As of the urge of the report from the global independent commission: Education of Health Professionals for the 21st Century entitled “Health professionals for a new century: Transforming education to strengthen health systems in an interdependent world”, calls for a move from formative to transformative education. These have been creating the challenges and opportunities available to the nursing profession and academic institutions responsible in producing future nurses to the realities of their population health, health care system, and workforce needs. During June 4-6, 2014, The Faculty of Nursing, Mahidol University had a privilege to host the First Asian Congress in Nursing Education (ACINE) entitled “Transformative Nursing Education for Global Health” at Rama Gardens Hotel, Bangkok. The congress was entirely dedicated to Associate Professor Dr. Tassana Boontong, on her 72nd birthday anniversary celebration, for remarkable contribution she has made to nursing education and nursing profession in Thailand and the region. Associate Professor Dr. Tassana Boontong currently serves as President of Thailand Nursing and Midwifery Council, and also was the former Dean of Faculty of Nursing Mahidol University as well as the vice-president and senator of the Thai Parliament.

H.R.H Princess Maha Chakri Sirindhorn presided over the opening ceremony which was followed by the opening innovation exhibition and poster presentation on June 4, 2014 during 3:30-4:30 p.m. Four renowned professors who were nationally and internationally recognized leaders in nursing education were invited as speakers for all three-day keynote sessions.

Associate Professor Dr. Tassana Boontong, the first keynote speaker, addressed the development of nursing education in Thailand and Asia, and reflected on past experiences to the future challenges for transformative nursing education. The other three keynote speakers shared their perspectives and experiences on transformative education for global health. Professor Dr. Alaf Meleis, in her presentation of “Transformative nursing education: A challenge for global health”, raised the issue of personnel shortage globally in meeting the Millennium Development Goals (MDG’s) for healthy communities and the unbalanced focus on care rather than prevention that requires dramatic strategies that utilize innovations and inter-professional education. Professor Dr. Rajata Rajatanavin, in his presentation of “Inter-professional education: Contribution to global health, addressed capacity building of the university graduates through transformative inter-professional education strategy to achieve the 21st century skills. Professor Dr. Kathleen Potempa presented “One world: East and West united for world health” using a story of global engagement with international partnership that can have impact on global health. Strengthening collaboration through health education can be used as a vehicle for changes in individual and community health across boundaries and borders.

In addition, two panels of “A Doctorate in Nursing… Contributing to the Profession” and “Asian Nurses’ Competency for Global Health” and the concurrent sessions of research presentation regarding innovations in nursing education helped facilitate collaboration and information sharing towards improving quality of nursing education.

There were more than 560 participants from Thailand and other 11 countries joined the conference. Importantly, the Faculty of Nursing received kind co-operation and support from the following institutions/organization for being co-hosts of this congress, Thailand Nursing and Midwifery Council, The Nurses’ Association of Thailand, The Consortium of Dean and Head of Nursing Education Institutions under Ministry of Public Health, and World Health Organization South East Asia Regional Office.

This 3-day first Asian Congress in Nursing Education in Thailand has provided valuable opportunity for all participants to discuss issues on nursing education such as the educational challenges, highlights on transformative nursing education, information and expertise, strategies to develop networking among the leading nursing schools to prepare nursing graduates for 21st century skills. The Faculty of Nursing, as the first nursing school in Thailand, looks forward to be a “Nursing Education HUB” of academic development and advances for nursing and midwifery education and practice in the region.

Summarized by Assoc. Prof. Kanaungnit Pongthavornkamol and Assist. Prof. Somsiri Rungamornrat

Basic Good Clinical Practice (GCP) for Research Involving Human Subjects

Research Promotion and Development Office (RPDO) was delighted to welcome Dr. Pravich Tanyasittisunthon as a guest speaker of this training course for academic staffs at Faculty of Nursing, Mahidol University. Dr. Pravich Tanyasittisunthon is a Co-Medical Director of Medical Research Network of the Consortium of Thai Medical Schools and an expert for Good Clinical Practice (GCP) training program nationwide. This training course comprises valuable information and understanding on research involving human subjects, medical and clinical research, ethical principles for conducting clinical trial in human subjects, principles of GCP, and International Conference on Harmonization Guidelines for Good Clinical Practice (ICH GCP).

The differences between research itself and research involving human subjects are identified clearly by Dr. Pravich Tanyasittisunthon. On one hand, research composed of systematic investigation utilizing scientific method which collected information could be applied to generalized know ledge and/or contributed to internal improvements of a program, service, and quality assurance purposes. On the other hand, research involving human subjects relates to human subjects including healthy volunteers. It also includes physical and psychological interventions, observation, collection, storage, and dissemination of information relating to human individuals.

Types of medical research are primary and secondary research. Primary research includes basic, clinical, and epidemiological research. Secondary research involves meta-analysis and review or systematic review. However, for new drug manufacturing against emerging diseases, drug development process and clinical research for drug or vaccine trial in human research have to maintain quality standard including validity and reliability for scientific standard and human subject protection for ethical standard.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical research trials that involve the participation of human subjects. Compliance with GCP standard provides public assurance that the rights and safety of subjects who participate in clinical trials are well-protected. Concordance with ethical principles according to Declaration of Helsinki and Belmont Report such as respect for person, beneficence, non-maleficence, and justice ensure that the clinical trial data and collected information are credible.
Protection of human subjects is important in clinical research. The authors of this article present an issue involving how IRBs consider the protocol of research ethics, of which the subject is the prospective participants in clinical trials, called "parent studies." The objective of the ethics study is to assess the "motivations, understanding and attitude" of the subjects about taking part in the trial. The ethics study collects data from the subjects of clinical sites, and requires the initial access from the parent-study. If the subjects give the permissions, then the staffs of the parent-study will offer only the subjects' contact information to the authors. This recruitment process burdens the parent-study with the time for IRB reviews. The authors refer to the Office for Human Research Protection (OHRP) guidance about the criteria of engagement in human subject of an institute that is "an institute is not engaged in human subject research when the institute or its employees or agents do the following activities." These activities are to inform about the study, provide information about the research, contact investigators for enrollment, and obtain the permission. Only 14 IRBs accepted that the parent-study sites were not necessary to submit this ethics research protocol to IRB; 12 IRBs required the reviews from the sites' IRBs. For these 12 sites, 5 IRBs gave an option to send a letter of the contact information of the ethics research to subjects, instead of giving the subjects' contact information to the authors. This option is called "opt-in" sampling method, which arises as a consequence of lower response rates. The parent-study members refused to submit a protocol of ethics research to their IRBs, but they accepted only the process of sending the letters. Seven IRBs did not offer any choices except submitting the protocol. The members of 2 from 7 parent-studies refused to recruit the subjects but they amended the ethics research within their protocols, whereas 5 from 7 of the parent-study sites get the specific IRB approval for the ethics research. The important concern of the IRBs is about approaching the subjects who refuse to participate in the parent-study by the members of the parent-study. That might induce discomfort or coercion to the subjects. The authors discussed that each IRB had different considerations, although they followed the same OHRP guidelines. The authors argued that their ethics study is valuable because it illustrates how these subjects consider participating in the clinical study. However, it should not encounter different IRB's decision about subject recruitment. The authors give the comments that the IRBs might look at the different side in that interviewing the subjects who denied participating in the parent-study seem to be an extended from the parent-study.

Research of ethics is very important in describing how subjects made their decision in taking part in the study. All research involving human subjects have to get the approval from the IRB. Both investigators and IRBs have to concern basic ethical principles which include respect for person, risk and benefit, and justice. The issues from this article apply to IRB committees for making the decisions, or to researchers for recruiting the subjects of such kind of study will be discussed in part II.

Summarized by Wanna Phahuwatanakorn, RN, PhD. (IRB-NS Committee), Supinda Ruangjiratain, RN, PhD. (IRB-NS Committee)
ABSTRACT

Purpose: The purpose of this two-group, quasi-experimental study with repeated measures was to examine the effects of a 5-weekly health-promotion cancer support group intervention with three monthly telephone support on health-promoting behaviors and quality of life in Thai women with recently diagnosed breast cancer.

Methods: The sample consisted of 59 breast cancer women receiving treatment; 29 women were assigned to experimental group and 30 women to control group. Data were collected at three times: baseline prior to the intervention (T1), within two weeks of completion of 5-weekly 1 ½ hour group sessions (T2), and at six months (T3). Research instruments for data collection were Functional Assessment of Cancer Therapy–Breast scale and Health Promotion Life Style Profile II for assessing quality of life and health-promoting behaviors respectively. Repeated measures ANOVA was used for data analysis.

Main findings: The results revealed that women in experimental group, compared with those in control group, demonstrated significant improvement of health-promoting behaviors and quality of life both in short-term (Week 5-7) and long-term (6 months).

Conclusion and recommendations: These findings suggest that the health promotion cancer group support may be an efficacious psychosocial intervention for changing health behaviors and improvement of quality of life in Thai women with breast cancer during and after treatment. Nurses should promote cancer support group participation aiming at changing health-promoting behaviors for patients with cancer as a crucial part of their nursing care.

Keywords: Cancer support group, Health-promoting behaviors, Quality of life, Breast cancer

Lecturer Aphorn Khamkon was awarded a master degree in nursing science (medical and surgical nursing) by the Faculty of Nursing, Chiang Mai University in 2002. She has joined the Department of Medical Nursing, Faculty of Nursing, Mahidol University in 2011. Recently, she received a doctoral degree of philosophy (nursing) (International and Collaborative with Foreign University Program) from Faculty of Nursing and Faculty of Medicine, Ramathibodi Hospital, Mahidol University. Her doctoral dissertation was focused on breast cancer preventive behaviors among Thai women with a family history of breast cancer.

Nowadays, mortality rate still increases in Thai women with breast cancer. Based on recent literature review, it was discovered that breast cancer preventive behaviors including regular breast cancer screening and healthy behaviors recommended for reducing risk of breast cancer. Dr. Aphorn Khamkon has paid significant attention to develop the model and program aimed to motivate women with high risk of breast cancer to perform breast cancer preventive behaviors. This program will decrease the risk of breast cancer especially in high risk group. Moreover, her research work commits not only on breast cancer but also other cancers. Dr. Aphorn Khamkon has conducted quantitative and qualitative studies on this issue to further develop an effective intervention for the better health of Thai people.

Publications:

According to ICH E6 2.1.2.13, International Conference on Harmonization Guidelines for Good Clinical Practice (ICH GCP) involves a standard practice on generating clinical research trials in human subjects. Principles of ICH GCP can depict as follows; performing research trials concerning ethical principles and guidelines, maintaining protocol and scientific standards, administering responsibilities of investigators regarding the protocol approved by IRB or ethics committee, gaining freely given informed consent prior to trial participation of each subject, handling data quality and data integrity respecting privacy and confidentiality of required protocol guidelines, manufacturing and storing of investigational product, and establishing a system to assure quality control and verify quality assurance. The objective of ICH GCP guideline is to provide a unified international standard to facilitate the mutual acceptance of clinical data by the regulatory authorities in involving countries and the World Health Organization (WHO). Thus, the ICH GCP guideline must be accomplished when conducting clinical trial data that are intended to be submitted to regulatory authorities and required international publication. Moreover, Dr. Pravich had emphasized on importance and regulation on an establishment of ethically sounded clinical research in human subjects and maintenance of globally recognized standard for conduct of those clinical trials strictly.

References
2. ICH E6 (R1), Current Step 4 version dated 10 June 1996.