



A New Role for Chinese Nurses: The Clinical Research Nurse in Clinical Trials

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Conflict of Interest

- The following authors have no conflict of interest to declare.

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Global MD

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Objectives

- Describe the specialty of Clinical Research Nursing
- Describe the current status and nurse involvement of clinical trials in China
- Discuss the core curriculum presented to the Nurses in China

Objective #1

- Describe the specialty of Clinical Research Nursing



The National Clinical Research Nursing Consortium

“Although nurses are integral and assumed to be essential to the clinical research team, there is no generally accepted, standardized definition of the role of the clinical research nurse.”

Nursing Outlook, 2011

Clinical Research Nursing as a Specialty

- Publication of a white paper defining the role of the Clinical Research Nurse

Hastings CE, Fisher CA, McCabe MA, The National Clinical Research Nursing Consortium. Clinical research nursing: A critical resource in the national research enterprise. Nurs Outlook , 2011.



Specialty Organization Task Force

- Co-Chairs:
 - Shaunagh Browning, Georgetown University
 - Nicole Hansen, UC, Davis
- Members to the task force:
 - Margaret McCabe, Boston Children's
 - Madelene Ottosen, UTH, TMC
 - Sue Peterson, OHSU
 - Mary Jane Williams, UW Hospital
 - Joyce Oglesby, Emory University

Current Vision and Mission of IACRN

Vision

- Clinical Research quality and safety through specialized nursing practice.

Mission

- The International Association of Clinical Research Nurses is a professional nursing organization. Its purpose is to define, validate and advance clinical research nursing as a specialty practice and to support the professional development of registered nurses who directly or indirectly impact the care of clinical research participants.

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. ”

1. International Association of Clinical Research Nurses (2012)

Clinical Research Nursing Specialty Domain of Practice



2. CRN 2010 Domain of Practice Committee 2009

Objective #2

- Describe the current status and nurse involvement of clinical trials in China

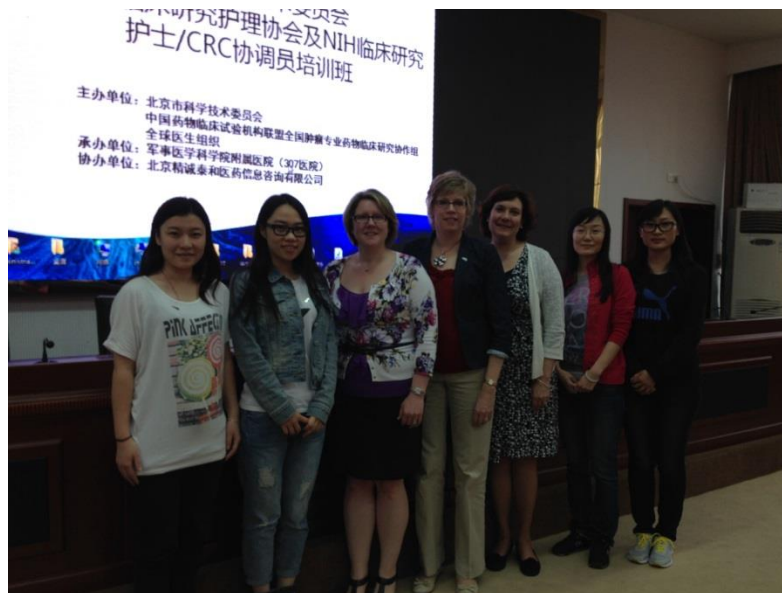


Current Status of Clinical Trials in China

- Status of clinical research largely unknown.
- 2009 – State Food and Drug Administration of China (SFDA) and the Ministerial Ordinance No. 28 of Health, Labor and Welfare of Japan signed a MOU to promote multiregional clinical trials
- Clinical Research efforts in China is a priority and Pharmaceutical companies desire to conduct trials in China is growing

Statistics on Nurses in China

- 2013 - 2.49 million nurses
- 2010- 40% of nurses are associate trained
- Young woman's career – over 40% of nurses are an average 25 years of age



GCP training in China

- Minimum requirement for physicians and nurses to participate in clinical trials.
- Recently study by Yoshida et al. found that out of 7 Beijing hospitals
 - 47% of physicians had an annual GCP training
 - No data on number of nursing that have GCP training
 - Suggested that nurses have far less training on GCP

3. Yoshida et al. 2012

Clinical Research Nurses in China

- There is currently no formal training for Clinical Research Nurses in China
- GCP training is required for Chinese nurses to work in Clinical Research Centers.



- Discuss the core curriculum presented to the Nurses in China



IACRN Educational Mission

- Provide professional development to CRNs internationally
- Benefit both the conduct of the research and enhance welfare of participants.
- Provide high quality annual educational conferences in the United States



IACRN Annual Conference

- 2009 IACRN Held its first meeting in Boston
Nurses Bridging the Gap in Clinical & Translational Research



IACRN and Core Curriculum in Clinical Research Nursing

- 2012 Global MD supports 6 nurses from China to attend IACRN conference in Houston, TX
- Discussion with nurses attending demonstrated the value of education around the role of the CRN
- 2014 IACRN in collaboration with Global MD began work on Core Curriculum in Clinical Research Nursing

IACRN Core Curriculum

- Course presented over 2 days
- Approximately 150 nurses
- Beijing, China from April 26-27, 2014



IACRN Core Curriculum

- Provided GCP content with case studies and examples
- Demonstrated the impact that CRNs have throughout the domains of practice.
- Time was allotted for examination of cultural differences between US practice and those in China

IACRN Core Curriculum Content

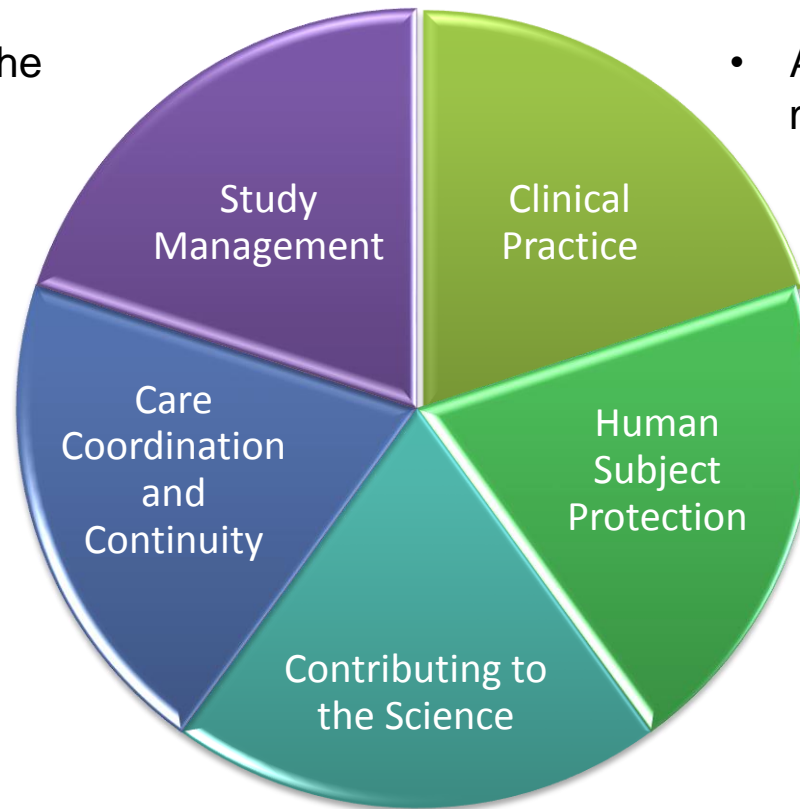
- Day 1
 - Overview of clinical research
 - The fundamentals of Clinical Research Nursing
 - Introduction to human subjects protection
 - Protocol review and approval
 - Institutional Review Boards
 - Informed consent
 - Conflict of interest and research compliance

IACRN Core Curriculum Content

- Day 2
 - Drug Development Process
 - Study Feasibility
 - Recruitment and retention
 - Vulnerable populations
 - Study Conduct
 - Adverse events and safety monitoring
 - Clinical trials quality management
 - Roles and responsibility of the research team
 - Professional role development

Clinical Research Nursing Specialty Domain of Practice

- Documentation of the IC process



- Address therapeutic misconception
- Initial and ongoing consent/assent process
- Support participant in decision making

Future Plans

- Improve upon the training based on course evaluations
- Provide training annual throughout different providences in China
- Empower Chinese Clinical Research Nurses to lead this course in the future.
- Provide 3-6 month internship in various settings in the US where CRNs are working

Impact

Education that focuses beyond the tasks associated with the clinical trials management and empowers CRNs globally to lead the clinical trials process is essential.



References

1. International Association of Clinical Research Nurses (2012) “Enhancing Clinical Research Quality and Safety Through Specialty Nursing Practice” . Scope and Standards of Practice Committee Report.
2. CRN 2010 Domain of Practice Committee 2009. Building the Foundation for Clinical Research Nursing: Domain of Practice for the Specialty of Clinical Research Nursing. 2009. National Institutes of Health Clinical Center, Nursing and Patient Care Services. Available at http://www.cc.nih.gov/nursing/crn/DOP_document.pdf
3. Yoshida Y, Zhang Y, Yoshida Y, Ma D and Wang P. Current situation of clinical trials in Beijing, China. Contemporary Clinical Trials 2012;33:583-588.