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Nursing responsibilities in clinical trials in the Istanbul University Oncology Institute and the implementation of education programmes

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Nurses can have an important role in patient awareness of advantages of clinical trials both for individuals in terms of improved care and for society through the advance merit of the understanding of cancer and its treatment.

The roles of nurses in a research setting are; staff nurse as a primary caregiver, clinical nurse specialist as a consultant, educator and advanced practitoner, and research nurse as a collaborator and liaison.

Considering the increasing importance of a nurse in a clinical trial, an education programme was developed. The education programme which was planned for doctorate students included: Introductions to clinical trials, instructions for patients, investigators and study personnel, collecting adverse events and adverse reaction data in clinical trials. In the end of this programme nursing responsibilities in clinical trials were discussed and determined as follow:

- Knowledge of preclinical information and rationale for basis of study
- Clinical expertise with assessment skills that promote recognition of side effects
- Patient education
- Assistance with ensuring informed consent
- Patient and staff advocacy
- Anticipation and documentation of treatment and disease effects
- Knowledge and aplication of ethical considerations
- Planning for implementation of research
- Education of staff about theory, rationale, and objectives of research
- Develop teaching materials spesific to protocol
- Collaboration with all health care resources
- Liaison between patient and physician, nurse and physician relationships and concerns
 - Liaison to drug companies and Cancer Therapy Evaluation Program
- Collection of patient data, review of medical records.

In conclusion, it was decided that only the nurses who have master degree in medical nursing could participate in clinical trials as a research nurse. And the ongoing education programmes which were structured for master degree nurses have been planned and developed.

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Qualifying the palliative care at the Roskilde County Hospital – A quality development project

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Background: During the recent years Roskilde County Hospital have focused on the possibilities to improve quality of care for incurable patients. The Danish Ministry of Health granted financial support in the years 1998–1999 to carry out project to improve and quality palliative care.

Purpose: Two major purposes are identified: 1. To upgrade the professional qualifications of palliative care and treatment given to terminal patients. 2. To optimise the co-ordination between the hospital and the primary health sector.

Method: The project has three phases. *1st Phase:* The analysis phase (01.10.98–28.02.99). Different needs and wishes of staff at Roskilde County Hospital and the primary health sector were identified using questionnaires and focus interviews. *2nd Phase:* The action phase (01.03.99–01.09.99). Based on the analysis of phase one a number of activities are initiated to achieve the overall goals of the projects. *3rd Phase:* The evaluation and reporting phase (01.09.–13.09.99). The phase will consist not only of an analysis and documentation of the a activities of the project but also present recommendations for the future palliative care at the Roskilde County Hospital.

Results and Conclusion: The poster presentation will consist of (1) results from the studies in phase 2, (2) summary of recommendations to the future palliative care and (3) significant results from the project with specific attention to interdisciplinary activities.

Venous central line management and complications in patients treated with high-dose chemotherapy and circulating hemopoietic progenitor support (PBPC)

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Purpose: Non totally implanted venous central line is an useful device in high-dose chemotherapy program and it is cheaper than totally implanted venous catheters.

Methods: From January Œ98 to February, 99, 28 patients (pts) entered into high-dose chemotherapy program. Twenty-two pts had solid tumors (18 metastatic breast cancer, 2 high risk breast cancer, 2 advanced ovarian cancer) and 6 with hematological malignancies (4 non Hodgkin lymphomas, 1 Hogdkin's disease, and 1 multiple myeloma). Median age was 45 yrs (range 34–60). A total of 34 blood cell transplant (BCT) procedures (20 single, 6 double, 3 triple) have been performed. In all pts a bilumen catheter 14G/14G (Arrow Int. Inc., Reading, PA,) was implanted using the Seldinger technique in the succlavian vein before PBPC mobilization. This procedure and the management was performed on an outpatient basis.

Results: In 19 pts (69%) the catheter has never been replaced with a median duration of 108 days (range, 30–180). In 9 pts (31%) the catheter has been replaced after a median of 75 days (range, 10–120). Clinical evidence of infection and thrombotic occlusion were the reasons of replacement in 4/9 pts (45%) and in 5/9 (55%) of pts, respectively. These complications were not observed in the 2 pts who underwent triple BCT and occurred only in 2/6 of pts who underwent a double BCT.

Conclusions: The complication rate observed in our experience indicate that non totally implanted catheters are safe and a careful management may contribute to reduce the costs of procedures mainly in pts treated with double and triple BCT.

3 POSTER

The communication of bad news - A Rotterdam perspective

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Purpose: The implementation of a guideline for Doctors and Nurses with respect to the communication of bad news to outpatient and clinical patients.

Method: On average we have three or four patients per week for whom further treatment is of no value. By using a common approach by both doctors and nurses it is hoped to achieve a radical improvement in our approach to the introduction of palliative care.

Results: Before the patient is released for home care, or for transfer to another hospital or hospice an informative discussion takes place with the patient and his or her relatives.

Conclusion: The aim is to guarantee an optimal communication with the patient by implementing our guidelines.

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Safe handling of cytotoxic drugs in Slovenia

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Purpose: Analytical investigation of the circumstances in Slovenian health care centers was made in order to denote the number of nurses handling cytotoxic drugs, the frequency of their involvements, their experience with safe handling, the use of safety materials and work conditions of exposed personnel.

Methods: From March to November 1966, we visited 16 health care institutions in Slovenia and interviewed 188 nurses who were continually or occasionally involved in handling cytotoxic drugs. The inquiry was anonymous and performed on volunteers only. The questionnaire was tested by a pilot study followed by descriptive statistics data processing.

Results: Of 188 nurses, 58% were involved in nursing patients on cytotoxic drugs, as well as preparing and administering these drugs, and 23% were in charge of nursing only: 16% administered more than 20 chemotherapies per week, whereas 62% administered up to 5 chemotherapies per week. They obtained most of their knowledge from their colleagues at work and technical literature. Some changes detected in nurses handling the cytotoxic drugs were personal observances (fatigue, headache). Only 5% of the interviewees had been medically examined before they started to work

with cytotoxic drugs. All nurses used gloves for preparing and administering hazardous drugs and in nursing patients on cytotoxic drugs; 48% of nurses never used gowns; 39% prepared drugs in vertical-airflow biological safety cabinets.

Conclusions: Due to the inadequate list of personnel dealing with cytotoxic drugs, insufficient knowledge of and experience with cytotoxic drugs, irregular use of safety gowns and other safety materials in preparing and administering cytotoxic drugs, we decided to prepare recommendations on safe handling of cytotoxic drugs in health care comprising, (1) standards, (2) national legislation on protective measures, and (3) post-graduate training of personnel.

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Intensity Modulated Radiotherapy (IMRT) of prostate cancer: A greater demand for quality control and daily treatment accuracy.

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We implemented an IMRT technique for irradiation of patients with prostate cancer. The increased complexity of the IMRT technology has imposed a modification of the quality control program for daily treatment verification. As the margins around the target are smaller, the day to day setup accuracy was, off-line, verified by measurement of the table height position.

Methodology: Patients are treated using a 3-dimensional conformal radiation technique. Three beams in the transverse plane with a anisotropic margin of 1.5 cm around the target (prostate + seminal vesicles) were used to obtain a hemegeneous dose distribution. Gantry angles were 0.116 an 244° in all cases. Collimator and table isocenter rotations were always zero. The rectum, bladder and both femoral heads were considered as the organs at risk. Treatments were delivered bij means of a SL-18-MLC AND SL-25-MLC in a forced step-and-shoot mode executed by a prototype dynanic MLC (Elekta, Crawley-UK).

From the treated patients all available data of the table height position were collected and stored in a database (Excel 5.0) on a personal computer.

Conclusion: This poster will show the expansion of the QC in proces

control needed to use this technique appropriate, safe and efficient.

Daily accurate reproducibility is shown in the data of variation of the table height position.

126 POSTER

The need for frequent stimulation and help of the investigators for a good managment in the "TDM study"

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Purpose: We initiated a prospective study involving local oncologists, gastroenterologists and surgeons as well as radiologists and biologists in order to evaluate the routine tomodensitometric follow up and cost benefit ratio in patients with metastatic colorectal cancer.

Patients: Patients have colorectal cancers with hepatic or pulmonary metastases and receive chemotherapy. The study is not a therapeutic trial. The aim is to look for correlations between clinical, biological and radiological markers that are the efficacy parameters usually required to evaluate chemotherapy (WHO criterious for response and survival). The effect of 3 or 4 chemotherapy courses is determined by radiological response, evolution of the clinically measured lesions, tolerance and turnor markers. After assesment the patients are classed in 2 groups: responding patients considered as having progressive disease who will have further receive another treatment.

Monitoring: In this study the theorical and true inclusions graphs are similar and 100 patients were initially planned and actually enrolled. During the study, the participants have been motivated for meetings and radiologists for review of CT scan. At 62 patients, missing data number is <10% and none lost to follow up. About 50 additionnal patients were initially considered for eligibility but were not included.

Conclusion: Datamanagment from the beginning to the end, information to investigators for study progress, anticipation of visits by calendars (sent to doctors, radiologists and biologists), collection and report of data on case report form by the research assistant have probably contributed to the correct rate of inclusions and good data collection.

127 POSTER

Comfortable patients in protocoled trials

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Alm: Through well-informed nurses to achieve the highest possible level of safety for the patients receiving medical/radiation therapy.

Methods:

- Continuity in the nursing
- Primary nursing
- Empathy/care
- Data collection
- Information (general/specific)
- Establish contact to other treatment groups
- Establish contact to the physician responsible for the protocol
- Verbal and written information
- Instruction/support/counselling to patients and relatives
- Coordination

Results: Well-informed patients participate actively in their own treatment and share responsibility for their treatment and protocol course. Also, the patients have more energy enabling them to complete the treatment. There is a higher level of responsibility in the patients as well as in the nurses, and furthermore, the patients experience a higher level of trust in the nurses/doctors and thereby also in the public health care system.

Visions: That an even larger group of patients gets the opportunity of similar nursing and course of treatment.

128 POSTER

Guideline for patients undergoing chemoembolization

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Chemoembolization is one of the current treatments for the liver tumor, whether it is a primary tumor or if it is metastatic. This procedure is in our environment very infrecuent and unknown for the larger part of the people.

Our service is one of the two sites where chemoembolization is performed in our country. The chemoembolization have many possible side effects and risks due it involves the injecting of chemotherapy through a cateter inserted via the femoral artery reaching finally into the liver artery that feeds the tumor.

Due to the risk this procedure brings, it must be known by the patient so he may colaborate knowingly in the previous preparation and during and after the procedure to get a good result, thus avoiding forseen risks.

With the purpose of improving and helping the patient to get his colaboration, we created this guideline, which is handed to the patient when the phisycian suggest this treatment. We are currently evaluating the use fullness of this material for ameliorate the patient's compliance.

129 POSTER

Use of alginate dressings in the care of chronic wound

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Cancer patients after surgery are often in a poor psycho-physical condition, and often in a phase of catabolism before surgery. This results in worse healing of the surgical wound, which may entail a prolonged healing per secundam and the so-called chronically infected surgical wound.

Nursing care is aimed at achieving an optimally short healing time, less painful wound dressing, reduced nursing care burden and shorter hospitalization periods. Our study included 6 operated patients with an open infected surgical wound. In the first 14 days after surgery, the patients were treated with dressings of 10% Betadine in 0.9% saline solution 4 times daily, and with alginate dressings thereafter. Already after few days of alginate dressings use, the healing process was found to have improved considerably, as compared to standard dressings. Furthermore, a directed systemic antibiotic therapy in combination with alginate dressings effectively eliminated the surgical wound infection.

Conclusion: The use of alginate dressings in the care of chronically infected surgical wounds contributed towards shorter surgical wound healing process, improved quality of patients' life, and reduced nursing care burden. Taking into account shorter hospitalization time, the cost-benefit ratio is positive, regardless the price of alginate dressings.