# **IRISH RESEARCH NURSES NETWORK**

12<sup>th</sup> Annual General Meeting & National Conference: RESEARCH NURSES & MIDWIVES ROADMAP River Lee Hotel, Cork 13th & 14th November, 2019









#### Foreword



On behalf of the IRNN Working Group I am delighted to welcome you to our twelfth annual AGM and conference. Research Nursing and Midwifery in Ireland has come a long way since 2008 when the IRNN had their first meeting in the Davenport Hotel, Dublin. Since 2018, the IRNN has been the Irish lead for the Whitehouse Report, members of the steering committee for Clinical Research Development Ireland (CRDI)'s 'Future Investment In Clinical Research' Report and contributed to the Health Research Board (HRB)'s 'Review of the Clinical Research Infrastructures in Ireland'.

There are still many challenges, but by working together with stakeholders such as the HRB and HSE we can continue to highlight the importance of the role and the necessity of a skilled research nurse/ midwife resource to support the conduct of high-quality research in the healthcare setting.

The theme of the conference is 'Research Nurses & Midwives Roadmap' and we are delighted to present the results from our 'Count Me In' survey. The aim of this survey was to determine how many research nurses/midwives are currently working in Ireland, where they are located, the terms of employment and their roles and responsibilities.

We are privileged to have expert speakers to talk about their research and their experiences in developing the role of research nurses and midwives. The Second Forum includes speakers presenting their own research projects. Abstracts submitted for this session, and for the poster presentations, are included in your conference pack. Please take time to review the posters during refreshment breaks.

The commitment of IRNN to promoting excellence in clinical research, and providing a platform for networking, education and support, continues to be recognised in a very tangible way in the form of funding from the HRB to support the professional development of clinical research nurses and midwives. This includes funding for the annual conference and the IRNN/ HRB Research Nurse/Midwife Support & Development Grant.

The IRNN conference is not just for nurses and midwives – we are delighted to welcome colleagues from other healthcare disciples, science, industry and patient organisations who join us today. We hope you enjoy the day, and very much welcome your comments and feedback.

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Dr Hazel A Smith Chairperson IRNN

With special thanks to: The Health Research Board (HRB), HRB Trials Methodology Research Network (HRB-TMRN), HRB Clinical Research Coordination Ireland (HRB-CRCI), 4D Pharma Cork Ltd and LongBoat.

## **IRNN COMMITTEE MEMBERS**



Dr Hazel A. Smith, Registered Midwife; PhD. IRNN Chairperson Contact: <u>smith.hazelann@gmail.com</u>

Ms Carole Schilling, Registered General Nurse; MSc Nursing. IRNN Vice-Chairperson Current Role: IRNN Project Manager, based at RCSI Clinical Research Centre Contact: <u>caroleschilling@rcsi.ie</u>

Dr Veronica McInerney, Registered General Nurse; PhD. IRNN Secretary Current Role: Early Phase and Cell Therapy Trial Manager at CRF NUI Galway Contact: <u>veronica.mcinerney@nuigalway.ie</u>

Ms Helen Vaughan, Registered General Nurse; MSc. IRNN Communications Officer Current Role: Clinical Research Nurse for Breast Research at University Hospital Waterford Contact: <u>helenvaughan@rcsi.ie</u>

Ms Jean Foley, Registered General Nurse; PG Certificate Clinical Research Nursing. IRNN Co-Treasurer Current Role: Clinical Research Nurse, HRB Clinical Research Facility Cork Contact: jean.foley@ucc.ie

Niamh Kelly, Registered General Nurse; IRNN Co-Treasurer Current Role: Clinical Nurse Manager 2, HRB Clinical Research Facility Cork Contact: <u>niamh.kelly@ucc.ie</u>

Deirdre Hyland, Registered General Nurse & Registered Midwife; MSc Nursing. Current Role: Senior Research Nurse/Director of Research Nurse Education at RCSI Clinical Research Centre Contact: dhyland@rcsi.ie

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Derval Reidy, Registered General Nurse; MSc. Nursing
 Current Post: Assistant Director of Nursing at the Wellcome Trust/ HRB CRF at St James's Hospital.
 Contact: reidyde@tcd.ie

**Thora El Sayed**, Registered General Nurse; Certificate Nursing, Higher Diploma Clinical Research Nursing, **Current Post:** Senior Clinical Research Nurse. **Contact**:

**Claire Magner**, Registered General Nurse and Registered Children's Nurse; PhD. **Current Role:** Assistant Professor/Lecturer in Children's Nursing, University College Dublin **Contact:** claire.magner@ucd.ie



**Anjali Patel**, Registered General Nurse; Higher Diploma Clinical Research Nursing; MSc Public Health **Contact:** <u>anjsukha@gmail.com</u>

Seán Kearns, Registered General Nurse; PG Certificate Clinical Research Current Role: Clinical Research Nurse in St Vincent's University Hospital Contact: <a href="mailto:sean.kearns@ucd.ie">sean.kearns@ucd.ie</a>

Debra O'Hare, Registered General Nurse; Current Role: Oncology Research Co-Ordinator, Cork University Hospital Cancer Trials Unit Contact: <u>DebraD.OHare@hse.ie</u>

Valarie Trimble, Registered General Nurse & Registered Midwife; PG Certificate Clinical Research Nursing.

**Current Role:** Clinical Research Nurse at the Wellcome Trust/HRB CRF, St James's Hospital; **Contact:** <u>trimblev@tcd.ie</u>

Siobhan Egan, Registered General Nurse /Registered Nurse Intellectual Disability;
 MSc. Current Role: Clinical Nurse Manager 2 at Health Research Institute, UHLG
 Contact: <u>SiobhanMary.Egan@hse.ie</u>



Elaine Conway, Registered General Nurse; MSc. Nursing Current Role: Senior Research Nurse at Clinical Research Unit, University of Limerick Contact: <u>Elaine.conway@ul.ie</u>





## Wednesday 13th November 2019

14:00-14:30	Registration & Refreshments	Hotel Foyer	
	Annual General Meeting (Open to IRNN Members Only)	Room 3	
14:30-15:30	Update on IRNN Activities - Hazel A Smith, Chairperson Communications Update – Helen Vaughan, Communications Offic Treasurers Report – Jean Foley/ Niamh Kelly, co-Treasurers HRB Grant Update – Deirdre Hyland, HRB/IRNN Grant PI Proposals Any Other Business		
	Masterclass	Room 3	
16:00-17:30       host a masterclass on undertak         This is funded by the HRB-TM		oughton and Andrew Hunter) will ng your own qualitative research. RN and open to both IRNN and Registration is required.	
19:00	Evening meal Mirror Room		







# **SPEAKERS PROFILES: MASTERCLASS**



Dr Andrew Hunter, PhD MSc RMN Dip CBT.

Andrew is a lecturer in mental health nursing and is postgraduate programme coordinator at the National University of Ireland Galway. He worked in a range of clinical settings, delivering CBT and IPT. He has two main research areas; the use of qualitative research in trials and psychosocial interventions use and education in mental health care.

Dr Hunter is co-chair of The Qualitative Research in Trials (QUESTS) Centre. The QUESTS Centre promotes high quality qualitative research in trials, undertakes primary research of same and provides education on the use of qualitative research and trials.



Dr Catherine Houghton, PhD HDip MHSc RGN, RSCN, RN

Twitter: @houghtoncath @QUESTScentre @n\_nursing

Catherine is a lecturer in the School of Nursing and Midwifery, NUIG. She is a registered general and children's nurse. Catherine worked in University Hospital Galway, Ireland, the Addenbrooks NHS Trust in Cambridge, UK and Children's

Health Ireland at Crumlin. She lectures primarily on the Bachelor of Nursing Degree Programme, and also teaches and supervises research at Undergraduate and Postgraduate level. Catherine received the NUIG President's Teaching Excellence Award in 2016 and received a further nomination in 2017. Her current research interests are in qualitative research and evidence synthesis, trial methodologies and dementia.

Sincere thanks to the Trials Methodology Research Network (TMRN) and Qualitative Research in Trials (QUESTS) Centre for facilitating and presenting.





	CONFERENCE AGENDA			
09:00-10:00	Registration & Refreshments; Poster Viewing			
10:00	Welcoming Remarks: Dr Hazel A Smith (Chair of the IRNN)			
Forum 1	Chairperson: Prof Joe Eustace (Chair	of HRB-CRCI SMT; Director of CRF-C)		
10:15-10:30	Opening Address	Dr Siobhan O' Halloran: Chief Nursing Officer, Department of Health		
10:30-11:00	Are we there yet? Nurses - are you the passenger or the driver?	Ms Helen Pidd: UKCRF Network Director; Operational Director, NIHR/WT CRF, Manchester		
11:00-11:30	'Count Me In' Survey: A Report on the Clinical Research Nurse/Midwifery workforce in Ireland	Ms Carole Schilling: IRNN 'Count Me In' Project Manager		
11:30-12:00	Refreshments and	d Poster Viewing		
12:00-12:15	Launch of the updated	IRNN orientation pack		
Forum 2	Chairperson: Dr Patricia Leahy-Warren (Chair of the Maternal and Infant Health Research Theme at the School of Nursing and Midwifery, UCC)			
12:20-12:25	Research Forum Introduction and Remarks	Dr Patricia Leahy-Warren		
12:25-12:45	Awareness among clinical researchers in Ireland of changes introduced by ICH-GCP E6(R2)	Ms. Ruben Keane: Quality & Regulatory Affairs Manager, UCC		
12:45-13:05	INCA <sup>™</sup> Technology directs the appropriate treat- ment path for uncontrolled asthma patients	Ms. Lorna Lombard: Clinical Research Nurse, RCSI		
13:05-13:25	Supporting Children with Complex Needs at Home: Challenges for Advanced Community Care Nurses	Ms. Cora O'Leary: Clinical Practice Specialist, Resilience Care		
13:25-14:10	Lunch and Poster Viewing			
14:10-14:30	A Qualitative Evidence Synthesis of Clinical Research Nurses' Experiences of their role.	Ms. Orlaith Hernon: Clinical Research Nurse, NUIG		
14:30-14:40	Panel Discussion			
Forum 3	Chairperson: Dr Avril Kennan (CEO of the Medical Research Charities Group)			
14:40-14:50	Chairs remarks and launch of the PPI Working Group Resource Platform	Dr Avril Kennan		
14:50-15:20	Enabling a culture towards research and innova- tion in nursing and midwifery clinical practice	Prof Eileen Savage: Vice Dean of Graduate Studies, College of Medicine and Health, UCC		
15:20-15:50	Destination Unknown: How IDS-TILDA had to make its own roadmap	Prof Mary McCarron: Director of the Trinity Centre for Ageing and Intellectual Disability		
15:50-16:05	HRB-CRCI update and comments	Dr Fionnuala Keane: COO, Clinical Research Coordination Ireland		
16:05-16:20	Chairpersons remarks: Presentation of prizes and close of conference	Dr Hazel A Smith: Chair of the IRNN		









# **SPEAKERS PROFILES: CONFERENCE**



**Dr. Siobhan O' Halloran** Chief Nursing Officer **Twitter:** @chiefnurseIRE

Siobhan has had a distinguished career in nursing spanning over thirty years. Since 1999, she has held several key positions in the Irish health service with the Department of Health (DOH), the HSE and in the nursing education sector.

These include Nursing Adviser (DOH); Executive Director, National Implementation Committee (DOH), where she oversaw the transfer of all undergraduate nursing education to the third level sector; Executive Director, Health Reform (DOH); Nursing and Midwifery Services Director (HSE) advising the HSE Management Team and Board on policy direction regarding nursing and midwifery issues; Head of the School of Nursing, Midwifery, Health Studies and Applied Science at Dundalk Institute of Technology.

In January 2011, Dr O'Halloran was appointed HSE Assistant National Director with lead responsibility for Acute Services. Most recently, she was tasked with establishing the Programme Management Office within the Department of Health to implement the Government's health reform programme, Future Health.



#### Ms. Helen Pidd

UKCRF Network Director, and combines this with the role of Operational Director at the NIHR Manchester CRF. **Twitter:** @piddhelen; @NIHR\_UKCRFN

Helen Pidd joined the CRF development team in Manchester as the Nurse Manager in 1999 and was involved in the establishment of the CRF from day one. She developed the clinical research team and together with the Medical Director was responsible for growing the study portfolio. She then moved into the roles of Clinical Manager, Deputy Director prior to taking up her current

role as Operational Director. She was appointed as UKCRF Network Director in 2009. Helen has led on a number of national initiatives to support the development of the Clinical Research Nurse role including being a founder member of the writing group for The Competency Framework for Clinical Research Nurses. As a member of the NIHR Nurse Strategy Working Group, Helen has led on a number of projects including work to develop student placements in research areas.

In her role as Network Director Helen is able to share her passion for Clinical Research Nursing and Operational Development and has provided consultancy advice to a number of research facilities across the UK, Ireland and the US.



### Ms. Carole Schilling

Project Manager for the Irish Research Nurses Network (IRNN) Twitter: @cschill; @Irish\_RNN

Carole completed a BSc (Hons) in Nursing/RGN in 1993. After graduating Carole worked as an Intensive Care Nurse in general, neuro-medical and cardiovascular intensive care units. In 1998, Carole changed her career focus when she took on the position of Cardiology Research Sister.

In 1999, Carole graduated from King's College London with an MSc in Nursing. Carole moved to the Republic of Ireland in 2001 and continued to work as a Cardiology Research Nurse/Clinical Nurse Manager. In 2005, she moved into the Pharma Industry to work as a Clinical Research Associate, gaining experience across a broad range of therapeutic areas, which included respiratory, infectious disease, hepatology, oncology and ophthalmology.

Carole joined the Royal College of Surgeons Ireland (RCSI) Clinical Research Centre in March 2012 as a Senior Clinical Research Nurse. In 2013, she completed the level 9 post-graduate certificate in Nursing (Clinical Research). In 2015, Carole moved to the position of RCSI Quality & Regulatory Affairs Manager. This role involved responsibility for developing, implementing and maintaining quality management systems to ensure that all investigator led clinical trials sponsored by RCSI were in compliance with the protocol, GCP and applicable regulatory requirements. In November 2018, Carole was successful in securing the position of Project Manager for the IRNN workforce survey, *'Count Me In'*.



#### **Professor Eileen Savage**

Vice Dean of Graduate Studies, College of Medicine and Health, UCC. Twitter: @EileenSavage20; @uccnursmid; @ucc

Eileen Savage is Chair in Nursing in UCC and was Dean of the School of Nursing and

Midwifery from January 2012-October 2018. She is currently Vice Dean of Graduate Studies and Inter-professional Learning at the College of Medicine and Health UCC working in collaboration with the six health science disciplines in UCC. She has extensive leadership experience including research capacity building within the discipline of nursing. During her role as Dean of School, she spearheaded significant developments including a growth in research activity and income, and appointment of senior staff at professorial level; there is now an active vibrant culture of research with an emphasis on collaborative interdisciplinary research and large grant applications. Her experience in research capacity building includes being a Visiting Professor at the Ripas Hospital Darussalam Brunei, and at Airlannga University Surabaya, Indonesia. She is also a trainer with Evidence Synthesis Ireland drawing on her experience as a Cochrane Review author and reviewer.

Eileen has an established track record in research funding and publications. The main focus of her research is on chronic illness management, particularly self-management, symptom management (including mental health symptoms), and the relationship between physical and mental health and wellbeing. Professor Savage has completed studies funded by the Health Research Board, Ireland, Health Service Executive, Department of Health, the Irish Research Council for Humanities and Social Sciences, the Ombudsman Office for Children, and European Commission (Erasmus -multilateral programme).



### **Prof Mary McCarron**

Director of the Trinity Centre for Ageing and Intellectual Disability (TCAID), Principal Investigator of the IDS-TILDA study and Chair of Ageing and Intellectual Disability at Trinity College Dublin.

Twitter: @MccarrmMary; @ageingwithID; @IdsTilda

Since joining Trinity College Dublin in 2002, Professor McCarron has held many senior leadership roles, including Director of Research and Head of the School of Nursing and Midwifery which is now one of the largest Schools in the University and ranked 31st in the World 2016. In 2011, Professor McCarron was elected Dean of the Faculty of Health Sciences, with responsibility for the School of Nursing and Midwifery, School of Pharmacy and Pharmaceutical Sciences, School of Dental Sciences, Medicine, with a combined student body in excess of 4,000 and a staff of 650. She is a member of the Senior Executive Management team of the University.

Professor McCarron is the founder and Principal Investigator for the first ever Longitudinal Comparative Study on Ageing in Persons with Intellectual Disability (IDS-TILDA) to be conducted in Ireland or internationally. This study is a supplement to The Irish Longitudinal Study on Ageing (TILDA). The emerging IDS-TILDA data is informing needed policy responses to develop human and appropriate services for this increasingly at-risk group.

With extensive experience in working in the area of dementia in people with Down syndrome, Professor McCarron has led large longitudinal cohort studies spanning over 25 years. Her special interest is on the early detection and presentation of dementia, and in the development of humane approaches to care and support. She has been a key advisor of ageing and policy issues to various governmental and other groups at a national and international level. She has been successful in obtaining over €10,000,000 in research funding, as PI or collaborator, holding grants from a variety of national and international sources such as the Department of Health, Health Research Board, National Disability Authority, All Ireland Institute of Hospice and Palliative Care, the Atlantic Philanthropies and Horizon 2020.



### Dr. Fionnuala Keane HRB CRCI Chief Operating Officer Twitter: @HRB CRCI

Dr Fionnuala Keane graduated in 1994 with a B.Sc. Honours in Biochemistry and in 1999 with a PhD in Biochemistry from the National University of Ireland Galway. From Oct 1999 to Feb 2001 Fionnuala worked as a Postdoctoral Research Fellow in

molecular biology and neurochemistry at the Department of Biochemistry, UCD. She joined Novartis Ireland Ltd in Feb 2001 and worked there as a Central Nervous System Hospital Specialist with the sales and marketing team until June 2003. At this point Fionnuala joined ICORG, the All Ireland Co-operative Oncology Research Group and she remained in ICORG from July 2003 to May 2014. Fionnuala was appointed to the role of Development Lead for the HRB CRCI in May 2014 to develop and deliver a 5 year business plan in line with the HRB strategic objectives, working in close collaboration with the CRF/C directors. In May 2015 Fionnuala was appointed to the role of Chief Operating Officer for the HRB CRCI.

# **CHAIRS PROFILES: CONFERENCE**



#### **Professor Joe Eustace**

Prof. Joe Eustace is the Director of the HRB Clinical Research Facility at UCC (CRF-C), Chairman of the HRB CRCI Senior Management Team and Professor of Patient Focused Research at UCC. The CRF-C facility is co-funded by the University and by the Health Research Board and supports the design, conduct and analysis of Patient Focused Research throughout UCC and its affiliated

Medical Centres. He is also a Consultant Renal Physician at Cork University Hospital.

He graduated MB, BAO BCh (UCD) 1990 and undertook postgraduate training in General Internal Medicine and Nephrology in Dublin (1990-1996), Johns Hopkins University Hospital, Baltimore (1996-1999), and a NIH funded Fellowship in Clinical Epidemiology at the Johns Hopkins Bloomberg School of Public Health, (1997-1999), as part of which he completed a MHS (Clin Epi). He served as an Assistant Professor in the Johns Hopkins Faculty of Internal Medicine and in the Department of Clinical Epidemiology. His research has been funded by the NIH (NIDDK), NKF, the HRB and EI is focused on the methodological issues in Clinical Trial design, nutritional management of Chronic Kidney Disease and investigations into bone and vascular health in renal transplant recipients. He has authored or co-authored over 80 peer reviewed papers and is a co-applicant on the HRB Trials Methodology Research Network.



### Dr Patricia Leahy-Warren Twitter: @Pleahy w

**Dr Patricia Leahy-Warren** is a Senior lecturer, Chair of Academic Council Graduate Studies Committee, *Director of Graduate Studies and Chair of the Maternal and Infant Health Research* Theme at the School of Nursing and

Midwifery in University College Cork. Patricia is a registered nurse, midwife, and public health nurse. She has had national and international collaborative successes with research grants (HRB, NYCI, DoH, COST). She holds a Visiting Professorship at the Diakonova University, Oslo, Norway and an Adjunct Senior lecturer at Western Sydney University, Australia.

Patricia has published more than 80 refereed journal articles, book chapters and published reports and regularly gives papers at national and international conferences and seminars with many of these as an invited speaker. Her program of scholarship, teaching and research focuses on transition to motherhood, perinatal maternal and paternal mental health, breastfeeding and infant feeding decisions, postnatal care, supporting normal birth, kangaroo care, strengthening the universal health services for families and children and the remit of the public health nurse. Patricia also works with colleagues to research strategies to strengthen primary health care and the integration of acute and community services to enhance patient care. Patricia has experience with both qualitative and quantitative methodologies. She has undertaken systematic reviews, metasynthesis, prospective cohort studies, population based surveys, qualitative descriptive and mixed methods.

Patricia currently supervises 11 graduate degree students in both nursing and midwifery at MSc, Doctorate of Nursing and PhD. She has had five higher degree completions todate and these students have published over 15 papers during their candidature and presented over 20 conference papers.



#### Dr Avril Kennan

CEO of Health Research Charities Ireland Twitter: @HRCIreland; @avrilkennan

Avril has a PhD in genetics and many years subsequent lab experience working on rare human genetic conditions. She moved from the lab in 2007 to become a patient advocate with the patient organisation DEBRA Ireland. In her role there, as

Head of Research and Advocacy, she led many international initiatives including the development of clinical guidelines and a patient registry.

In her current capacity as CEO of Health Research Charities Ireland (HRCI) she supports a community of charities to engage fully in health research with the aim of increasing the quantity and quality of patient-relevant research. Avril is passionate about making science accessible, involving patients and the public in research from its earliest plans and basing healthcare on evidence.

# **Voting for Best POSTER & ORAL presenter**

Each attendee at the IRNN conference has the option of voting for best poster (first and second prize) and best oral presenter (from second forum)- abstract presentations). Oral abstracts are available on pages 13-14 and poster abstracts are on pages 15-23.

In your conference pack there is a voting sheet. We ask that you only vote once and just state your first and second preference for best poster award and first preference for best oral abstract only.

Voting boxes are available on the registration desk (for you to return your voting slip) and all poster votes should be submitted by the end of the lunch for the winners to be announced at the end of the conference. Research forum votes will be collected at the end of Forum 2.

We encourage you to visit the poster stands during the breaks and to share all events from the conference on Twitter using the hashtags #IRNN19 and #WhyWeDoResearch. This provides a platform for other research nurses/ midwives, who are unable to attend, the opportunity to see research undertaken by their peers and colleagues.







Research Forum 1:	Ruben E. Keane, Quality and Regulatory Affairs Director, HRB-Clinical Research Facility, Cork		
Abstract Title:	Awareness among clinical researchers in Ireland of changes introduced by revision 2 of ICH- Good Clinical Practice Guidelines and challenges and supports to its implementation		
Author/s:	Keane, R.E. & Rafter, M.	ane, R.E. & Rafter, M. E-mail: Ruben.keane@ucc.ie	

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. It is mandatory to adhere to ICH-GCP when carrying out clinical trials of Investigational medicinal products.

The revision of ICH-GCP implemented in 2017 was the first change to the standard since its introduction in1996. The main areas of change were requirements regarding:

Risk based sponsor quality management system, risk based monitoring, computer systems validation, principal Investigator supervision of staff and service providers, follow up of non-conformance, essential documents/ source documents.

There is a potential for everyone who organizes, manages and works in clinical trials to be affected by any changes to ICH-GCP at both sponsor and site. It is in this context that an anonymous survey was carried out among a sample of clinical researchers in Ireland regarding the changes with the aim of ascertaining:

The level of awareness of the changes and clinical researcher's perception of the changes.

What challenges were experienced by clinical researchers in the implementation of the changes

What supports assisted researchers in implementation of the changes

Suggestions for additional supports in implementing future changes

The results of the survey will be presented along with conclusions and recommendations.

Research Forum 2:	Lorna Lombard, Clinical Research Nurse, Royal College of Surgeons Ireland	
Abstract Title:	INCA <sup>™</sup> Technology directs the appropriate treatment path for uncontrolled patients with asthma.	
Author/s:	Lombard, L. Walsh, J. Plunkett, S. Mac Hale, E. Mulvey, C. Greene, G. Mokoka, M.C. & Costello, G.W. E-mail: Lornalombard@rcsi.com	

Uncontrolled asthma is characterized by poor symptom control and exacerbations requiring oral corticosteroids. A patient is deemed refractory to treatment if they remain uncontrolled despite adherence to guideline directed therapy and treatment of contributing factors (GINA 2019). We hypothesize that using INCA<sup>™</sup> technology we can distinguish between patients who are truly refractory to treatment and require type 2 targeted biologic treatments versus those who are not.

We report the outcome of two patients with uncontrolled asthma who were deemed to be refractory to treatment and candidates for type 2 targeted biologic treatments. They were both recruited into a multicentre, prospective, randomized controlled study of uncontrolled asthma (INCASUN). They were randomized into two study groups. Group one received INCA<sup>™</sup> directed inhaler education and their medication was adjusted according to the objective adherence. The second group was blinded to what the INCA<sup>™</sup> technology was recording. They received standard care and their medication was adjusted as per the GINA guidelines.

On completion of the study both patients remained uncontrolled despite optimizing treatment, this resulted in both being referred for type 2 targeted biologic treatments. The INCA<sup>™</sup> data was unblinded for the standard care group patient and it was revealed that this patient had suboptimal adherence negating the need for step up therapy.

Without an objective measure of adherence it is difficult to determine patients who are truly refractory to treatment. INCA<sup>™</sup> technology assists clinicians in identifying patients who require step up treatment while also preventing inappropriate prescribing where adherence is the real issue.

Research Forum 3:	Cora O'Leary, Nurse/Clinical Practice Specialist, Resilience Care	
Abstract Title:	Supporting children with complex needs at home: Challenges for Advanced Community Care Nurses	
Author/s	O'Leary C	

**Background:** Following a review of policy and practice in the provision of home care to children with complex needs in Ireland in 2014, a service framework was devised to guide commissioning and delivery of services to support these children and their families.

Aim: The aim of this research was to support nurses caring for children with complex medical needs by exploring the specific challenges faced by them in caring for these children within the home environment.

**Method:** Sequential mixed methodology approach was used. 100 questionnaires were administered, with a response rate of 67%. The questionnaire comprised 10 free text questions informed by a literature review on the subject of challenges in the home care setting for nurses caring for children with complex care needs. Responses were correlated into 3 main topics and presented for discussion at focus groups:

• Building trusting relationships; • Family home as the workplace • Training and education

Ethical approval was granted by Cork Clinical Research Ethics Committee in May 2017

**Results:** Participants self-selected to attend the focus groups. Concept maps were used as a method of note taking. The overarching themes that emerged from the focus group were:

• Family dependency • Care planning and competency • The nurse/parent relationship

The above were highlighted through discussions around shared areas of concern specifically, isolation (lone working), training needs, clinical competency and good care planning.

**Conclusion:** Nurses find working in the community setting rewarding and challenging in equal measures. In order to support nurses caring for children with complex needs at home, initiatives aimed specifically at the areas of shared concern were introduced to the organisation. These include Schwartz Rounds, a communication platform for all staff, structured clinical supervision sessions and a national clinical practice specialist

Research Forum 4:	Orlaith Hernon, Clinical Research Nurse, National University of Ireland, Galway	
Abstract Title:	A Qualitative Evidence Synthesis of Clinical Research Nurses' Experiences of their role.	
Author/s:	Hernon, O. Dalton, R. & Dowling , M. <b>E-mail:</b> Orlaith.hernon@nuigalway.ie	

**Aims:** To synthesise the available body of qualitative evidence relating to clinical research nurses' experiences of their role.

**Methods:** ENTREQ guidelines were followed for this qualitative evidence synthesis (QES). A systematic search of the literature in five databases was undertaken: CINAHL, Medline, Embase, Pubmed, Proquest. Blind screening of title and abstracts in Covidence<sup>©</sup>, the on-line software tool was undertaken.

Following screening for studies that met the inclusion criteria, the Critical Appraisal Skills Programme framework (CASP) tool was used to assess the quality of all included studies. Thomas and Harden's three-stage approach to thematic analysis was used to guide the synthesis. CERQual (Confidence in Evidence of Reviews of Qualitative Research) was utilised to assess confidence in review findings.

**Results:** Nineteen studies (one study was reported in two papers) (with a total of 232 nurses) were included in the synthesis. Three analytical themes with subthemes were identified: 'Becoming a research nurse'; 'Recruit, recruit, recruit'; 'The patient first'.

**Conclusions.** Clinical research nurses experience many challenges and obstacles in their role. A lack of understanding among non-research nursing colleagues for their role can result in difficulties when recruiting study participants. Clinical research nurses can experience internal conflict between being a patient advocate and adhering to a trial protocol

**Relevance to clinical practice.:** Clinical research nurses new to their role need education on the challenges they face and the importance of developing collaborative relationships with ward based staff who are important gatekeepers to patient recruitment. Ongoing support is needed to help negotiate internal conflicts that may arise.

Poster Abstract 1	Maria Spillane, Study Monitor, Clinical Research Facility – Cork, University College Cork	
Abstract Title:	Development of an Internal Quality Review Process for Essential Study Documents	
Author/s:	<u>Spillane, M.</u> Keane, R. Kelly, N. & Kelsey, M.	E-mail: maria.spillane@ucc.ie Twitter: @MariaSpillane

**Background:** Maintaining study documentation and source documents is an area that can be easily postponed, and is one of the most common findings from GCP inspections.<sup>1</sup> The Clinical Research Facility Cork (CRF-C) has recently developed a system of conducting Internal Quality Reviews of research studies run by its Operations team.

**Objectives:** To maintain the high quality standards of research carried out by the CRF-C; to minimise findings from monitoring visits and audits; and to ensure that studies are inspection-ready at all times.

**Methods:** The Clinical Management Team and Quality & Regulatory Affairs Director decide which studies will be reviewed once per quarter. A member of the Quality team reviews the Investigator Site File (ISF) and a percentage of the Source Documents for the selected studies.

**Results:** Between September 2018 and April 2019, 21 reviews were completed on 18 studies. The main findings with the ISF were: updated or relevant CV's/GCP certificates not filed (20%); relevant Ethics and Regulatory approvals not filed (15%); and incorrectly completed Delegation Logs (14%). Findings with the Source Documents included: insufficient or no documentation of AE's/SAE's (30%); poor documentation of study visits and consent process (22%); and de-identification of source documents (15%).

**Conclusions:** Study staff have reported favourably on the reviews and are now more aware of the importance of maintaining study documentation throughout the life-cycle of a study. The process has raised the quality of research study documentation at the CRF-C.

<sup>1</sup> 'Overview of GCP inspections including common findings', HPRA Information Day, Dublin, 23-10-2018 <u>https://www.eiseverywhere.com/ehome/345191</u>

Poster Abstract 2	Caroline O'Leary, Research Nurse, 4DPharma Cork	
Abstract Title:	Diagnosis and Treatment of IBS: A Role for Nurses	
Author/s:	<u>O'Leary, C</u> . Kelly, S. O'Meara, M. & O'Herlihy, E.	E-mail: c.oleary@4Dpharmaplc.com

Irritable Bowel Syndrome (IBS) is a common functional gastrointestinal disorder (FGID) with a prevalence of 10-15%, impacting on patients' quality of life and healthcare systems responsible for up to 50% of all gastrointestinal (GI) referrals.

IBS is challenging to diagnose partly due to non-specific/overlapping symptoms with other diseases e.g. inflammatory bowel disease. Diagnosis is mainly by exclusion and use of Rome criteria which focus on pain and subtyping patients based on their bowel habits. The usefulness of this instrument for diagnosis is questionable given the limited factors it assesses, coupled with the drop in prevalence being reported with the introduction of revised criteria in 2016 (Rome IV replacing Rome III).

Research has shown that IBS has many contributing factors which should be considered for more accurate diagnosis and treatment. Once such factor is the gut microbiota which is thought to play a role in IBS and which may be a useful tool to subtype patients and to select more appropriate therapies. The gut microbiota is also influenced by factors such as diet, medications and lifestyle. Knowledge on these aspects of a patient are useful to improve diagnosis and treatment for patients. We propose raising awareness on the importance of the microbiome in health and disease and the potential of microbiome-based therapeutics in the treatment of IBS, through a nurse-led initiative, educating and empowering healthcare professionals and patients.

Poster Abstract 3	Sinéad Plunkett, Clinical Research Nurse, Royal College of Surgeons in Ireland	
Abstract Title:	<b>T</b> ailo <b>R</b> ing nurse-led educational p <b>A</b> thways using the INCA <sup>™</sup> device as a Landmark (INCA- TRAIL); Assessing the effectiveness of acoustic based interventions in nurse-led asthma edu- cation on asthma related outcomes.	
Author/s:	<u>Plunkett, S</u> . Lombard, L. Walsh, J. Mac Hale, E. Mulvey, C. Greene, G. & Costello, R.W.	E-mail: sinéadplunkett@rcsi.ie

Asthma places a substantial burden on the public health and economy of Ireland averaging a cost of €472 million per year according to a recent report. Uncontrolled asthma places a greater demand on healthcare resources. In 2017, there was approximately 3 million G.P and practice Nurse consultations with almost 554,000 Emergency Department and specialist visits for asthma respectively.

Despite the introduction of gold standard educational strategies in self-management, almost 60% of people with asthma in Ireland remain uncontrolled in managing their condition. This recent report adds weight to the argument that current "one-size fits all" approaches to asthma education and self-management strategies shows little evidence in managing asthma or reducing the drain on healthcare resources in Ireland.

Literature from other European countries shows significant advantages from the implementation of educational asthma self-management programmes. By adopting these programmes it is expected that asthma costs could be reduced by €102 million a year, if the results from other countries was positioned from an Irish context.

To achieve improved long-term benefits, it is essential that a personalised educational intervention is supported by proven clinical effectiveness.

This proposed mixed methods study aims to compare the effectiveness of two nurse-led educational approaches on asthma related outcomes and self- management; one using INCA<sup>™</sup> technology as a landmark to provide educational interventions compared to standard clinical GINA educational guidelines. Results of this study will tailor personalised educational pathways using the INCA<sup>™</sup> technology and develop an educational tool to optimise asthma self-management in severe uncontrolled asthma patients.

Poster abstract 4	Joanne Walsh, Clinical Research Nurse, Royal College of Surgeons in Ireland	
Abstract Title:	Putting self-efficacy on the map, the impact of biofeedback on self-efficacy in adults with asthma. An MSc by Research Proposal.	
Author/s:	<u>Walsh, J.</u> Lombard , L. Plunkett, S. Mac Hale, E. Mulvey, C. Greene, G. Murray, B. Moore, Z. & Costello, RW.	E-mail: joannewalsh@rcsi.com Twitter: @INCA_team

Asthma affects up to 334 million people worldwide and has been increasing in prevalence over the past three decades. Ireland has one of the highest rates of asthma in the world, it is estimated that 890,000 people will experience asthma at some point in their lives (ITS, 2018).

Research shows that health education in asthma reduces healthcare utilisation by up to two thirds, this in combination with guided self-management strategies and essential skills increases asthma control and reduces risk (GINA, 2019). Despite this it is estimated that up to 60% of people in Ireland with asthma are uncontrolled (ITS, 2018).

Self-management combines biological, psychological and social intervention techniques with a goal of maximal function (Nakagawa-Kogan et al., 1988). It is the day to day tasks and home management strategies an individual must undertake to control or reduce the impact of disease on physical health status, guided by and in collaboration with healthcare providers (Barlow et al., 2002).

Effective asthma self-management relies heavily on the patient's confidence to accurately interpret their symptoms and follow through with the appropriate self-management strategy. Self-efficacy is a modifiable factor with the most influence on people's behaviour, adopting and sustaining health behaviour changes and improving health outcomes.

I propose to examine self-efficacy among adults with asthma, following a nurse led educational intervention using enhanced bio feedback of treatment use.

Poster Abstract 5	Leanne Hays, Postdoctoral Research Fellow, UCD & St Vincent's University Hospital	
Abstract Title:	The Role of the Research Coordinator/Nurse in Critical Care Research.	
Author/s:	Smyth, M. Hays, L.M.C. Brickell, K. & NicholE-mail: leanne.hays@ucd.ieA.D.Twitter: @ICCCTN	

The Research Coordinator/Nurse (RC/RN) is an essential member of the Intensive Care Unit (ICU) Research Team. At St. Vincent's University Hospital we coordinate a number of randomized controlled trials and global observational studies in our ICU.

The ICU RC/RN coordinates each step of the study process on the ground. We collaborate with both ICU and ED staff on a daily basis. Prior to study commencement we assess study feasibility at our site and apply for ethical approval for the study at our site. In order to ensure a study runs smoothly we generate a number of study tools to facilitate patient enrolment, data collection and the running of the study. On a daily basis we screen ICU patients for study eligibility and enrol and randomise eligible patients following discussion with the ICU consultant. We speak with families and patients and obtain assent/consent for study involvement. We ensure the study protocol is followed and support our nurses, doctors and allied health professionals in delivering the study intervention. We are responsible for the data collection and submission including follow-up telephone questionnaires at 6 months and up to 2 years.

Another aspect of our role is education, training and research dissemination. We hold regular research updates for multidisciplinary staff, interact with the NCHDs and support them in carrying out research, carry out study specific nurse training, update our staff on the studies we are involved in through our research board and disseminate published studies and current study information. We provide access to GCP training and support staff nurses to attend conferences. We are responsible for maintaining study documents at our site and archiving studies after completion. We also participate in conferences and interact with other ICU RCs throughout Ireland fostering collaboration. Overall, we seamlessly coordinate and integrate an extensive program of research in our ICU without hugely impacting the current workload of our staff.

Poster Abstract 6	Elaine Conway, CNM2, Heath Research Support Unit, Health Research Institute, U.L.	
Abstract Title:	Collaboration between the Health Research Institute, University of Limerick and Munster Rugby in the Concussion Study is a Win Win	
Author/s:	Hinchion, R. <u>Conway, E</u> . Mulvihill, J. Kearns, J. Ryan, M. Ross, A.M. Walsh, D.R. Egan, S. & Hayes, M.T.	Email: elaine.conway@ul.ie

The diagnosis of concussion relies heavily on a subjective assessment and our knowledge of how concussion affects athletes over time is limited [1] [2]. The Concussion Study currently running at the Clinical Research Support Unit of the University of Limerick's Health Research Institute in collaboration with Munster Rugby High Performance Centre, identifies and measures the proteins that are secreted by the cortical cells when the brain is injured in order to elucidate these key protein markers for post-concussion identification.

By examining the fluctuations of these key protein markers, the study team are gaining a better understanding of concussion-specific biomarkers in the blood that originate from the brain, on how we diagnose concussion and how rugby players recover post-concussion. This poster explores the collaborative approach of the CRSU in carrying out the delivery of this research project.

1) Yeomans, C., Kenny, I.C., Cahalan, R., Warrington, G.D., Harrison, A., Hayes, K., Lyons, M., Campbell, M.J. & Comyns, T.M. (2018) The Incidence of injury in amateur male rugby union: a systematic review and meta-analysis. *Sports Medicine*, 48 (4): 837–848

2) Mulvihill, J.J.E., Raykin, J., Snider, E.J., Schildmeyer, L.A., Zaman, I., Platt, M.O. Kelly, D.J. & Ethier, C.R. (2018) Development of a platform for studying 3D astrocyte 1 mechanobiology: compression of astrocytes in collagen gels. Annals of Biomedical Engineering, 46 (2): 365-374

Poster Abstract 7	Edel Dolan General Nurse (ICU), St Vincent's University Hospital	
Abstract Title:	Animal-Assisted Therapy: Alternative Therapy for Chronically Critically III Patients	
Author/s:	Dolan, E.	E-mail: edel.dolan@gmail.com
This clinical vignette poster depicts the results of a literature review conducted on animal-assisted therapy (AAT) on critically ill patients, specifically dog therapy. Although very few studies have been conducted in an ICU environment there are many studies that show its benefit in cardiology, paediatric care and rehabilitation to name a few.		
As critical care medicine advances, there is an ever-growing population of ICU survivors. Due to their higher level of nursing care needs, and the many side effects of treatment and medication, many are having longer stays in critical care. Pharmacologic treatment of such needs can worsen physical and mental outcomes and as such non-pharmacological and alternative therapies for chronically critically ill patients are being championed to improve patients experience in critically care.		
The benefits of ATT are wide and varied and include reduced anxiety, pain and stress while increasing mood, motivation and engagement in rehabilitation. While there are concerns around AAT in a critical care environ- ment including zoonotic infections, behavioural issues and cross infection between patients, these are mostly unfounded or easily avoidable.		
AAT has now been implemented in the authors ICU. The initial feedback from staff, patients and visitors has been overwhelmingly positive. This has led to the beginning of formal research into the effects AAT has on the critically ill patient.		
Poster Abstract 8	Vivienne Hanrahan, PhD Scholar (HRB-TMRN) & Registered Midwife, NUIG	
Abstract Title:	Recruiting women during pregnancy and childbirth enablers for trial recruiters: a qualitative evidence	
Author/s:	Hanrahan, V. Biesty L. & Gillies, K.	E-mail: v.hanrahan1@nuigalway.ie Twitter handle: @VivienneHanrah2
<ul> <li>Introduction: The PRioRiTy Study, identified and prioritised unanswered questions around trial recruitment research. We utilised qualitative research methods to answer Question 5 'What are the barriers and enablers for trial recruiters?' within the maternity care setting.</li> <li>Aim: The aim of this Qualitative Evidence Synthesis (QES) was to explore the evidence on the recruiter's experience and perceptions of recruiting women during pregnancy &amp; childbirth to trials. Specifically exploring: <ol> <li>The recruiter's perception and awareness of how their own role (e.g. clinical or non-clinical) might influence recruitment;</li> <li>The recruiter's perception and experience of how the 'type of trial' (i.e. pharmaceutical, non-pharmaceutical,) might influence recruitment;</li> <li>Explore the setting and environment in which recruitment is undertaken.</li> </ol> </li> <li>Methods: Using SPIDER, a broad search of electronic databases (PubMed, CINAHL, Embase, PsycINFO) &amp; grey literature (Scopus citation searches) returned 13,401 citations. Abstracts were independently screened by two reviewers, of these, 29 citations progressed to full text screening, resulting in 8 eligible papers. We designed a data extraction tool and critically appraised using CASP checklist. A thematical approach to coding &amp; synthesis was undertaken, applying CERQual for confidence in review findings.</li> <li>Results: We have preliminary results and expect the QES will be submitted for publication in December 2019.</li> </ul>		
<b>Potential Impact:</b> The review will, for the first time, systematically synthesise existing research on factors		

associated with recruitment to RCTs in maternity care from the recruiters' perspective. The findings will provide the basis of an exploratory qualitative study seeking to develop a statement of recommendation for future successful recruitment in maternity care.

Poster Abstract 9	Shauna Callaghan, Research and Staff Midwife, PhD Student, University College Dublin (UCD) & National Maternity Hospital	
Abstract Title:	Exploration of physical activity levels of women in early pregnancy and influencing factors: A multi-cohort study.	
Author/s:	<u>Callaghan, S.</u> Coughlan' B. Geraghty, A.A. & McAuliffe' F.	E-mail: shauna.callaghan@ucdconnect.ie Twitter handle: @ShaunaCallagha6

**Background:** Physical activity has important health benefits during pregnancy. Healthy women are recommended to undertake 150 minutes of moderate-intensity exercise per week. In Ireland, less than one-quarter of women meet recommendations, however limited data is available on Irish women's physical activity levels during pregnancy.

**Objectives:** To examine physical activity levels of women in early pregnancy and influencing factors.

**Methods:** Secondary data from 1,412 women participating in three RCTs during pregnancy between 2007-2019, in a tertiary referral hospital in Dublin, were included. Observational data including demographic and lifestyle data relating to physical activity was collected.

**Results:** Of the 1,412 women included, 76% were multiparous, 63% achieved third level education and 96% were Caucasian. Mean gestation was 14 weeks, mean age 32.34 years and mean BMI 27.38kg/m2. 17.6% (n=248) met recommendations for physical activity in early pregnancy. Women in early pregnancy were significantly more likely to meet exercise recommendations if they were primiparous (p<0.001), achieved third level education (p=0.002), and had a BMI between 18.5-24.9kg/m2. Women who met physical activity recommendations had a significantly lower weight (kg) (p=0.001) and BMI (p<0.001) in early pregnancy compared to those that did not. There was no significant difference in gestational age, ethnicity and maternal age between women who met physical activity recommendations and those that did not.

**Conclusions:** Physical activity is an important modifiable health factor during pregnancy, levels of exercise in early pregnancy is extremely low amongst Irish women. Support measures and improved education from midwives is needed to improve physical activity in pregnancy.

Poster Abstract 10	Shauna Callaghan, Research and Staff Midwife, PhD Student, UCD & National Maternity Hospital	
Abstract Title:	Exploring midwives' and obstetricians' knowledge of exercise, nutrition and gestational weight gain recommendations for women in pregnancy: Provisional findings	
Author/s:	<u>Callaghan, S. C</u> oughlan' B. Geraghty, A.A. & McAuliffe' F.	E-mail: shauna.callaghan@ucdconnect.ie Twitter handle: @ShaunaCallagha6

**Background:** Health and wellbeing in pregnancy is important for pregnancy outcomes and public health. Pregnancy potentially provides a 'teachable moment' for positive health behaviour change. Midwives and obstetricians, therefore, are uniquely positioned to positively influence this.

**Objectives:** To explore midwives' and obstetricians' knowledge regarding health promotion advice in pregnancy, specifically related to nutrition, gestational weight gain and exercise.

**Methods:** Quantitative data was gathered using a specifically designed questionnaire. Participants included midwives and obstetricians practicing in a Dublin teaching hospital.

**Results:** From preliminary findings of 55 participants, 65.5% were midwives and 54.6% of participants had above five years clinical experience. All participants stated health promotion was part of their maternity care provider role. Regarding health promotion education, 69% reported receiving some education during training, while 54.6% received subsequent education post qualification. 100% agreed that nutrition was important in pregnancy, although just 18.2% knew information relating to different energy requirements throughout pregnancy. 72.7% acknowledged gestational weight gain management as part of their clinical responsibility, however just 21.8% correctly identified appropriate recommendations. 69% correctly identified recommendations for physical activity during pregnancy.

**Conclusions:** Although health and wellbeing promotion is acknowledged by midwives and obstetricians as an important factor in their provision of care for women in pregnancy, there is a lack of knowledge amongst healthcare professionals in this area. It is important to improve knowledge levels in these key areas to enhance maternity care and ensure the provision of evidence-based information for women in pregnancy. We aim to reach 150 participants by January 2020.

Poster Abstract 11	Una Coleman, Research Nurse, CRF St James Hospital, Dublin 8	
Abstract Title:	'How to Ace your Monitor Visit Report Card'	
Author/s:	Coleman, U. E-mail: <u>colemanu@tcd.ie</u>	

**Introduction**: The 'CRF Monitor Visit Report Log' is a tool developed to aid with Site Monitor Visits. This easy to use, cost effective tool can be used by Study Monitors and Research Teams in any CRF. This tool supports in capturing findings and queries during monitoring visits. It has demonstrated to be an effective way to communicate between the interdisciplinary teams and dramatically reduce monitor visit queries. Having the skills to communicate research in an effective way has a positive impact on researchers themselves (Goubert, 2017).

**Aim/Purpose:** To assist the communication between CRAs and Clinical Research Co-Ordinators during a Site Monitoring Visit. Previously, queries that needed to be addressed had been labelled with post it notes which could easily go missing. The purpose of this development is to help the team address queries quicker and reduce the number of follow -up items on the Official Monitor Report.

**Methodology:** Previously, the research co-coordinator would sit in with the CRA to resolve any queries. This can be time consuming due to the busy Research Facility. Following a monitor visits an official report would be generated causing a high volume of work. This simple cost effective tool consists of a table to capture queries the monitor identifies and allow the research team to resolve the queries on the day of the visit. This log is kept in an allocated folder 'The Monitor Visit Report Folder'. At the end of the monitoring visit both the Research Co-Ordinator and Monitor are required to sign the log. Any queries or disputes can be addressed on site.

**Results and Conclusion:** Prior to using the MV Report Log we had 22 findings in July, 15 findings in August and 9 findings in September. We had a significant decrease in findings after we implemented the log - 4 findings in October, 3 findings in November and 2 findings in December. The quality team found the tool audit friendly. Data manager's workload decreased.

**References:** Goubert, D, 2017. Research Communication- why it matters. Available at: https://mind-mint.org/articles/research/why-it-matters (11/March/2019).

Poster Abstract 12	Carole Schilling, Irish Research Nurses Network Project Manager, RCSI	
Abstract Title:	'The Roles and Responsibilities of the Clinical Research Nurse & Midwife'	
Author/s:	<u>Schilling, C.</u> Hyland, D. Smith, H.A. McInerney, V. Kelsey, M. & Egan, S.	E-mail: caroleschilling@rcsi.ie Twitter:@cschill; @Irish_RNN

**Introduction:** The roles and responsibilities of Clinical Research Nurses and Midwives (CRN/Ms) vary between organisations and even from one post to another. A consequence of this inconsistency is an absence of standardised job descriptions, which clearly define the roles and responsibilities for each nursing grade. Furthermore, this impacts on salary, which may not adequately reflect the skills and experience of the CRN/M. One of the objectives of the IRNN *'Count Me In'* study was to identify the primary roles and responsibilities of CRN/Ms in Ireland.

**Methods:** 'Count Me In' was a national survey of CRN/Ms based in a variety of settings (e.g. universities, hospitals, industry, and primary care). The subject population was the entire CRN/M workforce in Ireland. The data collection tool was developed using SurveyMonkey<sup>®</sup>.

**Results:** Responses from 141 participants were analysed using the SPSS statistical tool. The roles and responsibilities undertaken by CRN/Ms were determined by the setting and type of research in which they were involved.

**Discussion:** Despite the pivotal role they play as members of the clinical research multidisciplinary team, the survey showed that CRN/Ms do not feel that their role is recognised or respected.

**Recommendations:** CRN/Ms should be employed at a grade appropriate to their roles and responsibilities, and prior clinical and research experience. Nationally approved competencies associated with the appropriate nursing and midwifery grades should be developed in addition to standardised job descriptions detailing the essential requirements for each grade.

Poster Abstract 13	Deirdre Hyland, Senior Clinical Research Nurse; Director of Research Nurse Education, RCSI	
Abstract Title:	Clinical Research Nursing: a Destination or a Detour?	
Author/s:	<u>Hyland, D.,</u> Schilling, C., Smith, H.A., McInerney, V., Kelsey, M. & Egan, S	E-mail: dhyland@rcsi.ie Twitter: @Irish RNN

**Introduction:** Nurses and Midwives have been employed in clinical research settings for over two decades in Ireland, with a surge in the number of posts in the past 10-15 years as more research facilities opened. However, there has been a failure to create a formally recognised role or career pathway for clinical research nurses or midwives (CRNMs), and the disparities described in the NCNM report in 2008 have not been addressed. The IRNN Count Me In study provided an opportunity to look at the terms and conditions of employment of CRNMs in 2019.

**Methods:** The Count Me In study was a survey of the entire population of CRNMs in Ireland. Distributed electronically, it attracted 141 participants, which was almost 3 times the enrolment in previous studies of this cohort. Data were analysed using SPSS version 25.

**Results:** The key results of the survey in relation to terms and conditions of employment are presented in this poster. Variables examined included: Length of time in current employment; Type of contract; Salary scale; Workplace and Employer; Role title; Satisfaction with role and available career pathway.

**Discussion:** Study findings showed that there is still considerable variation in the terms and conditions of CRNM roles, despite a perceived national approach to developing the clinical research infrastructure, with a lack of integration of the CRNM role into either health research strategy or health services.

**Recommendations:** The findings of the Count Me In study should inform future research strategies in the HRB, HEI and HSE.

Poster Abstract 14	Collette Devlin, Research Nurse, School of Allied Health, University of Limerick	
Abstract Title:	A randomised controlled trial exploring the impact of a dedicated Health and Social Care Professionals team in the Emergency Department on the quality, safety, clinical and cost- effectiveness of care for older adults	
Author/s:	Cassarino, M. Robinson, K. O'Shaughnessy, Í. Smalle, E. White, S. <u>Devlin, C. Q</u> uinn, R. Trépel, D. Boland, F. Ward, M.E. McNamara, O'Connor, M. McCarthy, G. Ryan, D. & Galvin, R.	E-mail: Collette.devlin@ul.ie

**Introduction:** Older adults are frequent users of emergency services and demonstrate high rates of adverse outcomes following emergency care. Evidence suggests that HSCP teams working in the emergency department (ED) can enhance the care of older adults but the quality of these studies is mixed. This randomised controlled trial explores the impact of early assessment and intervention by an ED-based HSCP team on the quality, safety and cost-effectiveness of care of older adults.

Methods: Consecutive ED attendees aged ≥65 years were considered eligible for inclusion and were screened for eligibility based on pre-defined inclusion criteria. Participants were randomised to either early assessment/ intervention by interdisciplinary team comprising a senior physiotherapist, senior occupational therapist and senior medical social worker or usual care. Primary outcomes included ED length of stay and hospital admission rates. Secondary outcomes included: patient satisfaction, function, quality of life, incidence of ED re-visits, hospital admissions, nursing home admission, healthcare utilisation and mortality at 30-day and 6-month follow-up. **Results:** Considering the first 238 participants, the intervention group spent significantly shorter time in the ED than the control group (7.33 vs. 14.15 median hours, p<0.001) and experienced lower admission rates (18.64% vs. 60%). At 30-day follow up, healthcare utilisation rates were higher in the intervention than control group (72.92% vs. 58.51%, p=0.04). There were no significant differences between the groups regarding satisfaction with their ED visit, function, quality of life or incidence of adverse outcomes at 30 days. Our cost-effectiveness analysis is ongoing.

**Conclusions:** Preliminary findings from our trial indicates that HSCPs working in team in the ED can contribute to improved older patients' care by reducing their duration of stay in the ED and increasing rates of discharge home. Participant recruitment and six month follow-up is continuing.

Poster abstract 15	Amy Stone, Research Nurse/ Operations Manager, Clinical Research Facility Cork	
Abstract Title:	CRF-C Study Coordinator Survey: Challenges Experienced During Clinical Trial Conduct	
Author/s:	Crowley, E. <u>Stone, A. Kelly</u> , N. & Kelsey, M.	E-mail: amy.stone@ucc.ie

**Background:** Patient recruitment is critical to clinical trial success. Recruitment is also one of the most challenging aspects of conducting clinical trials, with a substantial number of trials failing to reach their recruitment target. Insufficient recruitment can have considerable ethical, clinical and policy implications. Underpowered studies, due to insufficient recruitment, can give rise to type II errors which may lead to effective treatments being discarded before establishing the true value or effect.

**Methods:** Studies conducted in CRF-C which closed between January 2018 and April 2019 were reviewed. Study co-ordinators were interviewed to gather information regarding general study statistics and challenges faced during study execution. The data was analysed to explore and identify the main difficulties experienced during clinical trial conduct.

**Results:** 17 studies across 6 therapeutic areas were reviewed. Recruitment was the most widely reported challenge, with restrictive eligibility criteria cited as a recruitment challenge in 6 (35.3%) trials. Of the 6 studies that reported this challenge, 5 failed to reach recruitment target. Screen failures, recruitment windows and "other" challenges were also reported. Retention was not reported as a challenge in any of the trials.

**Conclusions:** Recruitment was identified as the principal challenge, with restrictive eligibility criteria being cited as a factor affecting recruitment by multiple study coordinators. Critical assessment and development of a recruitment plan during the feasibility process should be employed to mitigate against under recruitment in clinical trials.

Poster Abstract 16	Siobhan Egan, Research Nurse, ULHG/CRU/HRI	
Abstract Title:	'Never underestimate the power of a planted seed'- The successful implementation of a health literacy initiative to promote sepsis awareness at University Hospital Limerick Group.	
Author/s:	Egan, S. & Young, Y. E-mail: vonnie9@hotmail.com Twitter: @Siobhanegan2	

**Introduction:** This presentation describes the use of seed funding from the HRB /IRNN grant to introduce a health literacy initiative to promote sepsis awareness. According to the WHO (2019) health literacy refers to an individual's ability "gain access to, understand and use information in ways which promote and maintain good health for themselves, their families and their communities." Sepsis is the body's extreme response to an infection and is a life-threatening medical emergency. Without timely treatment, sepsis can rapidly lead to tissue damage, organ failure, and death.

**Aim**: Explore the impact of implementing a health literacy initiative to promote sepsis awareness for the public, patients and staff within ULHG.

Methods: In order to successfully implement this initiative the funding supported the following:

- 1. Creation of a fridge magnet highlighting sepsis recognition and symptoms. This resource promotes health literacy and provides easy access to information about sepsis.
- 2. Providing sepsis awareness workshops both at hospital and community venues for public and patient groups.
- 3. Projecting the signs and symptoms of sepsis onto the hospital building during visiting hours at ULHG.

**Results:** Both quantitative and qualitative data were obtained during this health literacy campaign. The success of this initiative is reflected the impact of the social media response including twitter activity surrounding the campaign. Pre and post confidence scores along with feedback from participants who attended the sepsis awareness workshops provide a measure to the impact of the initiative on participants understanding and awareness of sepsis.

**Conclusion:** The impact of the seed funding received from the IRNN and HRB provided a fantastic opportunity to positively impact patients, public and staff through health literacy including innovative approaches to sepsis awareness. The vision for the future is to secure further HRB funding to support a national health literacy sepsis education for primary school children.

Poster Abstract 17	Ann-Marie O'Callaghan, Clinical Research Nurse, Clinical Research Facility Cork	
Abstract Title:	Impact of New Data Protection Regulations on Clinical Trial Recruitment: A Research Nurse Perspective (The ImPaCT Study)	
Author/s:	<u>O'Callaghan, A.M.</u> Stone, A. Browne, S. Murphy, M & Spillane, M.	E-mail: annmarie.ocallaghan@ucc.ie

**Background:** Patient recruitment is critical to clinical trial success. Recruitment is also one of the most challenging aspects of conducting clinical trials, with a substantial number of trials failing to reach their recruitment target. Insufficient recruitment can have considerable ethical, clinical and policy implications. Underpowered studies, due to insufficient recruitment, can give rise to type II errors which may lead to effective treatments being discarded before establishing the true value or effect.

**Methods:** Studies conducted in CRF-C which closed between January 2018 and April 2019 were reviewed. Study co-ordinators were interviewed to gather information regarding general study statistics and challenges faced during study execution. The data was analysed to explore and identify the main difficulties experienced during clinical trial conduct.

**Results:** 17 studies across 6 therapeutic areas were reviewed. Recruitment was the most widely reported challenge, with restrictive eligibility criteria cited as a recruitment challenge in 6 (35.3%) trials. Of the 6 studies that reported this challenge, 5 failed to reach recruitment target. Screen failures, recruitment windows and "other" challenges were also reported. Retention was not reported as a challenge in any of the trials.

**Conclusions:** Recruitment was identified as the principal challenge, with restrictive eligibility criteria being cited as a factor affecting recruitment by multiple study coordinators. Critical assessment and development of a recruitment plan during the feasibility process should be employed to mitigate against under recruitment in clinical trials.

Poster Abstract 18	David O'Riordan, Pharmacovigilance Officer, University College Cork	
Abstract Title:	A mixed methods study exploring the knowledge, attitudes and practices to pharmacovigi- lance and adverse drug reaction (ADR) reporting in clinical trials	
Author/s:	<u>O Riordan, D.</u> Kinane, M. Walsh, K.A. Shiely, F. Eustace, J. & Bermingham, M.	E-mail: davidoriordan@ucc.ie Twitter: @davidoriordan7

**Purpose:** The purpose of this study was to explore the knowledge, attitudes and practices of health professionals working in clinical trials to pharmacovigilance and ADR reporting. Secondary objectives were to explore the reasons for underreporting of ADRs and to identify methods to optimise ADR reporting.

**Methods:** A mixed methods study comprising of responses from an online questionnaire and qualitative responses from semi-structured interviews and focus groups. The questionnaire was disseminated online from September to November 2018. Four focus groups and three semi-structured interviews were conducted with a random sample of those questionnaire participants who had provided their contact details. The qualitative interviews were conducted at a location convenient to the participant's place of work between October and December 2018.

**Results:** One hundred and forty-eight participants completed the questionnaire. The majority of participants were study coordinators/project managers, 28.6% (n=38). Poor knowledge or understanding of ADR reporting was the most frequently cited barrier to ADR reporting, 75% (n=93). The most common enabler to reporting was having a clear understanding of an ADR definition, 85.7% (n=108). Focus group and interview participants described the challenge of having a limited resource of staff to report an ADR. They welcomed the prospect of pharmacovigilance training and suggested face-to-face training would be preferred to an online version.

**Conclusion:** This study has highlighted some of the key factors that influence the reporting of ADRs in clinical trials in Ireland. Findings suggest that clinical trial staff should be supported by pharmacovigilance training as this could optimise ADR reporting.





### **RESEARCH NURSE AND MIDWIFE SUPPORT**

## The Health Research Board (HRB) have awarded grant funding to the Irish Research Nurses Network (IRNN) to support the professional development of clinical research nurses and midwives in Ireland (2018-2021)

The funding has been granted for 5 specified purposes:

- ⇒ Support for IRNN Annual National Conference and other IRNN activities
- ⇒ Conference and event attendance by IRNN members
- $\Rightarrow$  Seed funding for innovation or quality improvement initiatives
- ⇒ Funding for attendance at national and international committee/ working group meetings by IRNN representatives, where that person is a member or observer of the group
- ⇒ Completion of a national scoping exercise to ascertain the number of research nurse and midwife positions in Ireland, their employment structures, roles and responsibilities (Count Me In Study).

Research nurses/midwives who are members of IRNN can now apply for funding to engage in professional development activities as outlined in points 1-3 above. The applicant must be able to demonstrate that their planned activity is relevant to the research nurse/midwife role and will benefit their professional development and/or their organisation. The applicant is asked to avail of co-funding by their employer/organisation if at all possible. Full details of the application process, and application forms, are available on the IRNN website: <u>https://irnn.ie/grants/irnn-hrb-research-nurse-midwife-supportdevelopment-grant-open/</u>