disease and decreased hope, and those with increased need of both informal and formal assistance.

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Early stopping of 2 clinical trials for futility: an exploratory study of patients' reactions

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Background: Early stopping of clinical trials (CT) for efficacy or futility after interim analysis has been recently discussed in the literature. However, information for the clinician on support of and communication with the patient (pt) who abruptly halts trial therapy is lacking, and pt point of view has not been explored. The purpose of this study was to examine pt reactions to early futility stopping of 2 CTs.
Methods: The study was conducted with patients at NCI Naples enrolled in 2 international phase III adjuvant therapy trials for stage IV and stage III melanoma when the trials were interrupted at interim analysis for unlikelihood of demonstrating significant survival benefit for experimental therapy vs. placebo. A collaborative inquiry model was used allowing mutual exploration/understanding with pts while permitting the clinical research nurse (CRN) to provide support/education to patients transitioning to a new phase of care. Patients were notified in person of study closure by CRN and Investigator. CRNs conducted semistructured patient interviews twice, 6−10 weeks and 14−18 weeks after study closure to determine: patients' reactions to study closure, pt positive/negative experiences of CT participation, pt informational and emotional needs and further treatment plan, and to disclose treatment assignment.
Results: Mean time on study (random-closure) for interviewed stage IV pts (n. 16) was 28.8 months (range 4−72), Stage III pts (n. 60) was 33.7 months (range 11−72). Prominent emerging themes related to early stopping were: fear of doing nothing against the disease and of being abandoned by the health care team, both with diminishing impact at second follow-up; shock and denial at treatment cessation transforming to anger and bargaining; futility of participation in the CT transforming to satisfaction with results and/or altruism. Positive experiences reported were CRN-pt relationship, perceived facilitated access to health care team, enrolled pt cohort serving as an informal support group. Negative experiences reported were lack of treatment alternatives at study closure. Identified pt needs included reassurance and continued contact with CT team, information on alternative therapies, impact of trial therapy on future options, written communication about study closure.
Conclusion: Patients who abruptly end CT therapy require information and support in the transition to the next phase of care and CRN follow up provides the basis this support.

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A randomised crossover study of a nurse-led chemotherapy outreach project

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There are several reports regarding chemotherapy given in patients' homes. However, no studies have considered chemotherapy given at community hospitals. The aim of this study was to compare the outcomes of chemotherapy delivered at a cancer centre with the outcomes of chemotherapy given at four community hospitals (outreach). The services were compared in terms of patient safety, preference for location, quality of life and cost-effectiveness. Satisfaction and the perceived acceptability of the service from the staff perspective were assessed in a sub study (Pace et al 2007).
The study used a randomised crossover design to compare outcomes between two types of location. One group received their first two cycles of chemotherapy at outreach; the other group received theirs at the cancer centre. The patients then crossed over to receive their next two cycles at outreach or the cancer centre. Patients then chose where they preferred to receive their remaining cycles of chemotherapy. Side-effects were assessed using the Chemotherapy Symptom Assessment Scale (Brown et al 2001). Anxiety and depression were assessed using the Hospital Anxiety and Depression Scale (Zigmund and Snaith 1983). Economic analysis used a health state utility instrument EQ5D (Euroqol Group 1990) as well as patient and provider cost data.
42 patients were randomised, 35 female and 7 male. The majority 78% had breast cancer, there various other cancers including pancreatic, prostate and melanoma. A broad range of daycase chemotherapies were given, the majority (76%) of patients received an anthracycline based regime.
31 patients reached the end of the crossover period. There was an overwhelming preference for outreach chemotherapy, 97% chose the outreach location for the remainder of their treatments. There were no differences between groups regarding chemotherapy side-effects or levels of anxiety and depression. There were no adverse reactions during chemotherapy at any location. No outreach patients had to be referred back to the Cancer Centre immediately following treatment. There was no incidence of extravasation of chemotherapy. This study suggests that there are additional costs to providing the outreach service over current arrangements but that these are associated with a modest improvement in health state as measured by EQ5D and its associated "utility".
The recommendation of this study is that a permanent outreach chemotherapy service to community hospitals is established.