Current Situation of Research Nurse Education and Future Perspectives in Japan

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Who are involved in Clinical Trials?

- Patients.
- Others
  - Physician Investigators
  - Nurses !!
  - Biostatisticians
  - Clinical Research Coordinators
  - Data Managers

Etc.
Nurses in A Clinical Trial Team

- Team approach is the key for a successful clinical trials.
- Nurses are one of the critical parts of the clinical trial team.
  - “Nurse-CRCs”
  - “Clinical Nurses”
  - “Research Nurses”
- Questions are………
  - Are Clinical Nurses are contributing effectively as a team member?
  - What are roles of Clinical Nurses/Research Nurses in Japan?
Clinical Trials Nursing in Japan???

- Most clinical nurses are **not** interested in clinical trials.
  - Too busy for “other” nursing care
  - Clinical trial is more for doctors / CRCs, not for nurses.
- No nursing staff assignment for a trial.
  - Extra work
  - No motivation
  - CRCs at Clinical Trial Offices are barely assigned to no-indication-directed trials.
- No career ladder as “Research Nurse”
Registered Nurses (RNs) in Japan

- Total of 1,292,593 nurses in 2004.
- About 63% of jobs are in hospitals.
- RNs can specialize in specific health conditions / diseases through Japanese Nursing Association.
  - Certified Nurse Specialists – 2-year graduate school education (22 Universities)
    - 9 areas of CNS:
      - Child health, Women’s health, Critical care, Chronic care nursing etc.
      - Focus on nursing research, patient/staff education, ethical problems, and coordination of the care team in addition to advanced nursing care.
  - Certified Nurses – A 6 Months course education (31 training Centers)
    - 18 areas of CN:
      - Infection Control, Emergency, Breast Cancer, Visiting Nursing etc.
      - More focus in patient care.
  - No Graduate /Certification Courses for Clinical Trial Nursing
Who are CRCs?

- Clinical Research Coordinators (CRCs)
- In Japan, approximately a half of CRCs are nurses.
- Most of them belong to clinical trial offices in the hospitals.
- They work mainly for registration-directed clinical trials.
Nurses are suitable to support CT

- **Nursing experience** means
  - Having knowledge on disease (anatomy, etiology, symptoms, lab data, evaluation methods)
  - Prepared with good communication skills
  - Trained for assessment skills
  - Knowing how to work with physicians
  - Having an experience of coordination within the hospital

- Nurses are always beside the patients / families
  - Most frequent contact
What can research nurses do?  
(Lessons from the US)

- Belong to each medical department, not under nursing department
- Responsibilities for the patients
  - Screen for eligible patients
  - Provide copy of the informed consent and explain the details of the study
  - Schedule all study tests and visits
  - Assist with consent process and register patients on the study
  - Monitor/manage the patient throughout the study
  - See patient at each visit, prepare treatment,
  - Document all toxicities
Responsibilities for the study management:

- Ensure treatment plan and schedule are followed as outlined in the protocol
- Maintain all regulatory documents
- Report any deviations from the protocol
- Enter study data into database or CRFs
- Participate in audits
- Participate in start-up meetings
- Conduct training of other personnel
- Be a central contact for patients / family / sponsor / other study personnel
What can **clinical nurses** contribute? (Lessons from the US)

- Participate in research team meetings
- Carefully document patient assessments and side effects of therapy
- Reinforce treatment plan and return visit schedule
- Communicate with research team

More communication between CRCs and clinical nurses will be necessary
Merits for Nurses to be involved in Clinical Trials

- Recognition of CT as a part of nursing care
  - Nursing needs exist in CT
- Being a part of scientific contribution for new treatment development and establishment of standard treatment
- In depth knowledge on the standard treatment / the experimental treatment
  - Information source for the patients
- Becoming interested in research papers (Japanese/English)
- Close relationship with physicians / other professionals.
Empowerment of Nurses for CTs

Several approaches to improve knowledge and attitudes of nurses.

- To be interested in CTs and to recognize nursing needs in CTs.
- To define clearly the role and necessary competencies for both research nurses and for clinical nurses.
- To be involved in research professional organizations, such as SoCRA, ACRP, DIA, Japan Society of Clinical Pharmacology and Therapeutics, etc.
- To be certified in clinical research.
- To conduct research and write reports in clinical trial nursing as a nursing domain.
- To organize Special Interest Group in nursing societies.

Clinical Trial Nursing @ Japanese Society of Cancer Nursing (JSCN)
To establish a educational program for clinical trial nursing. (Post-baccalaureate certification course or master’s program ??)

- Special course works for licensed nurses
  - Clinical Trial design
  - Research methodology
  - Biostatistics
  - Epidemiology
  - Ethical, regulatory issues
  - Business management (Human resource management, Budgeting, etc.)

To establish a career path and career ladder of Research Nurses
To Be an Effective Education

1. The contents have to be related to educational needs of nurses
   - Relationship to daily practices

1. Obtaining higher education in CTs needs to be considered as a career UP.
Educational Programs for CRCs

- Ministry of Health, Labour and Welfare
- Ministry of Education, Culture, Sports, Science and Technology
- Japan Pharmacists Education Center
- Japanese Society of Hospital Pharmacists
- Japanese Nursing Association
- Japanese Association of Medical Technologists
- 2 graduate Schools
- In-serve programs in hospitals etc.
Continuous Education for CRCs in Japan

(Study Groups)
日本臨床研究支援ユニット (JCRSU)、CSPOR
JCOG (日本臨床腫瘍研究グループ)
WJTOG (西日本胸部腫瘍臨床研究機構)
JGOG (婦人科悪性腫瘍化学療法研究機構)
など

(Professional Societies)
SoCRA
日本癌治療学会、日本臨床腫瘍学会
CRCと臨床試験のあり方を考える会議
日本臨床薬理学会年会、日本がん治療学会
静岡ファルマバレー
各領域の学会が提供するコメディカルセミナー
など

Little consideration for the difference of the license.
Educational Environment for CRCs

- Increasing number of educational programs outside the hospitals
- Lack of educational programs within the institution
  - Research ethics
  - Regulatory requirements
  - Research methodology
  - Research Teams

- Educational specialist in Clinical Research Office (in the US)
  - No such a job (in Japan)
- A Introductory course and periodical seminar for research & Intra-net education (in the US)
  - Very limited number of in-house educational programs (in Japan)
To begin with …..

- To start reading the study protocol.
- To prepare a summary sheet of clinical trials conducted in the department.
- To use same evaluation method that is required in the trial.
- To share medical records.
- Then, nurses can easily check Eligibility / Treatment plan / tests orders for the study.
The 1st Clinical Research Seminar for Nurses

- On February 23, 2008 at the Kitasato University
- Sponsored by 平成19年度大学改革推進等補助金
  - 「地域医療等社会的ニーズに対応した質の高い医療人育成推進プログラム」臨床研究人材育成コンソーシアム」
- About 140 nurses participated
The seminar program

1. EBM and Clinical Trials
2. What Investigators Want to Say to Nurses
3. Clinical Trial Nursing
4. Introduction to Biostatistics
5. Roles and Responsibilities of Research Nurses in the US
6. Group Works:
   1. What can we do for the patients participating in clinical trials?
   2. What are obstacles for us to be involved in clinical trials?
Key words from the 1st nurse seminar

- Educational programs for clinical nurses regarding research
  - Education in nursing school
  - Continuous education for nurses
  - (New learning for nurses in administrative positions.)
- Job responsibilities of research nurse and clinical nurses
- Communication with the physician and gaining trust
- Nursing human resource allocation and job assignment
It may be a long process of…

- Our own education
- Education of nursing colleagues, the patients, the medical community, and the public.

「みなさんの話を聞いて、臨床試験のことを今日もう一度考え、そして、看護師の血がさわぐ思いがしました。」
Thank You.