



April 2013 IACRN Newsletter

2012 IACRN Conference Summary

The International Association of Clinical Research Nurses (IACRN) held its fourth annual conference in Houston, Texas, this past October 18-20, 2012. Under the broad theme of “Helping Tomorrow’s Patients Today,” topics discussed continuing trends in three major areas: aspects of clinical research nursing as a specialty; implications for genetics, genomics, and biobanking for research and clinical practice; and electronic documentation for clinical research.

Clinical Research Nursing as a Specialty

Kathleen Stevens, RN, EdD, ANEF, FAAN, UT Health Science Center, opened the 2012 Conference with her Keynote Address: Improvement Science: Impacting the Future through Clinical Research. In her address, Dr. Stevens presented a model of knowledge transformation emphasizing the use of evidence to guide quality management and clinical decision making. Dr. Stevens stressed the need to prepare the workforce to engage and participate in the process and provided an explanation of what Improvement Science entails.

Many presentations focused on varying aspects and dimensions of clinical research nursing roles, management, collaboration, recruitment and aspects of obtaining informed consent. The large number of presentations addressing these areas, including several from Ireland and the UK, is an indication that Clinical Research Nurses are embracing their specialty and are committed to demonstrating their particular professional expertise embodied within Clinical Research Nursing. The presentations included:

- Role of Nurse Practitioner Facilitating Clinical Research.
- Providing Clinical Research Nursing at the Point of Care.
- How Research Nurses can Expand their Role to Include Nursing-led Research.
- Advancing Role Recognition.
- Evaluating Scope and Standards for the Clinical Trials Nurse: Where do we go from here?

- Sharing Best Practice Models from the UK.
- Development of a CRN Education and Competency Assessment Program in Ireland.
- ABCs and 123s of Developing a Pediatric Clinical Nurse Research Program.
- Closed-Loop Insulin Delivery in Children < 7 years of Age.
- Core Competencies and Accreditation in Clinical Research Academic Programs.
- The Management of a Clinical Research Centre.
- Template for Successful Organization of an Academic Multicenter.
- Working Collaboratively When Five Sites Come Together.
- Challenging Aspects of Enrolling Inpatients in Clinical Studies.
- Challenges of Informed Consent – CRNs Improving the Process for the Future.
- Informed Consent for Pediatric Surgery Research – Lessons Learned.
- AND approximately 40 posters sharing Clinical Research Nursing best practice.

Quality Management

From Cincinnati Children's Hospital Medical Center, Michelle Dickey, MS, CFNP, CPNP, CCRC Director and Amy Hooper, RN, CCRC Quality Manager presented on "The Importance of a Quality Management Plan in a Clinical Research Setting." They traced the evolution of a comprehensive quality management program in the context of Vaccine Treatment and Evaluation Units (VTEU) across the NIH network. Their presentation highlighted the effectiveness of VTEU Clinical Research in rapid-response capability, testing novel vaccines, strengthening the nation's bio-defense and the variety of research areas of interest encompassed by VTEUs.

Genetics, Genomics and Biobanking

Kate L. Wilson, MS, CGC, UT HSC, gave a comprehensive presentation on "Performing an Assessment from a Genetic Perspective" including an overview of genetics in research nursing.

"The Past, Present and Future of Biobanking in Clinical Research" included three abstracts focusing on the important role of biobanks in clinical research. The presenters were from the University of Texas. Dr Yu spoke about professional and public perception toward genetic biobanks. She shared the historical aspect of biobanks, first used for individual scientific endeavors. After the 1990s there was a shift in focus and an aspect of sharing samples was introduced for the purpose of advancing technology and promoting translational science. She stressed that many potential participants have concerns about confidentiality and intention for use of the samples. She closed with a review of the nursing implications for education. Dr Sanner presented on best practice in biobank recruitment and retention highlighting potential barriers such as non-participation, loss to follow up and discontinuation of participation. She shared a model of collaboration among researchers and how it was enhanced through nurse involvement. The session was closed by Dr Udtha who presented on green technology using room temperature storage for human samples. She presented data using emerging new technologies to promote ambient temperature bio-stabilization technology. She stressed the importance of exploring such new technologies as researchers are faced with limited resources and increased storage requirements as the field of genetics and genomics research grows. Her preliminary data using an alternative to cold storage suggests that whole blood protected and stored at room temperature

provides adequate yield and purity for use in genetic studies. These three sessions highlight the need for clinical research nursing involvement in biobanking and genetic research.

Electronic Health Records in Clinical Research

Dean F. Sittig, PhD, UT HSC, School of Bioinformatics, gave an in-depth presentation on the UT HSC experience of implementing an electronic health records system (EHRs). He gave a short overview of the exponential growth of EHRs vendors since 2008 resulting from demonstrated improvement in quality, efficiency and patient access. He also emphasized potential for unexpected risks and consequences of implementing and using EHRs. While walking us thru the steps of implementation, he described the experience of encountering unexpected challenges of hardware and user difficulties and how these challenges were overcome. Dr. Sittig ended his presentation by showing how EHRs are already having a huge impact on clinical research activities by increasing research productivity. He strongly encouraged Clinical Research Nurses to learn how to maximize use of these systems and in turn minimize the chance for errors.

Distinguished Nurse Lecturer

Dr. Margaret McCabe, Director of Nursing Research for the Medical Services of Boston Children's Hospital, was awarded the 2012 Distinguished Nurse Lecturer. Dr. McCabe received her undergraduate degree from Niagara University (NU), Niagara Falls, NY, her Master's from University at Buffalo School of Nursing (UB SON) and her DNSc from Rush University, Chicago. She went on to complete two Post-Doctorate Fellowships, one in Boston at the Harvard School of Public Health Nursing Research Institute and a second at Yale University under the tutelage of Dr. Margaret Grey studying chronic fatigue in children. In her presentation, Dr. McCabe described her journey of becoming a Clinical Research Nurse with her own program of research and challenged each of us to find our passion and create our future.

Setting the Research Agenda for Clinical Research Nursing

In the closing Plenary Session, Clare Hastings, RN, PhD, FAAN, outlined an impressive research agenda for Clinical Research Nursing and announced the creation of the IACRN Research Committee. The IACRN Research Committee is dedicated to demonstrating the expertise of Clinical Research Nurses in clinical practice throughout the world.

Clinical Research Nursing: An Official Definition

Shaunagh Browning, RN, FNP-BC, IACRN President, presented the official IACRN definition of Clinical Research Nursing: "Clinical Research Nursing is the specialized practice of professional nursing focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol. This specialty practice incorporates human subject protection; care coordination and continuity; contribution to clinical science; clinical practice; and study management throughout a variety of professional roles, practice settings, and clinical specialties." This definition served to inform development of the IACRN 4-year strategic plan as well as goals and objectives for the IACRN Sub-committees. The creation of an additional new

subcommittee was announced: The Chapter Governance Committee dedicated to facilitating the creation of new IACRN Chapters around the globe.

For PowerPoint slides from this year's conference topics and for information on joining a subcommittee, please sign into the "member's only" section of the [IACRN](#) website.

Next year's conference is planned for October 23-25, 2013, in San Diego, CA. [\[click here\]](#)

Practice Corner

Informed consent documents have evolved into complex and lengthy forms that document the informed consent process and protect the legal interests of sites and sponsors(1). This evolution detracts from the primary aim of informing the subject about the research.

A task force at Cincinnati Children's Hospital Medical Center (CCHMC) convened in November 2011 to address the issue of both simplifying and improving readability of the informed consent document template. The task force included a community IRB member, faculty member, compliance department director, clinical research nurses, nurse practitioners and clinical research professionals from several hospital divisions with expertise in research. The initial step of using basic consent requirements as the model framework was completed by the 2nd meeting. The task force started with the well written and easy-to-understand assent form and added any missing required elements. The group also changed the format and design of the consent template and instructions. The previously embedded instructions were removed and placed in a column along the left side of the template, with required and optional elements labeled. A guidance document accompanied the template with additional suggestions, especially helpful for the new coordinator.

The document was pilot tested and then approved by the IRB seven months after the first meeting. The IRB members and pilot test users found it easier to use and more reflective of the informed consent process. The IRB staff felt the simplified and briefer format made it more difficult to easily identify required elements in preparation for IRB submission. The task force would have benefited from IRB staff membership at the onset, since they are both a customer using the process as well as the group that will be answering the users' questions during implementation.

The next step for the task force is to do empirical testing of the new consent form to see if the goal of better informing the user is improved.

References

1. Goldfarb NM. The Three-Page Informed Consent Form *Journal of Clinical Research Best Practices* January 2012;Vol. 8, No. 1.

Presenting at an IACRN Conference Supports Magnet

ANCC's Magnet Recognition Program was developed to recognize healthcare organizations that provide excellence in nursing practice. Cincinnati Children's Hospital Medical Center (CCHMC) is a Magnet recognized pediatric hospital dedicated to improving child health and transforming delivery of care through fully integrated, globally recognized research, education, and innovation. The hospital employs 80 research registered nurses (RNs) across 21 divisions. As part of Magnet Model Component, Structural Empowerment, recognition of nursing (SE15), our nurses understand the importance of self-governance and decision-making structures and processes that establish standards of practice. We also realize that as part of this Magnet component, connecting with professional organizations/associations with similar goals will improve patient outcomes and the health of the communities we serve. By partnering with IACRN, a professional organization dedicated to advancing the research nursing profession and who recognize the value of research nursing, we are able to extend our influence to the nursing community at large (local, state, national, international) to contribute to these goals. For the past two years, the research nurses at CCHMC shared new knowledge and processes with other research nursing professionals at the IACRN conference either through oral or poster presentations. After the last conference, we decided to submit a Magnet story sharing our success at the conference and were quite excited to learn that this story would be included in this year's 2012 CCHMC Nursing Annual Report.

President's Corner

April 2013

2013 began my last year as President of IACRN. As I reflected on the organization and the opportunity I have had to lead this organization as President-Elect and President for the last 3 years I am humbled and honored. The passion of the membership that I witnessed at our Annual

Conference in Houston in Texas this past October was moving. In addition, these CRNs took the passion and translated it into the work they are doing. I heard about CRNs advocating for changing the consent template at their organization to increase participant understanding, CRNs in Ireland and China working to create and improve education for Clinical Research Nursing, CRNs in Boston coming together to create inter-institutional collaborations, and CRNs sharing best practices in genetics, pediatrics, diabetes, and many more outstanding initiatives. IACRN is able to bring all these ideas together under one specialty organization that represents the needs of Clinical Research Nurses across the world. As a founding member I have been privileged to see the vision grow to this reality and I am certain the other founding members of IACRN would feel the same. The Annual Conference in Houston Texas is now a wonderful memory. The speakers, the posters, the networking were just a few things that made the meeting memorable. If you missed it be sure to save the date for this years meeting in San Diego California October 23-25, 2013. The Meeting Planning Committee has great things in store and our outstanding membership will certainly shine once again by sharing their passion in their work.

The business of IACRN is moving at mach pace. At the Annual Meeting the Board of Directors introduced the 4 Year Strategic Plan. The Strategic Plan is posted on the website for your reference. Please check it out here [[Strategic Plan](#)] and see what we have in store. We are already making great strides to accomplishing these goals. We have plans for an Educational Webinar this spring. We have hired a professional management company, Lyons Den Solutions, to help with the meeting planning, sponsorship, and grants and membership growth. Committees have been defined and leadership put into place to drive forward the goals of those committees. I would encourage you to see our website for details about the committees and volunteering for one that sounds of interest to you. [[click here](#)] Each of you has so much to offer.

This year's election was a huge success; more membership voted than any past year. I would like to congratulate Brian Beardsley, Secretary for 2013-2015 and Jennifer Allison, Member-at-Large 2013-2015 and welcome them to the [Board of Directors](#). I would also like to thank all those who put their names forth as candidates. We look forward to working with you in other ways.

I am excited to see where we will go in my last year as President and thankful for having had this opportunity. I also feel confident that we have in place the structure and leadership to continue to grow and share our mission and vision. I hope that you will stay involved and share with me in the wealth of knowledge and passion that IACRN membership possesses.