autopsies and organ retention. Parents should be provided with full information and not be coerced into accepting an autopsy examination, and these discussions should be with an appropriately trained professional. Our study provides important information for parents. If a termination has been carried out because of anomalies detected by ultrasound scan, by declining an autopsy, parents will remain ignorant of information that might change the recurrence risk in one in four cases and have a one in 13 chance for missing confirmation of a high (one in four) recurrence risk.

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Comparison of requirements of research ethics committees in 11 European countries for a non-invasive interventional study

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Editorial by Glasziou and Chalmers

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The Declaration of Helsinki states that every experimental procedure involving human subjects should be approved by a research ethics committee.[1] All signatory countries must enact the declaration but can also add local requirements which do not reduce the protection. Research ethics committees are well established, though they have been criticised.[2]

I aimed to describe how countries vary in their requirements for research ethics committees for exactly the same trial protocol. The study was nested within a trial, in 11 signatory countries, of a leaflet intervention aimed at improving the involvement of older patients during consultations with their general practitioners. The trial outcome measures were questionnaires for the general practitioners and their patients before and after the intervention. The documents relevant to research ethics committees comprised the letter of invitation, information leaflet, and questionnaires for patients (patient's pack); the similar, but different general practitioner's pack; and the intervention consultation leaflet.

Participants, methods, and results

I piloted a questionnaire, based on experiences in previous multinational studies,[3] and then sent it to the researcher in each country (see bmj.com). The questionnaire asked for details of processes in getting approval from research ethics committees for the trial. I received responses from all partners—Austria, Belgium, Denmark, France, Germany, Israel, the Netherlands, Portugal, Slovenia, Switzerland, and the United Kingdom (table).

In Belgium, application was made to one research ethics committee. In Slovenia, the application also needed the protocol in English. In the United Kingdom, the 20 copies of the application needed all documents. Changes to the UK patient invitation letter required by the committee were resubmitted for chair's approval. The whole process took 10 weeks.

In all countries where researchers made applications, in addition to office costs, the researcher's time was used to prepare the application. This was two days in Slovenia and five days in the United Kingdom. In Israel, although approval of the research ethics committee was not needed, one day of researcher's time was taken in discovering this.

Comment

Countries clearly differ in their requirements for approval by a research ethics committee for an identical study. If all countries are meeting the principles of the Declaration of Helsinki, then the striking variations mean we are too careful in some countries or too lax in others. The United Kingdom has an arduous process for gaining ethical approval for a non-invasive intervention study.

The risks of inappropriate requirements include unnecessarily delayed studies and extra costs without any increased protection for participants. Disintegration of study protocols is also a high risk, and, therefore, UK partners may be unwelcome in international studies.

In countries where researchers do not apply for approval of a research ethics committee they are not being unethical. In the Netherlands, guidelines distinguish between studies where approval is and is not necessary.[4] Not all medical research needs all the principles of the Declaration of Helsinki—for example,

P+ *The questionnaire completed by researchers is on bmj.com*

Responses to questions on obtaining approval from research ethics committees in different countries

	Belgium	Slovenia	United Kingdom	Denmark	Israel	Netherlands	Portugal	Austria	France	Germany	Switzerland
Approval got:											
Yes, compulsory	√	√	√								
No, but checked with committee first				√	√	√	√				
No, not necessary								√	√	√	√
If no, criteria for needing approval	—	—	—	Biomedical research	All human research	All human research. Questionnaires or interviews, only if time consuming, mentally burdensome, or for vulnerable people	Clinical trials	Clinical trial with drugs	Intervention, medication, or physical risk	Not if regarded as a quality improvement activity	Intervention studies
Documents submitted:											
Protocol		√	√		√						
Patient's pack*	√	√	√		√						
General practitioner's pack*		√	√								
Researchers' CV		√	√		√						
Changes required?	No	No	Yes, minor		No						

*The patient's pack comprised a letter of invitation, information leaflet, and questionnaires for patients; the general practitioner's pack was similar but different.

research that requires only answering questions, without risk of psychological distress.[5] The sooner this concept is implemented by committeees in all countries, the sooner we can stop unnecessary applications which are both risky and costly.

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Competing interests: HH is an active researcher who has applied for, and will continue to apply for, the approval of research ethics committees in the United Kingdom for studies she leads.

Ethical approval: Not needed.

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Sex ratios in healthcare occupations: population based study

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Thirty years ago a clear dichotomy existed between the healthcare occupations of men and women. If feminists' predictions were correct—that equal opportunities legislation would widen occupational choices for everyone[1]—there should by now be a trend towards equal numbers of men and women in occupations that were formerly male or female dominated. We aimed to support or refute the feminists' predictions by comparing the sex ratio in healthcare occupations in 1971 with the ratio in 2001.

Methods and results

We used census data for 1971 and 2001 (obtained respectively from *New Zealand Statistics*[2] and the New Zealand's government statistics website, www.stats.govt.nz) to examine the situation before and after the introduction of legislation on equal opportunities for men and women in employment. We used data only for workers aged 18-44 years because this was the age group that would reflect any changes that might have occurred as a result of the legislation. We defined a healthcare worker as anyone working face to face with people who have health or disability problems.

If more than 90% of those employed in an occupation belonged to one sex, we considered the occupation to be "male dominated" or "female dominated." If more than 70% belonged to one sex, we considered the occupation to be "mostly male" or "mostly female." If the proportions of men and women were between 30% and 70%, we considered the occupation to be "balanced." We used χ^2 tests to test the significance of the differences in proportions between 1971 and 2001.

For healthcare workers aged 18-44 in 1971, there were 10 male dominated and 13 female dominated occupations; the table shows the numbers of staff in the 10 male dominated occupations and the top 10 female dominated occupations. Each of the 10 male

P+ *A figure showing the change in sex ratios in occupations is at bmj.com*