Symposium

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Nursing protocol committees, one of three steps to improve quality

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The Department of Oncology at Finsencenter continuously treats patients according to 35 chemotherapy protocols of phase I, II, and III trials. The clinical research nurses (RN) in CRU are involved in 24 of these protocols. The RN's supervise that the investigations are carried out according to the principles of Good Clinical Pratice (GCP). To improve quality CRU has implemented several quality improvement.

The three steps in the quality improvement program, are: 1) Nursing Protocol Commitees (NPC) since 1993, a standard procedure for initiation of a protocol. 2) An education programme for nurses and doctors in the basic principles of clinical research (6 hours including a clinical case story). 3) RN's are connected to clinical wards, as protocol-supervisors.

Each NPC consists of one RN, two nurses, and one physician. The NPC discuss the impact on the everyday work the protocols have for the departments, in order to prevent predictable problems.

Aim: 1) To give coordination and implementation of new protocols into clinical practice. 2) To give the committee-members a profound knowledge about the protocols, in order to make them feel responsible. 3) To secure a general information about and understanding of the clinical research processes.

Conclusion: The speech will present some of the specific tools used in the NPC to secure a high quality, as well as experience and results obtained. Further the effect of the education program and the function of RN's in the clinical wards will be briefly presented.

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A core curriculum for cancer clinical trials

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Nurses are perceived as essential component of the clinical trials research process. They play an important role in patient and family information and education, treatment administration, monitoring toxicities and organization of the follow-up. The nurses' participation in clinical trials is rendered very difficult by a number of factors, including the lack of clarity of their role in the specific trial, the high workload, the conflict of responsibilities, the lack of education in research in general and in clinical trials methodology.

The EORTC-ONSG planned a core-curriculum on cancer clinical trials specifically aimed at nurses involved in clinical trials, in order to increase nurses' understanding of the clinical trials methodology, their full involvement in clinical trials and thus increase the quality of the care of the cancer patients recruited in clinical trials. The curriculum is a second level course, directed to nurses involved in clinical trials: it aims to offer a discussion arena at European level in order to expand the knowledge and share experiences on issues relevant to the nurses' role.

The development, philosophy, aims and contents of the curriculum will be described and discussed.

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Nursing summaries of clinical trials

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Nurses are increasingly involved in clinical trials. Any nurse involved in clinical trials may perform one or more of the following roles: patient educator, patient ally, direct care giver, coordinator of care and research administrator of research resources and participant in the conduct of the study. In order to be able to perform correctly all their functions and work in a multidisciplinary collaborative team, nurses must be fully aware of:

(a) the trial protocol. rationale of the treatment, selection criteria for patient inclusion, experimental treatment planned, known side effects;
(b) their role: the observations and interventions required such as laboratory tests to be performed and symptoms to be observed;
(c) patients reasons for participation.

Since there is often a high workload in an oncology unit and little time for reading the entire protocol, a nursing summary of the protocol can be a helpfull instrument. Nursing summaries consists of practical shorthand information, and are in a way a translation of the medical protocol into nursing daily practice. Since there is a need for a standard approach in the preparation of the summaries, the EORTC-Oncology Nursing Study Group (EORTC-ONSG) proposing a "master" nursing summary which should be a compulsary complement to the research protocol.

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The implementation of nursing summaries

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A nursing summary of the medical protocol is a document that provides a short and easy to read selection of relevant protocol information. The potential benefit of implementing nursing summaries is an overall improvement of the quality of the study by (a) increasing the reliability of nursing care regarding patient safety (b) standardizing monitoring and care of patients (c) standardizing preventive measures (d) proposing similar management of complications related to experimental treatments. Nurses involved in cancer clinical trials are faced continously with new treatment modalities and demands for new nursing skills. A desire to maintain the status quo and/or resistance to change is a human trait. Implementation of a new innovation, in this case nursing summaries, has to be performed carefully and can contain the following phases: (1) Assessment phase (2) Diagnosis phase (3) Planning phase (4) Intervention phase (5) Evaluation phase. Difficulties in implementing innovations will be discussed. Nursing summaries can be prepared centrally by the group responsible for the research protocol, while the unit/wards involved in the research can customize or adapt it to local needs. Examples of nursing summaries will be proposed and commented on.

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Measurement of workload in clinical trials

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As research in the treatment of cancer progresses, so the number of clinical trials increases. Proof of this is seen in the increase in the number of patients and trials handled by the EORTC Data Center each year. Nurses working in institutions where clinical studies are performed on a regular basis will consequently be nursing more study patients. Additional studies are conducted within an institution or a geographical area, or with the aid of the industry. Present day trials are more intensive and complex, admissions tend to be shorter, budgets are being decreased and patients are requiring additional nursing interventions and more compact care. One aspect addressed by the European survey (1990–91) conducted by the ONSG was to describe the extent of participation of nurses in clinical trials and identified major nursing tasks and activities. In this paper we will consider measurement of workload by referring to the literature and to general practice regarding these additional tasks and activities