technologies like internet, CD-Roms and video recordings. Many medical reference books are published for non-health care providers.

When a patient is offered the possibility to participate in a clinical trial, the healthcare professional must take into consideration not only the stage of the patients' disease and the treatment history, but also the type of study (Phase I, II or III) and its focus e.g. toxicity, therapeutic benefits or supportive care treatment. Information must be given in a clear and correct manner according to GCP norms.

Most of the information patients receive about treatment options, especially in the case of a clinical trial, is provided by a physician, usually an investigator or a co-investigator. It is not always current practice that nurses are involved in the information process about a study.

This presentation will focus on:

- the role of nurses in the information process;
- how nurses react to this challenge;
- which problems nurses face when patients are assertive or do not want any information.

Encouraging patients to actively participate in decisions regarding their treatment is a challenging task and requires precise skills. By using a personalised approach and clear communication methods, nurses contribute to the maintainence of the balance between research interests and patients' needs.

1416

Informed consent forms: what is the impact?

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Clinical trials are an essential part of the process of developing new and better cancer therapies. For trials involving human subjects, respect for the individual patients' autonomy requires that research subjects give their informed consent. In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. While there is a general consensus on the need for informed consent, there is still an unanswered question on how to achieve a meaningful informed consent. Many factors have an impact on the comprehension of informed consent information. Part of the process for providing the necessary information has been the use of written information and consent forms prior to participation in a clinical trial. The value of this approach has been questioned by some studies which highlight the difficulties that patients have recalling this information while others have focused on the problem of the readability of the forms. Research has showed that consent forms are often written at a scientific level that is too difficult for most study participants to comprehend. The content of consent forms consists of advanced medical technologies, study design, potential risk considerations, legal and regulatory issues, institutional practices etc. The amount of information as well as the complexity affects the readers ability to understand the information given and can be a barrier for the informed consent process.

Literature supports that simplify, can improve readers' comprehension of written materials. Patient reading levels can be assessed. Nurses who participate in developing written information must begin to recognise the diversity of skills and to implement measures for assessing readability. The process of informed consent is a communication process through which nurses can help patients to understand the information. It is imperative that nurses explore novel approaches to communicate cancer clinical trial informed consent information in a understandable manner to enhance effective patient decision-making.

1417

How can education improve the supportive role of the nurses? The core curriculum for cancer clinical trials and the manual for research nurses

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Many authors emphasize the importance of the staff nurse being knowledgeable about the research and the research process. Nurses, when asked to rank six proposals that would be helpful in increasing knowledge in order to participate in clinical trials listed courses (73%), seminars (67.6%), practical training (60.4%), symposia (50.5%), newsletters (44%) and brochures (36%). Nurses involved in cancer clinical trials have to be aware of the various roles they are expected to perform: participate in the informed consent process, educate patients and staff, provide direct care support to the patient and family, administer drugs and collect data on toxicities, act as patients' advocate, coordinator and administrator, and should be educated to perform them properly. The offer of educational opportunities for nurses involved in cancer clinical trials varies from country to country. Two educational initiatives will be presented.

The Core Curriculum for Cancer Clinical Trials, prepared by the Oncology Nurses Group of the EORTC aims at improving nurses' knowledge of the principles, methods and conduct of cancer trials. The core-curriculum provides a framework on which to design courses to train nurses to participate in cancer clinical trials, and for caring for the trial patients.

The Manual for Research Nurses, written by members of the Early Clinical Studies Group Research Nurses aims at providing research nurses with a handbook together with a reference book. The main objective of the manual is to assist (new) research nurses in understanding the processes and procedures of planning, initiating and monitoring clinical trials. The manual describes theoretical and practical knowledge about clinical trials and their performance and is useful for daily research nursing practice as well as for courses in research nursing.

Providing oncology (research) nurses with adequate knowledge will improve their proficiency as members of the clinical research team. This will improve both the care for patients participating in clinical trials and the quality of data collected.

Workshops

Workshop: English

1418

Altered body image – Nursing interventions for image enhancement

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Many written resources have been published to assist the patient and the caregivers in coping with an altered body image, experienced during and after cancer therapy. The various degrees of psychosocial distress is well known and often discussed. The practical aspects though, are not often incorperated within the provided information.

Developing new programs, influencing changes in existing models to enhance the patients changed body image and therefore promoting quality of life, can and should be encouraged.

Purpose and Aims: The purpose and aims of the workshop will be to enable nurses to:

- identify high risk patient populations.
- review the nursing role in helping the patient set reatlistic goals toward enhancing their outward appearance
- actively practice a few simple, cost containing interventions which are applicable anywhere in the world, and
- inform healthcare professionals about current information resources