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ABSTRACT #1 - POSTER

THE RESEARCH NURSE’S ROLE IN GENE TRANSFER FOR SEVERE COMBINED IMMUNE DEFICIENCY X-1 (SCID-X 1) USING A SELF-INACTIVATING GAMMA RETROVIRAL VECTOR
Grace Yoon\(^1\) and Lucinda Williams
\(^1\)Boston Children’s Hospital, Boston, MA

There has been an explosion of basic scientific discoveries in the field of Genetics over the past two decades awaiting translation into human therapies; with the ultimate goal of improving human health. Gene therapy, the science of inserting corrective genes into human cells, is a promising technology that is now employed in a limited number of clinical trials. This new frontier provides clinical research nurse coordinators with an important opportunity and role on study teams operationalizing these complex but innovative trials fraught with unique regulatory, ethical and clinical challenges. During this session, the role of the research nurse coordinator in a gene transfer trial designed to treat children with Severe Combined Immunodeficiency X-Linked (SCID-X) will be explained.

Children’s Hospital Boston is the coordinating site for this international gene transfer research study. The complexities of the scientific design and the highly interdisciplinary nature of this trial require an experienced nurse project manager who is able to oversee and coordinate all of the many “moving parts” of the study. This challenging trial employs the full range of research nursing expertise and skills: Consultation, collaboration, family and staff education, culturally competent care, application of system knowledge and coordinating a complex sequence of trial activities from harvesting the subject’s stem cells, viral vector gene insertion and infusion of the manipulated cells to the study subject.

ABSTRACT #2A – SYMPOSIUM A1

THE MANAGEMENT OF A CLINICAL RESEARCH CENTRE, ENCOMPASSING THE EVOLVING CAREER STRUCTURE AND PROFESSIONAL DEVELOPMENT OF THE IRISH CLINICAL RESEARCH NURSE
Mary McGrath
University College of Dublin CRC St Vincent’s University Hospital, Dublin, Ireland

The presenter will outline her role as Clinical Research Centre Manager, which includes many facets such as clinical practice, people management, operational management, strategic management & professional development support through a National Network for Clinical Research Nurses (CRN’s) The session will include a description of a Good Clinical Practice Systems inspection that was carried out in UCD Clinical Research Centre in June 2011 by the Irish Medicines Board (IMB) This was the first such inspection in Ireland. As there was no quality assurance person employed in the CRC, the business of coordinating the inspection fell on the CRC manager. Following the IMB inspection, CRC management have reviewed all written procedures to develop more rigid quality systems.

Kendre & Foxcroft (2001) described an evolving career structure for CRN’s in the UK in order to build on research capacity and infrastructure. The speaker will outline the development of roles within the Irish Clinical Research Centres to date in light of a report by National Council for Nursing and Midwifery (2008) which stated that ‘the role as it exists is hidden and diverse and lacks development’. The session outlines the key issues identified in that report and will follow the progress of expansion for career pathways for CRN’s employed in Clinical Research Centres. The presenter will outline her role in stimulating a partnership approach between employers and hospital nurse management in order to support research nurses in professional development endeavors. This work led to the title of the
presenter’s research proposal which aims to interview directors of nursing in all teaching hospitals in Ireland to explore the value of Clinical Research Nurse in their respective hospital.

**ABSTRACT #2B – SYMPOSIUM A1**

**DEVELOPMENT OF A CLINICAL RESEARCH NURSE EDUCATION AND COMPETENCY ASSESSMENT PROGRAM IN IRELAND**

Deidre Hyland
Clinical Research Centre, Beaumont Hospital, Dublin, Ireland

The Royal College of Surgeons in Ireland (RCSI) Clinical Research Centre (CRC) was the first purpose built academic CRC in Ireland. When it opened in 2000 the need for structured programs of education and preparation of clinical research nurses (CRNs) in Ireland was quickly apparent, however, there were no suitable courses available in Ireland. The best available option was to attend distance learning programs in the United Kingdom. The CRC nurse manager worked closely with the Faculty of Nursing & Midwifery in RCSI to design a program that would meet these needs but, despite enthusiasm being expressed by stakeholders, there was no core funding to proceed.

In 2008 the Dublin Centre for Clinical Research (DCCR) was founded. Funded by the Health Research Board and the Wellcome Trust, the remit of the DCCR is to provide the infrastructure—the physical space, facilities and trained staff—needed to support collaborative clinical research studies across Dublin involving the Trinity College Dublin (TCD), University College Dublin (UCD) and RCSI Medical Schools and their teaching hospitals. This included a commitment to facilitating clinical research nurse education.

This presentation will outline the process of developing and running a postgraduate educational program for CRNs in Ireland. The program commenced in 2009 and has run annually since then. The purpose of the program is to prepare nurses that have the knowledge, attitudes and skills to practice at a higher level as CRNs. A secondary aim is to articulate the specific skills and knowledge that CRNs possess. This is being achieved through implementation of a competency assessment schedule that must be completed in the clinical area. Our program has been accredited by the National University of Ireland and by An Bord Altranais (Irish Nursing Board), and allows progression to major academic awards.

**ABSTRACT #2C – SYMPOSIUM A1**

**HOW RESEARCH NURSES CAN EXPAND THEIR ROLE TO INCLUDE NURSING-LED RESEARCH**

Elaine Mac Hale
Clinical Research Centre, Beaumont Hospital, Dublin, Ireland

Up until the end of the 20th century, Nurses in Ireland were trained following an apprentice style system that was very task orientated. Nurse training is now a primary degree programme completed in the University setting. Having completed training in the 1980’s as a registered general and paediatric nurse I progressed through a clinical career that ultimately led me to clinical research nursing.

My presentation will outline my career path and how it led me back into nursing education generally and then more specifically into clinical research education. Having re-entered the work environment after a career break I recognised the need to develop and maintain my competencies so I completed BSc Nursing Management 2008-2010 followed by the Post graduate Certificate in Nursing (Clinical Research) 2009-2010 where I was part of first student intake to this newly designed program. Currently I am in the final year of a Master of Science through Research.
I will also discuss my current responsibilities as a research nurse and how I came to add a nursing research component to the medically-led research study which I was coordinating.

My research question is: “What is the impact of a nurse led education programme on compliance with inhaler use in patients with Asthma”.

An overview of the medical-led study (Inhaler Compliance Assessment (INCA)) will be provided, to include the design and methodology of the study. This will then lead to the trigger for my research, which will be described in detail. This will include the Aims, Objectives, Methodology and Tools used, including the development and validation of questionnaires, and a scoring system for inhaler technique. The results will be discussed and some anecdotal stories shared.

ABSTRACT #3 - POSTER

RETENTION STRATEGIES FOR A 30 YEAR PEDIATRIC LONGITUDINAL STUDY
Carol Griesser
Baylor College of Medicine, Houston, TX

The purpose of this paper is to share my experiences managing a longitudinal research project. For 20 years, I held the position of research nurse to the Congenital Cytomegalovirus Longitudinal Study at Baylor College of Medicine and Texas Children’s Hospital. This 30 year-long study follows 237 study subjects with congenital CMV infection from birth to adulthood. It examines the long-term effects and predicts the long-term outcome of congenital CMV infection.

What I have learned is study subject retention is crucial for longitudinal study success. Subjects were enrolled shortly after birth and followed periodically throughout childhood, adolescence, and a final young adult age study visit. Maintaining subject participation and keeping attrition low is the most difficult and challenging part of my job.

The goal to continued study participation was accomplished by incorporating several key strategies. Establish a good rapport and work to develop a long term relationship with the subject and subject’s parents. Keep current and detailed contact information for each subject. Be available to provide support to answer questions or concerns associated with the study or other issues related to how congenital CMV affects their child. Foster continuity of care by assisting and coordinating specialty health care services as needed.

At every study subject visit, the family is personally greeted and escorted to their appointments. Upon completion of a study follow-up visit, an expression of appreciation and gratitude is given to subjects in the form of an age appropriate gift. As needed, transportation and other travel expenses are reimbursed by the study.

Between study visits, ongoing contact and communication is maintained with subjects and their parents. Birthday and holiday card mail outs let them know they are thought of and maintains rapport. Letting families know about the latest CMV research advances through newsletters and other updates shows them their contribution matters.

Using these retention strategies has made an important impact on the success of the study. Our subject follow-up rate remains high and we have established strong relationships with subjects and their families who are committed to the success of the Congenital CMV Longitudinal Study.
ABSTRACT #4 - POSTER

USING YOUR OWN MEDS WHEN YOU ARE BEING ADMITTED TO THE CLINICAL RESEARCH CENTER
Linda Godfrey-Bailey
Harvard Catalyst Clinical Research Center at Beth Israel Deaconess Medical Center, Boston, MA

Research patient’s admissions to the Harvard Catalyst Clinical Research Center at Beth Israel Deaconess Medical Center (CRC) were disrupted on many occasions due to the research patient bringing their usual medication to the hospital in unlabeled containers or several medications mixed in one container. This prevented the research pharmacist from being able to verify that the medications were the correct dose and frequency and within the date of expiration, so the medications the patient brought in could not be used during the admission per hospital policy and pharmacy regulations. In these situations the study principal investigator would be asked to cover the cost of the medications being dispensed from the hospital pharmacy, which is problematic for investigators since this would be an unbudgeted cost to their grants. The CRC does not have the funds available to cover these non research medication costs either. To help address this problem an educational tool was developed to explain how medications must be labeled to allow the patient to use their own medications while admitted; using graphics and minimal written instructions at a 10th grade reading level. The tool is available in both English and Spanish. The tool was reviewed with content experts for face validity, and was found to be clear and understandable. The tool was distributed to study staff to share with their research patients before the planned admission. Since its inception the frequency of patients bringing improperly labeled medications to their research admissions has decreased.

ABSTRACT #7 - POSTER

USING CASE STUDIES TO INTEGRATE A NEW MODEL OF CARE
Earlian Jackson¹, Karen Amer, Deborah Ellen Boyle, Marilla Geraci, Susan Goo, Madeline Gupta, Brenda Justement, Beth Lee, Bruce Steakley, Karen Amer, Deborah Ellen Boyle, Marilla Geraci, Susan Goo, Madeline Gupta, Brenda Justement, Beth Lee, and Bruce Steakley
¹National Institutes of Health Clinical Center, Bethesda, MD

The National Institutes of Health Clinical Center is a facility dedicated to research. A new Clinical Research Nurse Model of Care (CRN MOC) which described the roles and dimensions of the CRN Domain of Practice was implemented in 2010. The Shared Governance Performance Improvement Committee (PIC) planned an evaluation of the unit level implementation of the Model of Care in 2011, which included case presentations and discussions of how the cases reflected the MOC. This process prompted discussion and stimulated interest in further focus on the MOC in the mental health clinic, where CRNs have established roles for autonomous professional CRN practice.

Following the PIC case presentation guidelines, a unit performance improvement (PI) project was developed in the mental health clinic. Target outcomes included increasing professional presentation skills, applying the MOC to clinical practice, and developing appreciation of clinic peers’ implementation of the CRN role. Each CRN presented a case, and developed a PowerPoint presentation to exemplify aspects of the MOC, based on their clinic CRN role. The MOC provided a framework which facilitated discussion of cases which in turn stimulated discussion related to clinical practice and role definition. Case presentations were incorporated into unit staff meetings, with good attendance and active participation at each session. This forum introduced peer review, fostered a collaborative unit atmosphere, and added knowledge and appreciation of each other’s CRN practice roles. The presentations demonstrated that CRNs across varied research groups were similarly able to apply the
CRN dimensions and tenets in their practice roles. These discussions generated interest in and established a framework for continued professional growth. Although clinic CRNs support different research studies, this process was empowering for the clinic nurses and has increased mutual support and collaboration among clinic team members.

ABSTRACT #8 - POSTER

PROTECTING A VULNERABLE POPULATION: THE ROLE OF THE PERINATAL RESEARCH FACILITATION CORE AT THE UNIVERSITY OF COLORADO DENVER ANSCHUTZ MEDICAL CAMPUS, AURORA, COLORADO
Christine Reed¹, Anne Lynch, Nanette Santoro, William Hay, and Alison Lakin
¹Children’s Hospital Colorado, Aurora, CO

Since its inception in 1979 the Perinatal Clinical Translational Research Center (PCTRC) has evolved into a specialized unit providing expert nursing research support to Neonatal Intensive Care, Newborn Nursery and Labor and Delivery protocols. The PCTRC, a component of the Child Maternal Health (CMH) program of the Colorado Clinical and Translational Sciences Institute (CCTSI), facilitates recruitment and implementation of over 20 perinatal protocols at several institutions and is the common denominator among a vast pool of investigators.

Healthy newborns, preterm infants, and pregnant women represent a unique and limited group of subjects for clinical investigation. In order to safely and ethically recruit this population into multiple overlapping studies and promote equitable recruitment among investigators, the Perinatal Research Facilitation Core (PRFC) has emerged as a unique and valuable resource for researchers across our campus. This core was organized in response to the following concerns: an increasing volume of research protocols, the need for “traffic control” when research teams enroll participants into longitudinal studies, and the commitment to protect research participants from “research fatigue”. The PRFC is organized around a Perinatal Research Facilitation Committee composed of senior faculty and administrators from across campus who meet to discuss complex issues related to perinatal research and to provide direction to the PCTRC and the Triage Committee; a Triage Committee that meets monthly to review perinatal research protocols in prenatal clinic, on Labor and Delivery and in the Neonatal Intensive Care Units; and a Recruitment Database. The aims of the Triage Committee are: to assess the feasibility of the proposed research; identify overlap with existing studies, foster collaboration among investigators, and establish priorities among protocols.

The Perinatal Research Facilitation Core has been in existence for two years. Strong collaborations with the University of Colorado Hospital, the IRB, CTRC, the School of Medicine, College of Nursing, and the Colorado School of Public Health have contributed significantly to the success of this innovative process. Despite the ongoing competition for potential research participants, our system continues to streamline recruitment, facilitate investigator collaboration, and encourage the success of multiple perinatal research studies at our Institution.

ABSTRACT #9 - POSTER

RESEARCH SUBJECT SATISFACTION SURVEYS: IMPLEMENTATION AND OUTCOMES FOR RESEARCHERS
Paula Smailes
The Ohio State University, Columbus, OH
Utilizing a Research Subject Satisfaction Survey can be instrumental for the success of any clinical research site. The survey can be given at the end of participation or at certain intervals for longer studies. The main goal from the survey feedback should be site quality assurance and improvement. However, if the performance of particular staff members is mentioned, the survey can also be used for staff annual evaluations. Participants can be excellent sources of staff conduct.

To implement a tool such as this, Institutional Review Board may be needed. A cover letter should also be included to explain the purpose of the survey and thought will be needed for how the site can keep the surveys anonymous. Results can be collected from a single study or mixed together with multiple ongoing studies, depending on how the results may be used at the research site. Examples of what could be obtained include how well study visits were executed, staff professionalism; site facilities; and effective methods of recruitment.

Research nurses and staff often wear many hats to execute a study and in doing so, may overlook the importance of how their site operations are perceived by the subject. It can be challenging enough to recruit subjects. Once they are enrolled, sites should do their best to maintain a positive and safe environment for subjects. Use of this tool not only can help to determine if that goal is being met, it can also simultaneously show the subject that their opinion is valued and that they are important. This is crucial because without them, there would be no clinical research.

**ABSTRACT #10 - POSTER**

**PROGRAM EFFECTIVENESS PILOT STUDY OF THE IMPLEMENTATION OF EVIDENCE BASED PRACTICE (EBP) INTO NURSING PRACTICE IN MAINLAND CHINA**

Xiaokun Liang1, Clare Hastings, Li Yang, Cheryl Fisher, Zhiying Bao, Chunping Ni, and Gwenyth Wallen

1Global MD China CME Training Project, Beijing, China

Objectives: To test the reliability of instruments translated into Chinese to measure EBP beliefs, organizational readiness, and EBP implementation. To assess the impact of a workshop on beliefs and implementation of EBP in Chinese nurses.

Background: International professional organizations for health practitioners endorse the tenet that practitioners should have their clinical decision making grounded in research, training, and practice expertise. Organizational environment and patient/family preferences must also be considered when adopting changes in practice. Whether striving to implement practice innovations or to understand genetics and genomics as they relate to their clinical practice, clinical research nurses in Mainland China will need to be adept at problem solving approaches to practice such as evidence based practice. A 2-day EBP workshop was offered to selected nurse leaders in Beijing and Xian, China.

Methods: Questionnaires were administered pre (N=238) and post (N=214) workshop to measure EBP beliefs, organizational readiness, EBP implementation, nurses’ retention, nurses’ intent to leave, group cohesion, and job satisfaction. Analyses of variance (ANOVA) and analyses of covariance (ANCOVA) were performed to test between-group differences for those who attended the workshop and those who did not.

Results: Internal reliability for EBP Beliefs, Organizational Culture & Readiness, and EBP Implementation scales were 0.87, 0.96 and 0.95 (pre-workshop), 0.88, 0.95 and 0.95 (post-workshop), respectively. Overall, more senior, manager level, and those with higher education were in EBP workshop group as compared to the non-workshop group. Mean age and previous EBP exposure experiences were similar in both groups. Overall, organizational culture and readiness for EBP were positively related to EBP beliefs, EBP implementation, job satisfaction, and group cohesion. EBP beliefs and EBP implementation
were also significantly correlated \((r=0.21, p<0.01)\). Workshop participants had higher EBP implementation scores post workshop, while non-EBP workshop groups’ scores decreased. \((18.6-19.6 \text{ vs. } 21.6-15.5; F=6.19, p=.013)\). However, after controlling for years of experience and highest education level, none of the outcome variables showed significantly different changes from before to after workshop between EBP and non-EBP groups.

Conclusions: Chinese translations of the EBP Beliefs, Organizational Culture & Readiness, and EBP Implementation scales had excellent internal reliability. The nurses’ beliefs and implementation of EBP are significantly correlated with organization culture and readiness for EBP however it is unclear whether one workshop for nurse leaders can contribute to improvements in the EBP beliefs and implementation throughout an organization.

**ABSTRACT #11 - POSTER**

**THE ACHIEVEMENTS AND CHALLENGES OF THE CLINICAL TRIAL NURSE-SPECIAL INTEREST GROUP (CTN-SIG) OF THE JAPANESE SOCIETY OF CANCER NURSING (JSCN)**
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Background: The number of clinical research coordinators (CRCs) is increasing in Japan. Half of the CRCs have a background as nurses. However, most clinical nurses and nursing students have few opportunities to learn about clinical trials, being unfamiliar with the concept of clinical trial/research nursing (CTN/RN). Against this backdrop, the Clinical Trial Nurse-Special Interest Group (CTN-SIG) was established within the Japanese Society of Cancer Nursing (JSCN) in 2006 to enlighten nurses about CTN/RN in Japan, especially in oncology. We review our past activities and consider future plans.

Purpose: To clarify the achievements and challenges of the CTN-SIG.

Methods: Peer review of our activities to date among CTN-SIG members.

Results: The CTN-SIG has made information about CTN/RN readily available to JSCN members. The number of CTN-SIG members has doubled in the last five years. The CTN-SIG has provided three learning opportunities per year to its members, under the themes of “The ethics of clinical research”, ”The role and the practice of CTN/RN” and ”Present state of CTN/RN”. We identified current trends and issues in the field of CTN/RN.

Challenges: CTN-SIG members constitute less than 1% of JSCN membership. There are far fewer clinical nurses than CRCs in the CTN-SIG. We should consider ways of increasing the number of clinical nurses in clinical research fields. The CTN-SIG made a brochure in 2008 to provide clinical nurses with information about clinical research. We should make greater efforts to develop tools and resources about CTN/RN.

Conclusions: The CTN-SIG has demonstrated the importance of CTN/RN to nurses in Japan. Although the number of CTN-SIG members is increasing, there are relatively few clinical nurses in the CTN-SIG. All nurses must have basic knowledge about evidence-based practice including clinical research. The CTN-SIG needs to offer effective learning opportunities and enhance leaning tools and resources about CTN/RN.

**ABSTRACT #13 – CONCURRENT SESSION A2**

**ADVANCING ROLE RECOGNITION THROUGH PROFESSIONAL NETWORKING AND COLLABORATION**
Mary Larkin¹, Lauren Donahue, Catherine A. Griffith, Kerry Milaszewski, Linda Pitler, and Amy Sbrolla
Background: There is a lack of role clarity within clinical research nursing (CRN). Furthermore, awareness and understanding of the role by the nursing community at large needs to be improved. CRN is often used interchangeably with research nursing. As we strive to advance practice and achieve specialty designation, delineation of the role is imperative and can be achieved through research, publication, education of peers and professional networking and collaboration.

Objective: The aim is to describe the process of networking and collaboration within the research and nursing communities to heighten awareness of the CRN role within the Boston area from 2008 to the present. The steps, tools and logistical considerations are shared with the intent to provide examples for other groups to replicate as desired.

Implementation: The sequence of steps taken include the following: establishing a forum for knowledge sharing, problem solving and community building at one large academic medical center called the Research Nurse RoundTable (RNRT), collaborating with an affiliating institution to replicate the model, disseminating results via presentations at local and national conferences, publication of 2 manuscripts regarding the CRN role, establishing a local IACRN chapter, collaborating with other targeted research entities including the Munn Center for Nursing Research and the Research Subject Advocacy Group at Harvard Catalyst (RSA).

Outcome: The RNRT has been a sustainable forum for 4 years at 2 institutions. The pilot chapter has completed a year of active involvement with requests from several surrounding cities for information. The leaders of the RNRT and Boston chapter meet quarterly with nursing research leaders and are discussing ways to support each others practice. Chapter and RSA leaders are discussing aspects that are common to each group’s mission regarding advocacy, education and community involvement.

Implications: Professional networking and collaboration has heightened the awareness of the CRN role within our professional community. Efforts by CRNs to disseminate information, educate the nursing and research community about their role and unique body of knowledge will add value to our contributions as research professionals and strengthen the discipline of clinical research nursing.

ABSTRACT #14 - POSTER

GOOD CLINICAL PRACTICE (GCP) SYSTEMS INSPECTION OF A CLINICAL RESEARCH CENTRE BY THE IRISH MEDICINES BOARD
Mary McGrath¹, Peter Doran, Hazel Bergin, Helen Vaughan, Natasha Duff, Helen Campion, and Daniel White
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A GCP Systems inspection was carried out in University College Dublin (UCD) Clinical Research Centre (CRC) in June 2011 by the Irish Medicines Board (IMB). This was the first such inspection in Ireland. As we know, compliance with the GCP standard provides public assurance that the rights, safety & well-being of trial subjects are protected and that clinical trial data are credible.

To ensure that no critical or major findings were found and to prepare for an opportunity to interact positively with the IMB, a detailed plan was formulated to prepare & execute the systems inspection. A team was set up involving management & research staff that developed a working plan for the inspection. The strategy identified a responsible person & date to be achieved for each action point. This plan was reviewed twice weekly during the month prior to the inspection. Communication with all stakeholders including the various pharmaceutical companies was paramount.
We were requested by the IMB to submit the following documents, prior to the inspection:

- Copies of all Standard Operating Procedures (SOP's) related to the conduct of Clinical Trials.
- Job descriptions and Curriculum Vitae of all personnel involved in the conduct of trials at the CRC.
- A listing of all Commercial and Non Commercial Clinical Trials being conducted at the CRC.

Following the IMB inspection, UCD CRC have reviewed all written procedures to reflect more closely to actual practice & to overall develop more rigid quality systems. A corrective & preventative action plan (CAPPA) was formulated & accepted by the regulatory authority (IMB) which included a full reconciliation & assessment of all procedures/processes along with written procedures. Extra systems were put in place for the management of training & recording of same. Revised written agreements between the Principal Investigators and the CRC were agreed with legal oversight.

**ABSTRACT #15 - POSTER**

**CREW RESOURCE AND QUALITY MANAGEMENT WILL REDUCE CLINICAL RESEARCH ERRORS**

_Margaret E. Ottenbacher¹_, H. Lynch, T. Pfannenstiel, R. Rivera, A. Inniss, and D. Powell

¹University of Texas Medical Branch, Galveston, TX

Objectives/specific aims : Errors in research specimen collection result in increased costs, loss of data, and may increase risks to research participants and decrease investigator satisfaction. To improve the quality and integrity of research data acquired on the UTMB Clinical Research Center and the UTMB/NASA Flight Analog Research Unit, we developed baseline measures of data integrity, identifying problems leading to erroneous data, and implemented changes through crew resource and quality management.

Methods/study population: In 2009, we initiated crew resource management (CRM) and a Quality Management Program to reduce errors in the collection and processing of body fluid samples and the proper delivery of fixed composition meals. A universal set of tools: check lists, cross checks, and time outs were developed and refined, with unique tools created for certain protocols. Metrics that portray Administrative, Nursing Services, Core Laboratory, Bionutrition, and Subject Safety activity are displayed monthly on a dashboard. Bi-monthly quality management meetings are attended by CRC staff, leadership, hospital QM, with liaison from the IRB.

Results/anticipated results: The combined census on our CRCs is approximately 1800 outpatient visits and 1500 inpatient days per year. We process ~ 22,500 urine, 15,000 blood samples and 4300 fixed composition meals annually. Errors have been significantly reduced from 4-5 per week to 4-5 per month.

Discussion/significance of impact: Training in concepts originally introduced by the aviation industry has allowed staff an active role in tool design and monitoring. Unit leaders promote CRM and QM in all areas. Investigator satisfaction has increased. Crew resource and quality management are effective in reducing research errors.

**ABSTRACT #16 - POSTER**

**FROM RESEARCH TO PRACTICE: DETERMINING OPTIMAL WASTE VOLUME FROM AN IV CATHETER**

_Rachel Baker¹_, Suzanne Summer, Amy Shova, Jane Khoury, Michelle Lawrence, and Cathy McGraw

¹Cincinnati Children’s Hospital, Cincinnati, OH
When obtaining blood samples from an intravenous (IV) catheter, a “waste” amount is drawn to remove saline from the catheter before the blood sample is obtained. In an attempt to provide evidence based care, research nurses searched the literature to determine the optimal volume of waste to be removed before obtaining a sample from an IV. They found that existing evidence was inconsistent in how much waste to draw. Next, the group conducted a study to address these gaps in the literature. The study addressed the research question: What is the minimum waste volume that can be drawn from an IV catheter to obtain a subsequent undiluted blood sample? Sixty healthy volunteers were enrolled, IV catheters were inserted, and blood samples were obtained at baseline and following waste volumes ranging from 0.5mL to 3mL. The statistically significant stabilizing point was 1mL of waste. It was concluded that nurses obtaining blood samples from an IV catheter should draw a minimum of 1mL of waste before obtaining a sample.

This study was presented at the IACRN conference in the past. Since that presentation, we have moved the research to practice following the Conceptual Model for Translating Evidence into Clinical Practice. On an institutional level, we provided research findings to the Nursing Professional Practice Council at our hospital and a minimum waste volume is being incorporated into a new revision of our hospital’s peripheral IV policy. On a larger level, we’ve submitted the research findings for publication to a peer-reviewed journal. We are proposing this Poster presentation as a follow-up to our previous Poster and as a format to discuss ways that we used the findings to affect change on our unit, in our hospital, and at a larger level.

ABSTRACT #17 - POSTER

OPERATIONAL CHALLENGES IN MANAGING A NATIONAL PATIENT REGISTRY AND BIOREPOSITORY
Nancy Shaffer1 and Grace Yoon
1Boston Children’s Hospital, Boston, MA

Boston Children’s Hospital has initiated the first national registry and biorepository of myelodysplastic syndrome (MDS) and bone marrow failure (BMF) patients, sponsored by the National Institutes of Health (NIH). This patient registry uses observational study methods to collect data to evaluate outcomes for BMF and MDS patients who were diagnosed before age 35, and specifically aims to identify genes associated with diseases that cause MDS and BMF. Samples collected for the MDS/BMF biorepository include bone marrow, blood, saliva, and skin biopsies. All samples are tested for specific genes that have been linked to MDS and BMF-related diseases. Extensive health information is also abstracted from the medical records. New samples from each subject are submitted to the biorepository on a yearly basis, and chart review is performed every six months to one year. Some operational challenges with managing the MDS/BMF patient registry and biorepository at the coordinating site include: inadequate staff at all study sites for subject recruitment and follow-up, ensuring that biological specimens from each subject are sent to the biorepository at the coordinating site on a yearly basis, tracking specimens, capturing and cleaning large quantities of data, and site and subject retention. Managing a large-scale national patient registry and biorepository at the coordinating site is challenging, and an organizational framework for managing each aspect of the study must be followed.

ABSTRACT #18 - POSTER

ULTRASOUND GUIDED VENIPUNCTURE AND IV PLACEMENT: IMPROVING RESEARCH OUTCOMES
Rebecca Harper1, Rachel Baker, and Carrie Keininger
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In our research unit, we recently had an increase in the number of studies enrolling bariatric participants. Among these participants, we noticed an increase in the number of attempts nurses made to achieve a successful venipuncture or intravenous (IV) catheter placement, an increase in the number of infiltrates when IV medications were pushed through IVs, and an increase in the number of study visits being discontinued as a result of IV failure. After looking at different options to change these outcomes, we decided to purchase an ultrasound machine and train our research nurses in ultrasound guided venipuncture and IV placement. Even though the need for a change in venipuncture and IV placement procedures initially became evident through our experiences with the bariatric participants, after receiving training in ultrasound guided venipuncture and IV placement, research nurses were able to add this to their available techniques to improve successful venous access among all research participants. In addition, research nurses began providing this service to clinical patients and a charge was created for this service.

This Poster will describe the process of introducing ultrasound into our clinical research nurses’ practice, the training and competency developed for nurses to acquire this skill, and data on the improved outcome for participants and improved research outcomes when ultrasound was used.

**ABSTRACT #19 - POSTER**

**ENGAGING STAFF IN RESEARCH THROUGH DIFFERENT EDUCATIONAL AND TRAINING METHODS**

Carrie Keininger¹, Rebecca Harper, and Rachel Baker ¹Cincinnati Children’s Hospital, Cincinnati, OH

Cincinnati Children’s Clinical Translational Research Center (CTRC) performs studies in both outpatient and inpatient units that also conduct clinical care. The nursing staff in these areas need to have skills to perform good research. In order to facilitate these skills and engage the staff in research the CTRC research nurse coordinators use a variety of educational and training methods. These methods/trainings range from informational e-mails about upcoming research studies, one-on-one education sessions with staff that will be performing a new skill for a specific study, original videos demonstrating best research practices, as well as engaging them in research by presenting data on studies that they have been a part of in the CTRC.

Adapting educational and training methods for research helps to target specific staff needs. Just information about a new study, reviewing skills on how to conduct study procedures, or meeting with staff on specific study needs all translates to good research practices as well as staff members being invested in the research being conducted. Therefore this brings better outcomes to for the study and the studied population.

Presented in this Poster will be information on the various educational and training methods that we have utilized with the Cincinnati Children’s CTRC staff.

**ABSTRACT #20 - POSTER**

**THE CLINICAL RESEARCH NURSE CONTRIBUTES TO SCIENCE THROUGH INVOLVEMENT IN A PHASE II TRIAL OF RAD001 PLUS CARBOPLATIN IN PATIENTS WITH TRIPLE-NEGATIVE METASTATIC BREAST CANCER**

Brian Beardslee¹, Jasmeet Singh, Matthew Volm, Yelena Novik, James Speyer, Marlene Meyers, and Amy Tiersten ¹New York University Medical Center, New York, NY
Significance and Background: The clinical research nurse at a large academic cancer treatment center provides support to clinical trials engaged in the development and testing of targeted cancer treatment therapies. The following report supports the “contributing to science” dimension of the proposed Domain of Practice for the Specialty of Clinical Research Nursing which involves the contribution as a research team member to development of new ideas for study, explorations of innovations arising for clinical research findings to practice.

Purpose: Triple negative breast cancer cells are unable to repair double stranded DNA breaks and have sensitivity to platinum agents. Rapamycin acts synergistically with platinum agents to produce apoptosis and inhibit proliferation in breast cancer cell lines. Combination of RAD001 (oral mTOR inhibitor) and Carboplatin may have activity in triple-negative breast cancer.

The primary objective of this single stage open label Phase II study was to estimate the clinical benefit (complete remission (CR) + partial remission (PR) + stable disease (SD) >6 months) and the toxicity of the combination of Carboplatin and RAD001 in women with triple negative metastatic breast cancer who have had 0-3 prior chemotherapy regimens for metastatic disease. The original Carboplatin AUC 6 every 3 weeks with RAD001 run-in of 5mg daily to then 10mg daily was amended to Carboplatin AUC 5 followed by Carboplatin AUC 4 with RAD001 5mg daily due to thrombocytopenia.

Results: 24 patients recruited - median age 58 with 1 CR, 4 PR’s and 2 SD’s lasting > 6 months. One SD achieved in a patient progressing on single agent Carboplatin at study entry. Median duration of CR+SD+PR to date is 13 weeks (range of 6-60 weeks). 5 patients had grade 3/4 thrombocytopenia and 4 patients had grade 3 neutropenia (no febrile neutropenia). 1 patient experienced grade 3 dehydration. Estimated clinical benefit rate is 50% (95%C.I.: 24%, 76%). Median time to progressions or death is 87.5 days from start of treatment; with 1 death to date on the study.

Conclusions: The study has achieved its primary objective of demonstrating clinical benefit of RAD001-Carboplatin combination in triple negative metastatic breast cancer. Dose limiting thrombocytopenia was an unexpected side effect requiring protocol amendment.

ABSTRACT 21 - POSTER

IMPLEMENTATION OF A TRAINING PROGRAM TO TEACH CORE CLINICAL RESEARCH SKILLS
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Often, knowledge gained by new clinical research professionals (CRPs) (e.g. research nurses and clinical research coordinators) is based on hands-on training, mentorship, online programs, informal communications, and participation in professional organizations. No federal mandates are required to be employed as a CRP, besides nursing licensure for research nurses. Clinical research certification exists but is not required. At our academic medical center, learning to conduct clinical research has largely been an informal process with no formal educational plan. Due to growth in research at our institution since 2007 (34% increase in personnel and 24% increase in external funding), the need became more acute.

In early 2011, a team of research professionals was formed to address and satisfy this need. A 13-module course was conceived and covered topics such as: protocol development, recruitment, documentation, study management, problem reporting, data management and biostatistics. This program is targeted to those with approximately one year in clinical research. Subject matter experts developed their own content and edits were made to provide a uniform style to the materials. The
development process was iterative and included drafts, as well as conceptual and practical dry runs prior to the initial delivery of the course.

In February 2012 a pilot class was recruited from representative populations within the institution to provide detailed feedback. Attendees included investigators, research nurses, project managers, regulatory personnel, and research coordinators. Feedback was collected and long term follow-up will be assessed. Plans are in place for implementing a self-study option.

This collaborative effort serves the needs of the research nurse community as well as the broader community involved in the coordination of research. The multitude of therapeutic areas represented by our teaching staff has allowed us to share best practices across the institution and could similarly be shared outside our institution.

ABSTRACT #23 - POSTER

CLINICAL RESEARCH NURSES’ DESCRIPTIONS AND PERCEPTIONS OF RESEARCH ACTIVITIES PERFORMED BY NURSE AND NON-NURSE CLINICAL RESEARCH COORDINATORS
Carolynn Thomas Jones¹, Lynda Wilson, and Clare Hastings
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Nursing roles in clinical research have evolved in the last three decades including career positions with a wide variety of job titles. Nurses assume many roles in clinical research including study planning, implementation, participant management, data management, and evaluation. Clinical research management has emerged as a specialized nursing role, although there is a need for research to clarify the specific competencies and activities of this role. As a result of staffing, economic factors, and lack of knowledge or policy, many clinical research activities have been delegated to individuals who do not have a nursing background. Such delegation could have a negative impact on study quality, participant safety; and site compliance; however, no studies were identified to assess the frequency with which specific clinical research activities are conducted by nurses and by non-nurse clinical research managers.

The purpose of this study was to determine the perceptions of nurses who are engaged in clinical research about the research activities performed by nurse and non-nurse research coordinators. Data will be presented from a survey of IACRN nurse attendees at the third annual meeting of the IACRN in Bethesda, MD. After obtaining IRB approval, nurse attendees were invited to complete an anonymous paper survey to ascertain descriptions and perceptions of clinical research job activities being performed by nurse clinical research coordinators (NCRC) and non-nurse clinical research coordinators (NNCRC), with and without supervision. A previously validated list of 59 clinical research nurse job activities was utilized in the survey. Participants were asked to check whether each of the 59 activities was performed or should be performed at their sites by NCRC, NNCRC with direct supervision and/or NNCRC without supervision. Plans for future research using focus group sessions of experienced study coordinators will be elucidated.

ABSTRACT #24 - CONCURRENT SESSION C2

CONDUCTING AN INTERDISCIPLINARY REVIEW OF CORE COMPETENCIES FOR GRADUATES OF CLINICAL RESEARCH ACADEMIC PROGRAMS
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Currently no generally accepted definitions of roles and responsibilities required educational preparation, professional certification or experience necessary to participate in the conduct of clinical research exists. Globalization of the clinical research enterprise has resulted in considerable variability in quality of clinical trial conduct and credentials of those who conduct clinical research. Many professional groups within the clinical research enterprise are now attempting to define the required core competencies of those individuals who they represent. Groups have been working independently with no attempt to harmonize their efforts and little validation of the product by stakeholders. The Consortium of Academic Programs in Clinical Research (CoAPCR) have consolidated competencies from the various groups into a set of nine distinct competency domains. A preliminary step toward validating CoAPCR competencies was to conduct a workshop in June, 2012, during the 48th Annual Meeting of the Drug Information Association (DIA). The objectives of the workshop were to inform audience of the current efforts to define the roles and responsibilities of various individuals taking part in the clinical research enterprise; to give the audience an opportunity as stakeholders to provide feedback on the validity of core competencies; and to use the stakeholder feedback to help facilitate the harmonization of the different efforts now underway. Perspectives on competencies from the pharmaceutical physicians and clinical investigators; nursing; and clinical trial staff were presented along with the nine consolidated CoAPCR competency domains. The audience was divided into tables based on stakeholder perspectives (Pharma/CRO, Site, Regulatory and Academia). A discussion of the validity of the competencies facilitated by moderators will be presented. Compilation of participant demographics and group consensus on competency validity will be presented.

ABSTRACT #25 - POSTER

APPLICATION OF A GENOMIC KNOWLEDGE INVENTORY TO PRACTICING PEDIATRIC NURSES
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As genome science is translated to clinical practice, the nursing workforce must prepare to integrate genetics and genomics into patient care. To support that work, a set of nursing genetic and genomic competencies (the Essentials) has been broadly endorsed by professional nursing organizations in the United States. In addition, the American Association of Colleges of Nursing (AACN) has identified genetics and genomics as essential concepts in both baccalaureate and masters nursing education (AACN, 2008; 2011). Although efforts are under way to integrate genetic and genomic knowledge into nursing education, most practicing nurses are unlikely to have had formal education in genetics or genomics. The Genomic Nursing Concept Inventory (GNCI) is a 31-item instrument developed to measure nurses’ knowledge of key concepts underlying the Essentials. The psychometric features of the GNCI have been reported among baccalaureate nursing students, but not in practicing nurses. This pilot study will explore (a) the psychometric performance of the GNCI among practicing nurses and (b) the level of genetic and genomic knowledge among practicing pediatric nurses.

Approximately 500 pediatric nurses will be invited to complete the GNCI using a Web-based survey. Demographic data will also be collected. Data analysis will estimate the psychometric performance of the GNCI in pediatric nurses, a population in which it has not previously been tested. Psychometric features of the scale as a whole, including difficulty and internal consistency reliability, will be described. Individual item analysis will also be reported, including item difficulty and discrimination. In addition, results will measure the nurses’ knowledge of genetic and genomic concepts most relevant to contemporary nursing practice.

This study serves as a pilot in preparation for broader scale deployment among practicing nurses. In addition, findings will indicate the psychometric properties of the GNCI among pediatric nurses. Finally,
understanding pediatric nurses’ knowledge of genomics and genetics will inform continuing education planning.

**ABSTRACT #26 – CONCURRENT SESSION B2**

**DEVELOPMENT OF A SELF-PACED LEGO® EDUCATIONAL TOOL TO TEACH NURSES GENETIC CONCEPTS**  
Catherine Ricciardi\(^1\), Amanda Gruhl, and Kathleen M. Vandiver  
\(^1\)Massachusetts Institute of Technology, Cambridge, MA

Research nurses often serve as the primary contact for patients and research participants regardless of practice setting and will increasingly be called upon to provide education on genetic and genomic related screenings, treatments, and data collection. Genomic medicine is quickly being integrated into clinical guidelines transforming healthcare by the incorporation of genomic tests or therapeutics into routine care (Feero, Guttmacherz & Collin’s, 2010). The ten leading causes of mortality have a genetic or genomic component (Calzone, et al., 2010), most of which are of a chronic nature requiring treatments that are genetically influenced, which further illustrates the potential impact of genomic medicine. The current use and the promise of genetically influenced prevention and treatment modalities highlights that health care has reached the age of genomic medicine (Feero, 2010).

To meet the need of practicing nurses to understand genetic concepts, the Massachusetts Institute of Technology developed a participatory learning workshop tailored for contemporary nursing practice. Participant feedback from previously held workshops served as the inspiration to design and field-test an interactive, kinesthetic genetic education module intended to facilitate the translation of complex genetic and genomics concepts into clinical practice. The MIT design team created a self-paced educational kit using LEGO molecules to teach pharmacogenetics and recruited thirty practicing RN’s for the field test. Due to the warfarin’s broad clinical use and high incidence of metabolism related adverse events, this drug was chosen to demonstrate the significance of genetic variants on the drug’s metabolism with the LEGO-based models. In addition to Warfarin, approximately 80% of all clinical drugs (Zhou SF, LIU JP, Chowbay B, 2009) are metabolized by CYP 450 proteins and is relevant to safe clinical practice. In conclusion, the development of this kinesthetic educational kit should provide a simple and effective approach to teaching pertinent genetic concepts to practicing health care providers.

**ABSTRACT #27 – POSTER**

**IMPLEMENTING A NEW MODEL OF CARE IN A CLINICAL RESEARCH SETTING: EVALUATING CHANGE**  
Roger Brenholtz\(^1\), Marilla Geraci, Mary Myers, Sue Johnson, Claiborne Miller-Davis, Helen Mayberry, and Deborah Kolakowski  
\(^1\)National Institutes of Health Clinical Center, Bethesda, MD

The 2010 Model of Care for Clinical Research Nursing (MOC) affirmed nurses’ commitment to primary nursing as a framework that assigns accountability for the achievement of clinical and research outcomes. Given broad guidelines, each clinical area was charged with implementing the MOC with the understanding that formal competencies were under development. Feedback from Clinical Research Nurses (CRN) detailing the successes and challenges of implementing the MOC was determined to be important in for validation and to achieve the full potential of the CRN role.

The Nursing Practice Council requested that the Performance Improvement Committee (PIC) evaluate the implementation of the MOC. In PIC meetings case presentations of nurse’s experiences...
implementing the MOC at the unit level were introduced. Primary nursing is a key element of the Clinical Research Nursing MOC. Case studies described the clinical and research objectives, the primary nurse goals and outcomes, the role of the primary CRN in coordinating the care, and supporting clinical research and the research participant.

These case presentations were the framework used to stimulate discussion and evaluate the effectiveness of the implementation of the MOC at the unit level. Twenty-seven case presentations by PIC representative’s facilitated unit based discussions in July 2011. Following the presentation, CRNs were asked to complete a questionnaire focused on nursing practice and the nurse’s role in making a difference as a primary nurse. The survey questions were aimed at assessing the nurse’s preparation to implement the four tenets of the MOC: accountability, advocacy, continuity of care and expertise. The survey contained four open ended and eight quantitative questions using a 4 point Likert scale. All inpatient, day hospital and ambulatory clinics participated with a survey response of over 330 nurses. Findings and recommendations from the MOC survey will be discussed.

**ABSTRACT #28 - POSTER**

**ENSURING PATIENT SAFETY TOMORROW THROUGH INTERDISCIPLINARY COLLABORATION TODAY: IMPLEMENTATION OF THE PEDIATRIC PEANUT ORAL IMMUNOTHERAPY PROTOCOL**

Catherine Griffith¹, Wayne G. Shreffler, Joshua Holewinski, Alissa Brennan, Patricia Moran, and Elisabeth S. Stieb

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Background: Beginning with the IOM report, *Crossing the Quality Chasm*, collaboration and good communication among health care teams have been top priorities to ensure quality patient care in both research and non-research settings. A recent focus has been on research study team member competency with implications for study patient safety and maintenance of data integrity. To achieve good clinical practice, having an awareness and understanding of these competencies and an appreciation of true collaboration is necessary by all research study team members.

Objective: The objective is to illustrate interdisciplinary collaboration and individual competency among research study team members during implementation of a pediatric peanut oral immunotherapy research protocol (PNOIT) in a Northeastern Clinical Research Center (CRC). Types of collaboration and steps taken to ensure patient safety and data integrity are described at selected points during protocol implementation.

Implementation: Using principles of team-based care and core competencies for interdisciplinary collaborative practice, shared goals were defined and refined with emphasis on clearly outlining each member’s role. Mutual trust and synergy were attained through effective communication during sessions devoted to problem solving, clarifying protocol orders and study-visit workflow, designing the nurses’ flow sheet and a system for distribution/management of the peanut flour intervention and rescue medications, and targeted education for nutritionists, nurses, and patients.

Using a Modified Delphi Technique, protocol orders were finalized after 5 iterations among interdisciplinary study team members. 10 clinical research nurses achieved consensus on the nurses’ flow sheet after 4 iterations and final design for rescue medication management was achieved with the second pilot system. An IND was filed for the scale used to weigh peanut flour.

Outcome: PNOIT has been successfully implemented with 15 patients enrolled of the N=32. To date, patient safety has been achieved as measured by numbers of protocol violations and numbers of mislabeled specimens over 111 patient visits, (0/111) respectively.
Implications: With a focus on interdisciplinary collaboration and study member competencies, synergy is created related to problem solving and effective communication throughout all phases of protocol implementation. The PNOIT implementation model can serve as an example for other study teams to follow.

**ABSTRACT #29 – CONCURRENT SESSION A2**

**INFORMED CONSENT FOR PEDIATRIC SURGERY RESEARCH: LESSONS LEARNED FROM THE CONSENT PROCESS IN PEDIATRIC CLINICAL TRIALS**

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**Background:** It is the legal and ethical responsibility of investigators to ensure that informed consent is obtained for participation in research. Corresponding to concerns about clinical research in children, issues and challenges in informed consent for pediatric clinical trials in surgery have become more pressing.

**Objective:** To review and discuss the informed consent process in pediatric surgery research by characterizing the challenges of the process and providing some examples from recent clinical trials at the department.

**Outcomes:** In an ideal situation parents and children enrolled in research should fully comprehend the purpose, scientific design, and therapeutic details of the study; a goal extremely difficult to accomplish especially when enrolling newly diagnosed children to randomized surgical clinical trials requiring parental permission and assent prior to the initiation of therapy. With this time constraint, obtaining a truly informed consent has been a challenging endeavor for pediatric clinical investigators. However, this does not mean that a reasonable level of understanding, allowing for informed consent, and voluntary participation in clinical studies, cannot be achieved. Our recent clinical trials have shown that the process of informed consent could be improved by utilizing a staged approach to the process allowing parents to rationally consider information about the research study. Moreover, it’s been learned that in order to maximize the children’s and parents’ understanding of the informed consent process it has to be a continual one, rather than a one time event.

Variables in the informed consent and assent process that researchers need to be aware of for their impact on the process are: different developmental and cognitive capabilities of children, individual life experience and cultural background. Taking into account these variables, the researcher could tailor the informed consent and assent process to the appropriate level of the child and parents: enhancing their knowledge and ensuring continuity of the process, decreasing anxiety, demonstrating commitment, and obtaining accurate rates of proper refusals.

**Conclusion:** Lessons learned from our recent pediatric clinical trials regarding the consent process, the complex nature of assent, the impact of cultural variables, life experiences, and more effective means of communication will shape our future approaches and help to improve the process.

**ABSTRACT #30 – CONCURRENT SESSION B2**

**CLOSED- LOOP INSULIN DELIVERY IN CHILDREN LESS THAN 7 YEARS OF AGE**

Kaitlyn Williams¹ and Gwen Corr  
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The closed loop insulin study was conducted over 6 months. Patients were admitted to the Clinical Research Unit for a two night inpatient stay. Upon admission, patients are randomized to the Standard Therapy day (home routine) and Closed Loop Therapy day (insulin dosing determined by study team). All subjects complete both types of therapy.

Nursing care was complex and required thorough and methodical planning. Education for this study included a completion of study based competencies in all aspects of the study including; equipment management, operation, signs and symptoms of hypo/hyperglycemia, and blood glucose sampling. Data collection tools for glucose monitoring; carbohydrate counting and side effect management were developed, and modified as needed. Flow sheets were created to document blood glucose monitoring, along with diet sheets to document meals and carbohydrate counts.

On admission, the subject’s insulin pump was replaced with an Animas Ping insulin pump, to allow for standardization of therapy. A blood drawing IV was placed for blood sampling via a safe set, to minimize the volume of blood discard during frequent sampling. To control blood sugars consistently, subjects had preordered meals that followed the standard inpatient diabetes meal and snack schedule. Glucose levels were monitored as often as every 10 minutes, depending on the standard versus closed loop therapy days.

Nursing collaborated closely with the multidisciplinary study team to promote safe implementation of study interventions, minimizing risk or pain to participants. Nursing efforts contributed significantly to the success of this complex study.

**ABSTRACT #31 - POSTER**

**AN EVALUATION OF THE IMPACT OF A RESEARCH NURSE EDUCATION PROGRAMME ON CLINICAL PRACTICE**

Deidre Hyland  
Clinical Research Centre, Beaumont Hospital, Dublin, Ireland

This Poster will present an analysis of the effect participation in a tailored clinical research nurse education programme has on practice in the research setting. The Postgraduate Certificate in Nursing (Clinical Research) is run annually in the Faculty of Nursing & Midwifery, Royal College of Surgeons in Ireland. The programme aims to generate in participants the essential knowledge, attitudes and competencies to support the practice of clinical research and to fulfill their remit as nurses within a research setting. Content is delivered through a combination of face-to-face lectures and web-based mechanisms (blended learning).

Research nurses complete three taught modules, assessed by completion of written assignments. They are also required to complete a competency assessment schedule with the support of a mentor in their workplace. This includes submission of a reflective portfolio. Challenges facing students include dedicating time to attend lectures, the need to engage in self-directed learning and limited financial support from employers.

Three cohorts of students have graduated, either by completing stand-alone modules or the complete programme. A survey is underway of all nurses who have completed one or more modules of the programme to determine the impact participation has had on their everyday practice as research nurses. An anonymous questionnaire will explore the following:

- Do participants feel more confident in their role?
- Has their contribution within the research team developed or expanded?
- Has completion of the programme/module influenced their practice?
- Have they had opportunities for academic or career progression?

Information will also be elicited about what aspects of the programme were most beneficial and whether, in retrospect, the participant would recommend changes or additions to the content and delivery of the programme. Results will be analysed using the Statistical Package for Social Sciences (SPPS) and descriptive statistics will be presented using graphs and text. At the time of abstract submission provisional results are not yet available.

**ABSTRACT #32 - POSTER**

**THE IMPACT OF A NURSE-LED EDUCATION PROGRAMME ON COMPLIANCE WITH INHALER USE IN PATIENTS**

**Elaine Mac Hale**

Clinical Research Centre, Beaumont Hospital, Dublin, Ireland

This Poster presents the findings of a study conducted by a clinical research nurse in tandem with a medical-led clinical trial for completion of a Master’s programme.

**Introduction:** Incorrect inhaler usage is a significant problem in asthma management, resulting in poor control of asthma symptoms. The ability of patients to correctly use their inhaler might be directly linked to inhaler technique education. Education may result in better inhalation technique, improved compliance and asthma control. The economic burden of asthma is very substantial and is one of the highest among chronic diseases. In the United States of America, approximately 5-7 billion dollars is wasted because of inhaler misuse per year (Fink, 2005). Research question: “What is the impact of a nurse-led education programme in promoting compliance with inhaler use in patients with Asthma”.

**Methodology:** This is a quantitative study engaging a quasi-experimental pre-test and post-test design. A cohort of 21 patients who met the inclusion criteria were recruited from the Out-Patient Department over a period of six months. During each stage, the patient was asked to demonstrate how they take their inhaler. Any errors in technique were identified and rectified. Their demonstration was measured through observation and the use of an Inhaler Proficiency Schedule (IPS). The participant was also asked a series of specific questions in relation to their condition, confidence level with self-administration of their inhaler, and adherence to prescribed frequency of use.

**Results:** The findings in this study show that inhaler education improves technique, promotes compliance and increases participant confidence levels in taking an inhaler, and as a result asthma symptoms improve. It also emerged that participants believed they were taking their inhaler correctly and so assumed that education drives were not targeted at them.

**ABSTRACT #33 – CONCURRENT SESSION A2**

**TEMPLATE FOR SUCCESSFUL ORGANIZATION OF AN ACADEMIC MULTICENTER TRAUMA TRIAL**

**Jeanette Podbielski**, Charles Wade, Rene Sauer, and Steve Kosmach

1 University of Texas Health Science Center - Houston

**INTRODUCTION:** Organizing a multisite clinical trial is often complicated and can result in multiple delays. The Pragmatic, Randomized Optimal Platelet and Plasma Ratio trial is a key example of how an academic infrastructure can successfully implement a clinical trial requiring Exception from Informed Consent (EFIC) which entails multiple levels of oversight: the local UTHealth IRB for the clinical and data
coordinating centers, the Resuscitation Outcomes Consortium (ROC), the National Heart Lung and Blood Institute (NHLBI), the Federal Drug Administration (FDA), the Department of Defense (DoD), Health Canada and the 11 other participating sites’ IRBs.

METHODS: The infrastructure incorporated personnel with previous trauma trial experience including: physicians, statisticians, medical writers, epidemiologists, ethicists, financial administrators, research nurses and assistants, laboratory experts, informatics specialists, and regulatory experts. In the event certain expertise was not immediately available in the established infrastructure, consultants were recruited. Time and efforts from all parties involved resulted in the organizational structure shown in Figure 1. A systemized communication plan was developed and included the organization of sub-committees formed by the co-investigators and a regular meeting schedule. Both public and password-protected websites are accessible to ensure continuous and consistent communication.

RESULTS: Currently, the 12 sites participate in ongoing monthly teleconferences and biannual in-person meetings. The protocol has been approved by UTHealth IRB, ROC, NHLBI, FDA and is awaiting final approval from the DoD HRPO, which will include Sec Army signature, and Health Canada. Following the completion of the community consultation requirements, each site will acquire final IRB approval to enroll patients. Anticipated start date for enrollment is July 2012.

CONCLUSION: An organized communication and meeting plan is a key component to protocol initiation and management. Personnel must be identified from the beginning of the concept and should include representatives from the sponsor, clinical, administrative, laboratory and statistical analysis sides.

ABSTRACT #34 - POSTER

THE PATH TO SUCCESS: DOES YOUR SITE HAVE ALL THE BUILDING BLOCKS TO SET UP A STEM CELL CLINICAL CENTER?

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Cardiovascular clinical research can be daunting as frequently the subject population is very ill, and/or may have been ill for many years. Stem cell clinical research is a new and exciting field, offering hope to cardiovascular patients. Utilizing stem cells in clinical research can be very complex. This overview will include six key items necessary to establish a clinical research site utilizing stem cells in research.

- Investigational Review boards familiar with stem cell clinical trials
- Harvesting stem cells for autologous studies
- Orchestrating treatment day with a large, multidisciplinary team
- Locating and involving cell processing teams
- Management of stem cell transport and storage
- Establishing satellites for stem cell studies

Knowledge of these seven components at each site is necessary in order to develop a reliable timeline for startup. Texas heart Institute has been involved in clinical research using stem cells in the cardiovascular population since 2003. Minneapolis Heart Institute Foundation and the University of Florida at Gainesville began developing their stem cell center for cardiovascular research in 2004.

ABSTRACT #35A - SYMPOSIUM C1

GENETIC BIOBANKS: OUR PAST, PRESENT, AND FUTURE. A FOCUS ON PROFESSIONAL AND PUBLIC PERCEPTION TOWARDS GENETIC BIOBANKS

Erica Yu
The purpose of this presentation is to review the historical development of genetic biobanks and the way they have evolved over time because of the need for translational research and rapid advancement of technology. The health professionals’ attitude and public perception toward genetic biobanking will be discussed along with the media’s portrayal of genetic research. Genetic biobanks have grown in number around the world and nursing leadership has adopted competency standards for all genetic nursing practices. The involvement of nurses has increased and is projected for future significant increase as biobanking plays an essential role in the translational research. The attitude towards genetic biobanks among health professionals will be presented. The public interests and media attentions on the ethical, legal, and technical considerations of biobanking may play a pivotal role in policy development. Public opinion on issues surrounding genetic biobanks such as confidentiality, informed consent, and ownership of information will be discussed.

**ABSTRACT #35C - SYMPOSIUM C1**

**BIOBANK RECRUITMENT AND RETENTION: IS THERE A BETTER WAY?**

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With the research need for large amounts of patient demographic, clinical, and genetic data comes the need to educate health care providers and potential participants in the areas of genetic biobank organization and function. The purpose of this presentation is to address and discuss potential dilemmas surrounding genetic biobank participant recruitment and retention. A brief overview of the following issues will be provided: opt-in versus opt-out models of enrollment and informed consent, utilizing comprehensive technology, use of appropriate oversight, and dealing with loss to follow-up and non-participation. The objective of this presentation is to educate nurses interested in participating in biobank recruitment, retention, and management. Development and utilization of appropriate and efficient biobank participant recruitment and retention strategies is essential for a successful genetic biobank.

**ABSTRACT #35D - SYMPOSIUM C1**

**GREEN TECHNOLOGY: FOR ROOM TEMPERATURE STORAGE OF HUMAN SAMPLES**

*Malina Udtha*

University of Texas Health Science Center at Houston School of Nursing, Houston, TX

Biobanks and researchers engaged in epidemiological and clinical studies investigating the relationship between genetic variation and disease require DNA of high quality and quantity. Preservation of biospecimens for molecular biological applications traditionally involves freezing which increases laboratory and research project costs. Protection and stabilization of DNA at room temperature may eliminate the costs associated with freezer storage. The purpose of this presentation is to educate the researchers in clinical nursing about 1) the advances in DNA based technologies to preserve and store large number of biospecimens, 2) how the technology can be useful for biobanks, and 3) details about the method and significance of this technology.
ENROLLING PATIENTS IN THE INPATIENT SETTING-CHALLENGES AND UNIQUE ASPECTS
Raquel Bunge
The Methodist Hospital Research Institute, Houston, TX

Clinical research is especially challenging in the cardiovascular surgery. Most admissions to the hospital are not planned. In the cardiac surgery area, a majority of our patients come in with chest pain or recent MI and then are scheduled for a cardiac surgery or cath lab procedure. We have patients with heart failure that are decompensating and are admitted and evaluated for a cardiac mechanical assist device. The majority of patients are not aware of active clinical research trials when they are admitted to our hospital. They are expecting standard of care for their condition, however, most are receptive to hearing about the clinical research trials that are ongoing. Some of the trials (ie stem cell therapy) offer novel and advanced “cutting edge” treatment that provide more options to the patient. Despite these options, some patients may decide to go with the standard of care treatment, and their overall clinical condition may dictate this. Some patients will decline because they do not want something that they feel is not proven yet, or they feel that participating in research is an extra bother that they do not want to deal with (ie additional follow-up visits, tests), or they just feel like there is already so much for them to take in that the research is too much for them to handle at that time. These are all valid concerns and justifiably understandable.

The timing of consent can be a challenge. In order to properly consent a patient you need the following: ample time given to patient to read and ask questions; time to answer all questions and concerns prior to signing the consent; make sure there is no coercion or pressure was involved in the consent process. We need time to be able to do screening and baseline tests.

To address these challenges research nurses must educate patients and hospital staff (physicians, nurses, and ancillary staff) about ongoing clinical research. We need to be able to identify potential patients at the earliest possible time (at admission if possible). We must communicate well with units, staff, and ancillary departments about study requirements.

CHALLENGING ASPECTS IN ENROLLING INPATIENTS IN CLINICAL STUDIES
Janine Mazabob
St. Luke’s Episcopal Hospital, Houston, TX

Stroke is the third leading cause of death in the United States and the leading cause of adult disability. Impacting the current standard of stroke care is essential in order to impact mortality rates and improve patient outcomes.

An in-patient hospital setting presents unique challenges for clinical research and enrolling patients in studies during this emergent event. These challenges include identifying potential study participants early, evaluate the correct study for each particular patient and ensure tests and procedures are billed properly.

When providing emergent treatment to the acute stroke patient, competent multidisciplinary teams along with swift interventions are essential to improving outcomes to this patient population. Today’s research nurse is challenged to maintain patient enrollment and to identify the appropriate study for
each unique patient that is admitted to the hospital. In the midst of competing studies this can be challenging and a political conundrum.

Stem Cell therapy proposes a unique option in the treatment of the stroke patient. Ensuring that the patient and their family understand exactly what the therapy is and isn’t and the rational for this treatment option is key to enrollment. Providing assistance to the staff during stem cell harvest will lessen their fear and ensure that the proper protocols are followed.

Being present during the stem cell infusion further reinforces the research team’s commitment to the patient and the study. If possible being available at the initial outpatient follow-up visit makes it rewarding for the patient, and the team members that may also be available to meet with the patient.

Reporting to the Emergency Medical Service team that transported the patient will enhance the relationship with the ambulance providers, hospital and research team. If the patient is a transfer from an outside hospital reporting the patient outcome is also recommend and encourage.

Clear concise communication to the team, providing timely feedback to all team members including the Emergency Service personnel and celebrating success are all crucial when working with unique clinical research studies.

ABSTRACT #38 – CONCURRENT SESSION C2

SCOPE AND STANDARDS FOR THE CLINICAL TRIALS NURSE: WHERE DO WE GO FROM HERE?
Candida Barlow
St. John Health System Tulsa OK

This paper reviews and explores the role of the Clinical Trial Nurse involved in clinical research trials, with a focusing on exploring the nurse as a multidisciplinary member of a research team. An in depth assessment of the scope and standards for the clinical trial nurse (CTN) and identification of the benefits attained by utilizing a CTN within the clinical research framework is made. A review of the literature assesses the educational background, ethical standards, and professional skill sets acquired by the CTN. Furthermore, this paper compares and contrasts the nursing process to that of the research clinical trial nurse within the clinical research trial framework. The National Institutes of Health (NIH) has established a domain of practice for clinical research nurses an analysis of this domain will further identify the need to create a foundation for building scope and standards of the nurse researcher. The NIH care delivery and practice model framework will be utilized to evaluate each domain of practice to that of the scope and standards of the registered nurse set forth by the American Nurses Association (ANA). Identifying areas of collaboration, critical thinking, and appropriate delegation of trained research staff is discussed. The NIH is taking steps towards recognition of research nurses, is imperative that the ANA scope and standards be incorporated within the NIH to create a framework that will uphold the foundation of nursing practice as a profession. It is essential to quantify and qualify the role of the CTN within today’s clinical research filed by identifying the advanced practice research nurse as a specialty field within nursing practice. The analysis provides clarification and identification of rationales formalizing a position statement requesting advanced specialty practice recognition for the CTN.

ABSTRACT #39 - POSTER

NURSE IDENTIFIED INITIATIVES TO IMPROVE PARTICIPANT CARE IN THE CIRCADIAN RESEARCH UNIT
Judith Lauerman ¹ and Paula Autori

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The Intensive Physiologic Monitoring Unit at Brigham and Women’s Hospital conducts circadian research to study the effects of light, desynchronization of sleep/wake cycles, effects of melatonin on sleep patterns and insomnia, and metabolic and vascular effects of shift work. Studies vary in length of stay, but average about 6 days and take place in light settings ranging from extremely dim to very bright, which can be challenging for both staff and research participants.

The clinical research environment provides a unique setting for the development and implementation of initiatives to improve care of research participants. The changes on our unit occurred because the clinical research nurses asked “why?”

Nursing staff were able to identify two areas where care could be optimized by examining current procedures, proposing changes and tracking results.

1. Skin assessment: research participants require frequent application and removal of electrodes. The skin prep is slightly abrasive to insure good conductivity but can cause skin breakdown and discomfort. Assessment of the skin is difficult due to lighting levels and limited time when electrodes are removed. The previous tool allowed for documentation of site condition, but lacked a standardized approach for intervention.

2. Peripheral intravenous placement: nurses were able to update the previous skin prep to meet hospital and infection control guidelines and are currently examining participant and nurse satisfaction as part of a nursing research study.

Challenges to evoking change in this, or any, research setting include lighting, working within study specific parameters, strict standard operating procedures, resistance to change, and the possible effect any change might have on a study. Collaboration with the physician, the Principal Investigator, the Nursing Supervisor and the cooperation of all the research nurses were critical to the success of our initiatives.

**ABSTRACT #40 – POSTER**

**UNIVERSITY OF WISCONSIN CLINICAL RESEARCH UNIT (UW-CRU) WORKFLOW ANALYSIS**

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1University of Wisconsin Hospital and Clinics

Background: The University of Wisconsin’s Clinical Research Unit (UW-CRU) is dedicated to conducting clinical trials by supporting principal investigators across multiple disciplines. Research participant visits are scheduled and staffing assignments are made according to the expected complexity and timeline of protocol activities. The unique operational requirements of the UW-CRU place paramount importance on the efficient and fluid movement of a research participant through standard protocol activities from arrival to treatment. Work efficiencies impact both UW-CRU resources and research participant satisfaction. After conducting a review of the academic literature, little was found discussing research participant wait times on a research unit.

Purpose: This Quality Improvement Project (QIP) looked at research participants receiving oncology treatment on the UW-CRU. The purpose of this QIP is to contribute to general knowledge regarding efficient workflows on the UW-CRU, and identify variances impacting utilization of resources and quality of research participant care and satisfaction.

Methods: Over two, two-week periods, staff followed a representative group of 49 oncology patients through the standard protocol activities. Data were collected using tools developed by the QIP team.
These tools were used to collect data via multiple methods including 1) research participant survey, 2) treating nurse time point collection, and 3) charge nurse time point collection. Analysis of the data captured variances in research participant flow related to arrival, "pretreatment" activities, and time to administration of prescribed therapies and correlation with research participant satisfaction.

Results/findings: The data shows there is wide range of variability related to the time required to carry out protocol “pretreatment” activities. These variances directly impact UW-CRU resources and often conflict with research participant's perception of length of time to complete treatment, consequently affecting research participant satisfaction.

Implications for future work: Next steps include identifying ways to improve variances, presenting findings to stakeholders, implementing improvements, and expanding this to include all protocol activities conducted on the UW-CRU. By implementing efficient workflow, standardizing pretreatment activities, and communicating accurate timelines to the research participant, it is our hope that these findings will lead to improved utilization of time, staff, and financial resources and raise research participant satisfaction on the UW-CRU.