Clinicians and patients should be aware of association between endometriosis and malignancies [LETTER]. British Medical Journal (BMJ) 324 (7329), p. 115. 10.1136/bmj.324.7329.115 file

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Promoting patient safety in primary care

Honesty and openness may not be best policy

Editor—We were both surprised by Wilson et al who, in their editorial, ask everybody to send in reports of their errors.1 Our concerns remain regardless of whether or not such accounts are published anonymously. After all, the police have used anonymous medical research data in their investigations. A conviction of culpable and reckless behaviour was secured against a man after he had sexual intercourse with his girlfriend without telling her he was infected with HIV. The scientific evidence that secured the conviction came from confidential research data that were obtained with a police warrant.2

Furthermore, Wilson et al all say that for doctors to report their errors, patient consent will be needed. This means that the patient will know that an account of his or her care is to be published and may read it. He or she may ask his lawyers to read it. The lawyers may then be able to substantiate this published account as a confession of guilt or negligence.

Wherever and whoever we are, we must be careful as doctors what we say. For example, although we understand that no charges were brought, an incident last year highlighted this point. Police are to hold a murder inquiry into the case of Peter Brand, a Member of Parliament for the Liberal Democrat Party for the Isle of Wight and a general practitioner, who mentioned during a parliamentary debate that he had withdrawn treatment from a two year old boy with leukaemia at the parents’ request, to save him any more distress.3 This case had occurred in 1973, when he was a house officer.

However regrettable, we do live in a culture of blame. To admit professional mistakes of a minor nature may be straightforwardly forgivable. The admission, however, of a serious offence or negligence by doctors may result in litigation against them. Before discussing such matters in public, doctors should seriously consider whether honesty and openness are the best policy.

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Advice to authors

We prefer to receive all responses electronically, sent directly to our website. Processing your letter will be delayed unless it arrives in an electronic form.

We are now posting all direct submissions to our website within 24 hours of receipt and our intention is to post all other electronic submissions there as well. All responses will be eligible for publication in the paper journal.

Responses should be under 400 words and relate to articles published in the preceding month. They should include ≤5 references, in the Vancouver style, including one to the BMJ article to which they relate. We welcome illustrations. Please supply each author’s current appointment and full address, and a phone or fax number or email address for the corresponding author. We ask authors to declare any competing interest. Please send a stamped addressed envelope if you would like to know whether your letter has been accepted or rejected.

Letters will be edited and may be shortened.

Should NHS patients be allowed to pay extra for their care?

Patient payments bring new resources into system

Editor—Richards et al in their article raise the issue of patients contributing to payments for cancer drugs in Britain’s NHS.4 It is pleasing to see that times are changing for ethics committees even if the pervasive tone of self righteousness is a bit grating. If British politicians cannot manage to improve the NHS, why should a patient not pay for drug treatment perceived as beneficial? Would the group consider it unethical for a patient to pay for vitamin pills, special diets, alternative medicine, or a second opinion?

Over the next three years there is going to be a major shift in cancer care. New
molecularly targeted medicines that block specific signalling pathways and angiogenesis will become available. These will take the form of simple tablets, to be taken once a day. They will prolong survival by a few months in many cancers, but as the predictive power of genomics and proteomics rises, cancer will become a chronic, controllable disease. The cost will exceed the budget of Britain’s national cancer plan, which is just a catching up exercise on 30 years of underinvestment by successive governments. In a global society no group of armchair ethicists sitting in Nottingham can stop people ordering these new drugs through the internet and paying with their credit card. Debating the issue is futile.

What we can do is to ensure that the core cancer services offered to everyone by the NHS improve. The cancer plan provides an excellent structure but is underfunded. Creating the new bureaucracy has provided excellent spin for politicians who think they have “done cancer.” The reality is grim—agents for the new policy, clear examples of continuing postcode prescribing, overworked staff, and lack of consultation time. Allowing patients to pay for treatments outside the core is one way of bringing additional resources into the system. Another is to privatise their delivery.

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Debate is essential, not futile

Editor—Richards et al raise many ethical and legal issues, discussing whether or not NHS patients should be allowed to contribute extra money to their care? BMJ 2001;323:563-5. (9 September.)

1 Richards C, Dingwall R, Watson A. Should NHS patients be allowed to contribute extra money to their care? BMJ 2001;323:563-5. (9 September.)

2 Sikora K. COPayments for cancer drugs. Electronic response to Should NHS patients be allowed to contribute extra money to their care? BMJ 2001;323 bmj.com/cgi/eletters/323/7312/563#16524.

3 Anonymous. How consumers can and should improve research and healthcare. Lancet 2001;358:769. (3 November.)


Pрагmatism should rule, not policy committees

Editor—The approach at our cancer centre has been different to that reported in the paper by Richards et al.1 For non-funded cancer drugs, patients have been advised that they may continue under the care of their NHS consultant, who will supervise the administration of the cytotoxic agent as usual. The only difference from normal practice is that the hospital pharmacy sends an invoice for the drug cost to the patient. Although this is not perfect, it is satisfactory for the patient who requires a particular treatment that is otherwise unavailable on the NHS and who is willing and able to pay.

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1 Richards C, Dingwall R, Watson A. Should NHS patients be allowed to contribute extra money to their care? BMJ 2001;323:563-5. (9 September.)

Screening for Down’s syndrome

Antenatal screening has human costs

Editor—In their study Gilbert et al made no provision for the cost of counselling.1 I still hear from women who go for antenatal care and are screened without consent or counselling.2 Some of these women regret entering a conveyor belt process that ends up with an invasive procedure that causes a high rate of fetal loss. Gilbert et al, by highlighting the economic implications of screening, remind us that mothers and their unborn babies continue to be used in what is primarily a cost saving procedure.

1 Richards C, Dingwall R, Watson A. Should NHS patients be allowed to contribute extra money to their care? BMJ 2001;323:563-5. (9 September.)

Charges for NHS dental care have led to privatisation

Editor—Richards et al asked whether patients in the NHS should be allowed to contribute extra money to their care. In NHS dental primary care charges to patients have been high for over 10 years.3 NHS patients pay up to £360 towards just one course of treatment, and these charges now account for 80% of the full cost of most dental treatments performed in the NHS.

So have these patient charges improved NHS dental care? In theory, they should have, through additional funding, but after only a few years the government deducted any payments from patients from government payment to dentists, leaving us as unpaid tax collectors with no more funding and a lot more extra paperwork.

With many patients paying such high NHS charges, it was, however, a small step to ask patients to pay the full costs, or to join a low cost plan at about £12 per month to receive the high quality private dentistry that the government is unprepared to allow or fund properly in the NHS.

So are additional patient charges a good thing—they help the public to start “valuing” medical services while initially providing some additional funds. If the government stays true to form and start to count charges to patients as government funds, deducting these from grants, etc, then at least offering private quality care will be one step nearer for the public.

Modern patient care must come before thinking like a third world government, even if that means funding care outside the NHS. This is now well established in dental care in the United Kingdom, and medicine would do well to learn from NHS dentistry’s problems and solutions.

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1 Richards C, Dingwall R, Watson A. Should NHS patients be allowed to contribute extra money to their care? BMJ 2001;323:563-5. (9 September.)

References

1 Richards C, Dingwall R, Watson A. Should NHS patients be allowed to contribute extra money to their care? BMJ 2001;323:563-5. (9 September.)
screening in human terms has not been evaluated. By excluding the costs of counseling and disregarding mothers’ rights and the worth and value to society of children with Down’s syndrome, the study by Gilbert et al has severe limitations that should prevent us from embracing such screening strategies.

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Costings are crucial to model

Entror—Gilbert et al in their paper provide an analysis of cost and effectiveness of screening for Down’s syndrome using mathematical modelling. Costing of procedures undertaken in the NHS is difficult, and Gilbert et al conclude that four screening strategies are cost effective and efficient.

Nuchal translucency screening is apparently the cheapest procedure, at £4.40 per test, but there is no indication how this figure was derived. In a cost analysis undertaken for ultrasound scanning for the Royal College of Obstetrics and Gynaecology in 1995, the cheapest scan cost about £35. This figure was probably unreliable, but the discrepancy is large, and it is important to resolve it since the costs Gilbert et al quote for nuchal translucency screening are crucial to their model. If the costing is inaccurate then the conclusions of the study are likely to be incorrect.

The literature generally agrees that nuchal translucency screening together with serum testing seems an efficient screening method, or at least confirmed by this model. But the practical problems that surround implementation of such a programme nationally are formidable. Only about 7% of units are offering nuchal translucency screening. There are well recognised shortages of radiography staff and possibly inadequate facilities in some circumstances. Early screening demands effective counseling before a woman gets to the hospital, so she has time to consider her options.

One of the benefits of an early diagnosis is a surgical termination, but in this model only about one third of women had their diagnosis in time. Early diagnosis also increases the demand for chorion villus sampling, which is generally available only in fetal medicine centres, carries a higher miscarriage rate than amniocentesis and incurs higher laboratory costs. Currently about 60% of women in the United Kingdom are offered at least a double test. Gilbert et al indicate the weakness of that strategy, but it is a starting point, and the adoption of other analyses would not necessarily be difficult. Screening is likely to be more feasible to support during the second trimester than during the first, mainly because of the difficulties of implementing nuchal translucency measurements. This model suggests that a quadruple test may prove effective, and, although there would be an increased cost, the test entails automated, laboratory techniques and not those dependent on a skill—such as nuchal translucency screening. The challenge is to find a technique that is not only cost effective and safe but that is also feasible to implement nationally.

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Conclusions do not reflect reality

Entror—Gilbert et al have tried to identify the best approach for screening for Down’s syndrome. They have, however, fallen into the trap of uncritically evaluating the published literature. There is no statistical proof that the detection rate is significantly better for any of triple screening versus double screening, quadruple screening versus double or triple screening, or screening in the first trimester versus the second trimester, or that the integrated test is an improvement.

All studies of Down’s syndrome screening have had small numbers of examples of pregnancies positive for Down’s. Consequently, although false positive rates can be accurately assessed, the detection rate cannot. The confidence intervals about the detection rate are so wide that no one has yet proved that the superiority of one method over another is not entirely due to chance. It has also been known for a long time that with technological advancement we have been used to derive a population model that is used to estimate false positive and detection rates, large errors can result from an error in the estimate of the population variance for a single analyte giving rise to a hopelessly optimistic estimate of the effectiveness of a procedure.

Studies of the efficacy of nuchal translucency screening have all been interventional, and the quoted detection rate (of the order of 80%) therefore needs to be deflated to account for natural fetal losses. The effect of natural fetal loss is to reduce the detection rate for screening during the first trimester to less than 60%, making it comparable to screening during the second trimester. In addition, for nuchal translucency measurement, there is a far greater incidence of failure to be able to make a measurement than there is failure of biochemical testing to be able to produce a result, which further depresses the detection rate.

Finally, there are serious statistical doubts about the integrated test and worries about the ethics of withholding early positive results until a second test has been performed. The unit costs estimated for the different tests are also interesting. How can it be that an ultrasound test requiring 15–20 minutes of hands on technical work is cheaper than a biochemical test, when one person can analyse hundreds of samples per day?

Since the detection rates for nuchal translucency screening are grossly overestimated and the integrated test is expensive and unproved, the conclusion that these two modalities of screening represent the boundary of cost effectiveness cannot be left unchallenged.

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Modelling does not predict reality accurately

Entror—Gilbert et al conclude that, of the antenatal screening tests for Down’s syndrome, the integrated test is the most effective and safest strategy and that all other strategies result in more liveborn babies or miscarriages of unaffected pregnancies. Their conclusions are derived from mathematical modelling rather than trial data. This is particularly true when evaluating the integrated test, which has never been tested in a controlled trial nor even in a large uncontrolled demonstration project.

It is difficult to think of any area of medicine where health policy is so driven by modelling without the support of properly gathered clinical evidence. There are no controlled studies showing that serum or nuchal translucency screening is more effective than maternal age or reduces the rates at which invasive procedures are performed. By contrast, there is clear evidence that modelling does not accurately predict the effectiveness of screening programmes in practice. We reported a 68% antenatal detection rate over six years, screening by maternal age where routine anomaly scanning was also offered. Ford et al found that serum screening detected only 31% of cases of Down’s syndrome antenatally. The modelling relied on by Gilbert predicts that in the first study the detection rate should have been 32% and in the second 60%.

Modelling does not predict reality accurately for two reasons. Firstly, women do not behave as predicted. In Ford’s study only 71% accepted screening, so only 13 of 19 cases occurred in those screened. Only 11 of these 13 were screen positive, of which only six had invasive testing. Only four of the six chose
termination. In other studies many older mothers decline screening in favour of a definitive diagnostic test, increasing the amniocentesis rate above that predicted.

Secondly, modelling also fails because of inaccurate assumptions about the age structure of the antenatal population. The models assume that 5% of pregnant women are aged over 35 whereas nationally the proportion is 16.5% (launch of National Sentinel Caesarean Section Audit). In Southampton this resulted in over 65% of cases of Down's arising in older women.

Finally, Gilbert et al do not consider some of the negative impact of screening. Women increasingly complain that midwives and doctors are not interested in their pregnancies until they have ruled out Down's syndrome. Age based screening need be discussed with only a small segment of the population, who are often aware when planning their pregnancy of the higher risk of Down's. If we are to retain scientific credibility, planning their pregnancy of the higher risk of the population, who are often aware when controlled clinical trials and not models that are demonstrably inaccurate.

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Authors' reply

Editor—The questions about costs raised by Venn-Treloar, Whattle, and Reynolds were included in the full text version of the report on bmj.com, with further details in the technical report (www.wich.ucl.ac.uk/srrt/frmpubshtm).1 We included the costs of counselling before amniocentesis, chorionic villus sampling, or termination, but we assumed that screening options were discussed with all women at booking. As all women were assumed to have had a dating ultrasound scan, the cost of the nuchal fold translucency test relates to the additional time to take measurements, explain the results, and train ultrasonographers.

Reynolds seems to have missed the section in the methods that explains that the nuchal fold measurement was adjusted for verification bias. Howe makes the case for a modelling exercise. Differences between our detection rates and those from studies based on routine care will be strongly affected by uptake rates, referral practices, and verification bias. Modelling takes account of these factors to allow comparison of test performance and would still be required even if trials were feasible.

Finally, Reynolds raises an important point about the poor precision of the detection rate. One approach is to look for consistency of the characteristics of test performance. Meta-analyses of the results for biochemical markers produce comparatively precise results, which are consistent with the characteristics used in the analysis. But to take account of the correlation between markers we used test characteristics from a single large, archived dataset. Other archived datasets have given similar results.3 We believe that this approach gives the best estimates of test performance but accept that random error is not represented.

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Ratio of femoral length to tibial length needs to be evaluated extensively

Editor—Gilbert et al and Howe et al in their articles rely heavily on maternal age to screen for Down's syndrome.1,2 But maternal age is not so useful in India and other countries where early marriage is the norm and the social pressures for early motherhood are enormous. In our series, which included 5000 deliveries and seven babies with Down's syndrome, we saw that all babies with the syndrome were born to mothers younger than 35 years.

We reported in the American Journal of Perinatology our finding that the ratio of femoral length to tibial length remains remarkably constant around 1.15 (range 1.13-1.19) in fetuses after 13 weeks' gestation.3 Fetuses with Down's syndrome had this ratio greater than 1.2 (standard deviation 0.4.5) compared with normals. The youngest fetus with Down's syndrome in our sample was 22 weeks old at the time of measuring. We hope that this ratio will be evaluated more extensively and earlier in pregnancy, to see if these findings are valid in the early second trimester and across ethnic groups.

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Problems with temporary cardiac pacing

Ultrasoundography can aid central venous cannulation

Editor—In his editorial highlights problems with temporary cardiac pacing where the service is provided by doctors in training with inadequate supervision.1 An essential component of temporary pacing is obtaining central venous access. The failure


Nuchal translucency screening may help detect congenital heart disease

Editor—Screening for Down's syndrome during fetal life has received much attention, with over 350 articles in the medical literature over the past five years alone. The data on cost effectiveness provided by Gilbert et al are welcome, given the variable screening strategies offered by different NHS providers. Increased nuchal translucency may be a marker of many fetal diseases, and a discussion of its cost effectiveness should not be restricted to Down's syndrome alone.

Congenital heart disease is the most common type of fetal malformation (at least 8/1000 during fetal life), but only 25% of clinically significant malformations are actually detected prenatally in the United Kingdom, which is worse than any other type of fetal anomaly. Increased nuchal translucency is associated with congenital heart disease, independent of karyotypic abnormalities, with a sensitivity of 15-56%.4,5 Although far from perfect as a screening tool for congenital heart disease, nuchal scanning makes some contribution to prenatal detection of congenital heart disease and chromosomal abnormalities. This is highly relevant when the relative merits and cost effectiveness of prenatal screening strategies are evaluated.

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Training is essential
Entror—It was surprising to read in the editorial by Murphy that one of his proposed solutions to the problems with temporary cardiac pacing was to ask anaesthetists to step in to address a deficiency in general medical training. Central venous cannulation is an oft performed and sometimes life saving procedure, and lack of competence in this technique among physicians in training suggests that training needs to be changed.

With recent changes in training in anaesthetic and intensive care medicine there is an increasing number of preregistration training posts in anaesthesia. A growing number of senior house officer posts in intensive care medicine is also available to trainees from all medical backgrounds where competency based training in a wide range of procedures, including placement of central lines, is offered. Failing this almost all acute hospitals have some form of critical care unit where trainees and senior physicians are likely to be welcomed in order to attain and maintain competency in such procedures. Leaking advantage of such opportunities is surely a better way to address training issues while encouraging the development of even closer cooperation between the two specialties.

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Better training in general medicine is required
Editor—Temporary transvenous cardiac pacing is a life saving procedure and an important skill for emergency physicians to have.1 It is often a poorly taught procedure with potentially life threatening complications. It should not be embarked upon without due care, attention, and training. When possible, waiting and observing more stable patients overnight until the permanent pacemaker list is much more desirable. But potentially deskeliling the frontline may have equally disastrous consequences, as would transferring potentially unstable patients to other centres.

If trainees in general medicine are not to expected to perform temporary pacing then should the same be said for chest drains, central lines, and lumbar punctures? When specialty medicine does cover 24 hours patients will expect specialists performing their particular skill, but further deskeliling general medical trainees in the current climate may do more harm than good. What we need is better training in general medicine or an overhaul of acute medicine.

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Novices can reliably and safely perform temporary pacing from femoral route
Entror—A need for urgent temporary pacing remains in district general hospitals.1 External cardiac pacing is useful but is not always reliable and can be quite painful. Transferring patients to a specialist centre with recurrent syncope or significant hypotension, regardless of the use of isoprenaline infusions and external pacing is not acceptable.

What is required is a straightforward and reliable technique of transvenous temporary pacing that can be performed by a senior house officer, specialist registrar, or consultant with no or little recent experience. The two possibilities are balloon flotation catheters inserted through the subclavian or jugular vein and semirigid pacing wires through the femoral vein. Balloon flotation catheters work well and can be inserted by a novice with the aid of a simple instruction diagram, assuming that central access is achieved.2 Traversing the tricuspid valve can, however, be difficult in the presence of severe tricuspid regurgitation.

1 Murphy JJ. Problems with temporary cardiac pacing. BMJ 2001;323:527. (9 September.)

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1 Murphy JJ. Problems with temporary cardiac pacing. BMJ 2001;323:527. (9 September.)
The ideal solution for urgent transvenous temporary pacing by a novice is the femoral route and a standard wire. The anatomical landmarks are well defined, and access is reliably achieved. External compression on the femoral vein allows haemostasis if bleeding complications thrombolysis. The temporary wire readily crosses the tricuspid valve to take up a stable position, even in the presence of severe tricuspid reflux. Little manipulation is required within the heart because the wire follows a natural curve. This minimises procedure time and the incidence of ventricular arrhythmias. If there are concerns regarding incidence of infection the wire can be renewed with a new wire from the subclavian or jugular as a planned exercise allowing the possibility for teaching.

We conducted a feasibility study over a period of eight months to assess the ease with which senior house officers who had no or very little pacing experience could undertake femoral route pacing when instructed by a specialist registrar in cardiology (group A, 17 patients). A different senior house officer was invited to perform the procedure each time after a brief explanation. All achieved access without complication and a suitable pacing wire position under the guidance of the specialist registrar. This group was compared with the remainder undergoing temporary pacing performed by more experienced senior house officers alone or with supervision by their non-cardiology consultant (group B, 13 patients). Most in group B used jugular or subclavian access. Ethics approval was not sought because the study was a retrospective comparison of two groups undergoing a clinically indicated procedure by equally accepted techniques.

In group A, 1 of the 17 patients (6%) required repositioning and 10 (59%) were accepted techniques.

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Kingdom who can so easily be deceived, and their ability to diagnose childhood illnesses is seriously impaired.

I agree with Wilson that we need to have an open mind regarding the complex origins of childhood symptoms and illnesses, but unfortunately the Department of Health’s guidance and Wilson’s letter do not show such open mindedness.

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So far this has not been a subject that is discussed in full with patients. But a study of 1000 cases of endometriosis reported that, in 8.8% of cases, malignancy and endometriosis were both present in the same organ, but not necessarily microscopically contiguous, and higher if the lesions were located in different organs. Malignancies were also more commonly found in ovaries that contained endometriosis. Clear cell and endometrioid carcinomas were the malignancies most commonly seen in endometriotic ovaries, and there was clear association between these histological types and endometriosis. Clinicians and patients must be made aware of this association, especially when surgery is contemplated in comparatively young women.

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Competing interests: None declared.


Media could be used to better effect than inducing fear

Ennor—Lightfoot et al discussed responses to bioterrorist threats. One of the aspects that I found most interesting about the recent anthrax releases in the United States is the apparently disproportionate fear that they have produced among the population, fuelled, I think, by the media coverage they have been given.

According to a report published by the US Centers for Disease Control and Prevention on 25 September 2001, in 1999, 28 874 people died of firearms injuries, 19 102 of drug related causes, and 19 171 of alcohol related causes. Neither the statistics on drug deaths nor those on alcohol related deaths include accidents, homicides, or other causes indirectly related to their use. Given that the media are able to wield such massive influence, perhaps in the hoped for “new world order” they can do so in more useful ways.

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Endometriosis

Emphasis on medical treatment is misleading

Editor—In his review on endometriosis, Prentice sets out management strategies for treating painful symptoms resulting from endometriosis.1 He concludes that the first line treatment should be medical and that surgery should be reserved for cases in which medical treatment has failed or for patients with severe disease. We believe that the emphasis on medical treatment and the assertion that controversy exists over the precise role of surgery are misleading and may be responsible for physicians mismanaging their patients.

The evidence from randomised controlled trials for the medical and surgical management of endometriosis has recently been reviewed.2 A critical summary of the medical management has shown that there is little difference in effectiveness of various medical treatments, which only last while patients remain on treatment. The review also showed that surgical management is effective in the treatment of both painful symptoms and subfertility. Furthermore, there is a wealth of grade II and III evidence in the literature which supports laparoscopic surgery as the primary treatment modality for all stages of endometriosis.3

We believe that in the United Kingdom endometriosis is misdiagnosed in many patients who are having a laparoscopy, and many are not treated adequately because of the emphasis on medical management strategies.4 This almost certainly reflects the fact that only a few surgeons in the United Kingdom have the advanced endoscopy skills required to diagnose and then treat the disease laparoscopically. This is in marked contrast to the situation in the rest of Europe and North America, where surgical techniques using minimal access were first developed.

We recommend that medical treatments be used by primary care doctors for the short to medium term to control painful symptoms, before referral to hospital for surgery or while the patient is on the waiting list for surgery. Patients should be referred to units where laparoscopic diagnosis and surgery can be carried out during the same operation. Conservative, excisional, or ablative endoscopic surgery and not medical treatment should be the first line management of patients with endometriosis. This applies to women with any stage of the disease, but particularly those with endometriotic cysts, or infiltrating rectovaginal disease.1 5

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Clinicians and patients should be aware of association between endometriosis and malignancies

Editor—Prentice’s review highlights the difficulties encountered in clinical practice in relation to endometriosis.1 Clinicians should use abdominal or transvaginal ultrasound imaging of the pelvis when women present with pelvic pain, dysmenorrhoea, or dyspareunia to ascertain whether the ovaries are normal or contain endometriotic cysts. The presence of these cysts may indicate more widespread disease in the pelvis. This is important for women about to undergo major gynaecological surgery as unexpected extensive and severe endometriosis may lead to more surgery than had been discussed preoperatively or consented to by the patient. This has medicolegal implications.

Another issue is that of the association between endometriosis and ovarian cancer.

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