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South East Wales
Trials Unit

Uned Ymchwil
De-ddwyrain Cymru

South East Wales Trials Unit

Annual Report 2015 - 2016



Ymchwil Iechyd
a Gofal **Cymru**
Health and Care
Research **Wales**



Ariennir gan
Lywodraeth Cymru
Funded by
Welsh Government

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Foreword

Welcome to this annual report of South East Wales Trials Unit (SEWTU) activities and achievements from 1st April 2015. This represents the start of our new three-year programme of work funded by the Welsh Government and importantly the continuation of our mission to increase the number and quality of health and social care studies led by Welsh investigators.

The last year has been a period of important structural change for SEWTU as it has come together with two other established trials units to form the Centre for Trials Research at Cardiff University. The Centre is led by Professor Kerry Hood and encompasses a strong Cancer theme with research staff from the Wales Cancer Trials Unit and Haematology Clinical Trials Unit, in addition to our own team in SEWTU. A centre with a larger base of methodologists and specialist trials staff provides significant opportunities for innovation, development, learning, resilience and a major focus for research at a national and international level.

SEWTU staff have been investing in the activity required to make this happen and I am indebted to their enthusiasm to make this work. The benefit for me of compiling a report such as this is the opportunity it affords to reflect on the successes achieved and the quality and motivation of our own team across such a wide range of exciting research areas. Therefore, I wish to express my thanks to the Welsh Government, and to Cardiff University for maintaining their financial commitment to SEWTU, to the investigators who have entrusted with us their developing research ideas and to our own staff who have so skilfully made this research happen.

Professor Mike Robling
 Director, South East Wales Trials Unit,
 Centre for Trials Research

Introduction

What does South East Wales Trials Unit (SEWTU) do?

SEWTU has a mission to design, conduct, analyse and publish clinical trials and other well-designed studies. We maintain expertise in a number of specific clinical and methodological areas, although our portfolio of work covers diverse topics from pharmaceutical trials to the evaluation of complex interventions. This is because we retain an open-door for all good ideas from investigators across health and social care settings. We conduct methodological research around outcomes assessment, complex interventions and researching in complex environments. We run studies across Wales, the UK and internationally.

SEWTU has established itself at the cutting edge of complex and challenging trials, both methodologically and clinically. Its vision is to design and deliver internationally excellent, locally relevant applied research in health and social care. One particular trajectory for our research includes working in settings and in populations often excluded from research such as social care (e.g. nursing homes, children's social care) and people with neurodevelopmental disorders (e.g. learning disabilities).

SEWTU aims to:

- Improve the number and quality of trials and other well designed studies in health and social care led by Welsh investigators
- Coordinate multi-centre trials and other well designed studies across Wales, the UK and beyond
- Develop portfolios of expertise which are recognised both nationally and internationally
- Enhance collaborative working within the Health and Care Research Wales funding infrastructure and beyond
- Provide support and advice to staff working in health and social care to develop high quality research proposals

We have an international reputation for research within Infections, Children & Young People and Behaviour Change. This is evidenced by publications in high impact general medical journals. We have developed portfolios of work in Medical Devices and in The Older Person. (Figure 1).

The Unit has partnerships with other elements of the Health and Care Research Wales-funded infrastructure and the NHS and social care sector across South East Wales and beyond. We continue to develop the processes and systems to ensure that data and samples collected through prospective studies are made available for future research. By doing so we can increase the value to the public of the original investment in primary studies and the potential for greater learning and impact from our work.

The investment from Health and Care Research Wales into SEWTU in combination with that from Cardiff University supports a senior team responsible for strategic

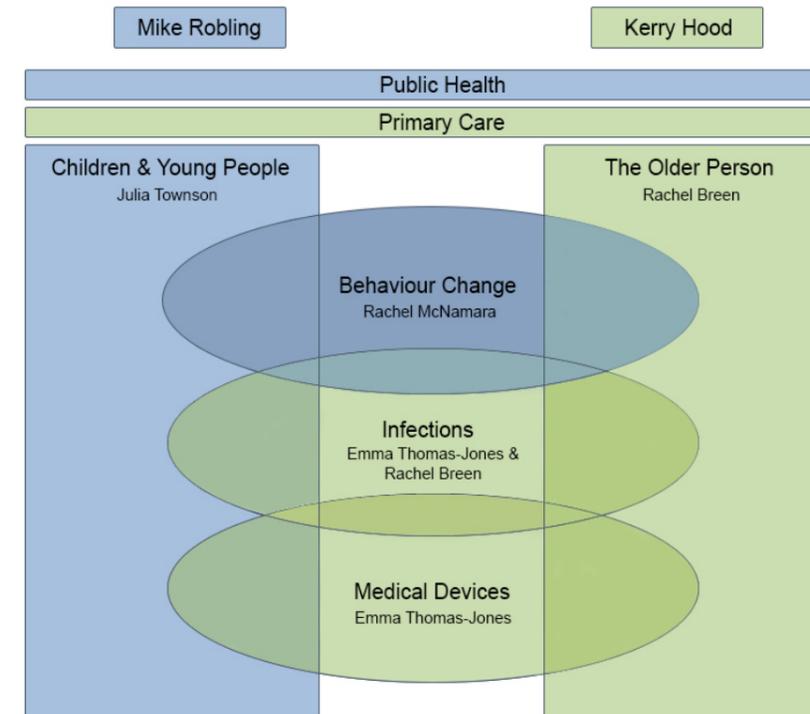


Figure 1: SEWTU Thematic Areas and Leads

and operational management of the unit. It provides for core methodological and professional services expertise in the form of trial managers, statisticians, qualitative methodologists, information systems, quality assurance, business management and communications (see 'Who is Who in SEWTU').

What does the Research Design and Conduct Service (RDCS) do?

The RDCS supports NHS and social care professionals in developing research projects for the benefit of the service users and the public within Wales.

The RDCS aims to:

- Support the development of a research and evaluation culture within partner organisations
- Support the development of a research methods training strategy for partner organisations
- Provide links to experienced researchers for partner organisations

The RDCS South East Wales is delivered by SEWTU. Its specific partner organisations are Cardiff and Vale, Cwm Taf and Aneurin Bevan University Health Boards, Velindre NHS Trust and Public Health Wales.



RDCS events are one way SEWTU supports increased research capacity in Wales

Who is Who in SEWTU



Mike Robling Director of SEWTU



Monica Busse Associate Director SEWTU



Rachel Breen Research Fellow



Richard Haggerty Communications Officer



Kerry Hood Director RDCS and Director of the Centre for Trials Research



Sue Channon Deputy Director RDCS



Lucy Brookes-Howell Senior Research Fellow



Damian McAuliffe Business Manager



Liz Merrifield QA Manager



Emma Thomas-Jones Research Fellow



Gareth Watson Head of Information Management

Rachel McNamara Research Fellow



Rebecca Playle Senior Research Fellow



Julia Townson Research Fellow



Work Packages

There are six work packages (WP) that comprise the SEWTU programme over the three years of its current activity. Each is described below and activity in this first year of our new programme.

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Unit development and management

What is it? The work package addresses staffing structure, management and systems that underpin the high quality delivery of unit research.

What resources are involved? Core members of SEWTU staff who contribute to this work package are those supporting quality management systems (QA manager, auditor), senior unit management and associated professional services staff.

What have we done in this year? We have formally instituted the new Centre for Trials Research. This has involved core SEWTU staff forming part of the cross-cutting teams for the Centre (Quality Assurance & Safety, Information Services, IT, Business management) and are now currently establishing common standard operating procedures (SOPs) and policies for the Centre. Completing this work (planned for end of August 2016) will enable us to renew our current registration as a UKCRC trials unit, this time as part of the Centre for Trials Research. This activity is also vital to maintain our regulatory responsibilities as a trials unit, which will include inspection by the Medicines and Healthcare products Regulatory Agency (MHRA). There are 45 fully registered trials units in the UK and registration requires core SOPs across 22 areas (a total of 60 SOPs for SEWTU).

UKCRC
Registered
Clinical
Trials Units



Working with other groups

What is it? This work package addresses developing and working closely with other research groups to design and run high quality studies. These would include other groups funded by Health and Care Research Wales as well as those elsewhere in Wales and beyond.

What resources are involved? Core members of SEWTU staff who contribute to this work programme include the unit directors, leads for the unit research themes and other senior methodologists.

What have we done in this year? SEWTU researchers are formally contributing to other Centres and Units funded by Health and Care Research Wales (for example, Wales Centre for Primary and Emergency Care Research: Professor Kerry Hood; the National Centre for Population Health and Wellbeing Research, Professor Mike Robling; Brain Repair And Intracranial Neurotherapeutics - Wales BRAIN Unit, Professor Monica Busse, Professor Kerry Hood). We have been developing with colleagues in North Wales our policy for embedding good practice in Welsh language in all our systems and processes. Although we remain to establish our plan for working with the Wales School for Social Care Research, we will be aiming to make progress with that now a new Director for the School has been appointed.



Professor Monica Busse, newly appointed Director of Mind, Brain and Neuroscience, is playing an important role in the new Wales BRAIN Unit

Development of new studies

What is it? This work package involves engaging with new and existing investigators to develop, submit and win research funding from key funders. This will include working within our stated research themes and also new areas as we retain an open-door policy for good research ideas.

What resources are involved? All research and many of our professional services staff are involved in this core activity. Commonly unit directors and leads for our core groups (statistics, trial management, qualitative methods) will initially meet and work with investigators and often other staff will join teams to develop new research ideas. Approaches may come directly to SEWTU members of staff or indirectly through the consultants working in the Research Design and Conduct Service hosted within SEWTU.

What have we done in this year? Fifteen new studies have been awarded in the reporting period (with a value in excess of £5M, more than £2.6M of which came directly into the unit) and a total of 35 grant application submissions. Four of the awarded studies are led by a SEWTU investigator and two studies are PhDs. We have 66 studies on our portfolio and in the last year we have reviewed 83 studies for unit adoption (accepting 81) via the SEWTU portfolio committee meaning that each of these would be worked on with the intention of submitting them for funding.

Oversight of funded studies

What is it? This work package involves the high-quality delivery of funded research as well as extensive dissemination.

What resources are involved? Senior researchers in SEWTU supported by core funding (directors, senior trial managers, senior statisticians, lead for qualitative methods) will contribute to this activity, in addition to study staff appointed to projects. The maintenance of and training in unit standard operating procedures supports this activity. We have previously run dedicated writing events to support the writing of publications from completed work, and we have continued this approach. We have also now appointed a new Communications Officer, Mr Richard Haggerty, to develop and support our communications strategy.

What have we done in this year? We have published 35 papers in scientific journals. The average impact factor for journals published in was 5 and 9% of our publications were in journals with an impact factor greater than 7. Some publications will be relevant to more than one SEWTU theme area. Our publications fell into the following unit themes: Behaviour Change (7), Children and Young People (11), Infections (8), Medical Devices (2) Methods (4) and the Older Person (4). We reported three studies as part of the NIHR Journals Series: 'All-Wales Licensed Premises Intervention to Reduce Alcohol-Related Violence' (AWLPI Study, Professor Simon Moore, Cardiff University), 'A feasibility randomised controlled trial of a motivational interviewing-based intervention for weight loss maintenance in adults' (WILMA study, Dr Sharon Simpson, Glasgow University), 'A randomised placebo-controlled trial of oral and topical antibiotics for children with clinically infected eczema in the community: the ChildRen with Eczema, Antibiotic Management (CREAM study)' (Dr Nick Francis, Cardiff University). We have published two Cochrane Systematic Reviews. In March 2016, unit staff contributed to the launch of the Wales Brain unit and end of study events for the Building Blocks trial (led by Dr Mike Robling) and OBS2 trial (led by Professor Peter Collins, Cardiff University).



Dr Mark Kelson, senior statistician and RDCS consultant

Methodology and professional development

What is it? This work package involves undertaking methodological research and developing the unit workforce.

What resources are involved? Most staff within the unit will contribute to this work package, including the directors and senior research staff.

What have we done in this year? A methods research theme has been established led by senior statistician Dr Mark Kelson and senior trial manager Dr Nadine Aawar. They have been working with the directors developing the methods strategy for the unit. Four methods papers have been published and we have contributed to a paper describing the work of Trials Forge Platform (www.trialforge.org) which is leading the development of trials methods (particularly efficient study designs). Professor Kerry Hood and Professor Mike Robling have been funded by the MRC Methodology Research Programme as co-investigators with lead Professor Laurence Moore (Glasgow University) to develop guidance on exploratory trials for complex public health interventions. Finally, we have five PhD students registered or supervised by SEWTU researchers.

Research Design and Conduct Service



The Research Design and Conduct Service provides one to one consultant support to NHS and social care professionals to enable them to develop high quality grant applications

What is it? The Research Design and Conduct Service South East Wales aims to provide a high quality and responsive research advisory service to the NHS and Social Care in South East Wales.

What resources are involved? A consultancy team, with directorial leadership and professional services, administrative and communications support form the core advisory service. During the course of the year there has been some change in team personnel with one of the core consultants, Dr Claire O'Neill undertaking a secondment before moving onto a new position. This has provided opportunities for other methodologists in SEWTU to start providing research consultancy.

What have we done in this year? A key aim for this year was to contribute to the new model of All Wales RDCS support alongside the other two hosted services in West and North Wales. This has resulted in the establishment of a single identity for the advisory service across Wales with a common charter, agreed targets, visual identity, online portal and consultant handbook. The main service activities have been to provide advice and support to 81 research ideas in the NHS or social care and to have supported the submission of 30 funding applications. As part of its mission, the RDCS has run two group outreach events. In September 2015 a one-day event attended by 45 delegates provided support for developing funding applications. In January 2016 a two-day non-residential writing retreat for 20 delegates provided support for individuals and teams in advance of funding submissions.

Key Achievements

Establishing research partnerships and priorities

Expertise in research with people with a learning disability

SEWTU has established a considerable national reputation as a centre for conducting high quality studies in the field of learning disabilities, with Dr Rachel McNamara as the unit lead. An example of one such study, which commenced this year, is 'Who's Challenging Who', led by Professor Richard Hastings from the University of Warwick.

This trial will test the effectiveness of a staff training intervention to improve support staff attitudes and empathy towards adults with learning disability and challenging behaviours. The study primarily addresses a recognised need for developing an effective workforce in adult social care.

What we will do: We aim to recruit 118 residential settings into the trial with two members of staff from each location. The Who's Challenging Who training course is a half-day in length and involves a co-trainer with a learning disability and challenging behaviour working with a co-trainer without disability.

A pilot study established the content of the training programme, which is now being evaluated in this trial. Involving the public has led to detailed feedback on the content of the training programme and the delivery of the course.

Potential for impact: As well as being grounded in longer-term research and theoretical development, Who's Challenging Who offers a practical solution to the inclusion of the perspectives of users with learning disability and challenging behaviours in staff training to directly impact social care practice.

The study is funded by National Institute for Health Research (NIHR), School for Social Care Research and Dr Rachel McNamara is the unit lead for the study

Research Priority Setting in Care Homes

Work undertaken by SEWTU researcher Victoria Shepherd this year aimed to develop an informed set of research priorities within the UK care home setting. The number of older people requiring long-term care is rising, with increasingly complex care needs. However, there is little evidence for much of the care provided in such homes partly because less research takes place in this setting compared with hospitals or the community. With a wide range of potential research topics and limited resources, this study sought to involve stakeholders in setting priorities for future research.

What we did: Care home staff across the UK were invited to form an 'expert panel'. They took part in a series of consensus building rounds using the Delphi technique to identify, and then rank, the topics they considered were most in need of further research.

What we found: Among the most highly rated themes were person-centred care, staffing levels and quality of staff in care homes, and end of life care. The next steps are further work to address the research questions identified as priorities and to explore the evidence-practice gap for areas with existing evidence that are not currently



Research Priority Setting in Care Homes has led to opportunities for researchers to focus on important but hitherto neglected areas of research

implemented. It also important to explore further the priorities of residents, their families and friends.



Victoria Shepherd in SEWTU is currently leading on the next phase of Research Priority Setting in Care Homes

Creating impact: This was the first study to establish research priorities for the long term care of older people in the UK. This is an essential part of the research cycle with many funders wishing to incorporate the findings of priority setting work into commissioning processes. To this end, the South East Wales Unit has organised an event for July 2016, which will involve researchers from all over Wales, PRIME Centre Wales and The Centre for Ageing & Dementia Research.

"This study provides an exciting opportunity for making sure that future research ... can be targeted towards areas that provide the most benefit. Older people deserve access to the best evidence-based care."

- Victoria Shepherd, lead investigator for Research Priority Setting in Care Homes project

Making an impact

Building Blocks

Children born to teenage mothers in the UK can face individual and social challenges that can have a detrimental long-term impact upon their life chances. Providing support early to new families is a policy priority across the UK. Professor Mike Robling, Director of Population Health Trials and lead for SEWTU, led the Building Blocks trial to assess the impact of one highly regarded home visiting intervention, the Family Nurse Partnership. In October 2015 the trial – the largest conducted in the world of this intervention - was reported in The Lancet.

The study found that despite an intensive programme of support provided to families in their homes, the expected benefits of the scheme were not evident in the short-term. However, by the time the trial results were available the programme was being provided to over 15,000 families at over 135 sites in England alone. Over the last year, the trial team has worked with service, practice and policy leads to consider how core messages from the trial should be disseminated to key stakeholders and to consider next steps for policy and research.

In February 2016, SEWTU hosted a large-scale stakeholder conference in Cardiff's SWALEC stadium to review the trial results and policy response. Attended by service, practice, policy leads and practitioners across the UK and researchers from the UK, continental Europe, Australia and the US the longer term research agenda in this area was explored. The Building Blocks team are currently undertaking a follow-up study (funded by NIHR Public Health Research) taking a novel approach to using routine data solely to explore the programme impact on child maltreatment.

To find out more, please visit: bit.ly/buildingblockstrial.



Developing high quality research

The core funding invested in SEWTU provides sustainability for experienced researchers able to deliver high quality studies. Two examples of work completed and reported on this year are The CREAM study led by Dr Nick Francis from the Division of Population Medicine and Seal or Varnish led by Professor Ivor Chestnut (both Cardiff University investigators).



Do antibiotics help improve symptoms in children with infected eczema?

Eczema is a common condition in young children and sometimes gets worse, possibly due to particular bacteria on the skin. In March 2016, Dr Nick Francis reported the results of his trial evaluating treatments for infected eczema in young children. In the study, 113 children received antibiotics by mouth or as a cream, or received no antibiotics at all over the course of one week. By using placebo treatment, which would appear as normal medication but in fact have no medical effect, none of the families were aware of what treatment they were receiving.

Dr Francis found that antibiotics may have no effect or may make the infected eczema worse. Antibiotics are unlikely to be beneficial after one week of treatment. The work was funded by the NIHR Health Technology Assessment Programme who have published the full report. The research team concluded that most children with less severely infected eczema offered standard steroids should not receive antibiotics. This study should now inform doctors and others caring for children with eczema making treatment choices.

The CREAM study was fully coordinated by SEWTU, and the unit lead was Dr Emma Thomas-Jones.

What works best to prevent tooth decay in young children?

Tooth decay remains a significant problem for children, particularly those from deprived backgrounds where levels of decay can be three times higher than in better off areas. In some areas, 69% of 12 year olds have decay in their permanent teeth. Most decay is found on the biting surface of the first molars, which erupt at age six. Two treatments are known to prevent decay - pit and fissure sealants applied to the biting surface and six-monthly applications of fluoride varnish.

What is not known is which of these two treatments works best, which is the most cost-effective and which is most acceptable to children and their parents. This is the question asked by Professor Ivor Chestnut and the Seal or Varnish team in SEWTU who successfully completed their study earlier this year.

The study compared the proportion of children who received the alternative treatments who are caries-free in their first molar teeth after three years. Although the results are yet to be reported in public, the findings from this study will be applicable across the NHS. This will be particularly relevant in areas of high need with greatest health inequalities.

Dr Rebecca Playle, senior lecturer in statistics, was the SEWTU lead on this study. Study results will be reported here: <http://www.nets.nihr.ac.uk/projects/hta/0810404>.



Publication highlights 2015-16

Atwan A1, Ingram JR, Abbott R, Kelson MJ, **Pickles T**, Bauer A, Piguet V. Oral fumaric acid esters for psoriasis. Cochrane Database Syst Rev. 2015 Aug 10;8:CD010497. doi: 10.1002/14651858.CD010497.pub2.

6.0

Macbeth F, Noble S, Evans J, Ahmed S, Cohen D, **Hood K**, Knoyle D, Linnane S, Longo M, Moore B, Woll PJ, Appel W, Dickson J, Ferry D, Brammer C, Griffiths G. Randomized Phase III Trial of Standard Therapy Plus Low Molecular Weight Heparin in Patients With Lung Cancer: FRAGMENT Trial. J Clin Oncol. 2016 Feb 10;34(5):488-94. doi: 10.1200/JCO.2015.64.0268

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Robling M, Bekkers M, Bell K, Butler CC, **Cannings-John R**, **Channon S**, Corbacho Martin B, Gregory JW, **Hood K**, Kemp A, Kenkre J, Montgomery AA, **Moody G**, **Owen-Jones E**, Pickett K, Richardson G, Roberts ZES, Ronaldson S, Sanders J, Stamuli E, Torgerson D. Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): a pragmatic randomised controlled trial. The Lancet, vol. 387, Issue 10014, pages: 146-155. 2016.

45.2

Teepe J, Little P, Elshof N, Broekhuizen BD, Moore M, Stuart B, Butler CC, **Hood K**, Ieven M, Coenen S, Goossens H, Verheij TJ; GRACE consortium. Eur Respir J. 2016 Jan;47(1):327-30. doi: 10.1183/13993003.00611-2015. Epub 2015 Nov 5. Amoxicillin for clinically unsuspected pneumonia in primary care: subgroup analysis.

6.4

White J, Zaninotto P, Walters K, Kivimäki M, Demakakos P, Biddulph J, Kumari M, De Oliveira C, Gallacher J, Batty GD. Duration of depressive symptoms and mortality risk: the English Longitudinal Study of Ageing (ELSA). Br J Psychiatry. 2016 Apr; 208(4): 337-342

8.0

Impact Factor



“Instability of care is thought to be one of the main reasons that many looked after children experience poor educational and health outcomes. This research will provide new evidence about how to increase stability and improve children’s and carers’ well-being. It breaks new ground in its research design and scale in the context of children’s social care in Wales.”

- Professor Sally Holland, the Children’s Commissioner for Wales and involved in early stages of winning funding for the Confidence in Care study

Research in social care

Our portfolio includes several studies within social care settings, an area that we keen to support and further develop. One study that we opened this year is an example of where we are doing this, the Confidence in Care study led by Professor Mike Robling.

The Big Lottery Fund Wales awarded a coalition of charities, including Cardiff University £4.75 million to improve outcomes for children living in foster care, residential children’s homes and kinship care. SEWTU are working with the Children’s Social Care Research and Development Centre, which is also based in Cardiff University,, to deliver the study.

The research will determine whether a training programme for foster carers improves outcomes for looked after children. The training aims to stabilise and enhance care and reduce the number of children and young people having to move home due to placement breakdown. Carers will be followed up for one year after receiving the training programme and outcomes compared to those who have not yet received the programme.

An exciting aspect of this study for SEWTU is that Confidence in Care is a consortium of five charities and academic bodies, including Cardiff University, The Fostering Network Wales, Action for Children, Barnardo’s and The Adolescent and Children’s Trust.

Developing professional practice



Ms Gwenllian Moody from SEWTU won the prize for best 'elevator pitch' for her PhD research

Society for Academic Primary Care

In March 2016, SEWTU co-hosted the South West Society for Academic Primary Care (SWSAPC) 2016 Annual Meeting along with colleagues in the Division of Population Medicine, Cardiff University. The event brought together over 160 experts and researchers in the field of primary care to present research intended to inform best practice. The South West region is the one of the largest and most active in the UK and SEWTU researchers have traditionally featured heavily in both regional and national meetings. This reflects its expertise in primary care, community-based studies and thematic strengths such as Infections and Children and Young People.



Dr Fiona Lugg presenting on Routine Data Linkage at SWSAPC 2016

Dr Emma Thomas-Jones (research fellow and senior trials manager) led the SEWTU contribution to the meeting organization. Researchers from SEWTU presented on a wide range of topics including care home settings, teenage mothers, point of care testing for urinary tract infection. The scientific meeting has always been an opportunity for career development for researchers and this was no exception with Ms Gwenllian Moody from SEWTU winning the prize for best 'elevator pitch' for her PhD research on measuring child maltreatment through the use of routine data sources.

Professional development

One of the reasons for establishing a trials unit in Cardiff back in 2006 was the need to develop a critical mass of experienced trials researchers and then to have an infrastructure to retain skilled staff. It is therefore particularly pleasing to see how staff in the unit are currently pursuing higher degrees alongside their own work. These include Gwenllian Moody (research assistant / data manager), David Gillespie (research associate / statistician), Vincent Poile (PhD student / developer), Dunla Gallagher (PhD student / data manager) and Nigel Kirby (Diploma in Clinical Trials).

Supporting new studies through core support

The PRINCESS Study

Core funding allows SEWTU researchers to develop new research ideas and funding applications with external investigators. Importantly it also enables our teams to support key set-up tasks required before funded activity can start. A good example of this is the PRINCESS (Probiotic to Reduce Infections iN CarE home reSidentS) study led by Professor Chris Butler (University of Oxford).

Older people living in care homes are prescribed far more antibiotics than the general population. However, high antibiotic use increases the risk of antibiotic resistance in care homes that can spread within care homes and to hospitals and the community. Infections in care home residents cost the NHS more than £54 million a year in hospitalisation alone. Reducing antibiotic use and antibiotic resistance could improve residents' quality of life, save money, and help preserve the usefulness of existing antibiotics.

There is an urgent need to reduce antibiotic resistance through infection prevention in care homes. Probiotics are live bacteria that may offer health benefits by improving immune function and reducing carriage of potentially harmful bacteria. However, research involving their effectiveness in care home residents is currently lacking.

The PRINCESS Study is funded (£1.8M) by the National Institute for Health Research Efficacy and Mechanism Evaluation (NIHR-EME) Programme. It is being co-ordinated by SEWTU in collaboration with the University of Oxford. The study will involve 330 residents from care homes in Wales and England. It is also the first major study funded by this prestigious funder run from Wales and extensive, complex early set-up work has been made possible through the core resource provided through SEWTU.

“Other than vaccination and good hygiene, there are few proven ways to prevent infections in older care home residents - so they represent an important target in efforts to combat antibiotic resistance. Our study should answer the question whether or not daily probiotics prevent infections.”

- Professor Chris Butler, Chief Investigator PRINCESS Study, University of Oxford



Public involvement and making research more relevant

Last year we have reviewed our approach to public involvement as we have come together with two other trials units to form the new Centre for Trials Research. We needed to reflect the variety of models of public involvement that may improve research. A good example of how public involvement has critically influenced how a study has been designed and conducted is the EDDY study. The study is led by Professor Lesley Lowes with SEWTU lead researcher, Julia Townson.

The study was funded by the Wales Government to develop an awareness campaign for the earlier detection of type 1 diabetes in children. Delays in diagnosing diabetes can be potentially life-threatening. The study was discussed at the Health and Care Research Wales Involving People Network meeting in February 2016.

Here, Julia and two parent representatives Stephen Thomas and Sarah Earle-Jones discuss their involvement in EDDY:



Julia Townson from SEWTU and Stephen Thomas at the Involving People Network Annual Meeting

Stephen: ... you brought us on board as parents to look at the intervention in schools. Some of us were parents with children with diabetes and some, like myself, were fortunate enough not to have children with type 1 diabetes. Why did you feel that it was important that you had that mix?

Julia: Parents with children with type1 diabetes are well aware of the symptoms. Therefore, it was important to canvas the opinions of those without to ensure the intervention had the most chance of success.

Stephen: ... you brought us together for a number of meetings to design the intervention. Did it go as you expected?

Julia: Well, in some ways yes and in some ways no. Yes, I was confident that parents would be able to design something - we were thinking a fridge magnet, that sort of thing, but what they came up with exceeded our expectations! The shopping bag was such a fantastic idea.

Stephen: What about you Sarah, what were your expectations?

Sarah: I had none! I arrived at the first meeting with some trepidation but I think to be honest that we all felt like that. By the end of the meeting I was excited by the task entrusted to us and felt quite passionately about the need to get information 'out there', to increase awareness of type 1 diabetes. I was shocked by the stories relayed to us by the other group members who were parents of children with type 1 diabetes.

Julia: What about your expectations Stephen?

Stephen: I guess, initially, I didn't have much in the way of expectations only that I was enthusiastic about taking part as although my daughter is not a diabetic my mother had type 1 diabetes. However, I was very pleased with the way that you set us up as a panel as we were there from the beginning and although you had ideas about the type of interventions, you were very open to our input.

Julia: Yes, we wanted as much of your input as possible. How did you think that your input changed things?

Stephen: We had a number of important conversations about the best way to raise awareness in a condition that is thankfully relatively rare ... Therefore, we felt, as a group, it was important to get the message across in a way that wasn't a single intervention which got lost but rather in the form of perhaps an everyday item so therefore, along with the leaflets and messages that were going into GPs we decided that using a bag, as with the 5p charge people are saving bags, would be an effective way of doing it.

Stephen: Sarah what did you think about your input?

Sarah: I too was impressed by the level of input that we were given and that our contributions were both valued and valid. It was an exciting project to be a part of and I feel a splash of pride when I notice the blue bags popping up as I'm out and about!

Working with the NHS

The Research Design and Conduct Service

A key means by which we work with the NHS and social care is through the Research Design and Conduct Service. The core consultant team are able to provide a range of methods support including overall study design, statistical design, outcome measurement, trial management, qualitative approaches. In addition they can also draw upon additional methodologists from SEWTU if capacity or research questions require that. The value and resilience of that approach was evidenced this year when a member of the core team moved on to a new position and we were able to ensure continuity of service through identifying existing staff.

The RDCS South East team provided support to a large number of submissions to the Health and Care Research Wales Research for Patient and Public Benefit (RfPBB) call, as one part of its overall record of submission this year. The service has been able to respond to 100% of all initial approaches within three working days. When surveyed about their experience of support provided, 72% described the advice received as 'very good' (a further 28% replied 'good') and 81% said that they would definitely use the RDCS again. The conversion rate of approaches to submissions was 37% for those providing feedback.

Good communication with the Health Board Research and Development departments is crucial to the work of the RDCS and we are in regular contact with them. The Research and Development Directors for each of the Health Boards sit on our steering group and this has met twice this year. We have also met with them individually on a quarterly basis to discuss the staff research support needs and research priorities within their organization.



Conclusions and Looking Forward



Conclusions

The investment in SEWTU by the Welsh Government and Cardiff University allows a core group of experienced researchers to work with new and existing Welsh investigators to deliver research that will be important to the Welsh public and internationally regarded. New work and new investigators may come through a variety of routes such as the RDCS, our established partnerships with other funded elements of the Health and Care Research Wales infrastructure, from academic partnerships within Cardiff University or other higher education institutions, or direct approaches from investigators to individual members of our team.

We are then able to develop ideas into research design with investigators and usually to submission for funding. If successful we can then work with investigators to either take full responsibility for running the study – full coordination, or work in partnership where SEWTU will play a defined role. We have areas of particular areas of expertise – such as Infections or Behaviour Change where we have continued to develop our portfolio and have leads within the unit who welcome approaches in their field. We have also welcomed investigators from outside those themed areas and are keen to be working in new areas that offer benefit for patients and the public in Wales.

Looking forward

In the next 12 months we will complete the process of forming the Centre for Trials Research led by Professor Kerry Hood, including registration as a single entity with the UKCRC. Other important changes in SEWTU will start to bear fruit with the appointment of further senior staff within the unit including Professor Monica Busse as Director for Mind, Brain and Neuroscience and Dr Rachel McNamara as senior research fellow and head for trial management.

In the last year we have been engaged with key initiatives such as the HealthWise Wales project led by Professor Shantini Paranjthy, expected to have a major impact on improving the health and wellbeing of people in Wales. We are also aiming to work closely with the new Wales School for Social Care Research both through the RDCS and on SEWTU studies. Finally, as we await the outcome of a number of recent funding submissions we optimistically look forward to new opportunities to innovate methodologically and provide evidence that will make a difference to the life of people in Wales and beyond.

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