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14. Other issues

469 The European Normative framework on the involvement of CF minors in clinical trials

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Background: During the past decades, important regulatory efforts have been made to develop a harmonized normative framework facilitating the conduct of paediatric clinical trials. Despite these efforts, a great variety in regulation continues to exist, and various important ethical issues are not addressed within the legal framework.

Objectives: To study the difficulties and opportunities in the implementation of European regulation in paediatric CF research practice.

Scope: The Declaration of Helsinki (1996 revision), the Convention on Human Rights and Biomedicine (and the additional protocol on biomedical research), the Clinical Trials Directive, and the draft EMEA-guideline on the ethical concerns for clinical trials performed in children.

Methods: Comparative law methodology, literature study.

Results:

1. Regulatory interventions mainly focus on the harmonization of existing GCP-guidelines and the development of a competitive research environment;
2. Despite far going harmonization efforts, contradictory provisions at the European level still exist;
3. The considerable freedom physicians have in implementing the ethical concerns and principles formulated in the legal framework, entails both dangers (e.g. bias, interpretation difficulties) and opportunities (e.g. truly addressing ethical concerns);
4. Although the informed consent conference is an excellent opportunity for professionals, minors, and their parents to discuss ethical concerns in research participation, the European legal framework hardly covers patient concerns other than safety and protection. In addition, the heterogeneity of the paediatric public is poorly addressed;
5. The European legal framework does not correct the varying economic interest in paediatric clinical trials.

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470 Client satisfaction within a paediatric District General Hospital (DGH) cystic fibrosis (CF) service

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Introduction: At our clinic we have a team of staff caring for 23 families (26 children) with CF. The team consists of, Consultant Paediatrician, Sp Registrar, Specialist CF Nurse, Respiratory nurses, Dietician, Physiotherapist. In addition we have ward, clinic, pharmacy and x-ray support staff all that have a special interest in CF. We have a shared care system of service with Alder Hey Children's Hospital, Liverpool, UK. The views of patients and their carers are of utmost importance within our service and indeed within the NHS.

A questionnaire was developed to assess the level of satisfaction our clients and their families have of the care they receive within a DGH.

The aim: To allow the team to assess the need for change and improvement and to ensure that any changes made were appropriate to the needs of the families we care for.

Method: The survey was based on a five point Likert scale with additional room for comments. 30 questionnaires containing 14 questions were posted out to families and patients over the age of 13 years, with SAE included to ensure anonymity.

Results: We had a return rate of 66%. The results showed a high rate of satisfaction with the services offered with 100% of returns showing either satisfied or very satisfied with the overall quality of care. Questions included satisfaction with professional services, clinic facilities, contact with staff and courtesy/privacy/dignity. Comments received from clients also reflected the high satisfaction levels reported.

Conclusion: The results allowed the team to understand changes needed to improve the service we offer and allowed the families we care for to express their views and concerns.

471 ECORN-CF project in the Czech Republic: first experiences

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ECORN-CF is a 36 month EU grant project (www.ecorn-cf.eu) with its major aim being establishment of a model reference network for European CF centres. This project should ease access to expert advice for CF patients, doctors, as well as other CF team members, by implementation of a multilingual web-based service. ECORN-CF should help to build and complete a European Consensus for care for CF patients when and where it is necessary. We started with the Czech Rep. website already in October 2007. After expected corrections at the very beginning, our website is now working successfully. We have received 25 questions, so far. It is surprising that about half of the questions are in Slovak and their spectrum is broad. Patients, parents and even other CF team members were asking about CF basics – like sweat chloride test, ABPA, *Pseudomonas* infection, atypical CF, adverse effects of corticosteroids, inhalators, uridine triphosphate therapy, airway clearance vests, having another baby, school attendance, social contributions etc. There were few questions from students writing their thesis on CF related topics. It is not always easy to answer a question and it is very useful to have the possibility to re-check answer correctness by other CF experts and also discuss these at regular project meetings. We advertised our project with the Czech CF lay organisation – CF Klub. Public acceptance of the project is very good. However, we get corrections of our answers after we had already posted them on the local website. We hope that in future more interesting questions will arrive and that we will manage a Slovak cooperating partner for many patients, parents and CF care team members in Slovakia.

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472 CF Education for respiratory trainees in one UK region

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Introduction: In order to comply with EEC directives, specialist medical training in the UK has been compressed to 5 years, and there is now little scope for providing experience in sub specialist areas. This is of particular importance in CF, where the numbers of patients are increasing and there are now more adults than children with the disease. We surveyed respiratory trainees in one UK region (North West) served by two large adult CF centres, to quantify current CF training practise and also to canvass their opinion regarding the minimum acceptable amount.

Method: An anonymous survey of 27 respiratory trainees at a regional training day.

Results: There was a wide variation in the amount of CF experience obtained. Four trainees received none, and a further 4 had no formal secondment to a CF unit. Of the remainder, one spent 2 weeks in a CF unit, sixteen 3 months, one 6 months, and one a year. As regards their view of the minimum experience necessary, only 2 indicated no formal attachment, relying on teaching days and a course. Of the remainder, twelve suggested 2 weeks in a CF unit, thirteen 3 months, and one 6 months. Only 9 indicated their training was adequate: 7 wanted more and 11 less (all these spent at least 3 months in a CF unit).

Conclusion: This survey has shown that current CF training in one UK region is variable, a pattern which is likely to be representative nationally. Trainees also had diverse views as to the minimum acceptable amount. This survey lends weight to the concept of a national organised training program for CF in the UK, to ensure an adequate level of knowledge amongst general respiratory physicians for this increasingly common disease.