Clinical & Scientific letters

Letters not directly related to articles published in *Clinical Medicine* and presenting unpublished original data should be submitted for publication in this section. Clinical and scientific letters should not exceed 500 words and may include one table and up to five references.

Ethics approvals and quagmires

All researchers are familiar with the phenomenon whereby a distant green field appears to present no obstacles, but on closer acquaintance is revealed as a deadly swamp which can be negotiated only with immense expenditure of time and trouble. Recent experience indicates that this may be just as true of research ethics approval as of research itself.

We report here the difficulties we experienced when several research ethics committees requested alterations to our patient information letter.

Our study covered a broad geographical area, and the Public Health Laboratory Service (PHLS) provided some of the study data; the requirements for ethical approval at that time resulted in ten separate submissions of our study documentation to nine research ethics committees.

Initial Multi-centre Research Ethics Committee (MREC) approval was gained without difficulty, but unfortunately the MREC-approved version was not accepted by the PHLS committee. By the time PHLS approval had been granted, the letter was significantly different from the original version approved by MREC. It was therefore necessary to resubmit this altered version (now acceptable to PHLS), to MREC who in turn requested further changes. Some of these changes were to phrases which had been accepted at the original consideration. Table 1 below lists some examples of the differences of opinion.

Nor was this the end of the story: our subsequent experience with the local research ethics committees was depressingly similar.

None of the above committees raised concerns about the scientific aims of our study, and almost all the amendments were to the patient information sheet. Although the committees' suggestions were generally sound, it was notable that requests for alterations of the same letter from different committees were widely variable, to the point of being mutually exclusive at times.

We feel that the RECs could have recognised that beyond a certain point, adjusting the phrasing of a patient letter is subject to the law of diminishing returns. There will always be differences of opinion about the precise wording to use when discussing an issue with a patient, and the fact that there was little agreement between the RECs illustrates very clearly the subjective nature of these judgements.

Despite the laudable aims of research ethics committees,

> *The purpose of a Research Ethics Committee in reviewing the proposed study is to protect the dignity, rights, safety and well-being of all actual or potential research participants*[1],

we suspect that the lengthy cycle of reviews and submissions required to achieve a letter acceptable to all committees had little practical benefit for our patients. At times it appeared to us that, in their enthusiasm to produce the best possible letter, the ethics committees were operating well beyond their original mandate as quoted above.

In addition, we found ourselves in an extremely awkward position when different ethics committees made conflicting demands. It was unfortunate that there was no mechanism whereby the various committees could negotiate directly with each other to achieve a unified opinion.

We wonder how many others have been discouraged from pursuing research interests after floundering in this quagmire.

References

1 Governance arrangements for NHS Research Ethics Committees July 2001. Department of Health website: www.doh.gov. uk/research/documents/gafrec.pdf

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Screening for thyroid disease in pregnancy: an audit

Recent studies have shown that subclinical hypothyroidism during early pregnancy may affect the neuropsychological development of children[1–3]. We developed local management guidelines for hypothyroidism during pregnancy. These guidelines were widely circulated in the hospital and community, and recommended thyroid function tests at booking (first hospital

Table 1. Examples of phrases that were acceptable to MREC but not to PHLS.

Section of patient letter	Accepted by MREC	Changes requested by PHLS	Changes requested by MREC
How did we get your name?	'Records of all cases … are kept centrally, in a database in Manchester.'	Start with an introduction before 'how we got your name' referring to how meningococcal disease is notifiable by law.	Delete 'in a database'
What will I be asked to do if I take part?	'We need a sample of your blood.'	'We would be grateful if you would let us take a sample of your blood.'	
What will I be asked to do if I take part?	'We may need to read through your hospital notes….'	'With your permission, we may need to read through your hospital notes….'	

antenatal visit) in those with a personal or family history of thyroid disease.

The records of 4,083 pregnant women attending the James Cook University Hospital, Middlesbrough from January to December 2000 were reviewed. 65 (1.6%) of these 4,083 women had known thyroid disease, and a further 486 (11.9%) had a family history of thyroid disease (Table 1). Therefore, according to our guideline, thyroid function screening was indicated in 551 (13.5%). However, we found that only 98 (17.8%) of the 551 had thyroid function checked at antenatal booking.

At booking, 60 (92.3%) of the 65 women with known thyroid disease had thyroid function tests performed. Seventeen (28.3%) had high TSH, and seven (11.7%) also had low free thyroxine (FT4). Four (6.2%) women with known thyroid disease had suppressed TSH with raised FT4. Only 38 (7.8%) of 486 women with a family history and who were not known to have thyroid disease were screened, and two had elevated TSH.

More than one quarter (28.3%) of pregnant women with pre-existing thyroid disease have a high TSH at booking. Checking thyroid function in women with known thyroid disease at booking (12–16 weeks gestation) may be too late, as the mother is the sole source of thyroxine for the fetus up to about 12 weeks gestation[4]. All women with thyroid disorders should ideally have optimised thyroid replacement prior to conception. Thyroid function tests (TSH and FT4) should be performed as soon as pregnancy is confirmed, and the dose of thyroxine amended as necessary at the earliest opportunity[5].

The UK has no national guidelines on screening thyroid function during pregnancy. However, a recent statement from The British Thyroid Association recommends checking thyroid function at booking in pregnant women with a past or family history of thyroid disease, with type 1 diabetes, and/or with symptoms of thyroid disease[6]. Thyroid screening in high-risk pregnant women has also been advocated by other authorities, including The Endocrine Society[7] and The American Association of Clinical Endocrinologists[8]. However, the present study shows that more than 80% of the high-risk pregnant women in our district were not screened despite the local development and circulation of guidelines.

Table 1. Thyroid function screening in pregnant women at antenatal booking (total n=4,083) at the James Cook University Hospital, Middlesbrough, UK for the year January to December 2000.

Sub-groups of pregnant women	Number in whom thyroid screening indicated (% of total)	Number in whom thyroid screening performed (% of those indicated)
With known thyroid disease		
Hypothyroidism*	49 (1.2%)	49 (100%)
Thyrotoxicosis (past/current)	15 (0.4%)	10 (66.7%)
Non-toxic goitre	1 (0.02%)	1 (100%)
Total	65 (1.6%)	60 (92.3%)
With family history of thyroid disease	486 (11.9%)	38 (7.8%)
High risk group (those with known thyroid disease and/or family history)	551 (13.5%)	98 (17.8%)

Includes primary hypothyroidism (n=42), post-thyroidectomy (n=6) and hypopituitarism (n=1)

References

1 Haddow JE, Palomaki GE, Allan WC, Williams JR *et al*. Maternal thyroid deficiency during pregnancy and subsequent neuropsychological development of the child. *N Engl J Med* 1999;**341**:549–55.

2 Pop VJ, Kuijpens JL, van Baar AL, Verkerk G *et al*. Low maternal free thyroxine concentrations during early pregnancy are associated with impaired psychomotor development in infancy. *Clin Endocrinol* 1999;**50**:149–55.

3 Lazarus JH, Kokandi A. Thyroid disease in relation to pregnancy: a decade of change. *Clin Endocrinol* 2000;**53**:265–78.

4 Vulsma T, Gons MH, de Vijlder JJM. Maternal-fetal transfer of thyroxine in congenital hypothyroidism due to a total organification defect of thyroid agenesis. *N Engl J Med* 1989;**321**:13–16.

5 Mandel SJ, Larsen PR, Seely EW, Brent GA. Increased need for thyroxine during pregnancy in women with primary hypothyroidism. *N Engl J Med* 1990;**323**:91–6.

6 www.british-thyroid-association.org/pregnancy.htm/

7 www.endo-society.org/pubrelations/pressReleases/archives/1999/hypothyroid.cfm/

8 www.acce.com/clin/guidelines/pregnancy.pdf/

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One stop swallowing clinic may be more effective than a new cancer clinic

Introduction

The relatively high mortality rates for cancer in the UK may partly be explained by delay in diagnosis[1]. To improve services, National Service Framework with the 'two-week cancer initiative' was set up with special clinics staffed by multidisciplinary teams to circumvent delays. These clinics have had limited success[2], while using scarce resources at the expense of 'non-urgent patients'[3]. We describe our experience of a specialty clinic setup in 1990, to assess and manage patients with swallowing disorders, and its role in the NHS today.

The Clinic

Our swallowing clinic serves as a regional centre for swallowing disorders, providing single stop consultation and Upper GI Endoscopy (UGIE) followed by review and if needed, fast track investigations including barium studies, oesophageal manome-