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.

1050 POSTER

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