Clinical pharmacy and clinical trials

Abstract CPC-002 Table 1 Qualitative evaluation of pharmacoeconomics study

Economics Evaluation T in adjuvant	Study Design	Data Collection	Analysis and Interpretation of results	Final Score	Total relative score
Blank	24/26	27/45	35/48	86	72.3%
Chen	23/26	30/45	37/48	90	75.6%
Dedes	24/26	31/45	35/48	90	75.6%
Essers	24/26	30/45	35/48	89	74.8%
Garrison	24/26	31/45	36/48	91	76.5%
Kurian	25/26	31/45	37/48	93	78.1%
Liberato	26/26	33/45	39/48	98	82.3%
Lidgren	26/26	34/45	38/48	98	82.3%
Millar	25/26	32/45	35/48	92	77.3%
Neyt	25/26	31/45	34/48	90	75.6%
NICE	26/26	42/45	40/48	108	90.7%
Norum	25/26	28/45	34/48	87	73.1%
Shiroiwa	26/26	31/45	38/48	95	79.8%
Skedgei	25/26	27/45	37/48	89	74.8%
Van Vlaenderen	24/26	31/45	36/48	91	76.5%
T in MBC					
Poncet	24/26	32/45	31/48	87	73.1%
Norum J	25/26	33/45	35/48	93	78.1%
Elkin	26/26	37/45	40/48	103	86.5%
Lidgren	26/26	36/45	38/48	100	84%
NICE (2002)	26/26	42/45	40/48	108	90.7%

Purpose To evaluate the economic impact of the different prescribing models for trastuzumab on overall costs for breast cancer treatments in the Piemonte Region.

Materials and Methods We systematically reviewed the MEDLINE-indexed, English-language literature to identify published, peer-reviewed economic analyses of trastuzumab in HER2 \pm treatment of breast cancer. We rated study quality as per the Drummond criteria.

Direct medical and unit costs were calculated from the perspective of a Regional health care system. We derived patient data by consulting a Regional administrative database and screening by File F File C and SDO for each patient treated in 2010. To obtain valid data, it is necessary to combine the data from this study into a single model, with an epidemiological measure from the Piemonte Cancer Registry. It is recommended to use an empirical Bayesian analysis to conduct this study because there is no single estimator for the parameters.

Results The search strategy identified 948 articles, of which 340 were citations. From the 608 remaining, 23 articles were considered suitable for full review based on the inclusion criteria. Of these, 15 considered adjuvant trastuzumab treatment only, seven examined metastatic breast cancer treatment and one considered treatment with trastuzumab beyond progression. The analysis of the accuracy of information provided by the information systems showed us that there was only 40% correspondence with the administrative database within Molinette Hospital.

Conclusions Preliminary results confirm the difficulty of obtaining accurate data from the administrative systems. We hope to obtain precise data on trastuzumab prescribing, and thus offer complementary information to cost-effectiveness analysis before the launching of a generic drug.

No conflict of interest.

A RETROSPECTIVE ANALYSIS OF THE SWITCHES FROM **ORIGINATOR AND BIOSIMILAR RECOMBINANT HUMAN ERYTHROPOIETINS IN CHRONIC KIDNEY DISEASE**

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Background Erythropoiesis stimulating agents (ESAs) has been shown to be highly effective in anaemia in chronic kidney disease (CKD). Various biological ESAs are available such as epoetin alfa, beta, darbepoetin alfa and C.E.R.A, including three biosimilars, epoetin alfa, zeta and theta. National regulations are trying to promote the prescription of the biosimilars, especially in ESA-naive patients. Switching between products is not recommended and the pharmacist can't replace one epoetin with another. However, changes do occur in clinical practise.

Purpose In the Pharmacy Department of the Palermo Local Health Unit (LHU) we observed that nephrologists frequently switch patients but not in order to reduce costs. Therefore, the aim of this study was to calculate the prevalence and patterns of switching and to evaluate the reasons for them and the results for these changes.

Materials and Methods Distributing all the epoetins, after a discharge or a DH (docetaxel/trastuzumab) regimen and ensuring appropriate continuity of care, the Department collected and retrospectively analysed an electronic database with all the prescriptions for both non-dialysis-dependent CKD or dialysis patients. Furthermore, haemoglobin levels (Hb) were collected, if available, from the paper prescriptions. The period of observations was January 2011– June 2012.

Results 2,711 patients received an epoetin for CKD (from a population of 750,550). 368 patients (13.6%) had been switched. Of this group, only 194 patients were evaluable (98 female, mean age 73.57+-SD:14.21). The inclusion criteria were: receiving ESAs for at least four months; less than 60 days between two prescriptions. Treatments were less commonly switched from biosimilars than originator formulations. Only in 7 cases did nephrologists cite the lack of efficacy of the ESA previously administered, with demonstrated worsening of the patient's clinical status (Aranesp 4, Mircera 2 and NeoRecormon 1). In 9 cases we assumed lack of efficacy of the first ESA, based on measurement of the haemoglobin (Hb) values. In the following prescription the clinicians switched and reported an Hb level lower than the first (≤10 g/L). In 24 cases, the ESAs varied with the prescriber. There was no reason for the switch or it was made for trivial reasons. 5 changes from the biosimilar were the pharmacist's wrong decision, due to not checking the patient's last prescription on the database. 5 changes from Mircera occurred after the announcement of a worldwide shortage. Only in 9 cases had the clinicians decided to shift toward a biosimilar on cost grounds. In the remaining cases, Hb levels remained stable before and after the switch. We can also state that no spontaneous reports of adverse drug reactions regarding ESAs have been received.

Conclusions Our results demonstrates that all the switches were well tolerated. This may support the use of biosimilars in terms of safety and efficacy and switches towards less expensive epoetins. The decision to start ESA treatment with a biosimilar must be considered, and it will also be possible to change pretreated patients.

No conflict of interest.

CPC-004 A REVIEW OF PHARMACISTSÍ INTERVENTIONS IN A NEUROLOGY DEPARTMENT

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Background The adult Department of Neurology is a 42-bed unit that includes an inpatient neurology ward, an inpatient stroke unit and a 10-bed neurological intensive care unit. The computerised physician order entry system available in our hospital is Omnipro. It enables the pharmacy resident to consult the cause of hospitalisation, nurse care, surveillance of medical parameters and to analyse prescriptions.

Purpose To describe the pharmacists' interventions (PIs).

Materials and Methods The resident validated prescriptions every day, could consult medical files in the Neurology ward and attended medical clinical rounds twice weekly. When a problem was identified in a prescription, the resident discussed it directly with the physician. Every PI was collected using a validated record sheet (Conort *et al*, J Pharm Clin, 2004).

Results The resident made 95 interventions during the eighteen-week study period. The physician acceptance rate of these recommendations was 92%. The most commonly identified drug-related problems were: inappropriate administration (19%), non-indicated drug (17%) and under dosage (12%). Nervous system drugs (24%), alimentary tract and metabolism drugs (17%) and cardiovascular drugs (14%) were the most frequently involved.

Conclusions The regular presence of the pharmacy resident on the neurology ward enabled him to be well integrated and to become familiar with inpatient specificities in the neurology department. Collaborative working relationships between pharmacists and physicians are the key to success and to reducing the number of potentially inappropriate prescriptions. The high physician acceptance rate is a good indication of intervention relevance. Recurrent problems were identified during this study. Data on interventions were presented to the pharmacy and therapeutic committee.

No conflict of interest.

CPC-005 A STUDY TO EVALUATE USTEKINUMAB IN PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

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Background Ustekinumab is a monoclonal antibody that binds with specificity and affinity to the p40 subunit of cytokines IL-12 and IL-23

Purpose To determine the short and long-term effectiveness of ustekinumab in patients with moderate to severe plaque psoriasis.

To determine the change from the baseline in the Dermatology Life Quality Index (DLQI).

To describe the safety profile of ustekinumab in clinical practise. **Materials and Methods** We reviewed the medical records of 31 patients who had been prescribed ustekinumab between October 2009 and July 2012 in our hospital. We noted the PASI (Psoriasis area severity index) and DLQI scores before and during the treatment and the adverse events reported by patients in their cheque-ups.

Clinicians typically consider at least 75% improvement (PASI75) in the disease to be a clinically meaningful improvement indicative of success

Results Data were unavailable in 3 patients.

42.4% (12) of patients were male and the median age was 44 years. The median baseline PASI score was 17.89 and the mean duration of psoriasis was 23.22 years.

15 patients (54%) completed a DLQI questionnaire. The median baseline DLQI score was 15.93 and the median DLQI score during the treatment was 1.26.

7 patients (25%) reported adverse events:

4 patients (14.4%) upper respiratory tract infection.

2 patients (7.2%) dyslipidaemia.

1 patient (3.6%) liver enzyme alteration.

1 patient (3.6%) basal-cell carcinoma.

1 patient (3.6%) generalised desquamative erythema.

There was only one adverse event that forced the suspension of treatment (generalised desquamative erythema).

Conclusions In our study, ustekinumab demonstrated a rapid onset of action and a high effectiveness, stable safety and a great improvement in the quality of life in patients with moderate to severe plaque psoriasis on up to 34 months of continuous therapy.

Abstract CPC-005 Table 1

	16 Weeks n = 28	6 Months n= 23	12 Months n= 17		24 Months n = 13	30 Months n= 10
PASI75(%)	82.1	91.3	94.1	92.9	76.9	90
PASI90(%)	71.4	69.6	47.1	50	46.2	50

No conflict of interest.

CPC-006 ADEQUACY OF CRITERIA FOR STARTING NATALIZUMAB IN PATIENTS WITH MULTIPLE SCLEROSIS

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Background Natalizumab is a monoclonal antibody authorised as second-line treatment after failure with interferon beta or in rapidly evolving severe relapsing-remitting multiple sclerosis (RRMS). Due to its high cost and safety profile, the appropriate selection of patients who will benefit most is of paramount importance.

Purpose To evaluate the adequacy of criteria for starting treatment with natalizumab in patients with multiple sclerosis (MS) based on the protocol approved in a tertiary hospital.

Materials and Methods Observational, retrospective analysis of patients treated with natalizumab between 2008 and 2011. Study data were obtained from clinical records.

Results 31 patients were treated with natalizumab, 26 women (83.9%) and 5 men (16.1%). Mean age was 38.8 years (SD = 9.1). Mean time between diagnosis and natalizumab start was 7.8 years (SD = 5.9). 29 patients (93.5%) had RRMS, 1 secondary-progressive MS (SPMS) and the other an intermediate disease between RRMS and SPMS. The mean number of relapses before treatment started was 3.7 (SD = 1.5) and the mean score for the expanded disability status scale was 3.3 (range 1–6). 27 patients (87.1%) had previously been treated with immunomodulatory drugs (interferon beta). In 4 patients (12.9%) natalizumab was first line treatment. All were diagnosed with rapidly evolving severe RRMS with gadoliniumenhancing lesions in brain magnetic resonance imaging and more than 2 disabling relapses in the previous year. At the end of the study 22 patients continued treatment and 9 had finished. These latter patients were categorised in two groups: short treatment duration (4 patients, median 5 months) and long treatment duration (5 patients, median 24 months).

Conclusions In our population, adequacy of criteria for starting treatment with natalizumab is appropriate and the drug was used for the authorised indications in more than 90% of patients.

No conflict of interest.

CPC-007 ADHERENCE PROBLEMS IDENTIFIED BY MOTIVATIONAL INTERVIEWING AND MEDICINES REVIEW IN STROKE PATIENTS

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Background Poor adherence to secondary prevention medicines occurs frequently in patients suffering a stroke or Transient