70 Invited Abstracts

patients are at home. The aim of the present RCT was to assess the effectiveness of a home care nursing programme compared with standard care in the management of treatment toxicities, anxiety, depression and quality of life in colorectal and breast cancer patients receiving oral capecitabine (Xeloda®).

Standard care involved patient education at hospital and medication for common toxicities. The home care programme additionally consisted of a home care nurse visit during the first week of chemotherapy, which provided patients with education about symptoms and their management. Weekly phone calls assessed and monitored symptoms, and provided emotional support and reassurance. Patients were assessed using weekly CTC toxicity scales, with anxiety, depression and quality of life scales administered every 6 weeks. Patients were followed up for 18 weeks (6 cycles). In this trial, 164 patients were randomised to receive either home care nursing (n = 83) or standard care (n = 81).

**Results:** Patients in the home care arm experienced significantly lower symptoms (composite score of all symptoms). More specifically, the had lower oral mucositis (P = 0.003), diarrhoea (P = 0.008), constipation (P = 0.008), nausea (P = 0.003), vomiting (P = 0.041), pain (P = 0.003), fatigue (P = 0.018) and insomnia (P < 0.0005), the majority of symptoms maintaining the improvement over the 6 cycles. There were also trends towards lower anxiety and indications of less service utilization in the home care group. No difference between the two groups was seen for hand-and-foot syndrome, quality of life and depression.

**Conclusions:** A nursing symptom management regimen-focused home care programme was able to better assist patients in managing treatment-related toxicities and support them during the treatment period than receiving standard care alone.

290 INVITED Cancer supportive care – creating opportunities within the DRG-system

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Treating cancer patients combines different professions and numerous transitions between in-patient and outpatient care settings. Awareness and continuity of supportive care are needed to improve the quality of the patients treatment experience and also clinical outcomes.

In this paper, first the reimbursement of supportive cancer care in the German DRG system in inpatient settings is analysed. Reimbursement opportunities and shortcomings are identified. In the second part, the traditional system is contrasted with the ongoing development of so-called flat fees for complex treatments ("Komplexpauschale") covering treatment both in ambulatory and in-patient care on a contractual basis between hopitals and ambulatory providers. For cancer care, so far a palliative care flat fee has been introduced allowing the reimbursment of integrated care contracts – these reimbursement rules are analysed towards their capacity to fulfill the need of cancer patients regarding access to and amount of supportive care offered as well as the capacity for guaranteeing continuity of care.

In the next part, the German developments on sector transcending flat reimbursment fees are contrasted with the international debate on revidence-based case rates and performance oriented multiple-sector reimbursement rates in cancer care. Problems and challenges remain when it comes to integrate an adequate level of supportive care into a system characterized by increasing economic pressures through flat fee reimbursements. With ever-increasing demands on nursing and medical care of cancer patients, the discussion of the role of specialized cancer nurses in providing supportive care in the German setting concludes the paper.

## Special Session (Wed, 23 Sep, 17:00-18:00) Circulating tumour cells

292 INVITED

Methods for detection of circulating tumour cells: potential & limitations

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Metastasis is the main cause of death in patients with solid epithelial tumours (i.e. carcinomas), which represent the majority of cancers in industrialized countries.

Extremely sensitive immunocytochemical and molecular assays are required to allow the unambiguous identification and characterization of single circulating tumor cells (CTC) in the peripheral blood and disseminated tumor cells (DTC) in the bone marrow (BM) as a common and easily accessible homing organ for cells released by epithelial tumors of various origins. Detection methods are usually used in combination with tumor cell enrichment procedures, including density gradient centrifugation (Ficoll-Hypaque separation), immunomagnetic procedures or size filtration methods to enrich tumor cells prior to their detection.

These enrichment and detection methods currently used for the detection of CTC/DTC will be reviewed with their potential and limitations.

293 INVITED Characterisation and monitoring of circulating tumour cells

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Early spread of tumor cells is usually undetected by current imaging technologies. Therefore, in patients with cancer and no signs of overt metastases, sensitive methods have been developed to detect circulating tumor cells (CTC) in the peripheral blood and disseminated tumour cells (DTC) in the bone marrow. These technologies can be classified into cytometric and/or immunological and molecular approaches. Interestingly, the bone marrow seems to be a common homing organ for cells derived from various epithelial tumors, and level 1a data from European and US groups have sustained the prognostic impact of DTC in the BM of breast cancer patients. Sequential peripheral blood analyses, however, are more convenient for patients than BM analyses in patients with solid tumours and many research groups are currently assessing the clinical utility of CTC for assessment of prognosis and monitoring of systemic therapy. In view of the plethora of prognostic indicators - especially in breast cancer - monitoring of CTC during and after systemic adjuvant therapy might provide unique information for the clinical management of the individual cancer patient and allow an early change in therapy years before the appearance of overt metastases signals incurability. There is an urgent need for biomarkers for real-time monitoring of the efficacy of systemic adjuvant therapy in individual patients. At present, the success or failure of anti-cancer therapies is only assessed retrospectively by the absence or presence of overt metastases during the post-operative follow-up period. However, overt metastases are, in general, incurable by most current therapies. The monitoring of CTC will provide new insights into the selection of tumor cells under biological therapies. Molecular characterization of DTC and CTC opens a new avenue for understanding early metastatic spread of tumour cells and might contribute to the identification of metastatic stem cells with important implications for future therapies.

294 INVITED
Detection and characterization of tumour cells in sentinel lymph
nodes and bone marrow of patients with breast cancer

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The sensitivity and accuracy of methods for tumour cell detection in sentinel lymph nodes and bone marrow from breast cancer patients is debatable. In a large collaborative study on samples obtained at time of primary surgery we have examined the presence of tumour cells by immunobead selection (IMS) and characterization, in many cases followed by molecular studies on a pure population of cancer cells specifically isolated by the CellPick system (MMI). The sentinel lymph nodes were cut in half, one half was disaggregated and used for IMS with an anti-EpCam antibody, and the other half for immunohistochemical (IHC) identification with an anticytokeratin antibody applied to ten sections of each node. The IMS method showed by far the highest sensitivity, but there was only a minimal overlap in results between the two methods. Verification of the cells identified with IMS as tumour cells was obtained by simultaneous binding of non-magnetic fluorescent beads coated with antibodies recognizing known breast cancer markers (Muc1, erbB2, EGFR, B7-H3). Surprisingly, such validated tumour cell positive samples were equally distributed between the IHC positive and negative groups. The results suggest important methodological problems inherent to both IMS and IHC detection approaches. To further investigate this, we used qRT-PCR and arrayCGH on the IMS selected cells followed by specific isolation of 5-20 bead-confirmed tumour cells. qRT-PCR targeting mammaglobin, AGR2, TFF1, and SBEM mRNA were positive with at least one marker in 50% of 60 IMS EpCam positive samples studied, but was negative in cells isolated from bone marrow. ArrayCGH