dose epidural adopts during the end stages of labour increases the chance of a birth without interventions such as forceps or Caesarean section.

'Low dose epidurals' are now the standard method of epidural pain relief offered to women in labour, and are popular, being chosen by around 30% of women giving birth in the UK.

BUMPES was a large Randomised Trial, led by Professor Peter Brocklehurst, of Birmingham Clinical Trials Unit. Over 3000 women, expecting their first baby were recruited from 41 participating sites in the UK,

between October 2010 and January 2014 including 296 women from the University Hospital of Wales in Cardiff. The study concluded that women adopting a position lying down on their side, rather than being upright, in the later stages of labour, were more likely to give birth to their baby without medical assistance.

Julia said the results of the trial, which was funded by the National Institute for Health Research, provided important new information for midwives and would help pregnant women, make informed choices about their position in the second stage of labour.

Julia said "as a team we were delighted to win this award. This study shows the importance of questioning the care we provide to women and showed that there are simple things we can do to

help women with epidural pain relief achieve the normal birth they desire".

"Getting the results of this study into midwifery practice is important for women. It is easy to implement and means that tens of thousands of women and babies in the UK, and hundreds of thousands of women and babies in the world, will be helped to have a straightforward birth and avoid a birth assisted with forceps, vacuum or Caesarean section."

"The study also demonstrated the importance of maternity units working together, and having midwives able to recruit the large numbers of women needed in clinical trials to provide us with clear answers to important research questions."



The winning paper can be accessed at <https://www.bmj.com/content/359/bmj.j4471>

SEPT
05

**Launch of the All Wales
Cancer Nurses and AHPs
Research Network**

10am -
4pm

**Free
event**

Meet Welsh nurse and AHP Chief Investigators in cancer research. Your opportunity to engage in and shape future research for the benefit of people with cancer in Wales.

Register free: cancernurses.eventbrite.co.uk



Future Forum Dates

Wednesday 18 July 2018 14:00 – 16:00

Research Forum @ Lecture Theatre 3, UGF A block UHW

R&D Update

Library Services to support your research: Rosemary Soper

The Model Ward: Nutrition & Hydration: CD&T

Friday 28 September 2018 10:00 – 12:00

MacMillan World's Biggest Coffee Morning

Tuesday 27 November 2018 14:00 – 16:00

Research Forum

13 March 2019 Events to celebrate British Science Week

*Seeking volunteers to help with activities

Monday 20 May 2019 International Clinical Trials Day

Events to be confirmed...

Tuesday 16 July 2019 14:00 – 16:00

Research Forum