efficacy endpoints were evaluated up to wk 13. Efficacy was evaluated by transfusions (weeks 5 to 13) and hematologic response at week 13. Safety analyses included hazard ratio (HR) estimates of events from a Cox regression analyses (stratified by study). Events were identified as follows: deaths based on reasons given for drug or study discontinuation, or fatal AE; progressive disease (PD) if given as reason for drug or study termination or end-of-study disease status; progression-free survival (PFS) as time until death or PD, whichever earlier; and thromboembolic events (TEs). To consistently define TEs, adverse events (AEs) across trials were mapped to a common reporting dictionary (MedDRA v.9).

Results: Analyses included 1515 pts (901 DA, 614 PBO). Demography was similar between DA and PBO groups: %women (54.6% and 52.0%, respectively) and mean (SD) ages (62.3 [12.3] and 62.3 [11.8] yrs). Results are presented in the table. The difference between groups in the rates of transfusions and hematologic response favored DA. Risk for a TE was 50% higher in DA group. Risks of death, DP, and PFS were similar between groups.

Conclusions: This analysis reconfirms data from DA RCTs, demonstrating a decrease in transfusions, improvement in hematologic response, and an increased risk of TE. Risks of PFS and death did not differ between groups.

	Difference* or HR (95% CI) [DA vs PBO]
Transfusion wk 5–13, Diff. in KM rate	−19.2* (−21.4, −16.9)
Hematologic response at wk 13, Diff. in KM rate	39.8* (37.1–42.5)
TEs	1.50 (0.97–2.33)
Death – On-study (OS)/OS+FU	1.14 (0.76–1.70)/0.99 (0.82–1.19)
Disease progression – OS	0.87 (0.70–1.09)
PFS – OS/OS+FU	0.91 (0.74–1.12)/0.88 (0.76–1.01)

OS = on-study; FU = follow-up; KM = Kaplan–Meier; HR = hazard ratio; Diff = difference (DA–PBO). HR < 1 favors DA. Hematologic response = Hb increase by $\geqslant 2$ g/dL or Hb $\geqslant 12.0$ g/dL.

1105 POSTER

A randomized trial of written information versus an interactive multimedia CD-ROM for improving informed consent to chemotherapy

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Background: This randomized controlled trial aimed to determine whether an interactive CD-ROM improved cancer patients' recall of chemotherapy treatment information over standard written information, and whether demographic, cognitive, and psychological factors better predicted recall than this mode of delivery.

Materials and Methods: One-hundred-and-one new patients about to commence chemotherapy were randomized to receive written information or a CD-ROM containing treatment information before giving informed consent. Patients' recall, concentration, short-term memory, reading comprehension, anxiety, depression, and coping styles were assessed with standardized measures pre-treatment. Anxiety and depression were also assessed during treatment.

Results: Seventy-seven patients completed tests for recall of treatment information before their second chemotherapy session. Intention-to-treat analyses indicated no significant differences between the written information and CD-ROM groups across recall questions of number of drugs received ($p = 0.43$), treatment length ($p = 0.23$) and treatment goal ($p = 0.69$). Binary logistic regressions indicated that for groups combined different variables predicted each of the recall questions. All three models were significant and although no individual predictors were significant, depression appeared to be the strongest most stable predictor of incorrect recall across models. Furthermore, presenting treatment information in the form of a multimedia CD-ROM was not found to significantly decrease patient anxiety ($p = 0.96$) or depression ($p = 0.65$) during treatment, although anxiety did significantly decrease over treatment time ($p = 0.000$).

Conclusions: An interactive CD-ROM did not improve cancer patients' recall of chemotherapy treatment information enough to warrant changes in informed consent procedures. However, different demographic, cognitive, and psychological variables do appear to predict recall of different aspects of treatment information highlighting the unique and complex nature of recall of chemotherapy information.

1106 POSTER

Prevalence, patterns and predictors of mood disorders in early breast cancer: results from 2208 women in the UK Standardisation of Breast Radiotherapy Trial (START)

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Aims: Psychological problems are common after breast cancer treatments. This study measured prevalence, patterns of change and clinical predictors of anxiety (A) and depression (D) over 5 years follow-up, plus the association of mood disorder with body image (BI) and sexual functioning (SEF).

Methods: Women in the quality-of-life (QL) study completed the HADS, Body Image Scale (BIS), and QL measures, at baseline 6, 12, 24 and 60 months. The independent effect of age, time from surgery, type of surgery, chemotherapy (CT) and endocrine therapy (ET) and change over time were tested using the Generalised Estimating Equations model, adjusting for baseline A or D. Associations with body image and sexual function were estimated using correlation analysis.

Results: 2208 women consented to the QL study; mean age 56.9 years, (range 26–87). 17.1% women had mastectomy, 82.9% underwent conservative surgery; 33% had received CT and most had started ET. Median time from surgery was 8.0 weeks (IQR 5.6–19.6). 2181 (99%) women completed baseline QL of whom 32% reported borderline or case A and 12% borderline or case D; overall point prevalence was 33%. There was no significant change in prevalence over time but 42.3% with case A and 33.6% women with case D at baseline had persistent mood disorder over 5 years. Older age, and lower baseline A predicted lower anxiety over time but only lower baseline D predicted subsequent depression. Higher A and D rates were associated with worse BI and SEF, with depression having a greater effect ($p < 0.001$).

Conclusions: Prevalence of A and D was stable over 5 years with increased anxiety compared to population figures. Mood disorders persisted in over one third of women but clinical factors had no predictive effect. Younger age and the interaction between mood disorder with body image and psychosexual problems have implications for clinical care.

Acknowledgments: On behalf of the START Trial Management Group

1107 POSTER

Changes in quality of life over time in 701 patients with esophageal cancer and Barrett's esophagus based on marital status

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Background: To evaluate the impact of marital status on changes in QOL over time in patients with esophageal cancer (EC) in comparison to Barrett's esophagus (BE) patients without cancer.

Materials and Methods: The Mayo Clinic Esophageal and Barrett's Esophagus Registry (EABE) is a multi-institutional resource that includes blood, fresh-frozen and formalin-fixed tissue, linked pathologic and clinical data, and serial validated symptom and quality of life (QOL) questionnaires obtained over time. The current investigation was performed using patients from the EABE Registry who had have completed at least 2 QOL assessments (at baseline and 1 year later) with a diagnosis of either BE or EC. Each QOL measurement consisted of the Linear Analogue Self Assessment (LASA) which contained 12 questions relating to overall QOL and sub-components of QOL, which are summarized in Table 1. Kruskal-Wallis tests were performed for the difference in continuous data between groups.

Results: 701 patients (489 BE and 212 EC) met the eligibility criteria. 584 were married and were 113 single at baseline (4 had an unknown marital status). For EC patients, there were significant differences in changes in QOL reporting between marital states for pain frequency, overall physical, and legal QOL subscores over time, with single patients showing higher net QOL changes in comparison to married patients. See Table 1. By comparison, BE patients without cancer showed no statistically significant difference between marital states in any QOL score.

Conclusions: Married patients with EC reported a decrease in overall physical and pain frequency QOL and less improvement in legal related QOL over time in comparison to single patients. BE patients without cancer did not show significant differences over time when evaluated in the same fashion.

Table 1: Change in QOL Scores over time by Marital Status for EC Patients

	Married (N = 180)	Single (N = 31)	p value
Fatigue	−0.4	−0.6	0.64
Finance	0.4	0.8	0.36
Legal	0.2	1.1	**0.04**
Overall Emotional	0.1	0.4	0.63
Overall Mental	0.1	0.3	0.61
Overall Physical	−0.4	0.7	**0.02**
Pain Frequency	−0.9	0.6	**0.03**
Pain Severity	−0.6	0.2	0.10
Social Activity	−0.1	0.0	0.90
Spiritual	0.0	0.3	0.42
Family/Friend Support	−0.2	0.1	0.13
Overall QOL	−0.3	0.3	0.24

Positive values indicates improvement

1108 POSTER

Health-related quality of life (HRQOL) and kidney cancer-related symptoms in patients with metastatic renal cell carcinoma (mRCC) treated with sunitinib versus interferon (IFN)-alfa: results for European and US subsample analyses in a randomized, multinational phase III trial

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Background: Sunitinib malate is an oral, multitargeted tyrosine kinase inhibitor of VEGFRs, PDGFRs, KIT, RET and FLT3, with antitumor and antiangiogenic effects. In an international, randomized phase III trial, sunitinib demonstrated statistically superior efficacy and HRQOL over IFN-alfa as first-line mRCC therapy ($P < 0.001$) [Motzer et al. NEJM 2007; 356: 115−24]. Here we explore the association between geography and treatment effect on patient-reported outcomes (PROs).

Methods: 750 mRCC pts were randomized 1:1 to sunitinib 50 mg PO QD in 6-wk cycles (4 wks on, 2 wks off) or IFN-alfa (9 MU SC TIW). HRQOL was measured by the Functional Assessment of Cancer Therapy-General (FACT-G) and its 4 subscales; the FACT-Kidney Symptom Index (FKSI) and its disease-related symptom subscale (FKSI-DRS); and the population-preference-based health state utility score (EQ-5D Index) and pt self-rated overall health state (EQ-VAS) from the EQ-5D self-report questionnaire. Pts completed questionnaires on days 1 and 28 of each cycle. Data were analyzed using repeated-measures mixed-effects models for the EU+ (France, Germany, Italy, Poland, Russia, Spain, UK, plus Australia and Canada; n = 400) and US (n = 346) subsamples.

Results: The overall post-baseline least-square means significantly favored sunitinib in all 9 PRO endpoints ($P < 0.05$), except EQ-5D in the US subsample (Table). Most of the 9 FKSI-DRS items also favored sunitinib (data not shown). These findings were consistent with the overall sample results. In general, the EU+ subsample had larger between-treatment differences.

HRQOL Endpoints	EU+ Subsample		US Subsample	
	Diff.*	P value	Diff.*	P value
FKSI	3.96	<0.0001	2.29	0.0007
FKSI-DRS	2.55	<0.0001	1.26	0.0009
FACT-G total score	6.01	<0.0001	4.56	0.0002
Physical well-being	1.56	0.0005	1.12	0.0148
Social/family well-being	1.33	0.0001	0.80	0.0269
Emotional well-being	0.80	0.0197	0.64	0.0363
Functional well-being	1.97	<0.0001	1.75	0.0003
EQ-5D index (utility score)	0.05	0.0066	0.01	0.4105
EQ-VAS	4.98	0.0004	4.01	0.0224

*All results favor sunitinib.

Conclusions: Sunitinib offers consistent HRQOL and kidney cancer-related symptoms advantages compared with IFN-alfa in the first-line treatment of mRCC for pts in both Europe and the US. These advantages were more pronounced in the EU+ sample, possibly reflecting differences in treatment experience or underlying differences in HRQOL reporting.

1109 POSTER

Can the incentive system in health care create behaviour changes in patient treatment?

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(This work is part of a master of management study; economic understanding in leadership.)

The Norwegian goverment through national cancerplan St.prp nr 61 (1997−98) made available 7.3 billion NOK to a national cancerplan. One of the main goals was to increase the capacity and quality of radiation therapy to palliative patients. Norway has a incentive system in radiation theraphy where the refund is connected to each beam field. And as we know, it is common that curative treatment uses many beams and fractions while palliative treatment uses few beams and few fractions. By these facts we can suppose that it is "bad business" to treat palliative patients with radiation theraphy. But no one in Norway has estimated this exactly.

By using ABC (Activity Based Costing) analysis (method) I wanted to estimate how the costing for polyclinical palliative and curative patients (undergoing radiation therapy) corresponds to the income from the refund system.

The ABC method is quite a new system to distribute indirect costs. Kooper (1998, pp. 79−80) define ABC as; ". . . an economic map of the organizations's expenses and profitability based on organizational activities . . . An activity-based cost system provides companies with an economic map of their operations by revealing the existing and (. . .) forecasted cost of activities and business processes, which, in turn, leads to knowledge of the cost and profitability of invidual products, service, costumer, and operating units".

351 patients were included in the project. That includes 5815 patient meetings in which 24.581 beams were given. Refund was 10,226,543 NOK plus a basis payment of 2,948,484 NOK. Total 13,175,025 NOK.

The total cost was estimated at 13,189,000 NOK. This includes wages of everybody working in the department, merchandise costs, electricity, cleaning etc. (write-downs on the building, the linac and other machinery was not included because it was given by the goverment).

The results show that the department

- has an undercoverage on each (average) polyclinical palliative patient of −10,232 NOK but
- has an overcoverage on each (average) polyclinical curative patient of +18,873 NOK

The project proves the hypothesis that it is "bad business" to treat palliative patients with radiation therapy. This is the opposite of the intention in the national cancerplan.

It is likely that this system gives palliative patients poorer treatment and less possibilities than if the refund system was better for this patients. That will be the next step to look into.

1110 POSTER

Management of anaemia in patient with cancer. Results of the F-ACT Study (French Anaemia Cancer Treatment)

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Background: anaemia is one of the most dreaded complications in patients with malignant pathologies. Its causes are varied and whatever its severity, the impact on the quality of life of the patient remains essential. This is why we carried out a large national survey with the goal to assess the prevalence and the management of anaemia in patients with malignant diseases.

Methods: the F-ACT (French Anaemia Cancer Treatment) study is a retrospective observational multicentric study conducted in 178 experts among 112 centers which treat patients with solid tumours and/or malignant haematological diseases. Assessment was performed over one day for each questioned expert.

Results: a total of 2782 patients were enrolled, including 1335 women (48%) and 1447 men (52%). The median age was 61 years (range: 18−93 years). There were 1892 (68%) patient with solid tumour and 890 (27%) patient with malignant haematological disease. The main sites of cancer localization were: breast (19%), colo-rectal (14%), lymphoma