Posters

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WELL BEGUN IS HALF DONE, A NURSING TASK FORCE INVOLVED IN PREPARATION FOR CLINICAL TRIALS

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Nurses are increasingly involved in clinical trials. In 1992, nurses of the Oncology and AIDS ward initiated a task force consisting of members of the nursing team, nurse specialists and executives, supported by the physicians involved. This task force translates clinical trials in oncology and AIDS patients into nursing protocols in order to set optimal conditions for all nurses in the ward to participate in clinical trials. It is structurally involved in all clinical trials on the ward. A rigorous procedure has been developed. All nurses on the ward have received a one-day course on principles and practice of this task force. This has led to a feeling of involvement of all nurses concerned. In the first period, lack of time, experience and coordination has proven to be the principle bottleneck. To overcome this problem, one nurse has been appointed as a central coordinator. After two years, the procedure has proven its value. Nursing protocols are developed before the start of the trial. Collaboration with the physicians involved has improved. The nursing team is motivated and able to perform increasingly difficult clinical trials. Admission of patients and nurse shifts are scheduled in relation to the demands of clinical trials. Nurses of the day-care ward are now also involved.

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CLINICAL TRIALS AND QUALITY OF LIFE ASSESSMENT (QOLA): THE NURSE'S VIEWPOINT

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Quality of life is an important concept in the oncology environment because the physical, psychological and social well being of patients are affected by the disease and the related treatments. The relevance of QoLA to nursing clinical practice has been documented in the literature. There is a need to use valid and reliable tools to plan appropriate nursing care, to evaluate the effect of nursing interventions and to justify activities. In clinical trials, the QoLA is being used increasingly to predict patients outcomes and to evaluate medical and nursing interventions.

Nurses' viewpoint of potential benefits and pitfalls related to quality of life assessment will be discussed. Among benefits, it is usually considered that interventions can be adjusted and individualized and the need for supportive care can be evaluated more accurately. As for pitfalls, QoLA causes an extra burden if poor introduction and/or incomplete guidelines are provided to patients and staff, and if its implementation is not properly coordinated. Proposals for implementing effective QoLA will be discussed. Basic requirements such as preliminary instructions and guidelines for administration of questionnaires, proposals for reducing missing evaluations and missing data will be presented.

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GENE THERAPY: NEW ISSUES FOR NURSES

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A gene, the single basic unit of the cell, defines who we are, the color of our eyes and hair and is also the basic unit of many different diseases. Discovery of the gene is a major breakthrough in our understanding of the basic make up of man and of the diseases which impact one's life.

In 1976, the first cancer gene was identified. Since then numerous studies have been done which demonstrate that cancer is a genetic disease in which a series of genetic alterations occur within one cell leading to malignancy. The development of knowledge about the genetic origin of cancer has led to novel approaches in the treatment of cancer. Approximately 10 different approaches to treating cancer with gene therapy are presently being researched such as genetically manipulated tumor vaccines and treatment with tumor suppressor genes. New approaches are being discovered every day.

The development of these new therapies have implications for nursing such as patient and nursing education, coordination of in and out patient services, research requirements, gene therapy administration, toxicity assessment, symptom management, patient care, moral/ethical issues and cost. Nurses need to be aware of all the issues surrounding this complex therapeutic modality and meet the challenge of the future of cancer care.

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INTRODUCING OF CLINICAL TRIALS IN SLOVENIA—A NEW CHALLENGE FOR MEDICAL NURSES

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At our Institute, a systematic approach to clinical trials (CT) was introduced two years ago, and since then we have been developing a profile of research nurses. First guidelines for CT were obtained from literature, at a course on CT in Belgium (EORTC), and another one on "How to Read and Use Results of Nursing Research" in Amsterdam (IKA). So far we have joined multicentric phase II and III CT within the framework of IBCS and EORTC, which are supported by individual pharmaceutical companies. Apart from these, we are also conducting some national CT on gastrointestinal and ORL disorders. During this time, approximately 1000 patients have been entered into our CT; of these, 15% were treated at our Institute.

Introducing a new approach is often not easily accepted by our surroundings; at the beginning, we had to face the resistance, fear and mistrust from both our co-workers and the patients. Therefore, at times we felt helpless and ineffective. Gradually, however, we have managed to overcome these difficulties. We are further encouraged by our patients who have been taking a more active approach to their treatment. The role of research nurses has not been fully determined yet. What shape it will take in the future largely depends on us—medical nurses. The position represents a great challenge, and an opportunity for dynamic work resulting in an improved quality of nursing care of cancer patients and better treatment results.

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CPT 11 PHASE I: NURSING EXPERIENCE

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As research nurses specialized in Phase I Studies (St), we participated at the CPT 11 one (Roger Bellon) in our unit from August 1990 to March 1993. This experience allows us to share a grateful knowledge about this St.

Material and Methods: 88 patients (pts) were treated with CPT 11 (30 min infusion every 3 weeks), receiving from 100 to 750 mg/m^2, 64 pts were evaluable. Nevertheless 190 pharmacokinetic St were evaluable out of 225. At the same time, due to the diarrheal toxicity of CPT 11, a second St concerning High-Dose Loperamide Protocol (HDLP) was conducted from 400 to 750 mg/m^2 of CPT 11. This second St included 23 evaluable pts.

Results: The main non-hematological toxicities shown for CPT 11 were: diarrhea (D), asthenia, alopecia, nausea and vomiting. During infusion, we also could describe a cholinergic syndrome easily suppressed by an atropinic treatment. The HDLP showed its efficiency to control CPT 11 induced D and allowed an high-dose escalation in CPT 11 Phase I St with an acceptable tolerance for pts.

The HDLP was set both by medical and nurse teams. This close collaboration between nurses, medical team and pts permitted one of the most interesting works conducted in our Phase I unit, mainly due to the increased educational role of nurses during the HDLP.

Pts seemed to feel more implicated and secured by the close contact with the research team during those 2 St conducted at the same time.