1049 POSTER

Development and evaluation of a web-based research ethics board (REB) review template

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Purpose: To develop and evaluate a web-based intranet Research Ethics Board (REB) protocol and consent template for REB members to review clinical research protocols systematically at the Princess Margaret Hospital (PMH), University Health Network (UHN), Toronto.

Methods: Building on an existing sophisticated information technology platform in the Radiation Medicine Program, we have initiated a web-based tool for reviewers to download and work from. The template has prompters to remind the reviewer to respond to areas such as study design, consent appropriateness etc.

Results: Systematic assessment of clinical research studies and subsequent electronic filing improves ethics review techniques. Presumably, this provides safer and more efficacious delivery of experimental therapy to patients.

Conclusion: Respecting the dynamic clinical research environment, the REB study review template must evolve with regulatory changes and research advances such as gene transfer technology; the process cannot be static. The electronic template will need to be updated routinely from the REB and patient perspective.

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Informing about biomedical research using an educational booklet: opinion survey in 129 French cancer patients

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Purpose: The purpose of this study was to evaluate patients' (pt) opinion on the content of an educational booklet (EB) informing on the objectives and the organisation of biomedical research in France and on the respect of their rights in case of participation to a clinical trial (Huriet law, 1988).

Patients and methods: 129 consecutive pts (46 men, 83 women, all types of cancers) treated at the Institut Paoli-Calmettes (Marseilles, France) and potentially candidate for a clinical trial (CT) were included in the study. They received the EB with the information letter and the informed consent sheet related to the CT. The EB explained the need for and the manner (including the legal context) in which CTs were conducted. Pts completed an opinion survey questionnaire (10 items).

Results: About 84% of respondents stated that the EB content was comprehensible for the majority of pts. However, 18.8% of pts required more information on the different phases of the CTs and 40.6% more information on their own treatments. If 90.6% of pts were quite or completely persuaded of the need of clinical experimentation in human, 41.4% were not or not entirely assured that they would receive all the information whether they decided to participate to a CT. Similarly, about 23% were not entirely assured that their rights would be respected. Only 9.6% of pts knew the existence of the local ethical committees (CCPPRB); its intervention (information provided by the EB) was not considered as reassuring by 28.6% of pts.

Conclusions: This study demonstrates that there is a need for medical teams involved in biomedical research to reassure the pts on the respect of their rights in case of participation to a CT, to provide more information on the different types of CTs and on the treatments proposed in the context of their disease. French public powers have to promote a better knowledge about the existence and the objectives of the local ethical committees.

1051 POSTER

Conceptual model for the webification of administrative papers

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Background: In late1999 it was decided at the Department of Oncology, the Finsen Centre, Rigshospitalet to cen-tralise the administration and management of medical guidelines and other treatment related written information.

Aims: The aim was to develop a web based solution fulfilling the following issues:

- Easy administration
- Easy to update and add new material
- Easy for user to find information
- All users have access to same information
- Secure against errors

Software Solution: For the first project more than 150 medical guidelines and other documents were collected amongst the senior doctors at the department. These documents were then edited by using a word template designed for this project. The aim was to ease the further processing in HTML Transit a commer-cially available program from the software vendor InfoAccess Inc.

With HTML Transit the Microsoft Word documents can be translated to HTML - without needing to understand HTML. In HTML Transit the entire document were gathered and structured in a manner suitable for web publishing, which involved creating of HTML Transit templates to insure a uniform translation and navigational issues. This was also done with respect to updating of new or revised documents in the future.

All information about the authors (owner of the document(s)) and document details (revisions dates) were stored in a MS Access database. This database was then used to automatically send email notifications with attached documents to the authors.

When the authors have updated the Word documents the system will detect that the source docu-ments have changes and will automatically update the web site with these changes.

Conclusion: Clinical guidelines related to treatment of patients have to be easy accessible and easy to update. This area is therefore suitable for IT solutions.

We have developed a system where it is easy for the users to find information because all the documents are placed at the same location and users can now make use of a search engine. At the same time the users can be sure that the information they receive are updated because the updating process is now on regular basis.

Developing this system has made our web site less prone to error due to less manual intervention.

In the future we will be working on making the administration of the system more effective and automate more tasks, At the moment we are working on a project were the documents are adapted to handle information on a Pocket PC's in a wireless network.

1052 POSTER

Cost-effectiveness of epoetin alfa (EPO) and darbepoetin alfa (DARB) based on hematopoietic response rates and cost of therapy

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Background EPO is effective in increasing hemoglobin (Hb) in anemic cancer patients (pts) receiving chemotherapy. DARB, which has been recently introduced, has a similar claim and it has been suggested that DARB is more cost effective (Glaspy 2002). Using a formal approach based on published trial data, we analyzed whether this can be substantiated.

Methods Data from 2 separate, multicenter, randomized, double-blind, placebo-controlled studies were evaluated. Hematopoietic response was defined as a $\geq$2 g/dL Hb increase or Hb $\geq$12 g/dL in the DARB study (Vansteenkiste 2002), and a $\geq$2 g/dL Hb increase in the EPO study (Littlewood 2001), with increases in both studies unrelated to transfusion. We chose response as our effectiveness measure because, unlike transfusion rates, it is not prone to differences in practice patterns. DARB was administered at a starting dose of 2.25 mcg/kg/week (wk) to 156 anemic (Hb $\leq$11 g/dL) pts with lung cancer; dose was doubled to 4.5 mcg/kg/wk if Hb had not increased >1.0 g/dL by wk 6 (12-wk blinded study treatment). EPO was administered at a starting dose of 150 IU/kg 3 times/wk to 251 anemic (Hb $\leq$10.5 g/dL) pts with multiple tumor types; dose was doubled to 300 IU/kg if Hb had not increased $\geq$1.0 g/dL by wk 4 (12-24 wk blinded study treatment). Relative cost effectiveness is addressed by the probabilities that the respective regimens are economically dominant over the alternatives. These probabilities are calculated by applying a recently published Bayesian methodology assuming that overall treatment costs (less drug costs) are proportional to effectiveness. Variances have been inflated by a factor of 2 to reflect additional uncertainty due to the different trials.

Results Response to DARB was 66% vs 24% for placebo (net response: 42%). Response to EPO was 70% vs 19% for placebo (net response: 51%). 42.9% of DARB pts (US FDA Package Insert) and 22.5% of EPO pts required dose-escalation. Based on unit cost of drug, available packaging, and % pts requiring dose escalation, mean 12-wk per pt cost for DARB

is £3665 and for EPO is £3469. The probability of economic dominance of DARB over EPO is estimated at 4.51%. The probability that EPO is more cost effective than DARB is estimated at 90.73%. When inflating the variance, these probabilities are 11.55% and 82.55%.

Conclusions Based on the currently available data, it is far more likely that EPO is more cost effective than DARB. Head-to-head trials are necessary to confirm these findings.

1053 POSTER

Indicators of high chemotherapy-induced nausea and vomiting treatment costs in German cancer centers

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Background: Chemotherapy-induced nausea and vomiting (CINV) remains a major adverse effect of cancer chemotherapy and has considerable economic impact.

Objective: To identify patient and treatment characteristics that were associated with high CINV costs.

Methods: Prospective, cross-sectional, cost-of-illness study conducted in 6 centers in Germany. 280 patients undergoing highly emetogenic chemotherapy were enrolled. Direct costs were evaluated from chart reviews and self-administered patients' questionnaires. The National Cancer Institute (NCI) scale was used to measure the level of emesis. Indicators of high costs were identified from a third party payer's perspective.

Results: 221 patients completed the diary and were evaluated. 26.1% and 63.0%, respectively, experienced at least one episode of vomiting or nausea. Only 35.1% reported neither vomiting nor nausea, despite antiemetic prophylaxis; 17.8% suffered from severe nausea, 3.4% from severe vomiting. 1 patient withdrew from chemotherapy because of CINV. Cost data are available for 96 patients at this time. Mean direct costs per cycle (prophylaxis and management of CINV) were Euros (E) 45.23 per patient, whether or not she/he suffered from CINV, and E 66.58 per patient who suffered from CINV. Patients on cisplatin who suffered from CINV incurred higher costs (E 87.02 per patient) than those receiving a non-cisplatin CTx regimen (E 58.00 per patient). Significantly more patients (57.1%) reported delayed than acute vomiting and/or nausea (6.3%). Patients with acute and no delayed CINV (n=6, 6%) cost less (E 26.84) compared with those experiencing no acute but delayed CINV (n=25, 26%): E 45.12 or both acute and delayed CINV (n=30, 31%): E 94.05. Patients with nausea only (n=34, 35%) incurred a cost of E 41.61, compared to those with emesis (n=29, 30%): E 97.53. Among the latter, 23 patients (23%) with NCI grades 1-2 emesis incurred cost of E 53.36 while 5 (5%) patients with NCI grades 3-4 emesis incurred costs of E 304.69.

Conclusion: Cisplatin-containing regimens, the occurrence of acute, and especially delayed CINV, and severe emesis (NCI grades 3-4 vs. grades 1-2) were strong indicators of high costs associated with CINV.

1054 POSTER

Cost analysis comparing brachytherapy versus surgery for carcinoma of the tonsillar fossa and/or soft palate

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Background: Using an organ function preserving protocol, in the Erasmus MC with brachytherapy (BT) or surgery (S) for tonsillar fossa (TF) or soft palate (SP) tumors, high localregional control (LRC) rates (80%-10 years) were observed. Moreover, late normal tissue sequelae, quality of life aspects and functional outcome scores have been found not dissimilar. The major late side effect being xerostomia illustrated the need for a more selective radiation treatment technique (Intensity Modulated Radiotherapy [IMRT]). For decision-making this paper focuses on comparison of full hospital costs of the different treatment options.

Material and Methods: From 1986-2001, T1-3 TF/SP tumors were treated by ERT to the primary and neck, followed by fractionated BT to the primary tumor. A neck dissection (ND) is performed for N+ disease (BT-group; 104 patients). If BT is not feasible, a resection with postoperative ERT is performed (S-group; 86 patients). LRC, disease free survival (DFS) and overall survival (OS) were calculated according to Kaplan Meier. Hospital costs, FU and costs for a relapse inclusive, were calculated for the treatment groups ERT and BT ± ND (group IA,B), S followed by ERT ± ND (group II) and IMRT and BT ± ND (group IIIA,B) (see table). These costs were compared to the costs computed for group III (future strategy).

Results: LRC, DFS and OS for BT+ND vs. S+ND at 5 years were 80% and 78%, 58% and 55%, 67% and 57%, respectively. Total costs for all groups are presented in the table below.

Total costs Tonsil + Soft Palate

Group	Treatment	Relapse	5-yrs FU	Total (Euro's)
IA ERT+BT	8031,12	6080,72	626,24	14.738,08
IB ERT+BT+ND	11.342,33	4827,57	609,96	16.779,86
II S	14.753,03	3930,68	604,25	19.287,96
IIIA IMRT+BT	8.300,98	6080,72	626,24	15.007,94
IIIB IMRT+BT+ND	11.612,19	4827,57	609,26	17.049,02

Conclusion: Excellent localregional tumor control was observed: at 10-yrs 80% for either modality. The total costs for BT were significantly less as opposed to S: 16.779,86 (IB) vs. 19.287,96 (II). Modality specific late side effects were not negligible (ulcer [BT], fibrosis / trismus [S]; both groups were in particular significantly affected by xerostomia). Fortunately, BT induced ulcers healed spontaneously in 88%. To reduce the morbidity of xerostomia we propose to further optimize our organ preservation protocol by implementing IMRT. This is of interest in particular given the costs of IMRT not being very dissimilar to BT: 15.007,94 (IIIa) vs. 14.738,08 (IA).

1055 POSTER

Economic burden of seven tumors by course of therapy and treatment failure

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Background: To evaluate economic burden associated with treatment of seven tumors of interest (TOI) by initial, secondary and palliative treatment course, and assess costs of failed treatment.

Methods: A retrospective cohort analysis was conducted using MarketScan claims databases of over 3 million US employees, spouses, dependents, and early retirees. Healthcare services utilization and treatment costs in newly diagnosed patients (pts) with TOI in 1999-2000 were analyzed. Costs standardized to monthly means were adjusted for age, gender, Charlson Comorbidity Index, region, follow-up period, and hospital mortality using ordinary least square regression. Treatment failure was defined by the need to switch regimen (secondary treatment) or palliative care following initial therapy. When assessing the costs of failure, pts receiving only palliative care and no initial therapy were excluded. Total cost of treatment failure was calculated as incremental cost between pts with initial therapy only and pts experiencing treatment failure.

Results: The study population consisted of 12,709 pts including 43% prostate, 22% colorectal, 16% lung, 5% brain, 3% ovarian, and 3% pancreatic cancer, and 8% non-Hodgkin's lymphoma (NHL). Mean length of stay per hospitalization was 3.1, 1.1 and 5.7 days for initial, secondary and palliative care, respectively. Mean monthly number of office visits was 6.1, 3.2 and 9.1 for initial, secondary and palliative care, respectively. Mean monthly costs were $8,125, $1,074 and $6,140 for initial, secondary and palliative care, respectively ($p<0.05$). Mean length of each treatment course was 6.3 months for initial, 8.9 months for secondary, and 6.4 months for palliative care. The mean total cost of treatment failure was $10,454 per month and $37,662 per study period. Brain cancer, followed by colorectal and lung cancer, was associated with the greatest cost of treatment failure per month, but aggressive NHL, ovarian and brain cancer pts had highest costs of failed treatment per study period.

Conclusions: While pts utilized healthcare services most frequently during palliative care, the highest costs incurred during initial treatment. The cost of treatment failure was higher than any treatment phase alone. Opportunity exists for new interventions and therapies that prevent or delay treatment failure, and offset the large economic burden associated with failed treatment of the seven tumors.