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definitive surgery to medical oncology assessment, and a higher rate of multiple operations. Potential strategies to reduce treatment delays for rural patients include the use of frozen section analysis of intra-operative sentinel nodes to reduce staged axillary dissections, minimising referral times to medical oncology by use of virtual multi-disciplinary meetings, improved efficiency in pathology reporting, and introduction of a breast cancer coordinator. Since delays in commencing chemotherapy are known to affect treatment efficacy, further resources are required to improve integration of rural surgical and medical oncology services.

Table: Time from surgery and medical oncology assessment to the commencement of adjuvant chemotherapy

Interval	Median time (weeks)			
	Rural cohort (n = 79)	Urban cohort (n = 94)	Difference (weeks)	p-value
Primary surgery to chemotherapy	8.9	4.3	4.6	<0.001
Definitive surgery to chemotherapy	6.3	3.9	2.4	< 0.001
Primary surgery to definitive surgery (when multiple operations needed)	(n = 34) 3.9	(n = 23) 3.0	0.9	0.2
Definitive surgery to medical oncology assessment	4.9	1.9	3.0	<0.001
Medical oncology assessment to chemotherapy	1.4	2.0	-0.6	0.07

3620 POSTER

Use of Darbepoetin Alfa for the Treatment of Chemotherapy-induced Anaemia in European Clinical Practice – Data From the CHOICE Study

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**Purpose**: A final analysis from the CHOICE study to assess the percentage of patients (pts) treated with darbepoetin alfa (DA) according to its European product label.

**Methods:** A prospective, multicentre, observational study (EudraCT Number: 2007–007665–21) assessed DA use among 1,900 pts with cancer in 11 European countries. Haemoglobin (Hb) levels and red blood cell (RBC) transfusion requirements were evaluated.

**Results:** Demographics: A total of 1,887 pts (mean $\pm$ SD age 62.4 $\pm$ 11.4 yr) were included in the full analysis set. Cancer types included: lung (n = 701); breast (n = 575); colorectal (n = 310); and ovarian cancer (n = 301); 1,585 pts (84%) had a current disease stage of  $\geqslant$ 3. Common chemotherapy regimes were platinum based (n = 574 [30%]), taxanes (n = 316 [17%]) or a combination of both (n = 215 [11%)).

Haemoglobin levels: At DA initiation (baseline [BL]), 1,051 pts (56%) had a Hb value <10 g/dL. Mean Hb level was 9.8±0.8 g/dL at BL, which increased to 10.7±1.8 g/dL at the end of the treatment period (EOTP). Complete records for the primary outcome (proportion of pts with a Hb level between 10 and 12 g/dL at week [wk] 9) were available for 1,170 pts (62%). A total of 596 out of 1,887 pts (32% [crude percentage]) had a Hb value of 10-12 g/dL (95% confidence interval [CI]: 30%,34%), 239 pts (13%) had a Hb value >12 g/dL and 335 (18%) had a Hb value <10 g/dL. Of pts still on study at wk 9 (1,081 pts): 517 pts (48%) had a Hb value in the target range of 10-12 g/dL (CI: 45%,51%); 172 pts (16%) had a Hb value >12 g/dL and 279 pts (26%) had a Hb value <10 g/dL; data were missing for 113 pts (10%). For pts with a BL Hb level <10 g/dL, the Kaplan-Meier percentage (K-M%; wk 1 to EOTP) achieving Hb levels ≥10 g/dL was 90% (Cl: 75%, 104%) with 10% (Cl: 7%, 12%) of pts having a Hb value >13 g/dL. RBC transfusions: From wk 5 to EOTP, 18% (K-M%) of pts required RBC transfusions (only pts in the study for  $\geqslant$ 29 days after starting DA treatment; CI: 16%,20%). Among pts with a BL Hb value <10 g/dL or  $\geqslant$ 10 g/dL, 22% (K-M%; CI: 19%,25%) and 13% (K-M%; CI: 10%,16%) received RBC transfusions, respectively.

Adverse events: Eleven out of 1,887 pts (5 with BL Hb <10 g/dL; 6 with BL Hb  $\geqslant$ 10 g/dL) reported DA treatment-related adverse drug reactions (6 were thromboses).

**Conclusions:** In agreement with the European product label for DA, the majority of pts initiated DA treatment at a BL Hb level <10 g/dL. DA was effective in achieving the recommended Hb target range.

3621 POSTER

Assessing 2-month Clinical Prognosis in Patients With Solid Tumours – Final Results of PRONOPALL Study

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**Background:** In 2008, we published our results of a prognostic score defined by 4 factors (Karnofsky index, number of metastatic sites, serum albumin and LDH levels) in a population of 177 hospitalized patients in two hospitals [1]. Albumin cutoff was 33 g/l and LDH cutoff was 600 ui/l. This score defined 3 different patients populations: A: low score (0 to 3), B: intermediate score (4 to 7) and C: high score (8 to 10). The survival rates at 2 months were 92.2±3.8% (population A), 42.7±5.2% (population B) and 8.3±4.6% (population C).

Methods: In order to validate this score with performance status (PS), we decided to start a second study in a large multicentric trial with a high proportion of out-patients.

Results: Between October 2009 and October 2010, 302 patients were included from 16 institutions. Inclusion criteria: adults patients with a solid tumour in palliative setting and with one or more of the three following criteria: life expectancy less than 6 months, PS  $\geq$  2, evidence of progressive disease during palliative chemotherapy. All patients signed an informed consent. At this time, 146 (48%) patients are evaluable for this first analysis. 13 patients are not eligible. Median age 64 years [37–87], women 60%, men 40%. PS 0–1 (43%), PS 2 (40%), PS 3–4 (17%). The most frequent primary sites: breast (39%), colon/rectum (23%), lung (15%), pancreas (10.5%), others (12.5%). One metastatic site (31%), two (37%), more than two (33%). Median LDH level: 362 ui/l [118–1314]. Median level of serum albumin was 36 g/l [20–54]. According the prognostic score, the 2-month survival rate and the median survival were 87% and 306 days [195–417] (population A, 72 patients), 60% and 75 days [53–97] (population B, 62 patients) and 18% and 15 days [7–23] (population C, 12 patients). These three populations are statistically different (p < 0.0001).

**Conclusions:** PRONOPALL confirms the three prognostic profiles defined by combination of these four factors and is useful in daily practice.

### References

[1] Assessing 2-Month Clinical Prognosis in Hospitalized Patients With Advanced Solid Tumours. Anne-Claire Barbot, Pascale Mussault, Pierre Ingrand and al. J Clin Oncol vol 26, p 2358–2543; 2008.

3622 POSTER

### **Audit Programmes Can Actually Improve Cancer Control**

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Background: The purpose of IKNL is to provide cancer patients and their families access to comprehensive and high-quality care, as close to home as possible. This service is directed towards improving professional, organisational and relational quality of oncology care. The Rotterdam area has 15 general hospitals and a university hospital. In 1996 an audit programme started to monitor and improve the quality of care in the general hospitals. Until 2011 these hospitals have been audited three times, the third started in 2008. After each round the focus was reassessed and has shifted from monitoring the organisation of care to measuring quality of care outcome with performance indicators. We evaluated the quality of care, the audit process and the perceived benefit of performing audits. In 2011 an comparable audit program in the whole country was started.

Material and Methods: The audit program concentrates on structure and process criteria. The auditing committee is peer based. The final audit report reflects the number of criteria and contains recommendations for improvement. The audit reports of these hospitals were analysed, comparing results in first, second and third round. The committee and hospital management received a questionnaire to evaluate the benefit of oncology audits. The auditing process itself was continuously evaluated and optimized with the Plan-Do-Check-Act cycle especially in the third round. Results: In all 15 hospitals, results on the audit criteria improved between the rounds. The remaining major issues are the poor availability of performance indicators as perceived by the professionals and the poor

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implementation of the PDCA cycle in their practice. The evaluation revealed that many improvements were realized by stimulus of a next upcoming audit. The committee and management valued the audit with a 7.7 and 8.2 (scale 0-10). The continuous process evaluation decreased audit reporting time from 43 (17–136) to 22 weeks (17–26).

Conclusions: During three rounds of auditing in nearly 15 years major improvement was demonstrated in quality of cancer care and the usefulness of auditing. The results show that oncology audit systems should be included in national cancer programs to improve structure and process of cancer care.

3623 POSTER

## The Cost of Herpes Zoster Among Autologous Hematopoietic Stem Cell Transplant Recipients With Medicaid Coverage

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**Background:** Medicaid comprises USA federally funded State programs, for persons regardless of age whose income and resources are insufficient to pay for healthcare.

Autologous hematopoietic stem cell transplant (AHCT) recipients have a high incidence of herpes zoster (HZ) following transplant procedure. We previously estimated the acute HZ incremental medical cost in privately insured AHCT US patients, at \$6,852 (95% CI \$2,554–11,553). The primary objective of this study was to estimate the incremental medical costs in similar individuals with Medicaid insurance.

Materials and Methods: Administrative claims from the MarketScan® Multi-State Medicaid Research Databases (1999–2007) were assessed to determine the incremental medical resource utilization (RU) and cost due to HZ. Cases were selected based on an ICD-9-CM diagnosis code for HZ following an AHCT procedure. Cases were propensity score matched (PSM) using demographic and clinical variables to AHCT controls without HZ. Analysis of potentially HZ related RU and costs was limited to claims in the 90 days following HZ diagnosis. Medical RU includes categories such as inpatient admissions, average length of stay, emergency room visits, number of outpatient visits, other outpatient services, outpatient prescriptions, etc. Differences were considered attributable to HZ. A two-part model (logistic regression/negative binomial generalized linear model) was used to quantify total incremental costs and adjust for remaining differences after PSM.

**Results:** Thirty-five HZ cases were included in the analysis (83% occurred within 1 year of AHCT). During the analysis period, there were 10 HZ hospitalizations, 2 cases of ophthalmic HZ and 6 cases of HZ neurological impairment. AHCT recipients with HZ had significantly more medical RU compared to controls (p < 0.05). AHCT patients with HZ had significant incremental medical costs due to HZ (Table 1).

Table 1. Potentially HZ related medical costs for AHCT recipients

	N	Observed	Adjusted*
AHCT with HZ	35	\$10,185	\$7,913
AHCT without HZ	35	\$1,034	\$874
Incremental cost (95% CI)	-	\$9,151	\$7,039 (\$1,704-10,999)

\*p < 0.0001.

**Conclusions:** Resource utilization data from this sample of 35 cases and controls covered by Medicaid suggests that HZ has a significant impact on the health, medical service use, and medical costs of AHCT patients. The HZ incremental cost, after adjusting for confounders, was \$7,039, similar to the one reported for privately insured patients (\$6,852). Future advances for the treatment or prevention of HZ in AHCT recipients should be given strong consideration to help alleviate this medical burden.

### 3624 POSTER Equity of Access to Radiotherapy

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Background: Radiotherapeutic treatments (RT) offered to patients in the three provinces of Romagna (AVR) suffer from a lack of homogeneity in

terms of access modality, timing of start of RT and type of RT administered. Delays in RT can lead to poorer cancer control rates, patient suffering and a strained doctor-patient relationship. Current regional criteria used for assigning treatment priority also have a wide margin of interpretation and are clearly out-of-date. Our aim is to propose an organizational model for AVR in order to create a single waiting list for access to RT and to establish a specific date for starting treatment based on common, updated priority criteria

Patients and Methods: Patients eligible for RT throughout the AVR will be enrolled onto this study, which will comprise 3 different steps:

- Definition of common criteria outlining RT priorities.
- Pilot study to evaluate the new criteria after implementation in an AVR Radiotherapy Unit.

• Creation of a single waiting list including all AVR Radiotherapy Units Results: The project was activated in March 2010 and a panel of experts was set up comprising radiotherapists, health physics specialists, oncologists, statisticians, palliative care physicians and healthcare management specialists. Due to the paucity of literature on waiting list and priority criteria for access to RT, the panel identified five categories of clinical conditions with details on timing from the request for consultation to the consultation itself (TO) and from consultation to start of treatment (T1) (Table).

Category	T0 (days)	T1 (days)	Example of clinical condition
Urgent	2.5	3	Oncologic emergencies
Priority level 1	7	21	Locally advanced unresectable head & neck tumours
Priority level 2	7	35	High-risk prostate cancer with indication for only RT
Deferable	14	46	Low-risk breast cancer after conservative surgery
Plannable	Not applicable	Not applicable	Chemo/radiotherapy- associated treatments

The second step of the project is ongoing and will terminate at the end of April 2011.

**Conclusions:** The definition of more appropriate and detailed common priority criteria to facilitate access to RT and the clarification of timing of the start of RT are the first steps needed to improve radiotherapy healthcare services offered to the AVR population.

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# 3625 POSTER Time and Motion Study of Breast Cancer Chemotherapy Administration in Community Based Oncology Practices

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**Background:** Little information is available on the resource utilization and patient time associated with the administration of IV chemotherapy in the treatment of metastatic breast cancer.

Materials and Methods: An observational time and motion study was conducted at 3 large U.S. private practice oncology centers. Time associated with drug preparation, premedication preparation and administration, and drug infusion was recorded by trained observers for 4 chemotherapy agents: docetaxel (n=17), nab-paclitaxel (n=15), gemcitabine (n=15), and ixabepilone (n=17). Labor time was defined as the time that a center staff member is actively engaged in the process of completing a task directly related to the infusion of the study drugs. Total process time was defined as the time required for the subject to receive a dose of study drug, inclusive of the time for accessing the IV line and premedication administration to completion of the study drug infusion.

Results: Drug preparation for docetaxel, nab-paclitaxel, gemcitabine, and ixabepilone was 7.7, 29.4, 6.3 and 5.8 minutes, respectively. The mean number of premedications used was 2.1, 1.5, 1.5 and 3.9, respectively. Premedication preparation and administration time was 29.0, 9.8, 23.1, and 67.2 mins, respectively. Study drug infusion times were 29.7 mins for nab-paclitaxel, 32.3 mins for gemcitabine, 68.4 mins for docetaxel and 189.5 mins for ixabepilone. Total labor time was greatest for ixabepilone (262.5 mins), followed by docetaxel (105.2 mins), nab-p (68.9 mins), and gemcitabine (61.6 mins). Total process time for patients was 332.3 mins for ixabepilone, 145.4 mins for docetaxel, 113.5 mins for gemcitabine and 105.1 mins for nab-paclitaxel.

Conclusions: Drug preparation did not contribute significantly to total process time except for nab-paclitaxel (27% of total process time), although nab-paclitaxel still had the shortest total process time (105.1 mins). Premedication administration adds approximately 20% to the total time except for nab-paclitaxel (9%). In this study, single agent treatment for metastatic breast cancer requires from 105 minutes to 332 minutes per infusion visit. Development of effective agents with shorter infusion times and less premedication may help office practices become more efficient.