Letters

Women need better information on routine mammography

Information on expected mortality reduction from attending screening must be correct

EDITOR—Thornton et al say that claims for the reduction in relative risk of death from breast cancer among women who are screened have ranged from 63% to 6%.[1] This is crucial information for women considering attending. Unfortunately the lower limit, attributed to our paper in the *BMJ* in 2000,[2] is no such estimate. The 6% refers to the reduction seen in death rates from breast cancer for invited women (including those screened and non-attenders) in 1998, from a programme that started between 1988 and 1995.

For reasons we explained in great detail in our paper (including the fact that many deaths in the 1990s will have been women with a diagnosis of breast cancer before any invitation to screening), this is most likely to estimate the beginnings of an effect—not the full effect. It is therefore inaccurate and extremely unhelpful to quote this figure to women as an estimated relative risk reduction from attending screening—it is not.

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Competing interests: None declared.

1 Thornton H, Edwards A, Baum M. Women need better information about routine mammography. *BMJ* 2003;327:101-3. (12 July.)
2 Blanks RG, Moss SM, McGahan CE, Quinn MJ, Babb PJ. Effect of NHS breast screening programme on mortality from breast cancer in England and Wales, 1996-8: comparison of observed with predicted mortality. *BMJ* 2000;321:665-9.

Framing is important in presenting risk information

EDITOR—Thornton et al argue that women need better information on breast screening.[1] A great deal of evidence is available on how risk should be presented to facilitate understanding.[2]

Absolute risks should be given more prominence than relative risks. The effects of the decision over the individual's lifetime should be presented rather than the effects in the next few years.

The way information is framed also influences the decisions people reach. Reductions in losses (such as "screening decreases mortality from 6% to 4%") are more persuasive than increases in gains (such as "screening increases survival from 94% to 96%").

Unless our aim is to manipulate, the influence of framing should be minimised by presenting risks of both gains (survival) and losses (mortality). People tend to understand data more easily if they are presented in the form of integers (3 in 10 people) rather than probabilities (30% of people). Any attempt to present risk information to women should make use of decision aids.[3]

Current breast cancer information leaflets do not contain information on absolute reduction in mortality or absolute risk of further investigation over the course of a screening career and do not use any decision aids.[4] Decision aids for breast cancer screening have been published that meet at least some of these requirements.[5] I hope they will be found in future leaflets.

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Competing interests: None declared.

1 Thornton H, Edwards A, Baum M. Women need better information about routine mammography. *BMJ* 2003;327:101-3. (12 July.)
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5 Marshall T, Adab P. Informed consent for breast screening: what should we tell women? *J Med Screening* 2003;10:22-6.

Understanding of principles of screening must be improved

EDITOR—I read the paper by Thornton et al and the reply by Patnick (see next letter) with interest.[1 2] Both the NHS breast screening programme and cervical screening programme have made great efforts to improve the understanding by women of the principles of screening since Anderson and I wrote a paper in 1999 that was critical of the information given.[3] Unfortunately there is clearly someway to go.

Patients remain confused. The BBC, quoting from a report by the Cancer Research UK psychosocial oncology group at the University of Sussex, says that patients were flummoxed by terms used to describe screening procedures for breast and bowel cancer and that more than half of the study group either did not know or showed partial understanding of breast cancer screening techniques such as mammography.[4]

Disappointingly, the leaflet to which Patnick refers (*Breast screening the facts*) omits to mention the potential consequences of being screened—namely, invasive biopsy procedures or even mastectomy, with their attendant morbidity.[2] Although these eventualities may only affect a minority of those being screened, they are surely worthy of mention in a pamphlet purporting to tell it how it is, especially since most of these women are healthy before undertaking the screening test.

Given the time and effort spent in ensuring that bereaved relatives are given appropriate information before their next of kin undergoes a postmortem examination, surely it is time the opportunity to provide truly informed consent was given to participants in screening programmes so they know exactly what they are signing up to.

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Competing interests: None declared.

1 Thornton H, Edwards A, Baum M. Women need better information about routine mammography. *BMJ* 2003;327:101-3. (12 July.)
2 Patnick J. Breast screening—the facts. bmj.com 2003. bmj.com/cgi/eletters/327/7406/101#34309 (accessed 6 Sep 2003).
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Women's needs inform contents of screening literature

EDITOR—Thornton et al think that women need better information about routine mammography.[1] We have produced a leaflet, *Breast screening the facts*, which is designed to ensure women are told what screening can and cannot achieve.[2]

It includes an explanation about false positive and false negative results and informs women about the use made of their personal information for audit, as set out in the General Medical Council guidance on confidentiality. Women should therefore be able to make an informed choice based on an understanding about why they are attending for screening, and what happens to their records after being screened.

The leaflet was extensively researched and tested to ensure that it is easy to understand. It was clear from the research that women wanted the right information at the right time, when it actually meant something to them.

We accept that some women may want further information, which is why we have included our website address in the leaflets (www.cancerscreening.nhs.uk).

The leaflet is being kept under constant review and research is under way on its impact on women's understanding of breast screening. The results, and new, relevant information, will be fed into the next edition of the leaflet.

We are confident that breast screening is saving lives, and we strongly encourage women to accept their invitation for a mammogram, but in the end it is not our choice: it's up to the individual woman.

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1 Thornton H, Edwards A, Baum M. Women need better information about routine mammography. *BMJ* 2003;327:101-3. (12 July.)
2 Health Promotion England in association with the NHS Cancer Screening Programmes, with advice and support from the Cancer Research Campaign Primary Care Education Research Group. *Breast screening the facts.* Health Promotion England, 2001.

Authors' reply

Editor—Responses to our paper identify the problems that underlie any attempt to produce honest, good quality information for healthy potential participants in routine mammography screening programmes. These hinge on the central question about the uncertainty of whether screening does more harm than good. Even so, current shortcomings in information provided are confirmed and identified, and constructive, practical suggestions for improvements offered.

In contrast to Peto and other researchers mentioned in our paper, Blanks and his colleagues claim to have teased out the different contributions to the reduction in breast cancer deaths.[1] However, since population screening began in the United Kingdom, numerous factors have affected worldwide mortality trends in breast cancer,[2] and systematic reviews of mammography have been published showing little or no reduction in mortality from good quality evidence.[3] Sophisticated qualitative methodologies and instruments have also been developed that could helpfully assess a range of non-biomedical outcomes important to consumers.[4]

Marshall and Nottingham offer suggestions for practical improvements that could be implemented immediately. Patnick's concern to provide women with what they want so that it "is easy to understand," rather than what they need to make a properly informed decision is somewhat patronising and does women a disservice. Sacrificing content to readability and presentation is unhelpful if you are to fulfil General Medical Council guidance that "you must ensure that anyone … can make a properly informed decision."

Prospective screening participants first need to know what their risk of getting the disease is, and their risk of dying of it, and the chances of undergoing invasive investigations as a result of attending screening. These and other facts are important if women are to go on to consider whether the harms and benefits of screening are worthwhile for them. Published decision aids are already available[5]: we suggest they be fed quickly into a new leaflet from the NHS Breast Cancer Programme.

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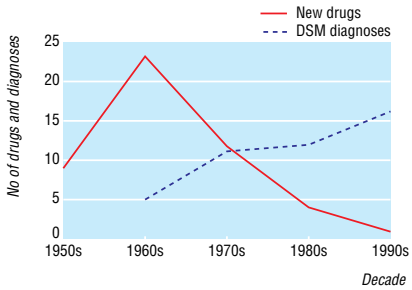
Separation of anxiety and depressive disorders



Inverse relation between number of new drugs patented for mood and anxiety disorders and number of anxiety and depressive diagnoses in DSM revisions

Normal rules of critical evaluation were presumably suspended

Editor—Shorter and Tyrer's conclusion that failure to advance (drug) treatment of anxiety and depression is related to wrong (disease) classification seems to be based on several false premises.[1]

Firstly, precise diagnosis is possible in mental disorders.

Secondly, drug licensing authorities require disease indications in standard (coded) diagnostic terms.

Thirdly, drugs are used only to treat disease (cause) not symptoms (effect).

Fourthly, drugs are the principal treatment agent in anxiety and depression.

Diagnosis in patients, particularly in mental illness, is simply a shortcut categorisation prompting further elucidation. Full appraisal of patients in the context of their environment, beliefs, and many other factors is a more appropriate guide to therapeutic choices, of which drug treatment is only one option.

The specification of product characteristics for the benzodiazepine librium lists among its licensed indications symptomatic treatment of anxiety, anxiety with other conditions (many diseases listed here), muscle spasm, symptomatic relief of acute alcohol withdrawal.[2] Clearly not the language of disease classification, this example refutes the second premise above.

Most clinicians know that anxiety and depression are symptoms (alone or together) found in situations (not necessarily disease) and conditions including schizophrenia, mood disorders, and phobic disorders. Calling symptoms disease is like telling a patient with headache that they have "cephalgia."

I am amazed that, to pursue its otherwise excellent scrutiny of the pharmaceutical industry's influence on medical practice, the *BMJ* has suspended its normal rules of critical evaluation to publish this paper, which sees conspiracy where clearly none exists.

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Competing interests: RW is managing director and majority shareholder of SafeScript Limited, a company that provides an electronic thesaurus based coded drug information database for electronic patient record systems.

1 Shorter E, Tyrer P. Separation of anxiety and depressive disorders: blind alley in psychopharmacology and classification of disease. *BMJ* 2003;327:158-60. (19 July.)
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New tools will lead to more valid classification system

Editor—Shorter and Tyrer's comments about the implications of separating depressive and anxiety disorders in the *American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders* (DSM) are perplexing, but not enlightening.[1]

Implying that this separation is impeding the development of new antidepressants, the authors cite an inverse relation between the number of patented new drugs and the number of DSM categories, then acknowledge that this association may not be causal. They call for companies to develop drugs targeting the heterogeneous category of mixed anxiety and depression but ignore the added cost resulting from the huge sample sizes of patients that would be needed to see even small drug effects.

Finally, the authors incorrectly assert that the drug industry significantly influences the diagnostic revision process. No facet of the DSM-IV revision process entailed any pharmaceutical company support.

We contend that the Food and Drug Administration's approval of compounds for multiple, diagnosis specific indications reflects their broad spectrum of efficacy and has no bearing on the pace of new drug development. Moreover, adopting broadly

defined indications could encourage overprescribing by blurring the diagnostic threshold that separates "normal" depression and anxiety from pathological states.

Certainly the biggest hindrance to both successful new drug development and the utility of the DSM classification is our current lack of understanding of the underlying pathophysiology of psychiatric disorders. New tools ranging from neuroimaging to functional genomics will help to elucidate the pathophysiology of mood and anxiety disorders, leading to a more valid classification system and, in turn, accelerated development of new medications.

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1 Shorter E, Tyrer P. Separation of anxiety and depressive disorders: blind alley in psychopharmacology and classification of disease. *BMJ* 2003;327:158-60. (19 July.)

Maybe pharmaceutical failure has created culture of niche diagnosis

EDITOR—Shorter and Tyrer provide an important case study in the way that medicine and science can become subverted by commercial pressures.[1] On one hand, new patents for drugs for mood and anxiety disorders have dwindled to almost nothing from a high point in the 1960s and 1970s. On the other, niche diagnoses have proliferated, apparently as a result of collusion between experts and the pharmaceutical industry. In the absence of new drugs for existing conditions, it seems, a good commercial alternative is to market the existing drugs as being effective for new diagnoses.

However, if we accept the existence of this association, the direction of causation is unclear. The authors believe that the failure to advance the treatment of anxiety and depression is related to the wrong classification—with the implication that use of a superior categorisation that no longer separates the two diagnoses would stimulate pharmaceutical innovation. But it could equally well be true that the proliferation of niche diagnoses is a commercial strategy that is a response to the absence of good new drug discoveries. After all, other sections of the industry have also experienced a falling off of new patents—for example, antibiotics.

Perhaps we will not have any new therapeutic agents for anxiety or depression, as we may have reached the limits of this pharmacological approach. The fact that these two symptoms tend to occur together in real life should not obscure that they are just that: symptoms, not diagnoses. A diagnosis provides an explanation of symptoms (and other manifestations of a disease process) that goes beyond their mere description, even if that does include a dimensional approach to defining illness. It is unclear that there is a diagnosis to find here, beyond the attempt to understand why some people—and some cultures—tend to respond in this way to adverse life situations.

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1 Shorter E, Tyrer P. Separation of anxiety and depressive disorders: blind alley in psychopharmacology and classification of disease. *BMJ* 2003;327:158-60. (19 July.)

Authors' reply

EDITOR—Our article merely points to an inefficiency in drug development that seems to be driven by commercial imperatives, and as the targets are phoney diagnoses no advance is made. If we merely promote new indications for old drugs and dump existing compounds when they lose their patents is it surprising that depression and anxiety remain such major causes of morbidity?

Weeks is right to assert that there is more to the treatment of mood disorders than drugs, but the negative effects of the splitting of anxiety and depression are not just confined to drug treatments: they apply across the board, leading to such confusion that herbal and homoeopathic remedies are often the preferred treatment options.[1] If we can match treatment to patterns of symptoms the outcome can be successful[2]; forcing them into diagnostic boxes with licensed indications is not the way forward.

First and Regier clearly believe that anxiety and depressive disorders are fundamentally different. Belief is not enough for a good classification; the evidence to date favours common genetic and psychological components to both anxiety and depressive disorders[3 4] and it is a more reasonable hypothesis to consider cothymia as the core state.

It also may be true, as Joffe suspects, that this proliferation of niche diagnoses is a consequence of the failure to find new drugs, but, if so, it should be exposed for what it is, and more attention given to the sad fact that two out of five patients with anxiety and depressive disorders show no real improvement in the long term.[5] We agree that we cannot make a categorical assertion that splitting anxiety and depression is the cause of failure to innovate and advance but in a parallel field, the treatment of schizophrenia, the use of more generic diagnostic terminology has been associated with greater drug innovation.[6]

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Competing interests: PT has received support from the Mental Health Foundation to evaluate the outcome of anxiety and depressive disorders.

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Study of plantar fasciitis treatment is flawed

EDITOR—Haake et al performed a multicentre randomised controlled trial of extracorporeal shock wave treatment for plantar fasciitis.[1] They say that their study is definitive and they therefore recommend against any further experimental testing of this treatment, but the study has sufficient methodological flaws to render their conclusions questionable.

Although the study seems to be well designed statistically, they do not highlight that fewer than half of their patients received minimal conservative care that includes stretching exercises and casting or night splinting before their inclusion in the study (data available online in web table B).

Such interventions have been shown to be effective.[2 3] Failure of such treatment is an essential aspect of the inclusion criteria for extracorporeal shock wave treatment. Including such patients in this study therefore violates one of the precepts of extracorporeal shock wave treatment—failure of previous standard conservative care. Physical treatment is not a substitute for stretching exercises as it occurs a few times a week, whereas stretching is performed three to four times daily.

The end point assessment makes much of several unvalidated rating scales for heel pain. However, the observation that 56% of the placebo group required further treatment, compared with 56% of the treatment group ($P < 0.008$, χ^2 test) is completely at odds with their rating scale results. Obviously, showing equivalence of outcome at the final follow up is uninterpretable because of this treatment bias during the follow up period.

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1 Haake M, Buch M, Schoellner C, Goebel F, Vogel M, Mueller I, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. *BMJ* 2003;327:75-7. (12 July.)
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Care and outcomes in young adults with type 1 diabetes

Services do not usually include psychological care

EDITOR—Services for younger people with diabetes nationally are poor[1]; many do not tailor services to working people in general, and most are ignorant of the specific lifestyles of younger people. People with diabetes are a great resource and could be enlisted to help shape services for others, but to achieve this a national strategy is needed for selection and training of suitable people to work with professionals to redesign services.

Active self management of diabetes is demanding physically and psychologically. The phrase "diabetes is not just for Christmas" comes to mind. For many years psychological support services for people with diabetes have been inadequate. There are too few psychologists or psychiatrists with knowledge of the demands of diabetes to make a difference.

The national service framework has gone some way to increasing the profile of psychological needs among people with diabetes, but without resources following nothing will change.[2] Training specialist nurses to deliver first level psychological care may help but is no substitute for properly trained mental health practitioners who are also required and not just for extreme problems.

Unless there is specific investment in managing younger adults with diabetes and in particular investing in the psychological care provided by specialists, young people will continue to receive poor care and vote with their feet.

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Competing interests: None declared.

1 Wills CJ, Swift PGF, Davies MJ, Mackie ADR, Mansell P. Retrospective review of care and outcome in young adults with type 1 diabetes. *BMJ* 2003;327:260-1. (2 August.)
2 Department of Health. *National service framework for diabetes service delivery*. London: DoH, 2003.

More laser treatment is used in England than the Netherlands

EDITOR—Wills et al retrospectively reviewed care and outcomes in young adults with type 1 diabetes.[1] I audited this hospital's results and compared them with those of a colleague in the Netherlands (table). My findings were similar to those of Wills et al, although the data were not as accurate as theirs.[1] Our patients seem to need a lot more laser treatment. Our results are better or equal to those in the rest of Birmingham, even taking into account that the hospital is in a comparatively wealthy area.

The reason for poor care in diabetes in the United Kingdom may be cultural, affecting both patients and professionals in accepting high glucose concentrations, etc, and organisational. Patients who do not attend are often left to their own devices, for example. But much of the reason must be down to resources. For every 1333 adult patients with diabetes we have one diabetes specialist nurse while our Dutch colleague has one diabetes specialist nurse for every 365 patients. Similarly, his patients certainly have much better access to insulin pumps (about 40% of patients with type 1 diabetes).

Although glargine has improved matters by helping patients to achieve good control, our diabetes team has not been successful in obtaining funding for more diabetes specialist nurses despite having tried its own management, the local primary care trust or strategic health authority, and the Department of Health. I imagine that this is because, politically, diabetes has a low profile.

Audit and comparison of data from diabetes clinics in the Netherlands and England, 2002 (with some changes since)

Clinic in the Netherlands	Diabetes and eye clinic in Sutton Coldfield
550 patients with type 1 diabetes	500 patients with type 1 diabetes (at a guess)
2000 patients with type 2 diabetes	3500 patients type 2 diabetes in area (approximate)
7 diabetes specialist nurses for adults	3 diabetes specialist nurses for adults
1 diabetes specialist nurse per 365 patients	1 diabetes specialist nurse per 1333 patients
Aim for HbA1c 7%	Target? (2003, HbA1c about 7.0)
2-4 weekly contacts between diabetes specialist nurse and patient until target reached	6-12 month review
Insulin regimens all flexible insulin dose,* injected, or pump	Limited help available for poorly controlled patients. Many insulin regimens twice daily (2003: many patients now taking glargine, but not strictly flexible insulin dose)
365 patients using pumps (290 with type 1 diabetes; 75 with type 2 diabetes)	4 patients using pumps (with severe retinopathy already)
1 consultant diabetologist (also responsible for inpatient care)	3 consultant diabetologists, responsible for hospital medical patients and on-call also (but these consultants treat many patients with many complications)
10 clinics a week	9 clinics a week
1 or 2 paediatric diabetes specialist nurses per 45 patients	1 paediatric diabetes specialist nurse full time equivalent per 130 patients (most European centres 1:35)
Psychologists used sometimes	Minimal psychology service, for children only
30 have had or are having laser for diabetic retinopathy	≥400 have had or are having laser treatment

*Adjusted according to carbohydrate for quick acting insulin and including long acting insulin twice daily with dose adjustment for normal eating (DAFNE) regimen.

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Identifying patients at low risk of bowel cancer

Personal or familial risk factors need to be mentioned

EDITOR—The crucial role played by general practitioners in controlling access to specialist services is emphasised by Thompson et al in their article on patients at low risk of bowel cancer in general practice.[1] For general practitioners to fulfil this gatekeeper role guidelines are welcome and needed to reduce the human and financial costs associated with inappropriate referral.

I am concerned that a personal or family history of colorectal cancer or inflammatory bowel disease were not mentioned as risk factors that should be taken into consideration when taking a history from a patient with new bowel related symptoms.[2–4] The presence of such risk factors would increase the likelihood of colorectal cancer and need for subsequent referral. Therefore it would be appropriate to mention them as important points to consider in the history when defining risk status.

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Competing interests: None declared.

1 Thompson MR, Heath I, Ellis BG, Swarbrick ET, Faulds Wood L, Atkin WS. Identifying and managing patients at low risk of bowel cancer in general practice. *BMJ* 2003;327:263-5. (2 August.)
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Authors' reply

EDITOR—A positive family history, particularly with many affected relatives or an affected relative below the age of 45, does significantly increase the lifetime risk of bowel cancer, and screening should be considered in these patients. Similarly, some patients with longstanding inflammatory bowel disease have a significant increase in risk of bowel cancer.

However, no data show that a positive family history in a patient with low risk symptoms further increases the probability of cancer to an extent where this patient should be treated more urgently on the basis of the two week standard.[1–3] Nevertheless, patients presenting to their general practitioners with lower gastrointestinal symptoms and a positive family history need to be managed differently as they are likely to be concerned. It is appropriate for these patients to be referred as described in the article for an urgent appointment in a

routine clinic, the "third way" of referral. Patients with inflammatory bowel disease at significant risk of bowel cancer not already under review should be referred on an urgent basis to a specialist clinic.

We emphasise that the risk of cancer is not the only factor determining the speed at which patients should be referred, and for anxious but low risk patients general practitioners should use the third way of referral.

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Tables for predicting survival for preterm births are updated

Editor—In 1999 we described mortality patterns among preterm neonates born to mothers resident in the former Trent health region.[1] The published predicted survival charts specific for birth weight and gestational age used data on all European and Asian live births, stillbirths, and late fetal losses from 22 to 32 weeks' gestation from a geographically defined population.

Such charts are believed to facilitate decision making by clinicians and parents. We acknowledge, however, that they require regular updating to allow for improvements in the survival of such infants.

The tables have now been updated using data from infants born between 1 January 1998 and 31 December 2001 to mothers resident in the then Trent health region. The data comprised 4112 births of infants known to be alive at the onset of labour. A total of 3885 infants (94.5%) were admitted to neonatal care, 3470 (89.3%) surviving to discharge home. The same statistical methods were used to produce the updated charts as described in the original paper.

These new charts can be accessed on bmj.com[2] They show a general increase in survival among neonates and are also believed to reflect more accurately survival among very small babies.

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Competing interests: None declared.

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Use eggs, not embryos, to derive stem cells

Editor—The European Commission's ethical guidelines on human stem cell research preclude the creation of embryos specifically for this purpose.[1] Although the Human Fertilisation and Embryology Act 1990 allows the creation of embryos for research in the United Kingdom, the House of Lords Select committee on stem cell research reported in February 2002 that embryos should not be created unless there is a demonstrable and exceptional need that cannot be met by the use of surplus embryos.[2]

We believe that embryos created to treat infertile couples are never truly surplus. In our clinics all normal embryos are used in treatment, cryopreserved for the couple's own future use,[3] or donated to another couple, or to research into infertility treatment. Like the European Commission, we are concerned about the ethics of using these embryos for stem cells. We propose an alternative solution.

Most in vitro fertilisation programmes discard hundreds of healthy human eggs each year because they are immature or do not fertilise with the partner's sperm. If these eggs were fertilised with sperm from a fertile donor, many would form viable embryos that could be used for stem cell derivation.

Infertility now affects one in six of the population but the success rate of in vitro fertilisation remains low.[4] Embryonic stem cells have huge promise and we think that ethically it is far preferable to create embryos specifically for this work from eggs that are currently discarded, rather than ask infertile couples to provide normal embryos that could be used in their own treatment.

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"Egg giving" is trading, not one way process of giving

Editor—A woman who provides eggs for another in return for a discount on the cost of her own treatment cannot be described as giving eggs.[1]

Giving is a one way process, typically a charitable act with no reward. To give in order to receive is simply trading.

Whether trading is the same as selling may depend on your point of view. As an economist, I can see no difference. The women involved are buying infertility services but paying in a different currency from those who pay in pounds.

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Time to clarify effect of socioeconomic class on subfertility

Editor—Why is socioeconomic status never considered in the epidemiology of subfertility, although some of the known causes such as obesity and smoking are strongly related to it?[1]

The emphasis on the effect of age on fertility perpetuates the myth that subfertility is a disease of affluence, experienced mostly by women who have high powered jobs or who are having such a good time that they delay motherhood. In effect, they bring the subfertility on themselves, an idea popular since the Victorian era.

Most subfertility is found in women—and men—who cannot afford expensive treatments. People who smoke and are obese are more likely to be comparatively poor and hence fall into this category. People who seek treatment that must be paid for are unlikely to be representative of the population at large. In developed countries direct evidence on socioeconomic status and infertility is never collected.

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