compared to younger patients (18–49 years: 9%; 50–59 years, 9%). At 6 months post-enrollment, a greater percentage of patients ⩾ 70 years of age were anemic (54%) compared to patients in the other age groups (range: 44% to 48%) and a greater percentage of these elderly patients had Hb levels < 10.0 g/dL (14%) compared to the other age groups (range: 10% to 11%). Overall, increasing age had a negative effect on WHO performance score at enrollment and during the 6-month survey; patients ⩾ 70 years had consistently lower WHO scores compared to younger patients. The majority of patients (72% overall) did not receive anemia treatment after enrollment. For patients who did receive treatment, more were in the older age groups (60–69 years: 29%; ⩾ 70 years: 31%) compared to younger patients (18–49 years: 25%; 50–59 years, 27%). Patients ⩾ 70 years received the most epoetin (16%) compared to other age groups (11% to 13%).
**Conclusions:** Patients of all ages have significant anemia, although elderly patients appear to have more anemia overall with lower Hb levels and worse WHO performance scores. Effective anemia treatment should be administered to cancer patients regardless of age to insure optimal patient management.

**1282** POSTER

**Economic analysis of aprepitant in patients receiving antiemetic prophylaxis with moderately emetogenic chemotherapy in France – results of a decision-analytic model**

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**Background:** Chemotherapy-induced nausea and vomiting (CINV) remains a major adverse effect of cancer chemotherapy. Aprepitant, a NK1 receptor antagonist, represents a new approach to antiemetic therapy.
**Objective:** To evaluate the economic implications of treatment with aprepitant relative to standard therapy for French patients undergoing moderately emetogenic chemotherapy (MEC)
**Methods:** A decision analytic model compared a 3 day aprepitant regimen (Day 1: aprepitant 125 mg P.O. in combination with ondansetron 8 mg P.O. twice daily and dexamethasone 12 mg P.O.; Day 2–3: aprepitant 80 mg P.O. once daily) to standard therapy (Day 1: ondansetron 8 mg P.O. twice daily and dexamethasone 20 mg P.O.; Day 2–3: ondansetron 8 mg P.O. twice daily) over a single chemotherapy cycle. The model was based on clinical results and healthcare resource utilization observed in a large clinical trial of aprepitant in MEC. Trial outcomes included complete response (no emesis, no rescue therapy), impact of CINV on daily life, and quality-adjusted life years (QALYs). QALY data were obtained from the literature. French costs were used to cost health care resources: a) hospital costs (http://www.atih.sante.fr/), b) ambulatory fees (http://www.ameli.fr/); and c) drug prices (http://www.gie-gers.fr/).
Sensitivity of results to changes in model parameters was investigated through a series of sensitivity analyses.
**Results:** In the aprepitant group (n = 429) 51.3% of the patients were complete responders over the entire chemotherapy cycle compared to 42.7% in the standard care group (n = 422). More patients were CINV-free over the entire chemotherapy cycle with aprepitant regimen (54.1%) compared to standard regimen (46.0%). Expected cost difference between aprepitant regimen and standard therapy was *1.07, with 98% of the aprepitant cost offset by savings in 5HT3 drug costs and healthcare resource use. Expected marginal cost-per-QALY-gained with aprepitant was *1,890. Results were robust with respect to all healthcare resource utilization costs, and most sensitive to costs of prophylactic 5HT3s and utilities for CINV health states.
**Conclusion:** Patients receiving aprepitant-based treatment for MEC had better CINV-related outcomes compared to patients receiving standard regimen with nearly all of the drug cost of aprepitant being offset. An aprepitant-based treatment for prevention of CINV in MEC patients appears to be cost-effective in France.

**1283** POSTER

**Darbepoetin alfa administered once every 3 weeks (Q3W) is effective for treating anaemia in patients receiving multicycle chemotherapy: results of a randomised, double-blind, active-controlled trial**

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**Background:** Darbepoetin alfa (Aranesp®; DA) is licensed in Europe for the treatment of chemotherapy-induced anaemia using either once weekly (QW) or Q3W administration. The Q3W schedule is convenient because it can be synchronized with many chemotherapy regimens, resulting in fewer visits and reduced burden to patients (pts). This study evaluated the comparability (non-inferiority) of a fixed starting dose of 500 mcg Q3W with 2.25mcg/kg QW DA, with respect to efficacy and safety.
**Methods:** This was a randomised, double-blind, double-dummy, active-controlled phase 3 study in 110 centres across Europe. Eligible subjects were ⩾ 18 years of age, anaemic (haemoglobin [Hb] < 11 g/dL), and diagnosed with a non-myeloid malignancy with ⩾ 12 weeks of planned chemotherapy. Pts were randomised 1:1 to Q3W or QW DA for 15 weeks. The primary endpoint was incidence of red blood cell transfusions from week 5 to end of treatment phase. Non-inferiority was determined if the 95% confidence interval (CI) of the difference in transfusions between groups did not exceed a pre-specified margin based on previous placebo-controlled studies of DA 2.25 mcg/kg QW. The primary analysis included pts who received ⩾ 1 dose and who were enrolled in the study until at least day 29. Secondary endpoints included change in Hb and FACT-F, and achievement of Hb ⩾ 11 g/dL.
**Results:** 705 pts were randomised; 672 were analysed for the primary endpoint. Demographic characteristics were similar between the 2 treatment groups. Transfusion incidence (95% CI) was 23% (19 to 28) and 30% (25 to 35) for the Q3W and QW groups, respectively (difference: −6.8 percentage points [−13.6 to 0.1]) We observed a similar difference in transfusion requirements between treatment groups after adjusting for stratification factors, and for pts with haematological and solid tumours. The proportion of pts achieving Hb ⩾ 11 g/dL was 84% (Q3W) and 77% (QW); pts achieving the dose-withholding limit of Hb ⩾ 13 g/dL was 24% (Q3W) and 22% (QW). The safety profile was similar for the 2 treatment groups, with no association between cardiovascular/thromboembolic adverse events and rapid rise in Hb levels or Hb ⩾ 13 g/dL. Fifty-seven percent (Q3W) and 58% (QW) of pts had ⩾ 3-point increase in FACT-F. In the Q3W arm, the median number of doses was five compared with 14 doses in the QW arm.
**Conclusions:** The Q3W regimen was comparable to the QW regimen since the upper limit of the CI of the transfusion incidence fell substantially below the pre-determined non-inferiority margin. These results demonstrate effective anaemia management with less frequent dosing of DA.

**1284** POSTER

**ECAS, MEWACAS and ACAS: Contrasts and comparisons of three regional, multinational, prospective anemia surveys in cancer patients**

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**Background:** European Cancer Anaemia Survey (ECAS) was the first survey to evaluate prospectively and objectively the prevalence, incidence, and management of anemia (Ludwig *et al*, *EJC* 2004) and define predictive risk factors for anemia (Van Belle *et al*, *Ann in Oncol* 2004 abstract) in a large population of cancer patients (pts). Pts (n = 15,367) with solid (78.9%) and hematological malignancies (21.1%) from 24 countries in 824 centers were followed for up to 6 months. Data demonstrate a high prevalence of anemia (67%) in cancer pts, particularly those undergoing chemotherapy (CT) [75%] and with no cancer therapy (40%), with an adverse effect on WHO performance status.
**Methods:** To facilitate comparable data on anemia from cancer pts in the Middle East/Western Asia (MEWA) region, the MEWA Cancer Anaemia Survey (MEWACAS) was instituted, a prospective, epidemiologic, observational survey conducted in 11 countries, including Cyprus, Egypt, Iran, Israel, Jordan, Kuwait, Lebanon, Libya, Malta, Saudi Arabia, and the United Arab Emirates. Additionally, a similar data collection record form was used in Australia in 24 cancer centres (Seshadri *et al*, *MJA* 2005) for the Australian Cancer Anaemia Survey (ACAS).
**Results:** Demographics of the three surveys differed slightly (see table below). There were 921 patients enrolled in MEWACAS and 694 pts were

enrolled in ACAS. Although the majority of MEWACAS pts (79.6%) and ACAS (85.4%) had WHO Performance scores of 0 or 1, low Hb levels were associated with poor WHO scores (2–4). Of the 858 MEWACAS pts with Hb values for analysis, 79.0% were anemic at some time during the survey. Anemia was most frequently reported in pts who received CT (81.3%), while anemia occurred in 74.6% of pts who did not receive cancer treatment at any time during the survey. Of the 602 ACAS pts with Hb values for analysis, 58% were anemic at some time, including 86% CT pts and 55% with no cancer therapy. Of the ever anemic pts, 66% MEWACAS, 77% ACAS and 61% ECAS pts did not receive anemia treatment. Of those who were treated, 16% MEWACAS, 7% ACAS and 3% ECAS received iron; 10% MEWACAS, 19% ACAS, and 15% ECAS were transfused; and 8% MEWACAS, 1% ACAS and 17% ECAS received epoetin. Hb at first transfusion was 8.7 g/dL MEWACAS, 8.8 g/dL ACAS and 8.6 g/dL ECAS and Hb at epoetin initiation was 8.9 g/dL MEWACAS, 9.7 g/dL ACAS and 9.9 g/dL ECAS

Comparisons among ECAS, MEWACAS and ACAS demographics

| Variable | ECAS | MEWACAS | ACAS |
|---|---|---|---|
| Mean age (yrs) | 57.8 | 50.9 | 59.7 |
| Males | 44% | 38% | 39% |
| % on CT | 40% | 44% | 64% |
| Mean Hb level at enrolment | 12.3 g/dL | 11.5 g/dL | 12.5 g/dL |
| % anemic at enrollment | 39% | 54% | 35% |
| % Solid/% Hem tumors | 79%/21% | 83%/17% | 72%/28% |
| Breast pts (%) | 22 | 37 | 26 |
| Lung pts (%) | 14 | 9 | 8 |
| Gynecological pts (%) | 12 | 5 | 6 |
| GI/colorectal pts (%) | 17 | | |

**Conclusions:** Data analyses from MEWACAS, ACAS and ECAS, although somewhat different in absolute numbers, produced similar conclusions: the prevalence and incidence of anemia are high and correlate significantly with poor performance status. Importantly, treatment for anemia is not optimized; only a minority of anemic pts is receiving treatment, despite accepted anemia treatment guidelines. Understanding these results may lead to better management of anemia in cancer pts with the goal of optimizing pt quality of life.

**1285** POSTER

**High incidence of hypocalcemia in patients with bone metastases from different kinds of neoplasms, treated with pamidronate and zoledronate**

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**Background:** Pamidronate and zoledronate are generally used for the treatment of bone metastases from different kind of neoplasms. Hypocalcemia and elevation of serum creatinine are expected adverse events during these therapies, although their actual incidence is unknown. The use of serum calcium and creatinine is therefore recommended. The aim of this retrospective study was to verify the real incidence of hypocalcemia and the elevation of serum creatinine during bisphosphonate treatment in patients with normal calcium and creatinine levels at baseline.
**Patients and methods:** We reviewed data from 187 consecutive patients (72 males, 115 females, mean age 61 years, range 32–88 years) affected by metastatic osteolitic (36.9%), osteoblastic (4.3%) and mixed (38.5%) bone lesions from different kinds of solid tumors (breast 44.4%, lung 26.2% prostate 4.3%, others 20.3%) and multiple myeloma (4.8%). Seventy-seven patients (41.2%) were treated with pamidronate (median numbers of cycles 6, range 1–26), 79 patients (42.2%) with zoledronate and daily calcium supplementation (median number of cycles 7, range 1–42) and 31 patients (16.6%) with both sequentially (pamidronate followed by zoledronate+calcium supplement). The normal ranges for calcium and creatinine were 2.10–2.60 mmol/l and 0.60–1.20 mg/dl respectively. Abnormal values were assessed according to the CTC Version 2.0.
**Results:** Overall, 92/187 patients (49.1%) had hypocalcemia: grade 1 in 43 patients (46.7%), grade 2 in 37 patients (40.2%), grade 3 in 11 patients (11.9%), grade 4 in 1 patient (1.1%); 17/172 patients (9.9%) had increased serum creatinine: grade 1 in 13 patients (76.5%), grade 2 in 4 patients (23.5%). All patients were asymptomatic. No significant correlation was found between serum abnormalities and type of primary tumor, type of bone metastases or type of bisphosphonate administered.
**Conclusions:** Our retrospective analysis shows a high incidence of grade 3–4 hypocalcemia. These results are significantly worse than expected and strongly support the need for monitoring plasmatic calcium and creatinine levels.

**1286** POSTER

**Living alopecia: Study on the impact of chemotherapy-associated alopecia in quality of life and daily activities in women with breast cancer**

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**Background:** Alopecia has been cited as one of the most disturbing anticipated side effect by women preparing for chemotherapy. The aim of this study was to evaluate the impact of chemotherapy-associated alopecia in quality of life (QoL) and daily activities in women with breast cancer (BC).
**Methods:** Consecutive BC patients (pts) under chemotherapy (at least 2 sessions) were enrolled in eight Portuguese oncology services between 2004 and 2005. The pts were asked to fulfil a questionnaire about chemotherapy side effects and alopecia impact on their QoL. Social support was also evaluated trough Lubben Social Network Scale.
**Results:** 463 pts were included. Mean age was 53.9±11 years, 10% had less than 40 years. Mean age at diagnosis was 50.5±11 years. 87% underwent different variants of mastectomy (66% performed radical mastectomy). The majority (88%) had a high social support level with a low risk for isolation, according with Lubben Social Network Scale. Since the beginning of chemotherapy 98.5% had at least one adverse effect (AE). 91.4% had alopecia, 79.9% fatigue, 74.5% nausea and 67.2% vomiting. The most distressing anticipated AE was alopecia, referred by 56% of the pts (followed by nausea, referred by 9% and vomiting 12%). 13% of the pts that anticipated alopecia as the most distressing adverse event considered not to do chemotherapy due to this effect. The mean age of those who considered alopecia as the most distressing AE was 52.8 vs 55.1 years (considering other AEs), $p = 0.02$. The groups were not significantly different in what concerns to marital status, educational level or surgery. When asked about what AE they would avoid, if possible, alopecia was referred by 48%. These pts considered that, in the family the ones that attribute greater importance to their physical aspect (alopecia) are their children. 66% of the pts considered the hypothesis of using a wig and 72% considered the use of a headscarf. 55% felt depressed and 45% took medication. Despite 12% of these pts mentioned that alopecia is worst than the cancer itself, 90% would chose a very effective treatment that provokes alopecia instead of a less effective treatment that not causes alopecia.
**Conclusion:** This study confirms that alopecia is one of the most important chemotherapy associated adverse effect with major impact in patients' quality of life.

**1287** POSTER

**Palonosetron plus aprepitant and dexamethasone is a highly effective combination to prevent chemotherapy-induced nausea & vomiting after emetogenic chemotherapy**

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**Background:** Palonosetron (PALO) is a pharmacologically distinct, second-generation 5-$HT_3$ receptor antagonist (RA) approved for prevention of chemotherapy-induced nausea & vomiting (CINV) after moderately and highly emetogenic CT. Aprepitant (APREP) is a $NK_1$ RA approved for prevention of CINV after highly-emetogenic chemotherapy (CT) when used with a 5-$HT_3$ RA & dexamethasone (DEX). The effect of the combination of this highly effective 5-$HT_3$ RA and APREP + DEX in patients receiving a variety of moderately to moderate-highly emetogenic chemotherapy is reported.
**Methods:** This multicenter, open-label pilot study evaluated the safety and efficacy of a single IV dose of PALO (0.25 mg on Day 1) in combination with 3 consecutive daily oral doses of APREP (125 mg on Day 1 and 80 mg on Days 2 and 3) and 3 consecutive daily oral doses of DEX (12 mg on Day 1 and 8 mg on Days 2 and 3) in the prevention of moderately emetogenic chemotherapy-induced nausea and vomiting. Complete response (CR; no emetic episodes, no rescue medication), patients with no emetic episodes